As filed with the Securities and Exchange Commission on June 27, 2014

Registration No. 333-

# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION
**Washington, D.C. 20549**

# FORM F-1
# REGISTRATION STATEMENT
***UNDER***
***THE SECURITIES ACT OF 1933***

# Auris Medical Holding AG

**(Exact Name of Registrant as Specified in Its Charter)**

**Not Applicable**
**(Translation of Registrant's name into English)**

| **Switzerland** | **2834** | **NOT APPLICABLE** |
|---|---|---|
| **(State or Other Jurisdiction of Incorporation or Organization)** | **(Primary Standard Industrial Classification Code Number)** | **(I.R.S. Employer Identification Number)** |

**Bahnhofstrasse 21**
**6300 Zug, Switzerland**
**+41 (0)41 729 71 94**
**(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)**

**Agent for Service of Process**
**National Corporate Research, Ltd.**
**10 East 40th Street**
**New York, New York 10016**
**(212) 947-7200**
**(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)**

***Copies to:***

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|---|---|

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

**CALCULATION OF REGISTRATION FEE**

| TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED | PROPOSED MAXIMUM AGGREGATE OFFERING PRICE (1) | AMOUNT OF REGISTRATION FEE |
|---|---|---|
| Common shares, nominal value CHF 0.40 per share | $86,250,000 | $11,109 |

(1) Estimated solely for the purpose of computing the amount of the registration fee pursuant to Rule 457(o) under the Securities Act of 1933, as amended.

**The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to such Section 8(a), may determine.**

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**The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.**

Subject to Completion Dated June 27, 2014

**PRELIMINARY PROSPECTUS**

## Shares

# Auris Medical Holding AG

## Common Shares

This is an initial public offering of Auris Medical Holding AG. We are offering of our common shares. No public market currently exists for our common shares. We expect our initial public offering price will be between $ and $ per common share. We intend to apply to list our common shares on the Nasdaq Global Select Market under the symbol "EARS."

**We are an "emerging growth company" as defined under the federal securities laws and, as such, will be subject to reduced public company reporting requirements. See "Prospectus Summary—Implications of Being an "Emerging Growth Company" and a Foreign Private Issuer."**

**Investing in our common shares involves a high degree of risk. See "Risk Factors" beginning on page 9.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

| | PER COMMON SHARE | TOTAL |
|---|---|---|
| Public Offering Price | $ | $ |
| Discounts and Commissions (1) | $ | $ |
| Proceeds, before expenses, to us | $ | $ |

(1) We refer you to "Underwriting" beginning on page 135 of this prospectus for additional information regarding total underwriter compensation.

Delivery of the common shares is expected to be made on or about , 2014. We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional common shares to cover over-allotments.

**Jefferies** **Leerink Partners**

**JMP Securities** **Needham & Company**

Prospectus dated , 2014

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Unless otherwise indicated or the context otherwise requires, all references in this prospectus to “Auris Medical” or the “Company,” “we,” “our,” “ours,” “us” or similar terms refer to Auris Medical Holding AG, together with its subsidiaries, except that when referring to the audited consolidated financial statements, the unaudited condensed consolidated interim financial statements and historical financial results, such terms refer to Auris Medical AG, together with its subsidiaries, prior to the corporate reorganization described in “Prospectus Summary — Corporate Information.” The trademarks, trade names and service marks appearing in this prospectus are property of their respective owners.

The terms “dollar,” “USD” or “$” refer to U.S. dollars and the term “Swiss Franc” and “CHF” refer to the legal currency of Switzerland.

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We have not authorized anyone to provide any information other than that contained in this prospectus or in any free writing prospectus prepared by or on behalf of us or to which we may have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We and the underwriters have not authorized any other person to provide you with different or additional information. Neither we nor the underwriters are making an offer to sell the common shares in any jurisdiction where the offer or sale is not permitted. This offering is being made in the United States and elsewhere solely on the basis of the information contained in this prospectus. You should assume that the information appearing in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or any sale of the common shares. Our business, financial condition, results of operations and prospects may have changed since the date on the front cover of this prospectus.

## PROSPECTUS SUMMARY

*This summary highlights information contained elsewhere in this prospectus. This summary may not contain all the information that may be important to you, and we urge you to read this entire prospectus carefully, including the "Risk Factors," "Business" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections and our consolidated financial statements, including the notes thereto, included elsewhere in this prospectus, before deciding to invest in our common shares.*

### Our Business

We are a clinical-stage biopharmaceutical company focused on the development of novel products for the treatment of inner ear disorders. Our most advanced product candidate, AM-101, is in Phase 3 clinical development for acute inner ear tinnitus under a special protocol assessment, or SPA, from the FDA, indicating that the FDA has evaluated the proposed design, size, and planned analysis of the trial and determined that they are acceptable to support regulatory approval of the product candidate with respect to effectiveness of the indication studied. In two recently completed Phase 2 clinical trials, AM-101 demonstrated a favorable safety profile, meaning a beneficial benefit-to-risk ratio based on the incidence and severity of adverse events, and statistically significant, meaning that the results obtained are not likely due to chance, improvement in tinnitus loudness and other patient reported outcomes. We are also developing AM-111 for acute inner ear hearing loss, and we expect to begin Phase 3 clinical development in the fourth quarter of 2014. We expect to have top-line Phase 3 clinical data for AM-101 and AM-111 in early 2016 and late 2016, respectively. Both acute inner ear tinnitus and hearing loss are conditions for which there is high unmet medical need, and we believe that we have the potential to be the first to market in these indications.

With two product candidates in Phase 3 clinical trials, we believe we are currently the clinically most advanced company working on inner ear therapeutics. We believe that AM-101 and AM-111 are the only drug candidates that have demonstrated positive efficacy in randomized placebo-controlled clinical trials in acute inner ear tinnitus and acute inner ear hearing loss. Our products are protected through intellectual property rights and, in addition, orphan drug status has been granted to AM-111. Orphan drug designation may provide for a period of orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, except in very limited circumstances, and entitles a drug sponsor to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and FDA user fee exemptions. The granting of orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

Our product candidates are injected under local anesthesia into the middle ear by a technique called intratympanic, or i.t., injection. Once injected into the middle ear, the active substance, which is formulated in a biocompatible gel, diffuses into the inner ear. The procedure is short, safe, has a long history of use and allows for highly targeted drug delivery with minimal systemic exposure, which is what occurs when the drug enters into the general blood stream. As with any local (topical) treatment administration, intratympanic injection allows for localized drug delivery to the target site of action. The procedure is performed by an ear, nose and throat, or ENT, specialist on an outpatient basis over one or more visits.

We expect to retain commercial rights in key markets for both AM-101 and AM-111, particularly the United States and key European markets. Outside these markets, we intend to seek partnerships that would maximize our products' commercial potential.

Our leading product candidates are as follows:

**AM-101 for acute inner ear tinnitus.** One of the frequent causes of acute inner ear tinnitus is traumatic insult such as exposure to excessive noise or middle ear infection (otitis media, or OM). Tinnitus, frequently perceived as a ringing in the ears, is the perception of sound when no external sound is present. Similar to pain, it is an unwanted, unpleasant and thus distressing sensation. Tinnitus may result in further symptoms

such as inability to concentrate, irritability, anxiety, insomnia, and clinical depression. In many cases, tinnitus significantly impairs quality of life and affects normal day-to-day activities. In October 2010, we submitted an Investigational New Drug, or IND, application for AM-101 for human clinical testing. We have conducted Phase 2 trials in this specific tinnitus population with AM-101 which demonstrated a favorable safety profile. Furthermore, in our Phase 2 clinical trials, AM-101 showed a dose dependent, persistent and clinically relevant improvement, meaning that the therapy had a practical effect, as compared to the placebo, in subjective tinnitus loudness as well as other patient reported outcomes, such as tinnitus annoyance, tinnitus severity, sleep difficulties and general tinnitus impact. Our Phase 3 clinical program, which is similar in design to our Phase 2 trial design, is being conducted under a SPA from the FDA and also incorporates guidance from the European Medicines Agency, or EMA. We expect to have top-line data in early 2016. We believe that AM-101 has the potential to become the first product approved for the treatment of acute inner ear tinnitus.

**AM-111 for acute sensorineural hearing loss.** We are developing AM-111 for the treatment of acute sensorineural hearing loss, or ASNHL. In sensorineural hearing loss, which is also referred to as inner ear hearing loss, there is damage to the sensory cells of the inner ear or the auditory nerve. ASNHL may be triggered by a variety of insults, such as exposure to excessively loud sound, infection, inflammation or certain ototoxic drugs. These insults may also result in tinnitus. Over 60,000 people in the United States are affected by sudden deafness annually. In our Phase 2 clinical trial, AM-111 showed a favorable safety profile. Furthermore, in patients with severe to profound ASNHL, we observed a clinically relevant improvement in hearing threshold, speech discrimination and a higher rate of complete tinnitus remission compared with placebo. We plan to begin two late stage clinical trials in ASNHL, including a pivotal Phase 3 trial in the fourth quarter of 2014. We expect to have top-line data from these trials in late 2016. We believe that, if approved, AM-111 could become the first FDA or EMA approved pharmaceutical treatment for ASNHL. AM-111 received orphan drug designation for the treatment of ASNHL from both the FDA and the EMA.

The following table summarizes our product development pipeline:

| Product | Indication | Preclin. | Phase 1 | Phase 2 | Phase 3 | Next Key Milestones[1] | |
|---|---|---|---|---|---|---|---|
| AM-101 Esketamine | *Acute inner ear tinnitus* | | | | | Data TACTT2<br>Data TACTT3 | Early 2016 |
| | *Post-acute inner ear tinnitus* | | | | | TACTT3 interim | Early 2015 |
| AM-111 D-JNKI-1 | *Acute inner ear hearing loss* | | | | | Start HEALOS<br>Start OVERT | Fall 2014<br>(Data late 2016) |
| | *Meniere's disease* | | | | | Start MENDOS | Mid 2015 |
| AM-102 Undisclosed | *Tinnitus* | | | | | Lead compound selected | Late 2014 |
| AM-123 Undisclosed | *Rhinology* | | | | | Lead compound selected | Late 2014 |

(1) Dates of key milestones are indicative and subject to change.

We believe we are a leader in the development of novel therapeutic products for inner ear disorders due to several factors, including:

- ***First mover advantage.*** With two product candidates in late stage clinical development, we believe we are currently the clinically most advanced company working on inner ear therapeutics.

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- ***Barriers to entry.*** Our products are protected not only through intellectual property rights but also by the orphan drug status granted to AM-111 as well as by the know-how across several disciplines that is required to formulate and reliably deliver drugs for the inner ear.
- ***Efficient commercialization.*** Given that the market for our therapeutic product candidates can be efficiently accessed through a limited number of specialist ENT physicians and specialist neurotologists, we intend to build our own sales force in order to commercialize these products in the United States and key European markets.
- ***Experienced management.*** Having been focused on developing therapeutic products for inner ear indications for over a decade, we believe that our senior management provides us with significant capabilities.

Our goal is to become the leading biopharmaceutical company focused on developing and commercializing novel therapeutics to treat inner ear disorders. The key elements of our strategy to achieve this goal are:

- ***Target inner ear disorders that have a defined pathophysiology and that are amenable to treatment.***
- ***Use drug delivery techniques and proprietary drug formulations for effective, safe and rapid local administration to the inner ear.***
- ***Bring AM-101 and AM-111 to market.***
- ***Build an efficient commercial infrastructure to maximize the value of our product candidates.***
- ***Expand our pipeline through internal development, academic collaborations, in-licensing and acquisitions.***

### Risks Associated with Our Business

Our business is subject to a number of risks of which you should be aware of before making an investment decision. These risks are discussed more fully in the “Risk Factors” section of this prospectus immediately following this prospectus summary. These risks include the following:

- We are currently a development stage company with limited operating history and a history of operating losses. Our accumulated deficit as of March 31, 2014 was CHF 39.0 million. We anticipate that we will continue to incur losses for the foreseeable future.
- We have a need for substantial additional funding before we can expect to become profitable from sales of our products.
- We depend on the success of AM-101 and AM-111, which are still in clinical development and may eventually prove to be unsuccessful.
- We have uncertainty surrounding whether any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.
- Our products may not gain market acceptance, in which case we may not be able to generate product revenues.
- If we fail to maintain our current strategic relationships with INSERM and Xigen, our business, commercialization prospects and financial condition may be materially adversely affected.
- Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

### Corporate Information

On April 22, 2014, we changed our name from Auris Medical AG to Auris Medical Holding AG and transferred our operational business to our newly incorporated subsidiary Auris Medical AG, which is now our main operating subsidiary. Investors in this offering will acquire, and this prospectus only describes the offering of, common shares of Auris Medical Holding AG. The offices of Auris Medical Holding AG are located at Bahnhofstrasse 21, 6300 Zug, Switzerland. Our telephone number is +41 (0)41 729 71 94.

Investors should contact us for any inquiries through the address and telephone number of our principal executive office. Our principal website is *www.aurismedical.com*. The information contained on our website is not a part of this prospectus.

**Implications of Being an "Emerging Growth Company" and a Foreign Private Issuer**

We qualify as an "emerging growth company" as defined in the Jumpstart our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting and other burdens that are otherwise applicable generally to public companies. These provisions include:

- a requirement to have only two years of audited financial statements and only two years of related Management's Discussion and Analysis of Financial Condition and Results of Operations disclosure in its initial registration statement; and
- an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002. See "Management's Discussion and Analysis—JOBS Act Exemptions."

We may take advantage of these provisions for up to five years or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.0 billion in annual revenue, have more than $700 million in market value of our common shares held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period. We may choose to take advantage of some but not all of these reduced burdens.

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer, or FPI, status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;

- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and

- the rules under the Exchange Act requiring the filing with the Securities and Exchange Commission, or SEC, of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events.

## THE OFFERING

*This summary highlights information presented in greater detail elsewhere in this prospectus. This summary is not complete and does not contain all the information you should consider before investing in our common shares. You should carefully read this entire prospectus before investing in our common shares including "Risk Factors" and our consolidated financial statements.*

| | |
|---|---|
| Issuer | Auris Medical Holding AG |
| Offering | We are offering common shares. |
| Offering price range | Between $ and $ per common share. |
| Voting rights | Our common shares have one vote per common share. |
| Over-allotment option | We have granted the underwriters the right to purchase up to an additional common shares from us within 30 days of the date of this prospectus to cover over-allotments, if any, in connection with the offering. |
| Common shares to be outstanding immediately after the offering | Immediately after the offering, we will have common shares outstanding, assuming no exercise of the underwriters' over-allotment option. |
| Listing | We intend to apply to list our common shares on the Nasdaq Global Select Market under the symbol "EARS." |
| Use of proceeds | We estimate that the net proceeds to us from the offering will be approximately $ million, assuming an initial offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds from the offering, together with cash and cash equivalents on hand, for:<br>- approximately $ to $ to fund research and development expenses for AM-101 up to approval;<br>- approximately $ to $ to fund research and development expenses for AM-111 up to approval;<br>- approximately $ to $ to fund other research and development activities; and<br>- the remainder for working capital and other financial corporate purposes.<br><br>See "Use of Proceeds." |
| Dividend policy | We have never paid or declared any cash dividends on our shares, and we do not anticipate paying any cash dividends on our common shares in the foreseeable future. See "Dividend Policy." |
| Lock-up agreements | We have agreed with the underwriters, subject to certain exceptions, not to offer, sell, or dispose of any common shares or securities convertible into or exchangeable or exercisable for any common |

| | |
|---|---|
| | shares during the 180-day period following the date of this prospectus. Members of our board of directors, our executive officers and holders of all or substantially all of our outstanding capital stock have agreed to substantially similar lock-up provisions, subject to certain exceptions. See “Underwriting.” |
| Risk factors | See “Risk Factors” and the other information included in this prospectus for a discussion of factors you should consider before deciding to invest in our common shares. |

The number of our common shares to be outstanding after this offering is based on common shares outstanding as of , 2014, but excludes the following:

- of our common shares issuable upon the exercise of options outstanding as of , 2014 at a weighted average exercise price of $ per common share; and
- of our common shares covered by additional awards available for future issuance under our equity incentive plans as of , 2014.

Unless otherwise indicated, all information contained in this prospectus assumes

- no exercise of the options described above;
- the conversion of all of our Series A, Series B and Series C preferred shares into common shares on a one-for-one basis upon the closing of this offering and the filing and effectiveness of our amendment and restatement of our articles of association to increase the number of our authorized common shares to shares immediately prior to the closing of this offering;
- an initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus; and
- no exercise of the option granted to the underwriters to purchase up to additional common shares to cover over-allotments, if any, in connection with the offering.

## SUMMARY CONSOLIDATED HISTORICAL AND OTHER FINANCIAL INFORMATION

The following summary consolidated historical financial information should be read in conjunction with "Presentation of Financial and Other Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements of Auris Medical AG, prior to our corporate reorganization, including the notes thereto, included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of results for the entire year.

The summary income statement and balance sheet data for and as of the years ended December 31, 2013 and 2012 of Auris Medical AG, prior to our corporate reorganization, are derived from the audited consolidated financial statements included elsewhere in this prospectus, which have been audited by KPMG AG. The summary income statement and balance sheet data for the three months ended and as of March 31, 2014 and 2013 are derived from the unaudited condensed consolidated interim financial statements included elsewhere in this prospectus. The unaudited financial data, in management's opinion, have been prepared on the same basis as the audited consolidated financial statements and related notes included elsewhere in this prospectus, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the financial information as of and for the periods presented.

We present the audited consolidated financial statements and the unaudited condensed consolidated interim financial statements in CHF and in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board, or IFRS.

| | FOR THE YEARS ENDED DECEMBER 31, | | FOR THE THREE MONTHS ENDED MARCH 31, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2014 | 2013 |
| | (in thousands of CHF except for share and per share data) | | | |
| **Income Statement Data:** | | | | |
| Research and development | (13,254) | (3,987) | (4,149) | (1,973) |
| General and administrative | (1,362) | (624) | (1,709) | (270) |
| Operating loss | (14,616) | (4,611) | (5,858) | (2,243) |
| Finance expense | (159) | (2) | (51) | (11) |
| Finance income | 76 | 10 | 50 | 24 |
| Loss before tax | (14,699) | (4,602) | (5,860) | (2,230) |
| Income tax expense | (306) | — | — | — |
| Net loss attributable to owners of the Company | (15,005) | (4,602) | (5,860) | (2,230) |
| Other comprehensive income: | | | | |
| Items that will never be reclassified to profit or loss: | | | | |
| Remeasurements of defined benefits liability | (58) | (55) | (17) | 43 |
| Items that are or may be reclassified to profit or loss: | | | | |
| Foreign currency translation differences | 32 | 22 | 5 | (30) |
| Other comprehensive income | (26) | (32) | (11) | 13 |
| Total comprehensive loss attributable to owners of the Company | (15,031) | (4,635) | (5,871) | (2,217) |
| Net loss per share (1) | | | | |
| Net loss per share, basic and diluted (2) | (1.01) | (0.40) | (0.32) | (0.19) |
| Weighted-average number of shares used to compute net loss per common share, basic and diluted | 14,917,064 | 11,581,450 | 18,055,273 | 11,581,450 |
| Pro forma net loss per common share (3) | | | | |
| Pro forma net loss per common share, basic and diluted (4) | (1.01) | (0.40) | (0.32) | (0.19) |
| Pro forma weighted-average number of common shares used to compute pro forma net loss per common share, basic and diluted | 14,917,064 | 11,581,450 | 18,055,273 | 11,581,450 |

(1) Includes preferred shares, which will be converted on a one-for-one basis upon the closing of this offering.

(2) Basic net loss per common share and diluted net loss per common share are the same because outstanding options and convertible loans (to the extent outstanding during the applicable time period) would be anti-dilutive due to our net loss in these periods.

(3) Pro forma to reflect the conversion of our Series A, Series B and Series C preferred shares into common shares on a one-for-one basis upon the closing of this offering and does not include the conversion of the convertible loan (to the extent outstanding during the applicable time period).

(4) Pro forma basic net loss per common share and diluted net loss per common share are the same because outstanding options and convertible loans (to the extent outstanding during the applicable time period) would be anti-dilutive due to our net loss in this period.

| | AS OF MARCH 31, 2014 | |
|---|---|---|
| | ACTUAL | AS ADJUSTED (1) |
| | (in thousands of CHF) | |
| **Balance Sheet Data:** | | |
| Cash and cash equivalents (2) | 18,535 | |
| Total assets | 20,862 | |
| Total liabilities | 3,985 | |
| Total shareholders' equity attributable to shareholders of the company (2) | 16,877 | |

(1) As adjusted balance sheet data gives effect to our issuance and sale of common shares in this offering at an assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(2) As adjusted cash and cash equivalents represents actual cash and cash equivalents, plus the assumed net proceeds of this offering. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our as adjusted cash and cash equivalents and as adjusted total shareholders' equity by CHF , assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

# RISK FACTORS

*You should carefully consider the risks and uncertainties described below and the other information in this prospectus before making an investment in our common shares. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common shares could decline and you could lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. See "Cautionary Statement Regarding Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors*.

## Risks Related to Our Business and Industry

***We are a development stage company and have a limited operating history and a history of operating losses. We anticipate that we will continue to incur losses for the foreseeable future.***

We are a development-stage biopharmaceutical company with limited operating history. Since inception, we have incurred significant operating losses. We incurred net losses (defined as net loss attributable to owners of the company) of CHF 15.0 million and CHF 4.6 million for the years ended December 31, 2013 and 2012, respectively, and net losses of CHF 5.9 million and CHF 2.2 million for the three months ended March 31, 2014 and 2013, respectively. As of March 31, 2014, we had an accumulated deficit of CHF 39.0 million.

Our losses have resulted principally from expenses incurred in research and development of our product candidates and from general and administrative expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts for our product candidates in clinical development AM-101 and AM-111 and seek to obtain regulatory approval and commercialization of our product candidates. In our financial year ending December 31, 2014, we expect to incur costs in the range of CHF 30 to 35 million associated with research and development.

To date, we have financed our operations through private placements of equity securities. We have no products approved for commercialization and have never generated any revenues from product sales. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are in the late stages of clinical development for our product candidates, but it may be several years, if ever, before we complete pivotal clinical trials and have a product candidate approved for commercialization and begin to generate revenues from product sales.

***We have never generated any revenue from product sales and may never be profitable.***

We have no products approved for commercialization and have never generated any revenue. Our ability to generate revenue and achieve profitability depends on our ability to successfully complete the development of, and obtain the marketing approvals necessary to commercialize, one or more of our product candidates. We do not anticipate generating revenue from product sales unless and until we obtain regulatory approval for, and commercialize, AM-101 or AM-111. Our ability to generate future revenue from product sales depends heavily on our success in many areas, including but not limited to:

- completing research and clinical development of our product candidates, including successfully completing Phase 3 clinical trials of AM-101 or AM-111;
- obtaining marketing approvals for our product candidates, including AM-101 or AM-111, for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for any approved product candidates and maintaining supply and manufacturing relationships with third parties that can conduct the process and provide adequate (in amount and quality) products to support clinical development and the market demand for our product candidates, if approved;
- launching and commercializing product candidates for which we obtain marketing approval, either directly or with a collaborator or distributor;
- obtaining market acceptance of our product candidates as viable treatment options;
- addressing any competing technological and market developments;

- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Because of the numerous risks and uncertainties with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies, domestic or foreign, to change our manufacturing processes, or to perform clinical, nonclinical, or other types of trials in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Additionally, if we are not able to generate sufficient revenue from the sale of any approved products, we may never become profitable.

We may be unable to develop and commercialize AM-101, AM-111 or any other product candidate and, even if we do, may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations. A decline in the value of our company could cause you to lose all or part of your investment.

***Even if this offering is successful, we expect that we will need substantial additional funding before we can expect to become profitable from sales of our products. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.***

We are currently advancing our product candidates AM-101 and AM-111 through clinical development. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we continue our ongoing and initiate new trials of AM-101 and AM-111 and initiate preclinical and clinical development of other product candidates. We expect that our total research and development expense in 2014 will be in the range of CHF 30 to 35 million. As of March 31, 2014, our cash and cash equivalents were CHF 18.5 million. We currently believe that the net proceeds of this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least the next          months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing, and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish, including any required milestone and royalty payments thereunder.

We expect that we will require additional capital to commercialize our product candidates AM-101 and AM-111. If we receive regulatory approval for AM-101 or AM-111, and if we choose to not grant any licenses to partners, we

expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We also expect to incur additional costs associated with operating as a public company following this offering. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are not able to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

***Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.***

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants and license and development agreements in connection with any collaborations. We do not have any committed external source of funds. In the event we need to seek additional funds we may raise additional capital through the sale of equity or convertible debt securities. In such an event, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property or future revenue streams. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

***We have a limited operating history and no history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.***

We began our current operations in 2003. Our operations to date have been limited to financing and staffing our company, developing our technology and developing AM-101, AM-111 and our other product candidates. We have not yet demonstrated an ability successfully to complete a large-scale, pivotal clinical trial, obtain marketing approval, manufacture a commercial scale product or conduct sales and marketing activities necessary for successful product commercialization. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical products.

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

***We depend entirely on the success of AM-101 and AM-111, which are still in clinical development. If our clinical trials are unsuccessful, we do not obtain regulatory approval or we are unable to commercialize AM-101 and AM-111, or we experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.***

We currently have no products approved for sale and have invested a significant portion of our efforts and financial resources in the development of AM-101 and AM-111, which are still in clinical development. Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on successful clinical development, obtaining regulatory approval and eventual commercialization of these product candidates. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug. The success of AM-101 and AM-111 will depend on several factors, including the following:

- completing clinical trials that demonstrate the efficacy and safety of our product candidates;
- receiving marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- acceptance of our product candidates by patients, the medical community and third-party payors,
- a continued acceptable safety profile following approval;
- competing effectively with other therapies; and
- qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize AM-101 or AM-111, which would materially adversely affect our business, financial condition and results of operations.

***Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results. If clinical trials of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.***

To obtain the requisite regulatory approvals to market and sell any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, the positive results generated to date in clinical trials for our product candidates do not ensure that later clinical trials will demonstrate similar results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

Clinical trials must be conducted in accordance with FDA, EMA and comparable foreign regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Institutional Review Boards, or IRBs, at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our product candidates produced under current good manufacturing practices, or cGMP, and other requirements. We depend on medical institutions and clinical research organizations, or CROs, to conduct our clinical trials in compliance with current good clinical practice, or cGCP, standards. To the extent the CROs fail to enroll participants for our clinical trials, fail to conduct the trial to cGCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

To date, we have not completed all clinical trials required for the approval of any of our product candidates. Enrollment in two Phase 3 clinical trials of AM-101 has begun; and we expect to begin a Phase 2 trial and a concurrent Phase 3 trial of AM-111 in the fourth quarter of 2014. The development of our other product candidates is less advanced and trials have not yet started.

The completion of clinical trials for our clinical product candidates may be delayed, suspended or terminated as a result of many factors, including but not limited to:

- the delay or refusal of regulators or IRBs to authorize us to commence a clinical trial at a prospective trial site and changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to ensure adequate statistical power to detect statistically significant treatment effects;
- negative or inconclusive results, which may require us to conduct additional preclinical or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns could cause us to suspend or terminate a trial if we find that the participants are being exposed to unacceptable health risks;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;
- lower than anticipated retention rates of patients and volunteers in clinical trials;

- our CROs or clinical trial sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a trial;
- delays relating to adding new clinical trial sites;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality or stability of the product candidate falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of the product candidate to complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials.

Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

Positive or timely results from preclinical or early stage trials do not ensure positive or timely results in late stage clinical trials or product approval by the FDA, the EMA or comparable foreign regulatory authorities. Products that show positive preclinical or early clinical results may not show sufficient safety or efficacy in later stage clinical trials and therefore may fail to obtain regulatory approvals. For example, although AM-101 achieved favorable results in our Phase 2 efficacy trial, we may nonetheless fail to achieve success in Phase 3 clinical trials of AM-101. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for the product candidates. The FDA, the EMA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe the data collected from clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. In the case of our late stage clinical product candidates, results may differ in general on the basis of the larger number of clinical trial sites and additional countries and languages involved in Phase 3 clinical trials.

In the case of AM-101 our endpoints in Phase 3 clinical trials are based on patient reported outcomes, some of which are captured daily from trial participants with electronic diaries. We have no assurance and cannot rely on past experience that the high frequency of questioning is not influencing the measured outcome. In addition, low compliance with daily reporting requirements may impact the trials' validity or statistical power. Under the SPA with the FDA we agreed to use the Tinnitus Functional Index, or TFI, as a co-primary efficacy endpoint in the TACTT2 trial; we also use the questionnaire as a secondary efficacy endpoint in the TACTT3 trial. We used a different tinnitus questionnaire in the previous clinical trials with AM-101, and there is no assurance that outcomes with the TFI will be qualitatively and quantitatively similar or the same. In the case of AM-111 we are evaluating the safety and efficacy in an idiopathic condition which implies a considerable heterogeneity in the etiology and natural history of the condition. This may have an impact on the safety and efficacy outcomes of our Phase 3 clinical trial. We cannot assure you that any Phase 2, Phase 3 or other clinical trials that we may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

If we are required to conduct additional clinical trials or other testing of AM-101, AM-111 or any other product candidate that we develop beyond the trials and testing that we contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with AM-101, AM-111 or our other product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements; or
- remove the product from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates, which may harm our business and results of operations. In addition, some of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of regulatory approval of AM-101, AM-111 or any other product candidate.

***If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.***

If our product candidates are associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon their development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in preclinical or early stage testing have later been found to cause side effects that restricted their use and prevented further development of the compound for larger indications.

In our clinical trials of AM-101 and AM-111 to date, adverse events have included procedure-related transient changes in tinnitus loudness, muffled hearing, ear discomfort or pain, incision site complications, and middle ear infections. A limited number of serious adverse events were observed (in 2.4% of patients enrolled in the AM-101 phase 2 program and in 4.5% of patients in the AM-111 phase 2 study); all (AM-101) or most (AM-111) were considered unrelated or unlikely related to the treatment. Occurrence of serious procedure- or treatment-related side effects could impede clinical trial enrollment and receipt of marketing approval from the FDA, the EMA and comparable foreign regulatory authorities. They could also adversely affect physician or patient acceptance of our product candidates.

Additionally if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product;
- regulatory authorities may require additional warnings on the label;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients; and
- our reputation and physician or patient acceptance of our products may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

***We depend on enrollment of patients in our clinical trials for our product candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts could be materially adversely affected.***

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. In our Phase 3 clinical trials of AM-101, we seek to enroll patients with acute inner ear tinnitus, meaning patients with symptom duration of three months or less, due to traumatic injury to their cochlea or otitis media. Thus, we must identify, recruit, enroll and dose patients with tinnitus caused by a pre-determined universe of factors in a limited time frame. Our product candidate AM-111, which is intended for patients with acute inner ear hearing loss, or ASNHL, has orphan drug designation for the treatment of ASNHL, which means that the potential patient population is more limited. In our planned Phase 2 and Phase 3 clinical trials of AM-111 the enrollment window is 72 hours from onset, meaning that we must enroll patients in a short time frame.

The specific target population of patients and therapeutic time windows may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

***We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage; and our product liability insurance may not cover all damages from such claims.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently we have no products that have been approved for commercial sale; however, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

We purchase liability insurance in connection with each of our clinical trials. For example, in connection with our Phase 3 trial for AM-101, we have a $50 million policy, which is subject to claim, geographical and other limits. It is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

***We have obtained orphan drug designation for AM-111 for the treatment of ASNHL by the FDA and the EMA, and we may rely on obtaining and maintaining orphan drug exclusivity for AM-111, if approved. Orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug exclusivity for AM-111, we may be subject to earlier competition and our potential revenue will be reduced.***

AM-111 has been granted orphan drug designation for the treatment of ASNHL by the FDA and EMA. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention, or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention, or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention, or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the European Union, orphan drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

Even though we have obtained orphan drug designation for AM-111 for the treatment of ASNHL in the United States and Europe, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug designation for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

***Due to our limited resources and access to capital, we must and have in the past decided to prioritize development of certain product candidates; these decisions may prove to have been wrong and may adversely affect our revenues.***

Because we have limited resources and access to capital to fund our operations, we must decide which product candidates to pursue and the amount of resources to allocate to each. As such, we are currently primarily focused on the development of AM-101 and AM-111 for the treatment of acute inner ear tinnitus and acute inner ear hearing loss, respectively. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, in particular for inner ear disorders, our business, financial condition and results of operations could be materially adversely affected.

***Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.***
Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

## Risks Related to Regulatory Approval of our Product Candidates

***We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.***
Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize one or more product candidates. We currently have two product candidates that have completed Phase 2 clinical trials. Enrollment in Phase 3 clinical trials of AM-101 has begun; and we expect to begin enrolling patients in a Phase 3 trial of AM-111 in the fourth quarter of 2014. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA, EMA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

Although certain of our employees have prior experience with submitting marketing applications to the FDA, EMA or comparable foreign regulatory authorities, we as a company have not submitted such applications for our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval, including reliance on foreign clinical data as studies of AM-111 to date have been conducted solely in the European Union;
- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical trials or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application, or NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or comparable foreign regulatory authorities that a product candidate’s risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, no product for the treatment of acute inner ear tinnitus or acute inner ear hearing loss has been approved by the FDA or the EMA. Accordingly, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and in additional foreign countries where we have commercial rights. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing, and

distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. Failure to obtain marketing authorization for our product candidates will result in our being unable to market and sell such products, which would materially adversely affect our business, financial conditional and results of operation. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

***Because we are developing therapies for which there is little clinical experience and, in some cases, using new endpoints, there is more risk that the outcome of our clinical trials will not be favorable. Even if the results of our trials are favorable, there is risk that they will not be acceptable to regulators or physicians.***

There are currently no drugs with proven efficacy for acute inner ear tinnitus or acute inner ear hearing loss. In addition, there has been limited historical clinical trial experience generally for the development of drugs to treat these conditions. Regulatory authorities in the United States and European Union have not issued definitive guidance as to how to measure the efficacy of treatments for acute inner ear tinnitus or acute inner ear hearing loss, and regulators have not yet established what is required to be demonstrated in a clinical trial in order to signify a clinically meaningful result and/or obtain marketing approval. We have designed our Phase 3 trials for AM-101 and AM-111 to include endpoints that we believe are clinically justified and meaningful. With regard to AM-101, the EMA indicated that a statistically significant improvement in tinnitus loudness that is supported by several secondary variables would demonstrate a clinically meaningful result. The FDA indicated that a improvement in tinnitus loudness supported by a co-primary efficacy point, such as the TFI questionnaire, would be clinically meaningful. However, no product has been approved for marketing based upon such guidance and we cannot be certain that AM-101 will be approved even if it were to demonstrate such results in its Phase 3 trial. With regard to AM-111, the EMA has issued guidance that a 10 dB improvement in hearing thresholds is clinically significant, in line with clinical practice. However, no product has been approved for marketing based upon such guidance and we cannot be certain that AM-111 will be approved even if it were to demonstrate such results in its Phase 3 trial. We have not sought or received any guidance from the FDA yet that would apply to acute inner ear hearing loss.

***Safety issues with isomers of our product candidates or with approved products of third parties that are similar to our product candidates, could delay or prevent the regulatory approval process or result in restrictions on labeling.***

Discovery of previously unknown problems, or increased focus on a known problem, with an approved product may result in restrictions on its permissible uses, including withdrawal of the medicine from the market. Esketamine, the active substance of AM-101, is an isomer of Ketamine, and may be affected by the safety of the drugs related to them. Although Ketamine has been used successfully in patients for many years, newly observed toxicities or worsening of known toxicities, in preclinical studies of, or in patients receiving, Ketamine, or reconsideration of known toxicities of Ketamine in the setting of new indications, could result in increased regulatory scrutiny of AM-101. For example, Ketamine is regulated by the Drug Enforcement Administration, or DEA, under the Controlled Substances Act as a Schedule III drug. DEA scheduling is a separate process that can delay when a drug may become available to patients beyond an NDA approval date, and the timing and outcome of such DEA process is uncertain. Although we have observed no abuse liability associated with AM-101 to date, if AM-101 were to be scheduled under the Controlled Substances Act, such scheduling could negatively impact the ability or willingness of physicians to prescribe AM-101 and our ability to commercialize it.

***Our special protocol assessment agreement with the FDA for our Phase 3 study of AM-101 does not guarantee any particular outcome from regulatory review, including ultimate approval and may not lead to a faster development or regulatory review or approval process.***

We have obtained agreement from the FDA on a special protocol assessment, or SPA, for the design of our U.S. Phase 3 trial of AM-101. We also designed our Phase 3 clinical trials for AM-101 based on scientific advice that we received from the EMA. The FDA's SPA process is designed to facilitate the FDA's review and approval of drugs by allowing the FDA to evaluate the proposed design and size of Phase 3 clinical trials that are intended to form the primary basis for determining a drug product's efficacy. Upon specific request by a clinical trial sponsor, the FDA will evaluate the protocol and respond to a sponsor's questions regarding, among other things, primary efficacy endpoints, trial conduct and data analysis, within 45 days of receipt of the request. The FDA ultimately assesses whether the protocol design and planned analysis of the trial are acceptable to support regulatory approval of the product candidate with respect to the effectiveness of the indication studied. All agreements and disagreements

between the FDA and the sponsor regarding a SPA must be clearly documented in a SPA letter or the minutes of a meeting between the sponsor and the FDA. However, a SPA agreement does not guarantee approval of a product candidate, and even if the FDA agrees to the design, execution, and analysis proposed in protocols reviewed under the SPA process, the FDA may revoke or alter its agreement in certain circumstances. In particular, a SPA agreement is not binding on the FDA if public health concerns emerge that were unrecognized at the time of the SPA agreement, other new scientific concerns regarding product safety or efficacy arise, the sponsor company fails to comply with the agreed upon trial protocols, or the relevant data, assumptions or information provided by the sponsor in a request for the SPA change or are found to be false or omit relevant facts. In addition, even after a SPA agreement is finalized, the SPA agreement may be modified, and such modification will be deemed binding on the FDA review division, except under the circumstances described above, if the FDA and the sponsor agree in writing to modify the protocol and such modification is intended to improve the study. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement.

We cannot assure you that our Phase 3 clinical trial of AM-101 will succeed, will be deemed binding by the FDA under our documented SPA, or will result in any FDA approval for AM-101. The TACTT2 Phase 3 clinical trial to be primarily conducted in the United States and Canada is expected to enroll approximately 330 patients. We expect that the FDA will review our compliance with the protocol under our SPA agreement and that it will conduct inspections of some of the approximately 60 sites where the trial will be conducted. We cannot assure you that each of the clinical trial sites will pass such FDA inspections, and negative inspection results could significantly delay or prevent any potential approval for AM-101. If the FDA revokes or alters its agreement under the SPA, or interprets the data collected from the clinical trial differently than we do, the FDA may not deem the data sufficient to support an application for regulatory approval, which could materially adversely affect our business, financial condition and results of operations. A revocation or alteration in our existing SPA could significantly delay or prevent approval of our application. Our SPA with the FDA and the scientific advice from the EMA does not ensure that AM-101 will receive marketing approval or that the approval process will be faster than conventional regulatory procedures.

***We do not have control over the actual number of study participants that are willing and eligible for enrollment in the open label follow-on safety studies, AMPACT1 and AMPACT2. Hence, the number of patients with safety data may fail to reach the levels specified and requested by the FDA.***

The FDA has requested from us safety data from chronic intermittent use of AM-101 by a minimum of 300 patients treated for six months and a minimum of 100 patients treated for one year, to support a new drug application filing for AM-101 in the treatment of acute peripheral tinnitus. We are seeking to address this request by offering all participants completing the TACTT2 and TACTT3 studies and continuing to meet certain criteria the option to roll over into an open label follow-on safety study (AMPACT1 and AMPACT2, respectively) and receive up to three treatment cycles with AM-101 over a period of up to nine months. Together with the three month TACTT study duration, this would cover up to 12 months of exposure. Although we believe that a substantial number of TACTT study participants will be willing and eligible for enrollment into the AMPACT studies, we have no control over the actual number and over the number of treatment cycles that the AMPACT participants will choose. Hence the number of patients with safety data over six months and over 12 months may or may not fail to reach the levels specified and requested by the FDA. In case of insufficient numbers, this will become a review issue at the time of the NDA. Although we plan to apply for an indication of acute inner ear tinnitus, rather than chronic inner ear tinnitus, we cannot ensure that the FDA will be satisfied with the data supporting our NDA if we are not able to enroll sufficient numbers of patients in AMPACT1 and AMPACT2.

***Even if our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

If marketing authorization is obtained for any of our product candidates, the product will remain subject to continual regulatory review and therefore authorization could be subsequently withdrawn or restricted. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials and surveillance to monitor the safety and efficacy of the

product candidate. In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, we will be subject to ongoing regulatory obligations and oversight by regulatory authorities, including with respect to the manufacturing processes, labeling, packing, distribution, adverse event reporting, storage, advertising and marketing restrictions, and recordkeeping and, potentially, other post-marketing obligations, all of which may result in significant expense and limit our ability to commercialize such products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and cGCPs for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations. The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

***Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.***

In the United States and the European Union, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system. These changes could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any products for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sale prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. Cost-reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act may result in a similar reduction in payments from private payors.

More recently, in March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law, among other things, increased rebates a manufacturer must pay to the Medicaid program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established a new Medicare Part D coverage gap discount program, in which manufacturers must provide 50% point-of-sale discounts

on products covered under Part D and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Further, the new law imposed a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance were enacted, which may affect our business practices with health care practitioners. Although we will not know the full effects of the Health Care Reform Law until applicable federal and state agencies issue regulations or guidance under the new law, the new law appears likely to continue the pressure on pharmaceutical pricing and may also increase our regulatory burdens and operating costs.

Moreover, other legislative changes have also been proposed and adopted in the United States since the Health Care Reform Law was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

In the European Union, proposed new clinical trial regulations will centralize clinical trial approval, which eliminates redundancy, but in some cases this may extend timelines for clinical trial approvals due to potentially longer wait times. Proposals to require specific consents for use of data in research, among other measures, may increase the costs and timelines for our product development efforts. Austerity measures in certain European nations may also affect the prices we are able to seek if our products are approved, as discussed below.

Both in the United States and in the European Union, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

***Our relationships with customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.***

Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, primarily in the United States, that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable healthcare laws and regulations, include the following:

- the U.S. healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under U.S. government healthcare programs such as Medicare and Medicaid;
- the U.S. False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the U.S. Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the transparency requirements under the Health Care Reform Law require manufacturers of drugs, devices, biologics and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals, and ownership and investment interests held by physicians or their immediate family members; and
- analogous laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

## Risks Related to Commercialization of Our Product Candidates

***We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.***

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the United States and other jurisdictions. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our product candidates.

We believe that our key competitors are Otonomy, Inc., or Otonomy, and Sound Pharmaceuticals, Inc., or Sound Pharma, both U.S. companies developing pharmaceutical treatments for ear disorders. In October 2013, Otonomy

announced the launch of a development program for the treatment of tinnitus, OTO-311, which may directly compete with our AM-101 product candidate. For OTO-311 the company acquired certain assets and rights to intellectual property related to the use of the NMDA receptor antagonist gacyclidine for the treatment of tinnitus from NeuroSystec Corporation. NeuroSystec was founded in 2004 and sought to develop a drug-device combination product that could provide sustained delivery of gacyclidine (NST-001) to the inner ear. A 2010 article in *European Archives of Otorhinolaryngology* by Wenzel et al. described how in a compassionate use study in Europe four out of six tinnitus patients receiving a constant perfusion of gacyclidine onto their round window membrane for 40 to 63 hours reported temporary relief, and one among them lasting relief. NeuroSystec initiated a Phase 1b trial with NST-001 in January 2009, but never published outcomes thereof and ceased activities in 2013. We expect Otonomy to reformulate gacyclidine in a poloxamer gel formulation targeting single dose administration. It has been reported that Otonomy targets an IND for OTO-311 in 2015. OTO-311's competitive strength will ultimately depend on the demonstration of clinical efficacy and safety and its comparison with AM-101.

As we plan to test AM-111's efficacy in Meniere's Disease, an inner ear disorder that affects balance and hearing, we will enter into competition with an Otonomy project, OTO-104, which is currently in a Phase 2b clinical trial in the United States and Canada. OTO-104 is a poloxamer-based gel formulation of micronized dexamethasone which is injected intratympanically in a single dose into the middle ear for the treatment of Meniere's Disease. Results from a 44-patient Phase 1b clinical trial with OTO-104 were reported by Lambert et al. in a 2012 article in *Otology and Neurotology*. The trial enrolled patients with unilateral Meniere's Disease who had experienced at least two vertigo episodes during a 28-day lead-in period (with an average of seven to eight vertigo episodes during that period). In the three months following the treatment, the frequency of vertigo episodes decreased in all treatment groups, ranging from -3.6 episodes in the placebo group to -4.2 episodes in the 3 mg treatment group and -3.9 episodes in the 12 mg treatment group. Although the article did not provide a definition of clinically meaningful change, it stated that the clinical trial demonstrated a clinically meaningful reduction for the active treatment groups because, after three months, there was a larger decrease in the number of vertigo episodes, relative to baseline, in the 12 mg group than in the placebo group.

In June 2006, Sound Pharma began clinical testing of an oral treatment for hearing loss (SPI-1005, ebselen). Its active substance mimics and prompts production of the glutathione peroxidase enzyme. In February 2014, Sound Pharma announced positive outcomes from a placebo-controlled Phase 2 clinical trial with SPI-1005 in the prevention and treatment of temporary inner ear hearing loss from listening to loud music with a mobile digital media player. Although AM-111 targets permanent rather than transient hearing loss, SPI-1005 may become a competing product if Sound Pharma seeks and manages to demonstrate clinical efficacy also in the prevention and treatment of permanent inner ear hearing loss.

The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technology obsolete or non-competitive. Our competitors may, among other things:

- develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer;
- obtain quicker regulatory approval;
- establish superior proprietary positions;
- have access to more manufacturing capacity;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these occur, our business, financial condition and results of operations could be materially adversely affected.

***The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.***

The successful commercialization of AM-101, AM-111 or our other product candidates will depend, in part, on the extent to which coverage and reimbursement for our products or procedures using our products will be available from

government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new technologies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of such challenges to prices and increasing levels of evidence of the benefits and clinical outcomes of new technologies, we cannot be sure that coverage will be available for AM-101, AM-111 or any other product candidate that we commercialize and, if available, that the reimbursement rates will be adequate. If we are unable to obtain adequate levels of coverage and reimbursement for our product candidates, their marketability will be negatively and materially impacted.

Our customers, including hospitals, physicians and other healthcare providers that purchase certain injectable drugs administered during a procedure, such as our product candidates, generally rely on third-party payors to pay for all or part of the costs and fees associated with the drug and the procedures adminstering the drug. These third-party payors may pay separately for the drug or may bundle or otherwise include the costs of the drug in the payment for the procedure. We are unable to predict at this time whether our product candidates, if approved, will be eligible for such separate payments. Nor can we predict at this time the adequacy of payments, whether made separately for the drug and procedure or with a bundled or otherwise aggregate payment amount for the drug and procedure. In addition, obtaining and maintaining adequate coverage and reimbursement status is time-consuming and costly.

Third party payors may deny coverage and reimbursement status altogether of a given drug product, or cover the product but may also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases at short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact the favorable status. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States.

The unavailability or inadequacy of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of our product candidates and the future revenues we may expect to receive from those products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

***Our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition and results of operations.***

Even if the FDA, the EMA or other regulatory authority approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If AM-101, AM-111 or any other product candidate that we develop does not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of AM-101, AM-111 or any of our product candidates that is approved for commercial sale will depend on a variety of factors, including:

- how clinicians and potential patients perceive our novel products;
- the timing of market introduction;
- the number and clinical profile of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration, particularly as AM-101 and AM-111 require multiple outpatient procedures to administer the drug;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market, particularly as AM-101 and AM-111 are being developed for the treatment of acute inner ear disorders and are thus dependent on a relatively rapid diagnosis and dosing process;
- marketing and distribution support;

- availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payors, both public and private; and
- other potential advantages over alternative treatment methods.

If our product candidates fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

In addition, the potential market opportunity of AM-101 and AM-111 are difficult to precisely estimate. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions could not have been assessed by an independent source in every detail. If any of the assumptions proves to be inaccurate, then the actual market for AM-101 and AM-111 could be smaller than our estimates of the potential market opportunity. If the actual market for AM-101 and AM-111 is smaller than we expect, or if the products fail to achieve an adequate level of acceptance by physicians, health care payors and patients, our product revenue may be limited and it may be more difficult for us to achieve or maintain profitability.

***We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable partners.***

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for AM-101, AM-111 and our other product candidates, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our drug candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

## Risks Related to Our Reliance on Third Parties

***We have several areas of disagreement with Xigen, and consequently our relationship with Xigen and our business, commercialization prospects and financial condition may be adversely affected.***

We have several areas of disagreement with Xigen S.A., or Xigen, with whom we have an agreement pursuant to which Xigen granted us an exclusive worldwide license to use specified compounds to develop, manufacture and commercialize “pharmaceutical products as well as drug delivery devices and formulations for local administration of therapeutic substances to the inner ear for the treatment of ear disorders” (the Area). We differ from Xigen in our interpretation of the definition of the Area. We interpret “Area,” as it pertains to pharmaceutical products, as not limited to local administration to the inner ear, but inclusive of the use of pharmaceutical products generally for the treatment of ear disorders (and that the limitation of “local administration to the inner ear” applies only to “drug delivery devices and formulations”). Xigen has adopted the interpretation that the license is limited to local administration for both pharmaceutical products and drug delivery and formulations. This difference in interpretation has no impact on our current or planned use of AM-111 delivered locally via intratympanic treatment.

In addition, in October 2013, Xigen assigned certain of the patents relevant to the agreement to Xigen Inflammation Ltd., an unaffiliated entity organized in Cyprus. We consider this transfer to be in breach of the agreement since our prior written approval was not sought, although Xigen Inflammation Ltd. has confirmed to us that the assignment of patents is without prejudice to our license for local administration. Xigen has also requested from us quantities of AM-111 for certain analyses, although we believe the quantities requested exceed what laboratories would generally require for such tests.

The agreement contains a confidentiality provision restricting the disclosure of the terms of the agreement. We believe that Xigen may have waived the confidentiality provision of the agreement by disclosing the terms of the agreement to Xigen Inflammation Ltd., although Xigen has denied that any disclosure of the agreement has been made to the assignee despite the assignee's assurance that the assignment was without prejudice to our license for local administration. Despite this, in connection with this offering, we sought Xigen's consent to disclose certain provisions of the agreement and file a redacted version of the agreement with the SEC. Xigen, however, was only willing to provide its consent if we agreed to limit the scope of the definition of "Area," desist from claims that the transfer of patents to Xigen Inflammation Ltd. was in breach of the agreement and provide Xigen with their requested quantities of AM-111 for analysis.

We believe Xigen's demands are unreasonable and unwarranted, and therefore we were not able to come to an agreement with Xigen prior to disclosing certain provisions of the agreement in this prospectus and filing a redacted version of the agreement. Xigen may consider such disclosure to be a breach of the confidentiality provision of the agreement. The agreement is governed by Swiss law, and the venue is Solothurn, Switzerland. In the opinion of our Swiss counsel, while there can be no assurances, this disclosure by us does not rise to the level of material breach that would allow Xigen to repudiate the agreement.

We cannot predict the result of these disagreements with Xigen and any litigation that may result. Xigen may attempt to repudiate the contract and initiate a claim for damages against us. According to our Swiss counsel, Xigen would have to show that it had suffered a loss due to the disclosure of the redacted agreement and certain provisions of the agreement in this prospectus, and the damages could be equal to the amount of the effective direct damage that Xigen proves it has suffered.

These disagreements, and in particular any resulting litigation, could result in substantial legal expenses, distraction to our management and employees and potentially the loss of our right to commercialize AM-111. No assurance can be given that these disagreements and any resulting litigation will not have a material adverse effect on our business, commercialization prospects for AM-111 and our other product candidates and our financial condition. For a description of our agreement with Xigen, please see "Business—Collaboration and License Agreements—Xigen."

***If we fail to maintain our current strategic relationships with INSERM and Xigen, our business, commercialization prospects and financial condition may be materially adversely affected.***

We have a co-ownership/exploitation agreement with the Institut National de la Santé et de la Recherche Médicale, or INSERM, governing the exploitation of any products derived from patents that resulted from our joint research program with INSERM that was conducted in 2003 to 2005. Under this agreement with INSERM, we are given the exclusive right to exploit the patents issuing from the filed patent applications for all claimed applications, including the treatment of tinnitus, in order to develop, promote, manufacture, cause to be manufactured, use, sell and distribute any products, processes or services deriving from such patents, including AM-101, in any country in which these patent applications have been filed during the term of the agreement. We alone are entitled to grant manufacturing or sales licenses for any patents to our subsidiaries and/or third parties. INSERM is entitled to use the inventions covered by the patents and applications for its own research purposes, free of charge, but may not generate any direct or indirect profits from such use. We have agreed to finance any additional research and development work necessary to obtain marketing authorizations for inventions covered by these patents and applications. If we fail to use reasonable efforts in carrying out this additional research, then INSERM may revoke the exclusivity of exploitation granted to us under this agreement. Additionally, we have an exclusive worldwide license from Xigen for the application of Xigen's novel intracellular peptide therapeutics in the area of ear disorders. These intellectual property rights have been the basis of our research and development of AM-101 and AM-111.

Good relationships with INSERM and Xigen are important for our business prospects. If our relationships with INSERM or Xigen were to deteriorate substantially or INSERM or Xigen were to challenge our use of their intellectual property or our calculations of the payments we owe under our agreements, our business, financial condition, commercialization prospects and results of operations could be materially adversely affected.

***We may seek to form additional strategic alliances in the future with respect to our product candidates, and if we do not realize the benefits of such alliance, our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.***

Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses and may require expertise, such as sales and marketing expertise, which we do not currently possess. Therefore, in addition to our relationships with INSERM and Xigen, for our AM-101 and AM-111 product candidates respectively, for one or more of our product candidates, we may decide to enter into strategic alliances, or create joint ventures or collaborations with pharmaceutical or biopharmaceutical companies for the further development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. We may also be restricted under existing and future collaboration agreements from entering into strategic partnerships or collaboration agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all, for any of our existing or future product candidates and programs because the potential partner may consider that our research and development pipeline is insufficiently developed to justify a collaborative effort, or that our product candidates and programs do not have the requisite potential to demonstrate safety and efficacy in the target population. If we are unsuccessful in establishing and maintaining a collaboration with respect to a particular product candidate, we may have to curtail the development of that product candidate, reduce the scope of or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense for which we have not budgeted. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue. Even if we are successful in establishing a new strategic partnership or entering into a collaboration agreement, we cannot be certain that, following such a strategic transaction or license, we will be able to progress the development and commercialization of the applicable product candidates as envisaged, or that we will achieve the revenues that would justify such transaction, and we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaboration partner devotes to the product development program;
- the collaboration partner may experience financial difficulties;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaboration partner could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors; or
- business combinations or significant changes in a collaboration partner’s business strategy may adversely affect our willingness to complete our obligations under any arrangement.

***We rely on third parties to conduct our nonclinical and clinical trials and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines, or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing nonclinical and clinical programs, including the clinical trials of AM-101 and AM-111. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on the CROs does not relieve us of our regulatory responsibilities. We and our CROs and other vendors are required to comply with cGMP, cGCP, and Good Laboratory Practice, or GLP, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the

European Union and comparable foreign regulatory authorities for all of our product candidates in nonclinical and clinical development. Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, trial sites and other contractors. If we or any of our CROs or vendors fail to comply with applicable regulations, the data generated in our nonclinical and clinical trials may be deemed unreliable and the EMA, FDA, other regulatory authorities may require us to perform additional nonclinical and clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical trials comply with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

If any of our relationships with these third-party CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. In addition, our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our on-going nonclinical and clinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects.

***We currently rely on third-party suppliers and other third parties for production of our product candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates.***

We currently rely on and expect to continue to rely on third parties, for the manufacturing and supply of chemical compounds for the clinical trials of our product candidates, including AM-101 and AM-111, and others for the manufacturing and supply of pre-filled syringes. For the foreseeable future, we expect to continue to rely on such third parties for the manufacture of any of our product candidates on a clinical or commercial scale, if any of our product candidates receives regulatory approval. Reliance on third-party providers may expose us to different risks than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable marketing application to the FDA or other regulatory authority. Although we have auditing rights with all our manufacturing counterparties, we do not have control over a supplier's or manufacturer's compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

In addition, the fact that we are dependent on our suppliers and other third parties for the manufacture, storage and distribution of our product candidates means that we are subject to the risk that our product candidates and, if approved, commercial products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could result in recalls or regulatory enforcement action that could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials may also adversely influence our business, financial condition and results of operations. Supply sources could be interrupted from time to time and, if interrupted, that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all.

Our current and anticipated future dependence upon others for the manufacturing of AM-101, AM-111 and any other product candidate that we develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

***The drug substance and drug product for our product candidates are currently acquired from single-source suppliers. The loss of these suppliers, or their failure to supply us with the drug substance or drug product, could materially and adversely affect our business.***

We do not currently, and do not expect to in the future, independently conduct manufacturing activities for our product candidates, including AM-101 and AM-111. We currently have a relationship with one supplier for the supply of the hyaluronic acid component of AM-101 and AM-111. We are reliant upon single source third party contract manufacturing organizations to manufacture and supply the drug substance and drug product and components thereof for each of AM-101 and AM-111. We do not currently have any other suppliers for the drug substance or drug product of our product candidates and, although we believe that there are alternate sources of supply that could satisfy our clinical and commercial requirements, and we have performed some preliminary investigations to assess this availability, we cannot assure you that identifying alternate sources and establishing relationships with such sources would not result in significant delay in the development of our product candidates. Additionally, we may not be able to enter into supply arrangements with alternative suppliers on commercially reasonable terms, or at all. A delay in the development of our product candidates or having to enter into a new agreement with a different third party on less favorable terms than we have with our current suppliers could have a material adverse impact upon on our business.

## Risks Related to Intellectual Property

***If we or our licensors are unable to obtain and maintain effective patent rights for our technologies, product candidates or any future product candidates, or if the scope of the patent rights obtained is not sufficiently broad, we may not be able to compete effectively in our markets.***

We rely upon a combination of patents, trade secret protection, and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary technology and products.

We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and products that are important to our business. This process is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates in the United States or in other foreign countries. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent

application related to our product candidates, or whether we were the first to make the inventions claimed in our owned patents or pending patent applications, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third party patent rights. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We, independently or together with our licensors, have filed several patent applications covering various aspects of our product candidates. We cannot offer any assurances about which, if any, patents will issue, the breadth of any such patent or whether any issued patents will be found invalid and unenforceable or will be challenged by third parties. Any successful opposition to these patents or any other patents owned by or licensed to us after patent issuance could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

***We may not have sufficient patent terms to effectively protect our products and business.***

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from generic medications.

While patent term extensions under the Hatch-Waxman Act in the United States and under supplementary protection certificates in Europe may be available to extend the patent exclusivity term for AM-101 and AM-111, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long. Specifically, Xigen is concurrently developing another indication for XG-102, the active substance of AM-111. Since for each product only a single patent can be selected for patent term extension, there may be a conflict of interest with respect to patent selection for extending patent terms covering two different indications of XG-102. It is possible that Xigen may select a patent that does not provide the longest patent term for the AM-111 indication developed by us. In addition, upon issuance in the United States any patent term can be adjusted based on certain delays caused by the applicant(s) or USPTO. For example, a patent term can be reduced based on certain delays caused by the patent applicant during patent prosecution.

While in both the United States and Europe there is a possibility to obtain market protection independent from any patent protection for up to 5 and 10 years from approval, respectively, there is no assurance that we can obtain such data exclusivity with respect to AM-101, AM-111, or any of our other product candidates. Our issued patents and pending patent applications are expected to expire for AM-101 between 2024 and 2028 and for AM-111 between 2020 and 2025, prior to any patent term extensions to which we may be entitled under applicable laws.

***Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Assuming the other requirements for

patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. The effects of these changes are currently unclear as the USPTO must still implement various regulations, the courts have yet to address any of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

***If we are unable to maintain effective proprietary rights for our technologies, product candidates or any future product candidates, we may not be able to compete effectively in our markets.***

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

Although we expect all of our employees and consultants to assign their inventions to us, and all of our employees, consultants, advisors, and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed or that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating such trade secrets. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations.

***Third-party claims of intellectual property infringement may expose us to substantial liability or prevent or delay our development and commercialization efforts.***

Our commercial success depends in part on our ability to develop, manufacture, market and sell our product candidates and use our proprietary technology without alleged or actual infringement, misappropriation, or other violation of the patents and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. Some claimants may have substantially greater resources than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture, or methods of treatment related to the use or manufacture of our product candidates. Although we generally conduct certain freedom to operate search and review with respect to our product candidates, we cannot guarantee that any of our search and review is complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture, or methods of use, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires or is finally determined to be invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

***Additional competitors could enter the market with generic versions of our products, which may result in a material decline in sales of affected products.***

Under the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic copy of an approved innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit an NDA under section 505(b)(2) that references the FDA's prior approval of the innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. Hatch-Waxman also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and reviewing) of an ANDA or 505(b)(2) NDA. These include, subject to certain exceptions, the period during which an FDA-approved drug is subject to orphan drug exclusivity. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication,

"Approved Drug Products with Therapeutic Equivalence Evaluations," known as the "Orange Book." If there are patents listed in the Orange Book, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in the ANDA what is known as a "Paragraph IV certification," challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the innovator, too, and if within 45 days of receiving notice the innovator sues to protect its patents, approval of the ANDA is stayed for 30 months, or as lengthened or shortened by the court.

Accordingly, if AM-101 and AM-111 are approved, competitors could file ANDAs for generic versions of AM-101 and AM-111, or 505(b)(2) NDAs that reference AM-101 and AM-111, respectively. If there are patents listed for AM-101 and AM-111 in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any patents that are granted and listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially. Should sales decline, we may have to write off a portion or all of the intangible assets associated with the affected product and our results of operations and cash flows could be materially and adversely affected.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

***The patent protection and patent prosecution for some of our product candidates is dependent on third parties.***

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents relating to our product candidates are controlled by our licensors. This is the case under our agreement with Xigen, where Xigen is entirely responsible for the prosecution and maintenance of the licensed patents and patent applications directed to AM-111. Xigen has no obligation to provide us any information with respect to such prosecution and we will not have access to any patent prosecution or maintenance information that is not publicly available. Although we monitor Xigen's ongoing prosecution and maintenance of the licensed patents, if Xigen or any of our future licensing partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering AM-111 or any of our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products. Specifically Xigen is concurrently developing another indication for XG-102, the active substance of AM-111. This may cause a conflict of interest and adversely affect Xigen's ability to prosecute the patent portfolio licensed to us in the best interest of our business. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties including with respect to the patents and applications licensed to us under our co-ownership and exploitation agreement with INSERM for AM-101, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to the date upon which we

assumed control over patent prosecution. We are required to consult and cooperate with INSERM regarding the prosecution, maintenance, and enforcement of, and in certain instances INSERM has the right to independently enforce, the relevant patents, which may place those patents at risk or hinder our ability to develop and commercialize those product candidates or protect our patent rights.

***If we fail to comply with the obligations in our intellectual property agreements, including those under which we license intellectual property and other rights from third parties, or otherwise experience disruptions to our business relationships with our licensors and partners, we could lose intellectual property rights that are important to our business.***

We are a party to a number of intellectual property license and co-ownership agreements that are important to our business and expect to enter into additional such agreements in the future. Our existing agreements impose, and we expect that future agreements will impose, various diligence, commercialization, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. Moreover, if we fail to comply with our obligations under our co-ownership and exploitation agreement with INSERM for AM-101, including certain commercialization requirements, or we are subject to a bankruptcy, INSERM may terminate the agreement and we may lose our rights to exclusively exploit and commercialize the applicable patents. In such event we would not be able to prevent INSERM from exploiting or licensing to the third parties the rights to exploit the applicable patents, which would have a material adverse effect on our ability to successfully commercialize the affected product candidates. Under our co-ownership agreement with INSERM we may be required to assign our rights in the relevant patents to INSERM if we choose not to or fail to continue to prosecute maintain or patents or patent applications in a given country or countries, in which event we would not be able to develop or market products covered by the applicable patents.

Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing or co-ownership agreement, including:

- the scope of rights granted under the agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor or partner that is not subject to the agreement;
- the sublicensing of patent and other rights;
- our diligence and commercialization obligations under the agreement and what activities satisfy those obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors or partners and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed or co-own prevent or impair our ability to maintain our current licensing or exclusivity arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

***We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.***

We currently have rights to the intellectual property, through licenses from third parties and under patents that we own, to develop our product candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. In addition, our product candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

For example, we sometimes collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our applicable product candidate or program.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a product candidate or program, we may have to abandon development of that product candidate or program and our business and financial condition could suffer.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming, and unsuccessful.***

Competitors may infringe our patents or the patents of our licensors. To counter such infringement, we may be required to file claims against those competitors, which can be expensive and time-consuming. If we or one of our licensing partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid, overbroad and/or unenforceable, or that we infringe the defendant's patents. In patent litigation in the United States, defendant counterclaims alleging invalidity, overbreadth and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability is unpredictable. A court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop a third party from using the technology in question on the grounds that our patents do not cover that technology. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could adversely affect us.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. We may not be able to prevent, alone or with our licensors, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common shares.

***We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.***

We employ and utilize the services of individuals who were previously employed or provided services to universities or other biotechnology or pharmaceutical companies. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise

used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employee's, consultant's or independent contractor's former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely impact our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***Our reliance on our advisors, employees and third parties requires us to share our intellectual property and trade secrets, which increases the possibility that a competitor will discover them or that our intellectual property will be misappropriated or disclosed.***

Because we rely on our advisors, employees and third-party contractors and consultants to research and develop and to manufacture our product candidates, we must, at times, share our intellectual property with them. We seek to protect our intellectual property and other proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of these advisors, employees and third parties to use or disclose our confidential information, including our intellectual property and trade secrets. Despite the contractual provisions employed when working with these advisors, employees and third parties, the need to share intellectual property and other confidential information increases the risk that such confidential information becomes known by our competitors, are inadvertently incorporated into the product development of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how, intellectual property and trade secrets, a competitor's discovery of our intellectual property or trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our intellectual property, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future may expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future, we may also conduct joint research and development programs that may require us to share intellectual property under the terms of our research and development or similar agreements. Despite our efforts to protect our intellectual property, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our intellectual property would impair our competitive position and have an adverse impact on our business.

***We may be subject to claims challenging the inventorship of our patents and other intellectual property.***

We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. As part of ordinary course

prosecution and maintenance activities, we determine whether to seek patent protection outside the U.S. and in which countries. This also applies to patents we have acquired or in-licensed from third parties. In some cases this means that we, or our predecessors in interest or licensors of patents within our portfolio, have sought patent protection in a limited number of countries for patents covering our product candidates. Competitors may use our technologies in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of our patents, the reproduction of our manufacturing or other know-how or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

## Risks Related to Employee Matters and Managing Growth

***Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.***

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have substantial experience with or been instrumental for us and our projects. Key management includes our executive officers Thomas Meyer, our founder, Chairman and Chief Executive Officer, Sven Zimmermann, our Chief Financial Officer and Bettina Stubinski, our Chief Medical Officer.

The loss of key managers and senior scientists could delay our research and development activities. Laws and regulations on executive compensation, including legislation in our home country, Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel. In Switzerland, new legislation affecting public companies has been passed that, among other things, (a) imposes an annual binding shareholders’ “say on pay” vote with respect to the compensation of executive management, including executive officers and the board of directors, (b) prohibits severance, advances, transaction premiums and similar payments to executive officers and directors and (c) requires companies to specify various compensation-related matters in their articles of association, thus requiring them to be approved by a shareholders’ vote. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement business strategy, which could have a material adverse effect on our business.

***We expect to expand our sales and marketing, development, and regulatory capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing, and to a lesser extent, drug development and regulatory affairs. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

### Risks Related to the Offering and our Common Shares

***The price of our common shares may be volatile and may fluctuate due to factors beyond our control.***

The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. The market price of our common shares may fluctuate significantly due to a variety of factors, including:

- positive or negative results of testing and clinical trials by us, strategic partners, or competitors;
- delays in entering into strategic relationships with respect to development and/or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole; or
- other events and factors beyond our control.

In addition, the stock market in general has recently experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of individual companies. Broad market and industry factors may materially affect the market price of companies' stock, including ours, regardless of actual operating performance.

***There was no public market for our common shares prior to this offering, and an active market in our common shares may not develop in which investors can resell our common shares.***

Prior to this offering there was no public market for our common shares. We cannot predict the extent to which an active market for our common shares will develop or be sustained after this offering, or how the development of such a market might affect the market price for our common shares. The initial public offering price of our common shares in this offering was agreed between us and the underwriters based on a number of factors, including market conditions in effect at the time of this offering, which may not be indicative of the price at which our common shares will trade following completion of this offering. Investors may not be able to sell their common shares at or above the initial public offering price.

***Certain of our existing shareholders will continue to own a majority of our common shares and as a result will be able to exercise significant control over us, and your interests may conflict with the interests of our existing shareholders.***

Following completion of this offering, our existing shareholders are expected to own approximately % of our common shares. Depending on the level of attendance at our general meetings of shareholders, these shareholders may be in a position to determine the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the shares represented at our general meetings of shareholders may control any shareholder resolution requiring an absolute majority of the shares represented, including the election of members to the board of directors of our company, certain decisions relating to our capital structure, the approval of certain significant corporate transactions and certain amendments to our articles of association. To the extent that the interests of these shareholders may differ from the interests of the company's other shareholders, the latter may be disadvantaged by any action that these shareholders may seek to pursue. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our common shares.

***Future sales, or the possibility of future sales, of a substantial number of our common shares could adversely affect the price of our common shares.***

Future sales of a substantial number of our common shares, or the perception that such sales will occur, could cause a decline in the market price of our common shares. Following the completion of this offering, we will have common shares outstanding (assuming no exercise of the over-allotment option) based on common shares outstanding as of , 2014 and additional common shares issuable upon the automatic

conversion of all of our outstanding preferred shares into common shares. This includes the common shares in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Approximately % of the common shares outstanding are expected to be held by existing shareholders. A significant portion of these common shares will be subject to the lock-up agreements described in the "Underwriting" section of this prospectus. If, after the end of such lock-up agreements, these shareholders sell substantial amounts of common shares in the public market, or the market perceives that such sales may occur, the market price of our common shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected. We also intend to enter into a registration rights agreement upon consummation of this offering pursuant to which we will agree under certain circumstances to file a registration statement to register the resale of the common shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such common shares. In addition, following the completion of this offering, we intend to cease any new grants under our existing equity incentive plans and to adopt a new omnibus equity incentive plan under which we would have the discretion to grant a broad range of equity-based awards to eligible participants. We intend to register all common shares that we may issue under this equity compensation plan. Once we register these common shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus. If a large number of our common shares or securities convertible into our common shares are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common shares and impede our ability to raise future capital.

***If you purchase common shares in this offering, you will suffer immediate dilution of your investment.***

The initial public offering price of our common shares is substantially higher than the as adjusted net tangible book value per common share. Therefore, if you purchase common shares in this offering, you will pay a price per common share that substantially exceeds our as adjusted net tangible book value per common share after this offering. To the extent outstanding options are exercised, you will incur further dilution. Based on the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $ per common share, representing the difference between our as adjusted net tangible book value per common share after giving effect to this offering and the assumed initial public offering price. In addition, purchasers of common shares in this offering will have contributed approximately % of the aggregate price paid by all purchasers of our common shares but will own only approximately % of our common shares outstanding after this offering. See "Dilution."

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

Our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common shares. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common shares to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

***We do not expect to pay dividends in the foreseeable future.***

We have not paid any dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. The proposal to pay future dividends to shareholders will in addition effectively be at the discretion of our board of directors after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitation pursuant to Swiss law or by our articles of association. See "Description of Share Capital and Articles of Association." Accordingly, investors cannot rely on dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares.

***We are a holding company with no material direct operations***

We are a holding company with no material direct operations. As a result, we would be dependent on dividends, other payments or loans from our subsidiaries in order to pay a dividend. Our subsidiaries are subject to legal requirements of their respective jurisdictions of organization that may restrict their paying dividends or other payments, or making loans, to us.

***We are a Swiss corporation. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.***

We are a Swiss corporation. Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in Switzerland. The rights of our shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and directors of companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board of directors is required by Swiss law to consider the interests of our company, our shareholders, our employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder. Swiss corporate law limits the ability of our shareholders to challenge resolutions made or other actions taken by our board of directors in court. Our shareholders generally are not permitted to file a suit to reverse a decision or an action taken by our board of directors but are instead only permitted to seek damages for breaches of fiduciary duty. As a matter of Swiss law, shareholder claims against a member of our board of directors for breach of fiduciary duty would have to be brought in Zug, Switzerland, or where the relevant member of our board of directors is domiciled. In addition, under Swiss law, any claims by our shareholders against us must be brought exclusively in Zug, Switzerland. See “Description of Share Capital and Articles of Association” and “Comparison of Delaware Law and Swiss Law.”

***Our common shares are issued under the laws of Switzerland, which may not protect investors in a similar fashion afforded by incorporation in a U.S. state***.

We are organized under the laws of Switzerland. A further summary of applicable Swiss company law is contained in this prospectus, see “Description of Share Capital and Articles of Association” and “Comparison of Delaware Law and Swiss Law.” However, there can be no assurance that Swiss law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the U.S., which could adversely affect the rights of investors.

***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.***

We are organized under the laws of Switzerland and our jurisdiction of incorporation is Zug, Switzerland. Moreover, a number of our directors and executive officers and a number of directors of each of our subsidiaries are not residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon us or upon such persons or to enforce against them judgments obtained in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our Swiss counsel that there is doubt as to the enforceability in Switzerland of original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent predicated upon the federal and state securities laws of the United States. Original actions against persons in Switzerland based solely upon the U.S. federal or state securities laws are governed, among other things, by the principles set forth in the Swiss Federal Act on International Private Law. This statute provides that the application of provisions of non-Swiss law by the courts in Switzerland shall be precluded if the result is incompatible with Swiss public policy. Also, mandatory provisions of Swiss law may be applicable regardless of any other law that would otherwise apply.

Switzerland and the United States do not have a treaty providing for reciprocal recognition and enforcement of judgments in civil and commercial matters. The recognition and enforcement of a judgment of the courts of the United States in Switzerland is governed by the principles set forth in the Swiss Federal Act on Private International Law. This statute provides in principle that a judgment rendered by a non-Swiss court may be enforced in Switzerland only if:

- the non-Swiss court had jurisdiction pursuant to the Swiss Federal Act on Private International Law;
- the judgment of such non-Swiss court has become final and non-appealable;
- the judgment does not contravene Swiss public policy;
- the court procedures and the service of documents leading to the judgment were in accordance with the due process of law; and
- no proceeding involving the same position and the same subject matter was first brought in Switzerland, or adjudicated in Switzerland, or was earlier adjudicated in a third state and this decision is recognizable in Switzerland.

***Our status as a Swiss corporation means that our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs.***

Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, the payment of dividends and cancellation of treasury shares must be approved by shareholders. Swiss law also requires that our shareholders themselves resolve to, or authorize our board of directors to, increase our share capital. While our shareholders may authorize share capital that can be issued by our board of directors without additional shareholder approval, Swiss law limits this authorization to 50% of the issued share capital at the time of the authorization. The authorization, furthermore, has a limited duration of up to two years and must be renewed by the shareholders from time to time thereafter in order to be available for raising capital. Additionally, subject to specified exceptions, including exceptions explicitly described in our articles of association, Swiss law grants pre-emptive rights to existing shareholders to subscribe for new issuances of shares. Swiss law also does not provide as much flexibility in the various rights and regulations that can attach to different categories of shares as do the laws of some other jurisdictions. These Swiss law requirements relating to our capital management may limit our flexibility, and situations may arise where greater flexibility would have provided benefits to our shareholders. See “Description of Share Capital and Articles of Association” and “Comparison of Delaware Law and Swiss Law.”

***We will be a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.***

Upon consummation of this offering, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Swiss laws and regulations with regard to such matters and intend to furnish quarterly financial information to the SEC, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each financial year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

***As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we will rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.***

We will be a foreign private issuer as of the effective date of this registration statement. As a result, in accordance with Nasdaq Listing Rule 5615(a)(3), we will comply with home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of Nasdaq.

Swiss law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we will not be subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present. Although Swiss law also requires that we adopt a compensation committee, we will follow home country requirements with respect to such committee. As a result, our practice will vary from the requirements of Nasdaq Listing Rule 5605(d), which sets forth certain requirements as to the responsibilities, composition and independence of compensation committees. In addition, in accordance with Swiss law, we have opted not to implement a nominating committee. To this extent, our practice varies from the independent director oversight of director nominations requirements of Nasdaq Listing Rule 5605(e).

Furthermore, in accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. Our practice thus varies

from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Our articles of association provide for an independent proxy holder elected by our shareholders, who may represent our shareholders at a general meeting of shareholders, and we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders. However, Swiss law does not have a regulatory regime for the solicitation of proxies and company solicitation of proxies is prohibited for public companies in Switzerland, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies. In addition, we have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

For an overview of our corporate governance principles, see “Description of Share Capital and Articles of Association.” As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

***We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act’s domestic reporting regime and cause us to incur significant legal, accounting and other expenses.***

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be a foreign private issuer as of June 30, 2015 (the end of our second fiscal quarter in the fiscal year after this offering), which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2016. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be United States citizens or residents, (ii) more than 50 percent of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

***We are an “emerging growth company,” and we cannot be certain if the reduced reporting requirements applicable to “emerging growth companies” will make our common shares less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an “emerging growth company,” we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies,” including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an “emerging growth company” in our initial registration statement we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We could be an “emerging growth company” for up to five years, although circumstances could cause us to lose that status earlier, including if the market value of our common shares held by non-affiliates exceeds $700 million as of any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an “emerging growth company” as of the following December 31 (our fiscal year end). We cannot predict if investors will find our common shares less attractive

because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the price of our common shares may be more volatile.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also subject us to regulatory scrutiny and sanctions, impair our ability to raise revenue and cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares.

We will be required to disclose changes made in our internal controls and procedures and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an "emerging growth company" for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

***If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our common shares and our trading volume could decline.***

The trading market for our common shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no or too few securities or industry analysts commence coverage of our company, the trading price for our common shares would likely be negatively affected. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrade our common shares or publish inaccurate or unfavorable research about our business, the price of our common shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common shares could decrease, which might cause the price of our common shares and trading volume to decline.

***We believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for our 2013 taxable year, and we expect to be a PFIC for our current year and for the foreseeable future.***

We believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for our 2013 taxable year, and we expect to be a PFIC for our current year and for the foreseeable future. In addition, we may, directly or indirectly, hold equity interests in other PFICs, or Lower-tier PFICs. Under the Internal Revenue Code of 1986, as amended, or the Code, we will be a PFIC for any taxable year in which (i) 75% or more of our gross income consists of passive income or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains.

If we are a PFIC for any taxable year during which a U.S. investor holds our shares, the U.S. investor may be subject to adverse tax consequences, including (i) the treatment of all or a portion of any gain on disposition as ordinary income, (ii) the application of a deferred interest charge on such gain and the receipt of certain dividends and (iii) compliance with certain reporting requirements.

For further discussion of the adverse U.S. federal income tax consequences of our classification as a PFIC, see "Taxation—Material U.S. Federal Income Tax Considerations for U.S. Holders."

## PRESENTATION OF FINANCIAL AND OTHER INFORMATION

We report under IFRS. None of the financial statements were prepared in accordance with generally accepted accounting principles in the United States. We present our consolidated financial statements in Swiss Francs and in accordance with IFRS.

The terms "dollar," "USD" or "$" refer to U.S. dollars, the term, "Swiss Francs" or "CHF" refers to the legal currency of Switzerland and the terms "€" or "euro" are to the currency introduced at the start of the third stage of European economic and monetary union pursuant to the treaty establishing the European Community, as amended. Unless otherwise indicated, all references to currency amounts in this prospectus are in Swiss Francs.

We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

Prior to our corporate reorganization, we conducted our business through Auris Medical AG, and therefore our historical financial statements present the results of operations of Auris Medical AG. On April 22, 2014, we changed our name from Auris Medical AG to Auris Medical Holding AG, transferred our operational business to our newly incorporated subsidiary Auris Medical AG and became a holding company for the group. Following this offering, our financial statements will present the results of operations of Auris Medical Holding AG.

## MARKET AND INDUSTRY DATA

This prospectus contains industry, market, and competitive position data that are based industry publications and studies conducted by third parties as well as our own internal estimates and research. These industry publications and third-party studies generally state that the information that they contain has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains statements that constitute forward-looking statements. Many of the forward-looking statements contained in this prospectus can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate” and “potential,” among others.

Forward-looking statements appear in a number of places in this prospectus and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to of various factors, including, but not limited to, those identified under the section entitled “Risk Factors” in this prospectus. These risks and uncertainties include factors relating to:

- our operation as a development stage company with limited operating history and a history of operating losses;
- our need for substantial additional funding before we can expect to become profitable from sales of our products;
- our dependence on the success of AM-101 and AM-111, which are still in clinical development and may eventually prove to be unsuccessful;
- the chance that we may become exposed to costly and damaging liability claims resulting from the testing of our product candidates in the clinic or in the commercial stage;
- uncertainty surrounding whether any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized;
- if our product candidates obtain regulatory approval, our being subject to expensive ongoing obligations and continued regulatory overview;
- enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialization;
- the chance that we do not obtain orphan drug exclusivity for AM-111, which would allow our competitors to sell products that treat the same conditions;
- dependence on governmental authorities and health insurers establishing adequate reimbursement levels and pricing policies;
- our products may not gain market acceptance, in which case we may not be able to generate product revenues;
- our reliance on our current strategic relationships with INSERM or Xigen and the potential failure to enter into new strategic relationships;
- our reliance on third parties to conduct our nonclinical and clinical trials and on third-party single-source suppliers to supply or produce our product candidates; and
- other risk factors discussed under “Risk Factors.”

Forward-looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

## USE OF PROCEEDS

We estimate that the net proceeds to us from the offering will be approximately $ , assuming an initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and offering expenses payable by us. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our net proceeds, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and offering expenses, by $ million. If the underwriters exercise in full their over-allotment option, we estimate that the net proceeds from this offering will be approximately $ million.

As of March 31, 2014, we had cash and cash equivalents of CHF 18.5 million. We intend to use the net proceeds from this offering, together with our cash and cash equivalents, as follows:

- approximately $ to $ to fund research and development expenses for AM-101 up to approval;
- approximately $ to $ to fund research and development expenses for AM-111 up to approval;
- approximately $ to $ to fund other research and development activities; and
- the remainder for working capital and other financial corporate purposes.

Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of net proceeds will vary depending on numerous factors, including the relative success and cost of our research, preclinical and clinical development programs, our ability to obtain additional financing, the status of and results from clinical trials of AM-101 and AM-111 and whether regulatory authorities require us to perform additional clinical trials of AM-101 or AM-111 in order to obtain marketing approvals. As a result, our management will have broad discretion in the application of the net proceeds of this offering, and investors will be relying on our judgment regarding the application of the net proceeds. In addition, we might decide to postpone or not pursue certain preclinical activities or clinical trials if the net proceeds from this offering and our other sources of cash are less than expected.

Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements for at least the next months. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending their use, we plan to invest the net proceeds of this offering in short- and intermediate-term interest-bearing investments.

## DIVIDEND POLICY

Since our incorporation, we have never paid a dividend, and we do not anticipate paying dividends in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. As a result, investors in our common shares will benefit in the foreseeable future only if our common shares appreciate in value.

Under Swiss law, any dividend must be proposed by our board of directors and approved by a shareholders' meeting. In addition, our auditors must confirm that the dividend proposal of our board of directors conforms to Swiss statutory law and our articles of incorporation. A Swiss corporation may pay dividends only if it has sufficient distributable profits brought forward from the previous business years ("*Gewinnvortrag*") or if it has distributable reserves ("*frei verfügbare Reserven*"), each as evidenced by its audited stand-alone statutory balance sheet prepared pursuant to Swiss law and after allocations to reserves required by Swiss law and its articles of association have been deducted. Distributable reserves are generally booked either as "free reserves" ("*freie Reserven*") or as "reserve from capital contributions" ("*Reserven aus Kapitaleinlagen*"). Distributions out of issued share capital, which is the aggregate nominal value of a corporation's issued shares, may be made only by way of a share capital reduction. See "Description of Share Capital and Articles of Association."

We are a holding company with no material direct operations. As a result, we would be dependent on dividends, other payments or loans from our subsidiaries in order to pay a dividend. Our subsidiaries are subject to legal requirements of their respective jurisdictions of organization that may restrict their paying dividends or other payments, or making loans, to us.

# CAPITALIZATION

The table below sets forth our cash and cash equivalents and our total capitalization (defined as total debt and shareholders' equity) as of March 31, 2014 derived from our unaudited condensed consolidated interim financial statements prepared in accordance with IFRS:

- on an actual basis; and
- on an as adjusted basis to give effect to (i) the conversion of our Series A, Series B and Series C preferred shares into common shares on a one-for-one basis upon closing of this offering, (ii) our issuance and sale of common shares in this offering, assuming an initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us and (iii) the filing and effectiveness of our amended and restated articles of association.

U.S. dollar amounts have been translated into Swiss Francs at a rate of USD to CHF 1.00, the official exchange rate quoted as of , 2014 by the U.S. Federal Reserve Bank. Such Swiss Franc amounts are not necessarily indicative of the amounts of Swiss Francs that could actually have been purchased upon exchange of U.S. dollars at the dates indicated and have been provided solely for the convenience of the reader. On , 2014, the exchange rate as reported by the U.S. Federal Reserve Bank was USD to CHF 1.00.

Investors should read this table in conjunction with our unaudited condensed consolidated interim financial statements included in this prospectus as well as "Use of Proceeds," "Selected Consolidated Financial and Other Information" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

| | MARCH 31, 2014 | |
|---|---|---|
| | ACTUAL | AS ADJUSTED |
| | (in thousands of CHF except share and per share data) | |
| Cash and cash equivalents (1) | 18,535 | |
| Total debt | — | |
| Shareholders' equity: | | |
| Share capital | | |
| Common shares, nominal value CHF 0.40 per share; 88,100 shares issued and outstanding on an actual basis; shares issued and outstanding on an adjusted basis | 35 | |
| Series A preferred shares, nominal value CHF 0.40 per share; 5,999,750 shares issued and outstanding on an actual basis; no shares issued and outstanding on an adjusted basis | 2,400 | — |
| Series B preferred shares, nominal value CHF 0.40 per share; 5,509,100 shares issued and outstanding on an actual basis; no shares issued and outstanding on an adjusted basis | 2,204 | — |
| Series C preferred shares, nominal value CHF 0.40 per share; 7,244,325 shares issued and outstanding on an actual basis; no shares issued and outstanding on an adjusted basis | 2,898 | — |
| Share premium | 48,233 | |
| Foreign currency translation reserve | 59 | |
| Accumulated deficit | (38,952) | |
| Total shareholders' equity attributable to owners of the company (1) | 16,877 | |
| Total capitalization (1) | 16,877 | |

(1) As adjusted cash and cash equivalents represents actual cash and cash equivalents plus the assumed net proceeds of this offering. Each $1.00 increase (decrease) in the assumed initial public offering price of $ per common share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our as adjusted cash and cash equivalents, total shareholders' equity and total capitalization, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same, by $ .

The table above does not include:

- of our common shares issuable upon the exercise of options outstanding as of , 2014 at a weighted average exercise price of per common share; and
- of our common shares covered by additional awards available for future issuance under our equity incentive plans as of , 2014.

## DILUTION

If you invest in our common shares, your interest will be diluted to the extent of the difference between the initial public offering price per common share and the as adjusted net tangible book value per common share after this offering. References to our common shares for time periods prior to this offering include our common shares and our Series A, Series B and Series C preferred shares.

At March 31, 2014, we had a net tangible book value of $ million, corresponding to a net tangible book value of $ per common share. Net tangible book value per share represents the amount of our total assets less our total liabilities, excluding intangible assets, divided by , the total number of our common shares outstanding at March 31, 2014.

After giving effect to the sale by us of the common shares offered by us in the offering and considering an offering price of $ per common share (the midpoint of the price range set forth on the cover page of this prospectus), after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us (excluding reimbursement to the underwriters for certain expenses as set forth in the Underwriting Agreement), our pro forma as adjusted net tangible book value estimated at March 31, 2014 would have been approximately $ , representing $ per common share. This represents an immediate increase in net tangible book value of $ per common share to existing shareholders and an immediate dilution in net tangible book value of $ per common share to new investors purchasing common shares in this offering. Dilution for this purpose represents the difference between the price per common share paid by these purchasers and net tangible book value per common share immediately after the completion of the offering.

The following table illustrates this dilution to new investors purchasing common shares in the offering.

| | |
|---|---|
| Assumed initial public offering price per share | |
| Net tangible book value per common share at March 31, 2014 | |
| Increase in net tangible book value per common share attributable to new investors | |
| As adjusted net tangible book value per common share after the offering | |
| Dilution per common share to new investors | |
| Percentage of dilution in net tangible book value per common share for new investors | % |

Each $1.00 increase (decrease) in the assumed initial offering price of $ per common share (the midpoint of the price range set forth on the cover page of this prospectus), respectively, would increase (decrease) the as adjusted net tangible book value after this offering by $ per common share and the dilution per common share to new investors in the offering by $ per common share, assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same.

If the underwriters were to fully exercise their over-allotment option, the as adjusted net tangible book value per common shares after the offering would be $ per common share, and the dilution per common share to new investors would be $ per share.

If the underwriters exercise their over-allotment option in full, the following will occur:

- the percentage of our common shares held by existing shareholders will decrease to approximately % of the total number of our common shares outstanding after this offering; and
- the percentage of our common shares held by new investors will increase to approximately % of the total number of our common shares outstanding after this offering.

The above discussion and tables are based on our actual common shares outstanding as of March 31, 2014 on an as adjusted basis and excludes:

- of our common shares issuable upon the exercise of options outstanding as of , 2014 at a weighted average exercise price of per common share; and

- of our common shares covered by additional awards available for future issuance under our equity incentive plans as of , 2014.

To the extent that outstanding options are exercised, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our shareholders.

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## EXCHANGE RATES

The following table sets forth, for the periods indicated, the high, low, average and period-end exchange rates for the purchase of U.S. dollars expressed in CHF per U.S. dollar. The average rate is calculated by using the average of the U.S. Federal Reserve Bank's reported exchange rates on each day during a monthly period and on the last day of each month during an annual period. On , 2014, the exchange rate as reported by the U.S. Federal Reserve Bank was CHF to $1.00.

| | PERIOD-END | AVERAGE FOR PERIOD | LOW | HIGH |
|---|---|---|---|---|
| | (CHF per U.S. dollar) | | | |
| **Year Ended December 31:** | | | | |
| 2009 | 1.0358 | 1.0824 | 0.9984 | 1.1893 |
| 2010 | 0.9369 | 1.0264 | 0.9369 | 1.1614 |
| 2011 | 0.9374 | 0.8802 | 0.7296 | 0.9755 |
| 2012 | 0.9155 | 0.9314 | 0.8949 | 0.9957 |
| 2013 | 0.8904 | 0.9241 | 0.8856 | 0.9814 |
| **Month Ended:** | | | | |
| October 31, 2013 | 0.9056 | 0.9025 | 0.8916 | 0.9163 |
| November 30, 2013 | 0.9047 | 0.9129 | 0.9047 | 0.9220 |
| December 31, 2013 | 0.8904 | 0.8933 | 0.8856 | 0.9052 |
| January 31, 2014 | 0.9052 | 0.9038 | 0.8948 | 0.9116 |
| February 28, 2014 | 0.8810 | 0.8937 | 0.8810 | 0.9050 |
| March 31, 2014 | 0.8840 | 0.8805 | 0.8712 | 0.8872 |
| April 30, 2014 | 0.8800 | 0.8828 | 0.8748 | 0.8921 |
| May 31, 2014 | 0.8944 | 0.8883 | 0.8744 | 0.8982 |
| June 2014 (through June , 2014) | | | | |

## SELECTED CONSOLIDATED FINANCIAL AND OTHER INFORMATION

The following selected consolidated historical financial information should be read in conjunction with "Presentation of Financial and Other Information," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the consolidated financial statements of Auris Medical AG, prior to our corporate reorganization, including the notes thereto, included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future and results of interim periods are not necessarily indicative of results for the entire year.

The summary consolidated income statement and balance sheet data for and as of the years ended December 31, 2013 and 2012 of Auris Medical AG, prior to our corporate reorganization, are derived from the audited consolidated financial statements included elsewhere in this prospectus, which have been audited by KPMG AG. The summary income statement and balance sheet data for the three months ended as of March 31, 2014 and 2013 are derived from the unaudited condensed consolidated interim financial statements included elsewhere in this prospectus. The unaudited financial data, in management's opinion, have been prepared on the same basis as the audited consolidated financial statements and related notes included elsewhere in this prospectus, and include all adjustments, consisting only of normal recurring adjustments, that management considers necessary for a fair presentation of the financial information as of and for the periods presented.

We present the audited consolidated financial statements and unaudited condensed consolidated interim financial statements in CHF and in accordance with IFRS.

| | FOR THE YEARS ENDED DECEMBER 31, | | FOR THE THREE MONTHS ENDED MARCH 31, | |
|---|---|---|---|---|
| | 2013 | 2012 | 2014 | 2013 |
| | (in thousands of CHF except for share and per share data) | | | |
| **Income Statement Data:** | | | | |
| Research and development | (13,254) | (3,987) | (4,149) | (1,973) |
| General and administrative | (1,362) | (624) | (1,709) | (270) |
| Operating loss | (14,616) | (4,611) | (5,858) | (2,243) |
| Finance expense. | (159) | (2) | (51) | (11) |
| Finance income | 76 | 10 | 50 | 24 |
| Loss before tax | (14,699) | (4,602) | (5,860) | (2,230) |
| Income tax expense | (306) | — | — | — |
| Net loss attributable to owners of the company | (15,005) | (4,602) | (5,860) | (2,230) |
| Other comprehensive income: | | | | |
| Items that will never be reclassified to profit or loss: | | | | |
| Remeasurements of defined benefits liability | (58) | (55) | (17) | 43 |
| Items that are or may be reclassified to profit or loss: | | | | |
| Foreign currency translation differences | 32 | 22 | 5 | (30) |
| Other comprehensive income | (26) | (32) | (11) | 13 |
| Total comprehensive loss attributable to owners of the company | (15,031) | (4,635) | (5,871) | (2,217) |
| Net loss per share (1) | | | | |
| Net loss per share, basic and diluted (2) | (1.01) | (0.40) | (0.32) | (0.19) |
| Weighted-average number of shares used to compute net loss per common share, basic and diluted | 14,917,064 | 11,581,450 | 18,055,273 | 11,581,450 |

| | AS OF DECEMBER 31, | | AS OF MARCH 31, |
|---|---|---|---|
| | 2013 | 2012 | 2014 |
| | (in thousands of CHF) | | (in thousands of CHF) |
| **Balance Sheet Data:** | | | |
| Cash and cash equivalents | 23,866 | 64 | 18,535 |
| Total assets | 26,252 | 866 | 20,862 |
| Total liabilities | 17,219 | 1,110 | 3,985 |
| Share capital | 6,487 | 4,633 | 7,537 |
| Total shareholders' equity attributable to owners of the company | 9,034 | (244) | 16,877 |

(1) Includes preferred shares, which will be converted on a one-for-one basis upon the closing of this offering.

(2) Basic net loss per common share and diluted net loss per common share are the same because outstanding options and convertible loans (to the extent outstanding during the applicable time period) would be anti-dilutive due to our net loss in these periods.

# MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with the information under "Selected Consolidated Financial and Other Information" and our consolidated financial statements, including the notes thereto, included in this prospectus. The following discussion is based on our financial information prepared in accordance with IFRS (unless otherwise indicated) as issued by the IASB, which might differ in material respects from generally accepted accounting principles in other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "Risk factors" and elsewhere in this prospectus.*

## Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel products for the treatment of inner ear disorders. Our most advanced product candidate, AM-101, is in Phase 3 clinical development for acute inner ear tinnitus under a special protocol assessment, or SPA, from the FDA. In two recently completed Phase 2 clinical trials, AM-101 demonstrated a favorable safety profile and statistically significant improvement in tinnitus loudness and other patient reported outcomes. We are also developing AM-111 for acute inner ear hearing loss, and we expect to begin Phase 3 clinical development in the fourth quarter of 2014. We expect to have top-line Phase 3 clinical data for AM-101 and AM-111 in early 2016 and late 2016, respectively. Both acute inner ear tinnitus and hearing loss are conditions for which there is high unmet medical need, and we believe that we have the potential to be the first to market in these indications.

To date, we have financed our operations through private placements of equity securities and short term loans. We have no products approved for commercialization and have never generated any revenues from royalties or product sales. As of March 31, 2014, we had cash and cash equivalents of CHF 18.5 million. Based on our current plans, we do not expect to generate royalty or product revenues unless and until we obtain marketing approval for, and commercialize, AM-101, AM-111 or any of our other product candidates.

Since inception, we have incurred significant operating losses. We incurred net losses (defined as net losses attributable to the owners of the company) of CHF 15.0 million and CHF 4.6 million for the years ended December 31, 2013 and 2012, respectively, and for the three months ended March 31, 2014 and 2013, we incurred net losses of CHF 5.9 million and CHF 2.2 million, respectively. As of March 31, 2014, we had an accumulated deficit of CHF 39.0 million. We expect to continue incurring losses as we continue our clinical and preclinical development programs, apply for marketing approval for our product candidates and, subject to obtaining regulatory approval of our product candidates, build a sales and marketing force in preparation for the potential commercialization of our product candidates.

## Collaboration and License Agreements

### *INSERM*

In 2006, we entered into a co-ownership/exploitation agreement with the Institut National de la Santé et de la Recherche Médicale, or INSERM, a publicly funded government science and technology agency in France. Pursuant to the terms of the agreement, we were granted the exclusive right to exploit any products derived from patents that resulted from our joint research program with INSERM that was conducted in 2003 to 2005 and led to the development of AM-101. Pursuant to the terms of the co-ownership/exploitation agreement, we are given the exclusive right to exploit the patents issuing from the filed patent applications for all claimed applications, including the treatment of tinnitus, in order to develop, promote, manufacture, cause to be manufactured, use, sell and distribute any products, processes or services deriving from such patents, including AM-101, in any country in which these patent applications have been filed during the term of the agreement.

As consideration for the exclusive rights granted to us under the agreement, we have agreed to pay INSERM a two tiered low single digit royalty (where the higher rate is due on any net sales above a certain threshold) on the net sales of any product covered by the patents (including the use of AM-101 in the treatment of tinnitus triggered by cochlear glutamate excitotoxicity) earned in each country in which these patent applications have been filed during

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the term of the agreement. We have also agreed to pay INSERM a low double digit fee on any sums of any nature (except royalties and certain costs) collected by us in respect of the granting of licenses to third parties.

***Xigen***

In October 2003, we entered into a collaboration and license agreement with Xigen S.A., or Xigen, pursuant to which Xigen granted us an exclusive worldwide license to use specified compounds to develop, manufacture and commercialize "pharmaceutical products as well as drug delivery devices and formulations for local administration of therapeutic substances to the inner ear for the treatment of ear disorders" (the Area). We also have a right of first refusal to license certain additional compounds developed by Xigen which may be used for the Area, specifically any cell permeable inhibitors to effectively block certain signal pathways in apoptotic processes.

Under this agreement, we made an upfront payment to Xigen of CHF 200,000 and we are obligated to make development milestone payments on an indication-by-indication basis of up to CHF 1.5 million and regulatory milestone payments on a product-by-product basis of up to CHF 2.5 million, subject to a mid-twenties percentage reduction for smaller indications, e.g., those qualifying for orphan drug status. To date, we have paid CHF 1.325 million to Xigen under the agreement. We will be required to pay Xigen a mid-single digit percentage royalty on net sales of each licensed product that uses a compound licensed under the agreement, which royalty for a given indication shall be partially offset by milestone payments we have paid for such indication, until the later of 10 years after the first commercial sale of any licensed product using such licensed compound in any country, and the first expiration of a patent owned by or exclusively licensed to Xigen that covers the use of such licensed compound in any country, subject to our obligation to enter into good faith negotiations with Xigen, upon expiration of the relevant patent on a licensed compound, about the conditions of our further use of such licensed compound.

## Financial Operations Overview

***Research and development expense***

Research and development expense consists principally of:

- salaries for research and development staff and related expenses, including employee benefits;
- costs for production of preclinical compounds and drug substances by contract manufacturers;
- fees and other costs paid to contract research organizations in connection with additional preclinical testing and the performance of clinical trials;
- costs of related facilities, materials and equipment;
- costs associated with obtaining and maintaining patents; and
- depreciation and amortization of tangible and intangible fixed assets used to develop our product candidates.

We expect that our total research and development expense in 2014 will be in the range of CHF 30 to 35 million. Our research and development expense mainly relates to the following key programs:

- *AM-101*. We have commenced a Phase 3 program of AM-101 comprising two Phase 3 studies and expect top-line date in early 2016. These two studies will be extended into two open label extension studies. We anticipate that our research and development expenses will increase substantially in connection with these clinical trials
- *AM-111*. We will soon commence two late stage clinical trials including a pivotal Phase 3 trial with AM-111. We anticipate that our research and development expenses will increase substantially in connection with the clinical trials of AM-111.
- *Other development programs*. Other research and development expenses mainly relate to our preclinical studies of AM-102 and AM-123. The expenses mainly consist of salaries, costs for production of the preclinical compounds and costs paid to academic research institutions in conjunction with preclinical testing.

Since inception of the Company in 2003, we cumulatively have spent a cash amount of approximately CHF 38 million on research and development activities which we would now group under research and development expenses for our IFRS accounts. Due to the absence of IFRS figures for the years prior to 2012, this amount is an

estimate only. For the years ended December 31, 2013 and 2012, we spent CHF 10.6 million and CHF 1.9 million, respectively, and for the three months ended March 31, 2014 and 2013, we spent CHF 2.5 million and CHF 1.7 million, respectively, on research and development expenses related to AM-101. For the same time periods, we spent CHF 1.0 million, CHF 1.0 million, CHF 1.2 million and CHF 0.07 million, respectively, on research and development expenses related to AM-111. These expenses exclude the milestone payment to Xigen for AM-111 as it was capitalized. Research and development expense is expected to increase as we advance the clinical development of AM-101 and AM-111 and to further advance the research and development of our pre-clinical product candidates. The successful development of our product candidates is highly uncertain. At this time we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our product candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;
- the cost, timing, and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish, including any required milestone and royalty payments thereunder.

A change in the outcome of any of these variables with respect to the development of AM-101, AM-111 or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct preclinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

***General and administrative expense***

Our general and administrative expense consists principally of:

- salaries for general and administrative staff and related expenses, including employee benefits;
- business development expenses, including travel expenses;
- professional fees for auditors and other consulting expenses not related to research and development activities;
- professional fees for lawyers not related to the protection and maintenance of our intellectual property;
- cost of facilities, communication and office expenses;
- IT expenses; and
- depreciation and amortization of tangible and intangible fixed assets not related to research and development activities.

We expect that our general and administrative expense will increase in the future as our business expands and we incur additional costs associated with operating as a public company. These public company-related increases will likely include costs of additional personnel, additional legal fees, accounting and audit fees, managing directors’ and supervisory directors’ liability insurance premiums and costs related to investor relations.

***Finance income***

Our policy is to invest funds in low risk investments including interest bearing deposits. Saving and deposit accounts generate a small amount of interest income. We expect to continue this investment philosophy.

***Finance expense***

Our finance expense consists principally of commercial banking fees and foreign exchange losses.

***Other comprehensive income***

Remeasurements of the net defined benefit liability, which comprise actuarial gains and losses, the return on plan assets (excluding interest) and the effect of the asset ceiling (if any, excluding interest), are recognized immediately in other comprehensive income.

We determine the net interest expense or income on the net defined benefit liability or asset for the period by applying the discount rate used to measure the defined benefit obligation at the beginning of the annual period to the then-net defined benefit liability or asset, taking into account any changes in the net defined benefit liability or asset during the period as a result of contributions and benefit payments. Net interest expense and other expenses related to defined benefit plans are recognized in profit or loss.

Assets and liabilities of our subsidiaries with functional currency other than CHF are included in our consolidated financial statements by translating the assets and liabilities into CHF at the exchange rates applicable at the end of the reporting period. Income and expenses for each consolidated statement of profit or loss and other comprehensive income are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transaction).

Foreign currency differences arising from translating the financial statements of our subsidiaries from currencies other than CHF are recognized in other comprehensive income and presented in the foreign currency translation reserve under equity in the statement of financial position. When a foreign operation is disposed of such that control, significant influence or joint control is lost, the cumulative amount in the translation reserve related to that foreign operation is reclassified to profit or loss as part of the gain or loss on disposal.

## Results of Operations

The numbers below have been derived from the unaudited condensed consolidated interim financial statements and our audited consolidated financial statements. The discussion below should be read along with these financial statements and it is qualified in its entirety by reference to them.

***Comparison of the three months ended March 31, 2014 and 2013***

| | THREE MONTHS ENDED MARCH 31, | | |
|---|---|---|---|
| | 2014 | 2013 | CHANGE |
| | (in thousands of CHF) | | % |
| Research and development | (4,149) | (1,973) | 110% |
| General and administrative | (1,709) | (270) | 532% |
| **Operating loss** | **(5,858)** | **(2,243)** | **161%** |
| Finance expense | (51) | (11) | 386% |
| Finance income. | 50 | 24 | 106% |
| **Loss before tax** | **(5,860)** | **(2,230)** | **163%** |
| Income tax expense. | — | — | |
| **Net loss attributable to owners of the company** | **(5,860)** | **(2,230)** | **163%** |
| **Other comprehensive income:** | | | |
| **Items that will never be reclassified to profit or loss** | | | |
| Remeasurements of defined benefits liability | (17) | 43 | |
| **Items that are or may be reclassified to profit or loss** | | | |
| Foreign currency translation differences | 5 | (30) | |
| **Other comprehensive income** | **(11)** | **13** | |
| **Total comprehensive loss attributable to owners of the company** | **(5,871)** | **(2,217)** | **165%** |

*Research and development expense*

| | THREE MONTHS ENDED MARCH 31, | | |
|---|---|---|---|
| | 2014 | 2013 | CHANGE |
| | (in thousands of CHF) | | % |
| **Research and development expense** | | | |
| Clinical projects | (2,404) | (1,063) | 126% |
| Preclinical projects | (564) | (400) | 41% |
| Drug manufacture and substance | (625) | (228) | 174% |
| Employee benefits | (370) | (224) | 65% |
| Other research and development expenses | (186) | (58) | 219% |
| **Total** | **(4,149)** | **(1,973)** | **110%** |

Research and development expense increased 110% from CHF 2.0 million in the three months ended March 31, 2013 to CHF 4.1 million in the three months ended March 31, 2014. Our research and development expense is highly dependent on the development phases of our research projects and therefore fluctuates highly from period to period. The variances in expense between the three months ended March 31, 2013 and the corresponding period in 2014 are mainly due to the following projects:

- *Clinical Projects.* In the three months ended March 31, 2014 we incurred higher clinical expenses due to ongoing Phase 3 TACTT2 and TACCT3 trials. In contrast, in the three months ended March 31, 2013, the Phase 2 TACTT1 trial was enrolling the last patient in February 2013 with a concomitant decline in spending.
- *Drug manufacture and substance.* In the three months ended March 31, 2014 we incurred substantial costs related to the manufacture, labeling and packaging and storage of supplies for clinical material for the AM-111 clinical trials that we expect to commence later in 2014. In the three months ended March 31, 2013, expense levels were lower and mostly related to analytical work, supplies and the manufacture of a pilot batch for the AM-111 drug substance.
- *Employee Benefits*. Employee expenses were higher in the three months ended March 31, 2014 than in the three months ended March 31, 2013 due to a higher headcount.

*General and administrative expense*

General and administrative expense increased 532% from CHF 0.3 million in the three months ended March 31, 2013 to CHF 1.7 million in the three months ended March 31, 2014. The increase was primarily related to higher legal and auditing expenses in relation to the preparations for this offering.

We expect that general and administrative expense will increase significantly in the future as our business expands and we continue to increase headcount as well as incur additional costs associated with operating as a public company.

*Finance income*

Finance income increased 106% from CHF 0.02 million in the three months ended March 31, 2013 to CHF 0.05 million in the three months ended March 31, 2014. Finance income in these periods consisted primarily of interest income recognized on short-term deposits.

Finance income increased in the three months ended March 31, 2014 as compared to the three months ended March 31, 2013 as a result of an increase in average cash and cash equivalents following our private placement of Series C preferred shares to new investors and of a convertible loan from the same investors with total net proceeds of CHF 24.1 million and CHF 13.8 million, in April and December 2013, respectively.

*Finance expense*

Finance expense increased 386% from CHF 0.01 million in the three months ended March 31, 2013 to CHF 0.05 million in the three months ended March 31, 2014. Higher finance expenses were mainly due to an increase in interest expenses due to the borrowing of the convertible loan from shareholders of CHF 13.8 million in December 2013.

*Remeasurements of defined benefits liability*

Remeasurements of the net defined benefit liability, which comprise actuarial gains and losses, the return on plan assets (excluding interest) and the effect of the asset ceiling (if any, excluding interest), decreased from CHF 0.04 million in the three months ended March 31, 2013 to CHF 0.02 million in the three months ended March 31, 2014.

*Foreign currency translation differences*

Foreign currency translation differences increased from a loss of CHF 0.03 million in the three months ended March 31, 2013 to a gain of CHF 0.01 million in the three months ended March 31, 2014. The increase was primarily related to unfavorable movements in the CHF/USD exchange. The average and the period-end CHF/USD exchange rates for the three months ended March 31, 2014 and 2013 were CHF 0.8928, CHF 0.8841, CHF 0.9301 and CHF 0.9494, respectively. The average and the period-end CHF/EUR exchange rates for the three months ended March 31, 2014 and 2013 were CHF 1.2233, CHF 1.2179, CHF 1.2281 and CHF 1.2170, respectively.

***Comparison of the years ended December 31, 2013 and 2012***

| | YEAR ENDED DECEMBER 31, | | |
|---|---|---|---|
| | 2013 | 2012 | CHANGE |
| | (in thousands of CHF) | | % |
| Research and development | (13,254) | (3,987) | 232 % |
| General and administrative | (1,362) | (624) | 118 % |
| **Operating loss** | **(14,616)** | **(4,611)** | **217 %** |
| Finance expense | (159) | (2) | 8713 % |
| Finance income. | 76 | 10 | 666 % |
| **Loss before tax** | **(14,699)** | **(4,602)** | **219 %** |
| Income tax expense | (306) | — | |
| **Net loss attributable to owners of the Company** | **(15,005)** | **(4,602)** | **226 %** |
| **Other comprehensive income:** | | | |
| **Items that will never be reclassified to profit or loss** | | | |
| Remeasurements of defined benefit liability | (58) | (55) | 6 % |
| **Items that are or may be reclassified to profit or loss** | | | |
| Foreign currency translation differences | 32 | 22 | 42 % |
| **Other comprehensive income** | **(26)** | **(32)** | **(20)%** |
| **Total comprehensive loss attributable to owners of the Company** | **(15,031)** | **(4,635)** | **224 %** |

*Research and development expense*

| | 2013 | 2012 | CHANGE |
|---|---|---|---|
| | (in thousands of CHF) | | % |
| **Research and development expense** | | | |
| Clinical projects | (8,753) | (1,687) | 419 % |
| Preclinical projects | (2,078) | (298) | 598 % |
| Drug manufacture and substance | (1,036) | (915) | 13 % |
| Employee benefits | (1,074) | (770) | 40 % |
| Other research and development expenses | (311) | (316) | (1)% |
| **Total** | **(13,254)** | **(3,987)** | **232 %** |

Research and development expense increased 232% from CHF 4.0 million in 2012 to CHF 13.3 million in 2013. Our research and development expense is highly dependent on the development phases of our research projects and therefore fluctuates highly from year to year. The variances in expense between 2012 and 2013 are mainly due to the following factors:

- *Clinical Projects*. In 2013 we completed the second Phase 2 study with AM-101. At the same time we incurred substantial costs related to the preparation of the AM-101 Phase 3 program (TACTT2 and TACTT3), notably for feasibility assessments, investigator and site selections, investigator meetings, validation and translation work on questionnaires and other study documents, procurement of electronic patient diaries, set-up of electronic data capture systems, databases and procedures as well as submissions to regulatory agencies and institutional review boards. In contrast, expense levels related to the AM-111 project decreased from 2012 levels because Phase 2 clinical trial work was completed.
- *Preclinical projects*. In 2013, we stepped up our activities related to project AM-102, including screening of compounds for a new pharmacological target in tinnitus. In addition, we initiated additional toxicology studies with repeated AM-101 dosing in rodents, and conducted reproduction toxicology studies with AM-111.
- *Drug manufacture and substance*. In 2013 we incurred substantial costs related to the manufacture, labeling and packaging of supplies for the AM-101 Phase 3 trials.
- *Employee benefits.* Headcount continued to increase in 2013 in line with the expansion of our research and development activities.

*General and administrative expense*

General and administrative expense increased 118% from CHF 0.6 million in 2012 to CHF 1.4 million in 2013. The increase reflects higher business activity levels as well as additional business development activities.

We expect that general and administrative expense will increase significantly in the future as our business expands and we continue to increase headcount as well as incur additional costs associated with operating as a public company.

*Finance income*

Finance income increased from CHF 9,894 in 2012 to CHF 75,747 in 2013. Finance income in these periods consisted primarily of interest income recognized on short-term deposits.

Finance income increased in 2013 as a result of an increase in average cash and cash equivalents following our private placement of preferred equity securities to new investors with total net proceeds of CHF 24.1 million in April 2013, and, to a lesser extent, a subsequent convertible loan from the same investors with total net proceeds of CHF 13.8 million in December 2013.

*Finance expense*

Finance expense increased from CHF 1,800 in 2012 to CHF 158,641 in 2013. Higher finance expense were mainly due to adverse currency movements in 2013.

*Income tax expense*

As we have never generated revenue or other taxable income, there have been no income taxes paid so far. We have recorded a deferred income tax expense of CHF 305,750 (related to taxable temporary differences) for 2013.

*Remeasurements of defined benefits liability*

Remeasurements of the net defined benefit liability, which comprise actuarial gains and losses, the return on plan assets (excluding interest) and the effect of the asset ceiling (if any, excluding interest), increased 6% from 2012 to 2013. The increase was primarily related to a higher actuarial loss partially offset by a higher return on plan assets.

*Foreign currency translation differences*

Foreign currency translation differences increased by 42% from 2012 to 2013. The increase was primarily related to unfavorable movements in the CHF/USD exchange. The average and the year-end CHF/USD exchange rates for the years ended December 31, 2013 and December 31, 2012 were CHF 0.9391, CHF 0.8894, CHF 0.9481 and CHF 0.9154, respectively. The average and the year-end CHF /EUR exchange rates for years ended December 31, 2013 and December 31, 2012 were CHF 1.2414, CHF 1.2255, CHF 1.2196 and CHF 1.2068, respectively.

### Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. To date, we have not generated any product sale revenue. We have financed our operations primarily through private placements of equity securities and loans from existing shareholders.

### Cash flows

***Comparison of the three months ended March 31, 2014 and 2013***

The table below summarizes our consolidated statement of cash flows for the three months ended March 31, 2014 and 2013:

| | THREE MONTHS ENDED MARCH 31, | |
|---|---|---|
| | 2014 | 2013 |
| | (in thousands of CHF) | |
| Cash used in operating activities . | (5,187) | (1,510) |
| Net cash used in investing activities | (57) | (12) |
| Net cash from financing activities . | (87) | 1,478 |
| Cash and cash equivalents at the beginning of the period . | 23,866 | 64 |
| **Cash and cash equivalents at the end of the period** | **18,535** | **21** |

The increase in cash used in operating activities by 244% from CHF 1.5 million in the three months ended March 31, 2013 to CHF 5.2 million in the three months ended March 31, 2014 was mainly due to higher research and development expenses and general and administrative spending.

The increase in net cash used in investing activities by 375% from CHF 0.012 million in the three months ended March 31, 2013 to CHF 0.057 million in the three months ended March 31, 2014 was due to higher investment in manufacturing equipment offset by an increase in interest income due to an increase in cash and cash equivalents.

The decrease in net cash from financing activities from CHF 1.5 million in the three months ended March 31, 2013 to CHF (0.087) million in the three months ended March 31, 2014 is mainly due to stamp duties on the shares issued in relation to the exercise of share options and the conversion of the convertible loan in January 2014, partially offset by the proceeds received through the exercise of share options.

***Comparison of the years ended December 31, 2013 and 2012***

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2013 and 2012:

| | YEAR ENDED DECEMBER 31, | |
|---|---|---|
| | 2013 | 2012 |
| | (in thousands of CHF) | |
| Cash used in operating activities . | (14,044) | (4,499) |
| Net cash used in investing activities | (35) | (53) |
| Net cash from financing activities . | 37,881 | 3,862 |
| Cash and cash equivalents at the beginning of the period | 64 | 753 |
| **Cash and cash equivalents at the end of the period** | **23,866** | **64** |

The increase in cash used in operating activities by 212% from CHF 4.5 million in 2012 to CHF 14.0 million in 2013 was mainly due to the substantial increase in development activities, notably clinical projects. The increase was partially offset by an increase in trade payables and accrued expenses.

The decrease in net cash used in investing activities by 34% from 2012 to 2013 reflected lower capital expenditures in dedicated manufacturing equipment.

The increase in net cash from financing activities from CHF 3.9 million in 2012 to CHF 37.9 million in 2013 is due to the private placement of our Series C preferred shares to new investors providing total net proceeds of CHF 24.1 million in April 2013 as well as a convertible loan from Series C shareholders providing CHF 13.8 million in December 2013.

***Cash and funding sources***

During the three months ended March 31, 2014, we did not obtain new financing except from the exercise of share options. As such, the table below summarizes our sources of financing for the years ended December 31, 2013 and 2012.

| | EQUITY CAPITAL AND PREFERRED SHARES | LOANS | TOTAL |
|---|---|---|---|
| | (in thousands of CHF) | | |
| 2013 | 24,111 | 13,770 | 37,881 |
| 2012 | 3,862 | — | 3,862 |
| **Total** | 27,973 | 13,770 | 41,743 |

Our sources of financing in 2013 included the private placement of our Series C preferred shares providing total net proceeds of CHF 24.1 million as well as a convertible loan from Series C shareholders providing CHF 13.8 million. Prior to the closing of the Series C financing round in April 2013, a bridge loan was provided by Altamira Pharma GmbH, a company wholly owned by our CEO; a portion of the net proceeds from our Series C financing were used to repay that loan.

Under the terms of the Series C investment agreement, we agreed that up to two further closings resulting in further capital increase and issuance of new Series C preferred shares may be completed (the “Second Closing” and/or, the “Third Closing”, respectively). Pursuant to the terms of the convertible loan agreement, on January 13, 2014 the lenders exercised their right to convert the full amount of the loan into Series C preferred shares, replacing the Second Closing of the Series C financing. The obligation of the Series C investors to effect the Third Closing is subject to the satisfaction or waiver in writing by the holders of Series C preferred shares holding at least two thirds of the Series C preferred shares of certain conditions, including the Company reaching certain milestones, such as setting the size and scope of the next clinical trial for AM-111 with regulators.

Our sources from financing in 2012 were the payment of additional premiums on Series B preferred shares originally issued in 2011 as well as the placement of Series B preferred shares held in treasury.

As of March 31, 2014, we had no long-term debt.

We have no ongoing material financial commitments, such as lines of credit or guarantees that are expected to affect our liquidity over the next five years, other than leases.

***Funding requirements***

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements at least through the end of 2014. We believe that the net proceeds of this offering, together with our existing cash and cash equivalents, will enable us to fund our operating expenses and capital expenditure requirements for at least      months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including but not limited to:

- the scope, rate of progress, results and cost of our clinical trials, nonclinical testing, and other related activities;
- the cost of manufacturing clinical supplies, and establishing commercial supplies, of our product candidates and any products that we may develop;
- the number and characteristics of product candidates that we pursue;

- the cost, timing, and outcomes of regulatory approvals;
- the cost and timing of establishing sales, marketing, and distribution capabilities; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish, including any required milestone and royalty payments thereunder.

We expect that we will require additional capital to commercialize our product candidates AM-101 and AM-111. If we receive regulatory approval for AM-101 or AM-111, and if we choose not to grant any licenses to partners, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. We also expect to incur additional costs associated with operating as a public company following this offering. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are not able to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

We may raise additional capital through the sale of equity or convertible debt securities. In such an event, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common shares.

For more information as to the risks associated with our future funding needs, see "Risk Factors."

### Contractual Obligations and Commitments

The following table presents information relating to our contractual obligations as of December 31, 2013:

| | PAYMENTS DUE BY PERIOD | | |
|---|---|---|---|
| | LESS THAN 1 YEAR | BETWEEN 1 AND 5 YEARS | TOTAL |
| | (in thousands of CHF) | | |
| Convertible loans (1) | 13,770 | — | 13,770 |
| Operating lease obligations (2) | 92 | 122 | 214 |
| **Total** | 13,862 | 122 | 13,984 |

(1) On December 9, 2013, the Company issued two non-interest bearing convertible loans to shareholders with a nominal value of CHF 13,769,976 and a maximum term of 12 months. On January 13, 2014 the convertible loan lenders exercised their conversion option, and the total loan amount of CHF 13,769,976 was converted into 2,607,950 Series C preferred shares of the Company. The Series C preferred shares were created as of January 27, 2014 from the Company's authorized capital. As a result, the Company's share capital increased from CHF 6,487,130 to CHF 7,536,510.

(2) Operating lease obligations consist of payments pursuant to non-cancellable operating lease agreements relating to our lease of office space and are not accounted for in the balance sheet. The lease term is 5 years with an early termination option as of March 2016.

### Off-balance sheet arrangements

As of the date of this prospectus, we do not have any, and during the periods presented we did not have any, off-balance sheet arrangements except for the Operating Lease mentioned above.

### Quantitative and Qualitative Disclosures About Market Risk

***Credit Risk***

We manage credit risk on a group basis. Credit risk arises from cash and cash equivalents and deposits with banks, as well as from other receivables. Our policy is to invest funds in low risk investments including interest bearing deposits. For banks and financial institutions, only independently rated parties with a minimum S&P rating of "A" are accepted. Receivables are not past due and not impaired and include only well-known counterparties.

We hold cash and cash equivalents in our principal operating currencies (CHF, USD and EUR).

***Market Risk***

In the ordinary course of our business activities, we are exposed to various market risks that are beyond our control, including fluctuations in foreign exchange rates, and which may have an adverse effect on the value of our financial assets and liabilities, future cash flows and profit. As a result of these market risks, we could suffer a loss due to adverse changes in foreign exchange rates. Our policy with respect to these market risks is to assess the potential of experiencing losses and the consolidated impact thereof, and to mitigate these market risks.

***Interest rate risk***

We are not currently exposed to significant interest rate risk because we have no borrowings at variable interest rates, no fixed rate financial liabilities at fair value through profit or loss and no derivatives. Our only variable interest-bearing financial asset is cash at banks. The effect of an increase or decrease in interest rates would only have an immaterial effect in profit or loss.

***Currency Risk***

We operate internationally and are exposed to foreign exchange risk arising from various exposures, primarily with respect to the US Dollar and Euro. Foreign exchange risk arises from future commercial transactions, recognized assets and liabilities and net investments in foreign operations. To manage foreign exchange risk we maintain foreign currency cash balances to cover anticipated future purchases of materials and services in foreign currencies.

As of December 31, 2013, a 5% increase or decrease in the USD/CHF exchange rate with all other variables held constant would have resulted in a CHF 175,115 (2012: CHF 2,081) increase or decrease in the net result. A 5% increase or decrease in the EUR/CHF exchange rate with all other variables held constant would have resulted in a CHF 107,672 (2012: CHF 23,047) increase or decrease in the net result.

As of March 31, 2014, a 5% increase or decrease in the USD/CHF exchange rate with all other variables held constant would have resulted in a CHF 59,183 (2013: CHF 21,461) increase or decrease in the net result. Accordingly, a 5% increase or decrease in the EUR/CHF exchange rate with all other variables held constant would have resulted in a CHF 58,958 (2013: CHF 40,546) increase or decrease in the net result.

We have subsidiaries in the United States and Ireland, whose net assets are exposed to foreign currency translation risk. Due to the small size of these subsidiaries the translation risk is not significant. In the future we intend to maintain foreign exchange balances matched to the currencies required to fund our primary costs, that is the conduct of our clinical trials.

## Significant accounting policies and use of estimates and judgment

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with IFRS. The preparation of these financial statements requires us to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

While our significant accounting policies are more fully described in the notes to our audited consolidated financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

***Intangible assets***

*Research and development*

Expenditures on the research programs of the Company are not capitalized, they are expensed when incurred.

Expenditures on the Company's development programs are generally not capitalized except if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Company intends to and has sufficient resources to complete development and to use or sell the asset. For the development projects of the Company, these criteria are generally only met when regulatory approval for commercialization is obtained. Given the current stage of the development projects, no development expenditures

have yet been capitalized. Intellectual property-related costs for patents are part of the expenditure for the research and development projects. Therefore, registration costs for patents are expensed when incurred as long as the research and development project concerned does not meet the criteria for capitalization.

*Licenses*

Intellectual property rights that are acquired by the Company are capitalized as intangible assets if they are controlled by the Company, are separately identifiable and are expected to generate future economic benefits, even if uncertainty exists as to whether the research and development will ultimately result in a marketable product. Consequently, upfront and milestone payments to third parties for the exclusive use of pharmaceutical compounds in specified areas of treatment are recognized as intangible assets.

*Measurement*

Intangible assets acquired that have finite useful lives are measured at cost less accumulated amortization and any accumulated impairment losses.

*Subsequent expenditure*

Subsequent expenditure is capitalized only when it increases the future economic benefits embodied in the specific asset to which it relates. All other expenditure, including expenditure on internally generated goodwill and brands, is recognized in profit or loss as incurred.

*Amortization*

All licenses of the group have finite lives. Amortization will start once the Company's intangible assets will be available for use. Amortization of licenses is calculated on a straight line basis over the period of the expected benefit or until the license expires. The estimated useful life of the Company's licenses is 10 years from the date first available for use or the remaining term of patent protection. The Company assesses at each balance sheet date whether intangible assets which are not yet ready for use are impaired.

***Income tax***

Income tax expense comprises current and deferred tax. It is recognized in profit or loss except to the extent that it relates to a business combination, or items recognized directly in equity or in OCI.

*Current tax*

Current tax comprises the expected tax payable or receivable on the taxable income or loss for the year and any adjustment to tax payable or receivable in respect of previous years. It is measured using tax rates enacted or substantively enacted at the reporting date.

*Deferred tax*

Deferred income tax is recognized, using the balance sheet liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred tax is not recognized for:

- temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit or loss;
- temporary differences related to investments in subsidiaries to the extent that the Company is able to control the timing of the reversal of the temporary differences and it is probable that they will not reverse in the foreseeable future; and
- taxable temporary differences arising on the initial recognition of goodwill.

Deferred income tax is determined using tax rates and laws that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

Deferred tax assets and liabilities are offset only if certain criteria are met.

***Employee benefits***

The Company maintains a pension plan for all employees in Switzerland through payments to a legally independent collective foundation. This pension plan qualifies under IFRS as defined benefit pension plan. There are no pension plans for the subsidiaries in Ireland and the United States.

The Company's net obligation in respect of defined benefit plans is calculated by estimating the amount of future benefit that employees have earned in return for their service in the current and prior periods, discounting that amount and deducting the fair value of any plan assets.

The recognized asset is limited to the present value of economic benefits available in the form of any future refunds from the plan or reductions in future contributions to the plan. In order to calculate the present value of economic benefits, consideration is given to any minimum funding requirements.

Remeasurements of the net defined benefit liability, which comprise actuarial gains and losses, the return on plan assets (excluding interest) and the effect of the asset ceiling (if any, excluding interest), are recognized immediately in OCI. The Company determines the net interest expense (income) on the net defined benefit liability (asset) for the period by applying the discount rate used to measure the defined benefit obligation at the beginning of the annual period to the then-net defined benefit liability (asset), taking into account any changes in the net defined benefit liability (asset) during the period as a result of contributions and benefit payments. Net interest expense and other expenses related to defined benefit plans are recognized in profit or loss.

***Share-based compensation***

*Share Options*

The Company maintains various share-based payment plans in the form of stock option plans for its employees, directors and key service providers. Stock options are granted at the Board's discretion without any contractual or recurring obligations.

The share-based compensation plans qualify as equity settled plans. The grant-date fair value of share-based payment awards granted to employees is recognized as an expense, with a corresponding increase in equity, over the period that the employees become unconditionally entitled to the awards. The vesting of share options is conditional on the employee completing a period of service of three and four years respectively in accordance with Stock Option Plan A, or Plan A, and Stock Option Plan C, or Plan C. Stock Option Plan B, or Plan B, was created to provide shares for share based compensation plans; it was used in the years 2008 and 2009 and is still in effect. However, no options are currently outstanding under Plan B.

The amount recognized as an expense is adjusted to reflect the number of awards for which the related service and non-market performance conditions are expected to be met, such that the amount ultimately recognized as an expense is based on the number of awards that meet the related service and non-market performance conditions at the vesting date. Share-based payments that are not subject to any further conditions are expensed immediately at grant date. In the year the options are exercised the proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

*Valuation of share options*

The fair value of our shares is determined by our management and our board of directors, and takes into account numerous factors to determine a best estimate of the fair value of our common shares as of each grant date.

In our historic financing rounds we have mainly relied on the prior sale of stock method where the company and new investors negotiate the company's valuation at arm's length. Typical considerations in this method may include the type and amount of equity sold, the estimated volatility, the estimated time to liquidity, the relationship of the parties involved, the timing compared to the common shares valuation date and the financial condition and structure of the company at the time of the sale.

In this process, we have taken into consideration the guidance recommended by the American Institute of Certified Public Accountants, or AICPA, Audit and Accounting Practice Aid, specifically the Valuation of Privately-Held-Company Equity Securities Issued as Compensation. The most frequent types of private transactions and their relevance to the derived fair value of our shares are the "Simple preferred stock financing transaction" (AICPA 8.03

a. i. and ii.) with new investors. Our assumptions and estimates are highly complex and involve subjective assumptions. Changes in these underlying assumptions and estimates could significantly change our reported or expected financial performance.

Estimates by our management and our board of directors will not be necessary to determine the fair value of new awards once a public trading market for our common shares has been established in connection with the completion of this offering.

***Convertible loans***

Convertible loans are classified as financial liabilities and initially measured at fair value excluding transaction costs where these are not material. The difference to the nominal value is recorded directly in equity as a transaction with a shareholder in its capacity as shareholder. Subsequent to initial recognition, the convertible loans are measured at amortized cost using the effective interest method.

### Recent accounting pronouncements

Except for IFRS 9 for which the impact cannot be determined with sufficient reliability, there are no IFRS standards as issued by the IASB or interpretations issued by the IFRS interpretations committee that are effective for the first time for the financial year beginning on or after January 1, 2014 that would be expected to have a material impact on our financial position.

### JOBS Act exemptions

On April 5, 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company.” As an emerging growth company, we are electing to take advantage of the following exemptions:

- including the use of two years of audited financial statements as opposed to three years in our initial registration statement;
- not providing an auditor attestation report on our system of internal controls over financial reporting;
- not providing all of the compensation disclosure that may be required of non-emerging growth public companies under the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act;
- not disclosing certain executive compensation-related items such as the correlation between executive compensation and performance and comparisons of the Chief Executive Officer’s compensation to median employee compensation; and
- not complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (auditor discussion and analysis).

These exemptions will apply for a period of five years following the completion of our initial public offering or until we no longer meet the requirements of being an “emerging growth company,” whichever is earlier. We would cease to be an emerging growth company if we have more than $1.0 billion in annual revenue, have more than $700 million in market value of our common shares held by non-affiliates or issue more than $1.0 billion of non-convertible debt over a three-year period.

# BUSINESS

## Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel products for the treatment of inner ear disorders. Our most advanced product candidate, AM-101, is in Phase 3 clinical development for acute inner ear tinnitus under a special protocol assessment, or SPA, from the FDA. In two recently completed Phase 2 clinical trials, AM-101 demonstrated a favorable safety profile and statistically significant improvement in tinnitus loudness and other patient reported outcomes. We are also developing AM-111 for acute inner ear hearing loss, and we expect to begin Phase 3 clinical development in the fourth quarter of 2014. We expect to have top-line Phase 3 clinical data for AM-101 and AM-111 in early 2016 and late 2016, respectively. Both acute inner ear tinnitus and hearing loss are conditions for which there is high unmet medical need, and we believe that we have the potential to be the first to market in these indications.

With two product candidates in Phase 3 clinical trials, we believe we are currently the clinically most advanced company working on inner ear therapeutics. We believe that AM-101 and AM-111 are the only drug candidates that have demonstrated positive efficacy in randomized placebo-controlled clinical trials in acute inner ear tinnitus and acute inner ear hearing loss. Our products are protected through intellectual property rights and, in addition, orphan drug status has been granted to AM-111.

Our product candidates are injected under local anesthesia into the middle ear by a technique called intratympanic, or i.t., injection. Once injected into the middle ear, the active substance, which is formulated in a biocompatible gel, diffuses into the inner ear. The procedure is short, safe, has a long history of use and allows for highly targeted drug delivery with minimal systemic exposure. It is performed by an ear, nose and throat, or ENT specialist on an outpatient basis over one or more visits.

Our lead product candidate, AM-101, is targeting acute inner ear tinnitus. Tinnitus, frequently perceived as a ringing in the ears, is the perception of sound when no external sound is present. Similar to pain, it is an unwanted, unpleasant and thus distressing sensation. Tinnitus may result in further symptoms such as inability to concentrate, irritability, anxiety, insomnia, and clinical depression. In many cases, tinnitus significantly impairs quality of life and affects normal day-to-day activities.

Tinnitus is categorized as acute during the three months after onset and chronic when it persists for more than three months. Approximately 25% of American adults (50 million people) have experienced tinnitus with nearly 8% of American adults (16 million people) having frequent occurrences. Epidemiological studies reveal comparable prevalence rates for Europe. Among the tinnitus patients seen by general practitioners and ENT specialists in the United States and the top five European markets who reported seeing at least one tinnitus patient in the previous three months, approximately 36% of patients sought medical treatment during the first three months following tinnitus onset.

One of the frequent causes of acute inner ear tinnitus is traumatic insult such as exposure to excessive noise, or middle ear infection (otitis media, or OM). We have conducted Phase 2 trials in this specific tinnitus population with AM-101 which demonstrated a favorable safety profile. Furthermore, in our Phase 2 clinical trials, AM-101 showed a dose dependent, persistent and clinically relevant improvement, as compared to the placebo, in subjective tinnitus loudness as well as other patient reported outcomes, such as tinnitus annoyance, tinnitus severity, sleep difficulties and general tinnitus impact. Our Phase 3 clinical program, which is similar in design to our Phase 2 trial design, is being conducted under a SPA from the FDA and also incorporates guidance from the European Medicines Agency, or EMA. We expect to have top-line data in early 2016. We believe that AM-101 has the potential to become the first product approved for the treatment of acute inner ear tinnitus.

Our second product candidate, AM-111, is being developed for the treatment of acute sensorineural hearing loss, or ASNHL. In sensorineural hearing loss, which is also referred to as inner ear hearing loss, there is damage to the sensory cells of the inner ear or the auditory nerve. Hearing loss is a heterogeneous disorder of many forms with a variety of causes. ASNHL may be triggered by a variety of insults, such as exposure to excessively loud sound, infection, inflammation or certain ototoxic drugs. These insults may also result in tinnitus. Over 60,000 people in the United States are affected by sudden deafness annually. There are no currently approved pharmaceutical treatments for this patient population in the United States.

In our Phase 2 clinical trial, AM-111 showed a favorable safety profile. Furthermore, in patients with severe to profound ASNHL, we observed a clinically relevant improvement in hearing threshold, speech discrimination and a higher rate of complete tinnitus remission compared with placebo. We plan to begin two late stage clinical trials in ASNHL, including a pivotal Phase 3 trial in the fourth quarter of 2014. We expect to have top-line data from these trials in late 2016. We believe that, if approved, AM-111 could become the first approved pharmaceutical treatment for ASNHL. AM-111 received orphan drug designation for the treatment of ASNHL from both the FDA and the EMA.

### Strengths

We believe we are a leader in the development of novel therapeutic products for inner ear disorders due to several factors.

- ***First mover advantage.*** With two product candidates in late stage clinical development, we believe we are currently the clinically most advanced company working on inner ear therapeutics. We believe that AM-101 and AM-111 are the only drug candidates that have demonstrated positive efficacy in randomized placebo-controlled clinical trials in acute inner ear tinnitus and acute inner ear hearing loss. As a result, we believe we will be the first to market with FDA or EMA-approved products for these indications.
- ***Barriers to entry*.** Our products are protected not only through intellectual property rights but also by the orphan drug status granted to AM-111 as well as by the know-how across several disciplines that is required to formulate and reliably deliver drugs to the inner ear. Our proprietory gel formulation, its manufacturing and its application are part of our intellectual property, know-how and competitive advantage.
- ***Efficient commercialization.*** Given that the market for our therapeutic product candidates can be efficiently accessed through a limited number of specialist ENT physicians and specialist neurotologists, we intend to build our own sales force in order to commercialize these products in the United States and key European markets.
- ***Experienced management.*** Having been focused on developing therapeutic products for inner ear indications for over a decade, we believe that our senior management provides us with significant capabilities. Our Chief Executive Officer and founder, Thomas Meyer, has played several pivotal roles in our development and evolution. Prior to Auris Medical, he was the CEO of Disetronic, a fast growing Swiss diabetes care company sold to Roche in 2003. Other key members of our management team bring significant experience in clinical, product and business development in biopharmaceutical companies.

### Strategy

Our goal is to become the leading biopharmaceutical company focused on developing and commercializing novel therapeutics to treat inner ear disorders. The key elements of our strategy to achieve this goal are:

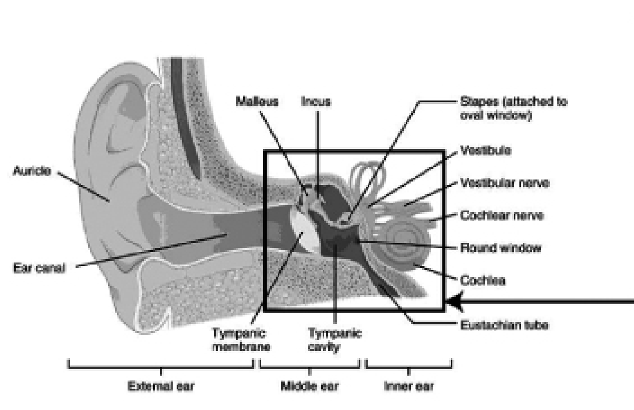
- ***Target inner ear disorders that have a defined pathophysiology and that are amenable to treatment.*** We are focusing on inner ear disorders for which the pathophysiology is well characterized, can be effectively targeted and where affected patients seek medical attention proactively.
- ***Use drug delivery techniques and proprietary drug formulations for effective, safe and rapid local administration to the inner ear.*** We are developing treatments for inner ear disorders based on i.t. injections into the middle ear. This short outpatient procedure allows us to deliver therapeutic concentrations of drug in a highly targeted fashion with only minimal systemic exposure. We are using proprietary, fully biocompatible and biodegradable gel formulations for optimum middle ear tolerance and effective diffusion of active substances into the inner ear.
- ***Bring AM-101 and AM-111 to market.*** We plan to focus most of our resources on the development and commercialization of our two lead product candidates. AM-101 is in two Phase 3 clinical trials, based on a SPA from the FDA and guidance from the EMA. We are preparing to initiate a pivotal Phase 3 trial for AM-111 in the fourth quarter of 2014.
- ***Build an efficient commercial infrastructure to maximize the value of our product candidates****.* We intend to build commercial operations in the North American market and in select European markets. In those markets, we expect our commercial operations to include specialty sales forces targeting ENTs and specialists in neurotology both in hospitals and in private practice. In other markets, we expect to seek partnerships that would maximize our products' commercial potential.

- ***Expand our pipeline through internal development, academic collaborations, in-licensing and acquisitions.*** Through our work with academic research partners on the pathophysiology of tinnitus and hearing loss and clinical development we have gained novel insights that will help us both to create new pipeline products that act by way of novel mechanisms as well as to expand the therapeutic focus for our existing product candidates beyond their current indications. We plan to further maximize our commercial potential through product life cycle management, and with licensing or acquisition of compounds that could augment our product offering in ENT disorders.

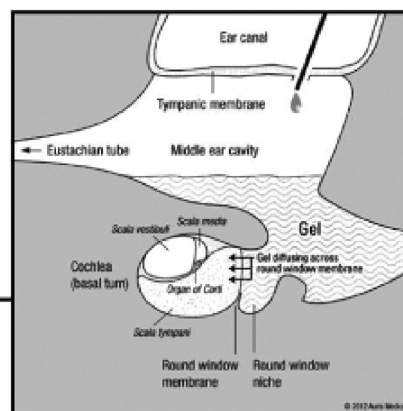
**The Inner Ear**

We have focused our drug discovery and development efforts on targeting the cochlea, which together with the vestibular system constitutes the inner ear. The snail-shaped cochlea is the sensory organ at the periphery of the auditory system, which transmits sound along the auditory pathway up to the brain for hearing. Acute insults to the cochlea from a variety of sources – for example, loud noise, infection or insufficient blood supply – may lead to excessive levels of glutamate, the principal neurotransmitter in the cochlea as well as other pathological processes. This in turn may damage cochlear hair cells, which tune and amplify sound inside the cochlea or convert mechanical movement into neural signals, as well as cochlear neurons. Such damage may result in the symptoms of inner ear hearing loss and/or inner ear tinnitus that can be transitory as natural repair mechanisms set in or that become permanent when hair cells or neurons die or are permanently injured.

*The human ear and its key elements*




*Principle of intratympanic injection*




*The human ear and its key elements (left). The external ear captures sound waves, amplifies and directs them through the ear canal to the ear drum, also known as the tympanic membrane, which transfers them further via the three small bones of the ossicular chain to the oval window of the inner ear. Here, the sound waves enter the fluid filled cochlea, travel up the turns and down again and are dissipated by the round window membrane. On their way through the cochlea, the sound waves are transduced by inner hair cells into neural activity by excitation of the cochlear nerve.*

*Principle of intratympanic injection (right). For the administration, the patient is positioned with the ear pointing up to ensure that the round window membrane is at the bottom of the middle ear. Following local anesthesia of the ear drum the drug is injected by the ENT into the middle ear, where it collects in the bottom part, allowing for diffusion of the active substance across the round window membrane.*

Because the cochlea is located deep inside the head and because it is separated from the middle ear by a combination of bone and membranes, the interior of the cochlea is a challenging location for drug delivery. We have chosen to deliver our products via i.t. injection across the ear drum (also known as the tympanic membrane) into the middle ear cavity. By formulating our products with biocompatible gels, we facilitate the diffusion of active substances across the round window membrane into the cochlea at clinically meaningful concentrations.

### Market

Inner ear disorders, including hearing loss, tinnitus, Meniere's Disease and balance disorders, are common and often inter-related conditions. Chronic inner ear disorders such as tinnitus and hearing loss are highly prevalent. According to a 2012 publication by Langguth and Elgoyhen in the journal *Expert Opinion in Pharmacotherapy*, approximately 25% of American adults (50 million people) have experienced tinnitus with nearly 8% of American adults (16 million people) having frequent occurrences. According to the National Institute on Deafness and Other Communication Disorders (NIDCD), 36 million Americans, or 17% of the adult U.S. population, have a hearing loss. Epidemiological studies reveal comparable prevalence rates for Europe.

According to a 2011 publication by Hall et al. in the journal *BMC Health Services Research*, among the tinnitus patients seen by physicians who reported seeing at least one tinnitus patient in the previous three months, approximately 36% of patients sought medical treatment during the first three months following the onset of the disorder. Over 60,000 people in the United States are affected by sudden deafness annually.

The market for ear disorders is underserved despite the fact that according to a 2007 report by the consulting firm NeuroInsights, hearing loss ranks among the top ten neurologic disorders by worldwide prevalence, ranking above attention deficit disorders, Alzheimer's disease and multiple sclerosis. There are three main reasons for this:

***Inner ear physiology.*** It has been extremely challenging for pharmaceutical companies to deliver drugs at effective concentrations to the inner ear. Like the eye, the inner ear is a protected space. Systemically administered drugs such as intravenous or oral formulations in doses high enough to reach effective inner-ear concentrations often bring unacceptable systemic toxicity.

***Heterogeneity of inner ear disorders.*** Hearing loss and tinnitus are symptoms of many different underlying etiologies, and they manifest themselves in many different ways. For example, tinnitus may be provoked by such different proximal causes as whiplash injury, excessive noise exposure, the flu or even certain dental problems. In some cases, the tinnitus originates inside the cochlea, but then becomes "centralized," that is, the phantom sound persists even long after the initial source of the sensation has been removed. There has been a dearth of knowledge about the pathophysiology of tinnitus and hearing loss, which has hindered the pharmaceutical industry in pursuing therapeutics in this area.

***Lack of clinical trial paradigms.*** Historically, there have been challenges regarding the clinical endpoints used in measuring changes in tinnitus. Since tinnitus usually is perceived only by the patient affected by it, there is no direct way of measuring it. Like pain, tinnitus assessments have to rely on subjective endpoints. Tinnitus assessments consist either of psychoacoustic measures, performed by audiologists and other hearing specialists and sometimes considered as "semi-objective," or they are based on patient reported outcomes, or PROs. Unlike in pain, there has been a lack of guidelines and validation work on these PROs, and the relevance and reliability of psychoacoustic measures as efficacy outcome variables have been questioned.

For these reasons, the industry's discovery and development of novel therapies for inner ear disorders has lagged far behind efforts in other therapeutic areas.

We are addressing each of these issues with our approach to developing therapeutics targeting the inner ear. Using i.t. injection to deliver our product candidates to the inner ear reduces systemic exposure. We target specific types of tinnitus and hearing loss that are addressable with drug-based therapies. We have worked with regulatory agencies to develop an acceptable clinical trial paradigm assessing subjective endpoints culminating, for example, in our SPA for AM-101.

### Our Localized Delivery Solution for the Inner Ear

The inner ear is a protected part of the body, analogous to the eye. It is hidden in the temporal bone, behind the middle ear and the ear drum. In addition, it is very tiny: the cochlea measures about the size of the fingernail on the little finger. Therefore, therapeutically targeting the inner ear is not easy. There is currently no FDA or EMA approved drug therapy for the treatment of inner ear disorders on the market.

The blood labyrinth barrier is a major physiological divider separating the inner ear from systemic circulation, critically preserving the inner ear's microenvironment. Systemic drug dose levels capable of having a therapeutic effect on the inner ear are often high enough to cause adverse side effects.

An alternative approach is to administer drugs locally through i.t. injection to maximize efficacy and minimize systemic side effects. With i.t. administration, the drug is injected via a needle through the anesthetized ear drum into the middle ear cavity. The drug then diffuses across the semi-permeable round window membrane (RWM) into the inner ear. Our lead product candidates are administered by i.t. injection. We chose this approach after thorough evaluation of all available alternatives because it offers the optimal combination of access, convenience, physician familiarity and safety. We formulated our product candidates specifically with i.t. delivery in mind.

One of the key shortcomings of current i.t. approaches is the use of injectable solutions that may easily drain off via the Eustachian tube, thus preventing or reducing effective diffusion into the cochlea. With our proprietary gel formulations for i.t. injections we overcome this "draining off," facilitate contact with the RWM and achieve effective diffusion into the cochlea.

Both AM-101 and AM-111 are formulated in a viscous gel of sodium hyaluronate that is biocompatible, biodegradable, and isotonic (that is, having the same salt concentration and therefore not causing any pressure build up on either side of the RWM). The gel has a neutral pH which helps minimize potential irritation to the ear. In addition, in the case of AM-111, we are employing D-TAT, a peptidic active transporter technology that allows the transport of a large molecule to the inner ear that would normally be blocked by the RWM. This novel use of D-TAT brings peptides not only behind the RWM but inside cells in the inner ear. To our knowledge, we are the first company to be delivering intracellular peptides to the inner ear using an active transporter such as D-TAT.

The i.t. injection procedure by which our therapeutics are delivered to the RWM is a minimally invasive procedure that is relatively simple to perform by an experienced ENT specialist. Most ENT physicians and neurotologists have a high degree of comfort with i.t. injection and it is well-accepted by patients. A billable procedure, i.t. injection is routinely reimbursed under a broader reimbursement code. For the injection, patients lie on a stretcher or on a reclined exam chair, treated ear up; the injection is performed under local anesthesia of the eardrum by an ENT specialist using a microscope. Following the procedure, patients rest for 20 to 30 minutes to ensure maximum physical contact of the drug with the RWM. The tympanic membrane heals rapidly, usually within a few days, and the procedure may be performed several times. Often performed in children suffering from ear infections, the reversible opening of the eardrum is one of the most frequent ENT procedures.

### Our Product Candidates

The following table summarizes our product development pipeline:

| Product | Indication | Preclin. | Phase 1 | Phase 2 | Phase 3 | Next Key Milestones[1] | |
|---|---|---|---|---|---|---|---|
| **AM-101** Esketamine | *Acute inner ear tinnitus* | | | | | Data TACTT2<br>Data TACTT3 | Early 2016 |
| | *Post-acute inner ear tinnitus* | | | | | TACTT3 interim | Early 2015 |
| **AM-111** D-JNKI-1 | *Acute inner ear hearing loss* | | | | | Start HEALOS<br>Start OVERT | Fall 2014<br>(Data late 2016) |
| | *Meniere's disease* | | | | | Start MENDOS | Mid 2015 |
| **AM-102** Undisclosed | *Tinnitus* | | | | | Lead compound selected | Late 2014 |
| **AM-123** Undisclosed | *Rhinology* | | | | | Lead compound selected | Late 2014 |

(1) Dates of key milestones are indicative and subject to change.

## AM-101 in Tinnitus

Our most advanced clinical program is AM-101, Esketamine hydrochloride gel, which has commenced Phase 3 clinical trials in acute inner ear tinnitus in both the United States under a SPA from the FDA and in Europe. Esketamine hydrochloride is a potent, small molecule non-competitive NMDA, or N-methyl-D-aspartate, receptor antagonist. AM-101 is formulated in a biocompatible gel and delivered via i.t. injection. It has demonstrated safety and efficacy in two Phase 2 clinical trials. Based on our SPA agreement with the FDA and scientific advice from the EMA, we have initiated two pivotal clinical trials with highly similar design, one in North America (Efficacy and Safety of AM-101 in the Treatment of Acute Peripheral Tinnitus 2, or TACTT2) and one in Europe, which we refer to as TACTT3. AM-101 has the potential to be the first drug to gain approval for treating acute inner ear tinnitus.

### *Tinnitus*

Tinnitus, frequently perceived as a ringing in the ears, is the perception of sound when no external sound is present. Similar to pain, it is an unwanted, unpleasant and thus distressing sensation. Tinnitus may result in further symptoms such as inability to concentrate, irritability, anxiety, insomnia, and clinical depression. In many cases, tinnitus significantly impairs quality of life and affects normal day-to-day activities.

Tinnitus is categorized as acute during the first three months and chronic when it persists for more than three months. The distinction between acute and chronic is based on the clinical observation that spontaneous recovery or complete remission of tinnitus is much more likely to occur in the first days, weeks and months following its onset. The chances of spontaneous recovery decline exponentially as the acute phase progresses. In the chronic stage, improvement is much more unlikely, and the therapeutic focus shifts from curing to managing the disorder. In some cases, tinnitus originates inside the cochlea, or the periphery of the auditory system, but then becomes “centralized,” that is, the phantom sound persists even long after the initial source of the sensation has been removed.

Tinnitus is a symptom that can be triggered by a variety of diseases or incidents such as noise trauma, infection, inflammation, vascular problems, temporomandibular joint dysfunction, head trauma or whiplash injury. In the majority of cases the tinnitus originates in the cochlea, but the precise mechanisms of tinnitus generation are still the subject of considerable debate and remain to be fully elucidated. In our development we are focusing on one particular, well-defined type of tinnitus generation based on glutamate excitotoxicity.

Acoustic trauma and other insults to the inner ear may trigger increased levels of extra-cellular glutamate, which in turn cause excessive activation of cochlear NMDA receptors. This process results in damage or killing of sensory cells and is thought to be responsible for abnormal spontaneous “firing” of auditory nerves, which may be perceived as tinnitus. Under normal circumstances, the NMDA receptors are thought to play no role in the auditory nerve’s transmission of nerve pulses that carry sound information. In case of a trauma such as excessive sound exposure these receptors are activated and thus tinnitus is triggered.

### *Current Therapies and Unmet Need*

Tinnitus treatments may be categorized according to whether they treat the underlying cause or provide symptomatic relief. It is rarely possible to treat the underlying cause. When it is possible, treatment often involves a surgical procedure to resect tumors or vascular abnormalities. In contrast, treatments to provide symptomatic relief are highly diverse, reflecting the general lack of understanding of the underlying pathophysiology.

Currently, the most widely employed treatment options include counseling, cognitive behavioral therapy, various forms of sound therapies, tinnitus retraining therapy, or TRT, herbal and vitamin supplements, ginkgo biloba, vasodilators, steroids, benzodiazepines and tricyclic antidepressants.

Sound-based therapies and TRT are some of the most commonly employed treatments for tinnitus. TRT is a non-pharmacological intervention that employs low-level sound emitted by a so-called “masking device” worn behind or in the ear. TRT also incorporates patient counseling to help habituate patients to their tinnitus. In those cases in which it is effective, TRT takes one to two years before patients “learn” to ignore tinnitus without the aid of a masking device. TRT can cost $2,500 to $3,000, including the masking devices. After an initial period of enthusiasm in the 1980s, masking devices declined in popularity among clinicians because it became clear that many patients who agreed to try them were nonusers six months later. While classic sound based therapies are based on broadband sound, newer therapies use sound individually tailored to the hearing loss and tinnitus characteristics.

Although there are no approved drugs in the United States for the treatment of tinnitus, there is widespread off-label use of drugs approved for other indications. The U.K. Royal National Institute for the Deaf reports that more than three million prescriptions are written each year in the United States and Europe for drugs that purport to offer tinnitus relief, drugs for which there is no proven efficacy.

The local anesthetic and antiarrhythmic drug lidocaine is the only substance to date that is known to attenuate tinnitus, albeit only temporarily. This illustrates that tinnitus can be addressed using pharmacological intervention. However, lidocaine causes severe vertigo and other side effects, preventing its widespread clinical use.

### *Our Solution – AM-101*

*Therapeutic rationale for AM-101 in tinnitus*

The active pharmaceutical ingredient of AM-101 is Esketamine hydrochloride, a well-known small molecule non-competitive NMDA receptor antagonist. As described above, acoustic trauma and other insults to the inner ear have been shown in animal studies to activate cochlear NMDA receptors. The antagonist effect of Esketamine towards the NMDA receptor aims to suppress the aberrant activity of the auditory nerve and thus diminish tinnitus.

The NMDA receptor was first validated as a target for the treatment of tinnitus using an animal behavioral model of tinnitus triggered by salicylate, the active substance of aspirin. Salicylate is known to trigger temporary tinnitus when administered in high doses. The animal model demonstrated that local administration of different NMDA antagonists to the inner ear allowed for suppression of salicylate induced tinnitus. Together with INSERM, we developed a much more clinically relevant model of tinnitus induced by acute acoustic trauma, or AAT. Unlike salicylate-induced tinnitus, AAT triggers glutamate excitotoxicity and may lead to irreversible damage to sensory cells. It does not result in tinnitus in all cases, but where it sets in, it may be permanent. In our pre-clinical trials, we demonstrated that AM-101 was able to suppress this type of tinnitus. Further preclinical work demonstrated that tinnitus could be suppressed even when drug was administered after the onset of tinnitus.

Toxicology and tolerability studies confirmed that AM-101 had no impact on hearing, even at much higher doses than those needed for suppressing tinnitus. Animal biodistribution studies showed rapid diffusion of the active substance into the cochlea. Concentrations decreased over several days due to clearance.

Ketamine has been used clinically for decades as an anesthetic and analgesic. Esketamine is the S-enantiomer of Ketamine and was introduced in a small number of markets outside the United States as a more potent NMDA receptor antagonist with more favorable side effects than racemic Ketamine. The development of AM-101 has benefitted from the long-standing clinical use of Ketamine and Esketamine as well as the wealth of published pharmacology, pharmacokinetic and safety data. We are using Esketamine in doses that result in systemic exposure several orders of magnitude lower than those seen when Esketamine is used as an anesthetic at clinically safe doses.

*Tinnitus endpoints*

Given the lack of existing tinnitus treatments, there have been no fully validated or universally accepted outcome measures for clinical trials. There are two fundamental types of efficacy outcome variables. Patient reported outcomes, or PROs, such as the visual or numerical rating of tinnitus loudness or tinnitus questionnaires provide direct subjective measures of tinnitus and its impact on sleep, relaxation, communication, emotions, social interactions and other factors. For example patients are asked a single question to rate the loudness of their tinnitus “right now” on a scale from 0 (“no tinnitus heard”) to 100 (“tinnitus extremely loud”). Among several tinnitus questionnaires, the 25 item TFI is the most recent. It was developed and validated broadly in line with the PRO guidelines of the FDA and was introduced in 2011 by Meikle et al. following extensive validation work in the journal *Ear & Hearing*. Alternatively, measures commonly referred to as psychoacoustic may be performed by an audiologist, which is why they are considered “semi-objective.” They seek to determine how loud a masking sound has to be to cover the tinnitus (minimum masking level, or MML) or how loud the tinnitus is compared to reference sound (equal loudness match).

In our Phase 2 clinical trials, PROs showed good responsiveness and consistent results, whereas psychoacoustic measures proved highly variable and unreliable. Therefore, following discussions with the FDA and EMA, it was

agreed that our Phase 3 clinical program for AM-101 will be based on PROs with the improvement of subjective tinnitus loudness being defined as the primary efficacy endpoint. As part of the SPA with the FDA, it was agreed that improvement as measured by the TFI questionnaire will serve as a co-primary efficacy endpoint in our TACTT2 trial.

### *AM-101 Clinical Development*

*Phase 1/2*

We conducted the first clinical evaluation of AM-101 in a Phase 1/2 double blind, randomized, placebo-controlled trial that included dose escalation from 0.03 to 0.81 mg/mL. The trial enrolled 24 patients suffering for up to three months from severe or disabling permanent inner ear tinnitus caused by AAT or sudden deafness and after unsuccessful steroid treatment. The primary objective of the trial was to evaluate the safety of intratympanically delivered AM-101. This first clinical trial showed that single doses of intratympanically administered AM-101 were well tolerated up to the highest tested dose of 0.81 mg/mL. Only small traces of Esketamine and its primary metabolite were detected in blood samples within the first hours following treatment administration.

*Phase 2*

Following successful completion of our Phase 1/2 trial, we conducted two multi-center Phase 2 trials, one in Europe (Treatment of Acute Inner Ear Tinnitus 0 or TACTT0) and the other in Europe and the United States (which we refer to as TACTT1).

TACTT0

TACTT0 was conducted at 28 European sites between March 2009 and May 2011. This trial was a double-blind, randomized, placebo controlled, multiple dose, parallel group, Phase 2 clinical trial. It enrolled patients with persistent inner ear tinnitus as a result of AAT, OM, or idiopathic inner ear hearing loss, or ISSNHL, occurring not more than three months prior, and with a MML of at least 5 dB. Trial participants received three i.t. administrations of AM-101 at dose levels of either 0.27 mg/mL or 0.81 mg/mL or placebo over three consecutive days. A total of 248 patients were randomized (approximately eighty per treatment group). The improvement in the MML was the primary efficacy endpoint. The improvement in subjective tinnitus loudness and in tinnitus annoyance were co-primary efficacy endpoints.

In this trial, AM-101 further demonstrated a favorable safety profile. AM-101 was well tolerated and had no negative impact on hearing. Adverse events were mostly local and related primarily to anticipated temporary changes in tinnitus loudness and muffled hearing following the i.t. injection procedure. These effects usually resolved with closure of the ear drum. In 93% of cases, the ear drum was fully closed five days after the last injection. Seven patients experienced a total of nine nonfatal serious adverse events, of which four occurred in the placebo group. All serious adverse events were considered either not related or unlikely related to treatment. In the placebo group, one patient died because of cardiomyopathy, which was considered unrelated.

Efficacy analysis revealed a differentiated picture. Overall, the trial failed to demonstrate a treatment benefit based on the change in the MML as there was no difference in outcomes between treatment groups. However, further analysis of certain pre-specified outcome variables and subgroups revealed consistent differences between changes in the MML and changes in PROs and substantial variability in MML measures. Unlike the MML, the PROs, including tinnitus loudness and tinnitus annoyance, indicated different outcomes in treatment groups. In addition, outcomes differed consistently between patients with tinnitus triggered by AAT or OM, and those with tinnitus caused by ISSNHL. In case of the latter, no treatment effects were evident. Lastly, outcomes in unilateral tinnitus patients (one ear affected) were superior to those in bilateral tinnitus patients.

The further efficacy analysis focused on the subgroup of patients with tinnitus caused by AAT or OM (n=118), that is, patients with well-established cochlear origin of tinnitus. It also focused primarily on unilateral tinnitus patients (n=84) since they allowed for a direct measure of a treatment effect, free from any interference arising from the other, untreated ear in bilateral tinnitus. For this AAT- and OM-subgroup, the trial demonstrated a dose-dependent and persistent improvement in PROs. Patients in this subgroup who received AM-101 at a dose level of 0.81 mg/mL showed a statistically significant improvement 90 days post-treatment in subjective tinnitus loudness and tinnitus annoyance as well as in tinnitus-related sleep difficulties and overall tinnitus impact compared with placebo. The improvement was dose dependent and statistically significant across all PROs in the analysis of covariance, or

ANCOVA, statistical test. The ANCOVA model is commonly used in statistics for testing for differences between multiple treatment groups, and takes into account the baseline value of the respective test variable (covariate). Similar, but less pronounced outcomes were observed when also bilateral tinnitus cases were included; the improvement in tinnitus loudness, sleep difficulties and overall tinnitus impact in the enlarged subgroup was still statistically significant.

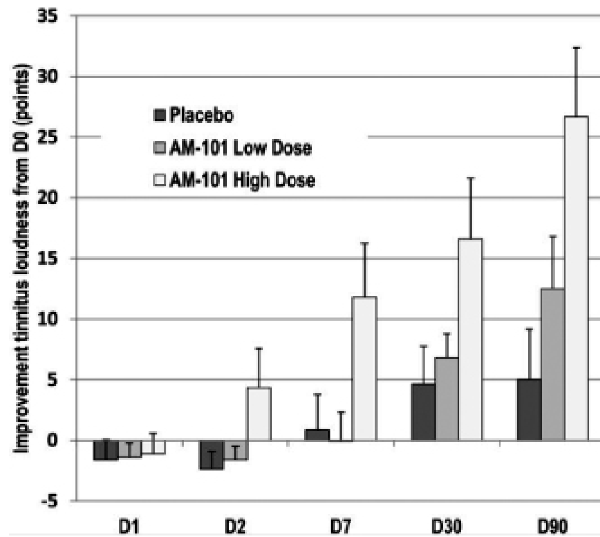
Improvement in tinnitus PROs

| | | AM-101 | |
|---|---|---|---|
| | PLACEBO | LOW DOSE | HIGH DOSE |
| **Point improvement in tinnitus loudness (0-100 point scale)** | | | |
| LS means (n) | 1.4 (23) | 16.0 (25) | 24.1 (29) |
| LS mean difference (95% confidence interval) | | 14.6 (1.4, 27.7) | 22.7 (10.3, 35.1) |
| P-value | | 0.0308* | 0.0005*** |
| **Point improvement in tinnitus annoyance (0-100 point scale)** | | | |
| LS means (n) | 10.8 (23) | 21.7 (25) | 27.8 (29) |
| LS mean difference (95% confidence interval) | | 10.9 (1.4, 23.2) | 17.0 (5.4, 28.6) |
| P-value | | 0.0805 | 0.0047** |
| **Point improvement in difficulties falling asleep (0-100 point scale)** | | | |
| LS means (n) | 11.8 (21) | 29.8 (15) | 38.7 (22) |
| LS mean difference (95% confidence interval) | | 18.1 (2.5, 33.6) | 26.9 (13.0, 40.9) |
| P-value | | 0.0234* | 0.0003*** |
| **Point improvement in tinnitus impact (0-24 point scale)** | | | |
| LS means (n) | 2.5 (22) | 5.5 (25) | 5.9 (27) |
| LS mean difference (95% confidence interval) | | 3.0 (0.1, 5.8) | 3.4 (0.8, 6.0) |
| P-value | | 0.0400* | 0.0124* |

*ANCOVA results for changes in PROs from baseline to Day 90 in patients with unilateral tinnitus following AAT or OM. Shown are least square (LS) means for treatment groups, differences for the active groups compared with placebo including 95% confidence interval and the p-value: * significant at 0.05 level; ** significant at 0.01 level; *** significant at 0.001 level. P-value is a conventional statistical method for measuring the statistical significance of clinical results. In clinical trials, the "p-value" is the probability that the result was obtained by chance. By convention, a "p-value" that is less than 0.05 is considered statistically significant. Tinnitus loudness, annoyance and difficulties falling asleep were rated by patients on a scale from 0 to 100 and tinnitus impact by the THI-12 questionnaire (maximum score 24 points).*

The improvement in PROs was gradual over the 90 day observation period. At Day 90 the mean improvement in tinnitus loudness was 48% in the AM-101 0.81 mg/mL group compared to 9% in the placebo group.

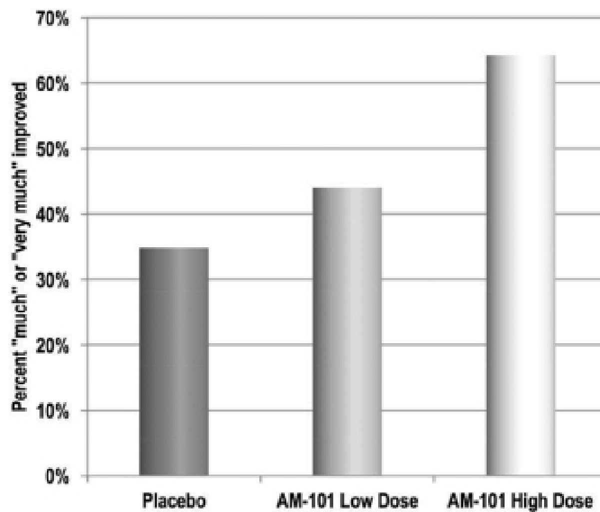
Improvement in tinnitus loudness over time




*Mean improvement of tinnitus loudness from baseline in patients with unilateral tinnitus following AAT or OM (n=84). Shown are changes from baseline D0 (before first injection) to D1 (before second injection), D2 (before third injection) and the follow-up visits at D7, D30 and D90. Whiskers: standard error mean.*

64% of patients in the high dose group rated their tinnitus severity at day 90 compared to baseline as “much improved” or “very much improved”, compared with 34% of patients in the placebo group. The majority of placebo treated patients reported only “somewhat improved” tinnitus severity.

Global patient impression of change in tinnitus severity




*Percentage of patients with unilateral tinnitus following AAT or OM (n=76) reporting at Day 90 “much improved” or “very much improved” tinnitus severity compared with baseline.*

Further analysis of efficacy results in the ISSNHL subgroup showed an unexpectedly high rate of spontaneous remission and substantial heterogeneity in outcomes. When patients with certain pre-specified tinnitus characteristics were excluded, a treatment effect was even observed with a majority of ISSNHL-tinnitus patients. Given the high variability and the uncertainty over the precise trigger of the tinnitus in ISSNHL, we decided to continue clinical development exclusively in tinnitus with established cochlear origin (such as AAT and OM).

TACTT1

TACTT1, our second double-blind, randomized, placebo-controlled Phase 2 clinical trial, was conducted between 2011 and 2013 in the United States, Belgium, Germany and Poland to complement the TACTT0 trial. The trial was not powered to demonstrate statistical significance between treatment groups, but rather designed to evaluate whether repeated doses were better than a single dose in attenuating tinnitus. Therefore no statistical hypotheses were defined, but the trial was expected to indicate relevant efficacy trends.

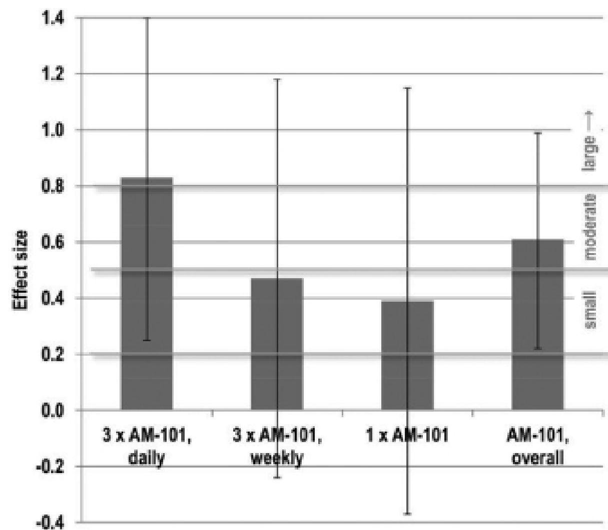
Enrollment consisted of 85 patients suffering from acute inner ear tinnitus following AAT or OM. Tinnitus after barotrauma and middle ear surgery were added as traumatic cases in addition to AAT.

Patients received single (Cohort 1) or multiple (Cohort 2: three injections over two weeks) doses of AM-101 at a dose level of 0.81 mg/mL or placebo. Each cohort had its own placebo group, and the placebo groups were pooled for certain statistical analyses describes below. Unlike TACTT0, this trial allowed bilateral treatment where tinnitus was present in both ears. The outcome measures in TACTT1 reflected insights gained from TACTT0. Specifically, subjective tinnitus loudness was selected as the primary efficacy measure, while the highly variable MML was monitored as a secondary readout.

TACTT1 demonstrated the safety and tolerability outcomes observed in the preceding trials. Again, there were no systemic side effects. One non-fatal serious adverse event was observed in the active treatment group; it was considered unrelated to the treatment. It further demonstrated the gradual improvement in PROs in AM-101 treated groups that had already been observed in TACTT0. The ANCOVA model in the primary efficacy analysis showed no statistically significant trend for improvement in subjective tinnitus loudness related to the number of injections (single dose AM-101, triple dose AM-101 and placebo pooled; p=0.084).

When comparing the improvement in tinnitus loudness in patients with unilateral tinnitus following traumatic injury to the cochlea or OM, treatment effects in TACTT1 were smaller than in TACTT0. The effect size was 0.83 where AM-101 had been administered three times over three consecutive days in TACTT0, 0.47 for three injections in weekly intervals (TACTT1) and 0.39 with single dose administration (TACTT1). The effect size is a commonly used standardized measure of the magnitude of observed effect to compare outcomes across different trials. Effect sizes between 0.5 and 0.8 are considered moderate, and above 0.8 as large. The observed differences in effect sizes suggest that repeated and concentrated application of AM-101 and hence concentrated inhibition of cochlear NMDA receptors provides superior treatment benefits. Over the two Phase 2 clinical trials, AM-101 0.81 mg/mL showed a statistically significant improvement in the AAT and OM group of patients when compared against placebo (p=0.002).

Effect size of tinnitus loudness improvement in TACTT0 and TACTT1




*Effect size of tinnitus loudness improvement from baseline to 90 days after last treatment administration for three different dose regimens – three doses over three consecutive days, three doses over two weeks, single dose – and pooled together in patients with unilateral tinnitus following AAT or OM (n=118) in the TACTT0 and TACTT1 trials. Effect size is calculated as mean difference in tinnitus loudness improvement between patients treated with AM-101 0.81 mg/mL and patients treated with placebo, standardized by the standard deviation. Whiskers: 95% confidence interval.*

As in the TACTT0 trial, psychoacoustic measures such as MML were marked by high variability, confirming their limited suitability and reliability as efficacy outcome measure.

***AM-101 Phase 3 Clinical Program***

With a clear regulatory plan in place based on our SPA with the FDA and scientific advice from the EMA, we have initiated two pivotal trials with AM-101 with highly similar design, one in North America (TACTT2) and one in Europe (TACTT3). TACTT2 will enroll 330 patients, while TACTT3 (Europe) will enroll 300 patients, both during the acute stage. In addition, TACTT3 will enroll another 300 patients during the post-acute stage (4 to 12 months from onset) since data from our Phase 2 clinical program suggest that AM-101 may be effective beyond the three month acute stage. Trial participants will receive three injections of AM-101 0.87 mg/mL or placebo over three to five days and will be followed for 84 days.

The same, well-defined patient population we used in Phase 2 (acute inner ear tinnitus following traumatic injury to the cochlea or OM) will be selected in our Phase 3 clinical trials. Furthermore, based on the data we have gathered on the various subjective clinical readouts, we believe we have identified the most reliable and relevant measures for efficacy. Efficacy endpoints include PRO measures of loudness and annoyance, the TFI as well as global patient scores of tinnitus status and change. Based on our discussions with the FDA and EMA, we agreed that psychoacoustic measures were not relevant or reliable enough for the purpose of measuring clinical efficacy of AM-101.

Based on our estimates regarding patient enrollment, we expect to have top-line data from this Phase 3 clinical program in early 2016.

Two further trials, AMPACT1 and AMPACT2 (AM-101 in the Post-Acute Treatment of Peripheral Tinnitus) will be nine-month open label extension trials conducted at the same sites as for TACTT2 and TACTT3. These extension trials will be open to participants who complete the TACTT2 or the TACTT3 trial and will evaluate the safety and local tolerance of up to three treatment cycles, each with three repeated doses of AM-101 0.87 mg/mL.

The extension trials were designed in response to the FDA's request for safety data from chronic intermittent use by tinnitus patients in support of a new drug application, or NDA, filing. Although we do not have any plans to seek a label for such use, the FDA considered such unintended use likely to occur. Therefore, we have designed these trials to provide further evidence of safety over a longer duration and also to study the effect of repeated administration over up to four treatment cycles in total.

## AM-111 in Hearing Loss

AM-111 is being developed for the treatment of ASNHL. In sensorineural hearing loss, there is damage to the sensory cells of the inner ear or the auditory nerve. Sensorineural hearing loss is also called "inner ear hearing loss". Hearing loss is a heterogeneous disorder of many forms with a variety of causes. ASNHL may be triggered by a variety of insults, such as exposure to excessively loud sound, infection, inflammation or certain ototoxic drugs. These insults may also result in tinnitus. According to an article by Rauch and Geller published in the *Journal of Comparative Effectiveness Research* in 2012, over 60,000 people in the United States are affected by sudden deafness annually. There are no currently approved treatments for this patient population.

AM-111 will soon enter two late stage clinical trials including a pivotal Phase 3 clinical trial in acute inner ear hearing loss. AM-111 contains a synthetic D-form peptide (D-JNKI-1) that protects sensorineural structures in the inner ear from stress-induced damage. AM-111 has been granted orphan drug status by both EMA and FDA for the treatment of ASNHL.

***Hearing Loss***

Hearing loss, like tinnitus, is a heterogeneous disorder of many forms with diverse etiology. There are two general categories: conductive hearing loss in which sound waves are not conducted efficiently to the inner ear due to build-up of earwax, fluid, or a punctured eardrum; and sensorineural hearing loss, in which there is damage to the inner ear or the auditory nerve. Acute hearing loss can occur in either category. Hearing loss is amenable to pharmaceutical intervention (and thus relevant to our drug development) only when it is sensorineural in origin. ASNHL is often accompanied by tinnitus.

There are two main types of acute hearing loss: hearing loss induced by trauma, such as from a loud rock concert or an explosion; and hearing loss that arises from unknown origins, that is, idiopathically, based on causes suspected to include changes in blood flow to the inner ear, bacterial and viral infections, autoimmune disease and others. The former is known as AAT for acute acoustic trauma. The latter is known as ISSNHL for idiopathic sudden sensorineural hearing loss. Together they can be defined as acute sensorineural hearing loss or ASNHL. In both cases, the onset is sudden. And in both cases, part of the initial hearing loss tends to recover naturally in the days and weeks following the loss; however, some of the loss may remain and, over time, become chronic in nature and less amenable to therapeutic intervention.

ASNHL differs from age-related hearing loss or hearing loss driven by chronic exposure to noise. Those types of hearing loss arise more slowly or on the basis of repeated insults, in slow motion. By contrast, in the case of ASNHL, the effects are felt immediately. This difference in the speed of progression is significant since sudden hearing losses are noticed much more readily.

ASNHL involves a variety of pathologic processes such as massive release of free reactive oxygen species, excessive and pathological stimulation of receptors on neurons by neurotransmitters like glutamate, and inflammation. These reactions, in turn, can damage sensorineural structures of the inner ear such as the sensitive inner and outer hair cells and nerve cells that line the interior of the cochlea. If the stress incident is severe enough, it may lead to permanent cochlear injury with irreversible loss of hair cells and nerve cells. Cell death occurs primarily through so-called programmed cell death, which is driven by damaged cells (apoptosis), and to a lesser extent also through necrosis, which is a passive consequence of gross injury to the cell.

The enzyme JNK is a signal transmitting enzyme that is stress-activated and regulates a number of important cellular activities. Stresses to the cochlea such as those described above, if severe enough, can activate the JNK signal transduction pathway, leading to the activation of transcription factors such as c-jun and c-fos that are found in the cell nucleus. This activation, in turn, activates genes encoding inflammatory molecules or promoting cell death.

***Current Therapies and Unmet Need***

Hearing loss may have a serious impact on people's personal and professional lives. Severe to profound hearing loss can result in high societal costs, mostly due to reduced work productivity, as reported in 2000 in the *International Journal of Technology Assessment in Healthcare.* Yet no treatment currently exists that has unequivocal evidence of efficacy for AAT or ISSNHL. There is no FDA- or EMA- approved drug on the market for hearing loss. The only remaining therapeutic option is a hearing aid or, in cases of deafness or near-deafness, a cochlear implant.

A patient with the acute form of hearing loss may recover on his or her own, especially if the loss is of low or moderate intensity and severity. This is due to intrinsic repair mechanisms inside the cochlea. However, in other cases the patient may recover only partially or not at all. In those cases, in the absence of effective treatment, acute hearing loss will become chronic and irreversible. There is currently no possibility to regrow or replace sensory structures inside the inner ear that are not recovered in the weeks immediately following the loss.

For ASNHL, non-specific treatments are frequently prescribed, mostly on an off-label empirical basis. These may include glucocorticoids and steroids such as prednisolone or dexamethasone; vasodilators such as pentoxyfilline; rheologics; ionotropics and local anesthetics; antioxidants and thrombolytics.

In the United States, most frequently oral prednisolone is administered for the treatment of ASNHL. Corticosteroids are intended to reduce inflammation and swelling in the ear that may be related to hearing loss. The U.S. treatment guideline issued in 2012 by the American Academy of Otolaryngology/Head & Neck Surgery for ISSNHL recommends oral steroids and hyperbaric oxygen as treatment options, but refrains from prescribing them in light of the low evidence level for their efficacy. Indeed, Nosrati-Zarenoe and colleagues presented in 2012 in the journal *Otology and Neurotology* the results of a Swedish placebo controlled trial with oral prednisolone in the treatment of ISSNHL that showed no therapeutic effect on hearing loss from active treatment.

***Our Solution – AM-111***

We are developing AM-111 as a treatment for acute inner ear hearing loss. AM-111 contains a synthetic D-form peptide (D-JNKI-1) that acts as a c-Jun N-terminal Kinase (JNK) ligand, thereby protecting sensorineural structures in the inner ear from stress-induced damage. We are developing D-JNKI-1 under a worldwide exclusive license for the treatment of ear disorders from Xigen S.A. (Switzerland). Like AM-101, AM-111 is delivered in a biocompatible gel formulation via i.t. injection. We have established the safety and preliminary efficacy of AM-111 in a Phase 2 clinical trial. We expect to initiate the next two late stage clinical trials in acute inner ear hearing loss, including a pivotal Phase 3 trial in the fourth quarter of 2014. The acute stage of hearing loss represents a window in time in which the inner ear can be protected from permanent hearing loss. AM-111 was granted orphan drug status by both EMA and FDA in 2005 and 2006, respectively.

*Therapeutic rationale for AM-111 in hearing loss*

The proprietary active pharmaceutical ingredient of AM-111 is D-JNKI-1, a 31 amino acid synthetic D-form peptide that binds to JNK and inhibits activation of transcription factors such as c-jun and c-fos, thereby protecting sensorineural structures from stress-induced inflammation and apoptosis. D-JNKI-1 comprises an active transporter sequence, or D-TAT, that enables AM-111 to cross the round window membrane quickly, diffuse widely throughout the cochlea, transfect sensorineural cells effectively and reach its target inside the cell nucleus. The D-form of the peptide provides for protease resistance and hence enhanced stability. AM-111 was shown to remain pharmacologically active for several days inside the cochlea. The D-form is necessary for AM-111 to cross the RWM.

By attenuating inflammation and protecting cells from apoptosis, we believe that AM-111 reinforces natural recovery processes and helps to prevent or minimize permanent damage respectively chronic hearing loss. AM-111's otoprotective effect has been demonstrated in various animal models of cochlear stress, including AAT, acute labyrinthitis (inflammation), drug ototoxicity (aminoglycosides), bacterial infection, cochlear ischemia and cochlear implantation trauma.

We conducted our preclinical development program for AM-111 in close collaboration with academic partners and various contract research organizations, or CROs. D-JNKI-1 was invented by Xigen S.A. in Lausanne, Switzerland. In

2003, we signed a Collaboration and License Agreement with Xigen, under which we in-licensed worldwide exclusive rights for use of D-JNKI-1 in the treatment of ear disorders. Under the agreement with Xigen, we have exchanged various preclinical and clinical data.

*Hearing loss endpoints*

Unlike tinnitus, where measures of therapeutic outcomes have to rely on PROs, the evaluation of hearing is based on psychoacoustic measures performed by audiologists. Audiometric procedures and equipment are highly standardized around the world; hearing thresholds are typically determined by presenting pure tones in the 250 Hz to 8 kHz range through headphones or ear inserts (air conduction) or through a vibrator placed behind the ear or on the forehead (bone conduction). An increase in volume of 10 dB is perceived as twice as loud. In other words, a person whose hearing thresholds improved by 10 dB can hear sounds at half the intensity level that was necessary before. A change of this magnitude is generally considered to be clinically relevant. In addition to pure tone audiometry usually speech audiometry is conducted, in which the audiologist measures a patient's ability to hear and correctly understand a series of monosyllabic words.

The primary efficacy endpoint in our Phase 2 clinical trial was hearing loss recovery from baseline to Day 7 at the three worst affected frequencies. The percentage improvement of the patient's hearing across an average of three frequencies was measured relative to baseline hearing loss. This percentage improvement and the percentage of patients with complete remission (hearing recovery to within 10 dB of the pre-ASNHL level) at Day 7 were co-primary endpoints. We also monitored change in the speech discrimination score, or SDS, which measures the correct understanding of 20 monosyllabic words presented to patients, as well as subjective tinnitus loudness as secondary outcome variables.

***AM-111 Clinical Development***

We have successfully completed two clinical trials of AM-111 that demonstrated its safety and efficacy. We are planning to initiate late stage clinical trials in the fourth quarter of 2014. We will conduct a pivotal Phase 3 clinical trial that largely follows the design of our previously completed Phase 2 clinical trial. In parallel, we are planning to conduct one more Phase 2 clinical trial to explore the potential benefits of repeated AM-111 dosing.

We have benefited several times from engaging in a protocol assistance procedure with the EMA, most recently for the design of the Phase 3 clinical development. We are planning to request a Pre-IND meeting with the FDA later in 2014. As such, we have not yet filed an IND.

We designed the planned pivotal Phase 3 clinical trial based on the outcomes from our Phase 2 clinical trial and our discussions with the EMA. We decided to make some adjustments to the definition of the target patient population to ensure that the trial enrolls only those subjects who have a clear medical need and in whom a clinically meaningful therapeutic benefit can be shown.

We expect to have top-line data from the two late stage clinical studies in late 2016. If their results are favorable, we plan to submit applications for marketing approval for AM-111 with the FDA and EMA in early 2017.

*Phase 1/2 Clinical Trial*

A Phase 1/2 clinical trial was conducted at two centers in Germany in January 2006, with 11 patients suffering from AAT due to New Year's firecracker accidents. Patients had at least 30 dB hearing loss by pure tone audiometry (average of 4 and 6 kHz) and were treated within 24 hours of onset.

Trial participants received a single dose of AM-111 at either 0.4 mg/mL or 2 mg/mL in a biocompatible gel formulation by i.t. injection into the most affected ear. The primary endpoint of the trial was the recovery of hearing thresholds from baseline to Day 30. AM-111 was well tolerated by all trial participants, regardless of the dose. Adverse events occurred in only small numbers and were either unrelated or considered unlikely to be related to the treatment. The Phase 1/2 trial provided the first indications of therapeutic benefit of AM-111 in humans.

*Phase 2 Clinical Trial*

To further evaluate the efficacy and safety of AM-111 we conducted a Phase 2b clinical trial between March 2009 and 2012. Since preclinical tests had demonstrated AM-111's otoprotective effects in many different types of cochlear stress, the patient population was expanded from AAT cases to also include patients affected by ISSNHL. In addition, based on observations from our Phase 1 clinical trial, we expanded the allowed time window from 24 to 48 hours from onset. The design for this Phase 2b trial was discussed with the EMA under a protocol assistance procedure.

The trial enrolled 210 participants who suffered from ASNHL (unilateral ISSNHL, uni- or bilateral AAT) with hearing loss of at least 30 dB at the average of the three worst affected frequencies (pure tone average; PTA) and onset not more than 48 hours previously. AM-111 was dosed at 0 mg/mL (placebo), 0.4 mg/mL (Low Dose) and 2.0 mg/mL (High Dose). All patients without a clinically relevant hearing recovery on Day 7 were given the option to take a course of oral prednisolone as a reserve therapy.

The trial consisted of a baseline assessment and four follow-up visits on Days 3, 7, 30, and 90. The primary efficacy endpoint was hearing loss recovery from baseline to Day 7 at the three worst affected frequencies. The percentage improvement of PTA relative to baseline hearing loss and the percentage of patients with complete remission (PTA recovering to within 10 dB of the pre-ASNHL level) at Day 7 were co-primary endpoints. We also monitored change in the speech discrimination score, or SDS, measuring the correct understanding of 20 monosyllabic words presented to patients, and subjective tinnitus loudness as secondary outcome variables.

AM-111 was safe and well tolerated in this trial. There were no statistically significant differences in the occurrence of clinically relevant hearing deterioration in the treated ear. Also, there were no apparent differences in the frequency of adverse events between placebo and AM-111 treated patients at any time points, no systemic side effects and no negative impact on balance or tinnitus. There were transient procedure related effects such as ear discomfort or pain, incision site complications or middle ear infection in less than 5% of cases. For nine patients, non-fatal serious adverse events were recorded (two, four and three patients in the placebo, AM-111 Low Dose and AM-111 High Dose, respectively). All serious adverse events were considered unlikely related or not related to the treatment with the exception of two ("deafness neurosensory", one in the placebo and one in the AM-111 High Dose group). All serious adverse events except two (diagnosis of internal auditory canal tumor, respectively neurofibromatosis type II, not related) had recovered or were recovering. The most common serious adverse event was "deafness neurosensory," as some severe or profound hearing loss patients with insufficient recovery, acute relapse or ongoing deterioration were hospitalized in Poland for infusion therapy in line with customary medical practice.

The trial demonstrated a statistically significant and clinically relevant improvement for the primary as well as the co-primary endpoints in patients with severe to profound ASNHL (those patients with hearing loss of at least 60 dB) treated with AM-111 0.4 mg/mL compared with placebo.

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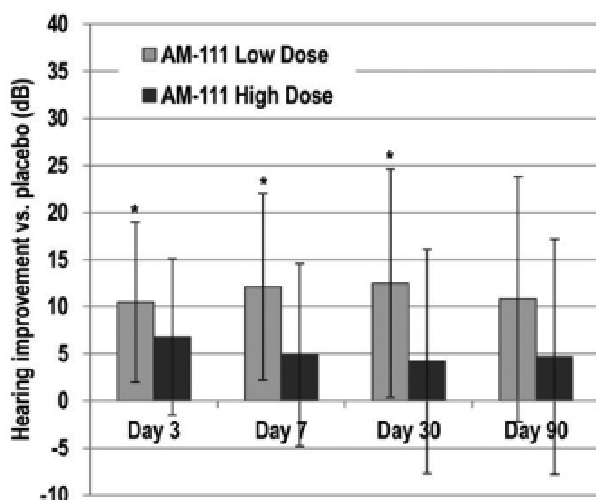
Improvement in hearing and speech discrimination

| | PLACEBO | AM-111 LOW DOSE | AM-111 HIGH DOSE |
|---|---|---|---|
| **Absolute hearing improvement, dB** | | | |
| LS means (n) | 17.9 (30) | 29.9 (29) | 22.7 (33) |
| LS mean difference (95% confidence interval) | | 12.1 (2.2, 22.0) | 4.9 (-4.8, 14.6) |
| P-value | | 0.017* | 0.319 |
| **Relative hearing improvement, %** | | | |
| LS means (n) | 30.9 (30) | 50.4 (29) | 37.6 (33) |
| LS mean difference (95% confidence interval) | | 19.5 (3.0, 35.9) | 6.6 (-9.6, 22.8) |
| P-value | | 0.021* | 0.419 |
| **Frequency complete hearing recovery, %** | | | |
| Mean (n) | 13.3 (30) | 31.0 (29) | 24.2 (33) |
| Odds ratio (95% confidence interval) | | 5.5 (1.1, 29.0) | 1.6 (0.4, 6.7) |
| P-value | | 0.044* | 0.530 |
| **Speech discrimination score improvement, % points** | | | |
| LS means (n) | 9.1 (29) | 27.4 (29) | 23.2 (33) |
| LS mean difference (95% confidence interval) | | 18.3 (3.1, 33.4) | 14.1 (0.7, 28.9) |
| P-value | | 0.019* | 0.061* |

*ANCOVA results for changes in hearing (absolute and relative to initial hearing loss) and speech discrimination score from baseline to Day 7 as well as frequency of complete hearing recovery in patients with severe to profound hearing loss. Shown are mean values for treatment groups (least square (LS) means for ANCOVA), differences for the active groups compared with placebo (odds ratio from logistic regression for frequency of complete hearing recovery) including 95% confidence interval and the p-value: * significant at 0.05 level.*

A clinically relevant and statistically significant therapeutic effect of AM-111 Low Dose was apparent at Day 3; it continued to Day 30 and leveled off somewhat by Day 90, but still remained clinically relevant.

Improvement in hearing over time

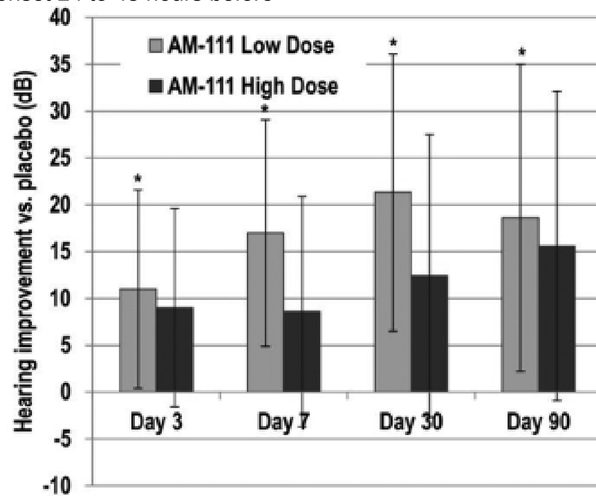



*Treatment effect of AM-111 as difference in hearing recovery over placebo from baseline to follow-up visits in patients with severe to profound hearing loss (n=92). A difference of 10 dB is considered clinically relevant. Whiskers: 95% confidence interval. * Significant at 5% level when compared to placebo.*

At Day 90, 42% of patients had achieved complete recovery as compared to 26% in the placebo group. The High Dose group overall showed improvement between the Low Dose and the placebo groups, without reaching statistical

significance. Sensitivity analysis showed that the therapeutic effect did not depend on early treatment: in patients who were treated more than 24 hours after ASNHL onset the treatment effect actually was larger as the rate of spontaneous recovery decreased.

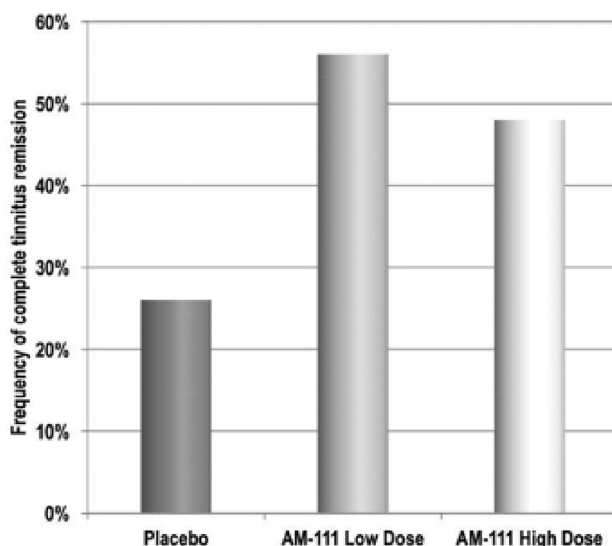
Improvement in hearing over time – ASNHL onset 24 to 48 hours before




*Treatment effect of AM-111 as difference in hearing recovery over placebo from baseline to follow-up visits in patients with severe to profound hearing loss treated 24 to 48 hours post ASNHL onset (n=66). A difference of 10 dB is considered clinically relevant. Whiskers: 95% confidence interval. * Significant at 5% level when compared to placebo.*

The superior hearing recovery in the AM-111 0.4 mg/mL group vs. placebo was supported by more frequent complete tinnitus remission. The latter finding, which was not yet apparent in the previous smaller Phase 1/2 clinical trial, suggests that preservation of sensory cochlear cells may help to prevent permanent tinnitus and hearing loss at the same time.

Complete tinnitus remission




*Percentage of severe to profound hearing loss patients and tinnitus at baseline whose tinnitus was completely resolved by Day 90 (n=77).*

In contrast to the patients with severe to profound hearing loss at baseline, there was no therapeutic benefit observed in patients with mild to moderate hearing loss (i.e. less than 60 dB) due to unexpectedly strong spontaneous recovery. Patients with mild hearing loss recovered essentially all of their initial hearing loss naturally, and those with moderate levels recovered most of it. In hindsight, the inclusion criteria for hearing loss severity had been set too low. Although there is consensus that spontaneous recovery can be substantial in ISSNHL, no reliable data had been available prior to our Phase 2b clinical trial, partly due to the dearth of placebo-controlled trials.

In the present trial, patients in the Low Dose group initially appeared to show greater improvement than those in the High Dose group. The difference, however, was not statistically significant for absolute PTA improvement and was much smaller or absent for the other efficacy outcomes.

*Planned Late Stage Clinical Trials*

Based on Phase 2 clinical trial outcomes and after obtaining guidance from the EMA, we decided to prepare two late stage clinical trials. The trials will focus on the severe to profound hearing loss population with ISSNHL as the onset factor and an enrollment time window that is extended from 48 to 72 hours. We are planning to conduct confirmatory testing of AM-111 0.4 mg/mL as well as to explore potential incremental therapeutic benefits from repeated administration and the use of a higher concentration. Animal studies show that the acute stage of inflammation following cochlear insults lasts up to 1 week; hence a second injection may prove beneficial. Since a “bell shaped” dose response curve was observed in animal studies, a concentration between 0.4 and 2.0 mg/mL may be even more effective than the low dose.

We are planning to conduct a Phase 2 clinical trial called OVERT (Efficacy and Safety of One Versus Two Doses of AM-111 in the Treatment of Acute Inner Ear Hearing Loss) primarily in Asia. We will recruit approximately 180 patients to evaluate the efficacy of two doses of AM-111 at 0.4 mg/mL or 0.8 mg/mL. We expect the trial to begin in the fourth quarter of 2014. We are further planning to conduct in parallel one pivotal Phase 3 trial called HEALOS (Efficacy and Safety of AM-111 in the treatment of Acute Inner Ear Hearing Loss) in European countries with approximately 240 patients. A single dose of either 0.4 mg/mL or 0.8 mg/mL of AM-111 will be compared to placebo. We anticipate this trial will begin in the fourth quarter of 2014.

*AM-111 in Meniere's Disease*

We are also planning to evaluate AM-111's efficacy and safety in Meniere's Disease. Meniere's Disease is an inner ear disorder that affects balance and hearing whose exact cause is unknown. It manifests with the following symptoms: vertigo, aural fullness, hearing loss and tinnitus. The symptoms primarily affect the low-frequency hearing range and, although they may fluctuate, in general they progress. The most prominent symptom is recurrent vertigo attacks. The primary cause of Meniere's Disease is thought to be an imbalance in the production and absorption of endolymph, one of two cochlear fluids. This results in endolymphatic hydrops, a condition where there are abnormalities in the quantity, composition and pressure of the endolymph within the inner ear. While it appears that all patients with the classical symptoms of Meniere's Disease have an endolymphatic hydrops the opposite is not true, as not all patients with hydrops have Meniere's Disease symptoms. It has been postulated that Meniere's Disease is caused by a latent Herpes Simplex Virus, or HSV, infection in sensory nerve ganglia. Specifically, it is proposed that Meniere's Disease is triggered by the reactivation of the HSV by stressful stimuli, viral replication and spread of the HSV resulting in inflammatory responses.

According to the National Institute on Deafness and Other Communication Disorders, there are 615,000 patients with Meniere's Disease in the United States, with 45,500 new cases diagnosed per year. There is no cure for Meniere's Disease. Management of the disorder includes treatment with anti-emetics or anti-histamines, low-salt diet and administration of diuretics to relieve endolymphatic pressure. In case of unresponsive first-line therapy, surgical interventions such as endolymphatic sac surgery or dissection of the vestibular nerve, or chemical destruction of vestibular hair cells by i.t. injections of the ototoxic drug gentamicin are considered.

By protecting sensory cells in the stress-injured cochlea we believe that AM-111 has the potential to be effective in attenuating some of the symptoms and long-term outcomes of Meniere's Disease, such as progressive sensorineural hearing loss. In addition to its anti-apoptotic and anti-inflammatory effects, AM-111's active substance has also been shown in vitro to attenuate replication of HSV and other types of viruses. Based on preclinical data, AM-111 has demonstrated that following round window membrane administration it is able to reach even the most remote part of the cochlea, which is most affected in Meniere's Disease, and is able to transfect sensory cells there. We are planning to evaluate AM-111's therapeutic potential for the treatment of Meniere's Disease first in an open-label clinical trial.

## Competition

We believe that we are the clinically most advanced company in the emerging field of inner ear therapeutics and that our innovative technology, knowledge, experience and scientific resources provide us with competitive advantages. However, we may face competition from different sources with respect to our product candidates AM-101 and AM-111 and our pipeline products or any product candidates that we may seek to develop or commercialize in the future. Because there are a variety of means to block the activity of NMDA receptors or the JNK pathway, our patents and other proprietary protections for AM-101 and AM-111 may not prevent development or commercialization of all viable product candidates that are different from our lead product candidates.

Any product candidates that we successfully develop and commercialize will compete with existing therapies, even if they are not licensed specifically for use in our target therapeutic indications or if they lack clear proof of efficacy. There exist no FDA or EMA approved products for the treatment of acute inner ear tinnitus or acute inner ear hearing loss; however, some drug products such as pentoxifylline, gingko biloba, corticosteroids, betahistine, trimetazidine or piracetam are frequently prescribed off-label. Some of them are even licensed as tinnitus or hearing loss treatments in certain countries of the European Union. We therefore may have to expend particular efforts in order to overcome established prescribing behavior.

Possible competitors may be biotechnology and pharmaceutical companies as well as academic institutions, government agencies and private and public research institutions, which may in the future develop products to treat acute inner ear tinnitus or acute inner ear hearing loss. Any product candidates that we successfully develop and commercialize will compete with new therapies that may become available in the future. We believe that the key competitive factors affecting the success of our product candidates, if approved, are likely to be efficacy, safety, convenience, price, tolerability and the availability of reimbursement from government and other third-party payors.

***Acute inner ear tinnitus***

There are a number of products in preclinical research and clinical development by third parties to treat tinnitus in the broader sense. Most of them are aiming to provide symptomatic relief (without treating the underlying cause) and targeting chronic rather than acute tinnitus. Examples include Tinnitus Retraining Therapy (TRT) or tinnitus maskers as well as more recent approaches like transcranial magnetic stimulation, vagus nerve stimulation, or customized sound therapy. Based on publicly available information, we have further identified, among others, the following drug product candidates that are currently in clinical development:

- Merz Pharmaceuticals GmbH has a product candidate that is a low affinity NMDA receptor antagonist and nicotinic acetylcholine receptor antagonist (neramexane) designed for oral treatment of tinnitus. In November 2011 Merz Pharma announced the suspension of its tinnitus development program with neramexane due to lack of efficacy in Phase 3 clinical trials in post-acute tinnitus; the product candidate is currently still being evaluated in a Phase 2 clinical trial by Merz's Japanese collaboration partner Kyorin Pharmaceutical Co., Ltd.
- Novartis Pharmaceuticals AG has a product candidate that is an AMPA receptor antagonist designed for oral administration (BGG492) and that has been tested in chronic tinnitus patients in a phase 2 clinical trial. The trial was completed in January 2012 with no outcomes being reported to date.

Since AM-101 targets a particular tinnitus generating mechanism during the acute stage, we consider these less specific products or product candidates as complementary rather than competing. Further progress in the development of AM-101 and in particular market approval may attract increased interest in developing treatments for acute inner ear tinnitus and may lead to the arrival of new competitors. For example, Otonomy Inc. acquired an early stage NMDA receptor antagonist product candidate (NST-001, gacyclidine) from Neurosystec Inc. in October 2013 and is planning to develop it as OTO-311 for i.t. injection.

***Acute inner ear hearing loss***

There are a number of product candidates in preclinical research and clinical development by third parties that aim to prevent or treat acute inner ear hearing loss. Based on publicly available information, we have identified, among others, the following product candidates:

- AudioCure Pharma GmbH has a ß-carboline product candidate (AC-002) in preclinical development that is designed for i.t. treatment of noise induced hearing loss in a gel-based formulation.
- Autifony Therapeutics Ltd. has a Kv3 potassium channel agonist product candidate (AUT00063) that is designed for oral administration and that is currently being evaluated in a phase 1 clinical trial with healthy volunteers. The company plans to develop AUT00063 for the treatment of age-related hearing loss and tinnitus.
- Sound Pharmaceuticals, Inc. has a product candidate (SPI-1005, ebselen), that mimics and prompts production of the enzyme glutathione peroxidase and is designed for oral administration, and that has been tested for the prevention and treatment of temporary inner ear hearing loss in a Phase 2 clinical trial.
- Otologic Pharmaceutics, Inc. has a product candidate (NHPN1010) designed for oral administration that combines the two free radical scavengers N-acetyl-cysteine (NAC) and HPN-07 and that is planned to enter clinical trials for noise induced hearing loss treatment in 2014.
- Southern Illinois University has an antioxidant product candidate (D-methionine) that is designed for oral administration in the prevention and treatment of noise induced hearing loss and currently being tested in a late stage study with the Department of Defense.

We believe that AM-111 is the only product candidate administered after an incidence of hearing loss that so far has demonstrated in a randomized, placebo controlled clinical trial a clinically relevant and statistically significant improvement in patients with severe to profound ASNHL and to have a therapeutic effect on tinnitus as well. To our knowledge, we are also the only company to have obtained orphan drug designation for a product candidate in the treatment of ASNHL in both the United States and the European Union. To the extent that other drug developers demonstrate clinical efficacy for their product candidates in the prevention and treatment of permanent hearing loss from ASNHL, our competitive position may be weakened, and the market exclusivity under the orphan drug designation may be circumvented.

***Meniere's Disease***

There are a number of other product candidates in preclinical research and clinical development that aim to treat Meniere's Disease. Based on publicly available information, we have identified, among others, the following product candidates:

- Otonomy Inc.'s product candidate OTO-104, a micronized dexamethasone formulated in a poloxamer gel designed for single dose i.t. injection that is currently being evaluated in a Phase 2b clinical trial in the United States and Canada in patients with unilateral Meniere's Disease.
- Synphora AB is evaluating a latanoprost product candidate designed for i.t. injections in a Phase 2 clinical trial in Meniere's Disease patients in Sweden.

We believe that AM-111, due to its ability to protect sensory cells in the stress-injured cochlea which has been demonstrated in various preclinical studies, and its ability to reach even the most remote, apical part of the cochlea, may offer therapeutic benefits in the treatment of Meniere's Disease. In the absence of animal models for the disorder, however, such potential may only be evaluated in clinical trials for which the outcome is uncertain at this point. To the extent that other drug developers may demonstrate clinical efficacy for their product candidates in the treatment of Meniere's Disease and receive market approval before us, we may have to demonstrate efficacy and safety as compared to such marketed product.

## Intellectual Property

***Patents***

We seek regulatory approval for our products in disease areas with high unmet medical need, great market potential and where we have a proprietary position through patents covering various aspects of our products, e.g., composition, dosage, formulation, and use, etc. Our success depends on an intellectual property portfolio that supports our future revenue streams as well as erects barriers to our competitors. We are maintaining and building our patent portfolio through: filing new patent applications; prosecuting existing applications and licensing and acquiring new patents and patent applications.

Despite these measures, any of our intellectual property and proprietary could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see "Risk factors-Intellectual property."

As of May 15, 2014 we own two (2) issued U.S. patents and four (4) pending U.S. patent applications along with foreign counterparts of such patents and applications in various jurisdictions. We co-own both of our issued U.S. patents, and one of our pending patent applications with INSERM, along with their foreign counterparts, pursuant to the terms of our co-ownership and exploitation agreement. In addition, as of March 1, 2014, we have exclusively licensed from Xigen ten (10) issued U.S. patents and four (4) pending U.S. patent applications, along with their foreign counterparts in various jurisdictions that cover the composition of matter or method of use of the JNK ligand peptides in a limited field including the intratympanic treatment of acute sensorineural hearing loss.

With respect to our issued patents in the United States and Europe, we may also be entitled to obtain a patent term extension to extend the patent expiration date. For example, in the United States, we can apply for a patent term extension of up to 5 years for one of the patents covering a product once the product is approved by the FDA. The exact duration of the extension depends on the time we spend in clinical trials as well as getting a new drug application approval from the FDA.

The patent portfolios for our two (2) leading product candidates as of May 15, 2014 are summarized below.

***AM-101***

We are the owner or co-owner of patents and patent applications relating to Ketamine or its use in inner ear tinnitus. In particular, we have an agreement entitled "Co-Ownership/Exploitation Agreement" with INSERM with respect to its Ketamine patent portfolio. We have rights to two (2) issued U.S. patents and two (2) pending U.S. applications

and corresponding patents and applications in other jurisdictions including, Europe, Australia, Canada, Japan, Brazil, China, Korea, Israel, Mexico and New Zealand, covering formulation and use of Ketamine. Our issued patents and pending patent applications relating to AM-101 are expected to expire between 2024 and 2028, prior to any patent term extensions to which we may be entitled under applicable laws.

***AM-111***

We are the exclusive licensee under our agreement with Xigen of a portfolio of patents and patent applications that relate, among other things, to JNK ligand peptides or their use in hearing loss. This portfolio includes ten (10) issued U.S. patents and four (4) pending U.S. applications along with their foreign counterparts in various jurisdictions including, Europe, Australia, Canada and Japan, that cover the composition of matter or method of use of the JNK ligand peptides. These licensed patents and patent applications relating to AM-111 are expected to expire between 2020 and 2025, prior to any patent term extensions to which we may be entitled under applicable laws.

***Proprietary Rights***

In addition to patent protection, we intend to use other means to protect our proprietary rights. We may pursue marketing exclusivity periods that are available under regulatory provisions in certain countries, including the US, Europe and Japan. For example, if we are the first to obtain market approval of a small molecule product in the United States, we would expect to receive at least 5 years of market exclusivity in the US.

Furthermore, orphan drug exclusivity has been or may be sought where available. Such exclusivity has a term of 7 years in the United States and 10 years in Europe. We have obtained orphan drug designation for AM-111 for the treatment of ASNHL in the United States and Europe. Orphan drug protection has been or may be sought where available if such protection also grants 7 years of market exclusivity.

We have obtained U.S. trademark registrations for Auris Medical Cochlear Therapies (and Design) and AURILIUM.

In addition, we rely upon unpatented trade secrets, know-how, and continuing technological innovation to develop and maintain our competitive position. We seek to protect our ownership of know-how and trade secrets through an active program of legal mechanism including assignments, confidentiality agreements, material transfer agreements, research collaborations and licenses.

## Collaboration and License Agreements

***INSERM***

In 2006, we entered into a co-ownership/exploitation agreement with the Institut National de la Santé et de la Recherche Médicale, or INSERM, a publicly funded government science and technology agency in France. Pursuant to the terms of the agreement, we were granted the exclusive right to exploit any products derived from patents that resulted from our joint research program with INSERM that was conducted in 2003 to 2005 and led to the development of AM-101. Pursuant to the terms of the co-ownership/exploitation agreement, we are given the exclusive right to exploit the patents issuing from the filed patent applications for all claimed applications, including the treatment of tinnitus, in order to develop, promote, manufacture, cause to be manufactured, use, sell and distribute any products, processes or services deriving from such patents, including AM-101, in any country in which these patent applications have been filed cduring the term of the agreement. We alone are entitled to grant manufacturing or sales licenses for any patents to our subsidiaries and/or third parties. INSERM is entitled to use the inventions covered by the patents and applications for its own research purposes, free of charge, but may not generate any direct or indirect profits from such use. Pursuant to the terms of our agreement with INSERM, we are required to finance research and development work towards achieving certain specified marketing authorizations, and to use best efforts in so far as commercially and financially feasible to develop, market, and obtain regulatory authorization for products covered by such patents.

As consideration for the exclusive rights granted to us under the agreement, we have agreed to pay INSERM a two tiered low single digit royalty (where the higher rate is due on any net sales above a certain threshold) on the net sales of any product covered by the patents (including the use of AM-101 in the treatment of tinnitus triggered by

cochlear glutamate excitotoxicity) earned in each country in which these patent applications have been filed during the term of the agreement. We have also agreed to pay INSERM a low double digit fee on any sums of any nature (except royalties and certain costs) collected by us in respect of the granting of licenses to third parties.

The agreement will remain in force until the last of the patents covered by the agreement expires or becomes invalid. The patent covered by the agreement with the latest expiration date expires in 2028. The agreement will be terminated if we cease operations or are liquidated, may be terminated by either party in case of non-performance by the other party and may be terminated by INSERM in the absence of sales of a product deriving from the patents for a period from when it first marketed and if such a product is not marketed for a period from the date when marketing authorization is obtained.

***Xigen***

In October 2003, we entered into a collaboration and license agreement with Xigen S.A., or Xigen, pursuant to which Xigen granted us an exclusive worldwide license to use specified compounds to develop, manufacture and commercialize “pharmaceutical products as well as drug delivery devices and formulations for local administration of therapeutic substances to the inner ear for the treatment of ear disorders” (the Area). We also have a right of first refusal to license certain additional compounds developed by Xigen which may be used for the Area, specifically any cell permeable inhibitors to effectively block certain signal pathways in apoptotic processes.

Under this agreement, we made an upfront payment to Xigen of CHF 200,000 and we are obligated to make development milestone payments on an indication-by-indication basis of up to CHF 1.5 million and regulatory milestone payments on a product-by-product basis of up to CHF 2.5 million, subject to a mid-twenties percentage reduction for smaller indications, e.g., those qualifying for orphan drug status. To date, we have paid CHF 1.325 million to Xigen under the agreement. We will be required to pay Xigen a mid-single digit percentage royalty on net sales of each licensed product that uses a compound licensed under the agreement, which royalty for a given indication shall be partially offset by milestone payments we have paid for such indication, until the later of 10 years after the first commercial sale of any licensed product using such licensed compound in any country, and the first expiration of a patent owned by or exclusively licensed to Xigen that covers the use of such licensed compound in any country, subject to our obligation to enter into good faith negotiations with Xigen, upon expiration of the relevant patent on a licensed compound, about the conditions of our further use of such licensed compound.

Under this agreement we and Xigen grant each other access to non-clinical or clinical data relating to the compounds licensed under the agreement free of charge for use in the other party’s proprietary development programs. We have also agreed, upon Xigen’s request, to offer third parties access to our non-clinical and clinical data relating to compounds licensed under the agreement for use outside the field of our license, provided that with respect to third party access, we are compensated for a portion of our costs in obtaining such data. Further, pursuant to our agreement, we and Xigen agreed to enter into a supply agreement within a specified period after the date of the agreement, which period has since passed, pursuant to which Xigen would supply us with licensed compounds. We did not enter into such a supply agreement with Xigen. Xigen supplied us with the active pharmaceutical ingredient for AM-111 for a period of time, but we presently are receiving our supply from an alternative supplier.

Xigen is responsible for maintaining the patents licensed to us under our agreement. New patents filed by us for specific inner ear indications or formulations of compounds licensed under our agreement are jointly owned by us and Xigen, and exclusively licensed to us in our field. We retain all know-how and other results from our development of compounds licensed under the agreement.

Our agreement with Xigen remains in effect until terminated. Either we or Xigen may terminate the agreement for the other party’s material breach or bankruptcy, in the event of force majeure, or after a specified period following the date of the agreement, if we are not progressing any activities with respect to the licensed compound. This period has passed for AM-111. In October 2013, Xigen assigned certain of the patents relevant to the agreement to Xigen Inflammation Ltd, Cyprus, an unaffiliated party.

There have been several areas of disagreement with Xigen, primarily related to interpreting the definition of the Area, the transfer of patents to Xigen Inflammation Ltd. and to the disclosure of certain provisions of the agreement in the context of this offering. For a discussion of these issues, please refer to “Risk Factors—Risks Related to our Reliance

on Third Parties—We have several areas of disagreement with Xigen, and consequently our relationship with Xigen and our business, commercialization prospects and financial condition may be adversely affected."

## Manufacturing

We currently rely on and expect to continue to rely on third parties for the supply of raw materials and to manufacture drug supplies for clinical trials of our product candidates, including AM-101 and AM-111. For the foreseeable future, we expect to continue to rely on such third parties for the manufacture of any of our product candidates on a clinical or commercial scale, if any of our product candidates receives regulatory approval. Reliance on third-party providers may expose us to more risk than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable marketing application to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

In addition, the fact that we are dependent on our suppliers and other third parties for the manufacture, storage and distribution of our product candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could result in recalls or regulatory enforcement action that could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials may also adversely influence our business, financial condition and results of operations. Supply sources could be interrupted from time to time and, if interrupted, that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all.

## Commercialization Strategy

Given our current stage of product development, we currently do not have a commercialization infrastructure. If any of our product candidates is granted marketing approval, we intend to focus our initial commercial efforts in the United States and select European markets, which we believe represent the largest market opportunities for us. In those markets, we expect our commercial operations to include our own specialty sales force that we will specifically develop to target ENTs and specialists in neurotology, both in hospitals and in private practice. In other markets, we expect to seek partnerships that would maximize our products' commercial potential.

## Government Regulation

### *Product Approval Process*

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. The U.S. Food and Drug Administration, or FDA,

under the Federal Food, Drug, and Cosmetic Act, or FDCA, regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

- the completion of preclinical laboratory tests and animal tests conducted under GLP regulations;
- the submission to the FDA of an Investigational New Drug, or IND, application for human clinical testing, which must become effective before human clinical trials commence;
- the performance of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product candidate for each proposed indication and conducted in accordance with cGCP;
- the submission to the FDA of a New Drug Application, or NDA;
- the FDA's acceptance of the NDA;
- satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with cGMPs; and
- the FDA's review and approval of an NDA prior to any commercial marketing or sale of the drug in the United States.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain.

Preclinical studies include laboratory evaluations of the product candidate, as well as animal studies to assess the potential safety and efficacy of the product candidate. The results of the preclinical studies, together with manufacturing information and analytical data, are submitted to the FDA as part of the IND, which must become effective before clinical trials may be commenced. The IND will become effective automatically 30 days after receipt by the FDA, unless the FDA raises concerns or questions about the conduct of the trials as outlined in the IND prior to that time. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can proceed.

Clinical trials involve the administration of the product candidates to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries. The FDA, the IRB or the clinical trial sponsor may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Clinical trials typically are typically conducted in three sequential phases prior to approval, but the phases may overlap. These phases generally include the following:

Phase 1. Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics.

Phase 2. Phase 2 clinical trials usually involve studies in a limited patient population to (1) evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance and optimal dosage and (3) identify possible adverse effects and safety risks.

Phase 3. If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 studies, the clinical trial program will be expanded to Phase 3 clinical trials to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical study sites.

Phase 4 clinical trials are conducted after approval to gain additional experience from the treatment of patients in the intended therapeutic indication and to document a clinical benefit in the case of drugs approved under accelerated approval regulations, or when otherwise requested by the FDA in the form of post-market requirements or commitments. Failure to promptly conduct any required Phase 4 clinical trials could result in withdrawal of approval.

The results of preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information on the manufacture, composition and quality of the product, are submitted to the FDA in the form of an NDA requesting approval to market the product. The NDA must be accompanied by a significant user fee payment. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).

Once the NDA submission has been submitted, the FDA has 60 days after submission of the NDA to conduct an initial review to determine whether it is sufficient to accept for filing. Under the Prescription Drug User Fee Act, or PDUFA, the FDA sets a goal date by which it plans to complete its review. This is typically 12 months from the date of submission of the NDA application. The review process is often extended by FDA requests for additional information or clarification. Before approving an NDA, the FDA will inspect the facilities at which the product is manufactured and will not approve the product unless the manufacturing facility complies with cGMPs and may also inspect clinical trial sites for integrity of data supporting safety and efficacy. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA is not bound by the recommendations of an advisory committee, but generally follows such recommendations in making its decisions. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA may require post-marketing testing and surveillance to monitor safety or efficacy of a product.

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its API will be produced, it may issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also approve the NDA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization.

***Special Protocol Assessment***

The FDA and an IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of a claim of effectiveness in an NDA. This process is known as a special protocol assessment, or SPA. Upon a specific request for a SPA by an IND sponsor, the FDA will evaluate the protocol. If a SPA agreement is reached, however, it is not a guarantee of product approval by the FDA or approval of any permissible claims about the product. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. In particular, the SPA agreement is

not binding on the FDA if previously unrecognized public health concerns later come to light, other new scientific concerns regarding product safety or efficacy arise, the IND sponsor fails to comply with the protocol agreed upon, or the relevant data, assumptions, or information provided by the IND sponsor when requesting a SPA agreement change, are found to be false statements or misstatements, or are found to omit relevant facts. A SPA agreement may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA, or if the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began.

***Orphan Drug Designation***

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biological product intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the US, or if it affects more than 200,000 individuals in the US there is no reasonable expectation that the cost of developing and making a drug product available in the US for this type of disease or condition will be recovered from sales of the product. Orphan product designation must be requested before submitting an NDA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same drug or biological product as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

***DEA Regulation***

The Drug Enforcement Administration, or DEA, regulates drugs that are controlled substances. Controlled substances are those drugs that appear on one of the five schedules promulgated and administered by the DEA under the Controlled Substances Act, or CSA, such as Ketamine, which is a Schedule III controlled substance. The CSA governs, among other things, the inventory, distribution, recordkeeping, handling, security and disposal of controlled substances. Any drug that acts on the central nervous system has the potential to become a controlled substance, and scheduling by the DEA is a separate process that may delay the commercial launch of a drug even after FDA approval of the NDA. Companies with a scheduled drug are subject to periodic and ongoing inspections by the DEA and similar state drug enforcement authorities to assess ongoing compliance with the DEA's regulations. Any failure to comply with these regulations could lead to a variety of sanctions, including the revocation or a denial of renewal of any DEA registration, injunctions, or civil or criminal penalties.

***Post-Approval Requirements***

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic

unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

***Foreign Regulation***

In order to market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA approval for a product, we would need to obtain the necessary approvals by the comparable foreign regulatory authorities before we can commence clinical trials or marketing of the product in foreign countries and jurisdictions. Although many of the issues discussed above with respect to the United States apply similarly in the context of the European Union, the approval process varies between countries and jurisdictions and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries and jurisdictions might differ from and be longer than that required to obtain FDA approval. Regulatory approval in one country or jurisdiction does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country or jurisdiction may negatively impact the regulatory process in others.

***Other Healthcare Laws***

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws restrict certain business practices in the biopharmaceutical industry. These laws include, but are not limited to, anti-kickback, false claims, data privacy and security, and transparency statutes and regulations.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory

exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for a statutory exception or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. The Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act, or collectively, PPACA, amended the intent requirement under the Anti-Kickback Statute and criminal healthcare fraud statutes (discussed below) such that a person or entity no longer needs to have actual knowledge of the statute or the specific intent to violate it in order to have committed a violation. In addition, PPACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below). Further, the civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

The federal false claims laws prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Recently, several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-covered, uses. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services.

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates — independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Additionally, the PPACA also included the federal Physician Payments Sunshine Act, which requires that certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members.

Also, many states have similar healthcare statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Certain states require the posting of information relating to clinical studies, pharmaceutical companies to implement a comprehensive compliance program that includes a limit on expenditures for, or payments to, individual medical or health professionals and track and report gifts and other payments made to physicians and other healthcare providers. If our operations are found to be in violation of any of the health regulatory laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion of products from reimbursement under government programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our products will be sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

### Pharmaceutical Coverage, Pricing and Reimbursement

In both domestic and foreign markets, our sales of any approved products will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, if approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our products will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by third-party payors. These third-party payors are increasingly focused on containing healthcare costs by challenging the price and examining the cost-effectiveness of medical products and services.

In addition, significant uncertainty exists as to the coverage and reimbursement status of newly approved healthcare product candidates. The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Furthermore, third-party payor reimbursement to providers for our product candidates may be subject to a bundled payment that also includes the procedure administering our products. To the extent there is no separate payment for our product candidates, there may be further uncertainty as to the adequacy of reimbursement amounts. Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. We cannot be certain that our product candidates will be considered cost-effective. Because coverage and reimbursement determinations are made on a payor-by-payor basis, obtaining acceptable coverage and reimbursement from one payor does not guarantee the Company will obtain similar acceptable coverage or reimbursement from another payor. If we are unable to obtain coverage of, and adequate reimbursement and payment levels for, our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition and future success.

Furthermore, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal

products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

### Healthcare Reform

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future results of operations as we begin to directly commercialize our products.

In particular, there have been and continue to be a number of initiatives at the U.S. federal and state level that seek to reduce healthcare costs. Initiatives to reduce the federal deficit and to reform healthcare delivery are increasing cost-containment efforts. We anticipate that Congress, state legislatures and the private sector will continue to review and assess alternative benefits, controls on healthcare spending through limitations on the growth of private health insurance premiums and Medicare and Medicaid spending, the creation of large insurance purchasing groups, price controls on pharmaceuticals and other fundamental changes to the healthcare delivery system. Any proposed or actual changes could limit or eliminate our spending on development projects and affect our ultimate profitability.

In March 2010, PPACA was signed into law. PPACA has the potential to substantially change the way healthcare is financed by both governmental and private insurers. PPACA, among other things, established: an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents; revised the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate program to utilization of certain injectable outpatient drugs, as well as prescriptions of individuals enrolled in Medicaid managed care organizations; required manufacturers to offer 50% point-of-sale discounts on negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D; and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

In the future, there may continue to be additional proposals relating to the reform of the United States healthcare system, some of which could further limit the prices we are able to charge for our products candidates, or the amounts of reimbursement available for our product candidates. If future legislation were to impose direct governmental price controls and access restrictions, it could have a significant adverse impact on our business. Managed care organizations, as well as Medicaid and other government agencies, continue to seek price discounts. Some states have implemented, and other states are considering, price controls or patient access constraints under the Medicaid program, and some states are considering price-control regimes that would apply to broader segments of their populations that are not Medicaid-eligible. Due to the volatility in the current economic and market dynamics, we are unable to predict the impact of any unforeseen or unknown legislative, regulatory, payor or policy actions, which may include cost containment and healthcare reform measures. Such policy actions could have a material adverse impact on our profitability.

Moreover, the recently enacted federal Drug Supply Chain Security Act imposes new obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. Among the requirements of this new federal legislation, manufacturers will be required to provide certain information regarding the drug product to individuals and entities to which product ownership is transferred, label drug product with a product identifier, and keep certain records regarding the drug product. Further, under this new legislation, manufacturers will have drug product investigation, quarantine, disposition, and notification responsibilities related to counterfeit, diverted, stolen, and intentionally adulterated products, as well as products that are the subject of fraudulent transactions or which are otherwise unfit for distribution such that they would be reasonably likely to result in serious health consequences or death.

### Properties

We lease approximately 3,250 square feet of office space in Basel, Switzerland. This property serves as the corporate headquarters of our principal operating subsidiary. We believe that our existing facility is adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

### Employees

As of June 1, 2014, we had 13 employees, eight of whom hold M.D. or Ph.D. degrees. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be good.

### Legal Proceedings

From time to time we may become involved in legal proceedings that arise in the ordinary course of business. During the period covered by the financial statements contained herein, we have not been a party to or paid any damages in connection with litigation that has had a material adverse effect on our financial position. No assurance can be given that future litigation will not have a material adverse effect on our financial position.

Table of Contents

# MANAGEMENT

## Executive Officers and Board of Directors

The following table presents information about our executive officers and directors. The term of each of our directors is one year and, accordingly, will expire one year from the date of our 2014 annual shareholder meeting on April 22, 2014.

| NAME | POSITION | AGE | INITIAL YEAR OF APPOINTMENT |
|---|---|---|---|
| **Executive Officers** | | | |
| Thomas Meyer | Chairman and Chief Executive Officer | 46 | 2003 |
| Bettina Stubinski | Chief Medical Officer | 47 | 2013 |
| Sven Zimmermann | Chief Financial Officer | 43 | 2014 |
| **Non-Executive Directors** | | | |
| Wolfgang Arnold | Director | 72 | 2007 |
| James I. Healy | Director | 49 | 2013 |
| Oliver Kubli | Director | 41 | 2010 |
| Alain Munoz | Director | 64 | 2007 |
| Antoine Papiernik | Director | 47 | 2013 |

Unless otherwise indicated, the current business addresses for our executive officers and directors is Auris Medical Holding AG, Bahnhofstrasse 21, 6300 Zug, Switzerland.

## Executive Officers

**Thomas Meyer, Founder, Chairman and Chief Executive Officer:** Mr. Meyer founded Auris Medical in April 2003. Prior to founding us, he was the Chief Executive Officer of Disetronic Group, a leading Swiss supplier of precision infusion and injection systems. He worked for Disetronic in various functions starting in 1988, becoming member of the board of directors in 1996, Deputy Chief Executive Officer in 1999 and Chief Executive Officer in early 2000. Prior to joining Disetronic, he advised several Swiss companies in strategy, marketing and corporate finance. He holds a Ph.D. in business administration from the University of Fribourg, Switzerland.

**Bettina Mirella Stubinski, Chief Medical Officer:** Dr. Stubinski has served as our Chief Medical Officer since September 2013. She previously spent nine years with Merck Serono, Geneva (Switzerland), her last position there being Head of Global Clinical Development Multiple Sclerosis. Prior to Serono she was employed with Novartis Consumer Health, and previous to that led the Clinical Research department of Berlin Chemie, a division of the Menarini Group, which she joined in 1996. Dr. Stubinski holds an M.D. with specialization in Clinical Neurophysiology from the Medical Faculty of the University of Genova, Italy, and started her career as a practicing Neurologist. In 2014 Dr. Stubinski obtained an executive M.B.A. at MIT's Sloan School of Management.

**Sven Zimmermann, Chief Financial Officer:** Mr. Zimmermann has served as our Chief Financial Officer since January 2014. He has over 10 years of experience in finance and equity capital markets. Before joining Auris Medical, Mr. Zimmermann was Chief Financial Officer of PregLem SA from June 2008 to March 2014 where he contributed to its acquisition by Gedeon Richter Plc in October 2010. Prior to PregLem SA, he worked as a Sell and Buy Side analyst for UBS in London and Zürich from March 2001 to June 2008. He has a degree in Biochemistry from the University of Fribourg, Switzerland and a PhD in Molecular Biology from the University of Zurich, Switzerland.

## Non-Executive Directors

**Wolfgang Arnold, Director:** Dr. Arnold has been a member of our board of directors since 2007. He is a professor emeritus in otolaryngology and head and neck surgery, and an internationally renowned expert in the field of inner ear disorders. Dr. Arnold has authored or co-authored more than 365 peer-reviewed scientific and medical articles and more than 10 textbooks. From 1992-2007, he served as Director of the Department of Otolaryngology, Head and Neck Surgery of the Technical University of Munich, Germany. He is still practicing today. Dr. Arnold holds an M.D. from the University of Munich.

**James I. Healy, Director:** Dr. Healy has been a member of our board of directors since April 2013. Dr. Healy has been a General Partner of Sofinnova Ventures, a venture capital firm, since June 2000. Prior to June 2000, Dr. Healy held various positions at Sanderling Ventures, Bayer Healthcare Pharmaceuticals (as successor to Miles Laboratories) and ISTA Pharmaceuticals, Inc. Dr. Healy is currently on the board of directors of Anthera Pharmaceuticals, Inc., Hyperion Therapeutics, Inc., Amarin Corporation, plc., InterMune, Inc., KaloBios Pharmaceuticals, Inc., and several private companies. Previously, he served as a board member of Durata Therapeutics, Inc., CoTherix, Inc. and Movetis NV and several private companies. Dr. Healy was nominated to our board of directors by Sofinnova Ventures. Dr. Healy holds an M.D. and a Ph.D. in Immunology from the Stanford School of Medicine and holds a B.A. in molecular biology and a B.A. in Scandinavian Studies from the University of California at Berkeley.

**Oliver Kubli, Vice-Chairman:** Mr. Kubli has been a member of our board of directors since June 2010. He is a Managing Director and member of the board of directors of Adamant Biomedical Investments AG, a life science asset management boutique, majority owned by Zürcher Kantonalbank (ZKB), Switzerland's third largest bank. Mr. Kubli is the Senior Portfolio Manager for several public health care funds. Prior to joining Adamant in 2008, he held various management positions at ZKB and was responsible for the global health care sector within the bank's Asset Management Division. Mr. Kubli started his career as a financial analyst and portfolio manager with UBS and Swiss Re. Mr. Kubli was nominated to our board of directors by Adamant. He is a chartered financial analyst (CFA) and holds a B.A. in Business Administration from the University of Applied Sciences, Zürich/Winterthur, Switzerland.

**Alain Munoz, Director:** Dr. Munoz has been a member of our board of directors since December 2007. He is an independent management consultant in the pharmaceutical industry and Venture Partner with Kurma Biofund, Paris. From 1990 to 2000, Dr. Munoz held various management positions with the Fournier Group, including Senior Vice President of the Pharmaceutical Division. He joined Fournier from Sanofi Research, where he first started as Director in the cardiovascular and anti-thrombotic products business and then as Vice President international development. Dr. Munoz is qualified in cardiology and anesthesiology from the University Hospital of Montpellier, France. He serves on the Board of Valneva SA, Umecrine Mood AB, Hybrigenics S.A. and Zealand Pharma A/S. He was nominated to our board of directors by Idinvest.

**Antoine Papiernik, Director:** Mr. Papiernik has been a member of our board of directors since April 2013. He is a Managing Partner at Sofinnova Partners, a French venture capital firm, which he joined in 1997. He serves on the boards of directors of Shockwave Medical, Inc., Pixium Vision, Stentys S.A., ReCord Medical, ProQR Therapeutics BV and Mainstay Medical Ltd. Mr. Papiernik was nominated to our board of directors by Sofinnova Partners. He has an MBA from the Wharton School of Business.

## Board Composition and Election of Directors After This Offering

Our board of directors is composed of six members. Each director is elected for a one year term. Upon the closing of this offering and the filing and effectiveness of our amended and restated articles of association, our articles of association will require our directors to retire once they have reached 75 years of age, subject to a special exception being granted by the general meeting of shareholders for up to two additional terms of office. The current members of our board of directors were appointed at a shareholders' meeting held on April 22, 2014 to serve until their successors are duly elected and qualified.

We will be a foreign private issuer. As a result, in accordance with the Nasdaq stock exchange listing requirements, we will rely on home country governance requirements and certain exemptions thereunder rather than relying on the stock exchange corporate governance requirements. For an overview of our corporate governance principles, see "Description of Share Capital and Articles of Association."

## Committees of the Board of Directors

Our board of directors will establish an audit committee and a compensation committee prior to the consummation of this offering.

### *Audit Committee*

The audit committee, which is expected to consist of Oliver Kubli, Alain Munoz and James I. Healy, will assist our board of directors in overseeing our accounting and financial reporting processes and the audits of our financial

statements. In addition, the audit committee will be directly responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Our board of directors has determined that Alain Munoz satisfies the "independence" requirements set forth in Rule 10A-3 under the Exchange Act and expects that upon the consummation of this offering Oliver Kubli will satisfy such "independence" requirements. Our board of directors has determined that Oliver Kubli qualifies as an "audit committee financial expert," as such term is defined in the rules of the SEC.

***Compensation Committee***

The compensation committee, which is expected to consist of Antoine Papiernik and Wolfgang Arnold, will assist our board of directors in overseeing our cash compensation and equity award recommendations for our executive officers along with the rationale for such recommendations, as well as summary information regarding the aggregate compensation provided to our executive officers. Swiss law requires that we adopt a compensation committee, so in accordance with Nasdaq Listing Rule 5615(a)(3), we will follow home country requirements with respect to the compensation committee. As a result, our practice will vary from the requirements of Nasdaq Listing Rule 5605(d), which sets forth certain requirements as to the responsibilities, composition and independence of compensation committees.

## Compensation of Directors and Executive Officers

For the year ended December 31, 2013, the aggregate compensation accrued or paid to the members of our Board of Directors and our executive officers for services in all capacities was CHF 418,332.

During the year ended December 31, 2013, we had no performance based compensation programs.

The amount set aside or accrued by us to provide pension, retirement or similar benefits to members of our board of directors or executive officers amounted to a total of CHF 6,836 in the year ended December 31, 2013.

## Employment Agreements

We have entered into employment agreements with our executive officers, Thomas Meyer, Bettina Stubinski and Sven Zimmermann. The employment agreements provide for the compensation that our executive officers are entitled to receive, including certain equity grants, and contain termination notice periods of four weeks for the first three months and then afterwards six-months' notice. Our agreement with Mr. Meyer contains a termination notice period of six months. The Company will have title to the intellectual property rights developed in connection with the executive officer's employment, if any. There is an 18 month non-compete period following the end of employment in our agreement with Mr. Meyer.

None of our directors have entered into service agreements with the Company. However, we may in the future enter into employment or services agreements with such individuals, the terms of which may provide for, among other things, cash or equity-based compensation and benefits.

## Equity Incentive Plans

Following the completion of this offering, we intend to cease issuing any new grants under our existing equity incentive plans and to adopt a new omnibus equity incentive plan under which we would have the discretion to grant a broad range of equity-based awards to eligible participants.

***Stock Option Plans***

In 2013 we established Plan C, in 2008 we established Plan A and Plan B. We refer to Plan A, Plan B and Plan C together as the Prior Plans. Each of the Prior Plans permits the grant of options, or Options, which are subject to transfer restrictions. As of March 31, 2014, there were            common shares underlying outstanding Options granted pursuant to Plan A and            common shares underlying outstanding Options granted pursuant to Plan C. There are no outstanding Options under Plan B.

*Plan Administration.* Under each of the Prior Plans, an Option, which can only be granted with the approval of our board of directors, is evidenced by an option agreement signed by the participant to indicate his or her acceptance of the Option subject to the terms and conditions of the applicable Prior Plan.

*Eligibility.* Under Plan A and Plan C, Options may be granted to directors, employees, advisors and agents of the Company. Under Plan B, Options may be granted to employees entitled to receive a portion of their remuneration in equity.

*Option Exercise Price*. The exercise price of each Option is set forth in the applicable option agreement. The exercise prices for currently granted and unexercised Options range from CHF 3.20 to CHF 5.28.

*Vesting Period.* Under Plan A and Plan C, the option period commences on the date of grant and lasts for five years and six years, respectively. Under Plan B, the option period commences on the date of grant and lasts for three months. Under Plan A and Plan C, Options vest after three years and four years, respectively. Options granted under Plan B are exercisable at any time during their term. Options granted under Plan A will vest and must be exercised within 60 days of the closing of this offering or will be forfeited.

*Amendment.* Our board of directors has the authority to amend each of the Prior Plans.

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## PRINCIPAL SHAREHOLDERS

The following table presents information relating to the beneficial ownership of our common shares as of , 2014 as if the conversion of our Series A, Series B and Series C preferred shares into common shares on a one-for-one basis had occurred, by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding common shares;
- each of our executive officers and directors; and
- all executive officers and directors as a group.

The number of common shares beneficially owned by each entity, person, executive officer or director is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any common shares over which the individual has sole or shared voting power or investment power as well as any common shares that the individual has the right to acquire within 60 days of , 2014 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all common shares held by that person.

Common shares that a person has the right to acquire within 60 days of , 2014 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all executive officers and directors as a group. As of the date of this prospectus, 3,693,175 common shares, or approximately 19.3%, are held by one record holder in the United States. Unless otherwise indicated below, the address for each beneficial owner is Auris Medical Holding AG, Bahnhofstrasse 21, 6300 Zug, Switzerland.

| SHAREHOLDER | SHARES BENEFICIALLY OWNED BEFORE THIS OFFERING | | SHARES BENEFICIALLY OWNED AFTER THIS OFFERING | | PERCENT OF SHARES BENEFICIALLY OWNED ASSUMING FULL EXERCISE OF OVER-ALLOTMENT OPTION |
|---|---|---|---|---|---|
| | NUMBER | PERCENT | NUMBER | PERCENT | |
| **5% Shareholders** | | | | | |
| Sofinnova Ventures Partners VIII, L.P. (1) | 3,693,175 | 19.3% | | | |
| Sofinnova Capital VII FCPR (2) | 3,551,150 | 18.6% | | | |
| Entities affiliated with ZKB (3) | 2,169,625 | 11.4% | | | |
| Entities affiliated with Idinvest Partners (4) | 1,731,900 | 9.1% | | | |
| **Executive Officers and Directors** | | | | | |
| Thomas Meyer, Ph.D. | 6,662,500 | 34.9% | | | |
| Wolfgang Arnold, M.D. | 6,250 | * | | | |
| Alain Munoz, M.D. (5) | 6,250 | * | | | |
| James I. Healy, M.D., Ph.D. (6) | 3,693,175 | 19.3% | | | |
| Oliver Kubli (7) | 2,169,625 | 11.4% | | | |
| Antoine Papiernik (8) | 3,551,150 | 18.6% | | | |
| Bettina Stubinski, M.D. | — | — | | | |
| Sven Zimmermann, Ph.D. | — | — | | | |

* Indicates beneficial ownership of less than 1% of the total outstanding common shares.

(1) James I. Healy and the other managing members of Sofinnova Management VIII, L.L.C., which is the general partner of Sofinnova Venture Partners VIII, L.P., share the power to vote or dispose of these shares and therefore may be deemed to have voting and

investment power with respect to such shares. Each of the managing members disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any. The address for Sofinnova Ventures Partners VIII, L.P. and Sofinnova Management VIII, L.L.C. is 2800 Sand Hill Road, Suite 150, Menlo Park, California 94025, USA.

(2) Consists of 3,551,150 common shares held by Sofinnova Capital VII FCPR. Sofinnova Partners SAS, a French corporation and the management company of Sofinnova Capital VII FCPR, may be deemed to have sole voting and investment power, and Denis Lucquin, Antoine Papiernik, Rafaele Tordjman and Monique Saulnier, the managing partners of Sofinnova Partners SAS, may be deemed to have shared voting and investment power with respect to such shares. All of the managing partners of Sofinnova Partners SAS disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein. The address for Sofinnova Capital VII FCPR is 16-18 Rue du Quatre Septembre, 75002 Paris, France.

(3) Consists of 575,000 common shares held by Adamant Global Generika Funds, 418,750 common shares held by Adamant Global Biotech Funds and 238,375 shares held by Adamant Global Medtech Funds (collectively, the “AG Funds”) and 937,500 common shares held by ZKB Pharma Vision Funds. Voting and investment power over the shares is exercised by Balfidor Fondsleitungs AG, Peter Merian-Strasse 47, 4002 Basel. The address for the AG Funds is c/o Adamant Biomedical Investments AG, Freischützgasse 3, 8004 Zürich, Switzerland. The address for ZKB Pharma Vision Funds is c/o Zurich Cantonalbank, Postfach, 8010 Zürich, Switzerland.

(4) Consists of 675,475 common shares held by Allianz Innovation 8 FCPI; 484,925 common shares held by Allianz Croissance 2005 FCPI; 381,025 shares held by Allianz Innovation 7 FCPI and 190,475 shares held by La Banque Postale Innovation 3 FCPI. Idinvest Partners is the investment management company of each of these entities (the “Idinvest Funds”). Idinvest Partners is the investment management company to each of the Idinvest Funds. Christophe Baviere and Benoist Grossmann are respectively CEO and Managing Partner of Idinvest Partners and as such represent the interests of the Idinvest Funds over the common shares held by them. Each of Christophe Baviere and Benoist Grossmann disclaim beneficial ownership of all applicable shares except to the extent of any pecuniary interest therein. The address for each of the Idinvest Funds is c/o Idinvest Partners, 117, avenue des Champs Elysées, 75008 Paris, France.

(5) Consists of 6,250 common shares held by Dr. Munoz.

(6) Consists of 3,693,175 common shares held by Sofinnova Ventures Partners VIII, L.P. Dr. Healy is a managing member of Sofinnova Management VIII, L.L.C., the general partner of Sofinnova Venture Partners VIII, L.P., and may be considered to have beneficial ownership of Sofinnova Venture Partners VIII, L.P.’s interest in us. Dr. Healy disclaims beneficial ownership of all shares held by Sofinnova Venture Partners VIII, L.P., except to the extent of his pecuniary interest therein.

(7) Consists of 1,232,125 common shares held by the AG Funds and 937,500 common shares held by the ZKB Pharma Vision Funds. Mr. Kubli is a Senior Portfolio manager for the AG Funds and the ZKB Pharma Vision Funds. He disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein.

(8) Consists of 3,551,150 common shares held by Sofinnova Capital VII FCPR. Mr. Papiernik disclaims any beneficial ownership of the shares held by Sofinnova Capital VII FCPR except to the extent of his pecuniary interest therein.

## RELATED PARTY TRANSACTIONS

### Series B Financing

In December 2007, we entered into an investment agreement pursuant to which we issued and sold an aggregate of 137,500 of our Series B preferred shares at a price per share of CHF 80 to certain investors. In March 2011, we issued an additional 40,750 Series B preferred shares to existing shareholders at an issue price of CHF 80 per share. In November 2011, we issued an additional 42,114 Series B preferred shares to existing and new shareholders at an issue price of CHF 120 per share. One third of the issue price was paid in 2011, the second third in March 2012 and the final third in June 2012. A total of 13,158 of the Series B preferred shares were held in treasury at December 31, 2011 and were sold from treasury in 2012 to new and existing shareholders at a price per share of CHF 120. Pursuant to a 25:1 forward stock split effected in December 2013, our Series B preferred shares currently equal 5,509,100 shares.

### Series C Financing

In April 2013, we entered into an investment agreement pursuant to which we issued and sold an aggregate of 185,455 of our Series C preferred shares at a price per share of CHF 132 for an aggregate purchase price of CHF 24,480,060 (the "Initial Closing") to certain investors. Pursuant to a 25:1 forward stock split, the shares issued in the Initial Closing now equal 4,636,375 Series C preferred shares.

Under the terms of the Series C investment agreement, we agreed that up to two further closings resulting in further capital increase and issuance of new Series C preferred shares may be completed (the "Second Closing" and/or, the "Third Closing", respectively). Pursuant to the terms of a convertible loan agreement, on January 13, 2014 the lenders thereunder exercised their right to convert the full amount of the loan into Series C preferred shares, replacing the Second Closing of the Series C financing. The obligation of the Series C investors to effect the Third Closing is subject to the satisfaction or waiver in writing by the holders of Series C preferred shares holding at least two thirds of the Series C preferred shares of certain conditions, including the Company reaching certain milestones, such as setting the size and scope of the next clinical trial for AM-111 with regulators.

The following table sets forth the number of our Series C preferred shares purchased by our 5% shareholders and their affiliates at the Initial Closing and upon the conversion of the convertible loan into Series C preferred shares, which replaced the Second Closing and taking into account the 25:1 forward stock split.

| NAME AND ADDRESS OF BENEFICIAL OWNER | C SHARES | PURCHASE PRICE (CHF) |
|---|---|---|
| Sofinnova Ventures Partners VIII, L.P (1) | 3,693,175 | 5.28 |
| Sofinnova Capital VII FCPR (2) | 3,551,150 | 5.28 |

(1) James I. Healy and the other managing members of Sofinnova Management VIII, L.L.C., which is the general partner of Sofinnova Venture Partners VIII, L.P., share the power to vote or dispose of these shares and therefore may be deemed to have voting and investment power with respect to such shares. Each of the managing members disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any.

(2) Consists of 3,551,150 shares held by Sofinnova Capital VII FCPR. Sofinnova Partners SAS, a French corporation and the management company of Sofinnova Capital VII FCPR, may be deemed to have sole voting and investment power, and Denis Lucquin, Antoine Papiernik, Rafaele Tordjman and Monique Saulnier, the managing partners of Sofinnova Partners SAS, may be deemed to have shared voting and investment power with respect to such shares. All of the managing partners of Sofinnova Partners SAS disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein.

### Series C Shareholders' Agreement

On April 5, 2013 all of our then existing shareholders entered into a shareholders agreement, or the Series C Shareholders' Agreement. The Series C Shareholders' Agreement will terminate upon the consummation of this offering.

Pursuant to the Series C Shareholders' Agreement, in the event of our initial public offering, all of our outstanding preferred shares will convert into our common shares. The conversion rate offering will be one-for-one, and therefore, upon the consummation of this offering, all of our outstanding preferred shares will convert into an aggregate of common shares, which will result in us having common shares outstanding after this offering.

### Convertible Loan Agreement

On December 9, 2013, the Company entered into a non-interest bearing convertible loan with Sofinnova Venture Partners VIII, L.P. and Sofinnova Capital VII FCPR, the lenders, with a nominal value of CHF 13,769,976 and a maximum term of 12 months. On January 13, 2014, the convertible loan lenders exercised their conversion option, and the total loan amount of CHF 13,769,976 was converted into 2,607,950 Series C preferred shares of the Company.

### Altamira Pharma GmbH Service Agreement

In January 2011, we entered into a service agreement with Altamira Pharma GmbH, Zuchwil, or Altamira, for the provision of strategic management services and support to the Company. Altamira is owned by our Chairman and CEO, Thomas Meyer. This agreement was terminated on January 31, 2014 with a final payment of CHF 14,500. During the years ended December 31, 2013, 2012 and 2011, we paid CHF 248,000, CHF 247,200 and CHF 247,200 respectively, to Altamira pursuant to the agreement.

### Altamira Pharma GmbH Loan Agreement

In January 2013, we entered into a loan agreement with Altamira for bridge financing in the form of unsecured revolving credit facilities of up to CHF 1,400,000 and up to EUR 300,000 at an annual interest rate of 5%. In April 2013, we repaid the loan in full in the amount of CHF 1,186,386 and EUR 258,847, including accrued interest, using the proceeds from our Series C financing.

### Registration Rights Agreement

Effective upon consummation of this offering, we intend to enter into a registration rights agreement with certain of our existing shareholders pursuant to which we will grant them customary registration rights for the resale of the common shares held by certain of our existing shareholders.

### Indemnification Agreements

We intend to enter into indemnification agreements with our directors and executive officers. The indemnification agreements and our articles of association require us to indemnify our directors and executive officers to the fullest extent permitted by law.

### Employment Agreements

Certain of our executive officers have entered into employment agreements with the Company, certain of which provide for notice of termination periods and include restrictive covenants. None of our directors have entered into service agreements with the Company. See "Management—Employment Agreements."

# DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

## The Company

We are a Swiss stock corporation (*Aktiengesellschaft*) organized under the laws of Switzerland. We were formed in 1998. We are currently registered in Zug, Switzerland. Our head office is currently located at Bahnhofstrasse 21, 6300 Zug, Switzerland.

## Share Capital

As of the date of this prospectus, our share capital is divided into common shares and three categories of preferred shares. Conditional upon the closing of the offering, all of our preferred shares will be converted into common shares, effective upon the registration of the revised articles of association with the commercial register of the Canton of Zug, Switzerland. See "—Articles of Association." Upon the closing of this offering, giving effect to (i) the issuance of the common shares to be sold in this offering and (ii) the conversion of our preferred shares into common shares on a one-for-one basis, our issued fully paid-in share capital will consist of CHF            , divided into            common shares with a nominal value of CHF 0.40 each and no preferred shares.

## Articles of Association

Prior to the closing of this offering, we intend to adopt amended and restated articles of association which will become effective upon the closing of this offering and the registration of the revised articles of association with the commercial register of the Canton of Zug, Switzerland. When we refer to our articles of association in this prospectus, we refer to our amended and restated articles of association as they will be in force upon the closing of this offering.

### *Ordinary Capital Increase, Authorized and Conditional Share Capital*

Under Swiss law, we may increase our share capital (*Aktienkapital*) with a resolution of the general meeting of shareholders (ordinary capital increase) that must be carried out by the board of directors within three months in order to become effective. Under our articles of association, in the case of subscription and increase against payment of contributions in cash, a resolution passed by an absolute majority of the shares represented at the general meeting of shareholders is required. In the case of subscription and increase against contributions in kind or to fund acquisitions in kind, when shareholders' statutory pre-emptive rights are withdrawn or where transformation of reserves into share capital is involved, a resolution passed by two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the nominal amount of the shares represented is required.

Furthermore, under the Swiss Code of Obligations, or the CO, our shareholders, by a resolution passed by two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the nominal amount of the shares represented, may empower our board of directors to issue shares of a specific aggregate nominal amount up to a maximum of 50% of the share capital in the form of:

- conditional capital (*bedingtes Kapital*) for the purpose of issuing shares in connection with, among other things, (i) option and conversion rights granted in connection with warrants and convertible bonds of the Company or one of our subsidiaries or (ii) grants of rights to employees, members of our board of directors or consultants or our subsidiaries to subscribe for new shares (conversion or option rights); or
- authorized capital (*genehmigtes Kapital*) to be utilized by the board of directors within a period determined by the shareholders but not exceeding two years from the date of the shareholder approval.

### *Pre-emptive Rights*

Pursuant to the CO, shareholders have pre-emptive rights (*Bezugsrechte*) to subscribe for new issuances of shares. With respect to conditional capital in connection with the issuance of conversion rights, convertible bonds or similar debt instruments, shareholders have advance subscription rights (*Vorwegzeichnungsrechte*) for the subscription of conversion rights, convertible bonds or similar debt instruments.

A resolution passed at a general meeting of shareholders by two-thirds of the shares represented and the absolute majority of the nominal value of the shares represented may authorize our board of directors to withdraw or limit pre-emptive rights and/or advance subscription rights in certain circumstances.

If pre-emptive rights are granted, but not exercised, the board of directors may allocate the pre-emptive rights as it elects.

With respect to our authorized share capital, the board of directors is authorized by our articles of association to withdraw or to limit the pre-emptive rights of shareholders, and to allocate them to third parties or to us, in the event that the newly issued shares are used for the purpose of:

- expanding the shareholder base in certain capital markets or in the context of the listing, admission to official trading or registration of the shares at domestic or international stock exchanges;
- granting an over-allotment option to underwriters in connection with a placement of shares;
- share placements, provided the issue price is determined by reference to the market price;
- the participation of our employees, members of the board of directors or consultants or of one of our subsidiaries in one or several equity incentive plans created by the board of directors;
- the acquisition of companies, assets, participations or new investment projects or for public or private share placements for the financing and/or refinancing of such transactions;
- for raising equity capital in a fast and flexible manner as such transaction would be difficult to carry out without the withdrawal of the pre-emptive rights of the existing shareholders;
- the acquisition of a participation in us by a strategic partner; or
- for all other reasons allowed by law pursuant to Article 652b, paragraph 2, of the CO.

### *Our Authorized Share Capital*

Under our articles of association, our board of directors is authorized at any time until , 2015 to increase our share capital by a maximum aggregate amount of CHF through the issuance of not more than shares, which would have to be fully paid-in, with a nominal value of CHF 0.40 each.

Increases in partial amounts are permitted. The board of directors has the power to determine the type of contributions, the issue price and the date on which the dividend entitlement starts.

The board of directors is also authorized to withdraw or limit pre-emptive rights as described above. This authorization is exclusively linked to the particular available authorized share capital set out in the respective article. If the period to increase the share capital lapses without having been used by the board of directors, the authorization to withdraw or to limit the pre-emptive rights lapses simultaneously with such capital.

Our common shares to be sold in this offering will be issued out of our authorized share capital. Accordingly upon the consummation of this offering, our authorized but unissued share capital will decrease by the amount of .

### *Our Conditional Share Capital*

*Conditional Share Capital for Warrants and Convertible Bonds*

Our share capital may be increased by a maximum aggregate amount of CHF 2,000,000 through the issuance of not more than 5,000,000 common shares, which would have to be fully paid-in, with a nominal value of CHF 0.40 each, by the exercise of option and conversion rights granted in connection with warrants and convertible bonds of the Company or one of our subsidiaries. Shareholders will not have pre-emptive rights in such circumstances. The holders of convertible bonds are entitled to the new shares upon the occurrence of the applicable conversion feature.

When issuing convertible bonds, the board of directors is authorized to withdraw or to limit the advance right of shareholders to subscribe to the convertible bond issuance:

- for the purpose of financing or refinancing the acquisition of enterprises, divisions thereof, or of participations or of newly planned investments of the Company; or
- if the issuance occurs in domestic or international capital markets including private placements. To the extent that the advance subscription rights are withdrawn i) the convertible bonds are to be issued at market conditions; ii) the term to exercise the option or conversion rights may not exceed seven years as of the date of the convertible bond issue; and iii) the exercise price for the new shares must at least correspond to the market conditions at the time of the convertible bond issuance.

*Conditional Share Capital for Equity Incentive Plans*

Our share capital may, to the exclusion of the pre-emptive rights of shareholders, be increased by a maximum aggregate amount of CHF 600,000 through the issuance of not more than 1,500,000 common shares, which would have to be fully paid-in, with a nominal value of CHF 0.40 each, by the exercise of option or conversion rights that have been granted to employees, members of the board of directors or consultants of the Company or of one of our subsidiaries through one or more equity incentive plans created by the board of directors.

***Uncertificated Securities***

Our shares are uncertificated securities (*Wertrechte*, within the meaning of art. 973c of the CO) and, when administered by a financial intermediary (*Verwahrungsstelle,* within the meaning of the Federal Act on Intermediated Securities, "FISA"), qualify as intermediated securities (*Bucheffekten*, within the meaning of the FISA). In accordance with art. 973c of the CO, we will maintain a non-public register of uncertificated securities (*Wertrechtebuch*). We may at any time convert uncertificated securities into share certificates (including global certificates), one kind of certificate into another, or share certificates (including global certificates) into uncertificated securities. Following entry in the share register, a shareholder may at any time request from us a written confirmation in respect of the shares. Shareholders are not entitled, however, to request the printing and delivery of certificates. We may print and deliver certificates for shares at any time.

***General Meeting of Shareholders***

*Ordinary/extraordinary meetings, powers*

The general meeting of shareholders is our supreme corporate body. Under Swiss law, ordinary and extraordinary general meetings of shareholders may be held. Under Swiss law, an ordinary general meeting of shareholders must be held annually within six months after the end of a corporation's financial year. In our case, this means on or before June 30.

The following powers are vested exclusively in the general meeting of shareholders:

- adopting and amending our articles of association;
- electing the members of the board of directors, the chairman of the board of directors, the members of the compensation committee, the auditors and the independent proxy;
- approving the annual report, the annual statutory financial statements and the consolidated financial statements, and deciding on the allocation of profits as shown on the balance sheet, in particular with regard to dividends and bonus payments to members of the board of directors;
- approving the compensation of members of the board of directors and executive management, which under Swiss law is not necessarily limited to the executive officers;
- discharging the members of the board of directors and executive management from liability with respect to their tenure in the previous financial year;
- dissolving the Company with or without liquidation;
- deciding matters reserved to the general meeting of shareholders by law or our articles of association or that are presented to it by the board of directors.

An extraordinary general meeting of shareholders may be called by a resolution of the board of directors or, under certain circumstances, by the Company's auditor, liquidator or the representatives of convertible bond holders, if any. In addition, the board of directors is required to convene an extraordinary general meeting of shareholders if shareholders representing at least ten percent of the share capital request such general meeting of shareholders in writing. Such request must set forth the items to be discussed and the proposals to be acted upon. The board of directors must convene an extraordinary general meeting of shareholders and propose financial restructuring measures if, based on the Company's stand-alone annual statutory balance sheet, half of our share capital and reserves are not covered by our assets.

*Voting and Quorum Requirements*

Shareholder resolutions and elections (including elections of members of the board of directors) require the affirmative vote of the absolute majority of shares represented at the general meeting of shareholders, unless otherwise stipulated by law.

A resolution of the general meeting of the shareholders passed by two-thirds of the shares represented at the meeting, and the absolute majority of the nominal value of the shares represented is required for:

- amending the Company's corporate purpose;
- creating or cancelling shares with preference rights or amending rights attached to such shares;
- cancelling or amending the transfer restrictions of shares;
- creating authorized or conditional share capital;
- increasing the share capital out of equity, against contributions in kind or for the purpose of acquiring specific assets and granting specific benefits;
- limiting or suppressing shareholder's pre-emptive rights;
- changing our domicile;
- dissolving or liquidating the Company.

The same voting requirements apply to resolutions regarding transactions among corporations based on Switzerland's Federal Act on Mergers, Demergers, Transformations and the Transfer of Assets, or the Merger Act (including a merger, demerger or conversion of a corporation) see "—Compulsory Acquisitions; Appraisal Rights."

In accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

*Notice*

General meetings of shareholders must be convened by the board of directors at least twenty days before the date of the meeting. The general meeting of shareholders is convened by way of a notice appearing in our official publication medium, currently the Swiss Official Gazette of Commerce. Registered shareholders may also be informed by ordinary mail. The notice of a general meeting of shareholders must state the items on the agenda, the proposals to be acted upon and, in case of elections, the names of the nominated candidates. Except in the limited circumstances listed below, a resolution may not be passed at a general meeting without proper notice. This limitation does not apply to proposals to convene an extraordinary general meeting of shareholders or to initiate a special investigation. No previous notification is required for proposals concerning items included in the agenda or for debates that do not result in a vote.

All of the owners or representatives of our shares may, if no objection is raised, hold a general meeting of shareholders without complying with the formal requirements for convening general meetings of shareholders (a universal meeting). This universal meeting of shareholders may discuss and pass binding resolutions on all matters within the purview of the ordinary general meeting of shareholders, provided that the owners or representatives of all the shares are present at the meeting.

*Agenda Requests*

Pursuant to Swiss law, one or more shareholders whose combined shareholdings represent the lower of (i) one tenth of the share capital or (ii) an aggregate nominal value of at least CHF 1,000,000, may request that an item be included in the agenda for an ordinary general meeting of shareholders. To be timely, the shareholder's request must be received by us at least 45 calendar days in advance of the meeting. The request must be made in writing and contain, for each of the agenda items, the following information:

- a brief description of the business desired to be brought before the ordinary general meeting of shareholders and the reasons for conducting such business at the ordinary general meeting of shareholders;
- the name and address, as they appear in the share register, of the shareholder proposing such business; and
- all other information required under the applicable laws and stock exchange rules.

Our business report, the compensation report and the auditor's report must be made available for inspection by the shareholders at our registered office no later than 20 days prior to the general meeting of shareholders. Shareholders of record may be notified of this in writing.

***Voting Rights***

Each of our shares entitles a holder to one vote, regardless of its nominal value. The shares are not divisible. The right to vote and the other rights of share ownership may only be exercised by shareholders (including any nominees) or usufructuaries who are entered in our share register at cut-off date determined by the board of directors. Those entitled to vote in the general meeting of shareholders may be represented by the independent proxy holder (annually elected by the general meeting of shareholders), another registered shareholder or third person with written authorization to act as proxy or the shareholder's legal representative. The chairman has the power to decide whether to recognize a power of attorney.

***Dividends and Other Distributions***

Our board of directors may propose to shareholders that a dividend or other distribution be paid but cannot itself authorize the distribution. Dividend payments require a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders. In addition, our auditors must confirm that the dividend proposal of our board of directors conforms to Swiss statutory law and our articles of association.

Under Swiss law, we may pay dividends only if we have sufficient distributable profits brought forward from the previous business years (*Gewinnvortrag*), or if we have distributable reserves (*frei verfügbare Reserven*), each as evidenced by our audited stand-alone statutory balance sheet prepared pursuant to Swiss law, and after allocations to reserves required by Swiss law and the articles of association have been deducted. We are not permitted to pay interim dividends out of profit of the current business year.

Distributable reserves are generally booked either as "free reserves" (*freie Reserven*) or as "reserve from capital contributions" (*Reserven aus Kapitaleinlagen*). Under the CO, if our general reserves (*allgemeine Reserve*) amount to less than 20% of our share capital recorded in the commercial register (i.e., 20% of the aggregate nominal value of our issued capital), then at least 5% of our annual profit must be retained as general reserves. The CO permits us to accrue additional general reserves. Further, a purchase of our own shares (whether by us or a subsidiary) reduces the distributable reserves in an amount corresponding to the purchase price of such own shares. Finally, the CO under certain circumstances requires the creation of revaluation reserves which are not distributable.

Distributions out of issued share capital (i.e. the aggregate nominal value of our issued shares) are not allowed and may be made only by way of a share capital reduction. Such a capital reduction requires a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders. The resolution of the shareholders must be recorded in a public deed and a special audit report must confirm that claims of our creditors remain fully covered despite the reduction in the share capital recorded in the commercial register. The share capital may be reduced below CHF 100,000 only if and to the extent that at the same time the statutory minimum share capital of CHF 100'000 is reestablished by sufficient new fully paid-up capital. Upon approval by the general meeting of shareholders of the capital reduction, the board of directors must give public notice of the capital reduction resolution in the Swiss Official Gazette of Commerce three times and notify creditors that they may request, within two months of the third publication, satisfaction of or security for their claims. The reduction of the share capital may be implemented only after expiration of this time limit.

Our board of directors determines the date on which the dividend entitlement starts. Dividends are usually due and payable shortly after the shareholders have passed the resolution approving the payment, but shareholders may also resolve at the ordinary general meeting of shareholders to pay dividends in quarterly or other installments.

For a discussion of the taxation of dividends, see "Taxation—Swiss Tax Considerations—Taxation of Common Shares—Swiss Federal Withholding Tax on Dividends and Distributions."

***Transfer of Shares***

Shares in uncertificated form (*Wertrechte*) may only be transferred by way of assignment. Shares that constitute intermediated securities (*Bucheffekten)* may only be transferred when a credit of the relevant intermediated securities to the acquirer's securities account is made in accordance with the relevant provisions of the FISA. Article 4 of our articles of association provides that in the case of securities held with an intermediary such as a registrar, transfer agent, trust corporation, bank or similar entity, any transfer, grant of a security interest or usufructary right in such intermediated securities and the appurtenant rights associated therewith requires the cooperation of the intermediary in order for such transfer, grant of a security interest or usufructary right to be valid against us.

Voting rights may be exercised only after a shareholder has been entered in our share register (*Aktienbuch*) with his or her name and address (in the case of legal entities, the registered office) as a shareholder with voting rights.

***Inspection of Books and Records***

Under the CO, a shareholder has a right to inspect our share register with respect to his own shares and otherwise to the extent necessary to exercise his shareholder rights. No other person has a right to inspect our share register. Our books and correspondence may be inspected with the express authorization of the general meeting of shareholders or by resolution of the board of directors and subject to the safeguarding of our business secrets. See "Comparison of Swiss Law and Delaware Law—Inspection of Books and Records."

*Special Investigation*

If the shareholders' inspection rights as outlined above prove to be insufficient in the judgment of the shareholder, any shareholder may propose to the general meeting of shareholders that specific facts be examined by a special commissioner in a special investigation. If the general meeting of shareholders approves the proposal, we or any shareholder may, within 30 calendar days after the general meeting of shareholders, request a court sitting in Zug, Switzerland, our registered office, to appoint a special commissioner. If the general meeting of shareholders rejects the request, one or more shareholders representing at least 10 percent of the share capital or holders of shares in an aggregate nominal value of at least CHF 2,000,000 may request that the court appoint a special commissioner. The court will issue such an order if the petitioners can demonstrate that the board of directors, any member of the board of directors or our executive management infringed the law or our articles of association and thereby caused damages to the Company or the shareholders. The costs of the investigation would generally be allocated to us and only in exceptional cases to the petitioners.

***Compulsory Acquisitions; Appraisal Rights***

Business combinations and other transactions that are governed by the Swiss Merger Act (i.e. mergers, demergers, transformations and certain asset transfers) are binding on all shareholders. A statutory merger or demerger requires approval of two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the nominal value of the shares represented.

If a transaction under the Swiss Merger Act receives all of the necessary consents, there are no appraisal rights and all shareholders are compelled to participate in such transaction.

Swiss corporations may be acquired by an acquirer through the direct acquisition of the share capital of the Swiss corporation. The Swiss Merger Act provides for the possibility of a so-called "cash-out" or "squeeze-out" merger if the acquirer controls 90% of the outstanding shares. In these limited circumstances, minority shareholders of the corporation being acquired may be compensated in a form other than through shares of the acquiring corporation (for instance, through cash or securities of a parent corporation of the acquiring corporation or of another corporation). For business combinations effected in the form of a statutory merger or demerger and subject to Swiss law, the Swiss Merger Act provides that if equity rights have not been adequately preserved or compensation payments in the transaction are unreasonable, a shareholder may request the competent court to determine a reasonable amount of compensation.

In addition, under Swiss law, the sale of "all or substantially all of our assets" by us may require the approval of two-thirds of the number of shares represented at a general meeting shareholders and the absolute majority of the nominal value of the shares represented. Whether a shareholder resolution is required depends on the particular transaction, including whether the following test is satisfied:

- a core part of the Company's business is sold without which it is economically impracticable or unreasonable to continue to operate the remaining business;
- the Company's assets, after the divestment, are not invested in accordance with the Company's statutory business purpose; and
- the proceeds of the divestment are not earmarked for reinvestment in accordance with the Company's business purpose but, instead, are intended for distribution to the Company's shareholders or for financial investments unrelated to the Company's business.

A shareholder of a Swiss corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights. As a result, such shareholder may, in addition to the consideration (be it in shares or in cash) receive an additional amount to ensure that the shareholder receives the fair value of the shares held by the shareholder. Following a statutory merger or demerger, pursuant to the Merger Act, shareholders can file an appraisal action against the surviving company. If the consideration is deemed inadequate, the court will determine an adequate compensation payment.

***Board of Directors***

Our articles of association provide that the board of directors shall consist of at least three and not more than nine members.

The members of the board of directors and the chairman are elected annually by the general meeting of shareholders for a period until the completion of the subsequent ordinary general meeting of shareholders and are eligible for re-election. Each member of the board of directors must be elected individually. Unless an exception is granted by the general meeting of shareholders, only persons who have not completed their seventy-fifth year of age on the election date are eligible for election.

*Powers*

The board of directors has the following non-delegable and inalienable powers and duties:

- the ultimate direction of the business of the Company and issuing of the relevant directives;
- laying down the organization of the Company;
- formulating accounting procedures, financial controls and financial planning;
- nominating and removing persons entrusted with the management and representation of the Company and regulating the power to sign for the Company;
- the ultimate supervision of those persons entrusted with management of the Company, with particular regard to adherence to law, our articles of association, and regulations and directives of the Company;
- issuing the annual report and the compensation report, and preparing for the general meeting of shareholders and carrying out its resolutions;
- informing the court in case of over-indebtedness.

The board of directors may, while retaining such non-delegable and inalienable powers and duties, delegate some of its powers, in particular direct management, to a single or to several of its members, managing directors, committees or to third parties who need be neither members of the board of directors nor shareholders. Pursuant to Swiss law and Article 15 of our articles of association, details of the delegation and other procedural rules such as quorum requirements must be set in the organizational rules issued by the board of directors.

*Indemnification of Executive Management and Directors*

Subject to Swiss law, Article 17 of our articles of association provides for indemnification of the existing and former members of the board of directors, executive management and their heirs, executors and administrators, against liabilities arising in connection with the performance of their duties in such capacity, and permits us to advance the expenses of defending any act, suit or proceeding to our directors and executive management.

In addition, under general principles of Swiss employment law, an employer may be required to indemnify an employee against losses and expenses incurred by such employee in the proper execution of their duties under the employment agreement with the employer. See “Comparison of Swiss Law and Delaware Law—Indemnification of directors and executive management and limitation of liability.”

We have entered or will enter into indemnification agreements with each of the members of our board of directors and executive management. See “Related Party Transactions—Indemnification Agreements.”

***Conflict of Interest, Management Transactions***

Swiss law does not have a general provision regarding conflicts of interest. However, the CO contains a provision that requires our directors and executive management to safeguard the Company’s interests and imposes a duty of loyalty and duty of care on our directors and executive management. This rule is generally understood to disqualify directors and executive management from participation in decisions that directly affect them. Our directors and executive

officers are personally liable to us for breach of these provisions. In addition, Swiss law contains provisions under which directors and all persons engaged in the Company's management are liable to the Company, each shareholder and the Company's creditors for damages caused by an intentional or negligent violation of their duties. Furthermore, Swiss law contains a provision under which payments made to any of the Company's shareholders or directors or any person associated with any such shareholder or director, other than payments made at arm's length, must be repaid to the Company if such shareholder or director acted in bad faith.

Upon the closing of this offering, our board of directors will adopt a Code of Business Conduct and Ethics that will cover a broad range of matters, including the handling of conflicts of interest.

***Principles of the Compensation of the Board of Directors and the Executive Management***

Pursuant to Swiss law, beginning at our first annual meeting as a public company in 2015 our shareholders must annually approve the compensation of the board of directors and the persons whom the board of directors has, fully or partially, entrusted with the management of the Company. The board of directors must issue, on an annual basis, a written compensation report that must be reviewed together with a report on our business by our auditor. The compensation report must disclose all compensation, loans and other forms of indebtedness granted by the Company, directly or indirectly, to current or former members of the board of directors and executive management to the extent related to their former role within the Company or not on customary market terms.

The disclosure concerning compensation, loans and other forms of indebtedness must include the aggregate amount for the board of directors and the executive management as well as the particular amount for each member of the board of directors and executive officer, specifying the name and function of each respective person.

Certain forms of compensation are prohibited for members of our board of directors and executive management, such as:

- severance payments provided for either contractually or in the articles of association (compensation due until the termination of a contractual relationship does not qualify as severance payment);
- advance compensation;
- incentive fees for the acquisition or transfer of corporations or parts thereof by the Company or by companies being, directly or indirectly, controlled by the us;
- loans, other forms of indebtedness, pension benefits not based on occupational pension schemes and performance-based compensation not provided for in the articles of association;
- equity securities and conversion and option rights awards not provided for in the articles of association.

Compensation to members of the board of directors and executive management for activities in entities that are, directly or indirectly, controlled by the Company is prohibited if the compensation (i) would have been prohibited if it was paid directly by the Company, (ii) is not provided for in the articles of association or (iii) has not been approved by the general meeting of shareholders.

Beginning in 2015, the general meeting of shareholders will annually vote on the proposals of the board of directors with respect to:

- the maximum aggregate amount of compensation of the board of directors for the subsequent term of office;
- the maximum aggregate amount of compensation of the executive management for the subsequent financial year.

The board of directors may submit for approval at the general meeting of shareholders deviating or additional proposals relating to the same or different periods.

In the event that at the general meeting of shareholders the shareholders do not approve a proposal of the board of directors, the board of directors must form a new proposal for the maximum aggregate compensation and the particular compensation for each individual, taking into account all relevant factors, and submit the new proposal for approval by the same general meeting of shareholders, at a subsequent extraordinary general meeting or the next ordinary general meeting of shareholders.

In addition to fixed compensation, members of the board of directors and executive management may be paid variable compensation, depending on the achievement of certain performance criteria. The performance criteria may

include individual targets, targets of the Company or parts thereof and targets in relation to the market, other companies or comparable benchmarks, taking into account the position and level of responsibility of the recipient of the variable compensation. The board of directors or, where delegated to it, the compensation committee shall determine the relative weight of the performance criteria and the respective target values.

Compensation may be paid or granted in the form of cash, shares, financial instruments, in kind, or in the form of other types of benefits. The board of directors or, where delegated to it, the compensation committee shall determine grant, vesting, exercise and forfeiture conditions.

***Borrowing Powers***

Neither Swiss law nor our articles of association restrict in any way our power to borrow and raise funds. The decision to borrow funds is made by or under the direction of our board of directors, and no approval by the shareholders is required in relation to any such borrowing.

***Repurchases of Shares and Purchases of Own Shares***

The CO limits our right to purchase and hold our own shares. We and our subsidiaries may purchase shares only if and to the extent that (i) we have freely distributable reserves in the amount of the purchase price; and (ii) the aggregate nominal value of all shares held by us does not exceed 10 percent of our share capital. Pursuant to Swiss law, where shares are acquired in connection with a transfer restriction set out in the articles of association, the foregoing upper limit is 20 percent. We currently do not have any transfer restriction in our articles of association. If we own shares that exceed the threshold of 10 percent of our share capital, the excess must be sold or cancelled by means of a capital reduction within two years.

Shares held by us or our subsidiaries are not entitled to vote at the general meeting of shareholders but are entitled to the economic benefits applicable to the shares generally, including dividends and pre-emptive rights in the case of share capital increases.

In addition, selective share repurchases are only permitted under certain circumstances. Within these limitations, as is customary for Swiss corporations, we may purchase and sell our own shares from time to time in order to meet imbalances of supply and demand, to provide liquidity and to even out variances in the market price of shares.

***Notification and Disclosure of Substantial Share Interests***

The disclosure obligations generally applicable to shareholders of Swiss corporations under the Swiss Act on Stock Exchanges and Securities Trading do not apply to us since our shares are not listed on a Swiss exchange.

Pursuant to art. 663c of the CO, Swiss corporations whose shares are listed on a stock exchange must disclose their significant shareholders and their shareholdings in the notes to their balance sheet, where this information is known or ought to be known. Significant shareholders are defined as shareholders and groups of shareholders linked through voting rights who hold more than five percent of all voting rights.

## Stock Exchange Listing

We intend to list our common shares on Nasdaq Global Select Market under the symbol “EARS.”

## The Depository Trust Company

Initial settlement of the common shares issued in this offering will take place on the consummation date of this offering through The Depository Trust Company, or DTC, in accordance with its customary settlement procedures for equity securities. Each person owning common shares held through DTC must rely on the procedures thereof and on institutions that have accounts therewith to exercise any rights of a holder of the shares.

## Transfer Agent and Registrar of Shares

Our share register will initially be kept by American Stock Transfer & Trust Company, LLC., which acts as transfer agent and registrar. The share register reflects only record owners of our shares. Swiss law does not recognize fractional share interests.

## COMPARISON OF SWISS LAW AND DELAWARE LAW

The Swiss laws applicable to Swiss corporations and their shareholders differ from laws applicable to U.S. corporations and their shareholders. The following table summarizes significant differences in shareholder rights between the provisions of the Swiss Code of Obligations (*Schweizerisches Obligationenrecht*) and the Swiss Ordinance against excessive compensation in listed stock corporations applicable to our company and the Delaware General Corporation Law applicable to companies incorporated in Delaware and their shareholders. Please note that this is only a general summary of certain provisions applicable to companies in Delaware. Certain Delaware companies may be permitted to exclude certain of the provisions summarized below in their charter documents.

| DELAWARE CORPORATE LAW | SWISS CORPORATE LAW |
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| *Mergers and similar arrangements* | |
| Under the Delaware General Corporation Law, with certain exceptions, a merger, consolidation, sale, lease or transfer of all or substantially all of the assets of a corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon. A shareholder of a Delaware corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights pursuant to which such shareholder may receive cash in the amount of the fair value of the shares held by such shareholder (as determined by a court) in lieu of the consideration such shareholder would otherwise receive in the transaction. The Delaware General Corporation Law also provides that a parent corporation, by resolution of its board of directors, may merge with any subsidiary, of which it owns at least 90.0% of each class of capital stock without a vote by the shareholders of such subsidiary. Upon any such merger, dissenting shareholders of the subsidiary would have appraisal rights. | Under Swiss law, with certain exceptions, a merger or a division of the corporation or a sale of all or substantially all of the assets of a corporation must be approved by two-thirds of the shares represented at the respective general meeting of shareholders as well as the absolute majority of the share capital represented at such shareholders' meeting. The articles of association may increase the voting threshold. A shareholder of a Swiss corporation participating in a statutory merger or demerger pursuant to the Swiss Merger Act can file an appraisal right lawsuit against the surviving company. As a result, if the consideration is deemed "inadequate," such shareholder may, in addition to the consideration (be it in shares or in cash) receive an additional amount to ensure that such shareholder receives the fair value of the shares held by such shareholder. Swiss law also provides that a parent corporation, by resolution of its board of directors, may merge with any subsidiary, of which it owns at least 90.0% of the shares without a vote by shareholders of such subsidiary, if the shareholders of the subsidiary are offered the payment of the fair value in cash as an alternative to shares. |
| *Shareholders' suits* | |
| Class actions and derivative actions generally are available to shareholders of a Delaware corporation for, among other things, breach of fiduciary duty, corporate waste and actions not taken in accordance with applicable law. In such actions, the court has discretion to permit the winning party to recover attorneys' fees incurred in connection with such action. | Class actions and derivative actions as such are not available under Swiss law. Nevertheless, certain actions may have a similar effect. A shareholder is entitled to bring suit against directors for breach of, among other things, their fiduciary duties and claim the payment of the company's damages to the corporation. Likewise, an appraisal lawsuit won by a shareholder will indirectly compensate all shareholders. Under Swiss law, the winning party is generally entitled to recover attorneys' fees incurred in connection with such action, provided, however, that the court has discretion to permit the shareholder whose claim has been dismissed to recover attorneys' fees incurred to the extent he acted in good faith. |

| DELAWARE CORPORATE LAW | SWISS CORPORATE LAW |
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| *Shareholder vote on board and management compensation* | |
| Under the Delaware General Corporation Law, the board of directors has the authority to fix the compensation of directors, unless otherwise restricted by the certificate of incorporation or bylaws. | Pursuant to the Swiss Ordinance against excessive compensation in listed stock corporations, the general meeting of shareholders has the non-transferable right, amongst others, to vote on the compensation due to the board of directors, executive management and advisory boards. |
| *Annual vote on board renewal* | |
| Unless directors are elected by written consent in lieu of an annual meeting, directors are elected in an annual meeting of stockholders on a date and at a time designated by or in the manner provided in the bylaws. Re-election is possible.<br><br>Classified boards are permitted. | The general meeting of shareholders elects annually (i.e. until the following general meeting of shareholders) the members of the board of directors and the members of the compensation committee individually for a term of office of one year. Re-election is possible. |
| *Indemnification of directors and executive management and limitation of liability* | |
| The Delaware General Corporation Law provides that a certificate of incorporation may contain a provision eliminating or limiting the personal liability of directors (but not other controlling persons) of the corporation for monetary damages for breach of a fiduciary duty as a director, except no provision in the certificate of incorporation may eliminate or limit the liability of a director for:<br><br>n any breach of a director's duty of loyalty to the corporation or its shareholders;<br>n acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;<br>n statutory liability for unlawful payment of dividends or unlawful stock purchase or redemption; or<br>n any transaction from which the director derived an improper personal benefit.<br><br>A Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any proceeding, other than an action by or on behalf of the corporation, because the person is or was a director or officer, against liability incurred in connection with the proceeding if the director or officer acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the corporation; and the director or officer, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. | Under Swiss corporate law, an indemnification of a director or member of the executive management in relation to potential personal liability is not effective to the extent the director or member of the executive management intentionally or negligently violated his or her corporate duties towards the corporation (certain views advocate that at least a grossly negligent violation is required to exclude the indemnification). Most violations of corporate law are regarded as violations of duties towards the corporation rather than towards the shareholders. In addition, indemnification of other controlling persons is not permitted under Swiss corporate law, including shareholders of the corporation.<br><br>Nevertheless, a corporation may enter into and pay for directors' and officers' liability insurance which typically covers negligent acts as well. |

| DELAWARE CORPORATE LAW | SWISS CORPORATE LAW |
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| Unless ordered by a court, any foregoing indemnification is subject to a determination that the director or officer has met the applicable standard of conduct:<br><br>- by a majority vote of the directors who are not parties to the proceeding, even though less than a quorum;<br>- by a committee of directors designated by a majority vote of the eligible directors, even though less than a quorum;<br>- by independent legal counsel in a written opinion if there are no eligible directors, or if the eligible directors so direct; or<br>- by the shareholders.<br><br>Moreover, a Delaware corporation may not indemnify a director or officer in connection with any proceeding in which the director or officer has been adjudged to be liable to the corporation unless and only to the extent that the court determines that, despite the adjudication of liability but in view of all the circumstances of the case, the director or officer is fairly and reasonably entitled to indemnity for those expenses which the court deems proper. | |
| *Directors' fiduciary duties* | |
| A director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components:<br><br>- the duty of care; and<br>- the duty of loyalty.<br><br>The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. | A director of a Swiss corporation has a fiduciary duty to the corporation only. This duty has two components:<br><br>- the duty of care; and<br>- the duty of loyalty.<br><br>The duty of care requires that a director act in good faith, with the care that an ordinarily prudent director would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose, all material information reasonably available regarding a significant transaction.<br><br>The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits in principle self-dealing by a director and mandates that the best interest of the corporation take precedence over any interest possessed by a director or officer.<br><br>The burden of proof for a violation of these duties is with the corporation or with the shareholder bringing a suit against the director. |

| DELAWARE CORPORATE LAW | SWISS CORPORATE LAW |
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| Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation. | Directors also have an obligation to treat shareholders equally proportionate to their share ownership. |
| *Shareholder action by written consent* | |
| A Delaware corporation may, in its certificate of incorporation, eliminate the right of shareholders to act by written consent. | Shareholders of a Swiss corporation may only exercise their voting rights in a general meeting of shareholders and may not act by written consents. |
| *Shareholder proposals* | |
| A shareholder of a Delaware corporation has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings. | At any general meeting of shareholders any shareholder may put proposals to the meeting if the proposal is part of an agenda item. Unless the articles of association provide for a lower threshold or for additional shareholders' rights:<br><br>n one or several shareholders representing 10.0% of the share capital may ask that a general meeting of shareholders be called for specific agenda items and specific proposals; and<br>n one or several shareholders representing 10.0% of the share capital or CHF 1.0 million of nominal share capital may ask that an agenda item including a specific proposal be put on the agenda for a regularly scheduled general meeting of shareholders, provided such request is made with appropriate notice.<br><br>Any shareholder can propose candidates for election as directors without prior written notice.<br><br>In addition, any shareholder is entitled, at a general meeting of shareholders and without advance notice, to (i) request information from the Board on the affairs of the company (note, however, that the right to obtain such information is limited), (ii) request information from the auditors on the methods and results of their audit, and (iii) request, under certain circumstances and subject to certain conditions, a special audit. |
| *Cumulative voting* | |
| Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation's certificate of incorporation provides for it. | Cumulative voting is not permitted under Swiss corporate law. Pursuant to Swiss law, shareholders can vote for each proposed candidate, but they are not allowed to cumulate their votes for single candidates. An annual individual election of all members of the board of directors for a term of office of one year (i.e. until the following annual general meeting) is mandatory for listed companies. |

| DELAWARE CORPORATE LAW | SWISS CORPORATE LAW |
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| *Removal of directors* | |
| A Delaware corporation with a classified board may be removed only for cause with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. | A Swiss corporation may remove, with or without cause, any director at any time with a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders concerned. The articles of association may require the approval by a qualified majority of the shares represented at a meeting for the removal of a director. |
| *Transactions with interested shareholders* | |
| The Delaware General Corporation Law generally prohibits a Delaware corporation from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or group who or which owns or owned 15.0% or more of the corporation's outstanding voting stock within the past three years. | No such rule applies to a Swiss corporation. |
| *Dissolution; Winding up* | |
| Unless the board of directors of a Delaware corporation approves the proposal to dissolve, dissolution must be approved by shareholders holding 100.0% of the total voting power of the corporation. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares. Delaware law allows a Delaware corporation to include in its certificate of incorporation a supermajority voting requirement in connection with dissolutions initiated by the board. | A dissolution and winding up of a Swiss corporation requires the approval by two-thirds of the shares represented as well as the absolute majority of the nominal value of the share capital represented at a general meeting of shareholders passing a resolution on such dissolution and winding up. The articles of association may increase the voting thresholds required for such a resolution. |
| *Variation of rights of shares* | |
| A Delaware corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise. | A Swiss corporation may modify the rights of a category of shares with (i) a resolution passed by an absolute majority of the shares represented at the general meeting of shareholders and (ii) a resolution passed by an absolute majority of the shares represented at the special meeting of the affected preferred shareholders. Shares that are granted more voting power are not regarded a special class for these purposes. |
| *Amendment of governing documents* | |
| A Delaware corporation's governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise. | The articles of association of a Swiss corporation may be amended with a resolution passed by an absolute majority of the shares represented at such meeting, unless otherwise provided in the articles of association. There are a number of resolutions, such as an amendment of the stated purpose of the corporation and the introduction of authorized and conditional capital, that require the approval by two-thirds of the votes and an absolute majority of the nominal value of the shares represented at a shareholders' meeting. The articles of association may increase the voting thresholds. |

| DELAWARE CORPORATE LAW | SWISS CORPORATE LAW |
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| *Inspection of Books and Records* | |
| Shareholders of a Delaware corporation, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose, and to obtain copies of list(s) of shareholders and other books and records of the corporation and its subsidiaries, if any, to the extent the books and records of such subsidiaries are available to the corporation. | Shareholders of a Swiss corporation may only inspect books and records if the general meeting of shareholders or the board of directors approved such inspection and only if confidential information possessed by a corporation is protected. A shareholder is only entitled to receive information to the extent required to exercise such shareholders' rights, subject to the interests of the corporation. The right to inspect the share register is limited to the right to inspect that shareholder's own entry in the share register. |
| *Payment of dividends* | |
| The board of directors may approve a dividend without shareholder approval. Subject to any restrictions contained in its certificate of incorporation, the board may declare and pay dividends upon the shares of its capital stock either:<br>n out of its surplus, or<br>n in case there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year.<br><br>Stockholder approval is required to authorize capital stock in excess of that provided in the charter. Directors may issue authorized shares without stockholder approval. | Dividend payments are subject to the approval of the general meeting of shareholders. The board of directors may propose to shareholders that a dividend shall be paid but cannot itself authorize the distribution.<br><br>Payments out of the Company's share capital (in other words, the aggregate nominal value of the Company's registered share capital) in the form of dividends are not allowed; however, payments out of share capital may be made by way of a capital reduction only. Dividends may be paid only from the profits brought forward from the previous business years or if the Company has distributable reserves, each as will be presented on the Company's audited annual stand-alone balance sheet. The dividend may be determined only after the allocations to reserves required by the law and the articles of association have been deducted. |
| *Creation and issuance of new shares* | |
| All creation of shares require the board of directors to adopt a resolution or resolutions, pursuant to authority expressly vested in the board of directors by the provisions of the company's certificate of incorporation. | All creation of shares require a shareholders' resolution. Authorized shares can be, once created by shareholder resolution, issued by the board of directors (subject to fulfillment of the authorization). Conditional shares are created and issued through the exercise of options and conversion rights related to debt instruments issued by the board of directors or such rights issued to employees. |

## COMMON SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common shares. Future sales of substantial amounts of our common shares in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of common shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our common shares in the public market after such restrictions lapse. This may adversely affect the prevailing market price and our ability to raise equity capital in the future.

Upon completion of this offering and the conversion of all of our Series A, Series B and Series C preferred shares into common shares on a one-for-one basis upon the closing of this offering, we will have common shares outstanding assuming the exercise in full of the underwriters' option to purchase additional common shares. Of these shares, common shares, or common shares if the underwriters exercise their option in full to purchase additional common shares, sold in this offering will be freely transferable without restriction or registration under the Securities Act, except for any common shares purchased by one of our existing "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining common shares existing are "restricted shares" as defined in Rule 144. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act. As a result of the contractual 180-day lock-up period described below and the provisions of Rules 144 and 701, these shares will be available for sale in the public market as follows:

### Rule 144

In general, a person who has beneficially owned our common shares that are restricted shares for at least six months would be entitled to sell such securities, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned our common shares that are restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of our common shares then outstanding, which will equal approximately common shares immediately after this offering, assuming no exercise of the underwriters' option to purchase additional shares; or
- the average weekly trading volume of our common shares on the during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale; provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

### Rule 701

In general, under Rule 701, any of our employees, directors, officers, consultants or advisors who purchases shares from us in connection with a compensatory share or option plan or other written agreement before the effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described below, beginning 90 days after the date of this prospectus, may be sold by persons other than "affiliates," as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by "affiliates" under Rule 144 without compliance with its one-year minimum holding period requirement.

### Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

### Registration rights

We intend to enter into a registration rights agreement upon consummation of this offering pursuant to which we will agree under certain circumstances to file a registration statement to register the resale of the shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such shares. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Related Party Transactions—Registration Rights Agreement.”

### Lock-up agreements

All of our directors, executive officers and the holders of all or substantially all of our capital stock have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common shares or such other securities for a period of 180 days after the date of this prospectus, subject to certain exceptions, without the prior written consent of Jefferies LLC and Leerink Partners LLC. See “Underwriting.”

## TAXATION

*The following summary contains a description of the material Swiss and U.S. federal income tax consequences of the acquisition, ownership and disposition of common shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase common shares. The summary is based upon the tax laws of Switzerland and regulations thereunder and on the tax laws of the United States and regulations thereunder as of the date hereof, which are subject to change.*

### Swiss Tax Considerations

This summary of material Swiss tax consequences is based on Swiss law and regulations and the practice of the Swiss tax administration as in effect on the date hereof, all of which are subject to change (or subject to changes in interpretation), possibly with retroactive effect. The summary does not purport to take into account the specific circumstances of any particular shareholder or potential investor and does not relate to persons in the business of buying and selling common shares or other securities. The summary is not intended to be, and should not be interpreted as, legal or tax advice to any particular potential shareholder/s, and no representation with respect to the tax consequences to any particular shareholder/s is made.

Current and prospective shareholders are advised to consult their own tax advisers in light of their particular circumstances as to the Swiss tax laws, regulations and regulatory practices that could be relevant for them in connection with the offering, the acquiring, owning and selling or otherwise disposing of common shares and receiving dividends and similar cash or in-kind distributions on common shares (including dividends on liquidation proceeds and stock dividends) or distributions on common shares based upon a capital reduction (*Nennwertrückzahlungen*) or reserves paid out of capital contributions (*Reserven aus Kapitaleinlagen*) and the consequences thereof under the tax laws, regulations and regulatory practices of Switzerland.

### Taxation of common shares

### Swiss Federal Withholding Tax on Dividends and Distributions

Dividend payments and similar cash or in-kind distributions on the common shares (including dividends on liquidation proceeds and stock dividends) that the Company makes to shareholders are subject to Swiss federal withholding tax *(Verrechnungssteuer)* at a rate of 35% on the gross amount of the dividend. The Company is required to withhold the Swiss federal withholding tax from the dividend and remit it to the Swiss Federal Tax Administration. Distributions based upon a capital reduction (*Nennwertrückzahlungen*) and reserves paid out of capital contributions (*Reserven aus Kapitaleinlagen*) are not subject to Swiss federal withholding tax.

The Swiss federal withholding tax may also apply to gains realized upon a repurchase of shares by the company, on the difference between the repurchase price and the nominal value of the shares (*Nennwertprinzip*); a different basis of taxation may apply under the capital contribution principle (*Kapitaleinlageprinzip*).

The Swiss federal withholding tax is refundable or creditable in full to a Swiss tax resident corporate and individual shareholder as well as to a non-Swiss tax resident corporate or individual shareholder who holds the common shares as part of a trade or business carried on in Switzerland through a permanent establishment or fixed place of business situated for tax purposes in Switzerland, if such person is the beneficial owner of the distribution and, in the case of a Swiss tax resident individual who holds the common shares as part of his private assets, duly reports the gross distribution received in his individual income tax return or, in the case of a person who holds the common shares as part of a trade or business carried on in Switzerland through a permanent establishment or fixed place of business situated for tax purposes in Switzerland, recognizes the gross dividend distribution for tax purposes as earnings in the income statements and reports the annual profit in the income tax return.

If a shareholder who is not a Swiss resident for tax purposes and does not hold the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes in Switzerland, receives a distribution from the Company, the shareholder may be entitled

to a full or partial refund or credit of Swiss federal withholding tax incurred on a taxable distribution if the country in which such shareholder is resident for tax purposes has entered into a treaty for the avoidance of double taxation with Switzerland and the further prerequisites of the treaty for a refund have been met. Shareholders not resident in Switzerland should be aware that the procedures for claiming treaty benefits (and the time required for obtaining a refund or credit) may differ from country to country.

Besides the bilateral treaties Switzerland has entered into an agreement with the European Community providing for measures equivalent to those laid down in Council Directive 2003/48/EC on taxation of savings income in the form of interest payments. This agreement contains in its Article 15 provisions on taxation of dividends which apply with respect to EU member states and provides for an exemption of Withholding Tax for companies under certain circumstances.

On 1 January 2013, treaties on final withholding taxes entered into by Switzerland with the United Kingdom and Austria came into force (each a "Contracting State"). The treaties require a Swiss paying agent, as defined in the treaties, to levy a flat-rate final withholding tax at rates specified in the treaties on certain capital gains and income items (including dividends), all as defined in the treaties, deriving from assets, including the common shares held in account or deposits with a Swiss paying agent by (i) an individual resident in a Contracting State, or (ii) if certain requirements are met, by a domiciliary company (*Sitzgesellschaft*), an insurance company in connection with a so-called insurance wrapper (*Lebensversicherungsmantel*) or other individuals if the beneficial owner is an individual resident in a Contracting State. Under the treaty with the UK, the tax rate for individuals resident and domiciled in the UK is 35% on dividends and 27% on capital gains, and, under the treaty with Austria, 25% on dividends and capital gains. The flat-rate tax withheld substitutes the ordinary capital gains tax and income tax on the relevant capital gains and income items in the Contracting State where the individuals are tax resident, unless the individuals elect for the flat-rate tax withheld to be treated as if it were a credit allowable against the income tax or, as the case may be, capital gains tax, due for the relevant tax year in the relevant Contracting State. Alternatively, instead of paying the flat-rate tax, such individuals may opt for a disclosure or the relevant capital gains and income items to the tax authorities of the Contracting State where they are tax residents. If Swiss federal withholding tax of 35% has been withheld on dividends, the Swiss paying agent will – to the extent provided in the applicable bilateral treaty for the avoidance of double taxation between Switzerland and the Contracting State – in its own name and on behalf of the relevant shareholder file with the Swiss tax authorities a request for the partial refund of the Swiss federal withholding tax. The Swiss federal withholding tax which is not refundable according to the bilateral tax treaty (residual tax) is credited against the flat-rate final withholding tax.

### Individual and Corporate Income Tax on Dividends

Swiss resident individuals holding the common shares as part of their private assets who receive dividends and similar distributions (including stock dividends and liquidation proceeds), which are not repayments of the nominal value (*Nennwertrückzahlungen*) of the common shares or reserves paid out of capital contributions (*Reserven aus Kapitaleinlagen*) are required to report such payments in their individual income tax returns and are liable to Swiss federal, cantonal and communal income taxes on any net taxable income for the relevant tax period. Furthermore, for the purpose of the Direct Federal Tax, dividends, shares in profits, liquidation proceeds and pecuniary benefits from shares (including bonus shares) are included in the tax base for only 60% of their value (*Teilbesteuerung*), if the investment amounts to at least 10% of nominal capital of the Company. All cantons, save for Neuenburg, have introduced similar partial taxation measures at cantonal and communal levels.

Swiss resident individuals as well as non-Swiss resident individual taxpayers holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to recognise dividends, distributions based upon a capital reduction (*Nennwertrückzahlungen*) and reserves paid out of capital contributions (*Reserven aus Kapitaleinlagen*) in their income statements for the relevant tax period and are liable to Swiss federal, cantonal and communal individual or corporate income taxes, as the case may be, on any net taxable earnings accumulated (including the payment of dividends) for such period. Furthermore, for the purpose of the Direct Federal Tax, dividends, shares in profits, liquidation proceeds and pecuniary benefits from shares (including bonus shares) are included in the tax base for only 50% (*Teilbesteuerung*), if the investment is held in connection with the conduct of

a trade or business or qualifies as an opted business asset (*gewillkürtes Geschäftsvermögen*) according to Swiss tax law and amounts to at least 10% of nominal capital of the Company. All cantons, save for Neuenburg, have introduced similar partial taxation measures at cantonal and communal levels.

Swiss resident corporate taxpayers as well as non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to recognise dividends, distributions based upon a capital reduction (*Nennwertrückzahlungen*) and reserves paid out of capital contributions (*Reserven aus Kapitaleinlagen*) in their income statements for the relevant tax period and are liable to Swiss federal, cantonal and communal corporate income taxes on any net taxable earnings accumulated for such period. Swiss resident corporate taxpayers as well as non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland may be eligible for dividend relief (*Beteiligungsabzug*) in respect of dividends and distributions based upon a capital reduction (*Nennwertrückzahlungen*) and reserves paid out of capital contributions (*Reserven aus Kapitaleinlagen*) if the common shares held by them as part of a Swiss business have an aggregate market value of at least CFH 1 million of represent at least 10% of the share capital of the Company or give entitlement to at least 10% of the profits and reserves of the Company, respectively.

Recipients of dividends and similar distributions on the common shares (including stock dividends and liquidation proceeds) who are neither residents of Switzerland nor during the current taxation year have engaged in a trade or business in Switzerland and who are not subject to taxation in Switzerland for any other reason are not subject to Swiss federal, cantonal or communal individual or corporate income taxes in respect of dividend payments and similar distributions because of the mere holding of the common shares.

### Wealth and Annual Capital Tax on Holding of Common Shares

Swiss resident individuals and non-Swiss resident individuals holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to report their common shares as part of their wealth and will be subject to cantonal and communal wealth tax to the extent the aggregate taxable net wealth is allocable to Switzerland.

Swiss resident corporate taxpayers and non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, will be subject to cantonal and communal annual capital tax on the taxable capital to the extent the aggregate taxable capital is allocable to Switzerland.

Individuals and corporate taxpayers not resident in Switzerland for tax purposes and not holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are not subject to wealth or annual capital tax in Switzerland because of the mere holding of the common shares.

### Capital Gains on Disposal of Common Shares

Swiss resident individuals who sell or otherwise dispose of the common shares realize a tax-free capital gain, or a non-deductible capital loss, as the case may be, provided that they hold the common shares as part of their private assets.

Capital gains realized on the sale of the common shares held by Swiss resident individuals, Swiss resident corporate taxpayers as well as non-Swiss resident individuals and corporate taxpayers holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, will be subject to Swiss federal, cantonal and communal individual or corporate income tax, as the case may be. This also applies to Swiss resident individuals who, for individual income tax purposes, are deemed to be professional securities dealers for reasons of, inter alia, frequent dealing and debt-financed purchases. Capital gains realized by resident individuals who hold the common shares as

business assets might be entitled to reductions or partial taxations similar to those mentioned above for dividends (*Teilbesteuerung*) if certain conditions are met (e.g. holding period of at least one year and participation of at least 10% of nominal capital).

Swiss resident corporate taxpayers as well as non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business, through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to recognize such capital gain in their income statements for the relevant tax period. Corporate taxpayers may qualify for participation relief on capital gains (*Beteiligungsabzug*), if the common shares sold during the tax period reflect an interest of at least 10% in the Company's capital or if the common shares sold allow for at least 10% of the Company's profit and reserve and were held for at least one year. The tax relief applies to the difference between the sale proceeds of common shares by the Company and the initial costs of the participation (*Gestehungskosten*).

Individuals and corporations not resident in Switzerland for tax purposes and not holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are not subject to Swiss federal, cantonal and communal individual income or corporate income tax, as the case may be, on capital gains realized on the sale of the common shares.

### Gift and Inheritance Tax

Transfers of common shares may be subject to cantonal and/or communal inheritance or gift taxes if the deceased or the donor or the recipient were resident in a Canton levying such taxes and, in international circumstances where residency requirements are satisfied, if the applicable tax treaty were to allocate the right to tax to Switzerland.

### Swiss Issuance Stamp Duty

The Company will be subject to and pay to the Swiss Federal Tax Administration a 1 percent Swiss federal issuance stamp tax (*Emissionsabgabe*) on the consideration received by it for the issuance of the Shares less certain costs incurred in connection with the issuance.

### Swiss Securities Transfer Tax

The purchase or sale of the common shares, whether by Swiss residents or non-Swiss residents, may be subject to Swiss securities transfer tax of up to 0.15 percent, calculated on the purchase price or the proceeds if the purchase or sale occurs through or with a Swiss bank or other Swiss securities dealer as defined in the Swiss Federal Stamp Duty Act as an intermediary or party to the transaction unless an exemption applies. The issuance of the common shares to the initial shareholders at the offering price is not subject to Swiss securities transfer tax.

### Material U.S. Federal Income Tax Considerations for U.S. Holders

In the opinion of Davis Polk & Wardwell LLP, the following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of common shares, but it does not purport to be a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire the common shares. This discussion applies only to a U.S. Holder that holds common shares as capital assets for tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential application of the provisions of the Internal Revenue Code of 1986, or the Code, known as the Medicare contribution tax and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding common shares as part of a hedging transaction, straddle, wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the common shares;
- persons whose functional currency for U.S. federal income tax purposes is not the U.S. dollar;
- entities classified as partnerships for U.S. federal income tax purposes;

- tax-exempt entities, including an "individual retirement account" or "Roth IRA";
- persons that own or are deemed to own ten percent or more of our voting stock; or
- persons holding shares in connection with a trade or business conducted outside of the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding common shares and partners in such partnerships should consult their tax advisers as to their particular U.S. federal income tax consequences of holding and disposing of the common shares.

This discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury regulations, and the income tax treaty between Switzerland and the United States, or the Treaty, all as of the date hereof, any of which is subject to change, possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of common shares who is eligible for the benefits of the Treaty and is:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders should consult their tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of common shares in their particular circumstances.

***Passive Foreign Investment Company Rules***

We believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for our 2013 taxable year, and we expect to be a PFIC for our current taxable year and for the foreseeable future. In addition, we may, directly or indirectly, hold equity interests in other PFICs, or Lower-tier PFICs. In general, a non-U.S. corporation will be considered a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income or (ii) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains.

Under attribution rules, if we are a PFIC, U.S. Holders will be deemed to own their proportionate shares of Lower-tier PFICs and will be subject to U.S. federal income tax according to the rules described in the following paragraphs on (i) certain distributions by a Lower-tier PFIC and (ii) a disposition of shares of a Lower-tier PFIC, in each case as if the U.S. Holder held such shares directly, even though holders have not received the proceeds of those distributions or dispositions directly.

If we are a PFIC for any taxable year during which a U.S. Holder holds our shares, the U.S. Holder may be subject to certain adverse tax consequences. Unless a holder makes a timely "mark to market" election or "qualified electing fund" election each as discussed below, gain recognized on a disposition (including, under certain circumstances, a pledge) of common shares by the U.S. Holder, or on an indirect disposition of shares of a Lower-tier PFIC, will be allocated ratably over the U.S. Holder's holding period for the shares. The amounts allocated to the taxable year of disposition and to years before we became a PFIC will be taxed as ordinary income. The amounts allocated to each other taxable year will be subject to tax at the highest rate in effect for that taxable year for individuals or corporations, as appropriate, and an interest charge will be imposed on the tax attributable to the allocated amounts. Further, to the extent that any distribution received by a U.S. Holder on our common shares (or a distribution by a Lower-tier PFIC to its shareholder that is deemed to be received by a U.S. Holder) exceeds 125% of the average of the annual distributions on the shares received during the preceding three years or the U.S. Holder's holding period, whichever is shorter, the distribution will be subject to taxation in the same manner as gain, described immediately above.

If we are a PFIC for any year during which a U.S. Holder holds common shares, we generally will continue to be treated as a PFIC with respect to the holder for all succeeding years during which the U.S. Holder holds common

shares, even if we cease to meet the threshold requirements for PFIC status. U.S. Holders should consult their tax advisers regarding the potential availability of a "deemed sale" election that would allow them to eliminate this continuing PFIC status under certain circumstances.

If the common shares are "regularly traded" on a "qualified exchange," a U.S. Holder may make a mark-to-market election that would result in tax treatment different from the general tax treatment for PFICs described above. The common shares will be treated as "regularly traded" in any calendar year in which more than a de *minimis* quantity of the common shares is traded on a qualified exchange on at least 15 days during each calendar quarter. Nasdaq, on which the common shares are listed, is a qualified exchange for this purpose. U.S. Holders should consult their tax advisers regarding the availability and advisability of making a mark-to-market election in their particular circumstances. In particular, U.S. Holders should consider carefully the impact of a mark-to-market election with respect to their common shares given that we may have Lower-tier PFICs for which a mark-to-market election may not be available.

If a U.S. Holder makes the mark-to-market election, the holder generally will recognize as ordinary income any excess of the fair market value of the common shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the common shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes the election, the holder's tax basis in the common shares will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on the sale or other disposition of common shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). Distributions paid on common shares will be treated as discussed below under "*Taxation of Distributions.*"

Alternatively, a U.S. Holder can make an election, if we provide the necessary information, to treat us and each Lower-tier PFIC as a qualified electing fund (a "QEF Election") in the first taxable year that we are treated as a PFIC with respect to the holder. A U.S. Holder must make the QEF Election for each PFIC by attaching a separate properly completed IRS Form 8621 for each PFIC to the holder's timely filed U.S. federal income tax return. Upon request of a U.S. Holder, we will provide the information necessary for a U.S. Holder to make a QEF Election with respect to us and will use commercially reasonable efforts to cause each Lower-tier PFIC which we control to provide such information with respect to such Lower-tier PFIC. However, no assurance can be given that such QEF information will be available for any Lower-tier PFIC.

If a U.S. Holder makes a QEF Election with respect to a PFIC, the holder will be currently taxable on its pro rata share of the PFIC's ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC. If a U.S. Holder makes a QEF Election with respect to us, any distributions paid by us out of our earnings and profits that were previously included in the holder's income under the QEF Election would not be taxable to the holder. A U.S. Holder will increase its tax basis in its common shares by an amount equal to any income included under the QEF Election and will decrease its tax basis by any amount distributed on the common shares that is not included in the holder's income. In addition, a U.S. Holder will recognize capital gain or loss on the disposition of common shares in an amount equal to the difference between the amount realized and the holder's adjusted tax basis in the common shares. U.S. Holders should note that if they make QEF Elections with respect to us and Lower-tier PFICs, they may be required to pay U.S. federal income tax with respect to their common shares for any taxable year significantly in excess of any cash distributions received on the shares for such taxable year. U.S. Holders should consult their tax advisers regarding making QEF Elections in their particular circumstances.

Furthermore, as discussed below, if we were a PFIC or, with respect to a particular U.S. Holder, were treated as a PFIC for the taxable year in which we paid a dividend or the prior taxable year, the 15% dividend rate with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If we were a PFIC for any taxable year during which a U.S. Holder held common shares, such U.S. Holder would be required to file an annual information report with such U.S. Holder's U.S. Federal income tax return on IRS Form 8621.

U.S. Holders should consult their tax advisers concerning our PFIC status and the tax considerations relevant to an investment in a PFIC.

***Taxation of Distributions***

Subject to the passive foreign investment company rules described above, distributions paid on common shares, other than certain *pro rata* distributions of common shares, will be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, it is expected that distributions generally will be reported to U.S. Holders as dividends. The amount of a dividend will include any amounts withheld by us in respect of Swiss taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in Swiss Francs will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Dividends paid by us will generally be taxable to a non-corporate U.S. Holder at the special reduced rate normally applicable to long-term capital gains, provided we are not a PFIC in the taxable year in which the dividends are received or in the preceding taxable year, so long as certain holding period requirements are met. As discussed above under "Passive Foreign Investment Company Rules," we expect to be a PFIC and, as a result, the special reduced rate is unlikely to be available currently with respect to dividends paid by us.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder's circumstances, Swiss income taxes withheld from dividends on common shares at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. Swiss taxes withheld in excess of the rate applicable under the Treaty will not be eligible for credit against a U.S. Holder's federal income tax liability. The rules governing foreign tax credits are complex, and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including the Swiss tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

***Sale or Other Disposition of Common Shares***

Subject to the passive foreign investment company rules described above, for U.S. federal income tax purposes, gain or loss realized on the sale or other disposition of common shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common shares for more than one year The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes.

***Information Reporting and Backup Withholding***

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

***Information With Respect to Foreign Financial Assets***

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to an interest in our common shares, subject to certain exceptions (including an exception

for common shares held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisers regarding the effect, if any, of this legislation on their ownership and disposition of the common shares.

***Transfer Reporting Requirements***

A U.S. Holder (including a U.S. tax-exempt entity) that acquires equity of a newly created non-U.S. corporation may be required to file a Form 926 or a similar form with the IRS if (i) such person owned, directly or by attribution, immediately after the transfer at least 10% by vote or value of the corporation or (ii) if the transfer, when aggregated with all transfers made by such person (or any related person) within the preceding 12 month period, exceeds $100,000. U.S. Holders should consult their tax advisers regarding the applicability of this requirement to their acquisition of the common shares.

## UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated , 2014, among us and Jefferies LLC and Leerink Partners LLC, as the representatives of the underwriters named below, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common shares shown opposite its name below:

| UNDERWRITER | NUMBER OF SHARES |
|---|---|
| Jefferies LLC | |
| Leerink Partners LLC | |
| JMP Securities LLC | |
| Needham & Company, LLC | |
| Total | |

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the common shares if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The common shares will constitute a new class of securities with no established trading market. The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common shares as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common shares, that you will be able to sell any of the common shares held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the common shares subject to their acceptance of the common shares from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

### Commission and Expenses

The underwriters have advised us that they propose to offer the common shares to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of $ per common share. The underwriters may allow, and certain dealers may reallow, a discount from the concession not in excess of $ per common share to certain brokers and dealers. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representative. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

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The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

| | PER COMMON SHARE | | TOTAL | |
|---|---|---|---|---|
| | WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES | WITH OPTION TO PURCHASE ADDITIONAL SHARES | WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES | WITH OPTION TO PURCHASE ADDITIONAL SHARES |
| Public offering price | $ | $ | $ | $ |
| Underwriting discounts and commissions paid by us | $ | $ | $ | $ |
| Proceeds to us, before expenses | $ | $ | $ | $ |

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $ . We have also agreed to reimburse the underwriters for certain expenses, including up to an aggregate of $30,000 in connection with the clearance of this offering with the Financial Industry Regulatory Authority, as set forth in the underwriting agreement.

### Determination of Offering Price

Prior to this offering, there has not been a public market for our common shares. Consequently, the initial public offering price for our common shares will be determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations will be prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common shares will trade in the public market subsequent to the offering or that an active trading market for the common shares will develop and continue after the offering.

### Listing

We intend to apply to have our common shares approved for listing on the Nasdaq Global Select Market under the trading symbol "EARS."

### Stamp Taxes

If you purchase shares offered in this prospectus, you may be required to pay stamp taxes and other charges under the laws and practices of the country of purchase, in addition to the offering price listed on the cover page of this prospectus.

### Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

### No Sales of Similar Securities

We, our executive officers, directors and holders of all or substantially all our outstanding capital stock have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-l(h) under the Securities Exchange Act of 1934, as amended, or

- otherwise dispose of any common shares, options or warrants to acquire common shares or securities exchangeable or exercisable for or convertible into shares of common shares currently or hereafter owned either of record or beneficially, or
- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC and Leerink Partners LLC.

This restriction terminates after the close of trading of the common shares on and including the 180th day after the date of this prospectus.

Jefferies LLC and Leerink Partners LLC may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

### Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, certain persons participating in the offering may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common shares at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either “covered” short sales or “naked” short sales.

“Covered” short sales are sales made in an amount not greater than the underwriters’ option to purchase additional shares of our common shares in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common shares or purchasing shares of our common shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

“Naked” short sales are sales in excess of the option to purchase additional shares of our common shares. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common shares in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of common shares on behalf of the underwriters for the purpose of fixing or maintaining the price of the common shares. A syndicate covering transaction is the bid for or the purchase of common shares on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriter’s purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common shares or preventing or retarding a decline in the market price of our common shares. As a result, the price of our common shares may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common shares originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common shares. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common shares on in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common shares in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker’s bid, that bid must then be lowered when specified purchase limits are exceeded.

### Electronic Distribution

A prospectus in electronic format may be made available by e-mail or on the web sites or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of common shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

### Other Activities and Relationships

The underwriter and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriter and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriter and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common shares offered hereby. Any such short positions could adversely affect future trading prices of the common shares offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

### Selling Restrictions

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the common shares or possession or distribution of this prospectus or any other offering or publicity material relating to the common shares in any country or jurisdiction (other than the United States) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any common shares or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of the common shares by it will be made on the same terms.

#### *European Economic Area*

In relation to each member state of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), an offer to the public of any common shares which are the subject of the offering contemplated by this prospectus supplement and the accompanying prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any common shares may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to any legal entity which is a "qualified investor" as defined in the Prospectus Directive;

- to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the underwriters or the underwriters nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

*provided* that no such offer of common shares shall require us or any of the underwriters to publish a prospectus pursuant to Article 3 of the Prospectus Directive or supplement a prospectus pursuant to Article 16 of the Prospectus Directive.

For the purposes of this provision, the expression an "offer common shares to the public" in relation to the common shares in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the common shares to be offered so as to enable an investor to decide to purchase or subscribe to the common shares, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State and the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State), and includes any relevant implementing measure in the Relevant Member State and the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

***United Kingdom***

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (the "Order") and/or (ii) high net worth entities falling within Article 49(2)(a) to (d) of the Order and other persons to whom it may lawfully be communicated (each such person being referred to as a "relevant person").

This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

***Australia***

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

***Hong Kong***

No securities have been offered or sold, and no securities may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal

or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong ("SFO") and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong ("CO") or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the securities has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the securities may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the securities will be required, and is deemed by the acquisition of the securities, to confirm that he is aware of the restriction on offers of the securities described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any securities in circumstances that contravene any such restrictions.

***Japan***

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the Initial Purchaser will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

***Singapore***

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the notes may not be circulated or distributed, nor may the notes be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore (the "SFA"), (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the notes are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the notes pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

***Switzerland***

The common shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a of the CO or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing relating to the common shares or this offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to this offering, the Company or the common shares has been or will be filed with or approved by any Swiss regulatory authority.

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## EXPENSES OF THE OFFERING

We estimate that our expenses in connection with this offering, other than underwriting discounts and commissions, will be as follows:

| EXPENSES | AMOUNT |
|---|---|
| U.S. Securities and Exchange Commission registration fee | |
| Nasdaq listing fee | |
| FINRA filing fee | |
| Printing and engraving expenses | |
| Legal fees and expenses | |
| Accounting fees and expenses | |
| Miscellaneous costs | |
| Total | |

All amounts in the table are estimates except the U.S. Securities and Exchange Commission registration fee, the listing fee and the FINRA filing fee. The Company will pay all of the expenses of this offering.

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## LEGAL MATTERS

The validity of the common shares and certain other matters of Swiss law will be passed upon for us by Froriep, Zurich, Switzerland. Certain matters of U.S. federal and New York State law will be passed upon for us by Davis Polk & Wardwell LLP, New York, New York, and for the underwriters by Latham & Watkins LLP, Washington, D.C.

## AUDITORS

At the ordinary annual general meeting on April 22, 2014 our shareholders appointed Deloitte AG as our auditor for the year ending December 31, 2014 as proposed by our board of directors. Accordingly KPMG AG was dismissed and was not re-elected for another term as our independent registered public accounting firm.

The report of KPMG AG on our financial statements for financial years ended December 31, 2013 and 2012 did not contain any adverse opinion or disclaimer of opinion and was not qualified or modified as to uncertainty, audit scope or accounting principles. There was no disagreement whatsoever relating to the years ended December 31, 2013 and 2012 and the period from January 1, 2014 through April 22, 2014 with KPMG AG on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreement, if not resolved to the satisfaction of the former auditor, would have caused them to make reference to the subject matter of the disagreement in connection with their report, or any “reportable event” as described in Item 16F(a)(1)(v) of Form 20-F.

We have provided a copy of the above statements to KPMG AG and requested that KPMG AG furnish us with a letter addressed to the SEC stating whether or not they agree with the above disclosure. A copy of that letter, dated June 27, 2014, is filed as an exhibit to the registration statement of which this prospectus is a part.

Deloitte AG has offices at General Guisan-Quai 38, 8002 Zurich, Switzerland, phone number +(41) 58 279 60 00.

## EXPERTS

The consolidated financial statements of Auris Medical AG as of December 31, 2013, 2012 and January 1, 2012 and for each of the years in the two-year period ended December 31, 2013, have been included herein in reliance upon the report of KPMG AG, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

The current address of KPMG AG is Badenerstrasse 172, CH-8004 Zurich, Switzerland.

## ENFORCEMENT OF JUDGMENTS

We are organized under the laws of Switzerland and our jurisdiction of incorporation is Zug, Switzerland. Moreover, a number of our directors and executive officers and a number of directors of each of our subsidiaries are not residents of the United States, and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon us or upon such persons or to enforce against them judgments obtained in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our Swiss counsel that there is doubt as to the enforceability in Switzerland of original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent predicated upon the federal and state securities laws of the United States. Original actions against persons in Switzerland based solely upon the U.S. federal or state securities laws are governed, among other things, by the principles set forth in the Swiss Federal Act on International Private Law. This statute provides that the application of provisions of non-Swiss law by the courts in Switzerland shall be precluded if the result was incompatible with Swiss public policy. Also, mandatory provisions of Swiss law may be applicable regardless of any other law that would otherwise apply.

Switzerland and the United States do not have a treaty providing for reciprocal recognition of and enforcement of judgments in civil and commercial matters. The recognition and enforcement of a judgment of the courts of the United States in Switzerland is governed by the principles set forth in the Swiss Federal Act on Private International Law. This statute provides in principle that a judgment rendered by a non-Swiss court may be enforced in Switzerland only if:

- the non-Swiss court had jurisdiction pursuant to the Swiss Federal Act on Private International Law;
- the judgment of such non-Swiss court has become final and non-appealable;
- the judgment does not contravene Swiss public policy;
- the court procedures and the service of documents leading to the judgment were in accordance with the due process of law; and
- no proceeding involving the same position and the same subject matter was first brought in Switzerland, or adjudicated in Switzerland, or was earlier adjudicated in a third state and this decision is recognizable in Switzerland.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the U.S. Securities and Exchange Commission a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. You may inspect and copy reports and other information filed with the SEC at the Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

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**AURIS MEDICAL AG**

**Condensed Consolidated Interim Statement of Profit or Loss and Other Comprehensive Income**
For the Three Months Ended March 31, 2014 and 2013
(in CHF)

| | NOTE | THREE MONTHS ENDED MARCH 31, 2014 | THREE MONTHS ENDED MARCH 31, 2013 |
|---|---|---|---|
| Research and development | | -4,149,230 | -1,973,132 |
| General and administrative | | -1,709,065 | -270,272 |
| **Operating loss** | | **-5,858,295** | **-2,243,404** |
| Finance expense | | -51,436 | -10,574 |
| Finance income | | 49,770 | 24,108 |
| **Loss before tax** | | **-5,859,961** | **-2,229,870** |
| Income tax expense | | — | — |
| **Net loss for the period attributable to owners of the Company** | | **-5,859,961** | **-2,229,870** |
| **Other comprehensive income:** | | | |
| **Items that will never be reclassified to profit or loss** | | | |
| Remeasurements of defined benefit liability | | -16,511 | 42,744 |
| **Items that are or may be reclassified to profit or loss** | | | |
| Foreign currency translation differences | | 5,490 | -29,552 |
| **Other comprehensive income, net of tax** | | **-11,021** | **13,192** |
| **Total comprehensive loss for the period attributable to owners of the Company** | | **-5,870,982** | **-2,216,678** |
| Basic and diluted loss per share | 10 | -0.32 | -0.19 |

The selected notes form an integral part of these condensed consolidated interim financial statements.

**AURIS MEDICAL AG**

**Condensed Consolidated Interim Statement of Financial Position**
As of March 31, 2014 and December 31, 2013
(in CHF)

| | NOTE | MARCH 31, 2014 | DECEMBER 31, 2013 |
|---|---|---|---|
| **ASSETS** | | | |
| **Non-current assets** | | | |
| Property and equipment | | 260,846 | 195,915 |
| Intangible assets | | 1,482,520 | 1,482,520 |
| **Total non-current assets** | | **1,743,366** | **1,678,435** |
| **Current assets** | | | |
| Other receivables | | 581,173 | 524,786 |
| Prepayments | | 2,070 | 183,137 |
| Cash and cash equivalents | | 18,535,023 | 23,865,842 |
| **Total current assets** | | **19,118,266** | **24,573,765** |
| **Total assets** | | **20,861,632** | **26,252,200** |
| **EQUITY AND LIABILITIES** | | | |
| **Equity** | | | |
| Share capital | 6 | 7,536,510 | 6,487,130 |
| Share premium | | 48,232,566 | 35,608,210 |
| Foreign currency translation reserve | | 59,485 | 53,995 |
| Accumulated deficit | | -38,951,559 | -33,115,689 |
| **Total shareholders' equity attributable to owners of the Company** | | **16,877,002** | **9,033,646** |
| **Non-current liabilities** | | | |
| Employee benefits | 9 | 344,585 | 328,342 |
| Deferred tax liabilities | | 327,637 | 327,637 |
| **Total non-current liabilities** | | **672,222** | **655,979** |
| **Current liabilities** | | | |
| Convertible loans | 8 | — | 13,711,200 |
| Trade and other payables | | 989,231 | 954,257 |
| Accrued expenses | | 2,323,177 | 1,897,118 |
| **Total current liabilities** | | **3,312,408** | **16,562,575** |
| **Total liabilities** | | **3,984,630** | **17,218,554** |
| **Total equity and liabilities** | | **20,861,632** | **26,252,200** |

The selected notes form an integral part of these condensed consolidated interim financial statements.

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**AURIS MEDICAL AG**

**Condensed Consolidated Interim Statement of Changes in Equity**
For the Three Months Ended March 31, 2014 and 2013
(in CHF)

| | | ATTRIBUTABLE TO OWNERS OF THE COMPANY | | | | |
|---|---|---|---|---|---|---|
| | NOTE | SHARE CAPITAL | SHARE PREMIUM | FOREIGN CURRENCY TRANSLATION RESERVE | ACCUMULATED DEFICIT | TOTAL EQUITY |
| **As of January 1, 2013** | | **4,632,580** | **13,341,942** | **22,275** | **-18,240,831** | **-244,034** |
| **Total comprehensive loss** | | | | | | |
| Net loss | | — | — | — | -2,229,870 | -2,229,870 |
| Other comprehensive income (-loss) | | — | — | -29,552 | 42,744 | 13,192 |
| **Total comprehensive loss** | | **—** | **—** | **-29,552** | **-2,187,126** | **-2,216,678** |
| **Transactions with owners of the Company** | | | | | | |
| Share-based payments | | — | — | — | 24,391 | 24,391 |
| **Balance at March 31, 2013** | | **4,632,580** | **13,341,942** | **-7,277** | **-20,403,566** | **-2,436,321** |
| **As of January 1, 2014** | | **6,487,130** | **35,608,210** | **53,995** | **-33,115,689** | **9,033,646** |
| **Total comprehensive loss** | | | | | | |
| Net loss | | — | — | — | -5,859,961 | -5,859,961 |
| Other comprehensive income (-loss) | | — | — | 5,490 | -16,511 | -11,021 |
| **Total comprehensive loss** | | **—** | **—** | **5,490** | **-5,876,472** | **-5,870,982** |
| **Transactions with owners of the Company** | | | | | | |
| Conversion of convertible loans | 8 | 1,043,180 | 12,717,655 | — | — | 13,760,835 |
| Share issuance costs | | — | -136,699 | — | — | -136,699 |
| Share-based payments | 7 | — | — | — | 40,602 | 40,602 |
| Share options exercised | 6 | 6,200 | 43,400 | — | — | 49,600 |
| **Balance at March 31, 2014** | | **7,536,510** | **48,232,566** | **59,485** | **-38,951,559** | **16,877,002** |

The selected notes form an integral part of these condensed consolidated interim financial statements.

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**AURIS MEDICAL AG**

**Condensed Consolidated Interim Statement of Cash Flows**
For the Three Months Ended March 31, 2014 and 2013
(in CHF)

| | NOTE | THREE MONTHS ENDED MARCH 31, 2014 | THREE MONTHS ENDED MARCH 31, 2013 |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| **Net loss** | | **-5,859,961** | **-2,229,870** |
| Adjustments for: | | | |
| Depreciation | | 14,904 | 6,879 |
| Unrealized exchange differences | | 5,880 | -28,213 |
| Net interest income | | 26,496 | 7,627 |
| Share-based payments | 7, 9 | 40,602 | 24,391 |
| Employee benefits | | -268 | 7,064 |
| Changes in: | | | |
| Other receivables | | -56,388 | -29,898 |
| Prepayments | | 181,067 | 84,325 |
| Trade and other payables | | 34,913 | 556,330 |
| Accrued expenses | | 426,059 | 91,836 |
| **Cash used in operating activities** | | **-5,186,696** | **-1,509,529** |
| **Cash flows from investing activities** | | | |
| Purchase of property and equipment | | — | -11,695 |
| Interest received | | 23,139 | 92 |
| **Net cash used in investing activities** | | **-56,697** | **-11,603** |
| **Cash flows from financing activities** | | | |
| Proceeds from share capital increase | | 49,600 | — |
| Share issuance costs | | -136,699 | |
| Increase in borrowings | | — | 1,485,422 |
| Interest paid | | — | -7,718 |
| **Net cash from financing activities** | | **-87,099** | **1,477,704** |
| **Net decrease in cash and cash equivalents** | | **-5,330,492** | **-43,428** |
| Cash and cash equivalents at beginning of the period | | 23,865,842 | 63,967 |
| Net effect of currency translation on cash | | -327 | 205 |
| **Cash and cash equivalents at end of the period** | | **18,535,023** | **20,744** |

The selected notes form an integral part of these condensed consolidated interim financial statements.

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AURIS MEDICAL AG

**Selected Notes to the Condensed Consolidated Interim Financial Statements**
as of March 31, 2014 and for the three months ended March 31, 2014 and 2013 (in CHF)

## 1. Reporting entity

Auris Medical AG (the "Company") is domiciled in Switzerland. The Company's registered address is at Falknerstrasse 4, 4001 Basel. These condensed consolidated interim financial statements comprise the Company and its subsidiaries (together referred to as the "Group" and individually as "Group entities"). The Company is the ultimate parent of the following Group entities:

- Auris Medical Inc., Chicago, United States (100%)
- Auris Medical Ltd., Dublin, Ireland (100%)

The Group is primarily involved in the development of pharmaceutical products for the treatment of inner ear disorders, in particular tinnitus and hearing loss. Its most advanced projects are in the late stage of clinical development.

## 2. Basis of preparation

***Statement of compliance***

These condensed consolidated interim financial statements (hereinafter "interim financial statements") have been prepared in accordance with International Accounting Standards ("IAS") 34 Interim Financial Reporting. They do not include all the information required for a complete set of financial statements prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). However, selected explanatory notes are included to explain events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since the last annual consolidated financial statements as of and for the year ended December 31, 2013. These interim financial statements were authorized for issue by the Company's Management on June 6, 2014.

***Foreign currencies***

These interim financial statements are presented in Swiss Francs (CHF), which is the Company's functional ("functional currency") and the Group's reporting currency.

Closing rates for the most significant foreign currencies:

| CURRENCY | | GEOGRAPHICAL AREA | REPORTING ENTITIES | MARCH 31, 2014 | DECEMBER 31, 2013 |
|---|---|---|---|---|---|
| CHF | Swiss Franc | Switzerland | 1 | 1.0000 | 1.0000 |
| USD | Dollar | United States | 1 | 0.8841 | 0.8894 |
| EUR | Euro | Europe | 1 | 1.2179 | 1.2255 |

Average exchange rates for the period for the most significant foreign currencies:

| CURRENCY | | GEOGRAPHICAL AREA | REPORTING ENTITIES | THREE MONTHS ENDED MARCH 31, 2014 | THREE MONTHS ENDED MARCH 31, 2013 |
|---|---|---|---|---|---|
| CHF | Swiss Franc | Switzerland | 1 | 1.0000 | 1.0000 |
| USD | Dollar | United States | 1 | 0.8928 | 0.9301 |
| EUR | Euro | Europe | 1 | 1.2233 | 1.2281 |

***Use of estimates and judgments***

In preparing these interim financial statements, management made judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets and liabilities, income and expense. Actual results may differ from these estimates.

As of and for the year ended December 31, 2013, the significant judgments made by management in applying the Group's accounting policies and the key sources of estimation uncertainty related to income taxes, development expenditures and employee benefits. Additional judgments made in applying accounting policies for the three months ended March 31, 2014 and 2013 are described below.

The Company is preparing for a proposed Initial Public Offering ("IPO") during the first quarter of 2014. All expenses related to the IPO preparations are expensed as incurred or accrued until the date at which it becomes probable (ie more likely than not) that the IPO would occur. Thereafter, costs directly attributable to the issuance of shares will be recorded as prepayments and subtracted from the proceeds of the IPO.

As of March 31, 2014 Management determined that successful completion of an IPO is not deemed to be more likely than not and therefore IPO costs both invoiced and accrued for a total of CHF 822,366 were recorded in General & Administrative expenses.

## 3. Significant accounting policies

Except as described below, the accounting policies applied in these interim financial statements are the same as those applied in the Group's consolidated financial statements as of and for the year ended December 31 2013.

The following amendments to standards and interpretations became effective on January 1, 2014 and have been adopted by the Group in the preparation of the interim financial statements as of and for the three months ended March 31, 2014:

- IAS 32—Offsetting Financial Assets and Financial Liabilities (Amendments)
- IFRS 10, IFRS 12, IAS 27—Investment Entities (Amendments)
- IAS 36—Recoverable Amount Disclosures for Non-Financial Assets (Amendments)
- IAS 39—Novation of Derivatives and Continuation of Hedge Accounting (Amendments)
- IFRIC 21—Levies

The adoption of these new amendments to standards and interpretations did not impact the Group's financial position or results of operations.

New standards, amendments to standards and interpretations that have been issued but are not mandatory for the financial year beginning after January 1, 2014, have not been applied in preparing these interim financial statements. None of these are expected to have a significant effect on the interim financial statements of the Group (the impact from IFRS 9 with an effective date of January 1, 2018 at the earliest cannot be determined yet with sufficient reliability).

The interim financial statements do not include all disclosures for critical accounting estimates and judgments that are required in the annual consolidated financial statements, and should be read in conjunction with the Company's annual consolidated financial statements as of and for the year ended December 31, 2013.

***Basis of consolidation***

There is no change to the policies disclosed in the Company's annual consolidated financial statements and which form the basis for the definition of Subsidiaries or elimination of transactions on consolidation.

## 4. Seasonality of operations

The business is not subject to any seasonality, but expenses are largely determined by the phase of the respective projects, particularly with regard to external development expenditures.

## 5. Financial instruments and risk management

The following table shows the carrying amounts of financial assets and financial liabilities:

| | MARCH 31, 2014 | DECEMBER 31, 2013 |
|---|---|---|
| **Financial assets** | | |
| **Loans and receivables** | | |
| Cash and cash equivalents | 18,535,023 | 23,865,842 |
| Other receivables | 523,675 | 451,206 |
| **Total financial assets** | **19,058,698** | **24,317,048** |
| **Financial liabilities** | | |
| **at amortized cost** | | |
| Convertible loans from shareholders | — | 13,711,200 |
| Trade and other accounts payable | 989,231 | 954,257 |
| Accrued expenses | 2,290,749 | 1,871,598 |
| **Total financial liabilities** | **3,279,980** | **16,537,055** |

***Fair values***

The carrying amount of cash and cash equivalents, other receivables, trade and other payables and accrued expenses is a reasonable approximation of their fair value.

The fair value of any other financial assets and liabilities for disclosure purposes is estimated by discounting the future contractual cash flows at the current market interest rate that is available to the Group for similar financial instruments.

***Financial risk factors***

The Group's activities expose it to a variety of financial risks: market risk, credit risk and liquidity risk. The Group's financial risk management objectives and policies are consistent with those disclosed in the annual consolidated financial statements as of and for the year ended December 31, 2013.

## 6. Capital and reserves

***Share capital***

The issued share capital of Auris Medical AG consisted of:

| | AS OF MARCH 31, 2014 | | AS OF DECEMBER 31, 2013 | |
|---|---|---|---|---|
| | NUMBER | CHF | NUMBER | CHF |
| Common shares with a nominal value of CHF 0.40 each | 88,100 | 35,240 | 72,600 | 29,040 |
| Preferred shares Series A with a nominal value of CHF 0.40 each | 5,999,750 | 2,399,900 | 5,999,750 | 2,399,900 |
| Preferred shares Series B with a nominal value of CHF 0.40 each | 5,509,100 | 2,203,640 | 5,509,100 | 2,203,640 |
| Preferred shares Series C with a nominal value of CHF 0.40 each | 7,244,325 | 2,897,730 | 4,636,375 | 1,854,550 |
| | **18,841,275** | **7,536,510** | **16,217,825** | **6,487,130** |

All shares are fully paid in. All disclosed numbers and nominal value of shares in these interim financial statements are adjusted for the 25:1 stock split effected in December 2013 unless otherwise indicated.

| | COMMON SHARES | | PREFERRED SHARES | |
|---|---|---|---|---|
| | 2014 | 2013 | 2014 | 2013 |
| As of January 1 | 72,600 | 72,600 | 16,145,225 | 11,508,850 |
| Shares issued | 15,500 | — | 2,607,950 | — |
| **As at March 31, 2014, and March 31, 2013** | **88,100** | **72,600** | **18,753,175** | **11,508,850** |

*Issue of common shares upon exercise of options*

On January 21, 2014, three beneficiaries of Option Plan A exercised their right to acquire common shares of the Company at CHF 3.20 per share. This has resulted in an increase in the number of outstanding common shares of 15,500 and an increase in the share capital of CHF 6,200. Total proceeds from the exercise to the company were CHF 49,600.

### 7. Share-based compensation

The interim financial statements do not include all disclosures for share-based payments that are required in the annual consolidated financial statements, and should be read in conjunction with the company's annual consolidated financial statements as of and for the year ended December 31, 2013.

The number of outstanding options at January 1, 2013 was 146,500. During the first quarter of 2013 options for a total of 50,000 common shares were granted under Option Plan A at an exercise price of CHF 4.80 per share. On January 1, 2014, there were 272,500 options outstanding. During the first quarter of 2014 15,500 options were exercised (see Note 6 Issue of common shares), and 97,500 options with an exercise price of CHF 5.28 under Option Plan C were granted. The fair value of the options granted during the first quarter of 2014 of CHF 2.89 per option was measured based on the Black-Scholes formula. On March 31, 2014 there were 354,750 options outstanding for all plans, of which 53,500 were vested.

Expenses of CHF 24,391 and CHF 40,602 were recorded for equity-settled share-based payment transactions in the first quarter of 2013 and the first quarter of 2014, respectively.

### 8. Convertible loans

On December 9, 2013, the Company issued non-interest bearing convertible loans to two shareholders with a nominal value of CHF 13,769,976 and a maximum term of 12 months. On January 27, 2014, the loans were converted at a ratio of CHF 5.28 per share into new Series C shares with nominal value of CHF 0.40 each. The company issued 2,607,950 Series C shares with a nominal value of CHF 0.40 each.

On the conversion date of the loan, the liability was derecognized and CHF 1,043,180 was recognized as share capital and CHF 12,717,655 as share premium.

| | MARCH 31, 2014 |
|---|---|
| **Convertible loans as at December 31** | **13,711,200** |
| Loss on derecognition | 9,141 |
| Imputed interest expense for the period | 49,635 |
| Derecognition of liability at conversion into equity | 13,769,976 |
| **Convertible loans at March 31, 2014** | **—** |

## 9. Employee benefits

| | THREE MONTHS ENDED MARCH 31, 2014 | THREE MONTHS ENDED MARCH 31, 2013 |
|---|---|---|
| Salaries | 461,230 | 206,560 |
| Pension costs | 29,218 | 19,055 |
| Other social benefits | 35,947 | 15,958 |
| Share option cost | 40,602 | 24,391 |
| Other employee cost | 15,814 | 15,009 |
| **Total employee benefits** | **582,811** | **280,973** |

## 10. Loss per share

| | THREE MONTHS ENDED MARCH 31, 2014 | THREE MONTHS ENDED MARCH 31, 2013 |
|---|---|---|
| Loss attributable to owners of the Company | -5,859,961 | -2,229,870 |
| Weighted average number of shares outstanding | 18,055,273 | 11,581,450 |
| **Basic and diluted loss per share** | **-0.32** | **-0.19** |

For the periods ended March 31, 2014 and 2013 basic and diluted loss per share is based on the weighted average number of shares issued and outstanding and excludes shares to be issued under the option plans (see Note 7) and, for the 2013 period only, conversion rights related to the convertible loans (see Note 8) as they would be anti-dilutive. In case the Group shows a profit in the future, the options may have a dilutive effect on earnings per share and will need to be included in the above calculation.

## 11. Related party transactions

In January 2014 the convertible loan lenders exercised their conversion option, and the total loan amount of CHF 13,769,976 was converted into 2,607,950 Series C shares of the Company (see Note 8).

The service agreement with Altamira Pharma GmbH, a company fully owned by the CEO, was terminated as of January 31, 2014 with a final payment of CHF 14,500. Since 2011 the CEO had been compensated under this agreement. The Company entered into an employment contract with the CEO effective January 1, 2014.

## 12. Events after the balance sheet date

Effective April 22, 2014, the Company reorganized its Swiss activities through the conversion of Auris Medical AG into a holding company (Auris Medical Holding AG) and the simultaneous transfer of its operating activities into a newly created company (Auris Medical AG), with an issued share capital of CHF 2.5 million. Effective May 21, 2014 the domicile of Auris Medical Holding AG was transferred from Basel to Zug; in addition, on May 21, 2014 a new subsidiary, Otolanum AG, was created with a share capital of CHF 100,000 and domicile in Zug.

**Report of Independent Registered Public Accounting Firm**

The Board of Directors
Auris Medical AG:

We have audited the accompanying consolidated statements of financial position of Auris Medical AG and subsidiaries (the "Company") as of December 31, 2013, 2012 and January 1, 2012, and the related consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows, for each of the years in the two-year period ended December 31, 2013. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Auris Medical AG and subsidiaries as of December 31, 2013, 2012 and January 1, 2012, and the results of their operations and their cash flows for each of the years in the two-year period ended December 31, 2013, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

KPMG AG

| /s/ Martin Rohrbach | /s/ Charles Errico |
|---|---|
| Martin Rohrbach | Charles Errico |

Zurich, Switzerland
March 18, 2014

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**AURIS MEDICAL AG**

**Consolidated Statement of Profit or Loss and Other Comprehensive Income**
For the Years Ended December 31, 2013 and 2012
(in CHF)

| | NOTE | 2013 | 2012 |
|---|---|---|---|
| Research and development | 17 | -13,253,638 | -3,986,691 |
| General and administrative | 18 | -1,362,211 | -623,812 |
| **Operating loss** | | **-14,615,849** | **-4,610,503** |
| Finance expense | 20 | -158,641 | -1,800 |
| Finance income | 20 | 75,747 | 9,894 |
| **Loss before tax** | | **-14,698,743** | **-4,602,409** |
| Income tax expense | 21 | -305,750 | — |
| **Net loss attributable to owners of the Company** | | **-15,004,493** | **-4,602,409** |
| **Other comprehensive income:** | | | |
| **Items that will never be reclassified to profit or loss** | | | |
| Remeasurements of defined benefit liability | 19 | -57,716 | -54,577 |
| **Items that are or may be reclassified to profit or loss** | | | |
| Foreign currency translation differences | | 31,720 | 22,275 |
| **Other comprehensive income** | | **-25,996** | **-32,302** |
| **Total comprehensive loss attributable to owners of the Company** | | **-15,030,489** | **-4,634,711** |
| Basic and diluted loss per share | 22 | -1.01 | -0.40 |

The notes form an integral part of these consolidated financial statements.

**AURIS MEDICAL AG**

**Consolidated Statement of Financial Position**
As of December 31, 2013, 2012 and January 1, 2012
(in CHF)

| | NOTE | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|---|
| **ASSETS** | | | | |
| **Non-current assets** | | | | |
| Property and equipment | 7 | 195,915 | 124,496 | 1,987 |
| Intangible assets | 8 | 1,482,520 | 357,520 | 357,520 |
| **Total non-current assets** | | **1,678,435** | **482,016** | **359,507** |
| **Current assets** | | | | |
| Current financial assets | 5 | — | — | 72,850 |
| Other receivables | 9 | 524,786 | 235,449 | 110,453 |
| Prepayments | 10 | 183,137 | 84,325 | 68,666 |
| Cash and cash equivalents | 11 | 23,865,842 | 63,967 | 752,874 |
| **Total current assets** | | **24,573,765** | **383,741** | **1,004,843** |
| **Total assets** | | **26,252,200** | **865,757** | **1,364,350** |
| **EQUITY AND LIABILITIES** | | | | |
| **Equity** | | | | |
| Share capital | 12 | 6,487,130 | 4,632,580 | 4,632,580 |
| Share premium | | 35,608,210 | 13,341,942 | 10,006,179 |
| Treasury shares | 12 | — | — | -526,320 |
| Foreign currency translation reserve | | 53,995 | 22,275 | — |
| Accumulated deficit | | -33,115,689 | -18,240,831 | -13,639,857 |
| **Total shareholders’ equity attributable to owners of the Company** | | **9,033,646** | **-244,034** | **472,582** |
| **Non-current liabilities** | | | | |
| Employee benefits | 19 | 328,342 | 242,646 | 178,524 |
| Deferred tax liabilities | 21 | 327,637 | — | — |
| **Total non-current liabilities** | | **655,979** | **242,646** | **178,524** |
| **Current liabilities** | | | | |
| Convertible loans | 14 | 13,711,200 | — | — |
| Trade and other payables | 15 | 954,257 | 424,877 | 170,863 |
| Accrued expenses | 16 | 1,897,118 | 442,268 | 542,381 |
| **Total current liabilities** | | **16,562,575** | **867,145** | **713,244** |
| **Total liabilities** | | **17,218,554** | **1,109,791** | **891,768** |
| **Total equity and liabilities** | | **26,252,200** | **865,757** | **1,364,350** |

The notes form an integral part of these consolidated financial statements.

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**AURIS MEDICAL AG**

**Consolidated Statement of Changes in Equity**
For the Years Ended December 31, 2013 and 2012
(in CHF)

| | | ATTRIBUTABLE TO OWNERS OF THE COMPANY | | | | | |
|---|---|---|---|---|---|---|---|
| | NOTE | SHARE CAPITAL | SHARE PREMIUM | TREASURY SHARES | FOREIGN CURRENCY TRANSLATION RESERVE | ACCUMULATED DEFICIT | TOTAL EQUITY |
| **As of January 1, 2012** | | **4,632,580** | **10,006,179** | **-526,320** | **—** | **-13,639,857** | **472,582** |
| **Total comprehensive loss** | | | | | | | |
| Net loss | | — | — | — | — | -4,602,409 | -4,602,409 |
| Other comprehensive income (-loss) | | — | — | — | 22,275 | -54,577 | -32,302 |
| **Total comprehensive loss** | | **—** | **—** | **—** | **22,275** | **-4,656,986** | **-4,634,711** |
| **Transactions with owners of the Company** | | | | | | | |
| Additional paid-in capital | 12 | — | 3,335,763 | — | — | — | 3,335,763 |
| Share based payments | 13 | — | — | — | — | 56,013 | 56,013 |
| Treasury shares sold | 12 | — | — | 526,320 | — | — | 526,320 |
| **Balance at December 31, 2012** | | **4,632,580** | **13,341,942** | **—** | **22,275** | **-18,240,831** | **-244,034** |
| **Total comprehensive loss** | | | | | | | |
| Net loss | | — | — | — | — | -15,004,493 | -15,004,493 |
| Other comprehensive income (-loss) | | — | — | — | 31,720 | -57,716 | -25,996 |
| **Total comprehensive loss** | | **—** | **—** | **—** | **31,720** | **-15,062,209** | **-15,030,489** |
| **Transactions with owners of the Company** | | | | | | | |
| Issue of ordinary shares | 12 | 1,854,550 | 22,625,510 | — | — | — | 24,480,060 |
| Share issuance costs | 12 | — | -359,242 | — | — | — | -359,242 |
| Convertible loans - equity component | 14 | — | — | — | — | 99,038 | 99,038 |
| Convertible loans - deferred tax | 21 | — | — | — | — | -21,886 | -21,886 |
| Share based payments | 13 | | | | | 110,198 | 110,198 |
| **Balance at December 31, 2013** | | **6,487,130** | **35,608,210** | **—** | **53,995** | **-33,115,689** | **9,033,646** |

The notes form an integral part of these consolidated financial statements.

**AURIS MEDICAL AG**

**Consolidated Statement of Cash Flows**
For the Years Ended December 31, 2013 and 2012
(in CHF)

| | NOTE | 2013 | 2012 |
|---|---|---|---|
| **Cash flows from operating activities** | | | |
| **Net loss** | | **-15,004,493** | **-4,602,409** |
| Adjustments for: | | | |
| Depreciation | 7 | 37,517 | 9,242 |
| Unrealized exchange differences | | 32,076 | 20,920 |
| Net interest income | 20 | -23,859 | -5,825 |
| Share based payments | 13 | 110,198 | 56,013 |
| Employee benefits | | 27,980 | 9,545 |
| Income tax expense | 21 | 305,750 | — |
| | | -14,514,831 | -4,512,514 |
| Changes in: | | | |
| Other receivables | | -288,765 | -125,782 |
| Prepayments | | -98,812 | -15,659 |
| Trade and other payables | | 530,080 | 254,063 |
| Accrued expenses | | 328,719 | -98,575 |
| **Cash used in operating activities** | | **-14,043,609** | **-4,498,467** |
| **Cash flows from investing activities** | | | |
| Purchase of property and equipment | 7 | -108,936 | -131,751 |
| Sale of financial assets | 5 | — | 72,850 |
| Interest received | 20 | 74,036 | 5,825 |
| **Net cash used in investing activities** | | **-34,900** | **-53,076** |
| **Cash flows from financing activities** | | | |
| Proceeds from share capital increase | 12 | 24,120,818 | 3,335,762 |
| Proceeds from issue of convertible loans | 14 | 13,769,976 | — |
| Sale of treasury shares | 12 | — | 526,320 |
| Interest paid | 20 | -9,915 | — |
| **Net cash from financing activities** | | **37,880,879** | **3,862,082** |
| **Net increase/(decrease) in cash and cash equivalents** | | **23,802,370** | **-689,461** |
| Cash and cash equivalents at beginning of the period | 11 | 63,967 | 752,874 |
| Net effect of currency translation on cash | | -495 | 554 |
| **Cash and cash equivalents at end of the period** | **11** | **23,865,842** | **63,967** |

The notes form an integral part of these consolidated financial statements.

**AURIS MEDICAL AG**

**Notes to the Consolidated Financial Statements**
as at December 31, 2013, 2012 and January 1, 2012
and for the years ended December 31, 2013 and 2012 (in CHF)

## 1. Reporting entity

Auris Medical AG (the "Company") is domiciled in Switzerland. The Company's registered address is at Falknerstrasse 4, 4001 Basel. These consolidated financial statements comprise the Company and its subsidiaries (together referred to as the "Group" and individually as "Group entities"). The Company is the ultimate parent of the following Group entities:

- Auris Medical Inc., Chicago, United States (100%)
- Auris Medical Ltd., Dublin, Ireland (100%)

The Group is primarily involved in the development of pharmaceutical products for the treatment of inner ear disorders, in particular tinnitus and hearing loss. Its most advanced projects are in the late stage of clinical development.

## 2. Basis of preparation

***Statement of compliance***

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). These are the Group's first consolidated financial statements prepared in accordance with IFRSs; accordingly IFRS 1 *First-time Adoption of International Financial Reporting Standards* has been applied. The Group's date of transition to IFRS is January 1, 2012.

These consolidated financial statements were approved by the board of directors of Auris Medical AG on March 14, 2014.

An explanation of how the transition to IFRSs has affected the reported financial position, financial performance and cash flows of the Group is disclosed in Note 26.

***Basis of measurement***

The consolidated financial statements are prepared on the historical cost basis, except for the revaluation to fair value of certain financial assets and the net defined benefit liability which is measured at the present value of the defined benefit obligation less the fair value of plan assets as described in Note 3.

***Functional and reporting currency***

These consolidated financial statements are presented in Swiss Francs (CHF), which is the Company's functional ("functional currency") and the Group's reporting currency.

***Use of estimates and judgments***

The preparation of financial statements in conformity with IFRSs requires management to make judgments, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions of accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Information about judgments made in applying accounting policies that have the most significant effects on the amounts recognized in the consolidated financial statements are described below.

***Income taxes***

As disclosed in Note 21 the Group has significant tax losses in Switzerland. These tax losses represent potential value to the Group to the extent that the Group is able to create taxable profits in Switzerland within 7 years of the

end of the year in which the losses arose. The Group has also some tax losses in the United States which may be used within 20 years of the end of the year in which losses arose, respectively for a shorter time period in accordance with prevailing federal and state law. The Group has not recorded any deferred tax assets in relation to these tax losses. The key factors which have influenced management in arriving at this evaluation are the fact that the business is still in a development phase and the Group has not yet a history of making profits. Should management's assessment of the likelihood of future taxable profits change, a deferred tax asset will be recorded.

***Development expenditures***

The project stage forms the basis for the decision whether costs incurred for the Group's development projects can be capitalized or not. Generally clinical development expenditures are not capitalized until the Group obtains regulatory approval (i.e. approval to commercially use the product), as this is considered to be essentially the first point in time where it becomes probable that future revenues can be generated and the project becomes commercially successful. Given the current stage of the development projects, no development expenditures have yet been capitalized. The group has capitalized certain milestone payments with regard to license payments.

As of each reporting date, the Group estimates the level of service performed by the vendors and the associated costs incurred for the services performed. As part of the process of preparing the Group's financial statements, the Group is required to estimate its accrued expenses. This process involves reviewing contracts, identifying services that have been performed on the Group's behalf and estimating the level of service performed and the associated cost incurred for the service when it has not yet been invoiced or otherwise notified of the actual cost.

***Employee benefits***

The Group maintains a pension plan for all employees in Switzerland through payments to a legally independent collective foundation. This pension plan qualifies under IFRS as defined benefit pension plan. There are no pension plans for the subsidiaries in Ireland and the United States.

The Group's net obligation in respect of defined benefit plans is calculated by estimating the amount of future benefit that employees have earned in return for their service in the current and prior periods, discounting that amount and deducting the fair value of any plan assets.

The recognized asset is limited to the present value of economic benefits available in the form of any future refunds from the plan or reductions in future contributions to the plan. In order to calculate the present value of economic benefits, consideration is given to any minimum funding requirements.

Remeasurements of the net defined benefit liability, which comprise actuarial gains and losses, the return on plan assets (excluding interest) and the effect of the asset ceiling (if any, excluding interest), are recognized immediately in OCI. The Group determines the net interest expense (income) on the net defined benefit liability (asset) for the period by applying the discount rate used to measure the defined benefit obligation at the beginning of the annual period to the then-net defined benefit liability (asset), taking into account any changes in the net defined benefit liability (asset) during the period as a result of contributions and benefit payments. Net interest expense and other expenses related to defined benefit plans are recognized in profit or loss.

## 3. Significant accounting policies

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements and in preparing the opening IFRS statement of financial position at 1 January 2012 for the purposes of the transition to IFRSs, unless otherwise indicated.

The accounting policies have been applied consistently by Group entities thereafter.

***Basis of consolidation***

*Subsidiaries*

Subsidiaries are entities controlled by the Group. The Group controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases.

*Transactions eliminated on consolidation*

All inter-company balances, transactions and unrealized gains on transactions have been eliminated in consolidation. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred.

***Segment reporting***

A segment is a distinguishable component of the Group that engages in business activities from which it may earn revenues and incur expenses, including revenues and expenses that relate to transactions with any of the Group's other components.

The Chief Executive Officer is determined to be the Group's Chief Operating Decision Maker (CODM) of the Group. He assesses the performance and allocates the resources of the Group as a whole, as all of the Group's activities are focusing on the development of pharmaceutical products for the treatment of inner ear disorder. Financial information is only available for the Group as a whole. Therefore, management considers there is only one operating segment under the requirements of IFRS 8, Operating Segments.

***Foreign currency***

*Foreign currency transactions*

Items included in the financial statements of Group entities are measured using the currency of the primary economic environment in which the entity operates. Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in profit or loss. Non-monetary items that are measured based on historical cost in a foreign currency are not re-translated.

*Foreign operations*

Assets and liabilities of Group entities whose functional currency is other than CHF are included in the consolidation by translating the assets and liabilities into the reporting currency at the exchange rates applicable at the end of the reporting period. Income and expenses are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transaction).

Foreign currency differences are recognized in Other Comprehensive Income and presented in the foreign currency translation reserve in equity. When a foreign operation is disposed of such that control is lost, the cumulative amount in the translation reserve related to that foreign operation is reclassified to profit or loss as part of the gain or loss on disposal.

Closing rates for the most significant foreign currencies:

| CURRENCY | | GEOGRAPHICAL AREA | REPORTING ENTITIES | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|---|---|---|
| CHF | Swiss Franc | Switzerland | 1 | 1.0000 | 1.0000 | 1.0000 |
| USD | Dollar | United States | 1 | 0.8894 | 0.9154 | 0.9351 |
| EUR | Euro | Europe | 1 | 1.2255 | 1.2068 | 1.2139 |

Average exchange rates for the year for the most significant foreign currencies:

| CURRENCY | | GEOGRAPHICAL AREA | REPORTING ENTITIES | 2013 | 2012 |
|---|---|---|---|---|---|
| CHF | Swiss Franc | Switzerland | 1 | 1.0000 | 1.0000 |
| USD | Dollar | United States | 1 | 0.9391 | 0.9481 |
| EUR | Euro | Europe | 1 | 1.2414 | 1.2196 |

***Property and equipment***

Property and equipment is measured at historical costs less accumulated depreciation and any accumulated impairment losses. Historical costs include expenditures that are directly attributable to the acquisition of the items. When parts of an item of tangible assets have different useful lives, they are accounted for as separate tangible asset items (major components). Depreciation is calculated on a straight-line basis over the expected useful life of the individual asset or the shorter remaining lease term for leasehold improvements. The applicable estimated useful lives are as follows:

| | |
|---|---|
| Production equipment | 5 years |
| Office furniture and electronic data processing equipment ("EDP") | 3 years |
| Leasehold improvements | 5 years |

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost of the item can be measured reliably. The carrying amount of the replaced part is derecognized. All other repairs and maintenance are charged to profit or loss during the financial period in which they are incurred.

Depreciation methods, useful lives and residual values are reviewed at each reporting date and adjusted if appropriate. When an asset is reviewed for impairment, the asset's carrying amount may be written down immediately to its recoverable amount, provided the asset's carrying amount is greater than its estimated recoverable amount. Management assesses the recoverable amount by assessing the higher of its fair value less costs to sell or its value in use.

Cost and accumulated depreciation related to assets retired or otherwise disposed are removed from the accounts at the time of retirement or disposal and any resulting gain or loss is included in profit or loss in the period of disposition.

***Intangible assets***

*Research and development*

Expenditures on the research programs of the Group are not capitalized, they are expensed when incurred.

Expenditures on the Group's development programs are generally not capitalized except if development costs can be measured reliably, the product or process is technically and commercially feasible, future economic benefits are probable, and the Group intends to and has sufficient resources to complete development and to use or sell the asset. For the development projects of the Group, these criteria are generally only met when regulatory approval for commercialization is obtained. Given the current stage of the development projects, no development expenditures except certain milestone payments have yet been capitalized (see note on Development Expenditures). Intellectual property-related costs for patents are part of the expenditure for the research and development projects. Therefore, registration costs for patents are expensed when incurred as long as the research and development project concerned does not meet the criteria for capitalization.

*Licenses*

Intellectual property rights that are acquired by the Group are capitalized as intangible assets if they are controlled by the Group, are separately identifiable and are expected to generate future economic benefits, even if uncertainty exists as to whether the research and development will ultimately result in a marketable product. Consequently, upfront and milestone payments to third parties for the exclusive use of pharmaceutical compounds in specified areas of treatment are recognized as intangible assets.

*Measurement*

Intangible assets acquired that have finite useful lives are measured at cost less accumulated amortization and any accumulated impairment losses.

*Subsequent expenditure*

Subsequent expenditure is capitalized only when it increases the future economic benefits embodied in the specific asset to which it relates. All other expenditure, including expenditure on internally generated goodwill and brands, is recognized in profit or loss as incurred.

*Amortization*

All licenses of the group have finite lives. Amortization will start once the Group's intangible assets will be available for use. Amortization of licenses is calculated on a straight line basis over the period of the expected benefit or until the license expires, whichever is shorter. The estimated useful life is 10 years or the remaining term of patent protection. The Group assesses at each balance sheet date whether intangible assets which are not yet ready for use are impaired.

***Impairment of non-financial assets***

Property and equipment and intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). An impairment loss is recognized as the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell or value in use. Impairment losses are recognized in profit or loss. Assets that were previously impaired are reviewed for possible reversal of the impairment at each reporting date. Any increase in the carrying amount of an asset will be based on the depreciated historical costs had the initial impairment not been recognized.

***Financial instruments***

The Group classifies its financial assets in the following categories: loans and receivables and available-for-sale financial assets.

The Company classifies non-derivative financial liabilities as other liabilities.

*Recognition and derecognition of non-derivative financial assets and liabilities*

The Group initially recognizes loans and receivables and debt securities issued on the date when they are originated. All other financial assets and financial liabilities are initially recognized on the trade date.

The Group derecognizes a financial asset when the contractual rights to the cash flows from the asset expire, or it transfers the rights to receive the contractual cash flows in a transaction in which substantially all of the risks and rewards of ownership of the financial asset are transferred, or it neither transfers nor retains substantially all of the risks and rewards of ownership and does not retain control over the transferred asset. Any interest in such derecognized financial assets that is created or retained by the Group is recognized as a separate asset or liability.

The Group derecognizes a financial liability when its contractual obligations are discharged or cancelled, or expire.

Financial assets and financial liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Group has a legal right to offset the amounts and intends either to settle them on a net basis or to realize the asset and settle the liability simultaneously.

*Non-derivative financial assets and liabilities—measurement*

*Loans and receivables*

These are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. Loans and receivables are initially recognized at fair value plus any directly attributable transaction costs. Subsequent to initial recognition, they are measured at amortized cost using the effective interest method, less any impairment losses. Loans and receivables are mainly comprised of other receivables and cash and cash equivalents.

*Cash and cash equivalents*

The Group considers all short-term, highly liquid investments that are readily convertible into known amounts of cash and which are subject to an insignificant risk of changes in value with original maturities of three months or less at the date of the purchase to be cash equivalents.

*Available-for-sale financial assets*

Available-for-sale financial assets are non-derivatives that are either designated in this category or not classified in any of the other categories. They are included in non-current assets unless the investment matures or management intends to dispose of it within 12 months of the end of the reporting period. These assets are initially recognized at fair value plus any directly attributable transaction costs. Subsequent to initial recognition, they are measured at fair value and changes therein, other than impairment losses and foreign currency differences on debt instruments, are

recognized in OCI and accumulated in the fair value reserve. When these assets are derecognized, the gain or loss accumulated in equity is reclassified to profit or loss.

*Non-derivative financial liabilities - measurement*

Non-derivative financial liabilities are initially recognized at fair value less any directly attributable transaction costs. Subsequent to initial recognition, these liabilities are measured at amortized cost using the effective interest method.

*Share capital*

All shares of the Company are registered shares and classified as part of shareholders' equity. Incremental costs directly attributable to the issue of the Company's shares, net of any tax effects, are recognized as a deduction from equity. The Company has not paid any dividends since its inception and does not anticipate paying dividends in the foreseeable future.

*Repurchase and reissue of ordinary shares (treasury shares)*

When shares recognized as equity are repurchased, the amount of the consideration paid, which includes directly attributable costs, net of any tax effects, is recognized as a deduction from equity. Repurchased shares are classified as treasury shares and are presented in the treasury share reserve. When treasury shares are sold or reissued subsequently, the amount received is recognized as an increase in equity and the resulting surplus or deficit (calculated as the difference between initial cost and fair value) on the transaction is presented within share premium.

*Convertible loans*

The difference to the initial recognition value is recorded directly in equity as a transaction with a shareholder in its capacity as shareholder. Subsequent to initial recognition, the convertible loans are measured at amortized cost using the effective interest method.

***Impairment of non-derivative financial assets***

Financial assets are assessed at each reporting date to determine whether there is objective evidence of impairment.

Objective evidence that financial assets are impaired includes:

- default or delinquency by a debtor;
- indications that a debtor or issuer will enter bankruptcy;
- adverse changes in the payment status of borrowers or issuers;
- the disappearance of an active market for a security; or
- observable data indicating that there is measurable decrease in expected cash flows from a group of financial assets.

For an investment in an equity security, objective evidence of impairment includes a significant or prolonged decline in its fair value below its cost. Available-for-sale equity securities that have a market value of more than 20% below their original cost, or have a market value below their original cost for a sustained six-month period will be considered as impaired.

*Financial assets measured at amortized cost*

The Group considers evidence of impairment for these assets at an individual asset level. An impairment loss is calculated as the difference between an asset's carrying amount and the present value of the estimated future cash flows discounted at the asset's original effective interest rate. Losses are recognized in profit or loss and reflected in an allowance account. When the Group considers that there are no realistic prospects of recovery of the asset, the relevant amounts are written off. If the amount of impairment loss subsequently decreases and the decrease can be related objectively to an event occurring after the impairment was recognized, then the previously recognized impairment loss is reversed through profit or loss.

*Available-for-sale financial assets*

Impairment losses on available-for-sale financial assets are recognized by reclassifying the losses accumulated in the fair value reserve to profit or loss. The amount reclassified is the difference between the acquisition cost (net of any

principal repayment and amortization) and the current fair value, less any impairment loss previously recognized in profit or loss.

***Income tax***

Income tax expense comprises current and deferred tax. It is recognized in profit or loss except to the extent that it relates to a business combination, or items recognized directly in equity or in OCI.

*Current tax*

Current tax comprises the expected tax payable or receivable on the taxable income or loss for the year and any adjustment to tax payable or receivable in respect of previous years. It is measured using tax rates enacted or substantively enacted at the reporting date.

*Deferred tax*

Deferred income tax is recognized, using the balance sheet liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred tax is not recognized for:

- temporary differences on the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit or loss;
- temporary differences related to investments in subsidiaries to the extent that the Group is able to control the timing of the reversal of the temporary differences and it is probable that they will not reverse in the foreseeable future; and
- taxable temporary differences arising on the initial recognition of goodwill.

Deferred income tax is determined using tax rates and laws that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

Deferred tax assets and liabilities are offset only if certain criteria are met.

***Employee benefits***

The Group maintains a pension plan for all employees in Switzerland through payments to a legally independent collective foundation. This pension plan qualifies under IFRS as defined benefit pension plan. There are no pension plans for the subsidiaries in Ireland and the United States.

The Group’s net obligation in respect of defined benefit plans is calculated by estimating the amount of future benefit that employees have earned in return for their service in the current and prior periods, discounting that amount and deducting the fair value of any plan assets.

The recognized asset is limited to the present value of economic benefits available in the form of any future refunds from the plan or reductions in future contributions to the plan. In order to calculate the present value of economic benefits, consideration is given to any minimum funding requirements.

Remeasurements of the net defined benefit liability, which comprise actuarial gains and losses, the return on plan assets (excluding interest) and the effect of the asset ceiling (if any, excluding interest), are recognized immediately in OCI. Past service costs, including curtailment gains or losses, are recognized immediately in general and administrative expenses within the operating results. Settlement gains or losses are recognized in general and administrative expenses within the operating results. The Group determines the net interest expense (income) on the net defined benefit liability (asset) for the period by applying the discount rate used to measure the defined benefit obligation at the beginning of the annual period or in case of any significant events between measurement dates to the then-net defined benefit liability (asset), taking into account any changes in the net defined benefit liability (asset) during the period as a result of contributions and benefit payments. Net interest expense and other expenses related to defined benefit plans are recognized in profit or loss.

***Share-based compensation***

The Group maintains various share-based payment plans in the form of stock option plans for its employees, members of the board of directors as well as key service providers. Stock options are granted at the Board's discretion without any contractual or recurring obligations.

The share-based compensation plans qualify as equity settled plans. The grant-date fair value of share-based payment awards granted to employees is recognized as an expense, with a corresponding increase in equity, over the period that the employees become unconditionally entitled to the awards. The vesting of share options is conditional on the employee completing a period of service of three and four years respectively in accordance with Stock Option Plans A and C. Stock Option Plan B was created to provide shares for share based compensation plans; it was used in the years 2008 and 2009 and is still in force. However, no options are currently outstanding under Stock Option Plan B.

The amount recognized as an expense is adjusted to reflect the number of awards for which the related service and non-market performance conditions are expected to be met, such that the amount ultimately recognized as an expense is based on the number of awards that meet the related service and non-market performance conditions at the vesting date. Share-based payments that are not subject to any further conditions are expensed immediately at grant date. In the year the options are exercised the proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

***Provisions***

Provisions are recognized when the Group has a present obligation (legal or constructive) as a result of a past event, where it is more likely than not that an outflow of resources will be required to settle the obligation, and where a reliable estimate can be made of the amount of the obligation. Provisions are not recognized for future operating losses. Provisions are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The unwinding of the discount is recognized as finance cost.

***Leases***

Leases in which a significant portion of the risks and rewards of ownership are retained by the lessor are classified as operating leases. Payments made under operating leases (net of any incentives received from the lessor) are charged to profit or loss on a straight-line basis over the period of the lease.

***Earnings/(loss) per share***

Basic earnings/(loss) per share are calculated by dividing the net profit/(loss) attributable to shareholders of the parent company by the weighted average number of shares outstanding during the period. Diluted earnings/(loss) per share are calculated by dividing the net profit/(loss) attributable to the shareholders of the parent company by the weighted average number of shares outstanding during the period adjusted for the conversion of all dilutive potential ordinary shares.

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## 4. New standards and interpretations not yet adopted

A number of new standards, amendments to standards and interpretations are effective for annual periods beginning after January 1, 2013, and have not been applied in preparing these consolidated financial statements.

| STANDARD/INTERPRETATION | | IMPACT | EFFECTIVE DATE | PLANNED APPLICATION BY THE GROUP |
|---|---|---|---|---|
| *New standards, interpretations or amendments* | | | | |
| IAS 32 | Offsetting Financial Assets and Financial Liabilities (Amendments) | 1) | January 1, 2014 | Reporting year 2014 |
| IFRS 10<br>IFRS 12<br>IAS 27 | Investment Entities (Amendments) | 1) | January 1, 2014 | Reporting year 2014 |
| IAS 36 | Recoverable Amount Disclosures for Non-Financial Assets (Amendments) | 1) | January 1, 2014 | Reporting year 2014 |
| IAS 39 | Novation of Derivatives and Continuation of Hedge Accounting (Amendments) | 1) | January 1, 2014 | Reporting year 2014 |
| IFRIC 21 | Levies | 1) | January 1, 2014 | Reporting year 2014 |
| IAS 19 | Employee Contributions (Amendments) | 1) | July 1, 2014 | Reporting year 2015 |
| Various | Annual Improvements to IFRSs 2010-2012 Cycle | 1) | July 1, 2014 | Reporting year 2015 |
| Various | Annual Improvements to IFRSs 2011-2013 Cycle | 1) | July 1, 2014 | Reporting year 2015 |
| IFRS 9 | Financial Instruments | 2) | January 1, 2017 at the earliest | To be determined |

1) No or no significant impacts are expected on the consolidated financial statements of the Group.
2) The impact on the consolidated financial statements of Group cannot yet be determined with sufficient reliability.

## 5. Financial instruments and risk management

The following table shows the carrying amounts of financial assets and financial liabilities:

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| **Financial assets** | | | |
| **Available for sale** | | | |
| Current financial assets | — | — | 72,850 |
| **Loans and receivables** | | | |
| Cash and cash equivalents | 23,865,842 | 63,967 | 752,874 |
| Other receivables | 451,206 | 141,589 | 9,902 |
| **Total financial assets** | **24,317,048** | **205,556** | **835,626** |
| **Financial liabilities** | | | |
| **at amortized cost** | | | |
| Convertible loans from shareholders | 13,711,200 | — | — |
| Trade and other accounts payable | 954,257 | 424,877 | 170,863 |
| Accrued expenses | 1,871,598 | 424,997 | 523,427 |
| **Total financial liabilities** | **16,537,055** | **849,874** | **694,290** |

***Fair values***

Current financial assets as at January 1, 2012, consisted of an unconsolidated minority investment in the company Xigen SA, Lausanne. The investment was valued at its fair value based on the sales price which was negotiated with Xigen's majority shareholder, in view of a sale in early 2012 (Level 2 in fair value measurement hierarchy).

The carrying amount of cash and cash equivalents, other receivables, trade and other payables and accrued expenses is a reasonable approximation of their fair value.

The fair value of any other financial assets and liabilities for disclosure purposes is estimated by discounting the future contractual cash flows at the current market interest rate that is available to the Group for similar financial instruments.

***Financial risk factors***

The Group's activities expose it to a variety of financial risks: market risk, credit risk, liquidity risk. The Group's overall risk management program focuses on the unpredictability of financial markets and seeks to minimize potential adverse effects on the Group's financial performance. Management identifies, evaluates and controls financial risks. No financial derivatives have been used in 2013 and 2012 to hedge risk exposures. The Group invests its available cash in instruments with the main objectives of preserving principal, meeting liquidity needs and minimizing foreign exchange risks. The Group allocates its liquid assets to first tier Swiss or international banks with an S&P credit rating of at least A.

***Liquidity risk***

The Group's principal source of liquidity is its cash reserves which are mainly obtained through the issue of new shares. The Group has succeeded in raising capital to fund its development activities to date and has raised funds that will allow it to meet short term development expenditures. The Company will require regular capital injections to continue its development work, which may be dependent on meeting development milestones, technical results and/or commercial success. Management monitors rolling forecasts of the Group's liquidity requirements to ensure it has sufficient cash to meet operational needs. The ability of the Group to maintain adequate cash reserves to sustain its activities in the medium term is highly dependent on the Group's ability to raise further funds. Consequently, the Group is exposed to continued liquidity risk.

The table below analyses the remaining contractual maturities of financial liabilities, including estimated interest payments as at reporting. The amounts disclosed in the table are the undiscounted cash flows:

| | CARRYING AMOUNT | LESS THAN 3 MONTHS | BETWEEN 3 MONTHS AND 2 YEARS | 2 YEARS AND LATER | TOTAL |
|---|---|---|---|---|---|
| **December 31, 2013** | | | | | |
| Convertible loans from shareholders | 13,711,200 | 13,769,976 | — | — | 13,769,976 |
| Trade and other accounts payable | 954,257 | 954,257 | — | — | 954,257 |
| Accrued expenses | 1,871,598 | 1,871,598 | — | — | 1,871,598 |
| **Total** | **16,537,055** | **16,595,831** | **—** | **—** | **16,595,831** |

| | CARRYING AMOUNT | LESS THAN 3 MONTHS | BETWEEN 3 MONTHS AND 2 YEARS | 2 YEARS AND LATER | TOTAL |
|---|---|---|---|---|---|
| **December 31, 2012** | | | | | |
| Trade and other accounts payable | 424,877 | 424,877 | — | — | 424,877 |
| Accrued expenses | 424,997 | 424,997 | — | — | 424,997 |
| **Total** | **849,874** | **849,874** | **—** | **—** | **849,874** |

| | CARRYING AMOUNT | LESS THAN 3 MONTHS | BETWEEN 3 MONTHS AND 2 YEARS | 2 YEARS AND LATER | TOTAL |
|---|---|---|---|---|---|
| **January 1, 2012** | | | | | |
| Trade and other accounts payable | 170,863 | 170,863 | — | — | 170,863 |
| Accrued expenses | 523,427 | 523,427 | — | — | 523,427 |
| **Total** | **694,290** | **694,290** | **—** | **—** | **694,290** |

***Credit risk***

Credit risk is managed on a Group basis. Credit risk arises from cash and cash equivalents and deposits with banks, as well as from other receivables. The Company's policy is to invest funds in low risk investments including interest bearing deposits. For banks and financial institutions, only independently rated parties with a minimum rating of "A" are accepted. Receivables were current as of December 31, 2013 and December 31, 2012, not impaired and included only well-known counterparties.

The Group has been holding cash and cash equivalents in the Group's principal operating currencies (CHF, USD and EUR) with international banks of high credit rating.

The Group's maximum exposure to credit risk is represented by the carrying amount of each financial asset in the consolidated statement of financial position:

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| **Financial assets** | | | |
| Cash and cash equivalents | 23,865,842 | 63,967 | 752,874 |
| Other receivables | 451,206 | 141,589 | 9,902 |
| **Total** | **24,317,048** | **205,556** | **762,776** |

As of December 31, 2013 and December 31, 2012 other receivables consisted of advance payments to supplier as well as claims for reimbursement of value added and withholding taxes (see Note 9).

***Market risk***

*Currency risk*

The Group operates internationally and is exposed to foreign exchange risk arising from various exposures, primarily with respect to US Dollar and Euro. Foreign exchange risk arises from future commercial transactions, recognized assets and liabilities and net investments in foreign operations. To manage foreign exchange risk Management maintains foreign currency cash balances to cover anticipated future purchases of materials and services in foreign currencies.

The summary of quantitative data about the exposure of the Group's financial assets and liabilities to currency risk was as follows:

| | 2013 | | 2012 | |
|---|---|---|---|---|
| **in CHF** | **USD** | **EUR** | **USD** | **EUR** |
| Prepayments | 11,321 | 112,133 | — | — |
| Other receivables | 145,636 | 273,438 | — | 143,835 |
| Cash and cash equivalents | 4,267,768 | 2,309,318 | 8,475 | 9,513 |
| Trade and other accounts payable | 334,896 | 502,645 | 15,746 | 287,520 |
| Accrued expenses | 219,304 | 435,046 | 38,194 | 247,785 |
| **Net statement of financial position exposure - asset/(liability)** | **3,870,525** | **1,757,198** | **-45,465** | **-381,957** |

As at December 31, 2013, a 5% increase or decrease in the USD/CHF exchange rate with all other variables held constant would have resulted in a CHF 175,115 (2012: CHF 2,081) increase or decrease in the net result. Also, a 5% increase or decrease in the EUR/CHF exchange rate with all other variables held constant would have resulted in a CHF 107,672 (2012: CHF 23,047) increase or decrease in the net result.

The Company has subsidiaries in the United States and Ireland, whose net assets are exposed to foreign currency translation risk. Due to the small size of the subsidiaries the translation risk is not significant.

*Interest rate risk*

In the period under review, the Group had no borrowings at variable interest rates. The Group had no fixed rate financial liabilities at fair value through profit or loss and no derivatives. Therefore a change in interest rates at the end of the reporting period would not affect profit or loss.

The only variable interest-bearing financial asset of the Group is cash at banks. As at December 31, 2013 an increase or decrease in interest rates by 50 basis points with all other variables held constant would have resulted in a CHF 119,329 (2012: CHF 320) increase or decrease in the net result.

*Other market price risk*

Following the sale of its minority stake in Xigen, the Group is not exposed to equity price risk or commodity price risk as it does not invest in these classes of investment.

***Capital risk management***

The Company and its subsidiaries are subject to capital maintenance requirements under local law in the country in which it operates. To ensure that statutory capital requirements are met, the Company monitors capital, at the entity level, on an interim basis as well as annually. From time to time the Company may take appropriate measures or propose capital increases to ensure the necessary capital remains intact.

## 6. Segment information

***Geographical information***

The Group's non-current assets by the Company's country of domicile were as follows:

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Switzerland | 1,678,435 | 482,016 | 359,507 |
| **Total** | **1,678,435** | **482,016** | **359,507** |

Non-current assets exclude financial instruments.

## 7. Property and Equipment

| | PRODUCTION EQUIPMENT | OFFICE FURNITURE AND EDP | LEASEHOLD IMPROVEMENTS | TOTAL |
|---|---|---|---|---|
| **At cost** | | | | |
| **As at January 1, 2012** | **—** | **75,240** | **—** | **75,240** |
| Additions | 123,330 | 8,421 | — | 131,751 |
| **As at December 31, 2012** | **123,330** | **83,661** | **—** | **206,991** |
| Additions | 43,420 | 48,384 | 17,132 | 108,936 |
| **As at December 31, 2013** | **166,750** | **132,045** | **17,132** | **315,927** |
| **Accumulated depreciation** | | | | |
| **As at January 1, 2012** | **—** | **-73,253** | **—** | **-73,253** |
| Charge for the year | -5,787 | -3,455 | — | -9,242 |
| **As at December 31, 2012** | **-5,787** | **-76,708** | **—** | **-82,495** |
| Charge for the year | -25,575 | -9,580 | -2,362 | -37,517 |
| **As at December 31, 2013** | **-31,362** | **-86,288** | **-2,362** | **-120,012** |
| **Net book value** | | | | |
| **As at January 1, 2012** | **—** | **1,987** | **—** | **1,987** |
| **As at December 31, 2012** | **117,543** | **6,953** | **—** | **124,496** |
| **As at December 31, 2013** | **135,388** | **45,757** | **14,770** | **195,915** |

As at December 31, 2013, 2012 and January 1, 2012 no items of property and equipment were pledged.

## 8. Intangible assets

| | LICENSES | TOTAL |
|---|---|---|
| **At cost** | | |
| **As at January 1, 2012** | **357,520** | **357,520** |
| **As at December 31, 2012** | **357,520** | **357,520** |
| Additions | 1,125,000 | 1,125,000 |
| **As at December 31, 2013** | **1,482,520** | **1,482,520** |
| **Accumulated amortization and impairment losses** | | |
| **As at January 1, 2012** | **—** | **—** |
| **As at December 31, 2012** | **—** | **—** |
| **As at December 31, 2013** | **—** | **—** |
| **Net book value** | | |
| **As at January 1, 2012** | **357,520** | **357,520** |
| **As at December 31, 2012** | **357,520** | **357,520** |
| **As at December 31, 2013** | **1,482,520** | **1,482,520** |

Intangible assets comprise upfront and milestone payments related to licenses. In 2013 a milestone payment of CHF 1,125,000 related to the AM-111 program was recorded.

Amortization will start once the intangible assets will be available for use, which will be the case after regulatory approval has been obtained and the related product will be available for use.

No amortization or impairment was recorded in 2013 and 2012.

## 9. Other receivables

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Advance payments to suppliers | 413,169 | 110,422 | — |
| Value added tax receivable (VAT) | 47,714 | 91,897 | 97,225 |
| Withholding tax receivable | 25,866 | 1,963 | 3,326 |
| Deposit for rent | 38,037 | 9,233 | 9,214 |
| Other receivables from third parties | — | 21,934 | 688 |
| **Total other receivables** | **524,786** | **235,449** | **110,453** |

Other receivables were not considered impaired in the years under review.

## 10. Prepayments

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Clinical projects | 114,076 | 67,158 | 46,900 |
| Insurance, social charges | 26,773 | 16,842 | 21,377 |
| Capital taxes | 32,910 | — | — |
| Other prepayments | 9,378 | 325 | 389 |
| **Total prepayments** | **183,137** | **84,325** | **68,666** |

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## 11. Cash and cash equivalents

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Cash in bank accounts | 23,865,165 | 63,020 | 752,338 |
| Petty cash | 677 | 947 | 536 |
| **Total cash and cash equivalents** | **23,865,842** | **63,967** | **752,874** |

## 12. Capital and reserves

***Share capital***

As of January 1, 2012, the share capital amounted to CHF 4,632,580, divided into 463,258 shares at a nominal value of CHF 10.00 each. Effective December 27, 2013, the nominal value of all shares was reduced from CHF 10.00 to CHF 0.40 each by way of a stock split 25:1. All shares are fully paid in.

Beside common shares, the Company had also preferred shares outstanding. Preferred shares have the same voting rights as common shares but enjoy a liquidation preference: in 2012, the Company had Series A and Series B preferred shares outstanding; in 2013 Series C preferred shares were issued. Series C shares carry a liquidation preference senior to Series B shares, which carry a liquidation preference senior to Series A shares, which in turn carry a liquidation preference to common shares.

All disclosed numbers and nominal value of shares in these financial statements are adjusted for the 25:1 stock split effected in December 2013 unless otherwise indicated.

The issued share capital of Auris Medical AG at December 31, 2013 consisted of:

| | NUMBER | CHF |
|---|---|---|
| Common shares with a nominal value of CHF 0.40 each | 72,600 | 29,040 |
| Preferred shares Series A with a nominal value of CHF 0.40 each | 5,999,750 | 2,399,900 |
| Preferred shares Series B with a nominal value of CHF 0.40 each | 5,509,100 | 2,203,640 |
| Preferred shares Series C with a nominal value of CHF 0.40 each | 4,636,375 | 1,854,550 |
| **Total, as at December 31, 2013** | **16,217,825** | **6,487,130** |

| | COMMON SHARES (NUMBER) | | PREFERRED SHARES (NUMBER) | |
|---|---|---|---|---|
| | 2013 | 2012 | 2013 | 2012 |
| As of January 1 | 72,600 | 72,600 | 11,508,850 | 11,508,850 |
| Shares issued for cash | — | — | 4,636,375 | — |
| **As at December 31** | **72,600** | **72,600** | **16,145,225** | **11,508,850** |

*Issue of preferred shares*

In 2011, the Company increased its share capital by CHF 421,140 through the issuance of 1,052,850 preferred shares Series B at an issue price of CHF 4.80 per share. One third of the issue price (nominal CHF 0.40 and premium CHF 1.20 per share) was paid in in 2011, the second third (CHF 1.60 premium per share) in March 2012 and the final third (CHF 1.60 premium per share) in June 2012. Total proceeds in 2012 were CHF 3,369,120 less CHF 33,358 in transaction costs. 328,950 of the newly issued preferred Series B shares were held in treasury at January 1, 2012 and sold to existing and new shareholders during 2012.

In April 2013, the shareholders approved the issue of 4,636,375 preferred shares Series C at an issue price of CHF 5.28 per share. All issued Series C shares were fully paid in.

In the event of an initial public offering, all of the outstanding preferred shares will convert into common shares.

*Authorized share capital*

In April 2013, the shareholders approved an extension and increase of the authorized capital of the Company. The Board is authorized to increase the share capital at any time until April 5, 2015 by the maximum amount of CHF 1,715,450 by issuing not more than 4,288,625 registered preferred shares Series C with a nominal value of CHF 0.40 each. The shares will have to be fully paid-in and have preference rights of Series C shares as described above. Please also refer to Note 25 (Events after the balance sheet date).

*Conditional share capital*

The share capital may be increased by the issuance of up to 927,650 fully paid registered Common Shares with a nominal value of CHF 0.40 per share and to the maximum amount of CHF 371,060 in execution of subscription rights, which may be granted to employees, members of the board of directors as well as key service providers (see Note 13 for further reference). The amount of the conditional capital remained unchanged in 2012 and 2013.

*Treasury shares*

The reserve for treasury shares comprises the cost of the Group's shares held by the Group. At December 31, 2013 and 2012 the Group did not hold any treasury shares. At January 1, 2012 the Group held 328,950 preferred shares Series B in treasury which were sold during 2012.

## 13. Share based compensation

***Description***

On November 21, 2008, one of the Group's entities established a share option program (Stock Option Plans A and B) for employees, members of the board of directors as well as key service providers to purchase shares in the Company. Plan A was amended and superseded by an updated version effective November 24, 2009, and replaced with amendments by Plan C for any future option grants effective April 5, 2013. Grants under Plan A and subsequently under Plan C were offered in each year with vesting periods of three and four years; grants under Plan B were made in 2008 and 2009 only. In accordance with these programs, holders of vested options are entitled to purchase common shares of Auris Medical AG at an exercise price equal to the value per share at the most recent financing round. All options are to be settled by the physical delivery of shares.

The key terms and conditions related to the grants under these programs are as follows:

| GRANT DATE / PLAN | NUMBER OF INSTRUMENTS (1) | VESTING CONDITIONS | CONTRACTUAL LIFE OF OPTIONS |
|---|---|---|---|
| **Stock option plan A** | | 3 years' service from grant date | 5 years |
| November 21, 2008 | 42,500 | | |
| April 28, 2009 | 3,000 | | |
| November 24, 2009 | 22,500 | | |
| April 26, 2010 | 8,500 | | |
| November 25, 2010 | 22,500 | | |
| April 27, 2011 | 16,250 | | |
| November 24, 2011 | 23,750 | | |
| April 23, 2012 | 16,250 | | |
| June 29, 2012 | 2,500 | | |
| October 19, 2012 | 5,000 | | |
| November 23, 2012 | 23,750 | | |
| January 1, 2013 | 50,000 | | |
| | **236,500** | | |
| **Stock option plan B** | | None | 3 months |
| November 21, 2008 | 34,375 | | |
| November 24, 2009 | 37,975 | | |
| | **72,350** | | |
| **Stock option plan C** | | 4 years'service from grant date | 6 years |
| September 24, 2013 | 21,250 | | |
| November 26, 2013 | 55,000 | | |
| | **76,250** | | |

(1) Number of instruments adjusted for the increase in the number of issued shares resulting from the 25:1 stock split in December 2013.

***Measurement of fair values***

The fair value of the options was measured based on the Black-Scholes formula.

| | STOCK OPTION PLAN | | |
|---|---|---|---|
| | PLAN C 2013 | PLAN A 2013 | PLAN A 2012 |
| Fair value at grant date | 3.03 | 2.43 | 2.43 |
| Share price at grant date | 5.28 | 4.80 | 4.80 |
| Exercise price | 5.28 | 4.80 | 4.80 |
| Expected volatility | 78% | 78% | 78% |
| Expected life | 4 years | 3 years | 3 years |
| Expected dividends | — | — | — |
| Risk-free interest rate | 1.0% | 1.0% | 0.7% |

The risk free interest rate was based on the average yield of published 10 year Swiss Federal Bonds in the reporting year. We have historically been a private company and lack company-specific historical and implied volatility information. Therefore, we estimate our expected volatility based on comparable public company data.

The total expenses recognized for equity-settled share-based payment transactions were CHF 56,013 in 2012 and CHF 110,198 in 2013.

The number and weighted average exercise prices of options under the share option program are as follows:

| | 2013 | | | 2012 | | |
|---|---|---|---|---|---|---|
| | NUMBER OF OPTIONS | WEIGHTED AVERAGE EXERCISE PRICE | WEIGHTED AVERAGE REMAINING TERM (Y) | NUMBER OF OPTIONS | WEIGHTED AVERAGE EXERCISE PRICE | WEIGHTED AVERAGE REMAINING TERM (Y) |
| Outstanding at January 1 | 146,500 | 3.66 | 3.29 | 109,000 | 3.20 | 3.70 |
| Forfeited during the year | — | — | — | -10,000 | 4.00 | — |
| Exercised during the year | — | — | — | — | — | — |
| Granted during the year | 126,250 | 5.09 | 5.24 | 47,500 | 4.80 | 4.77 |
| **Outstanding at December 31** | **272,750** | 4.32 | 3.64 | **146,500** | 3.66 | 3.29 |
| Exercisable at December 31 | 69,000 | 3.20 | 1.12 | 38,000 | 3.20 | 1.60 |

## 14. Convertible loans

On December 9, 2013, the Company issued non-interest bearing convertible loans to two shareholders with a nominal value of CHF 13,769,976 and a maximum term of 12 months. Between January 10 and January 17, 2014, the lenders as well as the Company have the right to convert the loans into new registered Series C shares with nominal value of CHF 0.40 each for CHF 5.28 per share. In case of non-conversion, the Company has the right to repay the convertible loans any time after February 1, 2014, and the obligation to repay them at the latest December 8, 2014.

The fair value of the convertible loans, recorded at initial recognition in “current liabilities,” was calculated using a market interest rate for an equivalent non-convertible loan (5% p.a.). The residual amount, representing the difference between the fair value and nominal value, is included in shareholders’ equity as a transaction with a shareholder in its capacity as shareholder.

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Convertible loan notes recognized in the balance sheet are calculated as follows:

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Nominal value of the convertible loans | 13,769,976 | — | — |
| Difference to fair value, recognized in equity | -99,038 | — | — |
| **Fair value on initial recognition** | **13,670,938** | **—** | **—** |
| Imputed interest expense | 40,262 | | |
| **Convertible loans at December 31** | **13,711,200** | **—** | **—** |

## 15. Trade and other payables

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Trade accounts payable - third parties | 946,215 | 410,065 | 145,431 |
| Other accounts payable | 8,042 | 14,812 | 25,432 |
| **Total trade and other payables** | **954,257** | **424,877** | **170,863** |

## 16. Accrued expenses

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Accrued research and development costs including milestone payments | 1,791,638 | 350,041 | 507,336 |
| Professional fees | 57,950 | 14,600 | 420 |
| Accrued Vacation & Overtime | 25,520 | 17,271 | 18,954 |
| Board of directors fees | 9,836 | 3,500 | 3,500 |
| Social security | 10,700 | 23,590 | 5,315 |
| Other accrued expenses | 1,474 | 33,266 | 6,856 |
| **Total accrued expenses** | **1,897,118** | **442,268** | **542,381** |

## 17. Research and development expense

| | 2013 | 2012 |
|---|---|---|
| Pre-clinical projects | 2,078,407 | 297,960 |
| Clinical projects | 8,753,398 | 1,687,368 |
| Drug manufacturing and substance | 1,036,152 | 915,368 |
| Employee benefits | 1,074,398 | 770,124 |
| Lease expenses | 74,065 | 35,556 |
| Patents and trademarks | 100,702 | 53,473 |
| Regulatory projects | 106,325 | 219,106 |
| Depreciation tangible assets | 30,191 | 7,736 |
| **Total research and development expense** | **13,253,638** | **3,986,691** |

### 18. General and administrative expense

| | 2013 | 2012 |
|---|---|---|
| Employee benefits | 195,739 | 116,251 |
| Business development | 479,027 | 86,231 |
| Travel expenses | 77,616 | 9,551 |
| Administration costs | 556,445 | 375,155 |
| Lease expenses | 3,968 | 2,340 |
| Depreciation tangible assets | 7,326 | 1,506 |
| Capital tax expenses | 42,090 | 32,778 |
| **Total general and administrative expenses** | **1,362,211** | **623,812** |

### 19. Employee benefits

| | 2013 | 2012 |
|---|---|---|
| Salaries | 836,686 | 711,883 |
| Pension costs | 78,917 | 50,046 |
| Other social benefits | 71,878 | 39,921 |
| Share option cost | 110,198 | 56,013 |
| Other employee cost | 172,458 | 28,512 |
| **Total employee benefits** | **1,270,137** | **886,375** |

***Benefit plans***

The Company participates in a retirement plan (the "Plan") organized through an affiliation to an independent collective foundation, that covers all of its employees in Switzerland including Management. The collective foundation is governed by foundation board. The board is made up of an equal number of employee and employer representatives of the different affiliated companies. The Company has no direct influence on the investment strategy of the collective foundation. Moreover, certain elements of the employee benefits are defined in the same way for all affiliated companies. This is mainly related to the annuity factors at retirement and to the interest allocated on the retirement savings. The employer itself cannot determine the benefits or how they are financed directly. The foundation board of the collective foundation is responsible for defining the investment strategy, for making changes to the pension fund regulations and in particular also for defining the financing of the pension benefits.

The old age benefits are based on retirement savings for each employee. To the retirement savings the annual retirement credits and the interest will be credited (there is no possibility to credit negative interest). At retirement age, the insured members can choose whether to take a pension for life, which includes a spouse's pension, or a lump sum. In addition to retirement benefits, the plans benefits also include disability and death benefits. Insured members may also buy into the scheme to improve their pension provision up to the maximum amount permitted under the rules of the plan and may withdraw funds early for the purchase of a residential property for their own use subject to limitations under Swiss law. On leaving the company, the retirement savings will be transferred to the pension institution of the new employer or to a vested benefits institution. This type of benefit may result in pension payments varying considerably between individual years. In defining the benefits, the minimum requirements of the Swiss Law on Occupational Retirement, Survivors and Disability Pension Plans (BVG) and its implementing provisions must be observed. The BVG defines the minimum pensionable salary and the minimum retirement credits. In Switzerland, the minimum interest rate applicable to these minimum retirement savings is set by the Swiss Federal Council at least once every two years. In 2013 and 2012 the rate was 1.5%.

The assets are invested by the collective foundation in a diversified portfolio that respects the requirements of the Swiss BVG. Under the Plan, both the Company and the employee share the costs equally. The structure of the plan

and the legal provisions of the BVG mean that the employer is exposed to actuarial risks. The main risks are investment risk, interest risk, disability risk and the risk of longevity. Through the affiliation to a collective foundation, the Company has minimized these risks, since they are shared between a much greater number of participants.

The following tables present information about the net defined benefit liability and its components:

***Change in defined benefit obligation***

| | 2013 | 2012 |
|---|---|---|
| Defined benefit obligation at January 1 | 1,030,145 | 658,061 |
| Service cost | 72,803 | 45,036 |
| Plan participants' contribution | 50,937 | 40,501 |
| Interest cost | 23,133 | 17,730 |
| Actuarial losses | 136,933 | 107,438 |
| Benefits paid | -107,303 | -15,318 |
| Transfer-in amounts of new employees | 419,593 | 176,697 |
| **Defined benefit obligation at December 31** | **1,626,241** | **1,030,145** |

The defined benefit obligation includes only liabilities for active employees. The weighted average modified duration of the defined benefit obligation at December 31, 2013 is 19.9 years (2012: 20.5 years).

***Change in fair value of plan assets***

| | 2013 | 2012 |
|---|---|---|
| Fair value of plan assets at January 1 | 787,499 | 479,537 |
| Interest income | 19,394 | 14,417 |
| Return on plan assets excl. interest income | 79,217 | 52,861 |
| Employer contributions | 50,937 | 40,501 |
| Plan participants' contributions | 50,937 | 40,501 |
| Benefits paid | -107,303 | -15,318 |
| Transfer-in amounts of new employees | 419,593 | 176,697 |
| Administration expense | -2,375 | -1,697 |
| **Fair value of plan assets at December 31** | **1,297,899** | **787,499** |

***Net defined benefit liability recognized in the balance sheet***

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Present value of funded defined benefit obligation | 1,626,241 | 1,030,145 | 658,061 |
| Fair value of plan assets | -1,297,899 | -787,499 | -479,537 |
| **Net defined benefit liability** | **328,342** | **242,646** | **178,524** |

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***Major asset categories***

| | 2013 | 2012 |
|---|---|---|
| Equities | 485,414 | 274,837 |
| Bonds | 476,329 | 306,337 |
| Real estate | 138,875 | 107,100 |
| Alternative investments | — | 1,575 |
| Cash | 197,281 | 97,650 |
| **Total** | 1,297,899 | 787,499 |

Substantially all equities, bonds and investments in real estate funds (included in real estate) have quoted market prices in active markets.

***Defined Benefit Cost***

| | 2013 | 2012 |
|---|---|---|
| Service cost | 72,803 | 45,036 |
| Net interest expense | 3,739 | 3,313 |
| Administration expense | 2,375 | 1,697 |
| **Total defined benefit cost for the year recognized in profit or loss** | **78,917** | **50,046** |

***Remeasurements of the Defined Benefit Liability***

| | | |
|---|---|---|
| Actuarial (gain)/loss arising from changes in financial assumptions | -44,737 | 49,754 |
| Actuarial (gain)/loss arising from experience adjustments | 181,670 | 57,684 |
| Return on plan assets excluding interest income | -79,217 | -52,861 |
| **Total defined benefit cost for the year recognized in Other comprehensive income (OCI)** | **57,716** | **54,577** |

In 2014, the Group expects to contribute approximately CHF 144,000 to the Plan.

***Assumptions***

| AT DECEMBER 31 | 2013 | 2012 |
|---|---|---|
| Discount rate | 2.20% | 1.95% |
| Future salary increase | 1.50% | 1.50% |
| Pension indexation | 0.00% | 0.00% |
| Mortality and disability rates | BVG 2010G | BVG 2010G |

***Sensitivity analysis***

Reasonably possible changes at the reporting date to one of the relevant actuarial assumptions, holding other assumptions constant, would have affected the defined benefit obligation by the amounts shown below.

| DECEMBER 31, 2013 | | |
|---|---|---|
| Change in assumption | 0.25% increase | 0.25% decrease |
| Discount rate | -63,257 | 68,928 |
| Salary increase | 12,747 | -12,423 |
| Pension indexation | 36,784 | N/A |
| Change in assumption | +1 year | -1 year |
| Life expectancy | 24,623 | -25,305 |

## 20. Finance income and finance expense

| | 2013 | 2012 |
|---|---|---|
| Interest income | 74,036 | 5,825 |
| Investment income | — | 1,216 |
| Net foreign exchange gain | 1,711 | 2,853 |
| **Total finance income** | **75,747** | **9,894** |
| Interest expense related parties | 50,177 | — |
| Bank charges | 2,454 | 1,800 |
| Net foreign exchange loss | 106,010 | — |
| **Total finance expense** | **158,641** | **1,800** |
| **Finance (expense)/income, net** | **-82,894** | **8,094** |

Interest expense on convertible loans in 2013 of CHF 40,262 was not cash relevant.

## 21. Taxation

The Group’s income tax expense recognized in the consolidated statement of profit or loss and other comprehensive income was as follows:

| | 2013 | 2012 |
|---|---|---|
| Current income tax expense | — | — |
| Deferred income tax expense | 305,750 | — |
| **Total income tax expense** | **305,750** | **—** |

The Group’s effective income tax expense differed from the expected theoretical amount computed by applying the Group’s applicable statutory tax rates of 23.7% (2012: 23.3%) as summarized in the following table:

| RECONCILIATION | 2013 | 2012 |
|---|---|---|
| Loss before income tax | -14,698,743 | -4,602,409 |
| Income tax at statutory tax rates applicable to results in the respective countries | -3,488,916 | -1,071,976 |
| Effect of unrecognized temporary differences | -1,343,556 | -823,403 |
| Effect of unrecognized taxable losses | 5,160,108 | 1,895,379 |
| Deferred tax recognised directly in equity | -21,886 | — |
| **Income tax expense** | **305,750** | — |

The tax effect of taxable temporary differences that give rise to deferred income tax liabilities as at December 31 is presented below:

| DEFERRED TAX LIABILITIES | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Intangible Assets | 327,637 | — | — |
| **Total** | **327,637** | **—** | **—** |

No income taxes were paid and no current income tax was recognized through profit or loss in the years ended December 31, 2013 and 2012. The Group has not recorded any provisions for current income taxes payable.

As of December 31, 2013, the Group had total gross tax loss carry forwards amounting to CHF 38.9 million, of which CHF 38.0 million related to Auris Medical AG in Switzerland and CHF 0.9 million to Auris Medical Inc. in the United States.

The Group's tax loss carry-forwards with their expiry dates are as follows:

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Within 1 year | 18,568 | 32,654 | 277,672 |
| Between 1 and 3 years | 3,755,427 | 2,087,009 | 2,119,663 |
| Between 3 and 7 years | 34,194,937 | 13,474,978 | 5,300,985 |
| More than 7 years | 938,560 | 785,439 | 397,762 |
| **Total** | **38,907,492** | **16,380,080** | **8,096,082** |

The tax effect of the major unrecognized temporary differences and loss carry-forwards is presented in the table below:

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| **Deductible temporary differences** | | | |
| Intangible assets | — | 1,526,406 | 2,352,971 |
| Employee benefit plan | 75,174 | 55,517 | 40,846 |
| Stock option plans | 56,262 | 31,012 | 18,196 |
| Accrued expenses | 26,097 | — | 390 |
| **Total potential tax assets** | **157,533** | **1,612,935** | **2,412,403** |
| **Taxable tempoary differences** | | | |
| Property and equipment | 4,719 | 4,626 | — |
| Intangible assets | 327,637 | 81,801 | 81,801 |
| Other receivables | — | 25,265 | — |
| Prepayments | — | — | 10,731 |
| Accrued expenses | — | 4,591 | — |
| **Total potential tax liabilities** | **332,356** | **116,283** | **92,532** |
| **Recognized deferred tax liability on intangible assets** | **327,637** | **—** | **—** |
| Offsetting potential tax liabilities with potential tax assets | 4,719 | 116,283 | 92,532 |
| Net potential tax assets from temporary differences not recognized | 152,814 | 1,496,652 | 2,319,871 |
| Potential tax assets from loss carry-forwards not recognized | 8,907,870 | 3,747,762 | 1,852,384 |
| **Total potential tax assets from loss carry-forwards and temporary differences not recognized** | **9,060,684** | **5,244,414** | **4,172,255** |

## 22. Loss per share

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 |
|---|---|---|
| Loss attributable to owners of the Company | -15,004,493 | -4,602,409 |
| Weighted average number of shares outstanding | 14,917,064 | 11,581,450 |
| **Basic and diluted loss per share** | **-1.01** | **-0.40** |

For the years ended December 31, 2013 and 2012 basic and diluted loss per share is based on the weighted average number of shares issued and outstanding and excludes shares to be issued under the Stock option plans (Note 13) and conversion rights related to the convertible loans (Note 14) as they would be anti-dilutive. In case the Group shows a profit in the future, the options may have a dilutive effect on earnings per share and will need to be included in the above calculation.

## 23. Commitments and contingencies

***Operating lease commitments***

On April 1, 2013, the Group entered into a lease for office space under an operating lease agreement with a cancelation option at the Company's discretion in March 2016. The lease agreement will expire in March 31, 2018 with an option to prolong it for a further 5 years.

The future minimum lease payments under non-cancellable operating leases that are not accounted for in the balance sheet were as of year-end were as follows:

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Within one year | 91,572 | 12,632 | 37,896 |
| Between one and five years | 122,096 | — | 12,632 |
| **Total** | **213,668** | **12,632** | **50,528** |

Office lease expenses of CHF 78,033 were booked in 2013 and of CHF 37,896 in 2012 in the consolidated statement of profit or loss and other comprehensive income.

## 24. Related party transactions

For the purposes of these consolidated financial statements, parties are considered to be related if one party has the ability to control the other party or exercise significant influence over the other party in making financial or operational decisions. Also parties under common control of the Group are considered to be related. Key management personnel are also related parties. In considering each possible related party relationship, attention is directed to the substance of the relationship, and not merely the legal form.

The prices on related party transactions are determined at arm's length.

***Compensation of the members of the Board of Directors and Management***

In 2013 the total compensation to Directors and Management was CHF 418,332 (previous year: CHF 287,320).

The fees paid to members of the board of directors of Auris Medical AG in 2013 for their activities as board members totaled CHF 10,500 (2012: CHF 8,750).

Non-executive Directors received part or all of their remuneration in stock options; travel and out of pocket expenses were reimbursed in cash by the Group. Executive Directors and Directors delegated and remunerated by a

Shareholder for its representation on the Board were not entitled to any specific remuneration for their Board membership and work.

The Chief Executive Officer was compensated in 2012 and 2013 by means of a management agreement between Auris Medical AG and Altamira Pharma GmbH, a company fully owned by the CEO. During 2013 and 2012, the Group paid CHF 248,000 and CHF 247,200, respectively, for the management services rendered.

CHF 74,145 (2012: CHF 31,370) was expensed for grants of stock options to members of the board of directors and Management. Contributions to post employment schemes amounted to CHF 6,836 and CHF 0 during the years 2013 and 2012. No termination benefits or other long term benefits were paid.

Members of the board of directors and Management held 187,500 and 87,500 Stock options as of December 31, 2013 and 2012, respectively.

In January 2013 Auris Medical AG obtained a bridge financing from Altamira Pharma GmbH through unsecured revolving credit facilities of up to CHF 1,400,000 and up to EUR 300,000 at an interest rate of 5% p.a. The bridge financing were repaid by the Group as of April 10, 2013. Interest of CHF 6,386 and EUR 2,847 was paid in 2013 under the agreements to the lender.

***Liabilities to related parties***

| | DECEMBER 31, 2013 | DECEMBER 31, 2012 | JANUARY 1, 2012 |
|---|---|---|---|
| Convertible loans from shareholders | 13,711,200 | — | — |
| Trade and other payables | 22 | 286 | — |
| **Total liabilities to related parties** | **13,711,222** | **286** | **—** |

The convertible loans from shareholders with a nominal value of CHF 13,769,976 are subordinated to any other indebtedness of the Group; they bear no interest (see Note 14).

| | 2013 | 2012 |
|---|---|---|
| Interest income related parties | — | — |
| Interest expense related parties | -50,177 | — |
| **Net interest income/(expense)—related parties** | **-50,177** | **—** |

In 2013 the interest expense to related parties includes the calculated effective interest on the convertible loans from shareholders and the interest on a bridge loan from a related party. No interest was paid to related parties in 2012.

### 25. Events after the balance sheet date

In January 2014 the convertible loan lenders exercised their conversion option, and the total loan amount of CHF 13,769,976 was converted into 2,607,950 Series C shares of the Company. The Series C shares were issued as of January 27, 2014 from the Company's authorized capital. As a result, the Company's issued share capital increased from CHF 6,487,130 at December 31, 2013 to CHF 7,536,510.

### 26. Transition to IFRSs

As stated in Note 2, these are the Group's first consolidated financial statements prepared in accordance with IFRS.

The accounting policies set out in Note 3 have been applied in preparing the financial statements for the periods ended December 31, 2013, 2012 and in the preparation of an opening IFRS statement of financial position at January 1, 2012 (the Group's date of transition).

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In preparing its opening IFRS statement of financial position, the Group has adjusted amounts reported previously in financial statements prepared in accordance with Swiss GAAP FER (Core FER). The latest period presented in the entity's most recent annual statements under Swiss GAAP FER was the year ended December 31, 2012. An explanation of how the transition from previous Core FER to IFRSs has affected the Group's financial position and financial performance is set out in the following tables and the notes that accompany the tables.

Reconciliation of Statement of Financial Position as previously reported:

| | | DECEMBER 31, 2012 | | | JANUARY 1, 2012 | | |
|---|---|---|---|---|---|---|---|
| | NOTE | PREVIOUS GAAP | ADJ. | IFRS | PREVIOUS GAAP | ADJ. | IFRS |
| **ASSETS** | | | | | | | |
| **Non-current assets** | | | | | | | |
| Property and equipment | a) | 104,278 | 20,218 | 124,496 | 1,987 | — | 1,987 |
| Intangible assets | b) | 385,823 | -28,303 | 357,520 | 275,099 | 82,421 | 357,520 |
| Non-current financial assets | c) | — | — | — | 72,850 | -72,850 | — |
| **Total non-current assets** | | **490,101** | **-8,085** | **482,016** | **349,936** | **9,571** | **359,507** |
| **Current assets** | | | | | | | |
| Current financial assets | c) | | | | — | 72,850 | 72,850 |
| Other receivables | e) | 125,027 | 110,422 | 235,449 | 110,452 | 1 | 110,453 |
| Prepayments | e) | 84,325 | — | 84,325 | 21,766 | 46,900 | 68,666 |
| Cash and cash equivalents | | 63,967 | — | 63,967 | 752,874 | — | 752,874 |
| **Total current assets** | | **273,319** | **110,422** | **383,741** | **885,092** | **119,751** | **1,004,843** |
| **Total assets** | | **763,420** | **102,337** | **865,757** | **1,235,028** | **129,322** | **1,364,350** |
| **EQUITY AND LIABILITIES** | | | | | | | |
| **Equity** | | | | | | | |
| Share capital | | 4,632,580 | — | 4,632,580 | 4,632,580 | — | 4,632,580 |
| Share premium | | 13,341,942 | — | 13,341,942 | 10,006,179 | — | 10,006,179 |
| Treasury shares | | — | — | — | -526,320 | — | -526,320 |
| Currency translation reserve | f) | 22,275 | — | 22,275 | — | — | — |
| Accumulated deficit | | -18,120,588 | -120,243 | -18,240,831 | -13,588,951 | -50,906 | -13,639,857 |
| **Total shareholders' equity attributable to owners of the Company** | | **-123,791** | **-120,243** | **-244,034** | **523,488** | **-50,906** | **472,582** |
| **Non-current liabilities** | | | | | | | |
| Employee benefits | d) | — | 242,646 | 242,646 | — | 178,524 | 178,524 |
| **Total non-current liabilities** | | **—** | **242,646** | **242,646** | **—** | **178,524** | **178,524** |
| **Current liabilities** | | | | | | | |
| Trade and other payables | | 424,877 | — | 424,877 | 170,863 | — | 170,863 |
| Accrued expenses | e) | 462,334 | -20,066 | 442,268 | 540,677 | 1,704 | 542,381 |
| **Total current liabilities** | | **887,211** | **-20,066** | **867,145** | **711,540** | **1,704** | **713,244** |
| **Total liabilities** | | **887,211** | **222,580** | **1,109,791** | **711,540** | **180,228** | **891,768** |
| **Total equity and liabilities** | | **763,420** | **102,337** | **865,757** | **1,235,028** | **129,322** | **1,364,350** |

Explanatory notes:

a) The calculation of depreciation of items of Property and equipment is performed on a pro rata basis under IFRS taking into account the date of acquisition of the item of property and equipment. Under previous GAAP, the calculation was performed based on the cost value at the end of the year for the full year, not taking in consideration the date of acquisition.

b) Under previous GAAP expenses for patent filings and the prosecution costs were capitalized and amortized over the remaining term of the patent. Under IFRS intellectual property related costs for patents are considered as part of the expenditure for the internal research and development projects. Consequently previously capitalized intangible assets with a net book value of CHF 385,823 and CHF 275,099 as at December 31, 2012 and January 1, 2012 respectively were removed from the balance sheet. On the other hand expenses related to acquired licenses of CHF 357,520 are capitalized under IFRS, these costs were expensed under previous GAAP.

c) The unconsolidated minority investment in the company Xigen SA was reclassified from non current financial assets to current financial assets as at January 1, 2012 under IFRS, because management intended to dispose of this investment in early 2012.

d) Under previous GAAP, no liability was recognized for the Group's pension plan organized through a legally independent collective foundation. Under IFRS this pension plan qualifies as a defined benefit plan. Accordingly the Group has recognized its obligation in respect of the plan in the statement of financial position in accordance with IAS 19 (see Note 19 Employee benefits).
e) As part of the transition process to IFRS, the Group has performed a detailed analysis of the various contracts, the level of services performed and the associated costs incurred. This process resulted in a restatement of accrued liabilities, prepayments and other receivables as at January 1, 2012 and December 31, 2012. Under previous GAAP a concept of prudence was applied in estimating service related accruals.
f) Cumulative translation adjustment: In accordance with IFRS 1.D13 the company has not applied IAS 21 with regard to the translation of foreign operations retrospectively. Accordingly, the cumulative translation differences for all foreign operations are deemed to be zero at the transition date.

Reconciliation of consolidated statement of profit or loss and other comprehensive income as previously reported**:**

| | | 2012 | | |
|---|---|---|---|---|
| | NOTE | PREVIOUS GAAP | ADJ. | IFRS |
| **Operating loss** | a) | **-4,532,348** | **-78,155** | **-4,610,503** |
| Financial result | b) | 33,490 | -25,396 | 8,094 |
| **Loss before tax** | | **-4,498,858** | **-103,551** | **-4,602,409** |
| Taxes | c) | -32,778 | 32,778 | — |
| **Net loss attributable to owners of the Company** | | **-4,531,636** | **-70,773** | **-4,602,409** |
| **Other comprehensive income/(loss):** | | | | |
| Remeasurement of defined benefit liability | | — | -54,577 | -54,577 |
| Currency translation difference | | 22,275 | — | 22,275 |
| **Other comprehensive loss** | | **22,275** | **-54,577** | **-32,302** |
| **Total comprehensive loss** | | **-4,509,361** | **-125,350** | **-4,634,711** |

Explanatory notes:

a) Under previous GAAP the consolidated statement of profit or loss and other comprehensive income was presented using a classification of expenses based on their nature, whereas under IFRS the Group elected to present expenses based on their function.

The differences of the operating loss compared to previous GAAP are related to the following expense items:

| | 2012 |
|---|---|
| Depreciation of property and equipment | 20,218 |
| Reversal capitalization of intellectual property related costs | -110,724 |
| Services related adjustments of accruals, receivables, prepayments | 86,726 |
| Expense for employee stock option plan | -56,013 |
| Incremental expense for defined benefit plan | -9,545 |
| Reclassification of insurance income from finance costs to G&A | 23,961 |
| Reclassification of expenses for capital taxes from taxes to G&A | -32,778 |
| **Operating loss adjustment** | **-78,155** |

b) Reclassification of an income from insurance from financial result to general and administrative expense of CHF 23,961 and currency difference adjustments of CHF 1,435 led to the adjustment of the financial result of CHF 25,396.
c) Under IFRS it is not appropriate to classify taxes on capital under income taxes, therefore the amount of capital taxes paid of CHF 32,778 was reclassified into general and administrative expenses.

Consolidated statement of cash flows:

| | 2012 | | |
|---|---|---|---|
| | PREVIOUS GAAP | ADJ. | IFRS |
| Cash used in operating activities | -4,380,675 | -117,792 | -4,498,467 |
| Net cash used in investing activities | -192,408 | 139,332 | -53,076 |
| Net cash from financing activities | 3,862,369 | -287 | 3,862,082 |
| Net effect of currency translation | 21,807 | -21,807 | — |
| **Net increase/(decrease) in cash and cash equivalents** | **-688,907** | -554 | **-689,461** |
| **Cash and cash equivalents at beginning of period** | **752,874** | **—** | **752,874** |
| Net effect of currency translation on cash | — | 554 | 554 |
| **Cash and cash equivalents at end of period** | **63,967** | — | **63,967** |

The main deviation in the presentation of the consolidated statement of cash flows for the year 2012 results from the different treatment of intellectual property related expenses. These expenses were capitalized under previous GAAP and presented as cash used in investing activities. Under IFRS these costs are expensed as incurred, consequently the related cash outflows form part of the cash used in operating activities.

Under IFRS currency translation differences resulting from the translation of foreign subsidiaries are excluded from the presented cash flows, except for currency translation differences on cash and cash equivalents. Under previous GAAP, the net effect of the currency translation was presented as a separate line item in the statement of cash flows.

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Through and including            , 2014 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

**Common Shares**

# Auris Medical Holding AG

**PRELIMINARY PROSPECTUS**

**Jefferies**

**Leerink Partners**

**JMP Securities**

**Needham & Company**

, 2014

## PART II

## INFORMATION NOT REQUIRED IN THE PROSPECTUS

### Item 6. Indemnification of Directors and Officers

Under Swiss law, a corporation may indemnify its directors or officers against losses and expenses (except for such losses and expenses arising from willful misconduct or negligence, although legal scholars advocate that at least gross negligence be required), including attorney's fees, judgments, fines and settlement amounts actually and reasonably incurred in a civil or criminal action, suit or proceeding by reason of having been the representative of, or serving at the request of, the corporation.

Subject to Swiss law, Article 17 of our articles of association provides for indemnification of the existing and former members of our board of directors, executive management, and their heirs, executors and administrators, against liabilities arising in connection with the performance of their duties in such capacity, and permits us to advance the expenses of defending any act, suit or proceeding to members of our board of directors and executive management.

In addition, under general principles of Swiss employment law, an employer may be required to indemnify an employee against losses and expenses incurred by such employee in the proper execution of their duties under the employment agreement with the company.

We intend to enter into indemnification agreements with each of the members of our board of directors and executive officers in the form filed as Exhibit 10.9 to this Registration Statement upon the closing of this offering.

In the underwriting agreement that we enter into in connection with the sale of the common shares being registered hereby, a form of which is filed as Exhibit 1.1 to this Registration Statement, the underwriters will agree to indemnify, under certain conditions, us, our directors, our officers and persons who control us within the meaning of the Securities Act against certain liabilities.

Insofar as indemnification for liabilities arising under the Securities Act of 1933, as amended, may be permitted to directors, officers and controlling persons of the Company, the Company has been advised that, in the opinion of the Securities and Exchange Commission, such indemnification is against public policy as expressed in the Securities Act of 1933, as amended, and is, therefore, unenforceable.

### Item 7. Recent Sales of Unregistered Securities

All numbers of shares and options in this Item 7 are adjusted for the 25:1 forward stock split effected in December 2013.

***Series B and Series C Preferred Shares***

In March 2011, we issued 1,018,750 Series B preferred shares to existing shareholders at an issue price of CHF 3.20 per share. In November 2011, we issued an additional 1,052,850 Series B preferred shares to existing and new shareholders at an issue price of CHF 4.80 per share. One third of the issue price (nominal CHF 0.40 and premium CHF 1.20 per share) was paid in 2011, the second third (CHF 1.60 premium per share) in March 2012 and the final third (CHF 1.60 premium per share) in June 2012. A total of 328,950 of the Series B preferred shares were held in treasury at December 31, 2011 and were sold from treasury in 2012 to new and existing shareholders at a price per share of CHF 4.80.

In April 2013, we issued and sold an aggregate of 4,636,375 of our Series C preferred shares at a price per share of CHF 5.28 for an aggregate purchase price of CHF 24,480,060 to certain investors.

In January 2014, Sofinnova Venture Partners VIII, L.P. and Sofinnova Capital VII FCPR, the lenders under a convertible loan to us, exercised their conversion option, and the total loan amount of CHF 13,769,976 was converted into 2,607,950 Series C preferred shares.

Pursuant to the Series C Shareholders' Agreement, in the event of our initial public offering, all of our outstanding preferred shares will convert into our common shares.

The Series B and Series C preferred shares were issued and sold in reliance upon the exemption from registration under Section 4(a)(2) of the Securities Act. We have used the proceeds from these offerings to repay the January 2013 loan agreement with Alfamira in full for the amount of CHF 1,186,386 and EUR 258,847, including accrued interest and for research and development and general corporate purposes.

***Option and restricted share grants***

The table below summarizes our options granted within the past three years. The grant of the options and the issuance of common shares upon the exercise of options described in the table below were or will be made pursuant to Regulation S under the Securities Act or Section 4(a)(2) of the Securities Act.

| GRANT DATE | NUMBER OF UNDERLYING OPTIONS | EXERCISE PRICE PER SHARE (CHF) |
|---|---|---|
| **Plan A** | | |
| April 27, 2011 | 16,250 | 3.20 |
| November 24, 2011 | 23,750 | 3.20 |
| April 23, 2012 | 16,250 | 4.80 |
| June 29, 2012 | 2,500 | 4.80 |
| October 19, 2012 | 5,000 | 4.80 |
| November 23, 2012 | 23,750 | 4.80 |
| January 1, 2013 | 50,000 | 4.80 |
| **Plan C** | | |
| September 24, 2013 | 21,250 | 5.28 |
| November 26, 2013 | 55,000 | 5.28 |
| March 18, 2014 | 97,500 | 5.28 |

**Item 8. Exhibits**

(a) The following documents are filed as part of this registration statement:

| | |
|---|---|
| 1.1* | Form of Underwriting Agreement |
| 3.1* | Form of Articles of Association |
| 4.1* | Registration Rights Agreement |
| 5.1* | Opinion of Froriep, Swiss counsel of Auris Medical Holding AG, as to the validity of the common shares |
| 8.1* | Opinion of Froriep, Swiss counsel of Auris Medical Holding AG, as to Swiss tax matters |
| 8.2 | Opinion of Davis Polk & Wardwell LLP, as to U.S. tax matters |
| 10.1† | Collaboration and License Agreement, dated October 21, 2003, between Auris Medical AG and Xigen SA |
| 10.2† | Co-Ownership and Exploitation Agreement, dated September 29, 2003, between Auris Medical AG and INSERM |
| 10.3 | Series C Investment Agreement, dated April 5, 2013 |
| 10.4 | Series C Shareholders' Agreement, dated April 5, 2013 |
| 10.5 | Convertible Loan Agreement, dated December 2013, between Auris Medical AG and Sofinnova Venture Partners VIII, L.P. and Sofinnova Capital VII FCPR |
| 10.6 | Service Agreement, dated January 2011 between Auris Medical AG and Altamira Pharma GmbH |
| 10.7 | Termination of Service Agreement, dated February 2014 between Auris Medical AG and Altamira Pharma GmbH |
| 10.8 | Loan Agreement, dated January 2013 between Auris Medical AG and Altamira Pharma GmbH |
| 10.9* | Form of Indemnification Agreement |
| 10.10 | English language translation of Lease Agreement between Auris Medical AG and Privera AG |
| 10.11 | Stock Option Plan A |
| 10.12 | Stock Option Plan C |
| 16.1 | Letter of KPMG AG, dated June 27, 2014, regarding change in the Company's independent registered public accounting firm |
| 21.1 | List of subsidiaries |
| 23.1 | Consent of KPMG AG |
| 23.2* | Consent of Froriep, Swiss counsel of Auris Medical Holding AG (included in Exhibit 5.1) |
| 23.3* | Consent of Froriep, Swiss counsel of Auris Medical Holding AG (included in Exhibit 8.1) |
| 23.4 | Consent of Davis Polk & Wardwell LLP (included in Exhibit 8.2) |
| 24.1 | Powers of attorney (included on signature page to the registration statement) |

* To be filed by amendment.
† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

(b) Financial Statement Schedules

None.

### Item 9. Undertakings

The undersigned hereby undertakes:

(a) The undersigned registrant hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(b) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(c) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

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## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Zug, Switzerland on June 27, 2014.

Auris Medical Holding AG

By: /s/ Thomas Meyer
Name: Thomas Meyer
Title: Chief Executive Officer

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KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Thomas Meyer and Sven Zimmermann and each of them, individually, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the U.S. Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on June 27, 2014 in the capacities indicated:

| NAME | TITLE |
|---|---|
| /s/ Thomas Meyer<br>Thomas Meyer | Chief Executive Officer and Director<br>(principal executive officer) |
| /s/ Sven Zimmermann<br>Sven Zimmermann | Chief Financial Officer (principal financial officer and principal accounting officer) |
| /s/ Wolfgang Arnold<br>Wolfgang Arnold | Director |
| /s/ Alain Munoz<br>Alain Munoz | Director |
| /s/ James I. Healy<br>James I. Healy | Director |
| /s/ Oliver Kubli<br>Oliver Kubli | Director |
| /s/ Antoine Papiernik<br>Antoine Papiernik | Director |
| /s/ Colleen A. DeVries<br>Colleen A. DeVries<br>SVP of National Corporate Research, Ltd. | Authorized Representative in the United States |

## EXHIBIT INDEX

(a) The following documents are filed as part of this registration statement:

| | |
|---|---|
| 1.1* | Form of Underwriting Agreement |
| 3.1* | Form of Articles of Association |
| 4.1* | Registration Rights Agreement |
| 5.1* | Opinion of Froriep, Swiss counsel of Auris Medical Holding AG, as to the validity of the common shares |
| 8.1* | Opinion of Froriep, Swiss counsel of Auris Medical Holding AG, as to Swiss tax matters |
| 8.2 | Opinion of Davis Polk & Wardwell LLP, as to U.S. tax matters |
| 10.1† | Collaboration and License Agreement, dated October 21, 2003, between Auris Medical AG and Xigen SA |
| 10.2† | Co-Ownership and Exploitation Agreement, dated September 29, 2003, between Auris Medical AG and INSERM |
| 10.3 | Series C Investment Agreement, dated April 5, 2013 |
| 10.4 | Series C Shareholders’ Agreement, dated April 5, 2013 |
| 10.5 | Convertible Loan Agreement, dated December 2013, between Auris Medical AG and Sofinnova Venture Partners VIII, L.P. and Sofinnova Capital VII FCPR |
| 10.6 | Service Agreement, dated January 2011 between Auris Medical AG and Altamira Pharma GmbH |
| 10.7 | Termination of Service Agreement, dated February 2014 between Auris Medical AG and Altamira Pharma GmbH |
| 10.8 | Loan Agreement, dated January 2013 between Auris Medical AG and Altamira Pharma GmbH |
| 10.9* | Form of Indemnification Agreement |
| 10.10 | English language translation of Lease Agreement between Auris Medical AG and Privera AG |
| 10.11 | Stock Option Plan A |
| 10.12 | Stock Option Plan C |
| 16.1 | Letter of KPMG AG, dated June 27, 2014, regarding change in the Company’s independent registered public accounting firm |
| 21.1 | List of subsidiaries |
| 23.1 | Consent of KPMG AG |
| 23.2* | Consent of Froriep, Swiss counsel of Auris Medical Holding AG (included in Exhibit 5.1) |
| 23.3* | Consent of Froriep, Swiss counsel of Auris Medical Holding AG (included in Exhibit 8.1) |
| 23.4 | Consent of Davis Polk & Wardwell LLP (included in Exhibit 8.2) |
| 24.1 | Powers of attorney (included on signature page to the registration statement) |

* To be filed by amendment.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

**Exhibit 8.2**

| | |
|---|---|
| **New York** | **Paris** |
| **Menlo Park** | **Madrid** |
| **Washington DC** | **Tokyo** |
| **São Paulo** | **Beijing** |
| **London** | **Hong Kong** |

Davis Polk & Wardwell LLP 212 450 4000 tel
450 Lexington Avenue 212 701 5800 fax
New York, NY 10017

June 27, 2014

Re: Auris Medical Holding AG Common Shares Offering

Auris Medical Holding AG
Bahnhofstrasse 21
6300 Zug
Switzerland

Dear Ladies and Gentlemen:

We are acting as United States counsel to Auris Medical Holding AG, a corporation organized under the laws of Switzerland (the “Company”), in connection with the Company’s Registration Statement on Form F-1 filed with the United States Securities and Exchange Commission (the “Registration Statement”). We have examined such matters of fact and law as we have deemed necessary or advisable for the purpose of this opinion.

We hereby confirm our opinion set forth under the caption “Taxation – Material U.S. Federal Income Tax Considerations for U.S. Holders” in the Prospectus Supplement.

We are members of the Bar of the State of New York, and we express no opinion as to the laws of any jurisdiction other than the laws of the State of New York and the federal laws of the United States.

We hereby consent to the use of our name under the caption “Taxation” in the Prospectus Supplement and to the filing, as an exhibit to the Registration Statement, of this opinion.

In giving such consent we do not admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act of 1933, as amended.

Very truly yours,

/s/ Davis Polk & Wardwell LLP
Davis Polk & Wardwell LLP

**Exhibit 10.1**

**CONFIDENTIAL TREATMENT REQUESTED UNDER RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.**

**[*****] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMMITTED MATERIAL HAS BEEN FILED SEPERATELY WITH THE COMMISSION.**

# Collaboration and License Agreement

**dated October 21, 2003 between**

**Auris Medical AG**

**and**

**Xigen SA**

Collaboration and license agreement, dated October 21, 2003 ("**AGREEMENT**"), by and among Auris Medical AG, Rütifeldstrasse 1, 4573 Lohn-Ammannsegg ("**AURIS**"), and Xigen SA, Chemin des Falaises 1, 1005 Lausanne ("**XIGEN**"; collectively the "**PARTIES**").

**R E C I T A L S:**

WHEREAS, XIGEN has developed a number of cell permeable inhibitors to effectively block certain signal pathways in apoptotic processes ("**COMPOUNDS**");

WHEREAS, AURIS is developing pharmaceutical products ("**PRODUCTS**") as well as drug delivery devices and formulations for local administration of therapeutic substances to the inner ear for the treatment of ear disorders ("**AREA**");

WHEREAS, XIGEN and AURIS have entered into a preliminary contract ("**CONTRACT**") on September 8, 2003, which shall be superseded collectively by this AGREEMENT and a supply agreement ("**SUPPLY AGREEMENT**"), as well as an equity investment agreement ("**EQUITY AGREEMENT**"); and

WHEREAS, the PARTIES wish to collaborate world-wide exclusively in the area of treatment of ear disorders, all as hereinafter set forth;

NOW, THEREFORE, in consideration of the agreements contained herein, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound hereby, the parties hereto agree to the following:

**0. PRELIMINARY REMARK**

The RECITALS to this AGREEMENT form an integral part hereof. Clause headings in this AGREEMENT are intended solely for convenience of reference and shall be given no effect in the interpretation of this AGREEMENT. All signed annexes to this AGREEMENT, whether attached at the time of signature hereof or at any time thereafter, shall be construed as an integral part of this AGREEMENT.

**1. SCOPE OF COLLABORATION**

1.1. AURIS wishes to in-license COMPOUNDS for use in the AREA ("**LICENSE COMPOUNDS**") from XIGEN and XIGEN wishes to out-license COMPOUNDS to AURIS for the development of PRODUCTS to be used in the AREA.

1.2. XIGEN will supply AURIS with the LICENSE COMPOUNDS under the terms of the SUPPLY AGREEMENT, which shall be entered into by the PARTIES within [*****] from the signing of this AGREEMENT.

1.3. XIGEN aims to optimise further LICENSE COMPOUNDS and to develop new COMPOUNDS for potential use in the AREA, either on its own or jointly with AURIS.

1.4. THE PARTIES will collaborate in the non-clinical and clinical development of LICENSE COMPOUNDS by sharing data to speed up time to market and reduce development costs.

## 2. LICENSE COMPOUNDS

2.1. Subject to the terms and conditions of this AGREEMENT XIGEN hereby grants AURIS the exclusive and sole right to use world-wide any existing COMPOUND or future COMPOUNDS (subject to 2.3. and 3.7) for the development, manufacturing, marketing and selling of PRODUCTS in the AREA. The LICENSE COMPOUNDS are defined in Appendix I to this AGREEMENT, which shall be amended to include any additional LICENSE COMPOUNDS.

2.2. XIGEN shall provide AURIS with all necessary specifications of the LICENSE COMPOUNDS required for development and registration purposes.

2.3. During the term of this AGREEMENT, AURIS has the right of first refusal for nine months to test and in-license any new COMPOUND which may also be used for the AREA ("**PROSPECTIVE COMPOUND**"); if AURIS decides not to in-license such PROSPECTIVE COMPOUND, XIGEN may offer it to other interested parties. XIGEN will notify AURIS promptly about the development and availability of any PROSPECTIVE COMPOUND.

2.4. AURIS will decide within [*****] from the date of closing of this AGREEMENT whether or not it will initiate the non-clinical or clinical development of a LICENSE COMPOUND into a PRODUCT.

2.5. AURIS has the right to grant sub-licenses in the AREA to the LICENSE COMPOUNDS. AURIS will promptly notify XIGEN of the identity of any sub-licensee and the scope of such sub-license.

2.6. Prior to the closing of this AGREEMENT, XIGEN and AURIS have entered into an agreement, whereas XIGEN develops for AURIS a LICENSE COMPOUND for potential use in the treatment of tinnitus. The conditions for the development of this LICENSE COMPOUND are defined in Appendix IV.

## 3. COLLABORATION

3.1. The PARTIES will inform each other regularly on the status of their research and development projects.

3.2. The PARTIES will coordinate non-clinical tests, clinical trials and regulatory undertakings in order to gain efficiency, save time and costs.

3.3. The PARTIES will grant each other access to their non-clinical or clinical data relating to the LICENSE COMPOUNDS [*****] for use in their proprietary development programmes. Upon XIGEN's request, AURIS will offer third parties access to such data for their development programmes with LICENSE COMPOUNDS outside the AREA, provided that AURIS shall be compensated by the receiving party for [*****] of AURIS's costs in obtaining such data. XIGEN shall seek access to any third party's non-clinical or clinical data relating to LICENSE COMPOUNDS for use outside of the AREA to make them accessible for AURIS upon request, subject to the third party willing to provide such access and asking to be compensated for such information transfer.

3.4. The PARTIES will review, coordinate and consolidate, as appropriate, safety and pharmacovigilance issues and data generated by either of them relating to the LICENSE COMPOUNDS.

3.5. The PARTIES will set up detailed procedures for handling adverse events (Standard Operating Procedures covering how to handle pharmacovigilance procedures, batch recall or withdrawal, and adverse event exchange and reporting).

3.6. AURIS will aim to include XIGEN as official partner in research consortia of common interest.

3.7. Upon AURIS's decision to develop a LICENSE COMPOUND into a PRODUCT, the PARTIES will enter into an agreement whereas AURIS will sponsor research and development work and XIGEN will optimise LICENSE COMPOUNDS and develop new COMPOUNDS for use in the AREA ("**SPONSOR AGREEMENT**"). Such SPONSOR AGREEMENT will be made for an initial term of [*****] with a renewal option, and shall be based upon a mutually agreed work plan and include regular reporting by XIGEN of the amount of work and costs incurred.

## 4. CONSIDERATION

4.1. AURIS will make an upfront payment to XIGEN at the closing of this AGREEMENT of CHF 200,000.

4.2. Subject to 3.7., AURIS will make annual payments to XIGEN under the SPONSOR AGREEMENT of at least [*****] during the initial term. This corresponds to at least [*****] full time equivalents of a qualified XIGEN senior scientist's time. XIGEN's and AURIS's contributions in terms of money, senior scientist's time, space, use of equipment, purchases of materials etc. shall be reasonably balanced overall at a ratio of [*****].

4.3. AURIS will make a milestone payment for each indication of CHF 1.5 million to XIGEN upon the successful completion of phase II of the clinical trials (if necessary with a phase IIb) with a LICENSE COMPOUND. The

trial is deemed successful in any case if subsequently a phase III clinical trial with the LICENSE COMPOUND will be conducted, or in case no further clinical trials are needed due to the grant of an orphan drug status or similar status.

4.4. AURIS will make a milestone payment of CHF 2.5 million to XIGEN upon receiving marketing approval for any PRODUCT making use of a LICENSE COMPOUND, whereas [*****] will be due upon approval in the USA, and [*****] upon approval in the European Union.

4.5. AURIS will make a milestone payment of CHF 200,000 to XIGEN upon initiation of the development programme for a PRODUCT using a LICENSE COMPOUND for the treatment of age-related hearing loss.

4.6. [*****] of the milestone payments for each indication will be credited against future royalty payments for such indication, spread evenly over [*****].

4.7. In case of a relatively small indication (e.g. qualifying for orphan drug status), the milestone payments for such LICENSE COMPOUND will be reduced by [*****].

4.8. AURIS will pay XIGEN a royalty of [*****] on net sales as defined below of all PRODUCTS that use a patented LICENSE COMPOUND from XIGEN for the AREA during the period that commences on the closing date of this AGREEMENT and ends on the later of (i) 10 years after the first market launch of any such PRODUCT in any country, or (ii) the first expiration of XIGEN's patent or exclusive license covering the use of such LICENSE COMPOUND in any country. For the avoidance of doubt, it is being understood that any device or accessory sold by AURIS, its affiliates, licensees or assignees in conjunction with a PRODUCT is excluded from the calculation of the royalty (e.g. pumps, catheters, syringes, surgical instruments), unless the following conditions are cumulatively met:

(a) the device or accessory constitutes a technically integral part of such PRODUCT,

(b) it could not be sold on a stand-alone basis or in conjunction with other products from third parties, and

(c) it is covered by a XIGEN patent or a patent jointly owned by the PARTIES.

In the event that the PRODUCT is sold by AURIS together with a device or accessory as a bundle, where such device or accessory is excluded from the calculation of royalty payments, standard at-arm's length prices for the device and accessory shall be deducted from the bundle price in order to obtain the net sales of the PRODUCT subject to royalty payment.

4.9. Net sales used for the calculation of the royalty ("**NET SALES**") mean the amount invoiced for all sales of PRODUCTS by AURIS or any of its affiliates, licensees, assignees or distributors at arm's length to a third party, after the following deductions:

(a) normal and customary trade, cash or quantity discounts, including any volume discount paid or credited to the third party, free samples of PRODUCTS, rebates and administrative fees (including U.S. Medicaid and Medicare programs and equivalents and other private or government sponsored rebates and administrative fees paid to purchasing groups),

(b) import, export, sales, use, excise and other consumption taxes and custom duties or tariffs, to the extent and up to the amount included as a separate item on the invoice, and any other governmental taxes (other than income taxes) or charges imposed upon the importation, use or sale of PRODUCTS,

(c) any charges for freight, postage, shipping, security or special handling or insurance,

(d) reasonable provisions for allowance for uncollectible amounts.

Any PRODUCT sold or otherwise transferred other than in an at arm's length transaction or in exchange for other property (e.g. barter) shall be deemed invoiced at the PRODUCT's ordinary market price to end users in the relevant country of sale, or failing such ordinary market price, at the arm's length price the PRODUCT would generally or on average be invoiced. NET SALES shall not include amounts invoiced for the PRODUCT transferred in a country as part of the clinical trials or other such studies prior to receipt of regulatory marketing authorization in such country.

4.10. The obligation to pay royalties pursuant to Section 4.8 shall commence with the first sale of any PRODUCT.

4.11. Royalties shall be payable in Swiss Francs within [*****] calendar days after the end of each quarter on the basis of NET SALES during the preceding quarter. Not later than the date on which a royalty payment is due, AURIS shall deliver to XIGEN a market sales report (the "**SALES REPORT**"), setting forth NET SALES of PRODUCTS achieved in the preceding quarter on a country-by-country basis in local currency as well as in Swiss Francs. Conversion from currencies other than Swiss Francs shall be made using the spot rate on the last business day of the quarter in which the NET SALES were made, as published in the "**Neue Zürcher Zeitung**". The first SALES REPORT will be due for the first quarter after receiving marketing approval for any PRODUCT in any country in which the first commercial sales of any PRODUCT are recorded.

4.12. XIGEN shall have the right to designate an independent accounting firm reasonably acceptable to AURIS, which shall have access to AURIS's sales records, and if necessary to the records of its affiliates, licensees or distributors (subject, in each case, to entering into a reasonable confidentiality agreement), during regular business hours and with ten days minimum prior notice, for the purpose of verifying NET SALES. No such verification shall be made more than once with respect to any calendar year. The cost of the accounting firm's services shall be borne by XIGEN, unless the accounting firm discovers that XIGEN has been underpaid by more than [*****] of the amount actually owed to XIGEN, in which case the cost shall be borne by AURIS.

4.13. For the avoidance of doubt, any new LICENSE COMPOUND developed jointly under the SPONSOR AGREEMENT as per section 3.7 or developed independently by Xigen as per sections 1.2 and 2.3 shall be subject to the same milestone and royalty payments as LICENSE COMPOUNDS already existing at the closing of this AGREEMENT, subject to 4.14.

4.14. If the LICENSE COMPOUND makes use of XIGEN's proprietary technology for transporting a certain compound to a specific site of action, but such compound has not been developed by XIGEN itself, and if AURIS has to purchase a license from a third party to obtain rights to use such COMPOUND for a PRODUCT, the PARTIES shall negotiate in good faith an appropriate reduction of the royalty rate and milestone payments to XIGEN.

## 5. INTELLECTUAL PROPERTY

5.1. XIGEN's patents and licenses on and to the LICENSE COMPOUNDS, which are listed in Appendix II, will remain its property. XIGEN will maintain such patents and licenses for the term of this AGREEMENT.

5.2. New patents for specific inner ear indications or formulations of LICENSE COMPOUNDS filed by AURIS shall be jointly owned and assigned to AURIS for exclusive use in the AREA. All costs related to the filing, prosecution and maintenance of such patents shall be borne by AURIS. XIGEN will have the option to obtain free of charge a world-wide exclusive license for the use of such formulations outside the AREA.

5.3. Patents on new compounds developed by XIGEN under the SPONSOR AGREEMENT shall be filed by AURIS and remain its sole property. XIGEN will have the option to obtain a royalty free and world-wide exclusive license for applications outside the AREA. If XIGEN elects to sub-license such right to a third party, AURIS shall receive a [*****] royalty on the net sales of any products sold by the third party based on such sub-license.

5.4. The PARTIES shall be under the obligation to pursue any infringement of their intellectual property on their own against any third party infringer at their sole cost and expense. Each party shall provide the pursuing party with all documents, information and assistance and shall take all action necessary to assist the pursuing party in its pursuit of the infringement. In case of co-owned intellectual property, AURIS shall defend the co-owned intellectual property on behalf of both parties, whereas the PARTIES share the costs on a [*****] basis. In that case, XIGEN shall provide AURIS with all documents, information and assistance and shall take all action necessary to assist AURIS in its pursuit of the infringement.

5.5. Subject to 3.3, all know-how and other results from the development of LICENSE COMPOUNDS into PRODUCTS by AURIS shall be its exclusive and sole property.

## 6. COVENANTS

6.1. Subject to 1.3 and 1.4 as well as AURIS not exercising its right of first refusal as defined in 2.3, XIGEN will not pursue either directly or indirectly any development, manufacturing, marketing or selling of COMPOUNDS and PRODUCTS, which would compete with AURIS in the AREA.

6.2. The PARTIES agree, also on behalf of their affiliates, for the term of this AGREEMENT not to solicit or induce employees of the other party to terminate their employment with the other party.

6.3. XIGEN will have the right to review all articles written on behalf of or in collaboration with AURIS referring to LICENSE COMPOUNDS prior to publication; XIGEN will submit any articles referring to the AREA prior to publication to AURIS for review. AURIS has the right to withhold any publications if such publication would compromise the registration of any intellectual property rights (e.g. patent registration).

6.4. AURIS will obtain sufficient product liability insurance and insurance coverage for non-clinical and clinical trials, where COMPOUNDS or LICENSE COMPOUNDS of XIGEN are used, as well as for commercial sales of PRODUCTS which use LICENSE COMPOUNDS.

6.5. XIGEN will obtain sufficient product liability insurance and insurance coverage for any defects and deficiencies in the LICENSE COMPOUNDS supplied to AURIS.

6.6. Each PARTY is entitled to receive confirmation from the other PARTY's insurance company certifying that there is reasonable insurance coverage with a minimum limit of liability of at least [*****] and that all

premiums are paid. If one PARTY fails to provide such information [*****] after having received a request for information, the other PARTY shall, based on this AGREEMENT, be entitled to receive such information directly from the insurance company. This section shall be considered being a consent of the failing PARTY that the insurance company shall be obliged to provide the relevant information to the requesting PARTY.

## 7. REPRESENTATIONS AND WARRANTIES

7.1. XIGEN owns solely, legally and beneficially all intellectual property rights or owns all exclusive licenses to such rights (with the right to grant sublicenses without any limitation) necessary to grant AURIS the rights to LICENSE COMPOUNDS as defined in article 2 of this AGREEMENT. No former or present employee of XIGEN owns or has claimed to own all or any part of the intellectual property rights related to the LICENSE COMPOUNDS. With regard to LICENSE COMPOUNDS, XIGEN to its best knowledge does not violate nor is likely to violate any right of any other party with respect to their intellectual property rights (whether registered or not), and no such claim of violation of any such rights is pending or threatened. To XIGEN's best knowledge, the use of XIGEN's intellectual property rights with regard to LICENSE COMPOUNDS does not and is not likely to infringe any company's or person's rights (including but not limited to intellectual property rights and contractual rights). XIGEN has no knowledge of nor received any notice alleging that it has infringed intellectual property rights with regard to LICENSE COMPOUNDS of any other person or company. XIGEN is not subject to any injunction, undertaking, or court order or order of any other authority of competent jurisdiction not to use or restricting the use of any of its intellectual property rights with regard to LICENSE COMPOUNDS. There exists no actual or threatened infringement or any event likely to constitute an infringement or breach by any third party of any of the intellectual property rights held or used by XIGEN with regard to LICENSE COMPOUNDS.

7.2. All information and documents communicated by XIGEN to AURIS and / or accessed to by AURIS relating to this AGREEMENT are complete, fair and true in all material aspects and none of such documents or information are of such nature as to mislead AURIS as to facts and circumstances relating to XIGEN, the LICENSE COMPOUNDS or to the representations and warranties of this AGREEMENT.

7.3. XIGEN has not failed to bring to the attention of AURIS any fact whatsoever, which is of such a nature that AURIS should reasonably consider that it would be of material relevance to the decision of a diligent collaboration and license partner whether or not to enter into a collaboration and license agreement or to the consideration offered by such a collaboration and license partner for the rights from such a collaboration and license agreement.

7.4. XIGEN has entered with CHUV/University of Lausanne on October 17, 2003, into a license agreement ("**CHUV/UNIL AGREEMENT**"). Those parts of the CHUV /UNIL AGREEMENT which are relevant to AURIS as sub-licensee to XIGEN are contained in Appendix III.

7.5. XIGEN warrants that in the event it ceases to operate before any patent assignment has taken place from the CHUV/UNIL, the CHUV/UNIL has agreed to grant AURIS a sole license in the AREA at the same financial terms and conditions.

7.6. The representations and warranties set forth in this AGREEMENT shall survive the closing date.

**8. INDEMNIFICATION**

8.1. From and after the closing of this AGREEMENT, XIGEN agrees to indemnify and hold harmless AURIS, their respective subsidiaries and affiliates, their respective successors and permitted assigns, and their respective officers, directors, employees and agents from, against and in respect of any and all losses, claims, demands, liabilities, assessments, damages, deficiencies, costs, expenses, actions or causes of action in respect thereof (including reasonable attorneys' fees and related costs) relating to or arising out of or in connection with

(a) any breach by XIGEN of any of its representations or warranties contained in this AGREEMENT,

(b) any breach by XIGEN of any of its covenants or agreements contained in this AGREEMENT,

(c) any LICENSE COMPOUNDS supplied to AURIS

8.2. From and after the closing of this AGREEMENT, AURIS agrees to indemnify and hold harmless XIGEN, their respective subsidiaries and affiliates, their respective successors and permitted assigns, and their respective officers, directors, employees and agents from, against and in respect of any and all losses, claims, demands, liabilities, assessments, damages, deficiencies, costs, expenses, actions or causes of action in respect thereof (including reasonable attorneys' fees and related costs) relating to or arising out of or in connection with any breach by AURIS of any of its representations or warranties contained in this AGREEMENT, and any breach by AURIS of any of its covenants or agreements contained in this AGREEMENT.

8.3. An indemnified party under this article 8 shall give prompt written notice to the indemnifying party of any liability or obligation in respect of which such indemnifying party has a duty to provide indemnity to such indemnified party.

8.4. Except for the indemnification obligations set forth in section 8.1 c) or as expressly provided in this AGREEMENT, neither XIGEN nor AURIS shall have any liability arising out of this AGREEMENT until the aggregate amount of such liabilities exceeds [*****], in which case all such liabilities shall be owed, and in no event will either party's aggregate liability hereunder exceed a total of [*****], and neither party shall have any claim against the other for breach of or any inaccuracy in any representation or breach of any warranty set forth herein unless such party shall have given the other party notice of such claim not later than [*****] after the closing of this AGREEMENT.

## 9. TERM OF AGREEMENT

9.1. The term of this AGREEMENT is indefinite.

9.2. This AGREEMENT may be terminated by either of the PARTIES with [*****] prior notice if AURIS has neither been using any LICENSE COMPOUNDS nor evaluating any new COMPOUND for use in the AREA for at least [*****] from the closing of this COLLABORATION AGREMENT. XIGEN has the right to terminate the AGREEMENT if AURIS does not commence any development programme with LICENSE COMPOUNDS within [*****] from the closing of this AGREEMENT.

9.3. Early termination of this AGREEMENT will be possible in case of material breach, force majeure, or the bankruptcy or liquidation of either one of the PARTIES.

9.4. Upon expiration of the relevant patent on a LICENSE COMPOUND, the PARTIES shall enter in good faith into negotiations about the conditions of AURIS using further such LICENSE COMPOUND, whereas such discussions shall take into consideration the effects of any potential or existing competition in the marketplace for the relevant PRODUCT.

## 10. MISCELLANEOUS

10.1. If any term or provision of this AGREEMENT shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this AGREEMENT shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

10.2. Nothing in this AGREEMENT shall be construed to constitute either PARTY as the partner, joint venture, agent, employee or affiliate of the other, it being intended that the parties shall remain independent contractors. Neither PARTY shall be liable for the obligations, liabilities or representations of the other PARTY provided this AGREEMENT stipulates the contrary.

10.3. Failure of any of the parties to enforce any of the provisions of this AGREEMENT or any rights with respect thereto shall in no way be considered as a waiver of such provisions or rights or in any way to affect the validity of this AGREEMENT. The waiver of any breach of this AGREEMENT by any party hereto shall not operate to be construed as a waiver of any other prior or subsequent breach.

10.4. This AGREEMENT may be modified or amended only by written agreement of the PARTIES and any provision hereof may be waived only by a document signed by the party waiving such provision.

10.5. This AGREEMENT and the rights and liabilities arising thereunder may not be transferred to third parties except with the prior written consent of the other PARTY to this AGREEMENT. Both PARTIES may, however, transfer this AGREEMENT and/or the rights and liabilities arising thereunder to an affiliated company, in which case the approval of the other PARTY shall be deemed to have been given.

10.6. The PARTIES as well as any person acting on behalf of any of them shall keep the terms and conditions of this AGREEMENT in strict confidence. The PARTIES agree to disclose no such terms and conditions to any third parties, except to their employees, affiliates, investors or consultants on a "**need to know**" basis and bound by respective confidentiality agreements.

10.7. For this AGREEMENT Swiss law shall apply.

10.8. The venue shall be Solothurn.

Xigen SA

By: /s/ Peter Harboe-Schmidt
Name: Peter Harboe-Schmidt
Title: Chairman & CEO

Auris Medical AG

By: /s/ Thomas Meyer
Name: Thomas Meyer
Title: Chairman & CEO

**Appendix I: List of LICENSE COMPOUNDS**

- JNK Inhibitors XG 101/102
- Beta cell and neuronal cell specific MKK7 inhibitors XG 201 CS
- Proprotein convertases
- IB1 Protein
- D-NR2B9C and L-NR2B9C

**Appendix II: List of XIGEN patents and licenses relevant for LICENSE COMPOUNDS**

**Patents licensed from CHUV/UNIL**

IDF 1/99
Design of cell permeable inhibitors of the c-Jun N-terminal kinase
Ch. Bonny, Inventor

USSN JNK Inhibitors
Filed 14 February, 2000 (continuation of US 60/158,774) Priority date 12 October 1999
Serial number 09/503,954
Status: Delivered on 26 August 2003
Published on 26 August 2003, patent number US 6,108,820

USSN CIP JNK & MKK7 Inhibitors
Filed 7 June 2002 (continuation of USSN 09/503,954 and addition of 60/347,062) Priority date 12 October 1999 & 9 January 2002 (on claims)
Serial number 10/165,250
Status: Pending
Published on 12 June 2003, patent number US 2003-0108539

USSN CIP2 JNK & MKK7 Inhibitors
Filed 9 June 2003. (continuation of USSN 09/503,954 and USSN CIP 10/165,250) Priority date 12 October 1999
Serial number 10/457,614
Status: Pending

USSN DIV JNK Inhibitors
Filed 3 October 2001 (continuation of USSN 09/503,954) Priority date 12 October 1999
Serial number 09/970,515
Status: Pending

USSN CON JNK Inhibitors
Filed 15 January 2003 (continuation of USSN 09/503,954 and 60/158,774) Priority date 12 October 1999
Serial number 10/342,683
Status: Pending

USSN MKK7 Inhibitors
Filed 9 January 2003 (continuation of 60/347,062) Priority 9 January 2002
Serial number 10/340,458
Status: Pending

PCT JNK Inhibitors
Filed 12 October 2000 (extension of USSN 09/503,954 and US 60/158,774) Priority date 12 October 1999
Serial number PCT/IB00/01538
Status: Pending
Published on 19 April 2001, patent number WO0127268 A2

AU JNK Inhibitors
Filed 12 October 2000 (extension of PCT/IB00/01538) Priority date 12 October 1999
Serial number 79382/00
Status: Pending

JP JNK Inhibitors
Japanese Nat'l filing date 11 April 2002 (extension of PCT/IB00/01538) Effective international filing date 12 October 2000
Priority date 12 October 1999
Serial number 2001-530472
Status: Pending
Published on 25 March 2003, patent number 2003-511071

EP JNK Inhibitors
Filed 12 October 2000 (extension of PCT/IB00/01538) Priority date 12 October 1999
Serial number 000969730.1
Status: Pending
Published on 23 April 2003, patent number EP1303600

CA JNK Inhibitors
Filed 12 October 2000 (extension of PCT/IB00/01538) Priority date 12 October 1999
Serial number 2,387,184
Status: Pending

US NATL JNK Inhibitors
Filed 12 October 2000 (extension of PCT/IB00/01538) Priority date 12 October 1999
Serial number 10/110,430
Status: Pending

PCT MKK7 Inhibitors
Filed 9 January 2003 (extension of USSN 10/340,458) Priority date 9 January 2002
Serial number PCT/IB03/00332
Status: Pending
Published on 17 July 2003, patent number WO 03/057725

PCT CIP JNK & MKK7 Inhibitors
Filed 9 January 2003 (extension of USSN 10/165,250) Priority date 12 October 1999
Serial number PCT/IB03/03094
Status: Pending

12-13/00

Use of proprotein convertase for the intracellular delivery of drugs and macromolecules

Ch. Bonny, Inventor

USSN Proprotein Convertase
Filed 15 October 2001 (continuation of US 60/240,315) Priority date 13 October 2000
Serial number : 09/978,831
Status: pending
Published on 28 August 2002, patent number US-2002-0120100

USSN CIP Proprotein Convertase
Filed 7 June 2002 (continuation of USSN 09/977,831) Priority date 13 October 2000
Serial number : 10/165,015
Status: pending
Published on 13 February 2003, patent number US 2003-0032594

PCT Proprotein Convertase
Filed 15 October 2001 (extension of USSN 09/977,831 and US 60/240,315) Priority date 13 October 2000
Serial number: PCT/IB01/02423
Status: pending
Published 18 April 2002, publication number WO02/31109

AU Proprotein Convertase
Filed 15 October 2001 (extension of PCT/IB01/02423) Priority date 13 October 2000
Serial number 2002220979
Status: Pending

JP Proprotein Convertase
Filed 15 October 2001 (extension of PCT/IB01/02423) Priority date 13 October 2000
Serial number 2002-534479
Status: Pending

EP Proprotein Convertase
Filed 15 October 2001 (extension of PCT/IB01/02423) Priority date 13 October 2000
Serial number 01986713.4
Status: Pending
Published on 24 September 2003, patent number EP 1 345 956

CA Proprotein Convertase
Filed 15 October 2001 (extension of PCT/IB01/02423) Priority date 13 October 2000
Serial number 2,425,610
Status: Pending

US NATL Proprotein Convertase
Filed 15 October 2001 (extension of PCT/IB01/02423) Priority date 13 October 2000
Serial number 10/399,127
Status: Pending

PCT CIP Proprotein Convertase
Filed 6 June 2003 (extension of USSN 10/165,015) Priority date 13 October 2000
Serial number: PCT/IB03/03097
Status: pending

**Patents Owned by Xigen**

Transcription factor Islet Brain (IB1)
Inventor: Waeber et Al.
(Assigned to Xigen)

USSN Islet Brain
Filed May 20, 1997
Application no: 859,201
Status: Delivered on March 9,1999
Patent number: 5,880,261

PCT
Filed 2 April, 1998
Application no: 98913958.9
International publication number: WO 98/44106
Status: Pending

## Appendix III: Relevant conditions of the CHUV/UNIL AGREEMENT

### ARTICLE 2 — GRANT

[*****]

## ARTICLE 5 — REPORTS AND RECORDS

[*****]

## ARTICLE 7 — INFRINGEMENT

[*****]

[*****]

## ARTICLE 8 — NO WARRANTIES AND LIABILITY

[*****]

[*****]

**ARTICLE 9 — CONFIDENTIALITY**

[*****]

**ARTICLE 10 — USE OF NAMES**

[*****]

**ARTICLE 12 — CHALLENGE OF THE PATENT RIGHTS**

[*****]

**ARTICLE 13 — BREACH AND CURE**

[*****]

**ARTICLE 14 — TERM OF THE AGREEMENT**

[*****]

[*****]

## ARTICLE 16 — MISCELLANEOUS PROVISIONS

[*****]

[*****]

**Appendix IV: Tinnitus Molecule development**

XIGEN will develop for AURIS the peptides D-NR2B9C and L-NR2B9C which could block the interaction between the PSD-95 protein and NMDA receptors and thus block tinnitus. NR2B9C as well as pTat-NR2B9C have already been described in scientific literature. However, the coupling of the NR2B9C with XIGEN's D-Tat molecule as well as the local administration of D-NR2B9C (or L-NR2B9C) for the treatment of inner ear disorders have not been published so far. XIGEN will supply AURIS with D-NR2B9C and L-NR2B9C for the in vitro and in vivo evaluation of the compound in tinnitus treatment (stage 1). If the results of the evaluation studies are unsatisfactory, further analysis and development work of up to 6 months may be necessary (stage 2).

D-NR2B9C and L-NR2B9C (collectively "**AM-102**") are developed under the terms of the AGREEMENT, subject to the following particular conditions:

1. AURIS will pay [*****] to XIGEN for the supply of [*****] of D-NR2B9C and [*****] of L-NR2B9C and support in drafting [*****] patents on the two compounds and/or the application

2. Regarding intellectual property, section 5.3 of the AGREEMENT shall apply

3. There shall be no milestone payments whatsoever (sections 4.3 and 4.4 of the AGREEMENT)

4. The royalty payments on NET SALES of AM-102 will be [*****] at a maximum. If AURIS has to obtain one or more licenses from third parties in order to be able to legally sell AM-102, the royalty payment shall be reduced in half (i.e. to [*****]).

In case that a second stage shall be deemed necessary by AURIS, the payment of AURIS to XIGEN for the additional development work and supplies shall be negotiated between the PARTIES in good faith.

**CONFIDENTIAL TREATMENT REQUESTED UNDER RULE 406 UNDER THE SECURITIES ACT OF 1933, AS AMENDED.**

**[*****] INDICATES OMITTED MATERIAL THAT IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST FILED SEPARATELY WITH THE COMMISSION. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE COMMISSION.**

**Exhibit 10.2**
INSERM 03233A30

**CO-OWNERSHIP/EXPLOITATION AGREEMENT**

**BETWEEN**

INSTITUT NATIONAL DE LA SANTÉ ET DE LA RECHERCHE MÉDICALE, a publicly funded government science and technology agency (*établissement public à caractère scientifique et technologique*), registered office: 101, rue de Tolbiac, 75654 Paris Cedex 13, represented by its Director General, Mr Christian Bréchot,

"INSERM",

**AND**

AURIS MEDICAL AG, registered office: Rütifeldstrasse 1, 4573 Lohn-Ammannsegg, Switzerland, represented by its Managing Director, Mr Thomas Meyer,

"AM".

AM and INSERM are referred to below individually as the "Party" and jointly as the "Parties".

**RECITALS**

1) AM is a research and development company specialising in ear, nose and throat pathologies.

2) On 29 September 2003 AM and INSERM entered into an agreement known as the "Collaboration and Licence Option Agreement Ref. 03233A10" governing the performance of a research programme entitled "Therapeutic evaluation of two NMDA receptor antagonists (7-CK and ketamine) and a c-Jun N-terminal kinase pathway (JNK) inhibitor in a behavioural model for tinnitus induced by sound trauma", (the "Study").

The agreement of 29 September 2003 comprises a certain number of provisions relating to the ownership of the results of the Study and their exploitation.

As part of their collaboration, AM has filed the following patent applications in the joint names of INSERM and AM:

- 29 March 2004: US Patent Application No. 10/812,298 entitled "Methods for the treatment of tinnitus induced by cochlear excitotoxicity";
- 29 March 2005: International Patent Application No. PCT/EP2005/003254;
- 28 September 2005: US Continuation-in-Part Application related to Application No. 10/812,298.

These patent applications are provided in Appendix 1 to this Agreement.

The Collaboration Agreement of 29 September 2003 also provides for the possible worldwide exclusive exploitation of the results of the Study, whether patented or not, by AM with effect from the date of notification of its decision to do so to INSERM.

AM having notified INSERM of its intention to exercise the exclusive licence option pursuant to the provisions of section 9.1 of the aforementioned Collaboration Agreement, the Parties agreed to determine the rules for managing the co-ownership of the results, whether patented or not, and the terms of their exploitation pursuant to the provisions of sections 8 and 9 of the Agreement of 29 September 2003.

**This having been set out, THE FOLLOWING IS HEREBY AGREED:**

## 1. DEFINITIONS

The definitions set out below apply to this Agreement. Where the context allows, the singular includes the plural and vice versa and the masculine includes the feminine and vice versa.

### 1.1 Patents

“Patents” means US Patent Application No. 10/812,298 entitled “Methods for the treatment of tinnitus induced by cochlear excitotoxicity” filed on 29 March 2004 in the joint names of INSERM and AM, International Patent Application No. PCT/EP2005/003254 filed on 29 March 2005, any foreign application filed on the basis of this application, any continuation, continuation-in-part, additional or divisional application and the resulting patents and any patent re-filed, re-granted or re-examined on the basis of this application.

### 1.2 Agreement

“Agreement” means this Agreement including the recitals, appendices and amendments which form an integral part of it.

### 1.3 Field of Application

“Field of Application” means the treatment of tinnitus and, more generally, all the applications claimed in the Patent.

### 1.4 Subsidiary

“Subsidiary” means any commercial company or partnership incorporated under French or foreign law which, through a capital share holding or any another means, holds at least 50% of the voting rights or rights to run the affairs of AM, controls AM, is controlled by AM or is placed under the same control as AM.

Rights granted to Subsidiaries under the terms of this Agreement apply only to corporate bodies which are Subsidiaries at the time the rights are exercised. If a corporate body should cease to be a Subsidiary during the term of this Agreement, the rights it has acquired as a Subsidiary will lapse immediately unless agreed otherwise in writing by INSERM.

1.5 Licence Holder

"Licence Holder" means any commercial company or partnership incorporated under French or foreign law which has acquired the right to develop, promote, manufacture or cause to be manufactured the Licensed Products under the Patents from AM. Neither third parties who acquire rights to distribute, market and sell the Licensed Products from AM, nor Subsidiaries are deemed Licence Holders.

1.6 Licensed Products

"Licensed Products" are any products, processes or services whose manufacture, production, use and/or sale constitutes an infringement of a claim of a Patent which has not been rejected, cancelled or otherwise invalidated by a final and absolute decision.

1.7 Income

"Income" means the net sales of Licensed Products made by AM and/or its Subsidiaries and/or its authorised Licence Holders less (1) the costs of returns and replacements, (2) discounts and other price reductions, (3) tax and (4) delivery costs (including insurance and transport). It is understood that such deductions shall not exceed [*****] of total income.

Income does not include intermediary sales of the Products between AM and its Subsidiaries or between the Subsidiaries themselves. Only the total amount invoiced by AM, its Subsidiaries and Licence Holders to third parties is taken into account in calculating Income. The calculation of Income does not include humanitarian sales or transfers or sales and transfers made in relation to clinical studies.

1.8 Development Work

"Development Work" means all the work and studies carried out directly by AM or on behalf of AM in order to develop and market the Licensed Products.

1.9 Territory

"Territory" means any country in which the Patents have been filed.

**2. CO-OWNERSHIP SHARE**

The Parties certify that they are jointly responsible for the invention claimed in Patent No. 10/812,298 and acknowledge that they are [*****] co-owners of the Patents.

**3. EXCLUSIVE EXPLOITATION BY AM**

The Parties agree that the Patents will be exploited exclusively by AM in the Field of Application in order, in particular, to develop, promote, manufacture, cause to be manufactured, use, sell and distribute the Licensed Products in the Territory during the term of this Agreement.

In consequence, INSERM shall refrain from exploiting, either directly or indirectly, the Patents in the Territory.

However, it is expressly agreed between the Parties that the exclusive exploitation granted to AM shall not prevent INSERM from using the inventions covered by the Patents for its own research purposes free of charge, its research purposes excluding, in particular, any direct or indirect profit-making.

AM alone will be entitled to grant manufacturing or sales licences for the Patents in the Field of Application and in the Territory to its Subsidiaries and/or third parties provided that it systematically informs INSERM of this fact and provides INSERM immediately upon signature of copies of the provisions of the relevant licence agreements relating to price, confidentiality and publication, patent infringement and warranties.

AM alone will be responsible for the proper performance of said licences and AM alone will be responsible to INSERM for ensuring that the Licence Holders perform all the obligations incumbent upon AM under this Agreement. In particular, AM undertakes to include in said licences confidentiality clauses similar to that contained in this Agreement and not to enter into licence agreements with terms longer than that of this Agreement.

## 4. DEVELOPMENT, MARKETING AND SALES

### 4.1 Development Work carried out prior to obtaining a Marketing Authorisation

The Parties acknowledge that the invention claimed in the Patent application filed on 29 March 2004 requires additional research and development work in order to obtain a “Marketing Authorisation”.

This additional study phase will be financed [*****] will decide on the clinical strategy and the nature of the research and development work to be carried out.

AM undertakes to inform INSERM of the progress of the Development Work on a regular basis. To this end, every year AM will send INSERM a written report outlining the progress of the development work, any pre-clinical and clinical studies which have been carried out, applications for marketing authorisations and any licence agreements entered into.

AM shall use its best efforts to conduct and complete the Development Work, whether directly or indirectly via its Subsidiaries or Licence Holders, in so far as this is commercially and financially feasible, with the objective of bringing the Licensed Products to the market.

AM therefore undertakes to comply with the relevant regulations applicable in France and abroad and with the guidelines of the competent authorities in the field of the Development Work and/or the marketing of the Licensed Products and to use its best efforts to obtain the authorisations required under the legislation and regulations applicable in the countries of theTerritory as quickly as possible.

AM will be responsible for obtaining and renewing the registrations and marketing authorisations for the Licensed Products in the Territory, either in its name [*****] or in the name and [*****] of any person it may designate, and for compliance with local legislation.

AM undertakes, in so far as the clinical studies organised by or at the instruction of AM are concerned, to perform all the obligations required under the legislation and regulations in force in the relevant countries and in the case of studies conducted in France with the

obligations of the Law of 20 December 1988 on the Protection of Persons Participating in Biomedical Research (*Loi du 20 décembre 1988 relative à la protection des personnes qui se prêtent à des recherches biomédicales*), as amended. AM indemnifies INSERM against any claim or legal action which may be taken against it by third parties in relation to such studies.

The Parties acknowledge that AM cannot warrant any success in fulfilling its obligations under the present section.

However, should AM fail to complete, either director or indirectly, phase II clinical trials (proof of therapeutic efficacy in human subjects as defined in ICH Guideline E8, General Considerations for Clinical Trials, 3.1.3.2) within [*****] of the signature of this Agreement and to initiate phase III clinical trials (as per above definition) within [*****] of publication of the results of the phase II clinical trials, the Parties shall consult with one another to evaluate the reasons for the delay in the development of the Licensed Products and, where appropriate, to determine the future of the relationship created by this Agreement. In such a case, and if it is shown that AM has failed to use reasonable efforts in carrying out the Development Work, INSERM may revoke the exclusivity of exploitation granted to AM under this Agreement subject to notification of its decision by registered letter with acknowledgement of receipt.

4.2 Marketing

AM is free to organise its promotional, manufacturing and distribution policy for the Products as it sees fit.

The name “INSERM” may not be used for any purpose whatever (in particular for promotional purposes and irrespective of the media used, whether video, poster, press pack, etc.) without the prior written consent of INSERM.

This provision shall remain in force notwithstanding the expiry or termination of this Agreement.

## 5. FINANCIAL TERMS AND CONDITIONS

5.1 General financial terms and conditions

In consideration of the exclusive right granted under this Agreement, AM undertakes:

- to provide the finances required to ensure the proper performance of the Development Work, it being understood that it is the responsibility of AM to define the means to be allocated for this purpose;
- to continue to bear [*****] the intellectual property costs relating to the Patent under the terms set out in section 6.1 of this Agreement,
- to pay INSERM a fee in respect of the exploitation of the Licensed Products under the terms set out in section 5.2 below.

5.2 Royalties

AM undertakes to pay INSERM a fee based on the Income from all Licensed Products at the rate of:

- [*****], if the Income earned across the entire Territory in one year is less than or equal to [*****];
- [*****] of that part of the Income earned across the entire Territory in excess of [*****] in one year.

The fee will be payable for each country from the date a Licensed Product is first marketed in the Field of Application until the [*****]. AM alone will be responsible for the payment of the fees to INSERM.

AM also undertakes to pay INSERM a fee of [*****] of any sums of any nature (except royalties) collected by AM and/or its Subsidiaries in respect of the grant of licences to Licence Holders with the exception of refunds of or contributions to research and development costs, clinical studies and marketing authorisation application costs.

5.3 Terms and conditions of fee payment

A statement of Income from the sale and marketing of Licensed Products and the sums collected in respect of licences granted by AM to the Licence Holders as at 31 December of each year approved by AM’s auditors shall be sent to INSERM on 30 April of the following year even where no sales have been made in the year in question.

Following acceptance of this statement by INSERM, the sums due in respect of the year in question shall be paid within [*****] of receipt of invoice issued by INSERM. The payments shall be made to “Monsieur l’Agent Comptable de l’INSERM au Compte [*****] – Recette Générale des Finances de Paris – 94, rue Réaumur 75104 – Paris Cedex 02”.

All sums due are subject to statutory taxes as applicable, in particular to VAT at the statutory rate in force at the time.

Sums duly collected by INSERM pursuant to this Agreement shall in all cases remain finally and absolutely the property of INSERM and shall not under any circumstances be returned to AM. Moreover, any sums owed by AM on the date of expiry or termination of this Agreement shall be paid to INSERM.

5.4 Default penalties

Any sum not paid to INSERM within the aforementioned periods shall attract default interest at the rate of [*****] of any delay calculated *prorata temporis* without prejudice to INSERM’s right to terminate this Agreement pursuant to section 9. Termination.

5.5 Audit

AM undertakes to keep and to ensure that its Subsidiaries and/or Licence Holders keep special accounts of the revenues received in respect of the sale of the Licensed Products including all the elements required to make a precise assessment of the commercial transactions carried out and to verify the fees.

These special accounts for each year will be made available to INSERM for a period of [*****] following the year in question.

At INSERM's request, but no more than once in each calendar year, AM will authorise an auditor chosen by INSERM to audit these accounts in order to verify that the fee has been calculated correctly. To this end, INSERM or the auditor of its choice will be entitled, subject to fifteen (15) days' advance notice, to enter AM's premises during AM's office hours.

The auditor's fees and expenses will be borne exclusively by INSERM except where, following said audit, the amount of the sums actually paid by AM to INSERM is adjusted by more than [*****], in which case the auditor's fees and expenses will be borne by AM.

## 6. INTELLECTUAL PROPERTY, INFRINGEMENT

6.1. Filing and renewal of Patent applications

AM shall manage Patent files as well monitor the process of Patent issuance and maintenance in collaboration with INSERM. AM shall, in particular, obtain INSERM's prior consent in respect of (i) the scope and content of all Patent applications and (ii) draft responses to patent office requests. For the purposes of this section 6, "the Patent issuance and maintenance" shall include but is not limited to the filing of applications, the conduct of interference and opposition proceedings and/or the re-examination of applications, re-issues and certificates of addition, continuation and continuation-in-part applications. The Parties undertake to use their best efforts to facilitate Patent filing and maintenance procedures.

INSERM undertakes, in particular, to supply AM with any documents of any nature (technical or administrative) which AM might need in relation to the issue or maintenance of Patents, and to provide technical and scientific assistance.

AM undertakes to bear exclusively all expenses relating to Patent filing, examination, extension and maintenance procedures in the countries in which the Patents have been filed or granted throughout the term of this Agreement. It is understood that the patent law firm responsible for the Patents will invoice AM directly for all intellectual property costs relating to the Patents.

If AM does not wish to maintain or continue procedures for extending or obtaining Patents in a given country, it shall inform INSERM within a reasonable period so that INSERM may, if it so desires, continue such Patent filing, extension or maintenance procedures at its own expenses and in its own name in the country in question. INSERM is bound to inform AM of its decision within sixty (60) days of receipt of such information. If no response is received within this period, INSERM shall be deemed to have waived its right to continue the Patent filing, extension and maintenance procedures.

If INSERM undertakes to continue Patent filing, extension, manintenace or defence procedures in place of AM at its own expenses and in its own name in given a country, AM

undertakes to return its ownership share in these Patents to INSERM free of charge and to waive its exclusive right of exploitation in the country or countries in question. AM therefore undertakes to provide all the signatures and documents required to enable INSERM to hold full ownership of said rights in the Patents in the country in question. AM will be entitled to a refund of any intellectual property costs incurred in the country in question and of the cost of transferring its ownership share. INSERM shall refund these costs on the basis of the revenues generated subsequently by the exploitation of the right.

6.2. Improvements

Improvements to the Patents which are made and financed by AM shall be the exclusive property of AM which will be entitled to file a patent application in relation to such improvements in its own name and at its own expenses.

6.3 Assignment

INSERM shall refrain from assigning its co-ownership share for as long as this Agreement is in force.

6.4 Infringement

INSERM and AM shall inform one another as soon as possible of any infringement which comes to their attention. The Parties shall liaise in order to decide on the best strategy to adopt.

In case of disagreement between the Parties as to the strategy to adopt, action shall be taken by AM which alone shall bear all procedural costs and any costs and damages awarded against it. AM shall also retain the benefit of any advantages which might result from such action.

If the Parties fail to reach an agreement, they may each act independently at their own expense and risk and retain the benefit of any advantages which might result from their respective actions. In such cases the notice stipulated in section L. 613-29 b) of the French Intellectual Property Code (*Code de la Propriété Intellectuelle*) is not required.

In countries where legislation forbids one of the Parties from acting independently, the other Party shall, when so requested and within the appropriate period, provide any power of attorney or authorisation required to allow the first Party to act for it.

In any event, the Parties undertake to provide one another with any documents and other elements they may require in connection with the aforementioned procedures.

AM shall act in the best joint interests of the Parties in any action which may prove necessary to defend the rights associated with the Patents and, in particular, should infringement proceedings be instituted by AM against a third party infringer or by a third party against AM.

If infringement proceedings are instituted against AM, AM will not be entitled to claim from INSERM any compensation, refund of sums paid or reduction of sums still to be paid under section 5 above at the time the court decision becomes final. However, AM may deduct [*****] of the amount of any damages awarded against it by a court, once they have

become enforceable, from the remuneration it owes to INSERM under section 5 of this Agreement up to a maximum reduction of [*****] of the amount of the remuneration payable to INSERM under the aforementioned section and, where applicable, staggering the sums to be deducted over several years of exploitation.

## 7. WARRANTY, INDEMNIFICATION

7.1. Warranties provided by INSERM

INSERM declares and warrants to AM that

- it is fully qualified to grant it the exclusive right of exploitation which forms the subject matter of this Agreement;
- the research carried out by INSERM under the Collaboration Agreement of 29 September 2003 was carried out in accordance with the principles and practices generally applied by the scientific community.

INSERM makes AM no other warranty of any nature, either express or tacit.

Nothing in this Agreement may be interpreted as constituting a warranty:

- on the part of INSERM or the inventors as to the successful filing, validity or scope of any of the Patents in any of the countries of the Territory;
- that the Patents do not infringe third party patents or any other third party intellectual property right;
- of the harmlessness, the appropriateness for a specific purpose or of the performance of the Patents by the end of this Agreement.

Nothing in this Agreement shall be interpreted as conferring on AM, either implicitly or in any other manner, any rights in any other INSERM patents.

The risks involved in the performance of this Agreement shall be borne by AM alone and AM accepts these risks. In case of the rejection or revocation of one or more Patents or if one or more Patents is made dependent on an earlier dominant patent, or if the Products were to be declared counterfeit due to the use of the Patents by an enforceable decision of the courts, INSERM will not be bound either to repay any sums already acquired or to reduce sums owing on the date of the final and absolute court order or to pay any damages to AM to compensate for the prejudice caused by said rejection, revocation, dependence or infringement.

7.2. Warranties provided by AM

AM indemnifies INSERM and the members of its staff against any claims that might arise from personal injury or damage to property suffered in connection with the manufacture, holding and/or use of the Patents or the sale and marketing of the Products by AM, its Subsidiaries and/or its Licence Holders.

AM waives its right to take action against INSERM if such complaints, claims, proceedings AM undertakes to ensure that its Subsidiaries and/or Licence Holders make the same commitment as it itself makes under the provisions of this section; this requirement shall be included in all licence agreements.

AM shall ensure that it, its Subsidiaries and/or Licence Holders have in place the necessary insurance to provide adequate cover for its liability in connection with the exploitation of the Patents.

AM, its Subsidiaries and/or Licence Holders alone will be liable for ensuring that the Products comply with the applicable legislation and regulations. AM, its Subsidiaries and/or Licence Holders may not call in warranty INSERM and are themselves alone liable in respect of their clients and/or any third parties for the quality and performance of the Products.

## 8. CONFIDENTIALITY, PUBLICATION

8.1. Confidentiality

Each Party undertakes to keep confidential and not to disclose or divulge to any party without the written consent of the other Party any information of any nature which may come to its attention in connection with this Agreement and, in particular, any confidential information relating to the Development Work, to the Patents or to the Licensed Products which it may receive in connection with this Agreement (the “Information”).

However, the following Information shall not be deemed to be confidential:

- information which is in the public domain on the date it is disclosed or is subsequently introduced into the public domain in good faith by a third party;
- information already known to the Party receiving it on the effective date of this Agreement, except if said Information is received from one of the Parties to this Agreement;
- information received by a third party who is entitled to disclose it.

In any event, it falls to the receiving Party to prove that the Information it receives is not confidential.

AM will be entitled to supply Information to third parties, including to its Subsidiaries and Licence Holders, in so far as the divulgation of this Information is useful or necessary to AM in exploiting the licence granted under this Agreement and in so far as the third party to whom this Information is provided is bound by a duty of confidentiality similar to that stipulated above.

The Parties undertake to take any measures that can reasonably be demanded to ensure that their obligations under this section 8 are performed by their staff and any person engaged by them in any position. AM shall include similar confidentiality obligations in any licence agreements it enters into with Licence Holders.

This duty of confidentiality shall remain in force throughout the term of this Agreement and for five (5) years after its expiry or termination.

8.2 Publication

Any publication by either Party, whether written or oral, relating to confidential Information is subject to the prior written consent of the other Party. In such a case, the other Party has a period of one month in which to accept, in certain cases subject to certain modifications, its publication or to request that said confidential Information be removed from the publication.

However, the other Party shall not withhold its consent without good reason.

**9. EFFECTIVE DATE, TERM**

This Agreement is effective as of the date of its signature by the last of its signatories. Subject to premature termination of the Agreement as provided for in section 10, this Agreement shall remain in force until the last of the Patents expires or becomes invalid.

**10. TERMINATION**

10.1 This Agreement may be terminated by one of the Parties in case of non-performance by the other Party of any of its obligations under this Agreement and, in particular, under sections 4, 5 and 8, if said Party has failed to remedy said non-performance within no more than thirty (30) days from the date of written notification of said non- performance.

10.2 This Agreement will, subject to written notification remaining unheeded within one (1) month and subject to the provisions of section L.621-28 of the French Commercial Code (*Code de commerce*), be terminated automatically if AM ceases trading or enters compulsory liquidation.

10.3 This Agreement may be terminated automatically by INSERM in the following cases:

- in the absence of sales of a Licensed Product for [*****] after market launch;
- in the total absence of sales of a Licensed Product for a period of [*****] with effect from the date of obtaining the marketing authorisation.

**11. GENERAL PROVISIONS**

11.1. No assignment

This Agreement is entered into *intuitu personae*. Consequently, this Agreement and all the rights and obligations attaching to it are personal, non-assignable and non-transferable except with the prior written consent of the other Party. This consent shall not be refused without good reason.

Where AM is taken over by, merged with, absorbed by or its activities are transferred to another company other than a Subsidiary or in the event of any other conversion of AM which alters the personal nature of this Agreement, the Agreement may be transferred only with the prior written consent of INSERM. This consent shall not be refused without good reason.

It is hereby agreed that any company to which the rights and obligations of one or other of the Parties are assigned will be subject to the same obligations as those incumbent on the Party in question under this Agreement unless the new parties together agree otherwise. Any amendment of the terms and conditions of this Agreement which are agreed and occur as a result of such a transfer, the name and address of the assignee, for example, shall be stipulated in writing and inserted in an appendix to this Agreement at the time of transfer.

11.2. *Force majeure*

The Parties shall be excused a failure to perform their obligations, and shall not be held liable or made to pay damages to the other Party where this failure of performance is due to a case of *force majeure* such as the disorganisation of its services resulting, in particular, from strike, resignation or any other event beyond its control.

11.3. Independent co-contractors

Under no circumstances shall this Agreement be interpreted as creating an association or de facto company between the Parties, each of them being considered as independent co-contractors.

11.4. Amendment

This Agreement cancels and replaces any prior agreements between the Parties relating to the subject matter of this Agreement and in particular the Agreement of 29 September 2003. Any amendment to this Agreement shall be made in writing and any such amendment shall be signed by an authorised representative of each of the Parties.

11.5. Communication

Until such time as a change of address is notified in writing, any communication or notification to the Parties shall be made by telex or fax confirmed by subsequent letter or by registered letter with acknowledgement of receipt to the addresses given below:

For INSERM: Inserm
101, rue de Tolbiac
75654 PARIS Cedex 13
*Tel: 01 44 23 60 40*
*Fax: 01 45 85 07 66*

For AM: Auris Medical AG
Ruetifeldstrasse 1
CH-4573 Lohn-Ammannsegg
*Tel: +41 32 677 05 67*
*Fax: +41 26 492 50 71*

 [Initials]

11.6 Public announcements and communications

Any public announcement or communication relating to the signature of this Agreement or its content or to the use of the name of one of the Parties or one of its agents or employees shall require the consent of the Party in question.

11.7. Waiver

Should either Party breach its obligations arising out of this Agreement and if the Party not in breach fails to exercise the rights accruing to it as a result of said breach, said failure to exercise its rights shall not be interpreted as a waiver of these rights in the future or in relation to a new similar breach by the Party in breach of its obligations arising out of this Agreement.

11.8. Registration

AM is fully authorised to carry out at its own expense any registration formalities applicable to this Agreement, in particular tax registration and registration in the National Patent Registers of the relevant countries in the Territory.

## 11. APPLICABLE LAW AND JURISDICTION

This Agreement is subject to French law.

In case of a difficulty occurring between the Parties in relation to the conclusion, interpretation, performance or termination of this Agreement, the Parties shall endeavour to settle their differences amicably.

In case of persistent disagreement, the Parties agree to submit to the jurisdiction of the Paris *Tribunal de Grande Instance*.

Executed at , in two (2) original copies.

| | |
|---|---|
| AURIS MEDICAL | INSERM 28 FEB 2006 |
| MANAGING DIRECTOR | DIRECTOR GENERAL |
| [signature] | [signature] [stamp: illegible] |
| Thomas MEYER | Christian BRECHOT |
| | Stamp: INSERM<br>For the Director General and by delegation |

**Exhibit 10.3**

*Execution Version*

# Series C

# Investment Agreement

This Series C Investment Agreement (the/this "**Agreement**") is made as of 5 April 2013 by and among Auris Medical AG, Falknerstrasse 4, 4001 Basel, Switzerland (the "**Company**"), the C Investors in the Series C investment round listed in Annex I attached to this Agreement (each a "**C Investor**" and together the "**C Investors**") and the existing shareholders of the Company listed in Annex I attached to this Agreement (each a "**Shareholder**" and together the "**Shareholders**"). Company, C Investors and Shareholders are collectively referred to as "**Parties**".

WHEREAS:

- Thomas Meyer (the "**Founder**") incorporated the Company as Fimacom AG with registered office in Lüterkofen, Switzerland, on 1 April 1998. The Company's name was changed to Auris Medical AG and its purpose amended to the current purpose on 22 May 2003. The Company's registered office was moved to Düdingen, Switzerland, on 21 June 2006 and to Basel, Switzerland on 28 March 2008;
- The Company is a stock corporation duly incorporated under the laws of Switzerland having its current registered address at Falknerstrasse 4, Basel, which is active in the development of pharmaceutical products for the treatment of inner ear disorders. It has a fully paid share capital of CHF 4,632,580, divided into (i) 2,904 registered common shares with a par value of CHF 10 each (the "**Common Shares**"), (ii) 239,990 registered preferred category A shares with a par value of CHF 10 each (the "A Shares"), and (iii) 220,364 registered preferred category B shares with a par value of CHF 10 each (the "**B Shares**"); and
- The C Investors wish to subscribe, in one or multiple tranches, for new C Shares with a par value of CHF 10 each having the rights and privileges set forth in the revised articles of association (the "**Articles of Association**") and in the Shareholders' Agreement, both in the form attached to this Agreement (the "**C Shares**" and with the Common Shares, the A Shares and the B Shares, the "**Shares**"), and to invest in the Company on the terms set out in this Agreement.

Now, therefore, the Parties hereto AGREE as follows:

## 1. Investment and Subscription for Shares

### 1.1. Subscription for Shares at Initial Closing

Subject to the terms and conditions of this Agreement, each C Investor agrees to make an equity investment in the Company by subscribing for shares and making contributions in cash to be paid at the Initial Closing as set forth in Annex II (column 'First Tranche/Initial Closing') in the upcoming capital increase of the Company (the "**Series C First Tranche Investment**").

The overall Series C First Tranche Investment shall be of CHF 24,480,060 corresponding to 185,455 new C Shares at a price of CHF 132 per share. The obligation to participate in the Series C First Tranche Investment round shall be several and not joint, and each C Investor shall be liable only for the amount set out opposite its name in Annex II (column "First Tranche/Initial Closing").

The Parties hereto, each in so far as they are concerned, hereby undertake to take all actions necessary to approve and implement the capital increase and C Share issue at Initial Closing (and, if applicable, at any subsequent closing under clause 2.6) in order to give effect to the provisions of this Agreement. In particular, the Shareholders will pass, and undertake to cause the board of directors of the Company to implement, the necessary resolutions.

The Shareholders hereby waive all preferential subscription rights in connection with the capital increase and C Share issue at Initial Closing (and, if applicable, at any subsequent closing under clause 2.5) under this Agreement.

1.2. Use of Proceeds

The Company intends to use the proceeds from the First Tranche investment to further develop its business and to reach the milestones set forth in clause 2.6.

## 2. Initial Closing

2.1. Initial Closing Date

The subscription for and issuance of the first tranche of the new C Shares ("**Initial Closing**") shall take place on 5 April 2013 at Aeschenvorstadt 67, 4010 Basel ("**Initial Closing Date**").

2.2. Pre-Initial Closing Actions

The C Investors shall have delivered to the Board their respective commitments substantially in the form set forth in Annex IV (duly completed) and shall have transferred on or before the Initial Closing Date their cash contributions to arrive in the blocked escrow bank account no. XXX-XXXXXX.XXX (XXX XXXX XXXX XXXX XXXX XXXX X) with UBS Basle for the nominal value of the shares (CHF 10 per Share) and in bank account no. XXX-XXXXXXXX.X (XXXX XXXX XXXX XXXX XXXX XXXX X) with UBS Berne (BIC: XXXXXXXXXX) for the due amount of the share-premium (*Agio*) on the relevant C Shares (CHF 122 per Share) or the equivalent in EUR in bank account XXX-XXXXXXXX.X (XXXX XXXX XXXX XXXX XXXX XXXX X) with UBS Berne (BIC: XXXXXXXXXX) or the equivalent USD in bank account XXX-XXXXXXXX.X (XXXX XXXX XXXX XXXX XXXX XXXX X) with UBS Berne (BIC: XXXXXXXXXX). The amounts in EUR and USD will be fixed on 2 April, 2013, 09.30 a.m. CET, at the prevailing spot exchange rate (mid-point).

Prior to or on the Initial Closing Date, each Shareholder shall have executed and delivered the restated and amended shareholders' agreement ("**Shareholders' Agreement**", Annex V). The Board shall only be obliged to accept C Investors as new shareholders of the Company and to enter them into the shareholders' register once the C Investors have executed the Shareholders' Agreement as well as the escrow agreement ("**Escrow Agreement**", Annex VI).

2.3. Conditions precedent to Initial Closing

The obligations of the C Investors to effect the Initial Closing Actions set forth in clause 2.4 shall be subject to the satisfaction or waiver on or by the Initial Closing Date of the following conditions:

(i) The Company's Board of Directors shall have resolved not to issue any further options and rights in connection with the current employee incentive plan (the "**A Stock Option Plan**") and to make any further issues pursuant to a plan to be adopted by the Board of Directors (including the consent of representatives of the C Investors to the Board of Directors) post closing, providing for option grants with a 4 year vesting scheme, no acceleration of vesting upon any initial public offering and in connection with an M&A/trade sale, and only acceleration upon a double trigger (i.e. a change of control + a termination without cause) (the "**C Stock Option Plan**");

(ii) No notice shall have been given to the Company by any of the C Investors to indicate that there has been a breach of the representations and warranties under Section 3 hereof;

(iii) There shall not have occurred, since 31 December 2012, any event, change or development which individually or in the aggregate, adversely and materially affects, or is reasonably likely to adversely and materially affect, the present or future legal, tax, economic or financial position of the Company, its assets, its liabilities or its present or future business ("**Material Adverse Change**"); and

(iv) The Company shall have duly executed Sofinnova Venture Partners VIII, L.P.'s standard management rights letter (the "**Management Rights Letter**", Annex VII) in connection with the present Series C Investment in such way to stay compliant with Federal ERISA requirements for VCOC.

If the conditions precedent are not met or waived by the Investors on the Closing Date, the Board shall cause the contributions received to be returned to the C Investors.

2.4. Initial Closing Actions

At the Initial Closing,

(a) the relevant Party/Parties shall deliver the following documents, duly executed and in form and substance satisfactory to the Company and the C Investors:

(i) Acceptance declarations of the New Directors, with legalized signatures;

(ii) Proxies from the Shareholders for the Extraordinary Shareholders' Meeting authorizing the proxy holder(s) to vote on and approve all resolutions set forth in Clause 2.4(b) below;

(iii) the Management Rights Letter;

(iv) Signed statement by the Board that, since 31 December 2012, no event, change or development which individually or in the aggregate, adversely and materially affects, or is reasonably likely to adversely and materially affect, the present or future legal, tax, economic or financial position of the Company, its assets, its liabilities or its present or future business has occurred ("**Material Adverse Change**");

(v) A duly signed application to the Register of Commerce of the Canton of Basel-Stadt regarding the resolutions of the Extraordinary Shareholders' Meeting;

(vi) Shareholders' Agreement duly executed by all Parties substantially in the form attached as Annex V;

(vii) Confirmation from UBS evidencing that all contributions of the C Investors have been paid in cash and fully credited to the Company's accounts specified in clause 2.2.;

(viii) Each C Investor shall deliver a duly signed original of its subscription form in accordance with clause 2.2. and Annex IV;

(ix) The Board shall issue its report regarding the capital increase (*Kapitalerhöhungsbericht*);

(x) Circular resolutions or minutes evidencing the Board resolution regarding the registration of the C Investors as owners with voting rights of the relevant number of C Shares subscribed by the respective C Investor in the Company's share register upon registration of the capital increase corresponding to the First Tranche Investment.

(b) Upon the delivery of the documents listed in clause 2.4(a) above, the following actions shall be performed:

(i) The Shareholders shall hold an extraordinary meeting (the "**Extraordinary Shareholders' Meeting**") where the Shareholders shall resolve/approve (i) an increase in capital of CHF 1,854,550 by the issuance of 185,455 new C Shares for an aggregate price of CHF 24,480,060, (ii) to renew and increase the Company's authorized share capital to the amount of up to CHF 1,715,450 so that up to 171,545 new C Shares can be issued, (iii) to delete the second conditional share capital of up to CHF 1,000,000 for the issuance of up to 100,000 B Shares, (iv) to adopt the Articles of Association of the Company, as attached as Annex III (to be amended as required by the register of commerce of the Canton of Basel-Stadt; hereinafter "**HR BS**"*), and (v) to elect Jim Healy and Antoine Papiernik as Board members of the Company (the "**New Directors**"); *It is understood and agreed among the Parties that the Extraordinary Shareholders' Meeting shall approve the Articles of Association as per Annex III, however with any changes and deletions requested by the HR BS, which shall not be subject to further discussions/negotiations.

(ii) The Board shall take the resolutions on the ascertainments and the execution of the Series C capital increase (*Feststellungsbeschluss*) in the presence of a public notary.

(c) The Company shall file the application with the Register of Commerce of the Canton of Basel-Stadt immediately upon receipt of the documents and performance of the actions above.

2.5. Post Closing Actions

As soon as possible after the registration of the capital increase pursuant to clause 2.4, the Company shall

(i) issue the C Share certificates subscribed for by the C Investors;

(ii) enter the new shareholdings into the Company's shareholder register;

(iii) deliver into escrow share certificates representing the new C Shares issued;

(iv) deliver to each C Investor a copy of the share certificate representing the C Shares subscribed for by that C Investor; and

(v) hold a Board meeting in which the Company's rules of organization shall be amended so as to reflect the Series C investment documents (in particular with regard to the protective provisions of Clauses 3 and 4 thereof), in a form reasonably agreeable to the C Directors.

2.6. Subsequent Closings

The Parties agree that up to two further closings (the "**Second Closing**" and/or, the "**Third Closing**", respectively) resulting in further capital increase and issuance of new C Shares (out of the authorized capital voted at the Initial Closing) as set forth in Annex II (columns "Second Tranche/Second Closing" and "Third Tranche/Third Closing"), may be completed as provided for, and subject to, clause 2.6.

The amount of the share-premium (*Agio*) on the relevant C Shares for any of the Second Closing or Third Closing ("**Agio Amount**") shall be, for each new C Share to be subscribed as per Annex II in such closing, the lower of (i) CHF 122 per share or (ii) the price (minus CHF 10) paid by at least one new financial institutional investor (excluding a strategic or corporate partner) who invests at least CHF 13,860,000 in such subsequent closing/closings (a "**Qualified Investor**").

The Company shall have the right to waive a Second Closing and/or a Third Closing, either (i) with the written consent of the holders of C Shares holding at least two thirds of C Shares, or (ii) in case an IPO (meaning the closing of a public offering by the Company of all or any part of the Company's share capital or any depository receipts representing such share capital whereby Shares are admitted to trading on the official listing or quotation on an internationally recognised stock exchange or trading association in compliance with applicable laws and regulations) where the per share price of the Common Shares being sold to the public is at least 2.5 times the applicable per share price of the C Shares (as appropriately adjusted for any stock splits, stock combinations or the like), or (iii) in the case of a trade sale of the Company pursuant to which the holders of C Shares will receive in cash at the closing an amount equal to at least CHF 264 per share (as appropriately adjusted for any stock splits, stock combinations or the like), in the case of (ii) or (iii) with such transaction taking place within 12 months from the Initial Closing Date.

2.6.1. Second Closing

The obligation of the C Investors to effect the Second Closing is subject to the satisfaction or waiver in writing by the holders of C Shares holding at least two thirds of the C Shares of the following conditions:

(i) the Company shall have entered into a Special Protocol Assessment Agreement for the TACTT2 study with the U.S. Food and Drug Administration ("FDA");

(ii) results from the Company's TACTT1 study shall be in line with the Company's previous clinical safety and efficacy data, as acknowledged by the Board;

(iii) either Sofinnova Ventures or Sofinnova Partners shall have confirmed within 30 days after notification by the Company that the Special Protocol Assessment Agreement with the FDA is acceptable to it and that it is agreed that the results from the TACTT1 study are in line with the previous clinical safety and efficacy data (such confirmation not to be unduly refused or withheld);

(iv) the Company shall have restated the representations and warranties on the date of the Second Closing pursuant to Clause 3 with, as the case may be, appropriate disclosures acceptable to the C Investors; and

(v) no Material Adverse Change since the Initial Closing or Third Closing, whichever is most recent, shall have occurred

((i) to (v) altogether the "**Second Closing Conditions**").

Within 10 days as from receipt by the Company of confirmation by Sofinnova Ventures and/or Sofinnova Partners as per condition precedent (iii) here above, and subject to satisfaction of the remaining Second Closing Conditions, the Second Closing shall take place as follows:

(a) the C Investors shall deliver to the Board their respective commitments substantially in the form set forth in Annex IV and shall have transferred their cash contributions to arrive in the blocked escrow bank account with UBS Basle for the nominal value of the C Shares (CHF 10 per share) and in bank account no. xxx-xxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxx x) with UBS Berne (BIC: xxxxxxxxxx) or any other account designated by the Company for the relevant Agio Amount for each subscribed C Share as per Annex II, *Column Second Closing*;

(b) the Board shall resolve on the increase in capital out of the authorized capital voted at the Initial Closing and issue 104,318 new C Shares to the C Investors as set forth in Annex II, *Column Second Closing*;

(c) in case of participation of a Qualified Investor, the Parties shall furthermore resolve on the increase in capital (either prior to the Second Closing by way of creation of a new authorised share capital or at the Second Closing by way of an ordinary increase of the share capital) and the Board shall issue the corresponding number new Series C Shares to the Qualified Investor;

(d) the Company shall file the application with the Register of Commerce of the Canton of Basel-Stadt immediately upon receipt of the necessary documents and resolutions, and proceed with the actions set forth in clause 2.5.

2.6.2. Third Closing

The obligation of the C Investors to effect the Third Closing is subject to the satisfaction or waiver in writing by the holders of C Shares holding at least two thirds of the C Shares of the following conditions:

(i) the Company shall have provided to the C Investors minutes from Company meetings with the FDA (end of Phase II or Pre-IND meeting) and with the EMA (scientific advice or protocol assistance meeting) that document the size and scope of the next clinical trial for AM-111;

(ii) either Sofinnova Ventures or Sofinnova Partners shall have confirmed within 30 days after notification by the Company that the minutes as per condition (i) here above are acceptable to it (such confirmation not to be unduly refused or withheld);

(iii) the Company shall have restated the representations and warranties on the date of the Third Closing pursuant to Clause 3 with, as the case may be, appropriate disclosures acceptable to the C Investors; and

(iv) no Material Adverse Change since the Second Closing or Initial Closing, whichever is most recent, shall have occurred

((i) to (iv) altogether the "**Third Closing Conditions**").

Within 10 days as from receipt by the Company of confirmation by Sofinnova Ventures and/or Sofinnova Partners as per condition precedent (ii) here above, and subject to satisfaction of the remaining Third Closing Conditions, the Third Closing shall take place as follows:

(a) the C Investors shall deliver to the Board their respective commitments substantially in the form set forth in Annex IV and shall have transferred their cash contributions to arrive in a blocked escrow bank account with UBS Basle for the nominal value of the shares (CHF 10 per Share) and in bank account no. xxx-xxxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxx) with UBS Berne (BIC: xxxxxxxxxxx) or any other account designated by the Company for the relevant Agio Amount for each subscribed C Share as per Annex II, *Column Third Closing*;

(b) the Board shall resolve on the increase in capital out of the authorized capital voted at the Initial Closing and issue up to 67,227 new C Shares to the C Investors as set forth in Annex II, *Column Third Closing*;

(c) in case of participation of a Qualified Investor, the Parties shall furthermore resolve on the increase in capital [either prior to the Third Closing by way of creation of a new authorised share capital or at the Third Closing by way of an ordinary increase of the share capital] and the Board shall issue the corresponding number new Series C Shares to the Qualified Investor;

(d) the Company shall file the application with the Register of Commerce of the Canton of Basel-Stadt immediately upon receipt of the necessary documents and resolutions, and proceed with the actions set forth in clause 2.5.

2.6.3. No specific order in subsequent closings

The Company may consummate the Third Closing and offer new C Shares to a Qualified Investor prior to the Second Closing should the Third Closing Conditions be met prior to the Second Closing Conditions; however, the Company shall not raise alternative private equity capital (other than a Qualified Investor joining the Second or Third Closing) prior to obtaining clarity with respect to the milestones associated with such Second and Third Closings. For purposes of clarity, the foregoing shall not be deemed to preclude an IPO.

## 3. Representations and Warranties

The Company hereby represents and warrants to each C Investor that the following representations are true and complete as of the date of the Initial Closing, as well as of the Second Closing and of the Third Closing, as applicable, except as otherwise indicated. For purposes of these representations and warranties, the term "**Company**" or "**Group**" shall include the Company and any subsidiaries of the Company, unless otherwise noted herein.

### 3.1. Authority

The Company and the Shareholders (other than, for the Initial Closing, the C Investors) have the authority to enter into and perform this Agreement and to carry out their obligations hereunder. This Agreement constitutes a legal, valid and binding obligation of each of them.

### 3.2. Related Persons

There are no existing contracts or arrangements to which the Company is a party and in which the Founder and/or any related person is interested (except for the mandate agreement and the loan agreement with Altamira Pharma GmbH, with registered seat in Zuchwil). In particular, there is not outstanding:

(i) any loan made to the Company by the Founder or any person connected with him;

(ii) any amount owing to the Company by the Founder or any person connected with him;

(iii) any security given by the Company in respect of any obligation of the Founder or a person connected with him; or

(iv) any claim by the Founder or by any person connected with him against the Company (other than for expenses properly incurred or compensation for employment accruing in the normal course of business).

The amounts (capital and interests) due to Altamira Pharma GmbH under the above mentioned loan agreement shall be repaid immediately after the Initial Closing out of the proceeds from the Series C First Tranche Investment.

### 3.3. Employment/Mandate Agreement

Except for the mandate agreement with Altamira Pharma GmbH, all employment, consultancy, agency or like contracts or arrangements relating to the previous employment, consultancy, agency or like arrangement of the Founder have been validly terminated and there is no claim or legal action, proceeding or arbitration in progress or, so far as the Founder is aware, threatened or pending against the Founder in relation to any such prior employment, consultancy, agency or like arrangements of the Founder. To the Company's best knowledge, no employee of the Company, nor any consultant with whom the Company has contracted, is in violation of any term of any employment contract, proprietary information agreement or any other agreement relating to the right of any such individual to be employed by, or to contract with, the Company because of the nature of the business conducted and proposed to be conducted by the Company; and the continued employment by the Company of its present employees, and the performance of the Company's contracts with its independent contractors will not result in any such violation. The Company has not received any notice alleging that any such violation has occurred. The

Company is not aware that any officer or key employee, or that any group of key employees intends to terminate their employment with the Company, nor does the Company have a present intention to terminate the employment of any officer, key employee or group of key employees. The Company has complied with all applicable laws and regulations respecting employment and employment practices, terms and conditions of employment, wages and hours and other laws related to employment, and there are no arrears in the payments of wages or other similar obligations.

3.4. Business

Except as disclosed to the C Investors regarding Altamira Pharma GmbH, the Founder is neither alone nor jointly with or as shareholder, adviser, consultant, agent or employee of any person directly or indirectly engaged in any business other than that of the Company.

3.5. Non-compete

The Founder is not subject to any restrictive covenant or non-compete or equivalent provisions under any contract or arrangement with any person which may restrict or prohibit the Founder from performing his obligations under the relevant employment or the mandate agreement, as the case may be, or this Agreement.

The Founder has no interest, directly or indirectly, in any privately owned business (at the exclusion of listed companies) which is or is likely to be competitive with the business of the Company.

3.6. No Confidentiality Arrangement

The Founder is not subject to any confidentiality or non-disclosure or like provisions under any contract or arrangement with any person which may restrict or prohibit the Founder from performing his obligations under the relevant employment or the mandate agreement, as the case may be, or this Agreement.

3.7. Organization and good standing

The Company is a corporation validly existing and in good standing under the laws of Switzerland. It has at all times carried on its business and conducted its affairs in all respects in accordance with its constitutional documents for the time being in force. The Company has the right to own property and transact business in all jurisdictions in which it transacts business in the manner in which the business is conducted and has all necessary licenses, consents, permits and authorities to do so and it has conducted its business in accordance with all relevant laws of all such jurisdictions. No resolutions have been passed or action taken amending the Articles of Association or otherwise requiring registration with the Commercial Register which are not reflected in this Agreement.

All returns and particulars, resolutions and other documents which the Company is required by law to file with or deliver to any relevant authority have been correctly made up, duly filed and/or delivered.

The Company has properly maintained all corporate records as required by the relevant applicable law. All books of account, relevant correspondence, minutes, financial, corporate and other records of whatsoever kind are complete and correct and have been maintained in accordance with sound business practice and the requirements of the applicable law and corporate regulations, give and reflect a true and fair view of all transactions entered into and of the financial, contractual and trading position of the Company, and do not contain any material inaccuracies or discrepancies of any kind.

3.8. Approval

No order, license, consent or approval of, or the giving of notice to, any person or authority is necessary to authorize the execution, delivery, completion and performance of this Agreement by the Company.

3.9. Capitalization and Participations

Immediately prior to the Initial Closing, the share capital of the Company consists of CHF 4,632,580 divided into 2,904 Common Shares with a nominal value of CHF 10 each, 239,990 A Shares with a nominal value of CHF 10 each and 220,364 B Shares with a nominal value of CHF 10 each. Immediately prior to the Initial Closing, the Company has a conditional share capital of CHF 371,060 consisting of 37,106 Common Shares with a nominal value of CHF 10 each, and a second conditional share capital of up to CHF 1,000,000 for the issue of up to 100,000 B Shares with a nominal value of CHF 10 each earmarked for holders of conversion and option rights issued in connection with bonds or similar financial instruments or loans of the Company or of subsidiaries thereof. Immediately prior to the Initial Closing, a total of 7,860 options are outstanding which were issued under the A Stock Option Plan. These options give their owners, after a vesting period of 3 years, the right to purchase Common Shares for 2 years at an issue price ranging from CHF 80 to CHF 120 each. A total of 1,520 options are vested on January 30, 2013. Immediately prior to the Initial Closing, the Company has an authorized share capital of CHF 1,600,000, authorizing the issue of up to 160,000 B-Shares with a nominal value of CHF 10 each, until 31 December 2014.

The Shareholders (excluding, at the Initial Closing, the C Investors) are the sole legal owners of, and have good and valid title, to 100% of the issued and outstanding shares of the Company, as specified in Annex II, *Columns Common, Series A and Series B*, free and clear of any lien.

The Company is the full and unrestricted owner of 16,730 registered shares of Laboratoires Auris SAS in liquidation, CEEI Cap Alpha, Avenue de l’Europe, 34940 Montpellier Cedex 09, France (“LASAS”), with a nominal value of EUR 10 each, which represents a participation of 50% in LASAS. LASAS is currently being wound up by a court appointed liquidator in the context of bankruptcy proceedings.

The Company is the full and unrestricted owner of 1,500 common shares of Auris Medical Inc., 444 North Michigan Avenue, Suite 1200, Chicago IL 60611, USA (“AMI”), without nominal value, representing a paid-in capital of USD 15,000. Each of the shares gives the same rights. No preference shares exist, nor do any shares granting special rights or subject to special restrictions exist, whether such special rights or restrictions be in respect of the shares themselves, their holders, the duration of holding the shares or any other matter.

The Company is the full and unrestricted owner of 100 ordinary shares of Auris Medical Ltd., The Black Church, St. Mary’s Place, Dublin 7, Ireland (“AML”), with a nominal value of EUR 1 each, representing a paid-in capital of EUR 100. Each of the shares gives the same rights. No preference shares exist, nor do any shares granting special rights or subject to special restrictions exist, whether such special rights or restrictions be in respect of the shares themselves, their holders, the duration of holding the shares or any other matter.

3.10. Licenses, Permits and Authorizations

The Company had and has all the licenses, permits and authorizations required which are necessary to carry on its business as presently conducted and as presently proposed to be conducted and the Company has complied with all terms and conditions of those. The fact that this Agreement is executed and the transactions contemplated herein are consummated will not lead to the automatic termination (i.e. a termination as a matter of law) of the Company's licenses, permits and authorizations and will also not give rise to any rights of the competent authorities or other third parties to terminate such licenses, permits and authorizations.

3.11. Real Estate Leases

The Company has valid leases, rental or leasing arrangements as to such real property leased by it to carry on its business. Said leases, rental or leasing arrangements are not in default and are free and clear of any lien.

3.12. Absence of Liens

The Company is the owner with good and saleable title free from all liens, charges, encumbrances, security interests or adverse claims of its assets. All assets used by the Company are in good workable condition save for normal wear and tear having regard to their age and usage, and have been regularly maintained.

3.13. No Conflict or Violation

Neither the execution, delivery and performance of this Agreement nor the consummation of the transactions contemplated hereby will result (i) in a breach of, or a default under, any term or provision of any contract to which the Company or the Founder is a party or by which any assets of any of them are bound, or of any constitutional document of the Company or would interfere in any material way with the ability of the Company and the Founder to consummate the transactions contemplated by this Agreement; (ii) to the Company's best knowledge, in a conflict with, or a default or event of default under, any term and provision of any laws, rules or regulations or any governmental, administrative or regulatory authority or any judgments, orders, rulings or awards of any court, arbitrator or judicial authority or governmental administrative on regulating authority or any other restriction of any kind by which the Company is bound; or (iii) in a termination or acceleration of, or a cancellation of any Material Contract as per clause 3.21.

3.14. Financial Statements

The Company has delivered to each C Investor

(i) audited financial statements for the Company for the business years 2008-2011 as well as final but not yet audited financial statements for the Company for the business year 2012;

(ii) final but not yet audited financial statements for Auris Medical Inc. for the business year 2012;

(iii) final but not yet audited financial statements for Auris Medical Limited for the business year 2012;

(iv) audited consolidated Group financial statements for the business years 2008-2011 as well as final but not yet audited consolidated Group financial statements for the business year 2012

(collectively the "**Financial Statements**"). The Financial Statements have been prepared in accordance with generally accepted accounting principles applied on a consistent basis. They fairly present in all material respects the financial condition and operating results of the Company as of the dates, and for the periods, indicated therein. Except as set forth in the Financial Statements, the Company has no material liabilities or obligations, contingent or otherwise, other than (i) liabilities incurred in the ordinary course of business subsequent to 31 December 2012 (ii) obligations under contracts and commitments incurred in the ordinary course of business and (iii) liabilities and obligations of a type or nature not required under generally accepted accounting principles to be reflected in the Financial Statements, which, in all such cases, individually and in the aggregate would not have a material adverse effect.

3.15. Compliance with Legal Requirements

To the Company's best knowledge, neither the Company, nor any of its directors, officers, employees or agents has violated any applicable laws, ordinances, regulations, decrees or orders of any government entity which are relevant to the business of the Company or done or omitted to do anything which is a contravention of any such laws, ordinances, regulations, decrees or orders. To the Company's best knowledge, the Company is not subject to, and has no reason to reasonably believe it may become subject to, any liability (contingent or otherwise) or obligation arising under any law, rule or regulation relating to or regulating health, safety, pollution or the protection of the environment.

3.16. Intellectual Property

The Company is entitled to use all intellectual property rights ("**IPRs**") necessary to conduct its present business. No former or present employee of the Company owns or has claimed to own all or any part of the IPRs used by the Company. To the Company's best knowledge, the use of the IPRs owned or licensed by the Company does not and is not likely to infringe any company's or person's rights (including but not limited to intellectual property rights and contractual rights). The Company has no knowledge of nor received any notice alleging that it has infringed IPRs of any other person or company. The Company is not subject to any injunction, undertaking, or court order or order of any other authority of competent jurisdiction not to use or restricting the use of any IPRs. To the Company's best knowledge, there exists no actual or threatened infringement or any event likely to constitute an infringement or breach by any third party of any of the IPRs held or used by the Company. To the Company's best knowledge, neither the execution and delivery by the Company of this Agreement, nor the carrying on of the business of the Company by the employees of the Company, nor the conduct of the business of the Company as presently conducted or as proposed to be conducted, will conflict with or result in a breach of the terms, conditions or provisions of, or constitute a default under, any contract, covenant or instrument under which any Company employee or consultant is now obligated. The Company does not believe it is or will be necessary to utilize any inventions of any of its employees (or people it currently intends to hire) made prior to or outside the scope of their employment by the Company.

3.17. Litigation

There has been no civil, criminal, governmental or other claim, action, suit, arbitration, inquiry, proceeding or investigation pending, and to the best knowledge not threatened or contemplated by or before any Swiss or foreign governmental agency, court, tribunal or arbitration body against the assets of the Company, nor is pending now or are there any indications that a third party will initiate such action, suit etc.

There is no action, suit, proceeding or investigation by the Company pending or which the Company intends to initiate.

3.18. Material Adverse Effects

Since 31 December 2012 and at all times up to the Initial Closing there has not been any event or condition of any character which materially adversely affects, or is likely to so affect, the Company's business operations, assets, condition (financial or otherwise), liabilities, earnings or prospects including but not limited to: (i) any waiver by the Company of a valuable right or of a material debt owed to it, (ii) any material change or amendment to a Material Contract, (iii) any material damage, destruction or loss to any material asset of the Company (whether or not covered by insurance), (iv) any labor trouble, or any event or condition of any character, materially adversely affecting the business or plans of the Company.

3.19. Conduct of Business

Since 31 December 2012 and at all times up to the Initial Closing, the Company has not, other than in the ordinary course of business and consistently with past practices (i) entered into any commitment, transaction or other action, and/or (ii) sold or otherwise disposed of any right, title or interest in or to any assets or properties of the Company or any revenues derived therefrom, and/or (iii) incurred or assumed, except under the loan agreement with Altamira Pharma GmbH, any indebtedness for money borrowed exceeding CHF 250,000 in the aggregate.

3.20. Disclosure

The Company has made available to C Investors in an electronic data room all the information reasonably available to the Company that the C Investors have requested for deciding whether to acquire the C Shares, including spending projections for 2013-2015 ("**Spending Projections**"). All information and documents communicated by the Company to C Investors and / or accessed to by C Investors during the due diligence are complete, fair and true in all material aspects and none of such documents or information are of such nature as to mislead C Investors as to facts and circumstances relating to the Company or to the representations and warranties on which the C Investors have relied in their decision to invest. The Spending Projections were prepared in good faith; however, the Company does not warrant that it will achieve any results assumed or projected in the Spending Projections.

3.21. Material Contracts

All contracts, arrangements, commitments, undertakings or obligations (a) to which the Company is a party and (b) which, whether by reason of their nature, term, scope, amounts or otherwise, are or are likely to be of material importance to its business, profits or assets, are not in the ordinary course of business, restrict the business of the Company in any way or contain change of control clauses or would be breached or terminated as a result of the transactions contemplated hereby

(collectively, the "**Material Contracts**") have been completely disclosed to the C Investors during the due diligence. To the Company's best knowledge all of the Material Contracts are valid, binding and enforceable in accordance with their respective terms. The written text of the Material Contracts covers the full scope of these agreements. The Company has performed all material obligations required to be performed by it under the Material Contracts and is not in default under or in breach of nor in receipt of any claim of default or breach under any Material Contract; to the Company's best knowledge, no event has occurred which with the passage of time or the giving of notice or both would result in a default, breach or event of non-compliance by the Company under any material Contract; neither the Company nor the Founder has a present expectation or intention of not fully performing all such obligations; the Company does not have any knowledge of any breach or anticipated breach by the other parties to any Material Contract.

The existence of a disagreement between the Company and Xigen S.A. regarding a Collaboration and License Agreement concluded on 21 October 2003, and in particular regarding the scope of the license, has been disclosed. This disagreement does not restrain or limit the Company in carrying out its development plans with AM-111.

None of the contracts which the Company is a party to entitles the contract counter party to a compensation (such as finders' fees, retrocessions or similar) which is not fully reflected in the Financial Statements.

## 4. Remedies

### 4.1. Survival of Warranties

Unless otherwise set forth in this Agreement, the representations and warranties of the Company contained in or made pursuant to this Agreement shall survive the execution and delivery of this Agreement and the Initial Closing, the Second Closing or the Third Closing, as applicable, for a period of twenty-four (24) months and any claims under clause 4.3. must be notified to the Company within a twenty-four (24) month period.

### 4.2. Enforcement

Each C Investor shall be entitled to enforce its rights in respect of the representations and warranties contained in this Agreement individually and the Company hereby agrees and undertakes to pay by way of indemnification and to indemnify fully, hold harmless and defend each such C Investor from and against any and all claims and/or liabilities, damages, penalties, judgments, assessments, losses, costs and expenses (including reasonable attorney's fees) suffered by it or the Company and arising out of, relating to, or based upon any inaccuracy or breach of any representation or warranty by the Company contained in this Agreement. The Parties explicitly exclude and waive Article 200 CO, if and to the extent applicable.

The Parties specifically agree and acknowledge that they shall not challenge or instruct the Company to challenge or question the enforceability of a warranty claim under this Agreement, in particular on the basis of Article 680 CO, which the Parties consider as non-applicable in this case. Should enforceability of a warranty claim be denied to a C Investor for breach of the representations and warranties, each Party shall ensure that such C Investor be nevertheless reimbursed and indemnified as contemplated hereunder.

Where a C Investor asserts a warranty claim, its claim shall be limited to a proportional share of its shareholding in the Company at the time of the claim.

4.3. Notification

Each C Investor will be notified by the Company, by registered letter with acknowledgement of receipt, of any breach of the representations and warranties contained in this Agreement ("**Company's Notification**"), no later than fifteen (15) business days from the moment that the Company becomes aware of the breach.

A C Investor wishing to assert a warranty claim under this Agreement shall notify the Company in writing on detecting a breach of the representations and warranties, describing such breach and any damage suffered by the C Investor as a consequence of such breach. In such notification, the C Investor shall provide evidence as to when the alleged breach was detected and confirmation that notification is being made to the Company within thirty (30) days of the date of detection. If the Investor fails to provide such evidence (provided it is available) or if the notification is not being made within thirty (30) days of detection of the alleged breach by the C Investor or of the Company's Notification whichever is later, the C Investor shall be deemed to have waived its claim. Article 201 CO is hereby waived, if and to the extent applicable.

If a C Investor has notified the Company of a breach of representations and warranties, the C Investor making the claim must commence litigation within one hundred and eighty (180) days after notification pursuant to clause 4.3. unless the claim by the C Investor is either settled before the expiry of such deadline or the C Investor and the Company agree in writing on an extension of the deadline. If the C Investor fails to meet such deadline, the claim concerned shall be foregone and unenforceable.

**5. Miscellaneous**

5.1. Notices

Any notice, request or instruction to be given pursuant to this Agreement shall be in writing, and shall be sent by registered mail or courier to the address as set forth in Annex I and shall become effective upon receipt by the Party to which it is addressed.

Any Party may at any time change its address by giving notice to the other Parties in the manner described in clause 5.1.

5.2. Severability

If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

5.3. Amendments

This Agreement including this clause may be modified or amended only by written agreement of the Parties and any provision hereof may be waived only by a document signed by the Party waiving such provision. Notwithstanding anything contained herein to the contrary, the Parties acknowledge and agree that this Agreement may be amended in writing by an instrument signed solely by the holders of 85% of the outstanding Shares in the Company (acting jointly) with binding effect on all other Parties; provided, however, that any such modification or amendment of any of the provisions of this Agreement shall neither affect any accrued rights of any other Party nor impose any greater liability or any more onerous obligation than those contained in this Agreement on the other Parties who do not sign such modification or amendment.

5.4. Assignment

This Agreement and the rights and liabilities arising hereunder may not be transferred to third parties except with the prior written consent of the other Parties to this Agreement. Any Party (except the Company) may, however, transfer this Agreement and/or the rights and liabilities arising hereunder in parts or in its entirety to an affiliated company in which it owns at least fifty-one (51) percent of all outstanding shares or voting rights, in which case the approval of the other Parties shall be deemed to have been given. The approval of the other Parties shall also deemed to have been given for transfer to an affiliated company that holds at least fifty-one (51) per cent of all outstanding shares or voting rights of one of the Parties.

5.5. Confidentiality

The Parties as well as any person acting on behalf of any of them shall keep the terms and conditions of this Agreement in confidence. The Parties agree to disclose no such terms and conditions to any third parties, except to their employees, affiliates, investors or consultants on a “need to know” basis and bound by respective confidentiality agreements. The foregoing confidentiality provision shall lapse upon the 3rd anniversary date of this Agreement.

Any disclosure or public announcement of any type whatsoever regarding this Agreement or its contents shall be made only with the prior written approval of the Parties, except as may be required under applicable law or stock exchange regulations, and then only after consultation with the Company.

5.6. Fees and Expenses

The Company will pay all legal and administrative costs of the financing at Closing and related to the interests of the Company, including reasonable fees and expenses for drafting and revising legal documentation. The C Investors and Shareholders shall pay all legal fees and expenses related to their interests. On production of appropriate receipts, the Company will reimburse the C Investors for such reasonable fees and expenses in an amount not to exceed a total of CHF 115,750.

5.7. Entire Agreement

This Agreement constitutes the entire agreement between the Parties and supersedes all prior agreements, understandings, negotiations and discussions, whether oral or written, between the Parties. There are no representations, warranties, conditions or other agreements, express or implied, statutory or otherwise, between the Parties in connection with the subject matter of this Agreement, except as specifically set forth herein and the Parties have not relied and are not relying on any other information, discussion or understanding in entering into and completing the transactions contemplated by this Agreement.

## 6. Governing Law and Jurisdiction

6.1. Governing Law

This Agreement shall be governed by and be in accordance with Swiss law, without reference to the principles of conflicts of law.

6.2. Jurisdiction

Any disputes between the Parties arising out of or in connection with this Agreement shall be subject to the exclusive jurisdiction of the Commercial Court of the Canton of Zurich, Switzerland.

Executed in 1 original.

**xxx Execution sheet on next page xxx**

**Sofinnova Venture Partners VIII, L.P.**

By: Sofinnova Management VIII, L.L.C.
its General Partner

By: /s/ Jim Healy
Jim Healy, Managing Member

**Sofinnova Capital VII FCPR**

By: Sofinnova Partners SAS
its General Partner

By: /s/ Antoine Papiernik
Antoine Papiernik, Managing Partner

**Auris Medical AG**

/s/ Thomas Meyer
Thomas Meyer, Chairman of the Board

**Allianz Innovation 7 FCPI**
**Idinvest Croissance 2005 FCPI**
**Allianz Innovation 8 FCPI**
**Banque Postale Innovation 3 FCPI**

Each and all by: ID Invest

By: /s/ Benoist Grossmann
Benoist Grossmann

**ZKB Pharma Vision Fonds**
**Adamant Global Healthcare Fonds**
**Adamant Global Generika Fonds**
**Adamant Global Biotech Fonds**

Each and all by: Balfidor Fondsleitung AG

By: /s/ Alexander Muller
Alexander Muller

/s/ Markus Pfister
Markus Pfister

**Phonak AG**

By: /s/ Thomas Meyer
Thomas Meyer (proxy)

/s/ Thomas Meyer

**Daniel Gutenerg** (by Thomas Meyer, proxy)

/s/ Thomas Meyer

**Gerhard Jansen** (by Thomas Meyer, proxy)

/s/ Thomas Meyer

**Martin Oberholzer** (by Thomas Meyer, proxy)

/s/ Thomas Meyer

**Oliver Walker** (by Thomas Meyer, proxy)

/s/ Thomas Meyer

**Heinz Winzel** (by Thomas Meyer, proxy)

**List of Annexes**

Annex I: List of Existing Shareholders

Annex II: Capitalization Table

Annex III: Articles of Association

Annex IV: Commitment Forms

Annex V: Shareholders' Agreement

Annex VI: Escrow Agreement

Annex VII: Management Rights Letter

**Annex I: Parties**

**C Investors:**

Sofinnova Venture Partners VIII, L.P.
2800 Sand Hill Road, Suite 150
Menlo Park, CA 94025

Sofinnova Capital VII FCPR
c/o Sofinnova Partners
17, rue de Surène
75008 Paris
France

**Shareholders:**

Thomas Meyer
Birkenweg 6
CH-4528 Zuchwil

IDinvest
117, Avenue des Champs-Elysées
FR-75008 Paris

Balfidor Fondsleitung AG
c/o Adamant Biomedical Investments AG
Freischützgasse 3
CH-8004 Zurich

Phonak AG
Laubisrütistrasse 28
CH-8712 Stäfa

Daniel Gutenberg
Inselweg 28
CH-8640 Hurden

Gerhard Jansen
Quellenrain 15
CH-3063 Ittigen

Martin Oberholzer
Rohnenrainweg 4
CH-8835 Feusisberg

Oliver Walker
Pestalozzistrasse 5
CH-5000 Aarau

Heinz Winzeler
Klotenerstrasse 13
CH-8304 Wallisellen

**Company:**

Auris Medical AG
Falknerstrasse 4
CH-4001 Basel

**Annex II: Capitalization Table**

| **Investor** | **Common** | | **Series A** | | **Series B** | | | **First Tranche Initial Closing** | | | **Second Tranche Second Closing** | | | **Third Tranche Third Closing** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *Shares* | *%* | *Shares* | *%* | *Shares* | *%* | *Fully Diluted + ESO* | *Shares* | *%* | *Fully Diluted + ESO* | *Shares* | *%* | *Fully Diluted + ESO* | *Shares* | *%* | *Fully Diluted + ESO* |
| **Thomas Meyer, CH-Zuchwil** | 2’904 | 100% | 239’990 | 100.0% | 23’606 | 10.7% | 56.6% | | | 40.6% | | | 35.0% | | | 32.2% |
| **IDinvest, FR-Paris** | | | | | 69’276 | 31.4% | 14.7% | | | 10.6% | | | 9.1% | | | 8.4% |
| *Allianz Innovation 7 FCPI* | | | | | 15’241 | | | | | | | | | | | |
| *Idinvest Croissance 2005 FCPI* | | | | | 19’397 | | | | | | | | | | | |
| *Allianz Innovation 8 FCPI* | | | | | 27’019 | | | | | | | | | | | |
| *Banque Postale Innovation 3 FCPI* | | | | | 7’619 | | | | | | | | | | | |
| **ZKB, CH-Zurich** | | | | | 86’785 | 39.4% | 18.4% | | | 13.2% | | | 11.4% | | | 10.5% |
| *ZKB Pharma Vision Fonds* | | | | | 37’500 | | | | | | | | | | | |
| *Adamant Global Medtech Fonds* | | | | | 9’535 | | | | | | | | | | | |
| *Adamant Global Generika Fonds* | | | | | 23’000 | | | | | | | | | | | |
| *Adamant Global Biotech Fonds* | | | | | 16’750 | | | | | | | | | | | |
| **Phonak AG, CH-Stäfa** | | | | | 22’080 | 10.0% | 4.7% | | | 3.4% | | | 2.9% | | | 2.7% |
| **Daniel Gutenberg, CH-Küsnacht** | | | | | 1’776 | 0.8% | 0.4% | | | 0.3% | | | 0.2% | | | 0.2% |
| **Gerhard Jansen, CH-Ittigen** | | | | | 8’632 | 3.9% | 1.8% | | | 1.3% | | | 1.1% | | | 1.0% |
| **Martin Oberholzer, CH-Feusisberg** | | | | | 1’269 | 0.6% | 0.3% | | | 0.2% | | | 0.2% | | | 0.2% |
| **Oliver Walker, CH-Aarau** | | | | | 2’500 | 1.1% | 0.5% | | | 0.4% | | | 0.3% | | | 0.3% |
| **Heinz Winzeler, CH-Wallisellen** | | | | | 4’440 | 2.0% | 0.9% | | | 0.7% | | | 0.6% | | | 0.5% |
| **Sofinnova Ventures** | | | | | | | | 94’545 | 51.0% | 14.4% | 53’182 | 51.0% | 19.4% | 34’273 | 51.0% | 22.0% |
| **Sofinnova Partners** | | | | | | | | 90’910 | 49.0% | 13.8% | 51’136 | 49.0% | 18.7% | 32’954 | 49.0% | 21.1% |
| | 2’904 | 100% | 239’990 | 100.0% | 220’364 | 100.0% | 98.3% | 185’455 | 100.0% | 98.8% | 104’318 | 100.0% | 99.0% | 67’227 | 100.0% | 99.1% |
| **Stock Options** | 7’860 | | | | | | 1.7% | | | 1.2% | | | 1.0% | | | 0.9% |
| | 10’764 | | 250’754 | | 471’118 | | 100.0% | 656’573 | | 100.0% | 760’891 | | 100.0% | 828’118 | | 100.0% |

Price per share Initial Closing 132
Price per share Second Closing 132
Price per share Third Closing 132

| | | **Initial Closing (CHF)** | **Second Closing (CHF)** | **Third Closing (CHF)** |
|---|---|---|---|---|
| **Sofinnova Ventures** | 51.0% | 12’479’940 | 7’020’024 | 4’524’036 |
| **Sofinnova Partners** | 49.0% | 12’000’120 | 6’749’952 | 4’349’928 |
| **TOTAL** | 100% | 24’480’060 | 13’769’976 | 8’873’964 |
| | | | | 47’124’000 |

Agio will be wired in CHF or equivalent in EUR/USD

**Annex III: Articles of Association**

**Statuten**
**Articles of Association**

**der**
**of**

**Auris Medical AG**
**(Auris Médical SA)**
**(Auris Medical Ltd.)**

**mit Sitz in**
**having its registered business seat in**

**Basel**
**Basle**

**Statuten der Auris Medical AG**

**I FIRMA, SITZ UND ZWECK DER GESELLSCHAFT**

**Art. 1**

**Firma und Sitz**

Unter der Firma

**Auris Medical**

**AG (Auris Médical SA)**

**(Auris Medical Ltd.)**

besteht eine Aktiengesellschaft mit Sitz in Basel.

Die Dauer der Gesellschaft ist unbeschränkt.

**Art. 2**

**Zweck**

Die Gesellschaft bietet Produkte und Dienstleistungen für die Behandlung von Erkrankungen des Hals-, Nasen- und Ohrenbereichs an.

Die Gesellschaft kann alle Geschäfte tätigen und Massnahmen ergreifen, die geeignet sind, den Gesellschaftszweck direkt oder indirekt zu fördern, wie beispielsweise Zweigniederlassungen im In- und Ausland errichten, sich an anderen Unternehmungen beteiligen, Kredite gewähren, Grundstücke erwerben, belasten und veräussern.

***Articles of Incorporation of Auris Medical Ltd.***

***I CORPORATE NAME, REGISTERED BUSINESS SEAT***

***Article 1***

***Business name and registered business seat***

*Under the corporate name*

***Auris Medical AG***

***(Auris Médical SA)***

***(Auris Medical Ltd.)***

*a company exists having its registered business seat in Basle.*

*The duration of the company is unlimited.*

***Article 2***

***Purpose***

*The company offers products and renders services for the treatment of diseases in the throat, nose and ear region.*

*The company may transact all business and take actions which are appropriate in order to promote directly or indirectly the company's purpose, such as opening branch offices and subsidiaries in Switzerland and abroad, acquiring participations in other businesses, granting credit facilities, acquiring, holding, and selling real estate.*

| **II AKTIENKAPITAL** | | ***II SHARE CAPITAL*** | |
|---|---|---|---|
| **Art. 3** | | ***Article 3*** | |
| **Höhe des Aktienkapitals, Anzahl, Art und Nennwert der Aktien** | Das Aktienkapital der Gesellschaft beträgt CHF 6’487’130 und ist in folgende Kategorien von Namenaktien eingeteilt: (i) 2’904 Namenaktien mit einem Nennwert von CHF 10 („Stammaktien”), (ii) 239’990 Vorzugsaktien der Kategorie A mit einem Nennwert von CHF 10 („Vorzugsaktien Kategorie A”), (iii) 220’364 Vorzugsaktien der Kategorie B mit einem Nennwert von CHF 10 („Vorzugsaktien Kategorie B”), und (iv) 185’455 Vorzugsaktien der Kategorie C mit einem Nennwert von CHF 10 (“Vorzugsaktien Kategorie C”). Sämtliche Aktien sind voll liberiert. | ***Amount of the share capital, numbers, types and nominal value of the shares*** | *The share capital of the company amounts CHF 6’487’130 and is divided into the following categories of registered shares: (i) 2’904 registered shares with a par value of CHF 10 (“Common Shares”), (ii) 239’990 registered preferred category A shares with a par value of CHF 10 (“Preferred Shares Category A”), (iii) 220’364 registered preferred category B shares with a par value of CHF 10 (“Preferred Shares Category B”), and (iv) 185’455 registered preferred category C shares with a par value of CHF 10 (“Preferred Shares Category C”). The share capital is fully paid-in.* |
| **Art. 3a** | | ***Article 3a*** | |
| **Genehmigtes Aktienkapital** | Der Verwaltungsrat ist ermächtigt, jederzeit bis zum 5. April 2015 das Aktienkapital im Maximalbetrag von CHF 1’715’450 durch Ausgabe von höchstens 171’545 vollständig zu liberierenden Vorzugsnamenaktien der Kategorie C mit den Vorzugsrechten wie in Art. 28a und 28b dieser Statuten festgehalten mit einem Nennwert von je CHF 10 zu erhöhen. Erhöhungen in Teilbeträgen sind gestattet. | ***Authorised share capital*** | *The board of directors is authorised, anytime until April 5, 2015, to increase the share capital by the maximum amount of CHF 1’715’450 by issuing not more than 171’545 registered preferred shares category C which will have to be fully paid-in and which have preference rights as per Articles 28a and 28b of these Articles of Incorporation, with a par value of CHF 10. Increases in partial amounts are permitted.* |
| | Der Erwerb der neuen Aktien sowie jede nachfolgende Übertragung der Aktien unterliegen den Beschränkungen von Art. 6 dieser Statuten. | | *The acquisition as well as the following transfers of such new shares is subject to the restrictions of article 6 of these Articles of Association.* |

| | | | |
|---|---|---|---|
| | Der Verwaltungsrat legt die Art der Einlagen, den Ausgabebetrag und den Beginn der Dividendenberechtigung fest. | | *The board of directors determines the type of contributions, the issue price and the date on which the dividend entitlement starts.* |
| | Nicht ausgeübte Bezugsrechte kann der Verwaltungsrat anderen Aktionären oder Dritten zuteilen. | | *The board of directors may assign not exercised subscription rights to other shareholders or third parties.* |
| | Der Verwaltungsrat ist berechtigt, das Bezugsrecht der Aktionäre zu beschränken oder auszuschliessen, wenn die neuen Vorzugsnamenaktien für neue Investitionsvorhaben und/oder die Finanzierung der Gesellschaft, insbesondere für Forschungs- und Entwicklungsprojekte verwendet werden. | | *The board of directors is authorised to limit or to abolish the shareholders' subscription rights if the new registered preferred shares are used for new investments and/or the financing of the company, in particular for research and development projects.* |
| **Art. 3b** | | ***Article 3b*** | |
| **Bedingtes Aktienkapital** | Das Aktienkapital kann sich durch Ausgabe von höchstens 37'106 voll zu liberierenden Stammaktien im Nennwert von je CHF 10 um höchstens CHF 371'060 erhöhen durch Ausübung von Optionsrechten, welche den Verwaltungsratsmitgliedern, der Geschäftsleitung, den Mitarbeitern sowie Beratern der Gesellschaft eingeräumt werden. Das Bezugsrecht der Aktionäre ist ausgeschlossen. Zum Bezug der neuen Aktien sind die jeweiligen Inhaber von Optionsrechten berechtigt. Der jeweilige Ausgabebetrag, der Zeitpunkt der Dividendenberechtigung und die Art der Einlagen werden vom Verwaltungsrat bestimmt. Nicht ausgeübte Bezugsrechte stehen zur freien Verfügung des Verwaltungsrates. | ***Conditional share Capital*** | *The share capital may be increased by the issuance of up to 37'106 fully paid registered Common Shares with a par value of CHF 10 per share and to the maximum amount of CHF 371'060 in execution of subscription rights, which are granted to the members of the board of directors, the management board, the employees and the company's advisors. The subscription rights of the shareholders are excluded. The respective holders of the option rights shall be entitled to acquire the shares. The respective issue price, the date on which the dividend entitlement commences and the type of contributions will be determined by the board of directors. Non-exercised subscription rights will be at the board of director's free disposal.* |

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| **Art. 4** | | ***Article 4*** | |
| **Aktientitel** | ***Die Gesellschaft kann anstelle von einzelnen Aktien Zertifikate ausgeben. Sämtliche Aktien und Zertifikate tragen die Unterschrift eines Mitglieds des Verwaltungsrates.*** | ***Share Certificates*** | *The company may issue share certificates which represent one or more shares. All shares and certificates are signed by at least one member of the board of directors.* |
| | Durch Statutenänderung kann die Generalversammlung jederzeit Namenaktien in Inhaberaktien oder Inhaberaktien in Namenaktien umwandeln. | | *The shareholders meeting may, at any time, convert registered shares into bearer shares or bearer shares into registered shares.* |
| **Art. 5** | | ***Article 5*** | |
| **Aktienbuch und Anerkennung der Aktionäre** | Die Namen und Adressen der Aktionäre werden in das Aktienbuch der Gesellschaft eingetragen, unter Angabe der Anzahl und Nummern der ihnen gehörenden Aktien oder Zertifikate. | ***Shareholder's Register and shareholders' admission*** | *Names and addresses of the shareholders shall be entered in the company's shareholders' register, under specification of the quantity and numbers of owned shares or certificates.* |
| | Im Verhältnis zur Gesellschaft wird als Aktionär oder als Nutzniesser nur anerkannt, wer im Aktienbuch eingetragen ist. | | *Towards the company only who is entered in the shareholders' register shall be deemed to be a shareholder or usufructuary.* |
| | Die Eintragung in das Aktienbuch setzt den Ausweis über den Erwerb der Aktie zu Eigentum oder die Begründung einer Nutzniessung voraus. | | *Entry into the shareholders' register is subject to the provision of evidence of the acquisition of the shares as owner or usufructuary.* |
| **Art. 6** | | ***Article 6*** | |
| **Übertragung** | Für die Übertragung von Aktien zu Eigentum oder Nutzniessung ist die Zustimmung des Verwaltungsrates erforderlich. | ***Transfer*** | *The transfer of shares, be it for ownership or usufruct purposes, is in any event subject to the approval by the board of directors.* |

Der Verwaltungsrat kann die Zustimmung aus wichtigen Gründen ablehnen. Als wichtige Gründe gelten:

*The approval may be refused by the board of directors for important reason. Important reasons shall include in particular the following:*

1. Das Fernhalten von Erwerbern, die ein Unternehmen betreiben, das mit der Gesellschaft in Konkurrenz steht, oder die an einem solchen Unternehmen beteiligt, von einem solchen angestellt oder sonst wie dafür tätig sind.

*1. Averting acquirers who carry on a business which competes with the company or who are interested in, employed by or otherwise engaged with or by such a business.*

2. Die Verhinderung des Verlustes der wirtschaftlichen Selbständigkeit der Gesellschaft, namentlich durch die direkte oder indirekte Beherrschung durch eine andere juristische Person oder durch die Eingliederung in einem Konzern.

*2. Avoidance of loss of the company's commercial independency, namely due to the direct or indirect control by another legal entity or due to the company's integration in a group of companies.*

3. Eine Übertragung im Widerspruch zu einer zwischen sämtlichen Aktionären bestehenden Vereinbarung.

*3. Non-compliance with an agreement binding upon all shareholders.*

Der Verwaltungsrat kann die Zustimmung ohne Angabe von Gründen verweigern, sofern die Gesellschaft dem Veräusserer der Aktien anbietet, die Aktien für eigene Rechnung, für Rechnung anderer Aktionäre oder für Rechnung Dritter zum wirklichen Wert im Zeitpunkt des Gesuches zu übernehmen.

*The board of directors may refuse its approval without stating reasons, if the company has offered to the vendor to purchase the shares on its own account, on other shareholders' account or on the account of a third party at their real values at the time of the request.*

Die Zustimmung kann überdies verweigert werden, wenn der Erwerber nicht ausdrücklich erklärt, dass er die Aktien in eigenem Namen und auf eigene Rechnung erworben hat. Sind die Aktien durch Erbgang, Erbteilung, eheliches Güterrecht oder Zwangsvollstreckung erworben worden, so kann der Verwaltungsrat das Gesuch um Zustimmung nur ablehnen, wenn die Gesellschaft dem Erwerber die Übernahme der Aktien zum wirklichen Wert anbietet.

*The approval may furthermore be refused if the acquirer does not explicitly declare that the shares have been purchased in its own name and on its own account. If shares have been acquired by way of inheritance, upon division of an estate, pursuant to the law governing matrimonial property or upon foreclosure, the board of directors may reject the request for registration in the share register only if the company offers to acquire the shares at their real value.*

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| **Art. 7** | | ***Article 7*** | |
| **Bezugsrecht** | Bei der Erhöhung des Aktienkapitals hat jeder Aktionär Anspruch auf den Teil der neu ausgegebenen Aktien, der seiner bisherigen Beteiligung entspricht, sofern der Beschluss über die Kapitalerhöhung nicht etwas anderes bestimmt. | ***Subscription rights*** | *In the event of a capital increase, every shareholder is entitled to the proportion of the newly issued shares that corresponds to its existing participation, unless the resolution about the capital increase states anything different.* |
| **III ORGANE DER GESELLSCHAFT** | | ***III ORGANIZATION*** | |
| **Art. 8** | | ***Article 8*** | |
| **Organe** | Die Organe der Gesellschaft sind | ***Corporate Bodies*** | *The corporate bodies are* |
| | i. Die Generalversammlung | | *i. the shareholders meeting* |
| | ii. Der Verwaltungsrat | | *ii. the board of directors* |
| | iii. Die Revisionsstelle | | *iii. the auditors.* |
| **I. DIE GENERALVERSAMMLUNG** | | ***I. THE SHAREHOLDERS MEETING*** | |
| **Art. 9** | | ***Article 9*** | |
| **Einberufung** | Die Generalversammlung wird durch den Verwaltungsrat einberufen während für alle Beschlussfassungen, welche ein gemäss Art. 15 Abs. 3 besonderes Quorum benötigen, ein Vertreter des Aktionariats der Aktienkategorie C zustimmen muss, des weiteren nötigenfalls durch die Revisionsstelle, sowie in den vom Gesetz vorgesehenen Fällen einberufen. | ***Calling of Meetings*** | *Shareholders meetings shall be convened by the board of directors, including the positive vote of one representative of the preferred C shareholders for all decisions that require a specific majority under art. 15 para 3, if need be by the auditors and in the cases provided by law.* |

Die ordentliche Generalversammlung findet alljährlich innerhalb von sechs Monaten nach Abschluss des Geschäftsjahres statt. Ausserordentliche Generalversammlungen werden nach Bedarf einberufen.

*The ordinary shareholders meeting shall be held annually within six months after the close of the business year. Extraordinary shareholders meetings shall be called whenever necessary.*

Die Einberufung einer Generalversammlung kann auch von einem oder mehreren Aktionären, die zusammen mindestens 10% des Aktienkapitals vertreten, verlangt werden.

*The calling of a meeting of shareholders may also be requested by one or more shareholders whose combined holdings represent at least 10 % of the share capital.*

**Art. 10**

**Form der Einberufung**

Die Einladung zu ordentlichen und ausserordentlichen Generalversammlungen erfolgt spätestens 20 Tage vor dem Versammlungstag schriftlich an die im Aktienbuch eingetragenen Aktionäre, unter Angabe der Verhandlungsgegenstände und der Anträge des Verwaltungsrates sowie gegebenenfalls der Aktionäre, welche die Durchführung der Generalversammlung verlangt haben.

Die Einladung zur ordentlichen Generalversammlung ist mit der Mitteilung zu verbinden, dass der Geschäftsbericht, der Revisionsbericht sowie das Protokoll der letzten Generalversammlung bei der Gesellschaft zur Einsicht aufliegen, und dass die Aktionäre die Zustellung dieser Dokumente verlangen können.

***Article 10***

***Form of convocation***

*The invitation convening ordinary or extraordinary general meeting must be made in writing at least 20 days prior to the day of the scheduled meeting to the shareholders entered in the share register, and it shall include the agenda items and the motions of both the board of directors and the shareholders who requested the holding of general meeting or the inclusion of an item on the agenda.*

*The invitation to the ordinary shareholders' meeting shall include that the business report, the auditors' report as well as the minutes of the last shareholders' meeting are available to the shareholders at the registered office of the company and that the shareholders may request the delivery of these documents.*

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| **Art. 11** | | ***Article 11*** | |
| **Universal-versammlung** | Die Eigentümer oder Vertreter sämtlicher Aktien können, falls kein Widerspruch erhoben wird, eine Generalversammlung ohne Einhaltung der für die Einberufung vorgeschriebenen Formvorschriften abhalten. Solange die Eigentümer oder Vertreter sämtlicher Aktien anwesend sind, kann über alle in die Kompetenz der Generalversammlung fallenden Gegenstände gültig verhandelt und Beschluss gefasst werden. | ***Convening, Universal Meeting*** | *The owners or representatives of all the shares may, if no objection is raised, hold a shareholders meeting without observing the formal requirements for the convening of the shareholders meeting. As long as the owners or representatives of all the shares are present, all subjects falling within the competence of the shareholders meeting may be validly discussed and decided upon at such meeting.* |
| **Art. 12** | | ***Article 12*** | |
| **Vorsitz** | Den Vorsitz in der Generalversammlung führt der Präsident des Verwaltungsrates, bei dessen Verhinderung ein anderes Mitglied des Verwaltungsrates. Der Vorsitzende bezeichnet die Stimmenzähler sowie den Protokollführer. | ***Chair*** | *The shareholders meeting shall be chaired by the Chairman, or, in his absence, by another member of the board of directors. The Chairman designates the scrutineers as well as a secretary for the minutes.* |
| **Art. 13** | | ***Article 13*** | |
| **Stimmrecht der Aktionäre und Vertretung** | Jede Aktie gibt Anrecht auf eine Stimme in der Generalversammlung. | ***Shareholders' voting rights and representation*** | *Each share entitles to one vote.* |
| | Ein Aktionär kann sich gestützt auf eine schriftliche Vollmacht durch einen anderen Aktionär oder eine Drittperson vertreten lassen. | | *Each shareholder may be represented by another shareholder or a third party authorized by a written power of attorney.* |

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| **Art. 14** | | ***Article 14*** | |
| **Befugnisse** | Der Generalversammlung der Aktionäre stehen folgende unübertragbare Befugnisse zu: | ***Powers*** | *The shareholders meeting has the following non-transferable powers:* |
| | 1. Die Festsetzung und Änderung der Statuten | | *1. to adopt and amend the Articles of Association;* |
| | 2. Die Wahl der Mitglieder des Verwaltungsrates sowie der Revisionsstelle | | *2. to elect and remove the members of the board of directors and the auditors* |
| | 3. Die Genehmigung des Jahresberichts | | *3. to approve the annual report* |
| | 4. Die Genehmigung der Jahresrechnung sowie die Beschlussfassung über die Verwendung des Bilanzgewinns, insbesondere die Festsetzung der Dividende | | *4. to approve the annual financial statements as well as to pass resolutions regarding the allocation of profits, in particular with regard to dividends* |
| | 5. Die Entlastung der Mitglieder des Verwaltungsrates | | *5. to grant discharge to the members of the board of directors* |
| | 6. Die Beschlussfassung über alle anderen, der Generalversammlung durch das Gesetz oder die Statuten vorbehaltenen Gegenstände | | *6. to pass resolutions regarding all matters reserved to the shareholders meeting by law or* |
| **Art. 15** | | ***Article 15*** | |
| **Beschlussfassung** | Die Generalversammlung fasst ihre Beschlüsse und vollzieht ihre Wahlen, sofern nicht eine zwingende Bestimmung des Gesetzes oder der Statuten etwas anderes bestimmt, mit der absoluten Mehrheit der vertretenen Stimmen. | ***Resolutions*** | *The shareholders meeting shall pass its resolutions and carry out its elections with an absolute majority of the share votes represented, to the extent that neither the law nor the Articles of Association provide otherwise.* |

Kommt bei Wahlen im ersten Wahlgang keine Wahl zustande, so findet ein zweiter Wahlgang statt, in welchem das relative Mehr entscheidet.

*For election where no appointment results from the first ballot, a ballot with a relative majority shall take place.*

Folgende Beschlüsse der Generalversammlung bedürfen zu ihrer Gültigkeit mindestens zwei Drittel der Stimmen aller Aktienkategorien, seien diese Stimmen anwesend oder vertreten durch einen Stimmrechtsvertreter mindestens zwei Drittel der anwesenden oder durch einen Stimmrechtevertreter vertretenen Stimmen der Vorzugsnamenaktien C und mindestens die Hälfte der anwesenden oder durch einen Stimmrechtsvertreter vertretenen Stimmen der Vorzugsnamenaktien B, wie auch der absoluten Mehrheit der anwesenden oder durch einen Stimmrechtsvertreter vertretenen Aktiennennwerte:

*The following resolutions of the shareholders' meeting require for their validity the approval of shareholders holding at least two-thirds of the outstanding shares in the company being present or represented by proxy, including at least two-thirds of the present or represented votes of the Preferred Shares Category C and at least half of the present or represented votes of the Preferred Shares Category B , as well as the absolute majority of the present or represented nominal values:*

1. Die Änderung des Gesellschaftszwecks

*1. amendment of the purpose of the company*

2. Einführung oder Aufhebung von Vorzugsaktien oder die Änderung von Vorzugsrechten solcher Aktien

*2. creation or cancellation of shares with preference rights or amendment of rights attached to such shares*

3. Die Aufhebung oder Änderung der Beschränkungen der Übertragbarkeit von Namenaktien

*3. cancellation or amendment of restricting the transfer of registered shares*

4. Eine genehmigte oder bedingte Kapitalerhöhung

*4. creation of an authorised or conditional share capital*

5. Die Kapitalerhöhung aus Eigenkapital, gegen Sacheinlage oder zwecks Sachübernahme und die Gewährung von besonderen Vorteilen

*5. increase the share capital by incorporation of reserves, by contributions in kind or for the purpose of acquiring specific assets and granting specific advantages*

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| 6. Das Eingehen von Schulden oder Verbindlichkeiten über den Gesamtwert von CHF 3’000’000 hinaus | *6. incurring debt of more than CHF 3’000’000 in aggregate at any time outstanding* |
| 7. Die Einschränkung oder Aufhebung des Bezugsrechtes | *7. limitation or suppression of shareholder’s pre-emptive rights;* |
| 8. Die Verlegung des Sitzes der Gesellschaft (davon ausgenommen sind Domiziländerungen innerhalb der Sitzgemeinde, die vom Verwaltungsrat beschlossen werden können) | *8. change of the company’s registered business seat or domicile (changes of the company’s domicile within the registered business seat are excluded from this rule and may be resolved by the board of directors)* |
| 9. Die Veräusserung oder Übertragung aller oder eines substantiellen Teils der Aktiven der Gesellschaft oder die Gewährung von Optionen auf einen solchen Erwerb, sei es in einem oder mehreren Rechtsgeschäften. | *9. sale or transfer of all or substantially all the company’s assets or the granting of any option to to the foregoing, in one or a series of transactions* |
| 10. Die Fusion, Zusammenlegung oder Spaltung der Gesellschaft und die Vornahme von Transaktionen, welche eine Auswirkung auf die Zuordnung der Stimmrechte unter den Aktionären hätten | *10. merging, consolidating or splitting the company and effecting any transaction or granting any right to effect any transaction or series of transactions wich would affect the allocation of voting rights among the shareholders* |
| 11. Die Wahl und Abwahl der Revisionsstelle | *11. appointment and removal of the auditors* |
| 12. Die Veränderung der Anzahl von Verwaltungsräten | *12. change of numbers of directors* |
| 13. Die Auszahlung von Dividenden oder der Rückkauf von Aktien. | *13. voting or paying a dividend or buying back any shares* |
| 14. Die Auflösung der Gesellschaft mit oder ohne Liquidation | *14. dissolving or liquidating the company* |

**Art. 16**

**Protokoll**

Ober die Generalversammlung wird ein Protokoll geführt, welches vom Vorsitzenden und vom Protokollführer zu unterzeichnen ist und damit als genehmigt gilt.

***Article 16***

***Resolutions***

*Minutes shall be kept at the shareholders meeting and shall be signed by the Chairman and by the Secretary so as to be validly approved.*

**II. DER VERWALTUNGSRAT**

**Art. 17**

**Zusammensetzung und Amtsdauer**

Der Verwaltungsrat besteht aus einem oder mehreren Mitgliedern.

Die Mitglieder des Verwaltungsrates werden jeweils auf die Amtsdauer von einem Geschäftsjahr gewählt. Die während einer Amtsdauer neu gewählten Mitglieder sind für den Rest der laufenden Amtsperiode gewählt. Wiederwahl ist möglich.

Die Vorzugsaktionäre Kategorie C haben Anspruch auf maximal zwei Vertreter im Verwaltungsrat. Die Vorzugsaktionäre Kategorie B haben Anspruch auf maximal zwei Vertreter im Verwaltungsrat. Die Vorzugsaktionäre Kategorie A haben Anspruch auf maximal einen Vertreter im Verwaltungsrat. Die gleiche Person kann von Vorzugsaktionären der Kategorie A, der Kategorie B und der Kategorie C bezeichnet werden. Die Vertreter der Vorzugsaktien C werden von den Vorzugsaktionären C zur Wahl vorgeschlagen. Die Vertreter der Vorzugsaktien B werden von den Vorzugsaktionären B zur Wahl

***II. THE BOARD OF DIRECTORS***

***Article 17***

***Composition and term***

*The board of directors shall consist of one or more members.*

*The members of the board of directors shall be elected for a term office of one year. The members elected during a term are elected for the rest of this term. Re-election is possible.*

*The preferred C shareholders are entitled to two representatives on the board of directors. The preferred B shareholders are entitled to a maximum of two representatives on the board of directors. The preferred A shareholders are entitled to a maximum of one representative on the board of directors. The same person can be designated the preferred A shareholders, the preferred B shareholders and the preferred C shareholders. The representatives*

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| | vorgeschlagen. Ein zusätzlicher Vertreter soll von den Vorzugsaktionären der Vorzugsaktien A, B und C gemeinsam vorgeschlagen werden, und zwar mit der Zustimmung von mindestens zwei Drittel der Vorzugsaktionäre C, mindestens 50% der Vorzugsaktionäre der Vorzugsaktie B und der absoluten Mehrheit des Aktienkapitals. Die Vorzugsaktionäre können auf Antrag ihre Vertreter in getrennten Versammlungen bezeichnen. Auf diese Versammlungen sind die Bestimmungen Ober die Generalversammlung sinngemäss anwendbar. | | *of the preferred C shares shall be proposed by the preferred C shareholders. The representatives of the preferred B shares shall be proposed by the preferred B shareholders. An additional representative shall be designated, jointly, by the preferred A shareholders, the preferred B shareholders and the preferred C shareholders, with the consent of at least two thirds of the preferred C shareholders, of B shareholders holding at least 50% of the preferred B shares and the absolute majority of the share capital. Upon requests of their representatives, the preferred shareholders can call in separate meetings, to which the rules applicable to the shareholders meeting shall apply analogously.* |
| **Art. 18** | | ***Article 18*** | |
| **Konstituierung** | Der Verwaltungsrat konstituiert sich selbst. Er bezeichnet seinen Präsidenten, einen Vizepräsidenten sowie einen Sekretär, der weder Aktionär sein noch dem Verwaltungsrat angehören muss. | ***Constitution*** | *The board of directors shall constitute itself. It shall further appoint its chairman, its vice-chairman and a secretary, who needs not be a shareholder or a member of the board of directors.* |
| **Art.19** | | ***Article 19*** | |
| **Einberufung** | Der Verwaltungsrat versammelt sich auf Einladung des Präsidenten, oder bei dessen Verhinderung, des Vizepräsidenten, so oft es die Geschäfte erfordern, jedoch mindestens einmal im Jahr. Jedes Mitglied des Verwaltungsrates kann jederzeit schriftlich und unter Angabe der Gründe vom Präsidenten die unverzügliche Einberufung einer Sitzung verlangen. | ***Calling of Meetings*** | *Meetings of the board of directors shall be called by its chairman or, in his absence, by its vice-chairman as often as business requires but at least once a year. Each member of the board of directors may at any time ask in writing the chairman, by stating the reasons, to convene immediately a meeting of the board of directors.* |

| **Art. 20** | | ***Article 20*** | |
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| **Beschlüsse** | Der Verwaltungsrat ist beschlussfähig, wenn die Mehrheit seiner Mitglieder anwesend ist. Dieses Beschlussfassungsquorum ist nicht erforderlich für Beschlüsse, die ausschliesslich Feststellungen und Statutenänderungen im Zusammenhang mit einer Kapitalerhöhung betreffen. | ***Resolutions*** | *The board of directors shall have a quorum when the majority of its members is present. This quorum requirement shall not apply to resolutions exclusively concerning statements and amendments to the Articles of Association in connection with an increase of the share capital.* |
| | Der Verwaltungsrat fasst seine Beschlüsse und vollzieht seine Wahlen mit der Mehrheit der abgegebenen Stimmen, Der Vorsitzende stimmt mit. Bei Stimmengleichheit steht dem Vorsitzenden der Stichentscheid zu. | | *The board of directors shall pass its resolutions with a majority of the votes. The Chairman shall vote. In the event of tie votes. The Chairman shall have a casting vote.* |
| | Folgende Beschlüsse bedürfen der Zustimmung von mindestens 4 Verwaltungsräten, von denen wenigstens zwei von den Vorzugsaktionären der Vorzugsaktien B oder C bestimmt wurden (einschliesslich eines Vertreters der Vorzugsaktionäre der Vorzugsaktie C): | | *The following decisions shall require the approval of at least four (4) directors, at least two of whom are representatives designated by the preferred B or C shareholders (including a representative of the preferred C shareholders):* |
| | 1. Die Entwicklung neuer Produkte (in Abweichung von denjenigen Produkte, welche im Business-Plan genannt sind); | | *1. developing new products (other than the products described in the company's business plan);* |
| | 2. Die Genehmigung des Business-Plans der Gesellschaft; | | *2. approving the Company's business plan;* |
| | 3. Die Ernennung und Abwahl des Geschäftsführers ohne wesentliche Begründung; | | *3. appointing or removing the managing director without important reasons;* |

4. Zahlungen zugunsten und Verträge mit Aktionären, deren Partner oder Angestellten oder Berater der Aktionäre oder deren Partner, es sei denn, solche Zahlungen oder Vertragsabschlüsse halten dem Drittvergleich (arm’s length terms) stand.

*4. payments to and agreements with shareholders, their affiliates or employees or consultants of shareholders or their affiliates except when such payments or agreements are made at arm’s length terms;*

5. Die Einberufung einer Generalversammlung, welche ein Quorum gemäss Art. 15 Abs. 3 dieser Statuten voraussetzt.

*5. convening a shareholders’ meeting requiring specific majorities as provided for under article 15 para 3 of these Articles of Association.*

Beschlüsse können auch auf dem Wege der schriftlichen Zustimmung (Brief, Telefax oder andere schriftliche Form) zu einem gestellten Antrag gefasst werden (Zirkulationsbeschlüsse), sofern nicht ein Mitglied die mündliche Beratung verlangt.

*Board resolutions can be passed by way of written consent (letter, facsimile or any other written form) to a motion (circular resolution), provided that a member does not require an oral discussion.*

**Art. 21**

**Protokoll**

Über Verhandlungen, Beschlüsse und Wahlen wird ein Protokoll geführt, dass vom Vorsitzenden und vom Sekretär zu unterzeichnen ist. Zirkulationsbeschlüsse sind in das Protokoll der nächsten Sitzung des Verwaltungsrates aufzunehmen.

Die Protokolle sind nachträglich vom Verwaltungsrat zu genehmigen.

***Article 21***

***Resolutions***

*Minutes of the deliberations and resolutions of the board of directors shall be kept and signed by the Chairman and the Secretary. Circular resolutions shall be included in the minutes of the next meeting of the board of directors.*

*The minutes are to be subsequently approved by the board of directors.*

**Art. 22**

**Aufgaben**

In die Zuständigkeit des Verwaltungsrates fallen alle Angelegenheiten, welche nicht nach Gesetz oder Statuten einem anderen Organ übertragen oder vorbehalten sind.

***Article 22***

***Tasks***

*All matters that are not transferred or delegated by law or these Articles of Association to another corporate body fall within the competence of the board of directors.*

**Art. 23**

**Unübertragbare Aufgaben**

Der Verwaltungsrat hat folgende unübertragbare und unentziehbare Aufgaben:

1. Die Oberleitung der Gesellschaft und die Erteilung der nötigen Weisungen;

2. Die Festlegung der Organisation;

3. Die Ausgestaltung des Rechnungswesens, der Finanzkontrolle sowie der Finanzplanung, sofern diese für die Führung der Gesellschaft notwendig ist;

4. Die Ernennung und Abberufung der mit der Geschäftsführung und der Vertretung betrauten Personen;

5. Die Oberaufsicht über die mit der Geschäftsführung betrauten Personen, namentlich im Hinblick auf die Befolgung der Gesetze, Statuten, Reglemente und Weisungen;

6. Die Erstellung des Geschäftsberichtes sowie die Vorbereitung der Generalversammlung und die Ausführung ihrer Beschlüsse; und

7. Die Benachrichtigung des Richters im Falle der Überschuldung.

Der Verwaltungsrat kann die Vorbereitung und die Ausführung seiner Beschlüsse oder die Überwachung von Geschäften Ausschüssen oder einzelnen Mitgliedern zuweisen. Er hat für eine angemessene Berichterstattung an seine Mitglieder zu sorgen.

***Article 23***

***Non-transfereable and irrevocable tasks***

*The board of directors has the following non-transferable and irrevocable tasks:*

*1. overall management of the company and issue the necessary directives;*

*2. determining the organisation;*

*3. organizing the accounting, the financial control, as well as the financial planning, as long as it is necessary to the company;*

*4. appointment and removal of the persons entrusted with the management and representation of the company;*

*5. ultimate supervision of the persons entrusted with the management, in particular with respect to compliance with the law, Articles of Association, regulations and directives;*

*6. preparation of the annual report, as well as the shareholders meeting and implementation of its resolutions; and*

*7. informing the judge in the event of overindebtness.*

*The board of directors may delegate the preparation and execution of its decisions or the supervision of business to committees or individual members. It has to ensure adequate reporting to its members.*

| Art. 24 | | *Article 24* | |
|---|---|---|---|
| **Übertragung von Aufgaben** | Der Verwaltungsrat ist unter dem Vorbehalt seiner unübertragbaren und unentziehbaren Aufgaben berechtigt, die Geschäftsführung nach Massgabe eines Organisationsreglementes ganz oder zum Teil an einzelne Mitglieder oder an Dritte zu übertragen. | ***Delegation of tasks*** | *Subject to non-transferable and irrevocable tasks, the board of directors may delegate, in part or wholly, the management to individual members or to third parties in accordance with the Organisational Rules.* |
| **III. DIE REVISIONSSTELLE** | | ***III. THE AUDITORS*** | |
| **Art. 25** | | ***Article 25*** | |
| **Wahl und Amtsdauer / Verzicht** | Die Generalversammlung wählt jeweils für eine Amtsdauer von einem Jahr als Revisionsstelle einen oder mehrere Revisoren. Die Revisoren haben den gesetzlichen Anforderungen bezüglich Befähigung und Unabhängigkeit zu entsprechen. | ***Election and term / waiver*** | *The shareholders meeting shall elect one or more auditors for a one year term. The auditors have to comply with the statutory requirements for qualification and independence.* |
| **IV. JAHRESRECHNUNG UND GEWINNVERTEILUNG** | | ***IV. ANNUAL ACCOUNTS AND PROFIT DISTRIBUTION*** | |
| **Art. 26** | | ***Article 26*** | |
| **Jahresrechnung** | Die Jahresrechnung wird jährlich abgeschlossen. Der Verwaltungsrat legt das Geschäftsjahr fest. | ***Annual accounts*** | *The annual accounts shall be established annually. The board of directors establish the fiscal year.* |
| **Art. 27** | | ***Article 27*** | |
| **Verwendung des Reingewinns** | Vom Reingewinn sind 5% der allgemeinen Reserve zuzuweisen, bis diese die Höhe von 20% des einbezahlten Aktienkapitals erreicht hat. Der Rest des verbleibenden Reingewinns sowie ein allfälliger Gewinnvortrag aus früheren Jahren stehen unter dem Vorbehalt der zwingenden gesetzlichen Bestimmungen zur freien Verfügung der Generalversammlung. | ***Use of net profit*** | *5% of the net profit shall be allocated to the general reserve until it has reached the level of 20% of the paid-up share capital. The rest of the remaining net income and any profit carried forward from previous years are subject to the mandatory statutory provisions for the disposal of the shareholders meeting.* |

**V. WEITERE BESTIMMUNGEN**

**Art. 28**

**Auflösung und Liquidation**

Die Generalversammlung kann die Auflösung und Liquidation der Gesellschaft beschliessen.

Die Liquidation wird durch den Verwaltungsrat durchgeführt, sofern die Generalversammlung nichts anderes beschliesst. Im übrigen gelten für die Auflösung und Liquidation die gesetzlichen Bestimmungen.

**Art. 28a**

**Liquidationsvorzug**

Nach erfolgter Tilgung der Schulden wird das Vermögen der Gesellschaft unter den Aktionären wie folgt verteilt:

1. den einbezahlten Ausgabepreis an diejenigen Aktionäre, die Vorzugsaktien der Kategorie C halten, bis zu einem maximalen Gesamtbetrag von CHF 47’124’000 (Franken siebenundvierzig Millionen einhundertzwanzigtausend); bei Nichterreichen des Gesamtbetrags wird die Auszahlung im Verhältnis des einbezahlten Ausgabepreises reduziert; danach

***V. FURTHER DISPOSITIONS***

***Article 28***

***Dissolution and liquidation***

*The shareholders meeting may resolve the dissolution and liquidation of the company.*

*The liquidation shall be carried out by the board of directors unless otherwise resolved by the shareholders meeting. For the rest, statutory provisions shall apply to the dissolution and liquidation.*

***Article 28a***

***Liquidation preference***

*Upon discharge of the debts, the company’s assets shall be distributed among the shareholders as follows:*

*1. the share issue price paid for Preferred Shares Category C by holders of such shares, up to a maximum amount of CHF 47’124’000 (forty seven million one hundred twenty-four thousand Swiss francs); if the total sum is not available, assets will be distributed in proportion to the amount paid in by each shareholder; and then*

2. den einbezahlten Ausgabepreis an diejenigen Aktionäre, die Vorzugsaktien der Kategorie B halten, bis zu einem maximalen Gesamtbetrag von CHF 20’000’000 (Franken zwanzig Millionen); bei Nichterreichen des Gesamtbetrags wird die Auszahlung im Verhältnis des einbezahlten Ausgabepreises reduziert; danach

3. den einbezahlten Ausgabepreis an diejenigen Aktionäre, die Vorzugsaktien der Kategorie A halten, bis zu einem maximalen Gesamtbetrag von CHF 5’872’345 (Franken fünf Millionen achthundertzweiundsiebzigtausenddreihundertfünfundvierzig); bei Nichterreichen des Gesamtbetrags wird die Auszahlung im Verhältnis des einbezahlten Ausgabepreises reduziert; danach

4. den Betrag von CHF 232’320 (Franken zweihundertzweiunddreissigtausenddreihundertzwanzig) an die Stammaktionäre; bei Nichterreichen des Gesamtbetrags wird die Auszahlung im Verhältnis der gehaltenen Nennwerte reduziert; danach gemäss Anteil am Aktienkapital an alle Aktionäre.

*2. the share issue price paid for Preferred Shares Category B by holders of such shares, up to a maximum amount of CHF 20’000’000 (twenty million Swiss francs); if the total sum is not available, assets will be distributed in proportion to the amount paid in by each shareholder; and then*

*3. the share issue price paid for Preferred Shares Category A by holders of such shares, up to a maximum amount of CHF 5’872’345 (five million eight hundred and seventy-two thousand three hundred and forty-five Swiss francs); if the total sum is not available, assets will be distributed in proportion to the amount paid in by each shareholder; and then*

*4. the amount of CHF 232’320 (two hundred thirty-two thousand three hundred and twenty Swiss francs) to all holders of Common Shares; and then to all shareholders in proportion to their shareholding in the company.*

**Art. 28b**

**Veräusserungsvorzug**

Im Falle eines Freihandverkaufs, einer Fusion, eines Verkaufs, einer Übertragung oder einer sonstigen Verfügung über alle oder wesentliche Teile des Vermögens der Gesellschaft, oder im Falle einer Transaktion, welche die Übertragung von mehr als 50% der Stimmrechte zur Folge hat, sofern der Erlös einer Vorzugsaktie C beim Verfügungsgeschäft eines oben genannten Falles nicht mindestens das 2.5-Fache des vom Vorzugsaktionär C bezahlten Ausgabebetrages erreicht , sollen für die Verteilung der Einkünfte an die Aktionäre die nachfolgende Veräusserungsvorzüge gelten:

***Article 28b***

***Exit Preference***

*In the event of a trade sale, merger or consolidation, sale, lease, transfer or other disposition of all or substantially all of the assets of the company or transaction in which 50% or more of the voting power of the company is transferred, where the per share cash return for Preferred Shares Category C at the closing of such event does not amount to at least 2.5 times the per share price paid by the preferred C shareholders for the Preferred Shares Category C, the proceeds available for distribution to the company’s shareholders, shall be allocated to the shareholders in the following order of precedence:*

(a) Vor allen Aktionären sollen zuerst die Inhaber von Vorzugsaktien C den Betrag ihrer Investition, und nicht mehr, erhalten und zwar bis zum Betrag in Höhe von CHF 47’124’000. Sollten die zur Verteilung zur Verfügung stehenden Einkünfte der Gesellschaft nicht ausreichen um entsprechende Zahlungen vollständig an die Vorzugsaktionäre der Vorzugsaktie C zu leisten, sollen die Einkünfte im Verhältnis zu den Investitionen in Vorzugsaktien C an die Vorzugsaktionäre C verteilt werden; und

*(a) First to the holders of Preferred Shares Category C then outstanding in the amount corresponding to the value of their investment and no more, up to a total amount of CHF 47’124’000, before any amount shall be paid to the holders of other shares. If the proceeds of the company available for distribution to its shareholders shall be insufficient to permit such payment in full to the holders of Preferred Shares Category C, then the proceeds of the company available for distribution to its shareholders shall be distributed among the holders of Preferred Shares Category C in proportion to their investment in respect of such C shares; and*

(b) Danach sollen die Inhaber von Vorzugsaktien B, Vorzugsaktien A und Stammaktien den Betrag im Wert ihrer Investition, und nicht mehr, erhalten und zwar bis zum Betrag in Höhe von CHF 27’000’000 und im Verhältnis ihrer Beteiligung am Aktienkapital der Gesellschaft. Sollten die zur Verteilung zur Verfügung stehenden Einkünfte nicht ausreichen um entsprechende Zahlungen vollständig an die Inhaber von Vorzugsaktien B, Vorzugsaktien A und Stammaktien zu leisten, sollen die Einkünfte unter den Inhaber von Vorzugsaktien B, Vorzugsaktien A und Stammaktien im Verhältnis zur Beteiligung am Aktienkapital verteilt werden, und

*(b) Then to the holders of B Shares, A Shares and common shares then outstanding in the amount corresponding to the value of their investment and no more, up to a total amount of CHF 27’000’000, to be distributed among them in proportion to their shareholding in the company, before any amount shall be paid to the holders of other Shares. If the proceeds available for distribution to the shareholders shall be insufficient to permit such payment in full to the holders of B Shares, A Shares and common shares, then the proceeds available for distribution shall be distributed among the holders of B Shares, A Shares and common shares in proportion to their shareholding in the company; and*

(c) danach sollen die noch verbleibenden Einkünfte an alle Aktionäre im Verhältnis zu ihren Beteiligungen an der Gesellschaft verteilt werden.

*(c) Thereafter, the remaining proceeds shall be paid to all of the shareholders in proportion to their shareholding in the company.*

**Art. 29**

***Article 29***

**Publikationsorgan**

Publikationsorgan für Bekanntmachungen der Gesellschaft ist das Schweizerische Handelsamtsblatt. Der Verwaltungsrat ist ermächtigt, weitere Publikationsorgane zu bezeichnen.

Mitteilungen an die Aktionäre können ausserdem brieflich an die im Aktienbuch eingetragenen Aktionäre erfolgen.

***Publications media***

*Publications for the company shall be made in the Swiss Official Gazette of Commerce. The board of directors is authorised to designate additional publication media.*

*Notices to shareholders can also be made by letter to the shareholders recorded in the share register.*

**VI. URSPRACHE**

***VI. ORIGINAL LANGUAGE***

**Art. 30**

***Article 30***

**Ursprache**

Im Falle von Abweichungen zwischen der deutschen und englischen Version dieser Statuten hat die deutsche Fassung Vorrang.

***Original language***

*In the event of discrepancies between the German and English version of these Articles of Association, the German text shall prevail.*

Basel, den 5. April 2013 / 5 April 2013

ZEICHNUNGSSCHEIN
*Commitment Form*
Sofinnova Capital VII FCPR

zeichnet bedingungslos and unwiderruflich 90’910 Namenaktien (Kategorie C) der Auris Medical AG, Basel, von je CHF 10.— Nennwert zum Ausgabepreis von je CHF 132.—. Die/Der Unterzeichnende verpflichtet sich, 100 % des gesamten Ausgabepreises der gezeichneten Aktien zu liberieren durch Barzahlung bis spatestens 5. April 2013

des Nominalwerts (Betrag CHF 909’100):

- auf Kto. xxx-xxxxxx.xxx (xxxx xxxx xxxx xxxx xxxx xxxx x) bei der UBS in Basel

des Agio (Betrag CHF 11’091’020):

- auf CHF-Kto. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxx x) bei der UBS Bern (BIC: xxxxxxxxxxx); oder
- den entsprechenden Betrag in US-Dollar auf USD-Kto.xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxx x) bei der UBS Bern (BIC: xxxxxxxxxxx); oder
- den entsprechenden Euro Betrag auf EUR-Kto. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxx x) bei der UBS in Bern (BIC: xxxxxxxxxxx).

*herewith subscribes, unconditionally and irrevocably, for 90,910 registered shares (C-Shares) of Auris Medical AG, Basel, with a par value of CHF 10.— each and an issuance price of CHF 132.—each. The undersigned hereby commits to pay 100 % of the total issuance price of the subscribed shares by contribution in cash by April 5, 2013 at the latest*

*for the nominal value of the shares (amount of CHF 909,100):*

- *into bank account no. xxx-xxxxxx.xxx (xxxx xxxx xxxx xxxx xxxx xxxx x) with UBS* Basle

*for the due amount of the share-premium — Agio (amount of CHF 11,091,020)*

- *into CHF bank account no. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxx x) with UBS Berne(BIC:• xxxxxxxxxxx); or*
- *the equivalent value in US-Dollar into USD bank account no. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxx x) with UBS Berne (BIC: xxxxxxxxxxx); or*
- *the equivalent va fe in Euro into EUR bank account xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxx x) ‘th UB. Berne (BIC: xxxxxxxxxxA).*

Place, date:

/S/ ANTOINE PAPIERNIK
Antoine Papiernik for Sofinnova Capital VII FCPR

ZEICHNUNGSSCHEIN

*Commitment Form*

Sofinnova Venture Partners VIII, L.P.

zeichnet bedingungslos and unwiderruflich 94’545 Namenaktien (Kategorie C) der Auris Medical AG, Basel, von je CHF 10.— Nennwert zum Ausgabepreis von je CHF 132.—. Die/Der Unterzeichnende verpflichtet rich, 100 % des gesamten Ausgabepreises der gezeichneten Aktien zu liberieren durch Barzahlung bis spatestens 5. April 2013

des Nominalwerts (Betrag CHF 945’450):

- auf Kto. xxx-xxxxxx.xxx (xxxx xxxx xxxx xxxx xxxx xxxxx) bei der UBS in Basel

des Agio (Betrag CHF 11’534’490):

- auf CHF-Kto. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxxx) bei der UBS Bern (BIC: xxxxxxx xxxx); oder
- den entsprechenden Betrag in US-Dollar auf USD-Kto. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx x) bei der UBS Bern (BIC: xxxxxxxxxxx); oder
- den entsprechenden Euro Betrag auf EUR-Kto. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx x) bei der UBS in Bern (BIC: xxxxxxxxxxx).

*herewith subscribes, unconditionally and irrevocably, for 94,545 registered shares (C-Shares) of Auris Medical AG, Basel, with a par value of CHF 10.— each and an issuance price of CHF 132.— each. The undersigned hereby commits to pay 100 % of the total issuance price of the subscribed shares by contribution in cash by April 5, 2013 at the latest*

*for the nominal value of the shares (amount of CHF 945,450):*

- *into bank account no. xxx-xxxxxx.xxx (xxxx xxxx xxxx xxxx xxxx xxxxx) with UBS Basle*

*for the due amount of the share premium — Agio (amount of CHF 11,534,490)*

- *into CHF bank account no. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxxx) with UBS Berne (BIC: xxxxxxxxxxx); or*
- *the equivalent value in US-Dollar into USD bank account no. xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxxx) with UBS Berne (BIC.• xxxxxxxxxxx); or*
- *the equivalent value in Euro into EUR bank account xxx-xxxxxxxx.x (xxxx xxxx xxxx xxxx xxxx xxxxx) with UBS Berne (BIC: xxxxxxxxxxx).*

Place, date:

/s/ Jim Healy

Jim Healy for Sofinnova Venture Partners VIII L.P.

**Escrow Agreement**

On this 5th day of April 2013, the following Escrow Agreement, restating and amending the Escrow Agreement dated 13 December 2007 with regard to clause 4.7., has been entered into by and among

Thomas Meyer
Birkenweg 6
CH-4528 Zuchwil

IDinvest
117, Avenue des Champs-Elysées
FR-75008 Paris

Balfidor Fondsleitung AG
c/o Adamant Biomedical Investments AG
Freischützgasse 3
CH-8004 Zürich

Phonak AG
Laubisrütistrasse 28
CH-8712 Stäfa

Daniel Gutenberg
Inselweg 28
CH-8640 Hurden

Gerhard Jansen
Quellenrain 15
CH-3063 Ittigen

Martin Oberholzer
Rohnenrainweg 4
CH-8835 Feusisberg

Oliver Walker
Pestalozzistrasse 5
CH-5000 Aarau

Heinz Winzeler
Klotenerstrasse 13
CH-8304 Wallisellen

Sofinnova Venture Partners VIII, L.P.
2800 Sand Hill Road, Suite 150
Menlo Park, CA 94025
USA

Sofinnova Capital VII FCPR
c/o Sofinnova Partners
17, rue de Surène
FR-75008 Paris

Auris Medical AG
Falknerstrasse 4
CH-4001 Basel

and

ante treuhand ag
Hauptstrasse 16
CH-3186 Düdingen
(„**Escrow Agent**")

**WHEREAS:**

(A) Auris Medical AG is a Swiss company with registered office at Falknerstrasse 4, 4001 Basel, Switzerland **(Company**).

(B) The shareholders of the Company **(Shareholders**) have entered into a shareholders agreement on or about the date of this agreement (the **Shareholders Agreement**).

(C) It is the Shareholders' intention that all present and future shares in the Company shall be deposited with the Escrow Agent, who shall only dispose of them upon unanimous written instructions duly signed by all shareholders or upon presentation of a final and binding decision or arbitral award of either an ordinary court or an arbitration court, as the case may be.

**NOW, THEREFORE,** the Parties have come to the following agreement:

1. Appointment of the Escrow Agent

1.1. Appointment

The Shareholders hereby appoint the Escrow Agent as escrow agent according to the terms and conditions of this Escrow Agreement. The Escrow Agent herewith declares that he assumes all rights and duties as escrow agent according to the terms and conditions of this Escrow Agreement.

1.2. <u>Fee</u>

For his services under this Escrow Agreement, the Escrow Agent shall be entitled to:

(a) an annual fee (the **Annual Fee**) for every full year from the date of this Escrow Agreement until its termination (for which purpose each year shall start on the day and month corresponding to the date of this Escrow Agreement). The Annual Fee shall be CHF 500, plus VAT. Annual Fees shall be due in advance, at the beginning of each year. If the Shares are deposited with the Escrow Agent for a period of less than an entire year, the fee shall be due pro rata temporis; and

(b) time fees based on the time spent by the Escrow Agent or any partner, employee or advisor of the Escrow Agent in the preparation, negotiation and performance of this Escrow Agreement (**Time Fees**). The rate charged per hour in respect of Time Fees shall be CHF 200, to be amended from time to time in accordance with reasonable standard hourly rates of the Escrow Agent. Time Fees, plus any VAT due thereon, will be invoiced by the Escrow Agent at least once a year and due for payment within 30 (thirty) calendar days of the date of the invoice.

1.3. <u>Release from Liabilities</u>

The Shareholders hereby release the Escrow Agent from any and all liabilities incurred in connection with the due performance of his duties under this Escrow Agreement except for liabilities resulting from the Escrow Agent's wilful misconduct or gross negligence. This release does not apply to breaches of clause 2.1 of this Escrow Agreement.

2. <u>Duties of the Escrow Agent</u>

2.1. <u>Custody Standard</u>

(a) The Escrow Agent shall hold the Shares in safe custody and shall not sell, pledge or otherwise encumber the Shares.

(b) The Escrow Agent shall ensure that the Shares are released pursuant to clause 2.4 only.

2.2. <u>Deposit of the Shares</u>

Immediately upon receipt thereof, the Escrow Agent shall deposit the Shares in a safe and secure place. The Escrow Agent shall confirm receipt of the Shares to the Shareholders in writing.

2.3. <u>Rights and Obligations in the Shares</u>

During the term of this Escrow Agreement, the Shareholders' voting rights and all other rights and obligations deriving from the ownership of the Shares, except those limited by the terms of this Escrow Agreement, will remain with the Shareholders. Dividends and other payments related to the Shares, if any, are to be paid directly to the Shareholders.

2.4. <u>Release of the Shares</u>

The Escrow Agent shall not release, deliver or otherwise transfer any of the Shares to any of the Shareholders or to any other person unless:

(i) the Escrow Agent has received joint written instructions from the Shareholders, or

(ii) in accordance with a final and enforceable order or award of a court or arbitration tribunal of competent jurisdiction, or

(iii) the Shareholders Agreement expires or is terminated with effect for all Shareholders.

Upon receipt of written instructions or a final and enforceable order or award, the Escrow Agent shall be obliged to deliver the Shares designated in accordance with such instructions, order or award.

The Escrow Agent may give the Shares into the temporary custody of the Company's corporate counsel, against written receipt and on written instruction from the board of directors of the Company only.

3. Term and Termination

3.1. Term

This Escrow Agreement shall continue in force for an indefinite period of time, unless terminated pursuant to clause 3.2.

3.2. Termination by the Shareholders

This Escrow Agreement may be terminated by the joint written consent of all of the Shareholders upon 10 (ten) business days' notice at any time.

This Escrow Agreement will be terminated automatically on delivery of all Shares by the Escrow Agent pursuant to clause 2.4.

3.3. Termination by the Escrow Agent

The Escrow Agent shall be entitled to terminate his appointment under this Escrow Agreement pursuant to Article 476 CO. In case of an early termination by the Escrow Agent, the Escrow Agent shall request the Board of Directors to name another Escrow Agent within thirty (30) days. If a substitute escrow agent is appointed, the Escrow Agent shall transfer the Shares to the substitute escrow agent in accordance with the instruction of the Board of Directors. If the Board of Directors does not name a substitute escrow agent or if the named substitute escrow agent is unable or unwilling to act as Escrow Agent, the Escrow Agent shall be entitled to deposit the Shares with the Court of First Instance of the District of Zurich (*Bezirksgericht Zürich 1*). The costs of such deposition shall be borne by the Shareholders.

3.4. Default of the Escrow Agent

In case of death or incapacity to act of the Escrow Agent, the Board of Directors will name another Escrow Agent within thirty (30) days. If the Board of Directors does not name a substitute escrow agent or if the named substitute escrow agent is unable or unwilling to act as Escrow Agent, the Shares shall be deposited with the Court of First Instance of the District of Zurich (*Bezirksgericht Zürich 1*). The costs of such deposition shall be borne by the Shareholders.

4. General Provisions

4.1. Scope of this Escrow Agreement

This Escrow Agreement shall be binding in respect of all of the shares in the Company that the Shareholders own, whether issued on the date of this Escrow Agreement or thereafter, and that are deposited with the Escrow Agent.

4.2. Future Shareholders

The parties agree that any person becoming a shareholder in the Company and having agreed in writing to be bound by this Escrow Agreement shall, by virtue thereof, become a party to, and shall be deemed a Shareholder under, this Escrow Agreement.

4.3. Effect on Third Parties

No person other than the parties hereto shall have any rights or benefits under this Escrow Agreement, and nothing in this Escrow Agreement is intended to confer on any person other than the parties hereto any rights, benefits or remedies.

4.4. Notices

(a) Any notice, request or instruction deemed by any Party to be necessary or desirable to be given to the other Parties, shall be in writing and shall be sent by registered mail or courier to the address first set forth above.

(b) Each Party may at any time change its address by giving notice to the other Parties in the manner described in clause 4.4 (a).

4.5. Entire Agreement

This Escrow Agreement, including any other documents referred to herein, constitutes the entire agreement and understanding among the Parties with respect to the subject matter hereof, and shall supersede all prior oral and written agreements or understandings of the Parties relating hereto.

4.6. Amendments and Waivers

Except as explicitly provided for in this Escrow Agreement, this Escrow Agreement may only be modified or amended by a document signed by all Parties. Any provision contained in this Escrow Agreement may only be waived by a document signed by the Party waiving such provision.

4.7. Assignment

Except as explicitly provided for in this Escrow Agreement, this Escrow Agreement and the rights and liabilities arising hereunder may not be transferred to third parties except with the prior written consent of the other Parties to this Escrow Agreement. Any Party (except the Company) may, however, transfer this Escrow Agreement and/or the rights and liabilities arising hereunder in parts or in its entirety to an affiliated company in which it owns at least fifty-one (51) percent of all outstanding shares or voting rights, in which case the approval of the other Parties shall be deemed to have been given. The approval of the other Parties shall also deemed to have been given for transfer to an affiliated company that holds at least fifty-one (51) per cent of all outstanding shares or voting rights of one of the Parties.

4.8. Severability; Good Faith

Should any part or provision of this Escrow Agreement be held to be invalid or unenforceable by any competent arbitral tribunal, court, governmental or administrative authority having jurisdiction, the other provisions of this Escrow Agreement shall nonetheless remain valid. In this case, the Parties shall endeavour to negotiate a substitute provision that best reflects the economic intentions of the parties without being unenforceable, and shall execute all agreements and documents required in this connection.

5. Governing Law

This Escrow Agreement shall be governed by and construed in accordance with the substantive laws of Switzerland, to the exclusion of the provisions on the conflict of laws.

Executed in 2 copies.

**Sofinnova Venture Partners VIII, L.P.**

By: Sofinnova Management VIII, L.L.C.
its General Partner

By: /s/ Jim Healy
Jim Healy, Managing Member

**Sofinnova Capital VII FCPR**

By: Sofinnova Partners SAS
its General Partner

By: ______________________________
Antoine Papiernik, Managing Partner

**Auris Medical AG**

______________________________
Thomas Meyer, Chairman of the Board

**Sofinnova Venture Partners VIII, L.P.**

By: Sofinnova Management VIII, L.L.C.
its General Partner

By: ______________________________
Jim Healy, Managing Member

**Sofinnova Capital VII FCPR**

By: Sofinnova Partners SAS
its General Partner

By: /s/ Antoine Papiernik
Antoine Papiernik, Managing Partner

**Auris Medical AG**

______________________________
Thomas Meyer, Chairman of the Board

**Sofinnova Venture Partners VIII, L.P.**

By: Sofinnova Management VIII, L.L.C.
its General Partner

By: ________________________________________
Jim Healy, Managing Member

**Sofinnova Capital VII FCPR**

By: Sofinnova Partners SAS
its General Partner

By: ________________________________________
Antoine Papiernik, Managing Partner

**Auris Medical AG**

/s/ Thomas Meyer
Thomas Meyer, Chairman of the Board

**ZKB Pharma Vision Fonds**
**Adamant Global Healthcare Fonds**
**Adamant Global Generika Fonds**
**Adamant Global Biotech Fonds**

Each and all by: Balfidor Fondsleitung AG

By: /s/ Alexander Müller
Alexander Müller

/s/ Markus Pfister
Markus Pfister

**Phonak AG**

By: /s/ Thomas Meyer
Thomas Meyer (proxy)

(except the Company) may, however, transfer this Escrow Agreement and/or the rights and liabilities arising hereunder in parts or in its entirety to an affiliated company in which it owns at least fifty-one (51) percent of all outstanding shares or voting rights, in which case the approval of the other Parties shall be deemed to have been given. The approval of the other Parties shall also deemed to have been given for transfer to an affiliated company that holds at least fifty-one (51) per cent of all outstanding shares or voting rights of one of the Parties.

4.8. Severability; Good Faith

Should any part or provision of this Escrow Agreement be held to be invalid or unenforceable by any competent arbitral tribunal, court, governmental or administrative authority having jurisdiction, the other provisions of this Escrow Agreement shall nonetheless remain valid. In this case, the Parties shall endeavour to negotiate a substitute provision that best reflects the economic intentions of the parties without being unenforceable, and shall execute all agreements and documents required in this connection.

5. Governing Law

This Escrow Agreement shall be governed by and construed in accordance with the substantive laws of Switzerland, to the exclusion of the provisions on the conflict of laws.

Executed in 2 copies.

**Allianz Innovation 7 FCPI**
**Idinvest Croissance 2005 FCPI**
**Allianz Innovation 8 FCPI**
**Banque Postale Innovation 3 FCPI**

Each and all by: ID Invest

By: /s/ Benoist Grossmann
Benoist Grossmann

**Allianz Innovation 7 FCPI**
**Idinvest Croissance 2005 FCPI**
**Allianz Innovation 8 FCPI**
**Banque Postale Innovation 3 FCPI**

Each and all by: ID Invest

By: /s/ Benoist Grossmann
Benoist Grossmann

**ZKB Pharma Vision Fonds**
**Adamant Global Healthcare Fonds**
**Adamant Global Generika Fonds**
**Adamant Global Biotech Fonds**

Each and all by: Balfidor Fondsleitung AG

By: /s/ Markus Pfister
Markus Pfister

/s/ Alexander Müller
Alexander Müller

**Phonak AG**

By: /s/ Thomas Meyer
Thomas Meyer (proxy)

/s/ Thomas Meyer
**Thomas Meyer**

/s/ Thomas Meyer

**Daniel Gutenberg** (by Thomas Meyer, proxy)

/s/ Thomas Meyer

**Gerhard Jansen** (by Thomas Meyer, proxy)

/s/ Thomas Meyer

**Martin Oberholzer** (by Thomas Meyer, proxy)

/s/ Thomas Meyer

**Oliver Walker** (by Thomas Meyer, proxy)

/s/ Thomas Meyer

**Heinz Winzeler** (by Thomas Meyer, proxy)

**Annex VI: Escrow Agreement**

For Escrow Agreement see Annex III to the Series C Shareholders’ Agreement, which Shareholders’ Agreement is Annex III to this Agreement.

Auris Medical
Cochlear therapies

Annex VII

Sofinnova Venture Partners VIII, L.P.
2800 Sand Hill Road, Suite 150
Menlo Park, CA 94025

*April 5, 2013*

**Re: Management Rights**

Ladies and Gentlemen:

This letter will confirm our agreement that pursuant to and effective as of your purchase of 94,545 shares of Series C Preferred Stock of Auris Medical AG (the "Company"}, Sofinnova Venture Partners VIII, L.P. (the "Investor") shall be entitled to the following contractual management rights, in addition to any rights to non-public financial information, inspection rights and other rights specifically provided to all investors in the current financing:

The Investor shall be entitled to consult with and advise management of the Company on significant business issues, including management's proposed annual operating plans, and management will meet with the Investor regularly during each year at the Company's facilities at mutually agreeable times for such consultation and advice and to review progress in achieving said plans.

The Investor may examine the books and records of the Company and inspect its facilities and may request information at reasonable times and intervals concerning the general status of the Company's financial condition and operations, provided that access to highly confidential proprietary information and facilities need not be provided.

If the Investor is not represented on the Company's Board of Directors, the Company shall give a representative of the Investor copies of all notices, minutes, consents and other material that the Company provides to its directors, except that the representative may be excluded from access to any material or portion thereof if the Company believes, upon advice of counsel, that such exclusion is reasonably necessary to preserve the attorney-client privilege, to protect highly confidential proprietary information or for other similar reasons. Upon reasonable notice and at a scheduled meeting of the Board of Directors or such other time, if any, as the Board of Directors may determine in its sole discretion, such representative may address the Board of Directors with respect to the Investor's concerns regarding significant business issues facing the Company.

The Investor agrees, and any representative of the Investor will agree, to hold in confidence and trust and not disclose any confidential information provided to or learned by it in connection with its rights under this letter.

The rights described herein shall terminate and be of no further force or effect upon (a) the consummation of the sale of the Company's securities pursuant to a registration statement filed by the Company under the Securities Act of 1933, as amended, in connection with a firm-commitment underwritten offering of its securities to the public or (b) the consummation of a merger or consolidation of the Company that is effected (i) for independent business reasons unrelated to extinguishing such rights and (ii) for purposes other than (A) the reincorporation of the Company in a different state or (B) the formation of a holding company that will be owned exclusively by the Company's stockholders and will hold all of the outstanding shares of capital stock of the Company's successor. The confidentiality provisions hereof will survive any such termination.

Very truly yours,

AURIS MEDICAL AG

By: /s/ Thomas Meyer
Title: Thomas Meyer, Chairman of the Board

AGREED AND ACCEPTED:

Sofinnova Venture Partners VIII, L.P.

By: Sofinnova Management VIII, L.L.C. its General Partner

By: ________________________
Jim Healy, Managing Member

The rights described herein shall terminate and be of no further force or effect upon (a) the consummation of the sale of the Company's securities pursuant to a registration statement filed by the Company under the Securities Act of 1933, as amended, in connection with a firm-commitment underwritten offering of its securities to the public or (b) the consummation of a merger or consolidation of the Company that is effected (i) for independent business reasons unrelated to extinguishing such rights and (ii) for purposes other than (A) the reincorporation of the Company in a different state or (B) the formation of a holding company that will be owned exclusively by the Company's stockholders and will hold all of the outstanding shares of capital stock of the Company's successor. The confidentiality provisions hereof will survive any such termination.

Very truly yours,

AURIS MEDICAL AG

By: ______________________________

Title: Thomas Meyer, Chairman of the Board

AGREED AND ACCEPTED:

Sofinnova Venture Partners VIII, L.P.

By: Sofinnova Management VIII, L.L.C.
its General Partner

By: /s/ Jim Healy
Jim Healy, Managing Member

**Exhibit 10.4**

*Execution Version*

# Series C

# Shareholders’ Agreement

This Shareholders' Agreement ("**Agreement**") is made as of 5 April 2013 by and among Auris Medical AG, Falknerstrasse 4, 4001 Basel, Switzerland ("**Company**") and the shareholders of the Company listed in Annex I attached to this Agreement (each a "**Shareholder**" and together the "**Shareholders**"). Company and Shareholders are collectively referred to as "**Parties**".

WHEREAS, Thomas Meyer (the "**Founder**") incorporated the Company as Fimacom AG with registered office in Lüterkofen, Switzerland, on 1 April 1998. The Company's name was changed to Auris Medical AG and its purpose to its current purpose on 22 May 2003. The Company's registered office was moved to Düdingen, Switzerland, on 21 June 2006 and moved again to Basel, Switzerland, on 28 March 2008;

WHEREAS, the Founder was issued with common shares (the "**Common Shares**") and A shares in consideration for his investments in the Company prior to 2007;

WHEREAS, in 2007 a syndicate of investors ("**B Investors**") made a Series B investment of CHF 11,000,000 in the Company, in the course of which they were issued with B shares in the Company (the "**B Shares**");

WHEREAS, in March 2011, a newly constituted syndicate of investors (the "**B2 Investors**"), all of whom were already B Investors and shareholders in the Company, made an investment of CHF 3,260,000 by way of subscription for B shares in the Company;

WHEREAS, in December 2011 a further syndicate of investors (the "**B3 Investors**") made an investment of CHF 5,053,680 by way of subscription for B shares in the Company (the "**Series B3 Investment**");

WHEREAS, following the closing of the Series B3 Investment, the Shareholders have amended and restated the initial 2007 Series B Shareholders' Agreement;

WHEREAS, a further syndicate of investors (the "**C Investors Syndicate**") has agreed to make an equity investment in the Company of up to CHF 47,124,000, possibly with at least one additional financial institutional investor (such financial institutional investor, as the case may be, and the C Investors Syndicate altogether the "**C Investors**", and each a "**C Investor**"), in exchange for which the C Investors shall receive new Series C Shares in the Company (the "**C Shares**") with rights and privileges as set forth in the amended articles of association of the Company attached to the investment agreement of this day (the "**Investment Agreement**") (as amended from time to time, the "**Articles**") and in this Shareholders' Agreement;

WHEREAS, the Parties wish to agree on and re-state the terms governing their relationship and the rights and obligations by and among them.

Now, therefore, the Parties agree as follows:

## 1. Condition Precedent

This Agreement shall only come into force and be binding on a Party upon the entry of the relevant Party as a shareholder in the Company’s share register or the entry into the trade registry of the capital increase reflecting the subscription of shares in the Company by such Party, whichever comes first.

## 2. General Principles

### 2.1. Scope

This Agreement shall govern the relationship and set forth the principles of cooperation between the Parties in their capacity as shareholders of the Company. This Agreement shall bind the Parties with respect to all of the shares in the Company (the “**Shares**”). If further Shares are acquired or obtained by the Parties, the provisions of this Agreement will also apply with respect to such further Shares.

This Agreement replaces the shareholders’ agreement between the Company and its shareholders dated 22 December 2011 and any prior shareholders’ agreement of the Company that may be in place.

In the event of a conflict or inconsistencies between the provisions of this Agreement and the Articles or the organizational rules of the Board of Directors of the Company, this Agreement shall prevail in all matters among and regarding the Shareholders.

### 2.2. General Undertaking

The Shareholders acknowledge their common interest in an exit within 12 months as from the date of the initial closing of the Series C investment, either (i) through a trade sale, pursuant to which the C Shareholders shall receive in cash at closing an amount equal to at least 2 times the applicable per share price of the C Shares, or (ii) through an IPO, where the per share price of the common shares being sold to the public is at least 2,5 times the applicable per share price of the C Shares (altogether a “**Qualified Exit Event**”).

In particular, to the extent that the terms and conditions of a Qualified Exit Event are customary and reasonable, the C Shareholders shall support such Qualified Exit Event.

### 2.3. Compliance

Each Shareholder undertakes to vote its Shares and to instruct its representative(s) on the board of directors of the Company (the “**Board**”) to comply with this Agreement and to cast their votes accordingly, so as to give effect to the provisions and principles laid down in this Agreement. Notwithstanding the foregoing, the members of the Board will not be bound by any instructions that contravene the applicable law, the Articles or resolutions validly adopted at a shareholders’ meeting.

**3. General Assembly of Shareholders**

Decisions of the General Assembly of Shareholders shall require a simple majority of the Shareholders present or represented, unless the Articles of Association of the Company, this Agreement or the mandatory provisions of the Swiss Code of Obligations require a qualified majority.

In particular, the Shareholders agree that the following decisions shall be resolved by the General Assembly of Shareholders and require the approval of Shareholders holding at least two thirds of the outstanding shares in the Company being present or represented by proxy, including at least two thirds of the present or represented votes of the C Shares, and at least 50% of the present or represented votes of the B Shares, as well as the absolute majority of the present or represented nominal values:

(i) amending the corporate purposes of the Company;

(ii) creating or cancelling Shares with preferred rights, or amending the rights attached to such Shares;

(iii) restricting the transfer of registered Shares;

(iv) creating authorized or conditional share capital;

(v) increasing the share capital by incorporation of reserves, by contribution in kind or for the purpose of acquiring specific assets and granting specific advantages;

(vi) incurring debt of more than CHF 3,000,000 in aggregate at any time outstanding;

(vii) limiting or suppressing the Shareholders’ pre-emptive rights;

(viii) changing the domicile or registered address of the Company (however, by way of exception, changes within Basel shall be subject to a decision of the Board and shall, therefore, not require any decision of the General Assembly);

(ix) selling or transferring all or substantially all the assets of the Company or the granting of any option to do the foregoing, in one or a series of transactions;

(x) merging, consolidating or splitting the Company and effecting any transaction or granting any right to effect any transaction or series of transactions which would affect the allocation of voting rights among the Shareholders;

(xi) appointing and removing the auditors;

(xii) changing the number of Directors;

(xiii) voting or paying a dividend or buying back any Shares; and

(xiv) dissolving or liquidating the Company.

In addition, and to the extent it is not included in the list above, the approval of the holders of two thirds of the C Shares shall be required for (i) any trade sale, merger or consolidation, sale, lease, transfer or other disposition of all or substantially all of the assets of the Company or transaction in which 50% or more of the voting power of the Company is transferred (an “**Exit Event**”) or (ii) the approval of any IPO (as defined in the Investment Agreement); unless, however, both (A) such transaction takes place within 12 months from the Initial Closing Date (as defined in the Investment Agreement) and (B) in the case of (i) above, the per share cash return for the C Shares at the closing of the Exit Event (such per share cash return to include the value of any separate cash distribution to the holders of C Shares made prior to

or concurrently with the Exit Event) is 2 or more times the applicable per share price of the C Shares (i.e. the price actually paid by the C Investor for each such C Share, as appropriately adjusted for stock splits, stock combinations or the like and hereinafter, the “**Applicable Series C Per Share Price**”), or in the case of (ii) above, the per share price of the Common Shares being sold to the public is 2.5 or more times the Applicable Series C Per Share Price.

## 4. Board of Directors; Observers

The Board shall consist of between 3 and 6 members (“**Directors**”) comprised of

(i) 2 members as the representatives of the C Investors, one of which shall be designated by Sofinnova Ventures and the other by Sofinnova Partners (the “**C Directors**”);

(ii) Up to 2 members as the representatives of the B Investors, B2 Investors and B3 Investors as follows: (a) as long as the aforementioned investors hold, together, at least 20% of the Company’s undiluted share capital, they shall be entitled to designate two representatives; (b) if the aforementioned investors hold, together, between 20% and 10% of the Company’s undiluted share capital, they shall be entitled to designate one representative (the up to two seats being allocated among eligible B Investors in the order of their percent stakes in the Company’s undiluted share capital);

(iii) 1 independent member jointly designated by the Founder and the Investors, with the consent of C Investors holding at least two thirds of the C Shares, of B Investors holding at least 50% of the B Shares as well as the absolute majority of the share capital;

(iv) the Founder, who will serve as the Board’s Chairman.

The term for the Chairman shall be one year.

If the share in the Company of a Shareholder directly represented on the Board subsequently falls below 10%, such Shareholder shall no longer be entitled to participate in the designation of Board representatives.

If an Investor holding at least 10% of the Company’s undiluted share capital is not represented on the Board, the Board shall upon reasonable notice invite a representative designated by such Investor (the “**Observer**”) to attend all Board meetings in a non-voting observer capacity. Each Observer shall receive copies of all notices, minutes, consents and other materials provided to Directors, provided however that the Observer shall agree to hold in confidence and trust and to act in a fiduciary manner with respect to all information so provided; and provided further, that the Company reserves the right to withhold any information and to exclude the Observer from any meeting or portion thereof if access to such information or attendance at such meeting could adversely affect the attorney-client privilege between the Company and its counsel or result in a conflict of interest.

The Board shall have a quorum when a majority of Directors are present. The decisions of the Board require a simple majority of the Directors who are in attendance. In case of a tied vote, the Chairman shall have a casting vote.

The following decisions shall require the approval of at least four (4) Directors, at least two of whom are representatives designated by Investors (including a representative of the C Investors):

(i) developing new products (other than the products described in the Company’s business plan);

(ii) approving the Company’s business plan;

(iii) appointing or removing the Managing Director without important reasons;

(iv) payments to and agreements with Shareholders, their affiliates or employees or consultants of Shareholders or their affiliates except when such payments or agreements are made at arm’s length terms.

Furthermore, shareholders’ meetings requiring specific majorities as provided for under clause 3. may only be validly convened if specific notice of such meetings is given to the C Directors simultaneously with the sending of the invitation.

Non-executive Directors shall receive part or all of their remuneration in stock options on Common Shares of the Company as resolved by the Board from time to time; travel and out of pocket expenses shall be reimbursed in cash by the Company on production of appropriate receipts. Executive Directors and Directors delegated and remunerated by a Shareholder for its representation on the Board shall not be entitled to any specific remuneration for their Board membership and work.

## 5. Restrictions on Transfer of Shares

5.1. No encumbrances

Subject to the provisions of this clause 5., no Party shall, except with the prior written consent of the other Parties, create or permit to subsist any pledge, lien, encumbrance, charge over or other collateral interest in, or grant any option or other rights in, all or any of its Shares.

5.2. Right of first refusal and tag along rights

5.2.1. Right of first refusal

5.2.1.1. Exercise of Right of First Refusal

The Investors have a right of first refusal (the “**Right of First Refusal**”) with respect to any Shares proposed to be sold by other Shareholders with a follow-on right to purchase any Shares offered for sale but not purchased by the other Investors. Before any Shareholder may sell Shares, he will give each Investor an opportunity, in accordance with the following paragraph, to purchase such Shares on a basis proportionate to the amount of Shares held by that Investor in proportion to the total of Shares held by the participating Investors.

Any Shareholder wishing to sell Shares ("**Selling Shareholder**") shall first send to each Investor (the "**Other Parties**") and the Company a written notice (the "**Notice**"), stating the number of Shares for sale, the price per Share, the name, domicile or registered office of the contemplated transferee (the "**Transferee**") and the other terms and conditions of the offer. Each of the Investors willing to exercise their right of first refusal shall give a notice thereof to the Selling Shareholder and the Company within 15 business days upon receipt of the notice of the selling intention. In no case shall the offering price and offering conditions be less favourable than those proposed to or by a third party within the last 180 days. If part or all of the Shares offered by the Selling Shareholder are not purchased by the Investors, but sold to one or more third parties, such sale must be on the same conditions and at the same price as offered to the Investors and the conditions of such sale must be communicated by the Selling Shareholder to the Board within 15 business days.

5.2.1.2. Implementation of Right of First Refusal

If the applications made by Other Parties represent a number of Shares in excess of those subject to the Right of First Refusal, they shall be allocated between them by the Company:

(i) based on their rights in the share capital within the limit of the applications made by them,

(ii) any possible surplus Shares being allocated between the Other Parties having manifested their intent to be allocated a number of Shares in excess of that to which they are entitled, pro rata to their interest in the share capital and within the limit of their application.

For the purposes of this clause, in determining each Party's respective rights to the share capital, account shall be taken of all Shares held by each Party on the date of the Notice by the Selling Shareholder.

If, within the imparted time period, meaning fifteen (15) days, no purchase offer is made or if the exercise of the Right of First Refusal does not cover all of the Shares subject to such right, the Selling Shareholder shall once again be entirely free to dispose of all of the Shares he/she/it contemplates selling but only on the same prices, terms and conditions as those proposed or agreed upon with the contemplated Transferee as set forth in the Notice by the Selling Shareholder, without prejudice to the other provisions of the Agreement (in particular the exit rights).

If, for any reason whatsoever, a sale of the Shares pursuant to the above paragraph does not take place within a period of sixty (60) days from the expiry of the period of fifteen (15) days referred to above, the Right of First Refusal procedure set forth above shall be repeated once again.

5.2.1.3. Exceptions to the Right of First Refusal

Subject to the Transferee's prior adherence to this Agreement, the following transactions shall fall outside the scope of the Right of First Refusal but shall be first notified to the Board (or to any other collegial body replacing it in the event of amendment to the bylaws of the Company), which shall be responsible for promptly informing the Parties thereof, through any means:

- any transfer of Shares by an Investor to any entity that (i) is under the control (direct or indirect) of that Investor or of the management company managing (directly or through a management agency agreement) that Investor, or (ii) holds (directly or indirectly) the control over that Investor or the management company managing (directly or through a management agency agreement) that Investor, and vice versa;
- any transfer of Shares by an Investor to its members, shareholders or partners, and vice versa, or to a secondary fund in case of liquidation or winding up of such Investor;
- any transfer of Shares by an Investor to a private holding company or trust of which it is the sole owner or beneficiary respectively, and vice versa;
- any transfer of Shares by the Founder to an asset holding company in which the Founder holds at least 95% of the voting rights, and vice versa;
- sales of Shares taking place pursuant to clauses 5.2.2 and 5.3 of this Agreement.

Transfers or sales of Shares pursuant to this clause shall only become effective when the acquiring party has agreed in writing to be bound by and to observe the provisions of this Agreement.

5.2.2. Tag along rights

If one or more Shareholders (the "**Selling Majority**") declares his/their intent to the other Shareholders to sell Shares representing 50% or more of the voting share capital to one or more acquirers in a single or related transactions, the other Shareholders will be entitled, as an alternative to the exercise of the right of first refusal, to sell their Shares on the same conditions and at the same price as the Selling Majority.

5.3. Drag along rights

Shareholders will vote in favour of an Exit Event, provided that such transaction is approved by (i) the Board, and (ii) Shareholders representing at least 75% of the Shares, and (iii) holders of C Shares representing at least two thirds of the then outstanding C Shares. The separate Series C vote as per subsection (iii) hereof shall however not apply in the event the holders of Series C receive in cash at the closing of the Exit Event an amount equal to at least 2 times the Applicable Per Share Series C Price. In any event, Shareholders will not be obliged to vote in favour of any Exit Event where other Shareholders own a majority by voting power of the shares of the acquiring corporation or will own a majority by voting power of the shares of the surviving corporation.

5.4. Board approval to transfer

For any sale of Shares in compliance with the requirements of this Agreement, the Parties shall procure that the Board approves the transfers and makes the respective entries in the share register of the Company. For any sale of Shares not made in compliance with the requirements of this Agreement, the Parties shall procure that the transfer is not approved by the Board, nor recorded in the share register of the Company.

Notwithstanding the foregoing, the Board may refuse its approval without giving reasons provided the Company offers to the disposing Shareholder to acquire the Shares on its own account, on the account of other Shareholders or for the account of third parties and at the actual value at the point in time of the request for approval.

5.5. Future shareholders

The parties agree that any person becoming a shareholder in the Company and having agreed in writing to be bound by this Shareholders’ Agreement shall, by virtue thereof, become a party to, and shall be deemed a Shareholder under, this Shareholders’ Agreement.

**6. Subsequent Increase of Capital and Anti-dilution**

New Shares or other participation instruments issued by the Company (excluding issuances in connection with acquisitions by the Company) must first be offered to the existing Shareholders on a pro rata basis in proportion to their existing shareholdings, unless such right of first subscription or participation has been waived by the Shareholders. Should any Shareholder choose not to subscribe for its full pro rata share, the remaining Investors shall have the right to subscribe for the remaining pro rata shares. Any remaining Shares may be offered to third parties for the same price and for the same terms and conditions. The Shareholders undertake to approve and to vote in favour of any issue of Shares to third parties on the terms of this clause 6.

**7. Liquidation and Exit Preferences**

7.1. Liquidation Preference

In the event of a dissolution or winding up of the Company with voluntary or involuntary liquidation (“**Deemed Liquidation**”), subject to clause 7.2, the proceeds available for distribution to the Company’s shareholders after redemption of all third parties’ claims and liquidation costs, shall be allocated to the Shareholders in the following order of precedence:

(a) First to the holders of C Shares then outstanding in the amount corresponding to the value of their investment and no more, up to a total amount of CHF 47,124,000 (such figure to be adjusted accordingly, both in this Shareholders’ Agreement and in the Articles, in case of a Qualified Investor investing in the Company pursuant to the Investment Agreement) before any amount shall be paid or any assets of the Company shall be distributed in respect of preference rights of other Shares. If the Deemed Liquidation proceeds of the

Company available for distribution to its shareholders shall be insufficient to permit such payment in full to the holders of C Shares, then the Deemed Liquidation proceeds of the Company available for distribution to its shareholders shall be distributed among the holders of C Shares in proportion to their investment in respect of C Shares;

(b) Thereafter, the remaining Deemed Liquidation proceeds of the Company shall be distributed to the holders of B Shares then outstanding in the amount corresponding to the value of their investment and no more, up to a total amount of CHF 20,000,000 before any amount shall be paid or any assets of the Company shall be distributed in respect of preference rights of other Shares. If the Deemed Liquidation proceeds of the Company available for distribution to its shareholders shall be insufficient to permit such payment in full to the holders of B Shares, then the Deemed Liquidation proceeds of the Company available for distribution to its shareholders shall be distributed among the holders of B Shares in proportion to their investment in respect of B Shares;

(c) Thereafter, the remaining Deemed Liquidation proceeds of the Company shall be distributed among the holders of A Shares up to the value of their investment, up to a total amount of CHF 5,872,345, before any amount shall be paid or any assets of the Company shall be distributed in respect of preference rights of other Shares. If the Deemed Liquidation proceeds of the Company available for distribution to holders of A Shares shall be insufficient to permit such payment in full to the holders of A Shares, then the Deemed Liquidation proceeds of the Company available for distribution to holders of A Shares shall be distributed among the holders of A Shares in proportion to their investment in A Shares.

(d) Thereafter, the remaining Deemed Liquidation proceeds of the Company shall be distributed among the holders of Common Shares up to the value of their investment, up to a total of CHF 232,320, before any amount shall be paid or any assets of the Company shall be distributed in respect of preference rights of other Shares. If the Deemed Liquidation proceeds of the Company available for distribution to holders of Common Shares shall be insufficient to permit such payment in full to the holders of Common Shares, then the Deemed Liquidation proceeds of the Company available for distribution to the holder of Common Shares shall be distributed among the holders of Common Shares in proportion to their investment in Common Shares.

Thereafter, the remaining Deemed Liquidation proceeds of the Company available for distribution to shareholders shall be paid to all of the Shareholders in proportion to their shareholding in the Company.

Without limiting the generality of the foregoing, the Shareholders acknowledge and agree that in case of a Deemed Liquidation by way of a transfer of all or part of the Company's assets, the Shareholders shall resolve on a dividend or liquidation of the Company in order to effect the liquidation preference under this clause 7.1.

7.2. Special Exit Event

In an Exit Event where the per share cash return for C Shares at the closing of the Exit Event (such per share cash return to include the value of any separate cash distribution to the holders of C Shares made prior to or concurrently with the Exit Event) does not amount to at least 2.5 times Applicable Series C Per Share Price (a “**Special Exit Event**”), the proceeds available for distribution to the Company’s shareholders (“**Exit Proceeds**”), shall be allocated to the Shareholders in the following order of precedence:

(a) First to the holders of C Shares then outstanding in the amount corresponding to the value of their investment and no more, up to a total amount of CHF 47,124,000 (such figure to be adjusted accordingly, both in this Shareholders’ Agreement and in the Articles, in case of a Qualified Investor investing in the Company pursuant to the Investment Agreement), before any amount shall be paid to the holders of other Shares. If the Exit Proceeds of the Company available for distribution to its shareholders shall be insufficient to permit such payment in full to the holders of C Shares, then the Exit Proceeds of the Company available for distribution to its shareholders shall be distributed among the holders of C Shares in proportion to their investment in respect of C Shares; and

(b) Then to the holders of B Shares, A Shares and Common Shares then outstanding in the amount corresponding to the value of their investment and no more, up to a total amount of CHF 27,000,000, to be distributed among them in proportion to their shareholding in the Company, before any amount shall be paid to the holders of other Shares. If the Exit Proceeds of the Company available for distribution to its shareholders shall be insufficient to permit such payment in full to the holders of B Shares, A Shares and Common Shares, then the Exit Proceeds of the Company available for distribution to its shareholders shall be distributed among the holders of B Shares, A Shares and Common Shares in proportion to their shareholding in the Company;

(c) Thereafter, the remaining Exit Proceeds shall be paid to all of the Shareholders in proportion to their shareholding in the Company.

7.3 Exit Event

In an Exit Event which is not a Special Exit Event, the Exit Proceeds shall be paid to all of the Shareholders in proportion to their shareholding in the Company.

**8. Anti-Dilution Adjustment**

In the event that the Company, on the Second Closing or on the Third Closing (as defined in the Investment Agreement) – assuming a Qualified Investor participates – or on another equity round of the Company issues equity or equity related securities at a subscription or purchase price (such price the “**New Equity Issue Price**”) below the price per new C Share paid upon the Series C First Tranche Investment (as defined in the Investment Agreement), the holders of the C Shares shall be entitled to purchase such number of additional C shares at nominal value so as to reflect a new blended Series C price that is equal to the New Equity Issue Price.

**9. Conversion of Shares**

In the event the General Assembly of Shareholders, including the consent of the holders of C Shares representing at least two thirds of the C Shares where required pursuant to Section 3 above, has validly resolved to list the Shares and/or offer them to the public, all preferred Shares shall be converted into ordinary Shares upon IPO. In addition, each holder of C Shares shall have the right to request at any time during the term of this Agreement the conversion of all or a part of its preferred Shares into Common Shares by providing notice to this effect to all other Shareholders and the Company.

The number of fully paid ordinary Shares into which the preferred Shares shall be converted will be equal to the number of preferred Shares being converted (1:1 ratio).

**10. Call Option**

The Investors shall have an exclusive and irrevocable option (the "**Call Option**") to purchase the Shares of another Party (the **"Restricted Party**") at forty percent (40%) below the fair market value and in proportion to their shareholdings or in such other proportions and/or other terms as they may agree in writing between them, if any of the following events (the "**Triggering Event**") occurs:

(i) the Restricted Party has pledged or otherwise encumbered or transferred its Shares in contravention of the provisions of this Agreement;

(ii) the Restricted Party becomes insolvent, bankrupt or petitions or applies to any court, tribunal or other body or authority for appointment of, or there shall otherwise be appointed, any administrator, receiver, liquidator, trustee or other similar officer of the Restricted Party or of all or a substantial part of the Restricted Party's assets.

The Restricted Party shall forthwith notify the Investors and the Company of the occurrence of any Triggering Event.

The Investors may exercise the Call Option within sixty (60) days following notification of the Triggering Event by notice to the Restricted Party and the Company. If the Call Option is not exercised within such sixty (60) day period or if the Investors do not exercise the Call Option over all of the Shares of the Restricted Party, the Company shall have the option to purchase the (remaining) Shares of the Restricted Party at forty percent (40%) below the fair market value, which option shall be exercised within ninety (90) days following notification of the Triggering Event.

The fair market value of the Restricted Party's Shares will be determined as follows:

(a) The fair market value shall be determined in due consideration of both the consolidated net equity and the projected future cash flows based on the most recent approved business plan of the Company, excluding any control premium for obtaining a majority of the voting rights in the Company.

(b) If the Parties, for any reason, cannot reach a binding agreement as to the fair market value of the Restricted Party's Shares within sixty (60) days of notice being given by the Company, the Parties shall appoint an independent appraiser by mutual agreement (the "**Appraiser**"). If the Parties cannot agree on the appointment of an Appraiser within seventy (70) days of the date of notice being given by the Company, the Appraiser shall be appointed by the President of the Zurich Chamber of Commerce. The Appraiser shall determine the fair market value of the Restricted Party's Shares (the "**Final Price**") in accordance with standard valuation methods on the basis of both the consolidated net equity and the projected future cash flows based on the most recent approved business plan of the Company and the value of comparator companies, excluding any control premium for obtaining a majority of the voting rights in the Company. The Appraiser's determination of the Final Price, which shall reflect the valuation methods applied, shall be issued in writing by registered mail to the Parties not later than ninety (90) days after the Appraiser's appointment and shall be final and binding upon the Parties.

Expenses incurred in connection with the purchase of the Shares of the Restricted Party, including the Restricted Party's own reasonable expenses, shall be borne by the Investors and/or the Company in proportion to the number of Shares purchased from the Restricted Party.

## 11. Information Rights

Shareholders are entitled to receive

(i) audited financial statements within 90 days after the end of each fiscal year, prepared in accordance with Swiss GAAP, IFRS or US GAAP as decided by the Board;

(ii) yearly budget at least 30 days prior to such financial year; and

(iii) quarterly business reports including a review of the Company's operations as well as unaudited quarterly financial statements within 60 days from the end of each quarter.

## 12. Escrow

All share certificates in respect of the Shares shall at all times be deposited under the name of each Shareholder with ante treuhand ag, 3186 Düdingen (the "**Escrow Agent**") according to the Escrow Agreement (the "**Escrow Agreement**", attached as Annex III to this Agreement). The Shareholders that are not yet party to the Escrow Agreement each undertake to execute and enter into the Escrow Agreement.

## 13. Duration

This Agreement shall remain in force for each Party as long as such Party has an equity interest in the Company. This Agreement shall terminate by operation of law for any Party that ceases to be a shareholder of the Company. In such event, this Agreement shall continue in full force and effect among the remaining Parties.

This Agreement shall terminate (except for the implementation of the preferences under clause 7, if applicable) upon the earlier of an IPO or an Exit Event.

This Agreement shall expire by operation of law ten (10) years after it has become effective, unless restated by the Parties at least three (3) months before such expiry.

## 14. Miscellaneous

### 14.1. No waiver

The failure of any of the Parties to enforce any of the provisions of this Agreement or any rights with respect thereto shall in no way be considered as a waiver of such provisions or rights or in any way to affect the validity of this Agreement. The waiver of any breach of this Agreement by any Party hereto shall not operate to be construed as a waiver of any other prior or subsequent breach.

### 14.2. Severability

If any term or provision of this Agreement shall for any reason be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other term or provision hereof, and this Agreement shall be interpreted and construed as if such term or provision, to the extent the same shall have been held to be invalid, illegal or unenforceable, had never been contained herein.

### 14.3. Amendments

This Agreement including this clause may be modified or amended only by written agreement of the Parties and any provision hereof may be waived only by a document signed by the Party waiving such provision. Notwithstanding anything contained herein to the contrary, the Parties acknowledge and agree that this Agreement may be amended in writing by an instrument signed solely by the holders of 85% of the outstanding Shares in the Company (acting jointly) with binding effect on all other Parties; provided, however, that any such modification or amendment of any of the provisions of this Agreement shall neither affect any accrued rights of any other Party nor impose any greater liability or any more onerous obligation than those contained in this Agreement on the other Parties who do not sign such modification or amendment.

### 14.4. Assignment

This Agreement and the rights and liabilities arising thereunder may not be transferred to third parties except with the prior written consent of the other Parties to this Agreement. Any Shareholder may, however, transfer this Agreement and / or the rights and liabilities arising hereunder in parts or in its entirety to an affiliated company in which it owns at least fifty-one (51) per cent of all outstanding shares or voting rights, in which case the approval of the other

Parties shall be deemed to have been given. The approval of the other Parties shall also be deemed to have been given for transfer to an affiliated company that holds at least fifty-one (51) per cent of all outstanding shares or voting rights of one of the Parties.

14.5. Confidentiality

The Parties each undertake that they will not divulge or communicate to any person (other than where relevant to their employees, affiliates, investors or consultants on a "need to know" basis and bound by respective confidentiality agreements) any information on the Company's business or affairs or about the content of this Agreement ("**Confidential Information**") except for such information that:

(i) was known or used by the receiving Party prior to its date of disclosure to the receiving Party as demonstrated by legally admissible evidence available to the receiving Party;

(ii) either before or after the date of the disclosure to the receiving Party is lawfully disclosed to the receiving Party by sources other than the disclosing Party rightfully in possession of the Confidential Information;

(iii) either before or after the date of the disclosure to the receiving Party becomes published or otherwise part of the public domain through no fault or omission on the part of the receiving Party;

(iv) is independently developed by or for the receiving Party without reference to or in reliance upon the Confidential Information as demonstrated by competent written records; or

(v) is required to be disclosed by the receiving Party to comply with applicable laws or regulations or to defend or prosecute litigation, provided that the receiving Party provides prior written notice of such disclosure to the disclosing Party and takes reasonable and lawful actions to avoid or minimize the degree of such disclosure.

14.6. Entire agreement

This Agreement constitutes the entire agreement between the Parties and supersedes all prior agreements, understandings, negotiations and discussions, whether oral or written, between the Parties regarding the subject matter hereof. There are no representations, warranties, conditions or other agreements, express or implied, statutory or otherwise, between the Parties in connection with the subject matter of this Agreement, except as specifically set forth herein and the Parties have not relied and are not relying on any other information, discussion or understanding in entering into and completing the transactions contemplated by this Agreement.

14.7. Governing law and jurisdiction

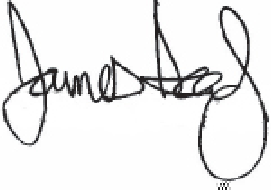
This Agreement shall be governed by and be in accordance with Swiss law. Any disputes between the Parties arising out of or in connection with this Agreement shall be subject to the exclusive jurisdiction of the Commercial Court of the Canton of Zurich, Switzerland.

Executed in 1 copy.

**xxx Execution sheet on next page xxx**

**Sofinnova Venture Partners VIII, L.P.**

By: Sofinnova Management VIII, L.L.C.
its General Partner



By ____________________________________
James Healy, Managing Member

**Sofinnova Capital VII FCPR**

By: Sofinnova Partners SAS
its General Partner

By ____________________________________
Antoine Papiernik, Managing Partner

**Auris Medical AG**

____________________________________
Thomas Meyer, Chairman of the Board

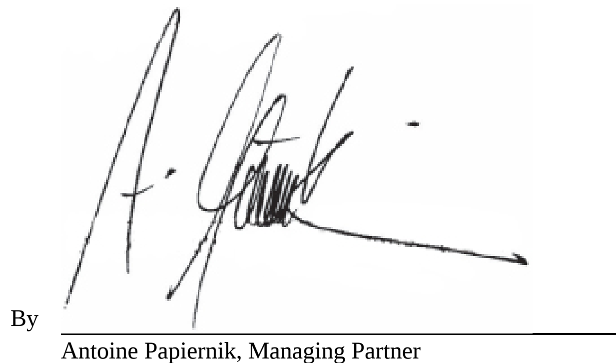
**Sofinnova Venture Partners VIII, L.P.**

By: Sofinnova Management VIII, L.L.C.
its General Partner

By __________________________________________
James Healy, Managing Member

**Sofinnova Capital VII FCPR**

By: Sofinnova Partners SAS
its General Partner



By __________________________________________
Antoine Papiernik, Managing Partner

**Auris Medical AG**

__________________________________________
Thomas Meyer, Chairman of the Board

**Sofinnova Venture Partners VIII, L.P.**

By: Sofinnova Management VIII, L.L.C.
its General Partner

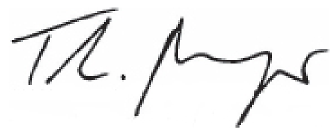
By ______________________________
James Healy, Managing Member

**Sofinnova Capital VII FCPR**

By: Sofinnova Partners SAS
its General Partner

By ______________________________
Antoine Papiernik, Managing Partner

**Auris Medical AG**



______________________________
Thomas Meyer, Chairman of the Board

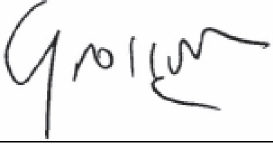
**Auris Medical AG**

________________________________________

Thomas Meyer, Chairman of the Board

**Allianz Innovation 7 FCPI**
**Idinvest Croissance 2005 FCPI**
**Allianz Innovation 8 FCPI**
**Banque Postale Innovation 3 FCPI**

Each and all by: ID Invest

By: 

Benoist Grossmann

**ZKB Pharma Vision Fonds**
**Adamant Global Healthcare Fonds**
**Adamant Global Generika Fonds**
**Adamant Global Biotech Fonds**

Each an all by: Balfidor Fondsleitung AG

By:

Alexander Müller

Markus Pfister

**Phonak AG**

By: ______________________

Thomas Meyer (proxy)

**Allianz Innovation 7 FCPI**
**Idinvest Croissance 2005 FCPI**
**Allianz Innovation 8 FCPI**
**Banque Postale Innovation 3 FCPI**

Each and all by: ID Invest

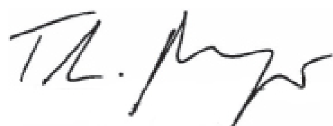
By: ______________________________
Benoist Grossmann

**ZKB Pharma Vision Fonds**
**Adamant Global Healthcare Fonds**
**Adamant Global Generika Fonds**
**Adamant Global Biotech Fonds**

Each and all by: Balfidor Fondsleitung AG

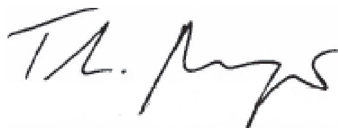
By: ______________________________ ______________________________
Markus Pfister Alexander Müller

**Phonak AG**



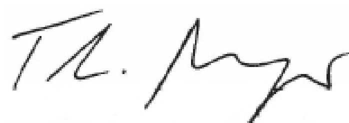
By: ______________________________
Thomas Meyer (proxy)

**Thomas Meyer**

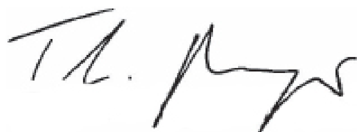


**Daniel Gutenberg** (by Thomas Meyer, proxy)

**Gerhard Jansen** (by Thomas Meyer, proxy)



**Martin Oberholzer** (by Thomas Meyer, proxy)



**Oliver Walker** (by Thomas Meyer, proxy)

**Heinz Winzeler** (by Thomas Meyer, proxy)

**Annex I: Shareholders**

**C Investors**

Sofinnova Venture Partners VIII, L.P.
2800 Sand Hill Road, Suite 150
Menlo Park, CA 94025

Sofinnova Capital VII FCPR
c/o Sofinnova Partners
17, rue de Surène
75008 Paris
France

**Other shareholders**

Thomas Meyer
Birkenweg 6
CH-4528 Zuchwil

IDinvest
117, Avenue des Champs-Elysées
FR-75008 Paris

Balfidor Fondsleitung AG
c/o Adamant Biomedical Investments AG
Freischützgasse 3
CH-8004 Zürich

Phonak AG
Laubisrütistrasse 28
CH-8712 Stäfa

Daniel Gutenberg
Inselweg 28
CH-8640 Hurden

Gerhard Jansen
Quellenrain 15
CH-3063 Ittigen

Martin Oberholzer
Rohnenrainweg 4
CH-8835 Feusisberg

Oliver Walker
Pestalozzistrasse 5
CH-5000 Aarau

Heinz Winzeler
Klotenerstrasse 13
CH-8304 Wallisellen

**Company:**

Auris Medical AG
Falknerstrasse 4
CH-4001 Basel

**Annex II: Investments and Shareholdings**

The Company’s capital structure <u>after</u> the closing of the Series C financing round closings is set forth below:

| **Investor** | **Common** | | **Series A** | | **Series B** | | | **First Tranche Initial Closing** | | | **Second Tranche Second Closing** | | | **Third Tranche Third Closing** | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | *Shares* | *%* | *Shares* | *%* | *Shares* | *%* | *Fully Diluted + ESO* | *Shares* | *%* | *Fully Diluted + ESO* | *Shares* | *%* | *Fully Diluted + ESO* | *Shares* | *%* | *Fully Diluted + ESO* |
| **Thomas Meyer, CH-Zuchwil** | 2’904 | 100% | 239’990 | 100.0% | 23’606 | 10.7% | 56.6% | | | 40.6% | | | 35.0% | | | 32.2% |
| **IDinvest, FR-Paris** | | | | | 69’276 | 31.4% | 14.7% | | | 10.6% | | | 9.1% | | | 8.4% |
| Allianz Innovation 7 FCPI | | | | | 15’241 | | | | | | | | | | | |
| Idinvest Croissance 2005 FCPI | | | | | 19’397 | | | | | | | | | | | |
| Allianz Innovation 8 FCPI | | | | | 27’019 | | | | | | | | | | | |
| Banque Postale Innovation 3 FCPI | | | | | 7’619 | | | | | | | | | | | |
| **ZKB, CH-Zurich** | | | | | 86’785 | 39.4% | 18.4% | | | 13.2% | | | 11.4% | | | 10.5% |
| ZKB Pharma Vision Fonds | | | | | 37’500 | | | | | | | | | | | |
| Adamant Global Medtech Fonds | | | | | 9’535 | | | | | | | | | | | |
| Adamant Global Generika Fonds | | | | | 23’000 | | | | | | | | | | | |

| | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Adamant Global Biotech Fonds | | | | | 16’750 | | | | | | | | | | | |
| **Phonak AG, CH-Stäfa** | | | | | 22’080 | 10.0% | 4.7% | | | 3.4% | | | 2.9% | | | 2.7% |
| **Daniel Gutenberg, CH-Küsnacht** | | | | | 1’776 | 0.8% | 0.4% | | | 0.3% | | | 0.2% | | | 0.2% |
| **Gerhard Jansen, CH-Ittigen** | | | | | 8’632 | 3.9% | 1.8% | | | 1.3% | | | 1.1% | | | 1.0% |
| **Martin Oberholzer, CH-Feusisberg** | | | | | 1’269 | 0.6% | 0.3% | | | 0.2% | | | 0.2% | | | 0.2% |
| **Oliver Walker, CH-Aarau** | | | | | 2’500 | 1.1% | 0.5% | | | 0.4% | | | 0.3% | | | 0.3% |
| **Heinz Winzeler, CH-Wallisellen** | | | | | 4’440 | 2.0% | 0.9% | | | 0.7% | | | 0.6% | | | 0.5% |
| **Sofinnova Ventures** | | | | | | | | 94’545 | 51.0% | 14.4% | 53’182 | 51.0% | 19.4% | 34’273 | 51.0% | 22.0% |
| **Sofinnova Partners** | | | | | | | | 90’910 | 49.0% | 13.8% | 51’136 | 49.0% | 18.7% | 32’954 | 49.0% | 21.1% |
| | 2’904 | 100% | 239’990 | 100.0% | 220’364 | 100.0% | 98.3% | 185’455 | 100.0% | 98.8% | 104’318 | 100.0% | 99.0% | 67’227 | 100.0% | 99.1% |
| **Stock Options** | 7’860 | | | | | | 1.7% | | | 1.2% | | | 1.0% | | | 0.9% |
| | | | 471’118 | | | | 100.0% | 656’573 | | 100.0% | 760’891 | | 100.0% | 828’118 | | 100.0% |

**Exhibit 10.5**

# LOAN AGREEMENT MADE AS OF 9 DECEMBER 2013

between

Sofinnova Capital VII FCPR / Sofinnova Venture Partners VIII, L.P.

and

Auris Medical AG

This loan agreement, as it may be amended at any time (the/this “**Agreement**”) is made as of 9 December 2013 between:

**Sofinnova Venture Partners VIII, L.P**., 2800 Sand Hill Road, Suite 150, Menlo Park, CA 94025, USA

and

**Sofinnova Capital VII FCPR**, c/o Sofinnova Partners, 16-18 Rue du 4 Septembre, 75002 Paris, France

(both together the “**Lenders**”);

and

**Auris Medical AG,** Falknerstrasse 4, 4001 Basel, Switzerland

(the “**Borrower**” or the “**Company**”).

(each the Lenders and the Borrower or the Company individually also a “**Party**”, and jointly the “**Parties**”)

**Preamble**

Whereas:

The Borrower has solicited the Lenders for the provision of capital to fund its expansion projects;

The Lenders have agreed to provide the Borrower with loans in the total amount of CHF 13’769’976 (the “**Loans**”), which shall be convertible into Series C Shares of the Company subject to and in accordance with the terms and conditions hereof.

NOW, THEREFORE IT IS AGREED AS FOLLOWS:

## 1. The Loans

The Lenders grant to the Borrower two Loans as follows:

- Sofinnova Venture Partners VIII, L.P. a Loan in the amount of CHF 7’020’024
- Sofinnova Capital VII FCPR a Loan in the amount of CHF 6’749’952

upon and subject to the terms and conditions of this Agreement.

The Loans shall be paid on 9 December 2013.

**2. Interest**

The Loans granted under this Agreement shall bear no interest.

**3. Repayment**

Unless the Lenders or the Borrower have exercised their right to convert the Loans in accordance with the terms of this Agreement, the Borrower shall have the right to repay the Loans at any time after 1 February 2014, at the latest at December 8, 2014.

**4. Subordination**

4.1. The Lenders hereby agree that the Loans under this Agreement shall be fully subordinated to any other non-subordinated indebtedness of the Borrower.

4.2. The Lenders hereby agree to make, if any, all declarations required by the auditors in respect of the subordination, so that the Loans can be treated as subordinated in the financial accounts of the Borrower.

**5. Disbursement and Payments**

5.1. All payments under this Agreement shall be in Swiss Francs (CHF):

(a) in full, without any deduction, set-off or counterclaim; and

(b) in immediately available cleared funds on the due date to the respective accounts of the Lenders or Borrower, as the case may be.

5.2. Payments to be made by the Lenders to the Borrower shall be made in the following bank account:

Beneficiary bank: UBS, 3000 Berne, Switzerland
Swift code: UBSWCHZH80A
Beneficiary name: Auris Medical AG, Falknerstrasse 4, 4001 Basel, Switzerland
Beneficiary IBAN no.: CH68 0023 5235 9E32 9052 0

5.3. Payments to be made by the Borrower to the Lenders shall be made to the bank accounts specified by the Lenders.

5.4. Any payment which is due to be made on a Friday, Saturday or day on which banks in Basel-Stadt are authorized or obligated by law to close or are generally closed shall be made on the next business day, meaning a day other than a Friday, Saturday or day on which banks in Basel-Stadt are authorized or obligated by law to close or are generally closed (the "**Business Day**")

5.5. The Lenders shall pay all costs, expenses, taxes and the like (and any interest payable on those amounts) to be borne by them in the currency in which they are incurred.

**6. Assignment and Transfer**

The Borrower may not assign or transfer any of his rights and obligations under this Agreement without the prior written consent of the Lenders.

**7. Conversion**

7.1. The Lenders shall have the unconditional right to convert the Loans in their entirety into new registered Series C Shares as follows:

- Sofinnova Venture Partners VIII, L.P. 53'182 new registered Series C Shares of the Borrower with a par value of CHF 10; and
- Sofinnova Capital VII FCPR 51'136 new registered Series C Shares of the Borrower with a par value of CHF 10 each.

The Lenders shall exercise their conversion right as per this clause 7.1. by sending between 10 January 2014 and 17 January 2014 a notice of conversion, duly signed by each of them, substantially in the form as set forth in Annex I and II (the "**Lender's Conversion Notice**").

7.2. The Company shall have the unconditional right to convert, by 31 January 2014 at the latest, the Loans in their entirety into new registered Series C Shares as follows:

- Sofinnova Venture Partners VIII, L.P. 53'182 new registered Series C Shares of the Borrower with a par value of CHF 10; and
- Sofinnova Capital VII FCPR 51'136 new registered Series C Shares of the Borrower with a par value of CHF 10 each.

The Company shall exercise its conversion right as per this clause 7.2. by sending between 10 January 2014 and 17 January 2014 a notice of conversion, duly signed, substantially in the form as set forth in Annex III and IV (the "**Borrower's Conversion Notice**").

7.3. The Conversion Price shall be the par value of Series C Shares in the amount of CHF 10 each plus the respective share-premium (the "**Agio Amount**") of CHF 122 per share.

7.4. The Parties agree that the number of new registered Series C shares into which the Loans can be converted shall be adjusted as required before the conversion in case of stock splits by the Borrower before completion of the conversion.

7.5. Within 10 days as from the receipt of the Notice of Conversion by the Borrower or the Lenders, the Parties shall take all necessary measures to satisfy the conversion of the Loan into Series C Shares in the Company as follows:

(a) the Borrower's board of directors shall resolve on the increase in capital out of the authorized capital and issue 104'318 new Series C Shares to the Lenders;

(b) the Borrower shall file the application with the Register of Commerce of the Canton of Basel-Stadt immediately upon receipt of the necessary documents and resolutions.

## 8. Remedies, Waivers, Amendments and Consents

8.1. Any amendment to this Agreement shall be in writing and signed by, or on behalf of, each party.

8.2. Any waiver of any right or consent given under this Agreement is only effective if it is in writing and signed by the waiving or consenting party. It only applies in the circumstances for which it is given and shall not prevent the party giving it from subsequently relying on the relevant provision.

8.3. No delay or failure to exercise any right under this Agreement shall operate as a waiver of that right.

8.4. No single or partial exercise of any right under this Agreement shall prevent any further exercise of the same right or any other right, under this Agreement.

8.5. Rights and remedies under this Agreement are cumulative and do not exclude any rights or remedies provided by law or otherwise.

## 9. Severance

9.1. The invalidity, unenforceability or illegality of any provision (or part of a provision) of this Agreement under the laws of any jurisdiction shall not affect the validity, enforceability or legality of the other provisions.

9.2. If any invalid, unenforceable or illegal provision would be valid, enforceable and legal if some part of it were deleted, the provision shall apply with whatever modification as is necessary to give effect to the commercial intention of the parties.

## 10. Counterparts

This Agreement may be executed and delivered in any number of counterparts, each of which is an original and which, together, have the same effect as if each party had signed the same document.

## 11. Notices

11.1. Each notice or other communication required to be given under this Agreement shall:

(a) be in writing, delivered personally or sent by registered post, courier service or facsimile transmission; and

(b) be sent:

to the Borrower at:
Auris Medical AG
Falknerstrasse 4
4001 Basel
Switzerland

to the Lenders at:

Sofinnova Venture Partners VIII, L.P.
2800 Sand Hill Road, Suite 150
Menlo Park, CA 94025
USA

Sofinnova Capital VII FCPR
c/o Sofinnova Partners
16-18 Rue du 4 Septembre
75002 Paris
France

or to such other address or contact details as are notified by one party to the other.

11.2. Any notice or other communication that the Lenders gives shall be deemed to have been received:

(a) if delivered personally or by courier service, at the time of delivery;

(b) if posted, at the expiration of 48 hours after the envelope containing the same was delivered into the custody of the postal authorities; and

(c) if sent by fax, at the time of completion of transmission by the sender, except that if a communication is received between 3:00 p.m. on a Business Day and 8:30 a.m. on the next Business Day, it shall be deemed to have been received at 8:30 a.m. on the second of such Business Days.

11.3. Any notice or other communication given to the Lenders shall be deemed to have been given only on actual receipt.

**12. Confidentiality**

It is agreed that the information contained in this Agreement shall be treated as strictly confidential.

**13. Governing Law**

The validity, interpretation and performance of this Agreement shall be governed by Swiss law.

**14. Settlement of Disputes**

Any dispute or disagreement arising out of, or in connection with, or in relation to, this Agreement shall be submitted to the Commercial Court of the Canton of Zurich.

This Agreement has been entered into on the date stated at the beginning of it.

The Annexes of this Agreement shall form an integral part hereof.

THE SIGNATURES OF THE PARTIES TO FOLLOW

LOAN AGREEMENT MADE AS OF 9 DECEMBER 2013 BETWEEN SOFINNOVA VENTURE PARTNERS VIII, L.P. AND SOFINNOVA CAPITAL VII FCPR AND AURIS MEDICAL AG

SIGNATURE PAGE:

The Borrower:

Auris Medical AG

The Lenders:

| Sofinnova Venture Partners VIII, L.P. | Sofinnova Capital VII FCPR |
|---|---|

LOAN AGREEMENT MADE AS OF 9 DECEMBER 2013 BETWEEN SOFINNOVA VENTURE PARTNERS VIII, L.P. AND SOFINNOVA CAPITAL VII FCPR AND AURIS MEDICAL AG

SIGNATURE PAGE:

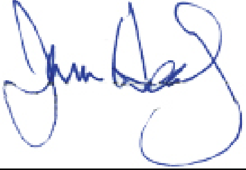
The Borrower:

Auris Medical AG

The Lenders:

**Sofinnova Venture Partners VIII, L.P.**

By: Sofinnova Management VIII, L.L.C.
its General Partner



By

Jim Healy, Managing Member

Sofinnova Capital VII FCPR

LOAN AGREEMENT MADE AS OF 9 DECEMBER 2013 BETWEEN SOFINNOVA VENTURE PARTNERS VIII, L.P. AND SOFINNOVA CAPITAL VII FCPR AND AURIS MEDICAL AG

SIGNATURE PAGE:

The Borrower:

______________________________

Auris Medical AG

The Lenders:

| ______________________________ | ______________________________ |
| --- | --- |
| Sofinnova Venture Partners VIII, L.P. | Sofinnova Capital VII FCPR |

Sofinnova Venture Partners VIII, L.P.
2800 Sand Hill Road, Suite 150
Menlo Park, CA 94025
USA

Attn.:
Board of Directors
Verwaltungsrat
Auris Medical AG
Falknerstrasse 4
4001 Basel

**Lenders’ Conversion Notice**

The undersigned, **Sofinnova Venture Partners VIII, L.P.**, herewith exercises its right to convert the loan in the amount of CHF 7’020’024 (the “**Loan**”) granted to Auris Medical AG in Basel (the “**Company**”) as agreed in clause 7 of the loan agreement signed on 9 December 2013, into 53’182 new registered Series C Shares (the “**Conversion Shares**”) of the Company with an issue price of CHF 132 per Conversion Share (with a par value of CHF 10 each). Accordingly, the undersigned herewith sets-off the Loan against its contribution for the Conversion Shares.

Accordingly, we kindly ask you to proceed pursuant to clause 7 of the loan agreement.

*Die Unterzeichnende, **Sofinnova Venture Partners VIII, L.P.**, erklärt hiermit entsprechend der Ziffer 7 des am 9. Dezember 2013 unterzeichneten Darlehensvertrages, ihr Recht zur Umwandlung des an die Auris Medical AG in Basel (die “Gesellschaft”) gewährten Darlehens im Umfang von CHF 7’020’024 in 53’182 neue Series C Shares (“Wandelaktien”) der Gesellschaft mit einem Ausgabepreis in Höhe von CHF 132 pro Wandelaktie (mit einem Nennwert von je CHF 10) auszuüben. Zu diesem Zweck verrechnet die Unterzeichnende ihre Darlehensforderung gegen die Wandelaktien.*

*Entsprechend bitten wir Sie höflich, die Schritte gemäss Klausel 7 des Darlehensvertrages vorzunehmen.*

Place, date

**Sofinnova Venture Partners VIII, L.P.**, represented by

| [—] | [—] |
|---|---|

**Annex II: Lenders' Conversion Notice**

---

Sofinnova Capital VII FCPR
c/o Sofinnova Partners
16-18 Rue du 4 Septembre
75002 Paris
France

Attn.:
Board of Directors
Verwaltungsrat
Auris Medical AG
Falknerstrasse 4
4001 Basel

**Lenders' Conversion Notice**

The undersigned, **Sofinnova Capital VII FCPR,** herewith exercises its right to convert the loan in the amount of CHF 6'749'952 (the "**Loan**") granted to Auris Medical AG in Basel (the "**Company**") as agreed in clause 7 of the loan agreement signed on 9 December 2013, into 51'136 new registered Series C Shares (the "**Conversion Shares**") of the Company with an issue price of CHF 132 per Conversion Share (with a par value of CHF 10 each). Accordingly, the undersigned herewith sets-off the Loan against its contribution for the Conversion Shares.

Accordingly, we kindly ask you to proceed pursuant to clause 7 of the loan agreement.

*Die Unterzeichnende, **Sofinnova Capital VII FCPR**, erklärt hiermit entsprechend der Ziffer 7 des am 9. Dezember 2013 unterzeichneten Darlehensvertrages, ihr Recht zur Umwandlung des an die Auris Medical AG in Basel (die "Gesellschaft") gewährten Darlehens im Umfang von CHF 6'749'952 in 51'136 neue Series C Shares ("Wandelaktien") der Gesellschaft mit einem Ausgabepreis in Höhe von CHF 132 pro Wandelaktie (mit einem Nennwert von je CHF 10) auszuüben. Zu diesem Zweck verrechnet die Unterzeichnende ihre Darlehensforderung gegen die Wandelaktien.*

Entsprechend bitten wir Sie höflich, die Schritte gemäss Klausel 7 des Darlehensvertrages vorzunehmen.

Place, date

**Sofinnova Capital VII FCPR**, represented by

[—]

[—]

Auris Medical AG
Falknerstrasse 4
4001 Basel
Switzerland

Attn.:
Board of Directors
Sofinnova Venture Partners VIII, L.P.
2800 Sand Hill Road, Suite 150
Menlo Park, CA 94025

**Borrower's Conversion Notice**

The undersigned, **Auris Medical AG,** herewith exercises its right to convert the loan in the amount of CHF 7'020'024 (the "**Loan**") granted by Sofinnova Venture Partners VIII, L.P. (the "**Lender**") as agreed in clause 7 of the loan agreement signed on 9 December 2013, into 53'182 new registered Series C Shares (the "**Conversion Shares**") of the Company with an issue price of CHF 132 per Conversion Share (with a par value of CHF 10 each). Accordingly, the Lender's Loan is set-off against the Conversion Shares.

We kindly ask you to countersign and return this Conversion Notice and the respective Subscription Form enclosed hereto.

*Die Unterzeichnende,* ***Auris Medical AG****, erklärt hiermit entsprechend der Ziffer 7 des am 9. Dezember 2013 unterzeichneten Darlehensvertrages, ihr Recht zur Umwandlung des von Sofinnova Capital VII FCPR (die "Darlehensgeberin") gewährten Darlehens im Umfang von CHF 7'020'024 in 53'182 neue Series C Shares ("Wandelaktien") der Gesellschaft mit einem Ausgabepreis in Höhe von CHF 132 pro Wandelaktie (mit einem Nennwert von je CHF 10) auszuüben. Damit gilt die Darlehensforderung der Darlehensgeberin gegen die Wandelaktien als verrechnet.*

*Wir bitten Sie höflich, diese Umwandlungsanzeige und den entsprechend beiliegenden Zeichnungsschein gegenzuzeichnen und an uns zurückzusenden.*

Place, date

**Auris Medical AG**, represented by / vertreten durch

[—]

[—]

**Sofinnova Capital VII FCPR**, represented by / *vertreten durch*

[—]

[—]

**Annex IV:** **Borrower's Conversion Notice**

---

Auris Medical AG
Falknerstrasse 4
4001 Basel
Switzerland

Attn.:
Board of Directors
Sofinnova Capital VII FCPR
c/o Sofinnova Partners
16-18 Rue du 4 Septembre
75002 Paris
France

**Borrower's Conversion Notice**

The undersigned, **Auris Medical AG,** herewith exercises its right to convert the loan in the amount of CHF 6'749'952 (the "**Loan**") granted by Sofinnova Capital VII FCPR (the "**Lender**") as agreed in clause 7 of the loan agreement signed on 9 December 2013, into 51'136 new registered Series C Shares (the "**Conversion Shares**") of the Company with an issue price of CHF 132 per Conversion Share (with a par value of CHF 10 each). Accordingly, the Lender's Loan receivable is set-off against the Conversion Shares.

We kindly ask you countersign and return this Conversion Notice and the respective Subscription Form enclosed hereto.

*Die Unterzeichnende,* ***Auris Medical AG****, erklärt hiermit entsprechend der Ziffer 7 des am 9. Dezember 2013 unterzeichneten Darlehensvertrages, ihr Recht zur Umwandlung des von Sofinnova Capital VII FCPR (die "Darlehensgeberin") gewährten Darlehens im Umfang von CHF 6'749'952 in 51'136 neue Series C Shares ("Wandelaktien") der Gesellschaft mit einem Ausgabepreis in Höhe von CHF 132 pro Wandelaktie (mit einem Nennwert von je CHF 10) auszuüben. Damit gilt die Darlehensforderung der Darlehensgeberin gegen die Wandelaktien als verrechnet.*

*Wir bitten Sie höflich, diese Umwandlungsanzeige und den entsprechend beiliegenden Zeichnungsschein gegenzuzeichnen und an uns zurückzusenden.*

Place, date

**Auris Medical AG**, represented by / vertreten durch

[—] [—]

**Sofinnova Capital VII FCPR**, represented by / *vertreten durch*

[—] [—]

# Mandate Agreement

**between**

**Auris Medical AG, Basel**
**and**
**Altamira Pharma GmbH, Zuchwil**

## Mandate

Auris Medical AG ("AMAG") herewith instructs and mandates Altamira Pharma GmbH ("APG") to provide support to AMAG in the strategic management of the business and in selected operational tasks.

## Fees

AMAG shall pay to APG a monthly fee of CHF 20'000.—, including VAT, and a lump-sum expense allowance of CHF 600.—. Expenses in excess of the lump-sum allowance incurred in relation with the execution of the mandate shall be charged separately and against receipt.

## Confidentiality

APG shall maintain secrecy over any and all business secrets and confidential information supplied based upon this agreement or of which it has obtained knowledge otherwise. This confidentiality obligation shall apply for the duration of this mandate and three years after its termination.

No confidentiality obligation shall apply if and to the extent that information concerned

- is in the public domain, or
- has become of public domain without act or failure of the concerned contractual party, or
- was / has been obtained rightfully by a third party, or
- already was in possession of the concerned contractual party.

Upon termination of this agreement, APG shall immediately return all documents, files, letters, schemes, equipment, products, software etc. belonging to AMAG, as well as copies and electronic records thereof, to AMAG.

## Non-competition clause

During this mandate, APG undertakes not to perform any activities which are directly or indirectly competing with AMAG.

**Intellectual Property Rights**

Inventions, creations, works and other Intellectual property are owned by AMAG to the extent as they are created in the performance of APG's contractual obligations.

**Duration of the Mandate**

This mandate is entered into for an indefinite period of time. Either party may terminate the agreement in writing with a 3-months' notice period, with effect as to the end of a month.

**Miscellaneous**

- If any provision of this agreement is held to be invalid, such invalidity shall not affect any other part of this contract.
- The place of jurisdiction is the City of Basle.

| | |
|---|---|
| Basle, 4 January 2011 | Zuchwil, 4 January 2011 |
| [Signature] | [Signature] |
| Auris Medical AG | Altamira Pharma GmbH |

EXECUTION VERSION

# SERVICE TERMINATION AGREEMENT

(hereinafter referred to as the/this "**Agreement**")

between

**Auris Medical AG**, Falknerstrasse 4, 4001 Basel

(hereinafter referred to as "**Auris**"),

and

**Altamira Pharma GmbH**, Birkenweg 6, 4528 Zuchwil

(hereinafter referred to as "**Altamira**")

(Auris and Altamira both referred to as "**Parties**")

**WHEREAS:**

- the Parties have entered into a service agreement / "Mandatsvereinbarung" dated as of 4 January 2011 (hereinafter referred to as "**Service Agreement**");
- under the Service Agreement Altamira has been rendering strategic management services and supported in selected operational tasks to Auris;
- the Parties wish to terminate the Service Agreement by way of mutual agreement with effect as of 31 January 2014;

Therefore, the Parties **agree** as follows:

## 1. Termination of Service Agreement

The Parties mutually state and agree that the Service Agreement has ended with effect as of 31 January 2014. Accordingly, the Parties mutually waive the termination period as set out in the Service Agreement.

**2. Final payment**

Auris agrees to make a final payment in the amount of CHF 14’500 (hereinafter referred to as “**Final Payment**”). The Final Payment shall be in full settlement of any and all claims of Altamira out of or in connection with the services rendered under the Service Agreement until 31 January 2014. The Final Payment shall be inclusive of all costs, expenses and taxes.

**3. Final Settlement and Waiver**

The Parties agree that with the execution of this Agreement, any and all mutual claims out of the Service Agreement or termination of the Service Agreement between the Parties shall have been fully and finally settled, with exception of the obligations of Altamira concerning confidentiality (“Vertraulichkeit”) and intellectual property rights (“Rechte an immateriellen Gütern”).

**4. Miscellaneous**

Should any provision of this Agreement be deemed or held to be wholly or partially invalid, ineffective or unenforceable, this shall not affect the validity, effectiveness or enforceability of the remainder hereof. The Parties hereby agree to replace any provision so severed by a provision, negotiated in good faith that achieves as closely as possible the original intention of the parties.

This Agreement (including this clause) may only be amended if the Parties confirm such amendment in writing.

This Agreement shall be exclusively interpreted, supplemented and governed by Swiss Law (Code of Obligations).

Place, Date: Zurich, 26.2.14

**Auris Medical AG**

Oliver Kubli
Vice Chairman

Wolfgang Arnold
Secretary

Place, Date: [illegible], 28.2.2014

**Altamira Pharma GmbH**

Thomas Meyer
Managing Director

## 2. Final payment

Auris agrees to make a final payment in the amount of CHF 14’500 (hereinafter referred to as “**Final Payment**”). The Final Payment shall be in full settlement of any and all claims of Altamira out of or in connection with the services rendered under the Service Agreement until 31 January 2014. The Final Payment shall be inclusive of all costs, expenses and taxes.

## 3. Final Settlement and Waiver

The Parties agree that with the execution of this Agreement, any and all mutual claims out of the Service Agreement or termination of the Service Agreement between the Parties shall have been fully and finally settled, with exception of the obligations of Altamira concerning confidentiality (“Vertraulichkeit”) and intellectual property rights (“Rechte an immateriellen Gütern”).

## 4. Miscellaneous

Should any provision of this Agreement be deemed or held to be wholly or partially invalid, ineffective or unenforceable, this shall not affect the validity, effectiveness or enforceability of the remainder hereof. The Parties hereby agree to replace any provision so severed by a provision, negotiated in good faith that achieves as closely as possible the original intention of the parties.

This Agreement (including this clause) may only be amended if the Parties confirm such amendment in writing.

This Agreement shall be exclusively interpreted, supplemented and governed by Swiss Law (Code of Obligations).

Place, Date: Kastanienbaum, 26.II.14

**Auris Medical AG**

Oliver Kubli
Vice Chairman

Wolfgang Arnold
Secretary

Place, Date: ______________________

**Altamira Pharma GmbH**

Thomas Meyer
Managing Director

**Exhibit 10.8**

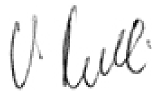
**Loan Agreement**
between
**Auris Medical AG**
and
**Altamira Pharma GmbH**

Altamira Pharma GmbH, Zuchwil, and Auris Medical AG, Basel (the “Parties”), agree to enter into a loan agreement (“Agreement”) as follows:

Altamira Pharma GmbH (“Lender”) is providing a revolving credit facility of up to CHF 250,000 and up to EUR 250,000 (“Loan Amount”) to Auris Medical AG (“Borrower”), starting January 11, 2013, for a maximum of 30 days at an annual interest rate of 5%. Lender agrees to transfer Loan Amount upon request either as a whole or in tranches to Borrower’s bank account(s) and Borrower agrees to pay back Loan Amount as well as accrued interest on February 11, 2013 at the latest to Lender’s bank account(s).

Basel, 9.1.2013

Auris Medical AG


Oliver Kubli

Prof Wolfgang Arnold

Zuchwil, 08.01.2013

Altamira Pharma GmbH

Dr Thomas Meyer

**Exhibit 10.10**

English Translation

[Letterhead of Privera AG]

Lease Agreement for Commercial Premises

between

Assetimmo Immobilien Anlagestiftung hereinafter the Landlord
Badenerstrasse 329
CH-8003 Zürich

represented by

PRIVERA AG hereinafter the Representative
Mühlematt Shopping
4104 Oberwil

and

Auris Medical AG hereinafter the Tenant
Aeschenvorstadt 37
4051 Basel

**Concerning the lease of premises in the property**

Falknerstrasse 2/4, CH-4001 Basel

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## 1. Terms used

Irrespective of the legal form or gender of a party, or the number of people or legal entities constituting a party, for ease of reference the generic terms “Landlord”, “Representative” and “Tenant” are used in this agreement.

## 2. Lease object

2.1 Location and surface area

The Landlord leases to the Tenant the below identified areas of the property referred to on the first page above, the location and area of which are outlined in red on the attached floor plan. The condition and composition of the lease object is described in the description of fit out also attached hereto. The stated surface areas are guidelines and may deviate from the actual surface areas. Any such deviations shall have no impact on the applicable rent or the formula for calculation of ancillary expenses.

| Base rent on conclusion of the agreement | | | | Annual | Monthly |
|---|---|---|---|---|---|
| **Ref. N0.** | **Level Object** | **surface m2 ca** | **CHF/ m2** | **Total CHF** | **Total CHF** |
| Net rent 21003.01.430010 | 3rd floor office | 300.2 | 275.00 | 82’555.00 | 6’880.00 |
| | Total | | | 82’555.00 | 6’880.00 |
| Ancillary expense advance 2100.01.430010 | 3rd floor office | 300.2 | 30.00 | 9’006.00 | 751.00 |
| | Total | | | 9’006.00 | 751.00 |
| Gross rent | Total | | | 91’561.00 | 7’631.00 |
| **Payable monthly in advance on the first day of the month** | | | | | **7’631.00** |

The amounts are in part rounded up or down for IT reasons.

2.2 Facades, Roof Areas, Common Areas

The right to dispose over walls, facades, roof areas and all common areas bordering on the rental areas remains exclusively with the Landlord.

Initials Landlord Initials Tenant

2.3 Surface area calculation

The calculation of surface areas is made from axis to axis, from the middle of separating walls and subdivisions, or the inner side of common areas. The surface so calculated as stated in this agreement is deemed to have been accepted with binding effect for both parties.

## 3. Purpose of usage

3.1 Type of use

The Tenant is entitled and obliged to use and operate the lease object during the whole contractual period as follows: **office premises**.

3.2 Usage by third parties

(see also Section 6.7)

The Tenant may sublease the lease object in whole or in part (art. 262 of the Code of Obligations) or assign the lease together with all rights and obligations to a third party (art. 263 of the Code of Obligations) only with the Landlord's prior written consent.

## 4. Start of lease, term of lease, option right, extension and termination

4.1 Start of lease

The lease commences on 01.04.2013.

The Tenant rents the lease object in accordance with the description of fit out and the floor plans. Any defects in the lease object will be recorded in a protocol at the time of handover of the lease object, and the protocol will be signed by both parties. If further defects appear in addition to those recorded in the protocol, the Tenant must give notice of these in writing within 30 days of the handover. In the absence of notice, the Tenant is assumed to have taken over the lease object in a condition suitable for the intended use.

4.2 Term of lease / termination

The lease is concluded for a fixed term (art. 255 para 2 of the Code of Obligations) and expires without notice on 31.03.2018 – subject to the option right pursuant to Section 4.3 below. The Tenant is granted a one-off unilateral right of termination per 31.03.2016 on giving 12 months' prior notice.

4.3 Option right

The Tenant is granted an option right to extend the minimum term of the lease agreement for a further 1 x 5 years. If it wishes to make use of this right, the Tenant must give notice to the Landlord in writing by registered letter at the latest 12 months prior to the first possible termination date, i.e. by 31.03.2017.

To the extent that the Tenant exercises its option right, the Landlord is entitled but not obliged to adjust the rent for the new contract period in accordance with the then relevant market conditions. If the parties cannot agree on the then applicable rent at the latest by 12 months prior to the first possible termination date, the declaration of exercise of the option will not result in the extension of the lease agreement and the agreement will terminate on 31.03.2018.

If the Tenant does not exercise the option right or does not do so on time, the lease terminates on 31.03.2018.

Any sub-lease or assignment of lease (art. 262 and art. 263 of the Code of Obligations) will have the effect that all option rights still existing and not exercised at the relevant point of time become ineffective.

**5. Rent and ancillary obligations**

5.1 Base rent on conclusion of the agreement

The annual base rent on conclusion of this agreement amounts to CHF 82’555.00.

5.2 Rent adjustments after start of the lease

5.2.1 General

The valid base rent at the start of the lease (see Section 5.1) will be adjusted annually in line with the National Index of Consumer Prices of the Swiss Federal Statistical Office.

Index clause: 100.0% of the applicable minimum rent at the start of the lease will be adjusted annually in line with the National Index of Consumer Prices in accordance with the following formula.

$$\frac{\text{base rent x new index}}{\text{base index}} = \text{new rent}$$

The base index is given by the index position of 99.1 points as per 11/2012: (basis December 2010 = 100 points).

The first adjustment of the base rent may occur on 01.04.2014. The following rent adjustments may occur once per calendar year on the first day of any month.

5.2.2 Value-enhancing investments

Value-enhancing investments and additional expenditure by the Landlord and costs for substantial renovations entitle the Landlord to increase the rent, also during the fixed contract term, by applying an appropriate rate for interest, amortization and maintenance

Initials Landlord Initials Tenant

pursuant to the applicable legal provisions for lease contracts. Such adjustments will be notified to the Tenant in the form required by law by giving 3 months' notice in advance of the first day of any month.

5.3 Rent payments

The rent must be paid in monthly installments in advance, at the latest on the first day of each month, for the first time pro rata temporis on the first day of the lease.

5.4 Ancillary expenses

5.4.1 General

Ancillary expenses are not included in the base rent and must be paid in addition by the Tenant. An advance on ancillary expenses of CHF 751.00 is due on the first of each month, for the first time pro rata temporis on the first day of the lease.

Ancillary expenses include:

Heating and hot water expenses

- Fuels
- Electricity for the operation of burners and pumps
- Cleaning of the heating system, including the oil tank
- Periodical maintenance of the heating system, including the oil tank
- Recordal of usage and the invoicing service for the counter, including servicing
- Servicing of the heating system (salary of employee)
- Invoicing costs (plus VAT)

Operating expenses

- Water and waste water
- Electricity
- Caretaker
- Cleaning (incl. windows, facade and snow clearance)
- Antennae and copyright payments
- Invoicing costs (plus VAT)
- All costs related to the use of the lease object, the common and public surfaces and infrastructure for use, cleaning and maintenance of:
    - Ventilation and air-conditioning systems

Initials Landlord Initials Tenant

- Fire alarm systems and fire-fighting equipment
- Burglary and alarm systems
- Escalators, elevators and lifting ramps
- Canalization and pump shafts

Shared advertising costs, contributions to the common parts etc. are not included in the ancillary expenses.

5.4.2 Invoicing

The Landlord will issue an annual invoice for the effective ancillary expenses, the balance of which must be paid within 30 days of presentation. Based on the annual invoice, the Landlord is entitled to reset the amount of the payments on account, also during the minimum contract period.

The invoice, respectively the share of ancillary expenses attributable to the Tenant, is calculated in accordance with a formula to be determined by an expert.

The Tenant is entitled to inspect the overall ancillary expense accounts with the receipts during a period of 30 days after presentation of the invoice. The ancillary expense accounts will be deemed accepted if the Tenant does not object in writing during this inspection period.

5.5 Interest

The above agreed payment dates are due dates on which the Tenant enters into default without further notice if rent payments remain outstanding. In this case, interest of 5% is due. In addition, the Tenant must reimburse the Landlord for default notice and collection expenses.

5.6 Value added tax

At the present date the leased area is not opted in [voluntarily subject to VAT]. Accordingly the rent is stated net of value added tax. The Landlord reserves the right to opt in the leased area at a future point in time. If the Landlord is considering an opt in, the Tenant undertakes to provide the Landlord promptly and free of charge with all documents relevant for the opt in. The Tenant will be notified accordingly at the relevant time.

If the leased area is opted in, the above rent and ancillary expenses as well as the shared costs will be deemed exclusive of any value added tax.

5.7 Taxes, fees, public charges

Taxes, fees, public charges, costs for electricity, gas and telephone and all other costs that arise exclusively from the operation of the Tenant's business are to be paid separately by the Tenant. Additional connection fees for water, electricity, waste disposal etc. that are incurred as a result of Tenant fit out of the lease object are to be paid by the Tenant.

## 6. Fit out and usage of the lease object

6.1 Condition and use of the lease object

6.1.1 Condition of the lease object

The lease object will be leased to the Tenant in accordance with the fit out description. This state was reflected accordingly in the calculation of the base rent. The fit out description, which is a fully integrated part of this lease agreement, states the binding cost allocation between the Landlord and the Tenant regarding the fit out, maintenance and renovation of the lease object. The obligations of the Landlord pursuant to the fit out description have been fulfilled in full. A fit out of the leased premises beyond the scope of the fit out description is considered as a Tenant fit out. Any fit out made by a previous Tenant that do not qualify as basic work and which is taken over by the Tenant is deemed done by him (= Tenant fit out). All costs for Tenant fit outs, their maintenance and removal are in all cases to be borne exclusively by the Tenant.

6.1.2 Modification of the lease object by the owner

- Replacement of flooring in the entire leased premises
  (cost ceiling CHF 30'000.00.)
- Painting of the entire leased area
  (cost ceiling CHF 10'000.00)
- Installation of tea kitchen with small fridge and dishwasher
  (cost ceiling CH 6'000.00)
- Installation of a shower
  (cost ceiling CHF 3'000.00)

The above mentioned fit out will be executed by the owner. If the Tenant's wishes regarding the fit out exceed the above-mentioned cost ceilings, these costs will be borne by the Tenant. (Acceptance of costs by the owner of CHF 49'000.00 including VAT)

6.1.3 Duty of care and tolerance

The Tenant undertakes to use the lease object with due care within the meaning of art. 257f of the Code of Obligations and in particular to maintain the lease object in a good and clean condition. The Tenant will be liable to pay compensation for damage that is not the result of proper use or force majeure. The Tenant is obliged to notify the Landlord

immediately of defects in the lease object for which the Tenant does not have to repair itself. In the absence of notice, the Tenant is liable for the resulting damage. The Tenant is obliged to comply with the rules issued by the Landlord regarding, amongst others, deliveries, use of the goods elevators, waste disposal etc. The Tenant is obliged to tolerate the passage of pipes, tubes and cables in the ceiling space and in the flooring without compensation.

6.1.4 Use

Use and purpose of usage of the lease object shall be based exclusively on the terms of this agreement and cannot be changed without the Landlord's prior written consent. The rights and requirements of the other tenants must be respected in a reasonable way.

6.1.5 Emergency exits and shelters

Emergency exits are to be kept free from obstructions. Shelters used for purposes other than civilian protection (storage, archive rooms etc.) must be available for use as civilian protection shelters at all times within 24 hours. No modifications may be made to the existing installations in such shelters.

6.1.6 Modification of the lease object

If the Tenant itself wishes to renovate or modify the lease object or its own installations inside the lease object at its own cost, it must obtain the prior written consent of the Landlord (art. 260a para 1 of the Code of Obligations). The Landlord may give approval subject to provision of security. The amount of the security is dependent on the overall cost estimate for the renovation works.

Subject to other individual written agreements, the Landlord gives any consent only under the express condition that the Tenant reinstates the lease object to its previous condition at the Tenant's own cost on termination of the lease agreement (art. 260a para 2 of the Code of Obligations). If the Landlord waives the right to require the reinstatement of the previous condition, the Tenant is obliged to leave the renovations unchanged in the lease object and the Tenant waives any claim for compensation therefore, where the renovations or modifications made by the Tenant have resulted in a value enhancement.

If the renovation or modification work involves electric installations, the Tenant is obliged to provide the Landlord after completion of the renovation work and without being requested to do so with an appropriate safety certificate of a certified electrician. The resulting costs will be borne by the Tenant. For each construction project, a principal's liability insurance is mandatory. Where approved interventions take place in the general parts of the building, in particular in the structure, installations and building shell, The Landlord has the right, to set requirements with regard to the planners and/or companies/products/systems to be used. The building structure must not be negatively affected.

Initials Landlord Initials Tenant

The Tenant takes all required measures to ensure that no construction worker liens are registered in connection with the Tenant's renovation and modification work and undertakes to use appropriate means (provision of security) to ensure the immediate deletion of such registrations. This applies already at the stage of the provisional-preventative registration. A breach of this obligation gives the Landlord, after unsuccessful warning with setting of a deadline to comply, a right of extraordinary termination of the lease agreement and to claim for compensation.

The Tenant bears all costs resulting from its modifications of the lease object. These costs include in particular the defense or assumption of claims by third parties such as compensation claims and claims for rent reduction of neighboring tenants as a result of construction noise, any compensation of costs for the removal of half-finished Tenant work of no value etc.

6.1.7 Building and business permits

The Tenant is responsible for obtaining all special permits that are necessary for the Tenant's business, and the costs therefore are to be borne by the Tenant.

6.2 Handover of keys

Security cylinders were installed on all exterior doors. Upon handover of the lease object, the Tenant receives 1 key per lock and 5 keys per security lock. The costs for additional keys have to be borne by the Tenant. Upon return of the lease object, the Tenant shall return all keys. In case of any key loss, the Tenant is responsible for all costs resulting from amendments to the master key plan of the property.

6.3 Insurance / surveillance

6.3.1 Responsibility

The Landlord obtains the usual liability and property insurance for the property at its own cost.

The Tenant is responsible for obtaining the insurance necessary for the operation of the Tenant's business such as insurance for theft, liability insurance, interruption of business insurance, employee and furnishings insurance and insurance for goods storage etc. and the costs resulting from this insurance are borne by the Tenant. The conclusion of a liability insurance policy is mandatory for the Tenant. In addition, all other investments and installations carried out and paid for by the Tenant are to be insured by the Tenant. Premium adjustments for progressive building insurance resulting from the Tenant fit out of the lease object are to be borne proportionately by the Tenant.

The Landlord assumes no responsibility for shop windows, lettering on shop windows, display cabinets, panes of glass, decoration of glass walls, company signs, neon writing etc. The Tenant is responsible for insuring against such damage. The Tenant alone is responsible for the safety (burglary, theft) and the surveillance of the leased rooms.

6.3.2 Delimitation of building and furnishing

The then valid provisions of the cantonal Building Insurance Institute shall apply to determine the delimitation between building and furnishings. In case of uncertainty, the cantonal Building Insurance Institute's assessment protocol shall prevail.

6.4 Company signs, advertising, lettering and marketing activities

6.4.1 Signage and lettering

Company and advertising signs, posters, display cabinets etc. may only be put up with the written consent of the Landlord and only at the points of the building intended therefor. The costs are borne by the Tenant. The Landlord decides on color, size, material, arrangement and order of the signs, whereby the wishes of the Tenant will be taken into consideration. The Tenant shall preferably use the original logo of its company. In case of renovation or change to the facades or other walls, the Tenant must remove and reinstall the signs and logos at its own cost.

Applications for the any required governmental permits are to be presented to the Landlord for signing in a form fit for approval. All costs and fees relating thereto are to be borne by the Tenant. In addition, the Tenant must pay the connection costs and for any electricity usage.

The Tenant is obliged to participate in the cost of information boards and advertising towers that may be in the interests of general customer orientation and to bear the relevant share of the costs.

The Tenant is obligated to refer to the property as a whole in its own advertising and to use the official sign of the property.

6.5 Parking spaces

If a parking garage is available to customers of the commercial property against payment, the costs for its service, surveillance, cleaning and maintenance are borne by the Landlord; the income belongs to the Landlord.

6.6 Right to inspect

The Landlord is entitled to enter the leased premises during business hours, on giving 24 hours advance notice, in order to preserve its ownership rights and for the necessary viewings for a re-rental.

6.7 Sublease

6.7.1 Permission

A sublease of all or part of the lease object requires the written consent of the Landlord. The Landlord may only withhold consent based on important reasons in accordance with the provisions of art. 262 of the Code of Obligations. Grounds of refusal include among others a change in the range of products or in the duty to pay VAT.

The Tenant undertakes that any sublease agreement will be concluded in writing and to require the sub-tenant to comply with all of the obligations in this lease agreement, in particular also concerning calculation and notification of turnover. One copy of the sublease agreement must be made available to the Landlord.

6.7.2 Liability

Also in case of a sublease, the Tenant will be fully liable for complying with all of its obligations under this agreement, in particular with regard to the use of the lease object pursuant to Section 3 and the payment in full of rent, ancillary expenses and contributions to the tenant association for advertising fees.

6.8 Maintenance by the Tenant

The Tenant is required to maintain the leased premises, the installations and facilities contained therein and the common areas and installations used by the Tenant in an orderly and clean condition.

Maintenance, servicing, repairs, renovation and replacement of the Tenant's technical installations and facilities is the Tenant's responsibility.

For all installations, machines and apparatus made available by the Landlord that are for the sole use of the Tenant, the Tenant must ensure at its own cost the regular maintenance in accordance with the recommendations of the manufacturer.

Any maintenance, renovation or repair work on the leased objects and facilities made available to the Tenant by the Landlord that is not attributable to ordinary wear and tear (i.e. in line with their use in accordance with the contract) will be at the Tenant's cost.

6.8.1 Instruction of work

Maintenance and repair work on the lease object, and in particular on the corresponding facilities and installations (also those outside the lease object), that is instructed by the Tenant must be conducted by certified experts.

The Landlord, or the representative mandated by the Landlord, is to be informed of the type, extent and duration of the work prior to the work being carried out.

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6.8.2 Minor repairs

The costs of all minor repairs within the lease object, where the cost does not exceed 1 % of the annual net rent or maximum CHF 2’000.00 in each individual case, are to be borne by the Tenant.

## 7. Return of the lease object

7.1 Return upon termination of the lease agreement

The lease object must be returned in a clean and good state on the day of termination of the lease (art. 267 of the Code of Obligations). The Landlord draws up a protocol that states the condition of the lease object. The protocol must be signed by both parties and constitutes a notice of defects within the meaning of art. 267a para 1 of the Code of Obligations for the objections recorded therein. The Landlord is entitled to have removed at the Tenant’s cost those defects stated in the protocol for which the Tenant is responsible. In case of subsequent discovery of defects that were not identifiable during the final inspection of the lease object, the Tenant is also responsible for these to the extent they have been notified by the Landlord immediately.

7.2 Re-instatement of the previous state / duty to dismantle

To the extent the Landlord has agreed pursuant to Section 6.1.6 to interior fit outs, renovations and modifications or the Tenant has taken over fit outs of the previous tenant and nothing to the contrary has been agreed in writing in the specific case, the Tenant must re-instate, at the end of the lease, in a professional manner and at the Tenant’s own cost, the original condition of the lease object pursuant to the fit out description. The same applies if such work has been conducted without the Landlord’s written consent.

## 8. Final provisions

8.1 Contractual security

8.1.1 Amount

To secure all claims arising from the lease agreement, the Tenant furnishes a cash security in the form of a rent deposit pursuant to art. 257e of the Code of Obligations or an irrevocable bank guarantee from a large or cantonal Swiss bank made out in favour of the Landlord, not the Representative, for an amount of CHF 38’000.00. The bank guarantee is indefinite or for the duration of the lease plus 12 months and is to be renewed accordingly upon exercise of the option right.

8.1.2 Time of delivery

The contractual security must be in the Landlord’s possession at the latest on commencement of the lease, i.e. the bank guarantee must be handed over to the Landlord or the deposit must be paid into the deposit account. If this is not done on time, the Landlord

may refuse the handover of the lease object to the Tenant until the bank guarantee or deposit has been provided. This right is also available to the Landlord if a handover of the lease object is agreed prior to the commencement of the lease and the security to be provided is not in the Landlord's possession at this point in time. As the delayed handover of the lease object is caused by the Tenant, the rent (net rent, ancillary expenses and any other agreed costs) is nevertheless due from the date of start of the lease; also the Tenant has no resultant claim for any compensation whatsoever.

8.2 Integrated elements of this agreement

The following attached documents constitute integral parts of this agreement:

Annex 1: floor plan

Annex 2: fit out description

8.3 Contract amendments

Amendments and supplements to this agreement and its integrated parts require the written form. This also applies to the waiver of the requirement of written form.

8.4 Duty of disclosure

The Tenant is obliged to inform the Landlord without delay with respect to all changes of a legal and business nature that have a substantial impact on the company's structure. All documents required by the Landlord are to be made available to the Landlord free of charge.

8.5 Severability

The invalidity or unenforceability of individual provisions of this agreement does not affect the legal validity of the agreement as a whole. The ineffective provision shall be replaced by a provision that comes closest legally and commercially to the original, unenforceable provision.

8.6 Subsidiary law and place of jurisdiction

Swiss law is exclusively applicable. If this agreement does not contain any provisions, or does not contain any provisions to the contrary, the provisions of art. 253 et seq. of the Code of Obligations on lease shall apply.

For any disputes arising out of this lease agreement, the parties submit to the competent authorities at the place where the object is located.

8.7 Copies of the agreement

This lease agreement is executed in duplicate and the parties each receive one executed copy.

Oberwil, 15 January 2013

| For the Landlord: the Representative<br>PRIVERA AG | The Tenant<br>Auris Medical AG |
| --- | --- |
| [Signature] | [Signature]<br>Thomas Meyer, Managing Director |

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# Stock Option Plan A

**Auris Medical AG**
**Aeschenvorstadt 37**
**4051 Basel**

## 1. Purpose

The purpose of this Stock Option Plan A (hereinafter referred to as the "Plan") is to recruit, retain and motivate persons in key positions at Auris Medical AG by offering additional incentives to achieve a high level of corporate performance.

## 2. Definitions

a) "Option Agreement" means an agreement entered into by the Company and each Participant setting forth the terms and conditions applicable to options granted under the Plan;

b) "Board of Directors" means the Board of Directors of the Company

c) "Company" means Auris Medical AG, in Basel

d) "Company's stock" means registered shares of the Company with a nominal value of CHF 10 each;

e) "Exercise Price" means the price at which stock of the Company may be purchased by a Participant pursuant to options granted under the Plan;

f) "Participants" eligible for awards under the Plan are directors, employees, advisors and agents of the Company as defined by the Board of Directors (individually "Participant");

g) "Shareholders' Agreement" means the agreement entered into by and among the shareholders of the Company on December 13, 2007.

## 3. Stock Option Rights

Stock options granted under the Plan give the Participants the right to purchase shares of the Company under the terms and conditions set forth in the Option Agreement.

## 4. Availability of Company's Stock

Subject to the Articles of Incorporation of the Company, the provisions of the present Plan and any other existing applicable regulations, the Board of Directors shall, in its sole discretion, determine the mode and conditions under which stock of the Company is made available to satisfy the purposes of the Plan.

## 5. Extent and Timing of the Option Grant

Subject to the provisions of the Plan, the Board of Directors may, upon proposal made by the CEO but in its sole discretion, select among all eligible Participants those to whom options shall effectively be granted. A grant of options in one year shall not preclude a grant of additional options in subsequent years. Likewise, a grant of options in one year shall not entitle a Participant to a grant of options in subsequent years.

The number of options to be granted in each year is determined by the Board of Directors in its sole discretion.

**6. Option Agreements / Date of Grant**

Options granted to an eligible Participant in any given year shall be granted by an Option Agreement that specifies in particular:

- the number of options granted;
- the exercise price;
- the duration of the options;
- the vesting period;
- the exercise terms and conditions; and
- such other provisions as the Board of Directors shall determine.

Option Agreements shall be dated and signed by the Participant and returned to the Board of Directors of the Company within 30 days of receipt. By signing the Option Agreements, the Participant accepts to be granted options subject to the terms and conditions of the Plan.

The Option Agreement shall not form part of any contract of employment between the Company and the Participant.

The date of the Option Agreement which, in principle, shall not be earlier than six (6) months after beginning of the employment or mandate between the Company and the Participant, is deemed to correspond to the date of grant of the options, save any earlier deemed date of grant fixed by the Board of Directors, in its sole discretion.

**7. Terms and Conditions**

Options granted under the Plan shall be subject to the following terms and conditions and shall contain such additional terms and conditions as the Board of Directors shall deem desirable. The Board of Directors of the Company retains the right, in its absolute discretion but under exceptional circumstances only, to grant options subject to terms and conditions different from those set forth in the Plan, in particular in this Section 7 of the Plan.

**7.1 Option Price**

Unless otherwise provided in the Option Agreement, options are granted to Participants free of charge.

**7.2 Duration**

Subject to Section 7.4, options granted under the Plan shall expire five (5) years after the date of grant. The Company shall not be held responsible for any consequences pertaining to such expiration.

**7.3 Vesting Period and Earliest Date of Exercise**

The options granted under the Plan are vesting after 3 (three) years. Cases where vesting is accelerated are reserved (see Section 7.4 below).

**7.4 Acceleration of Vesting**

In case of IPO, merger or change of control (hereinafter referred to as each a "Transaction") as well as in case of transfer of the Participant's employment contract to another employer arising out of the transfer of all or part of the Company's assets or activities to said employer, any option, even if not vested as per Section 7.3 above, shall:

- vest as from the written announcement of the Transaction to the Participants, but in any case on the closing date of the Transaction (which closing shall be announced by the Company by written communication to all Participants at the latest on the closing date) and shall become immediately exercisable upon vesting for a maximum duration of 60 days following the closing date of the Transaction (for the avoidance of doubt, it is precised that, in such case, the 5 year duration of Section 7.2 above is shortened to 60 days after the closing date of the Transaction);
- vest as from the written announcement to the Participant of the transfer of his employment contract to another employer, and become exercisable as per the Earliest Date of Exercise set forth in Section 7.3 above.

For the purpose of this Section:

- an IPO shall be defined as an initial public offering (or going public), which purports to a first sale to the public of stocks in the Company by way of issuing and listing of its shares;
- a merger shall be defined as the merger of the Company with or into another corporation (without liquidation);
- a change of control shall be defined as a transaction following which one party (or several parties acting together) acquires more than 51% of the voting rights of the Company;
- the closing date shall be the date on which the Transaction becomes effective.

**7.5 Exercise Price**

The Exercise Price of each option granted under the Plan shall be defined in the Option Agreement. It shall amount to not less than the pro rate valuation of the Company in its last financing round.

Each option shall pertain to one share only.

**7.6 Adjustments upon Changes in Capital Structure**

Subject to any required actions by the shareholders of the Company, the number of shares covered by each outstanding option respectively the exercise price of each outstanding option, shall be proportionately adjusted for any increase or decrease in the number of issued shares resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the shares.

In case of a subscription rights offering with a discounted subscription price, the exercise price for all outstanding options shall be adjusted according to generally accepted formulas adopted by the Board of Directors.

Any adjustment under this section shall be made by the Board of Directors, whose determination in that respect shall be final, binding and conclusive, save obvious mathematical mistakes.

**7.7 Exercise Procedure**

A Participant may exercise the options granted to him under the Plan by giving written notice (by registered mail) of such exercise to the Board of Directors which shall constitute the Participant's binding agreement to pay the Exercise Price, and which shall also contain the express written adherence to the Shareholders' Agreement as per Section 10 below.

The date upon which such written notice is sent to the Company shall be deemed to be the exercise date for the option.

**7.8 Financing**

The financing of the Exercise Price is the sole concern of the Participant.

In case of change of control of the Company to, the Company will use its best efforts to organizing setting off agreements.

**8. Non-transferability of Options**

Except as specifically authorized by the Board of Directors or the Plan, options and Option Agreements shall not be assignable or transferable by the Participant, including to other employees of the Company. Any attempted or executed assignment or transfer of an option or Option Agreement shall be null and void.

The transfer of options by reason of death or disability is reserved.

**9. Restricted Transferability of the Shares acquired upon Exercise of the Options**

The shares acquired upon exercise of the options will be registered shares each of nominal value of CHF 10 and subject to a restriction of transferability, as provided for by the Articles 685 and seq. of the Swiss Code of Obligations, the Articles of association of the Company and the Shareholders' Agreement.

**10. Adherence to the Shareholders' Agreement**

Any effective exercise of the options shall be subject to full adherence by express written consent from the Participant to the Shareholders' Agreement executed on December 13, 2007 or to any subsequent shareholder's agreement, and from such date of adherence, said Participant shall have all rights and obligations of a Shareholder, as defined by the Shareholders' Agreement.

**11. Termination of Employment**

11.1

In case of termination of the employment or agency / mandate agreement by a Participant or the Company during the vesting period, all unvested option held by such Participant upon the date of effect of such termination shall terminate, without compensation, payment or liability on the part of the Company, such termination being effective as of the date of the termination of the employment or agency / mandate agreement.

11.2

In case of termination of the employment by reason of death or permanent disability (recognized as such permanent disability by Swiss social security authorities and, in any case, evidenced to the satisfaction of the Board of Directors as causing the employment termination) of the Participant, only 50% of all unvested option held by such Participant shall terminate as per 11.1.

**12. Amendments**

The Board of Directors shall have the authority at any time to make amendments as necessary to carry out the purposes of the Plan. In no case shall the Board of Directors have the authority to amend the Plan to deprive any Participant of any earned benefit under the Plan.

**13. Interpretation**

Any question arising as to the interpretation of this Plan shall be in the full discretionary authority of the Board of Directors whose decision shall be final, conclusive and binding.

**14. Miscellaneous**

No Participant or employee of the Company shall have any claim or right to be granted an option under the Plan. Neither the Plan nor any action taken hereunder shall be construed as giving any Participant or employee any right to be retained by the Company.

**15. Entry into force**

The Plan is deemed to correspond to the specific Company regulations provided for by the Article 3b of the Articles of Incorporation of the Company, which allows the Board of Directors to determine the conditions under which options may be granted.

The Plan shall be effective as of November 24, 2009, amending and superseding the previous version of November 21, 2008. A copy shall be handed out to all receivers of options under the previous version.

Basel, 24 November 2009

For the Board of Directors

# Stock Option Plan C

**Auris Medical AG**
**Falknerstrasse 4**
**4001 Basel**

## 1. Purpose

The purpose of this Stock Option Plan C (hereinafter referred to as the "Plan") is to recruit, retain and motivate persons in key positions at Auris Medical AG as well as key service providers by offering additional incentives to achieve a high level of corporate performance.

The Stock Option Plan C will replace Stock Option Plan A for any future option grants effective as from April 5, 2013.

## 2. Definitions

a) "Option Agreement" means an agreement entered into by the Company and each Participant setting forth the terms and conditions applicable to options granted under the Plan;

b) "Board of Directors" means the Board of Directors of the Company;

c) "Company" means Auris Medical AG, in Basel;

d) "Company's stock" means registered shares of the Company with a nominal value of CHF 10 each;

e) "Exercise Price" means the price at which stock of the Company may be purchased by a Participant pursuant to options granted under the Plan;

f) "Participants" eligible for awards under the Plan are directors, employees, advisors and agents of the Company as defined by the Board of Directors (individually "Participant");

g) "Shareholders' Agreement" means the agreement entered into by and among the shareholders of the Company on April 5, 2013.

## 3. Stock Option Rights

Stock options granted under the Plan give the Participants the right to purchase shares of the Company under the terms and conditions set forth in the Option Agreement.

## 4. Availability of Company's Stock

Subject to the Articles of Incorporation of the Company, the provisions of the present Plan and any other existing applicable regulations, the Board of Directors shall, in its sole discretion, determine the mode and conditions under which stock of the Company is made available to satisfy the purposes of the Plan.

## 5. Extent and Timing of the Option Grant

Subject to the provisions of the Plan, the Board of Directors may, upon proposal made by the CEO but in its sole discretion, select among all eligible Participants those to whom options shall effectively be granted. A grant of options in one year shall not preclude a grant of additional options in subsequent years. Likewise, a grant of options in one year shall not entitle a Participant to a grant of options in subsequent years.

The number of options to be granted in each year is determined by the Board of Directors in its sole discretion.

**6. Option Agreements / Date of Grant**

Options granted to an eligible Participant in any given year shall be granted by an Option Agreement that specifies in particular:

- the number of options granted;
- the exercise price;
- the duration of the options;
- the vesting period;
- the exercise terms and conditions; and
- such other provisions as the Board of Directors shall determine.

Option Agreements shall be dated and signed by the Participant and returned to the Board of Directors of the Company within 30 days of receipt. By signing the Option Agreements, the Participant accepts to be granted options subject to the terms and conditions of the Plan.

The Option Agreement shall not form part of any contract of employment between the Company and the Participant.

The date of the Option Agreement which, in principle, shall not be earlier than six (6) months after beginning of the employment or mandate between the Company and the Participant, is deemed to correspond to the date of grant of the options, save any earlier deemed date of grant fixed by the Board of Directors, in its sole discretion.

**7. Terms and Conditions**

Options granted under the Plan shall be subject to the following terms and conditions and shall contain such additional terms and conditions as the Board of Directors shall deem desirable. The Board of Directors of the Company retains the right, in its absolute discretion but under exceptional circumstances only, to grant options subject to terms and conditions different from those set forth in the Plan, in particular in this Section 7 of the Plan.

**7.1 Option Price**

Unless otherwise provided in the Option Agreement, options are granted to Participants free of charge.

**7.2 Duration**

Subject to Section 7.4, options granted under the Plan shall expire six (6) years after the date of grant. The Company shall not be held responsible for any consequences pertaining to such expiration.

**7.3 Vesting Period and Earliest Date of Exercise**

The options granted under the Plan are vesting after 4 (four) years. Cases where vesting is accelerated are reserved (see Section 7.4 below).

### 7.4 Acceleration of Vesting

In case of (i) a change of control, defined as transaction following which one party (or several parties acting together) acquires more than 51% of the voting rights of the Company, and, cumulatively (ii) a subsequent termination of a Participant's employment agreement without cause during the vesting period, any option of such Participant, even if not vested as per Section 7.3 above, shall vest as from the written termination of said employment agreement and shall become immediately exercisable upon vesting.

### 7.5 Exercise Price

The Exercise Price of each option granted under the Plan shall be defined in the Option Agreement. It shall amount to not less than the pro rata valuation of the Company in its last financing round.

Each option shall pertain to one share only.

### 7.6 Adjustments upon Changes in Capital Structure

Subject to any required actions by the shareholders of the Company, the number of shares covered by each outstanding option respectively the exercise price of each outstanding option, shall be proportionately adjusted for any increase or decrease in the number of issued shares resulting from a stock split, reverse stock split, stock dividend, combination or reclassification of the shares.

In case of a subscription rights offering with a discounted subscription price, the exercise price for all outstanding options shall be adjusted according to generally accepted formulas adopted by the Board of Directors.

Any adjustment under this section shall be made by the Board of Directors, whose determination in that respect shall be final, binding and conclusive, save obvious mathematical mistakes.

### 7.7 Exercise Procedure

A Participant may exercise the options granted to him under the Plan by giving written notice (by registered mail) of such exercise to the Board of Directors which shall constitute the Participant's binding agreement to pay the Exercise Price, and which shall also contain the express written adherence to the Shareholders' Agreement as per Section 10 below.

The date upon which such written notice is sent to the Company shall be deemed to be the exercise date for the option.

### 7.8 Financing

The financing of the Exercise Price is the sole concern of the Participant.

## 8. Non-transferability of Options

Except as specifically authorized by the Board of Directors or the Plan, options and Option Agreements shall not be assignable or transferable by the Participant, including to other employees of the Company. Any attempted or executed assignment or transfer of an option or Option Agreement shall be null and void.

The transfer of options by reason of death or disability is reserved.

**9. Restricted Transferability of the Shares acquired upon Exercise of the Options**

The shares acquired upon exercise of the options will be registered shares each of nominal value of CHF 10 and subject to a restriction of transferability, as provided for by the Articles 685 and seq. of the Swiss Code of Obligations, the Articles of association of the Company and the Shareholders' Agreement.

**10. Adherence to the Shareholders' Agreement**

Any effective exercise of the options shall be subject to full adherence by express written consent from the Participant to the Shareholders' Agreement executed on April 5, 2013 or to any subsequent shareholder's agreement, and from such date of adherence, said Participant shall have all rights and obligations of a Shareholder, as defined by the Shareholders' Agreement in its current version.

**11. Termination of Employment**

11.1

Except for the provisions under 7.4, in case of termination of the employment or agency / mandate agreement by a Participant or the Company during the vesting period, all unvested option held by such Participant upon the date of effect of such termination shall terminate, without compensation, payment or liability on the part of the Company, such termination being effective as of the date of the termination of the employment or agency / mandate agreement.

11.2

In case of termination of the employment by reason of death or permanent disability (recognized as such permanent disability by Swiss social security authorities and, in any case, evidenced to the satisfaction of the Board of Directors as causing the employment termination) of the Participant, only 50% of all unvested option held by such Participant shall terminate as per 11.1.

**12. Amendments**

The Board of Directors shall have the authority at any time to make amendments as necessary to carry out the purposes of the Plan. In no case shall the Board of Directors have the authority to amend the Plan to deprive any Participant of any earned benefit under the Plan.

**13. Interpretation**

Any question arising as to the interpretation of this Plan shall be in the full discretionary authority of the Board of Directors whose decision shall be final, conclusive and binding.

**14. Miscellaneous**

No Participant or employee of the Company shall have any claim or right to be granted an option under the Plan. Neither the Plan nor any action taken hereunder shall be construed as giving any Participant or employee any right to be retained by the Company.

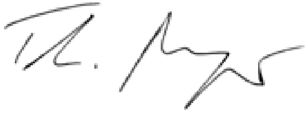
**15. Entry into force**

The Plan is deemed to correspond to the specific Company regulations provided for by the Article 3b of the Articles of Incorporation of the Company, which allows the Board of Directors to determine the conditions under which options may be granted.

The Plan shall be effective as of April 5, 2013.

Basel, April 22, 2013

For the Board of Directors



Thomas Meyer, Chairman

Wolfgang Arnold
(secretary)

**KPMG AG**
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Internet www.kpmg.ch

Securities and Exchange Commission
Washington, D.C. 20549

Zurich, June 27, 2014

Ladies and Gentlemen:

We were previously principal accountants for Auris Medical Holding AG (formerly Auris Medical AG) and, under the date of March 18, 2014, we reported on the consolidated financial statements of Auris Medical AG as of December 31, 2013, 2012 and January 1, 2012 and for each of the years in the two-year period ended December 31, 2013. On April 22, 2014, we were dismissed. We have read Auris Medical Holding AG's (formerly Auris Medical AG) statements included under the heading "Auditors" in its Form F-1 dated June 27, 2014, and we agree with such statements.

Very truly yours,

KPMG AG

| /s/ Martin Rohrbach | /s/ Charles Errico |
|---|---|
| Martin Rohrbach | Charles Errico |

**EXHIBIT 21.1**

**SUBSIDIARIES OF THE REGISTRANT**

| Name of Subsidiary | Jurisdiction of Incorporation or Organization |
| --- | --- |
| Auris Medical AG | Switzerland |
| Otolanum AG | Switzerland |
| Auris Medical Inc. | Illinois |
| Auris Medical Ltd. | Ireland |

**EXHIBIT 23.1**

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

The Board of Directors
Auris Medical Holding AG (formerly Auris Medical AG):

We consent to the use of our report dated March 18, 2014, with respect to the consolidated statements of financial position of Auris Medical AG and subsidiaries as of December 31, 2013, 2012 and January 1, 2012, and the related consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows, for each of the years in the two-year period ended December 31, 2013, included herein and to the reference to our firm under the heading “Experts” in the prospectus.

KPMG AG

| /s/ Martin Rohrbach | /s/ Charles Errico |
|---|---|
| Martin Rohrbach | Charles Errico |

Zurich, Switzerland
June 27, 2014

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Hong Kong

**Davis Polk**

**Richard D. Truesdell, Jr.**

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450 Lexington Avenue | 212 701 5674 fax
New York, NY 10017 | richard.truesdell@davispolk.com

June 27, 2014

**Re: Auris Medical Holding AG**
**Registration Statement on Form F-1**

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

Dear Mr. Riedler,

On behalf of our client, Auris Medical Holding 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 June 17, 2014. (the "**Comment Letter**").

In response to the comments set forth in the Comment Letter, the Company has revised the Registration Statement and is filing a revised version of the Registration Statement together with this response letter. The revised version of the Registration Statement also contains certain additional updates and revisions. We are also sending, under separate cover, a copy of the revised version of the Registration Statement (including newly-filed exhibits) and three marked copies of the Registration Statement showing the changes to the Registration Statement confidentially submitted on June 6, 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 version of the Registration Statement submitted herewith where the revised language addressing a particular comment appears.

AM-101 Clinical Development, page 76

*1. We note that your revised registration statement omits various tables and charts illustrating the results of your Phase 2 trials for AM-101 that were included in prior amendments to your draft registration statement. Please restore this information to your registration statement as such tables and charts provided important data about the results of these trials.*

**Response**: The Company respectfully advises the Staff that the tables and charts from page 73 through page 75 of the draft registration statement confidentially submitted on April 18, 2014 were inadvertently deleted. They have now been restored in the Registration Statement from page 77 through page 80.

*2. We note your disclosure that over two Phase 2 clinical trials, AM-101 showed a statistically significant improvement in the AAT and OM group of patients when compared against placebo. Please revise your disclosure to discuss whether the specific results of the TACTT1 trial with respect to subjective tinnitus loudness were independently statistically significant as compared to placebo.*

**Response**: The Company respectfully advises the Staff that the Company has revised the disclosure on page 79 to provide the requested information.

Collaboration and License Agreements
INSERM, page 88

3. *Please expand your disclosure regarding your co-ownership/exploitation agreement with INSERM to provide the duration of the agreement. If the duration of the agreement is conditioned on the expiration of patents, please provide the expiration dates of the related patents.*

**Response**: The Company respectfully advises the Staff that the Company has revised the disclosure on page 92 to provide the requested information.

Should any questions arise, please do not hesitate to contact me at (212) 450-4674, (212) 701-5674 (fax) or richard.truesdell@davispolk.com.

Thank you for your time and attention.

Sincerely,

/s/ Richard D. Truesdell, Jr.
Richard D. Truesdell, Jr.

cc: Via E-mail
Mr. Thomas Meyer, Chief Executive Officer
Mr. Sven Zimmermann, Chief Financial Officer