Filed with the Securities and Exchange Commission on May 4, 2015

Registration No. 333-203554

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

AMENDMENT NO. 1
TO
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)**

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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	AMOUNT TO BE REGISTERED(1)	PROPOSED MAXIMUM OFFERING PRICE PER SHARE(2)	PROPOSED MAXIMUM AGGREGATE OFFERING PRICE(1)(2)	AMOUNT OF REGISTRATION FEE(3)
Common shares, nominal value CHF 0.40 per share	6,900,000	$4.83	$33,327,000	$3,873

(1) Includes 900,000 additional common shares that may be purchased by the underwriters to cover over-allotments.
(2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) promulgated under the Securities Act of 1933, as amended and is based upon the average of the high and low sales prices of the common shares as reported on the NASDAQ Global Market on April 29, 2015.
(3) Previously paid.

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 May 4, 2015

PRELIMINARY PROSPECTUS

6,000,000 Shares

Auris Medical
Cochlear therapies

Auris Medical Holding AG

Common Shares

We are offering 6,000,000 of our common shares. Our common shares are listed on the Nasdaq Global Market under the symbol "EARS". On May 1, 2015, the last reported sale price of our common shares on the Nasdaq Global Market was $5.54 per common share.

We are an "emerging growth company" as defined under the federal securities laws and, as such, are 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 10.

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" for additional information regarding total underwriter compensation.

Delivery of the common shares is expected to be made on or about , 2015. We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase an additional 900,000 common shares to cover over-allotments.

Sole Book-Running Manager

Leerink Partners

Lead Managers

JMP Securities | **Needham & Company**

Co-Manager

LifeSci Capital

Prospectus dated , 2015

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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 (Auris Medical AG prior to the corporate reorganization described in "Prospectus Summary — Corporate Information"), together with its subsidiaries. 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.

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 Food and Drug Administration, or 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 expect to have top-line Phase 3 clinical data for AM-101 in the first quarter of 2016. We are also developing AM-111 for acute inner ear hearing loss. We are preparing two pivotal clinical trials in the treatment of idiopathic sudden sensorineural hearing loss, or ISSNHL, titled Efficacy and Safety of AM-111 in the treatment of Acute Inner Ear Hearing Loss, or HEALOS, and Efficacy and Safety of AM-111 as Acute Sudden Sensorineural Hearing Loss Treatment, or ASSENT. We expect to start enrollment in HEALOS in the third quarter of 2015 and in ASSENT in the first quarter of 2016. In addition, we are preparing a Phase 2 trial titled Efficacy and Safety of AM-111 in the Treatment of Surgery Induced Hearing Loss following Cochlear Implantation, or REACH. We expect to start enrollment in REACH in the third quarter of 2016. 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.

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, i.t. 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. 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.

Possible causes of acute inner ear tinnitus include 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, 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 the first quarter of 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, including hearing loss from acute acoustic trauma, ear surgery trauma and ISSNHL (also known as sudden deafness). 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. More than 66,000 new cases of sudden deafness are seen annually among the U.S. insured population.

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 are preparing three clinical trials for the treatment of ASNHL, including two pivotal Phase 3 trials (HEALOS and ASSENT) in the treatment of ISSNHL and one Phase 2 trial (REACH) in the treatment of surgery-induced hearing loss following cochlear implantation. Both ASSENT and REACH are planned to be conducted in the United States whereas HEALOS will be conducted in Europe and Asia. We plan to discuss certain aspects of the ASSENT study protocol with the FDA. We intend to start enrollment in HEALOS in the third quarter of 2015, in ASSENT in the first quarter of 2016 and in REACH in the third quarter of 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.

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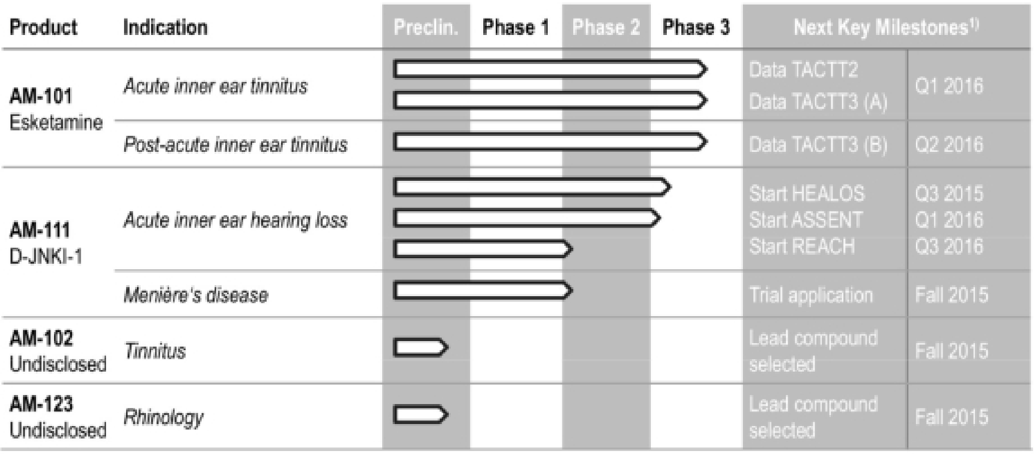
The following table summarizes our product development pipeline:



Product	Indication	Preclin.	Phase 1	Phase 2	Phase 3	Next Key Milestones[1]	
AM-101 Esketamine	Acute inner ear tinnitus					Data TACTT2 Data TACTT3 (A)	Q1 2016
	Post-acute inner ear tinnitus					Data TACTT3 (B)	Q2 2016
AM-111 D-JNKI-1	Acute inner ear hearing loss					Start HEALOS Start ASSENT Start REACH	Q3 2015 Q1 2016 Q3 2016
	Menière's disease					Trial application	Fall 2015
AM-102 Undisclosed	Tinnitus					Lead compound selected	Fall 2015
AM-123 Undisclosed	Rhinology					Lead compound selected	Fall 2015

(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.
- ***Barriers to entry.*** Our products are protected not only through intellectual property rights but also by the orphan drug status granted to AM-111 and 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 December 31, 2014 was CHF 52.1 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 Institut National de la Santé et de la Recherche Médicale, or INSERM, and Xigen S.A., or Xigen, our business, commercialization prospects and financial condition may be materially adversely affected.
- We have several areas of disagreement with Xigen, including the scope of our license and other terms of our collaboration and license agreement, the assignment by Xigen of certain of the patents covered by the license and Xigen's refusal to grant its consent for the disclosure of certain provisions of the agreement in connection with our initial public offering in 2014. Consequently our relationship with Xigen may be adversely affected and if significantly so could potentially result in the loss of AM-111 commercialization rights.
- 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 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.

We currently 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 continue to 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.

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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 6,000,000 common shares.
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 900,000 common shares from us within 30 days of the date of this prospectus to cover over-allotments, if any, in connection with this offering.
Common shares to be outstanding immediately after the offering	Immediately after this offering, we will have 35,018,891 common shares outstanding, assuming no exercise of the underwriters' over-allotment option.
NASDAQ Global Market symbol	"EARS."
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately $30.6 million, based on an assumed public offering price of $5.54 per common share, which is the last reported sale price on the Nasdaq Global Market as set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses. We intend to use the net proceeds from this offering for: ■ approximately $23 to $28 million (CHF 22.8 to CHF 27.8 million) to fund research and development expenses for AM-111; and ■ the remainder for early stage programs, working capital and other general corporate purposes. 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 90-day period following the date of this prospectus. Members of our board of directors, our executive officers and certain holders of our outstanding common shares have agreed to substantially similar lock-up provisions, subject to certain exceptions. The holders of our outstanding common shares who have agreed to enter into lock-up agreements and who are not members of our board of directors or our executive officers, have agreed to a lock-up term of 60 days following the date of this prospectus. 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 outstanding after this offering is based on 29,018,891 common shares outstanding as of April 27, 2015, which includes 29,010,391 common shares outstanding as of December 31, 2014 and 8,500 common shares issued upon exercise of options since December 31, 2014, but excludes 1,435,619 of our common shares as of April 27, 2015 of the 1,444,119 common shares as of December 31, 2014 covered by additional awards available for future issuance under our amended and restated articles of association, including 506,260 common shares issuable upon the exercise of options outstanding as of April 27, 2015 at a weighted average exercise price of CHF 4.90 per common share.

Unless otherwise indicated, all information contained in this prospectus assumes:

- no exercise of the options described above; and
- no exercise of the option granted to the underwriters to purchase up to 900,000 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 and other 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, 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.

The summary consolidated statement of profit or loss and other comprehensive loss data and consolidated statement of financial position data as of and for the year ended December 31, 2014 is derived from the audited consolidated financial statements included elsewhere in this prospectus, which have been audited by Deloitte AG. The summary consolidated statement of profit or loss and other comprehensive loss data for the years ended December 31, 2013 and 2012 is derived from the audited consolidated financial statements included elsewhere in this prospectus, which have been audited by KPMG AG.

We present the audited consolidated 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,		
	2014	2013	2012
	(in thousands of CHF except for share and per share data)		
Profit or Loss and Other Comprehensive Loss Data:			
Research and development	(17,705)	(13,254)	(3,987)
General and administrative	(4,489)	(1,362)	(624)
Operating loss	(22,194)	(14,616)	(4,611)
Finance expense	(208)	(159)	(2)
Finance income	4,216	76	10
Loss before tax	(18,185)	(14,699)	(4,602)
Income tax expense	—	(306)	—
Net loss attributable to owners of the Company	(18,185)	(15,005)	(4,602)
Other comprehensive loss:			
Items that will never be reclassified to profit or loss:			
Remeasurements of defined benefits liability, net of taxes of CHF O	(1,102)	(58)	(55)
Items that are or may be reclassified to profit or loss:			
Foreign currency translation differences, net of taxes of CHF O	(105)	32	22
Other comprehensive loss, net of taxes of CHF O	(1,207)	(26)	(32)
Total comprehensive loss attributable to owners of the Company	(19,392)	(15,031)	(4,635)
Net loss per share(1)			
Net loss per share, basic and diluted(2)	(0.66)	(1.01)	(0.40)
Weighted-average number of shares used to compute net loss per common share, basic and diluted	27,692,494	14,917,064	11,581,450

(1) For periods prior to the closing of our initial public offering in August 2014, net loss per share includes preferred shares, which were converted on a one-for-one basis upon the closing of our initial public offering. See Note 12 to our audited consolidated financial statements included elsewhere in this prospectus.

(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.

	AS OF DECEMBER 31, 2014	
	ACTUAL	AS ADJUSTED
	(in thousands of CHF)	
Statement of Financial Position Data:		
Cash and cash equivalents (2)	56,934	87,304
Total assets	59,493	89,863
Total liabilities	6,210	6,210
Share capital	11,604	14,004
Total shareholders' equity attributable to owners of the Company(2)	53,283	83,653

(1) As adjusted balance sheet data gives effect to our issuance and sale of 6,000,000 common shares in this offering at an assumed public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, but excludes 8,500 common shares which have been issued upon exercise of options since December 31, 2014.

(2) As adjusted cash and cash equivalents represents actual cash and cash equivalents, plus the net proceeds of this offering. Each $1.00 increase (decrease) in the assumed public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as 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 attributable to owners of the Company by CHF 5.6 million, 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. Similarly, each 100,000 increase (decrease) in the number of common shares offered by us in this offering would increase (decrease) our as adjusted cash and cash equivalents and as adjusted total shareholders' equity attributable to owners of the Company by CHF 0.5 million, assuming a public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions.

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 18.2 million, CHF 15.0 million and CHF 4.6 million for the years ended December 31, 2014, 2013 and 2012, respectively. As of December 31, 2014, we had an accumulated deficit of CHF 52.1 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 ended December 31, 2014, we incurred CHF 22.2 million in operating expenses, of which CHF 17.7 million were research and development costs, and we expect that our total operating expense in 2015 will be in the range of CHF 30.0 to 35.0 million (including AM-111 clinical Phase 3 expenses related to the start of HEALOS and preparations for ASSENT and REACH).

To date, we have financed our operations through the initial public offering of our common shares, private placements of equity securities and short term loans. 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.

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 operating expense in 2015 will be in the range of CHF 30.0 to 35.0 million (including AM-111 clinical expenses related to the start of HEALOS and preparations for ASSENT and REACH). As of December 31, 2014, our cash and cash equivalents were CHF 56.9 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 36 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 continue to incur additional costs associated with operating as a public company. 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, our shareholders' ownership interests will be diluted, and the terms of these new securities may include liquidation or other preferences that adversely affect our shareholders' rights as holders 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. AM-101 is in Phase 3 clinical development for acute inner ear tinnitus under a special protocol assessment, or SPA, from the FDA. We expect AM-111 to move into further Phase 2 and Phase 3 clinical development for acute sensorineural hearing loss following several discussions with the FDA and the EMA of certain aspects of the trials. We intend to start enrollment in HEALOS in the third quarter of 2015, in ASSENT in the first quarter of 2016 and in REACH in the third quarter of 2016. 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 (Tinnitus Handicap Inventory 12, THI-12). Unlike the THI-12, the TFI was developed and validated broadly in accordance with the FDA's guidance for patient-reported outcome measures and with the explicit aim of measuring treatment-related changes in tinnitus. In addition, the TFI covers all important domains of negative tinnitus impact including sleep difficulties, whereas the THI-12 does not include any sleep-related item. However, in spite of the methodological superiority of the TFI, there is no assurance that outcomes with the TFI will be qualitatively and quantitatively similar or the same as those that would result with the THI-12.

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 trials. In addition, in HEALOS and ASSENT, we extended the time window for enrollment into the study, from up to 48 hours to up to 72 hours, in response to results from the Phase 2 trial showing an increasing treatment effect the later the treatment was given. This was due to declining spontaneous recovery rates while the effects with active treatment held steady. Although spontaneous recovery is expected to decline further between 48 and 72 hours, we have no assurance that improvement achieved with the active treatment will remain stable.

Orphan drug designation for AM-111 was granted by the FDA and EMA for the treatment of acute sensorineural hearing loss, or ASNHL, an umbrella term that comprises hearing loss from acute acoustic trauma, or AAT, surgery-induced trauma or idiopathic sudden sensorineural hearing loss, or ISSNHL. We estimate ISSNHL to be the largest of the three subgroups. The broader, more general designation of ASNHL is based on the common pathophysiologic pathway shared by the three subgroups. Although we expect to obtain regulatory approval for the entire indication of ASNHL based on confirmatory efficacy and safety data that covers only one or two rather than all of the three subgroups, there can be no assurance that regulatory agencies will concur with this assumption at the time of the marketing approval procedure. In that case, it may not be sufficient to conduct HEALOS and ASSENT in the subgroup of ISSNHL and REACH in the subgroup of surgery-related trauma, as is currently planned.

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, which is also known as acute sensorineural 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 late stage clinical program with AM-111 we anticipate that the enrollment window will be 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. 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. AM-101 is in Phase 3 clinical development for acute inner ear tinnitus under a SPA from the FDA and based on scientific advice from the EMA. For HEALOS, we received protocol assistance from the EMA and feedback from the FDA through a pre-IND meeting in September 2014. In response to this feedback, we finalized the design of HEALOS. In addition, we submitted an IND for REACH that has become effective, and we plan to discuss certain aspects of the ASSENT trial with the FDA under that open IND. We intend to start enrollment in HEALOS in the third quarter of 2015, in ASSENT in the first quarter of 2016 and in REACH in the third quarter of 2016. 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;
- 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 operations. 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 an 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 FDA and EMA have indicated 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.

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 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 SPA, or will result in any FDA approval for AM-101. The TACTT2 Phase 3 clinical trial is being primarily conducted in the United States and Canada and is expected to enroll a total of 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. Based on roll-over rates observed so far, we believe that a substantial number of TACTT study participants will be willing and eligible for enrollment into the AMPACT studies, but ultimately 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 and, due to subsequent legislative amendments to the statute, will remain in effect through 2024 unless additional Congressional action is taken. 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. According to a recent public filing, Otonomy intends to develop a sustained-exposure formulation of gacyclidine that will provide a full course of treatment from a single i.t. injection and plans to file an IND with the FDA for OTO-311 and initiate a Phase 1 trial in 2015. OTO-311's competitive strength will ultimately depend on the demonstration of clinical efficacy and safety and its comparison with AM-101. Further, we intend to rely on our patent applications with broad disclosures to pursue claims relating to the use of polymers with NMDA antagonists in controlled-release topical compositions for the treatment of tinnitus.

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. Otonomy completed a Phase 2b clinical trial in the United States and Canada and, according to public filings, expects to report results in the second quarter of 2015 and to initiate a second pivotal trial of OTO-104 in 2015. 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. We intend to rely on our patent applications with broad disclosures to pursue claims relating to the use of poloxamers with steroids in controlled-release topical compositions for the treatment of Meniere's Disease.

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 administering 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 may be adversely affected, we could potentially lose our right to commercialize AM-111 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 our initial public 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 were 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 the prospectus relating to our initial public offering 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. While Xigen has taken no action as of the date of this prospectus, 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 the prospectus associated with our initial public offering, 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 each, for the supply of the active pharmaceutical ingredients and 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 2027, 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 patients 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.

Certain principal shareholders and members of our executive team and board of directors 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 such shareholders.

After this offering, a small number of shareholders will continue to own more than a majority of our outstanding 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. Approximately 69.9%, or approximately 57.9% after giving effect to this offering, of our common shares outstanding are held by affiliates. If 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 could be adversely affected. We have also entered into a registration rights agreement pursuant to which we have agreed under certain circumstances to file a registration statement to register the resale of common shares held by certain of our shareholders, as well as to cooperate in certain public offerings of such common shares. We have also filed registration statements to register all common shares and other equity securities that we have issued under our prior equity incentive plans or may issue under our new omnibus equity compensation plan. These common shares may be freely sold in the public market upon issuance, subject to certain limitations applicable to affiliates. If a large number of our common shares are sold in the public market, 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 assumed 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 an assumed public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, you will experience immediate dilution of $3.18 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 public offering price. In addition, purchasers of common shares in this offering will have contributed approximately 22% of the net proceeds received by us for all purchases of our common shares but will own only approximately 17% 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 has 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 and shareholders 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 are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are 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.

We 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 follow certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are a foreign private issuer. As a result, in accordance with Nasdaq Listing Rule 5615(a)(3), we 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 are not subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors regularly have scheduled meetings at which only independent directors are present.

Although Swiss law also requires that we adopt a compensation committee, we follow home country requirements with respect to such committee. As a result, our practice varies 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 varies 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 our initial public 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. We could be an "emerging growth company" until 2019, 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” until 2019. 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 depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure you that analysts will cover us or provide favorable 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 and 2014 taxable years, 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 and 2014 taxable years, 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) the obligation to comply 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 in Swiss Francs. None of the consolidated financial statements were prepared in accordance with generally accepted accounting principles in the United States.

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. 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. For fiscal years ending prior to April 22, 2014, our historical financial statements present the results of operations of Auris Medical AG, together with its subsidiaries. For fiscal years ending after April 22, 2014, our financial statements present the results of operations of Auris Medical Holding AG, together with its subsidiaries.

MARKET AND INDUSTRY DATA

This prospectus contains industry, market, and competitive position data that are based on 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 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 $30.6 million (or $35.3 million if the underwriters exercise in full their over-allotment option), based on an assumed public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each $1.00 increase (decrease) in the assumed public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, would increase (decrease) our net proceeds by $5.6 million, 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. Similarly, each 100,000 increase (decrease) in the number of common shares offered by us in this offering would increase (decrease) our net proceeds by $0.5 million, assuming a public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions.

As of March 31, 2015, we had cash and cash equivalents of CHF 49.7 million. We intend to use the net proceeds from this offering as follows:

- approximately $23 to $28 million (CHF 22.8 to 27.8 million) to fund research and development expenses for AM-111; and
- the remainder for early stage programs, working capital and other 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.

We expect that our total operating expense in 2015 will be in the range of CHF 30.0 to 35.0 million, including AM-111 clinical Phase 3 expenses related to the start of HEALOS and preparations for ASSENT and REACH. Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents, 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 36 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

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 standalone 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 December 31, 2014, derived from our audited consolidated financial statements, prepared in accordance with IFRS and included elsewhere in this prospectus:

- on an actual basis; and
- on an as adjusted basis to give effect to our issuance and sale of 6,000,000 common shares in this offering, at the assumed public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

U.S. dollar amounts have been translated into Swiss Francs at a rate of USD 1.0066 to CHF 1.00, the official exchange rate quoted as of December 31, 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 April 24, 2015, the exchange rate as reported by the U.S. Federal Reserve Bank was USD 1.0490 to CHF 1.00.

Investors should read this table in conjunction with our audited consolidated 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."

	DECEMBER 31, 2014	
	ACTUAL	AS ADJUSTED
	(in thousands of CHF except share and per share data)	
Cash and cash equivalents (1)	56,934	87,304
Total debt	—	—
Shareholders' equity:		
Share capital		
Common shares, nominal value CHF 0.40 per share; 29,010,391 shares issued and outstanding on an actual basis; 35,010,391 shares issued and outstanding on an adjusted basis	11,604	14,004
Share premium	93,861	121,831
Foreign currency translation reserve	(51)	(51)
Accumulated deficit	(52,131)	(52,131)
Total shareholders' equity attributable to owners of the company (1)	53,283	83,653
Total capitalization (1)	53,283	83,653

(1) As adjusted cash and cash equivalents represents actual cash and cash equivalents plus the net proceeds of this offering. Each $1.00 increase (decrease) in the assumed public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, would increase (decrease) our as adjusted cash and cash equivalents, as adjusted total shareholders' equity attributable to owners of the Company and as adjusted total capitalization by CHF 5.6 million, 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. Similarly, each 100,000 increase (decrease) in the number of common shares offered by us in this offering would increase (decrease) our as adjusted cash and cash equivalents, as adjusted total shareholders' equity attributable to owners of the Company and as adjusted total capitalization by CHF 0.5 million, assuming a public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions.

The table above is based on our actual common shares outstanding as of December 31, 2014 and does not include 1,444,119 of our common shares covered by additional awards available for future issuance under our amended and restated articles of association, including 419,010 of our common shares issuable upon the exercise of options outstanding as of December 31, 2014 at a weighted average exercise price of CHF 4.61 per common share (8,500 of which have been issued upon exercise of options since December 31, 2014).

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DILUTION

If you invest in our common shares, your interest will be diluted to the extent of the difference between the public offering price per common share and the as adjusted net tangible book value per common share after this offering.

At December 31, 2014, we had a net tangible book value of $52.1 million, corresponding to a net tangible book value of $1.80 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 29,010,391, the total number of our common shares outstanding at December 31, 2014.

After giving effect to the sale by us of the 6,000,000 common shares offered by us in the offering at the assumed offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, after deducting 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 as adjusted net tangible book value estimated at December 31, 2014 would have been approximately $82.7 million, representing $2.36 per common share. This represents an immediate increase in net tangible book value of $0.56 per common share to existing shareholders and an immediate dilution in net tangible book value of $3.18 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 public offering price per share	$5.54
Net tangible book value per common share at December 31, 2014	1.80
Increase in net tangible book value per common share attributable to new investors	0.56
As adjusted net tangible book value per common share after the offering	2.36
Dilution per common share to new investors	3.18
Percentage of dilution in net tangible book value per common share for new investors	57%

Each $1.00 increase (decrease) in the assumed public offering price of $5.54 per common share, which is the last reported sale price of our common shares on the Nasdaq Global Market as set forth on the cover page of this prospectus, would increase (decrease) the as adjusted net tangible book value after this offering by $0.16 per common share and the dilution per common share to new investors in the offering by $0.84 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 $2.43 per common share, and the dilution per common share to new investors would be $3.11 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 82.9% 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 17.1% 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 December 31, 2014 on an as adjusted basis and excludes 1,444,119 of our common shares covered by additional awards available for future issuance under our amended and restated articles of association, including 419,010 of our common shares issuable upon the exercise of options outstanding as of December 31, 2014 at a weighted average exercise price of CHF 4.61 per common share (8,500 of which have been issued upon exercise of options since December 31, 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.

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 April 24, 2015, the exchange rate as reported by the U.S. Federal Reserve Bank was CHF 0.9533 to $1.00. In this prospectus, translations from CHF to U.S. dollars were made at the rate of 0.9934 to $1.00, the official exchange rate quoted as of December 31, 2014 by the U.S. Federal Reserve Bank.

	PERIOD-END	AVERAGE FOR PERIOD	LOW	HIGH
	(CHF per U.S. dollar)			
Year Ended December 31:				
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
2014	0.9934	0.9195	0.8712	0.9934
Month Ended:				
October 31, 2014	0.9623	0.9528	0.9425	0.9670
November 28, 2014	0.9658	0.9642	0.9572	0.9702
December 31, 2014	0.9934	0.9753	0.9604	0.9934
January 31, 2015	0.9210	0.9443	0.8488	1.0195
February 28, 2015	0.9513	0.9361	0.9228	0.9540
March 31, 2015	0.9712	0.9798	0.9553	1.0074
April 1, 2015 (through April 24, 2015)	0.9533	0.9625	0.9504	0.9807

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SELECTED CONSOLIDATED FINANCIAL AND OTHER INFORMATION

The following selected consolidated financial and other 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, 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.

The summary consolidated statement of profit or loss and other comprehensive loss data and consolidated statement of financial position data as of and for the year ended December 31, 2014 is derived from the audited consolidated financial statements included elsewhere in this prospectus, which have been audited by Deloitte AG. The summary consolidated statement of profit or loss and other comprehensive loss data for each of the years in the two-year period ended December 31, 2013 and the summary consolidated statement of financial position data as of December 31, 2013 is derived from the audited consolidated financial statements included elsewhere in this prospectus, which have been audited by KPMG AG.

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

	FOR THE YEARS ENDED DECEMBER 31,		
	2014	2013	2012
	(in thousands of CHF except for share and per share data)		
Profit or Loss and Other Comprehensive Loss Data:			
Research and development	(17,705)	(13,254)	(3,987)
General and administrative	(4,489)	(1,362)	(624)
Operating loss	(22,194)	(14,616)	(4,611)
Finance expense	(208)	(159)	(2)
Finance income	4,216	76	10
Loss before tax	(18,185)	(14,699)	(4,602)
Income tax expense	—	(306)	—
Net loss attributable to owners of the Company	(18,185)	(15,005)	(4,602)
Other comprehensive loss:			
Items that will never be reclassified to profit or loss:			
Remeasurements of defined benefits liability, net of taxes of CHF O	(1,102)	(58)	(55)
Items that are or may be reclassified to profit or loss:			
Foreign currency translation differences, net of taxes of CHF O	(105)	32	22
Other comprehensive loss, net of taxes of CHF O	(1,207)	(26)	(32)
Total comprehensive loss attributable to owners of the Company	(19,392)	(15,031)	(4,635)
Net loss per share (1)			
Net loss per share, basic and diluted (2)	(0.66)	(1.01)	(0.40)
Weighted-average number of shares used to compute net loss per common share, basic and diluted	27,692,494	14,917,064	11,581,450

(1) For periods prior to the closing of our initial public offering in August 2014, net loss per share includes preferred shares, which were converted on a one-for-one basis upon the closing of our initial public offering. See Note 12 to our audited consolidated financial statements included elsewhere in this prospectus.

(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.

	AS OF DECEMBER 31,	
	2014	2013
	(in thousands of CHF)	
Statement of Financial Position Data:		
Cash and cash equivalents	56,934	23,866
Total assets	59,493	26,252
Total liabilities	6,210	17,219
Share capital	11,604	6,487
Total shareholders’ equity attributable to owners of the Company	53,283	9,034

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 as issued by the IASB (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 an 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 expect to have top-line Phase 3 clinical data for AM-101 in the first quarter of 2016. We are also developing AM-111 for acute inner ear hearing loss. We are preparing two pivotal clinical trials in the treatment of idiopathic sudden sensorineural hearing loss, or ISSNHL, titled HEALOS and ASSENT. We expect to start enrollment in HEALOS in the third quarter of 2015 and in ASSENT in the first quarter of 2016. In addition, we are preparing a Phase 2 trial titled REACH in order to test AM-111 in the treatment of surgery-induced hearing loss following cochlear implantation. We expect to start enrollment in REACH in the third quarter of 2016. 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 the initial public offering of our common shares, 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 December 31, 2014, we had cash and cash equivalents of CHF 56.9 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 18.2 million and CHF 15.0 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, we had an accumulated deficit of CHF 52.1 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 were 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 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.

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;
- costs related to the preparation of regulatory filings and fees; and
- depreciation and amortization of tangible and intangible fixed assets used to develop our product candidates.

We expect that our operating expenses in 2015 will be in the range of CHF 30.0 to 35.0 million (including AM-111 clinical Phase 3 expenses related to the start of HEALOS and preparations for ASSENT and REACH), the majority of which we expect to be research and development expense. 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 data in the first quarter of 2016. These two studies are 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 are preparing two pivotal clinical trials in the treatment of idiopathic sudden sensorineural hearing loss, or ISSNHL, titled HEALOS and ASSENT. We expect to start enrollment in HEALOS in the third quarter of 2015 and in ASSENT in the first quarter of 2016. In addition, we are preparing a Phase 2 trial titled REACH in order to test AM-111 in the treatment of surgery-induced hearing loss following

cochlear implantation. We expect to start enrollment in REACH in the third quarter of 2016. We anticipate that our research and development expenses will increase substantially in connection with commencement of additional 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 55.7 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, 2014, 2013 and 2012, we spent CHF 12.5 million, CHF 10.6 million and CHF 1.9 million, respectively, on research and development expenses related to AM-101. For the same time periods, we spent CHF 4.8 million, CHF 1.0 million and CHF 1.0 million, respectively, on research and development expenses related to AM-111. In addition, we incurred research and development expenses related to our earlier stage projects. These expenses exclude the milestone payments to Xigen for AM-111 as they were 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;
- administration costs including 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 and IT expenses;
- cost of facilities, communication and office 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 currency exchange losses.

Other comprehensive loss

Remeasurements of the net defined benefit (pension) 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 in other comprehensive loss.

We determine the net interest expense or income on the net defined benefit (pension) 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 our consolidated financial statements included elsewhere herein. The discussion below should be read along with these consolidated financial statements and it is qualified in its entirety by reference to them.

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Comparison of the years ended December 31, 2014 and 2013

	YEAR ENDED DECEMBER 31,		
	2014	2013	CHANGE
	(in thousands of CHF)		%
Research and development	(17,705)	(13,254)	34%
General and administrative	(4,489)	(1,362)	230%
Operating loss	**(22,194)**	**(14,616)**	**52%**
Finance expense	(208)	(159)	31%
Finance income	4,217	76	5,466%
Loss before tax	**(18,185)**	**(14,699)**	**24%**
Income tax expense	0	(306)	(100)%
Net loss attributable to owners of the Company	**(18,185)**	**(15,005)**	**21%**
Other comprehensive loss:			
Items that will never be reclassified to profit or loss			
Remeasurements of defined benefits liability, net of taxes of CHF 0	(1,102)	(58)	1,808%
Items that are or may be reclassified to profit or loss			
Foreign currency translation differences, net of taxes of CHF 0	(105)	32	(431)%
Other comprehensive loss	**(1,207)**	**(26)**	**4,541%**
Total comprehensive loss attributable to owners of the Company	**(19,392)**	**(15,031)**	**29%**

Research and development expense

	YEAR ENDED DECEMBER 31,		
	2014	2013	CHANGE
	(in thousands of CHF)		%
Research and development expense			
Clinical projects	(12,142)	(8,753)	39%
Preclinical projects	(1,160)	(2,078)	(44)%
Drug manufacture and substance	(1,384)	(1,036)	34%
Employee benefits	(1,718)	(1,074)	60%
Other research and development expenses	(1,301)	(313)	316%
Total	**(17,705)**	**(13,254)**	**34%**

Research and development expense increased 34% from CHF 13.3 million in 2013 to CHF 17.7 million in 2014. Our research and development expense is dependent on the development phases of our research projects and therefore fluctuates significantly from year to year. The variances in expense between 2013 and 2014 are mainly due to the following factors:

- *Clinical projects*. Beginning in February and March 2014 we enrolled patients in two AM-101 Phase 3 trials, namely TACTT2 and TACTT3. In addition, roll-over of study participants into the open-label follow-on studies AMPACT1 and AMPACT2 started in May/June 2014. This resulted in the incurrence of substantial service and pass through costs from our CROs and other service providers. In 2013, AM-101 clinical costs were lower as Phase 2 completed in February and we mainly incurred costs related to the preparation for the Phase 3 trials (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). For AM-111, in 2014, we incurred significantly higher clinical costs for the preparation of the Phase 3 program, most notably, feasibility assessments, as well as investigator and site selections. In contrast, in 2013 expense levels related to the AM-111 project were lower because a Phase 2 clinical trial had been completed.

- *Preclinical projects*. In 2014 we finished toxicology studies with repeated AM-101 dosing and therefore incurred lower expenses as compared to 2013. In contrast, in 2014 we incurred higher expenses for AM-111 as we started a repeated dose toxicology study and finalized the analytical assay development. Costs incurred in 2013 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 2014 we incurred substantial costs related to the manufacture of clinical supplies for AM-111 in preparation for the Phase 3 trial program as well as for analytical development and validation. In contrast, in 2013 we mainly incurred costs related to the manufacture, labelling and packaging of supplies for the AM-101 Phase 3 trials.
- *Employee benefits*. Headcount continued to increase in 2014 in line with the expansion of our research and development activities as well as our administrative functions.

General and administrative expense

	YEAR ENDED DECEMBER 31,		
	2014	2013	CHANGE
	(in thousands of CHF)		%
General and administrative expense			
Employee benefits	(1,137)	(196)	481%
Administration costs	(2,014)	(556)	262%
Initial public offering costs, expensed	(822)	0	100%
Other	(516)	(610)	(15)%
Total	**(4,489)**	**(1,362)**	**230%**

General and administrative expense increased 230% from CHF 1.4 million in 2013 to CHF 4.5 million in 2014.

- *Employee benefits*. Headcount continued to increase in 2014 in line with the expansion of our administrative staff after becoming a publicly listed company.
- *Administration costs*. The increase reflects higher legal and auditing expenses in connection with the preparation for our initial public offering and expenses associated with operating as a public company after August 2014
- *Initial public offering costs, expensed*. These initial public offering costs result from management assessing that successful completion of the initial public offering was not deemed to be more likely than not as of March 31, 2014. Subsequent to March 31, 2014, initial public offering costs were deducted from equity. No such costs were incurred in 2013.
- *Other*. These costs were on aggregate broadly in line with 2013 and comprise facility, business development and travel costs.

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 75,747 in 2013 to CHF 4.2 million 2014. Finance income in 2013 consisted primarily of interest income recognized on short-term deposits.

Finance income increased substantially in 2014 primarily because of unrealized exchange gains due to the appreciation of the U.S. dollar (in which most of our cash was denominated after the initial public offering) against the CHF (our functional currency) as well as a result of an increase in average cash and cash equivalents following our initial public offering of common shares.

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Finance expense

Finance expense increased from CHF 158,641 in 2013 to CHF 207,825 in 2014. Higher finance expenses were mainly due to net foreign currency exchange losses on our financial liabilities.

Income tax expense

As we have never generated revenue or other taxable income, there have been no income taxes paid so far. In 2014, we recorded a deferred income tax loss of CHF 32,761, which was offset with an income tax gain of CHF 32,761.

Remeasurements of defined benefits liability

Remeasurements of the net defined benefits 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 1,808% from 2013 to 2014. The increase was primarily related to a higher actuarial loss arising from changes in financial assumptions and experience adjustments, partially offset by a higher return on plan assets.

Foreign currency translation differences

Foreign currency translation differences decreased by 431% from 2013 to 2014. The decrease was primarily related to changes in the opening and closing balance of the group's currency translation adjustments.

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)	8,713 %
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 loss:			
Items that will never be reclassified to profit or loss			
Remeasurements of defined benefit liability, net of taxes of CHF 0	(58)	(55)	6 %
Items that are or may be reclassified to profit or loss			
Foreign currency translation differences, net of taxes of CHF 0	32	22	42 %
Other comprehensive loss, net of taxes of CHF 0	**(26)**	**(32)**	**(20)%**
Total comprehensive loss attributable to owners of the Company	**(15,031)**	**(4,635)**	**224 %**

Research and development expense

	YEAR ENDED DECEMBER 31,		
	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	(313)	(317)	(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.

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 expenses 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 benefits 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 rate.

Liquidity and Capital Resources

Since inception, we have incurred significant operating losses. To date, we have not generated any revenue. We have financed our operations through the initial public offering of our common shares, private placements of equity securities and short term loans.

Cash flows

Comparison of the year ended December 31, 2014 and 2013

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2014 and 2013:

	YEAR ENDED DECEMBER 31,	
	2014	2013
	(in thousands of CHF)	
Cash used in operating activities	(19,316)	(14,044)
Net cash used in investing activities	(1,186)	(35)
Net cash from financing activities	49,609	37,881
Net effect of currency translation on cash	3,961	0
Cash and cash equivalents at the beginning of the period	23,866	64
Cash and cash equivalents at the end of the period	**56,934**	**23,866**

The increase in cash used in operating activities by 38% from CHF 14.0 million in 2013 to CHF 19.3 million in 2014 was mainly due to an increase in research and development expenses as well as general and administrative spending.

Cash used in investing activities reflects, in both 2014 and 2013, cash used in the purchase of property, plant and equipment (manufacturing equipment and office furniture) offset by interest received. In 2014, it also includes a CHF 1.125 million cash milestone payment to Xigen.

Cash from financial activities, in 2014, is primarily driven by a net inflow of CHF 50.04 million from our initial public offering in August 2014. In 2013 net cash from financing activities reflects proceeds from 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.

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
Net effect of currency translation on cash	0	1
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

The table below summarizes our sources of financing for the years ended December 31, 2014, 2013 and 2012.

	EQUITY CAPITAL AND PREFERRED SHARES	LOANS	TOTAL
	(in thousands of CHF)		
2014	50,038	—	50,038
2013	24,111	13,770	37,881
2012	3,862	—	3,862
Total	**78,011**	**13,770**	**91,781**

Our sources of financing in 2014 included the initial public offering of 10,113,235 common shares providing net proceeds (after underwriting fees, initial public offering and share issuance costs) of CHF 50.04 million.

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 additional 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 to effect the Third Closing was waived by the Company and the Series C investors.

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 December 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 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 36 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. 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 new 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, 2014:

	PAYMENTS DUE BY PERIOD		
	LESS THAN 1 YEAR	BETWEEN 1 AND 5 YEARS	TOTAL
	(in thousands of CHF)		
Operating lease obligations (1)	104	59	163
Total	**104**	**59**	**163**

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

Under the terms of our collaboration and license agreement with Xigen, we are obliged to make development milestone payments on an indication-by-indication basis of up to CHF 1.5 million upon the successful completion of a Phase 2 clinical trial 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, upon receiving marketing approval for a product. The milestones are not included in the table above as they have not met the recognition criteria for provisions and the timing of these is not yet determinable as it is dependent upon the achievement of earlier mentioned milestones.

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. Other receivables are not past due or 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 currency 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 currency 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 currency exchange risk arising from various exposures, primarily with respect to the US Dollar and Euro. Foreign currency exchange risk arises from future commercial transactions, recognized assets and liabilities and net investments in foreign operations. To manage foreign currency exchange risk we maintain foreign currency cash balances to cover anticipated future purchases of materials and services in foreign currencies.

As of December 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 2,212,604 (2013: CHF 175,115) 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 24,086 (2013: CHF 107,672) 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 currency 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 Company have finite lives. Amortization will start once the Company's intangible assets are 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 other comprehensive loss.

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 when there is a legally enforceable right to set off tax assets against tax liabilities and when they relate to income taxes levied by the same taxation authority and the Company intends to settle its tax assets and liabilities on a net basis.

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, 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, from the grant date, in accordance with Plans A and C. Under the Auris Medical Holding AG Long Term Incentive Plan ("the 2014 Plan"), 50% of granted share options vest after a period of service of two years from the grant date and the remaining 50% vest after a period of service of three years from the grant date. Plan B was created to provide shares for share based compensation plans; it was used in the years 2008, 2009 and 2014 and is still in force. 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.

Following the completion of our initial public offering, option pricing and values are determined based on quoted market prices of our common shares.

Recent accounting pronouncements

See Note 4 to our audited consolidated financial statements included elsewhere in this prospectus for a full description of recent accounting pronouncements, including the expected dates of adoption and effects on the Company's financial condition, results of operations and cash flows.

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:

- 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, or PCAOB 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 until 2019 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 expect to have top-line Phase 3 clinical data for AM-101 in the first quarter of 2016. We are also developing AM-111 for acute inner ear hearing loss. We are preparing two pivotal clinical trials in the treatment of idiopathic sudden sensorineural hearing loss, or ISSNHL, titled HEALOS and ASSENT. We expect to start enrollment in HEALOS in the third quarter of 2015 and in ASSENT in the first quarter of 2016. In addition, we are preparing a Phase 2 trial titled REACH in order to test AM-111 in the treatment of surgery-induced hearing loss following cochlear implantation. We expect to start enrollment in REACH in the third quarter of 2016. 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.

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.

Possible causes of acute inner ear tinnitus include 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 the first quarter of 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 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. In the United States, more than 66,000 patients covered by health insurance are treated for 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 are preparing two pivotal clinical trials in the treatment of idiopathic sudden sensorineural hearing loss, or ISSNHL, titled HEALOS and ASSENT. We expect to start enrollment in HEALOS in the third quarter of 2015 and in ASSENT in the first quarter of 2016. In addition, we are preparing a Phase 2 trial titled REACH in order to test AM-111 in the treatment of surgery-induced hearing loss following cochlear implantation. We expect to start enrollment in REACH in the third quarter of 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 proprietary gel formulation, its manufacturing and its application are part of our intellectual property, know-how and competitive advantage. In addition, we believe that our intellectual property broadly directed to polymer-based formulations for the treatment of middle or inner ear disorders will serve as barriers to entry beyond our current products.
- ***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

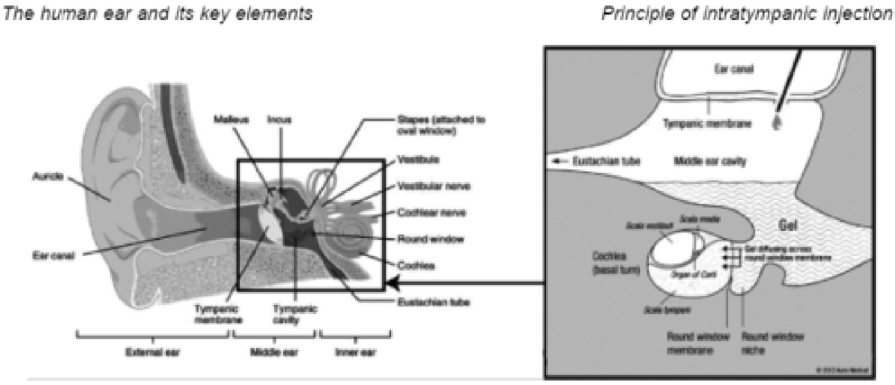
Our goal is to become the leading biopharmaceutical company focused on developing and commercializing novel therapeutics to treat inner ear disorders. The key elements of our strategy to achieve this goal are:

- ***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 expect to have top-line data in the first quarter of 2016. We are preparing three clinical trials for the treatment of ASNHL, including two pivotal Phase 3 trials (HEALOS and ASSENT) in the treatment of ISSNHL and one Phase 2 trial (REACH) in the treatment of surgery-induced hearing loss following cochlear implantation. We intend to start enrollment in HEALOS in the third quarter of 2015, in ASSENT in the first quarter of 2016 and in REACH in the third quarter of 2016.
- ***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 (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. We selected its viscosity in a way that the free movement of the ossicular chain, which transfers the vibrations of the eardrum to the inner ear, is not impacted. The presence of highly viscous gels in the middle ear may cause transient conductive hearing loss.

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.

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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 Data TACTT3 (A)	Q1 2016
	Post-acute inner ear tinnitus					Data TACTT3 (B)	Q2 2016
AM-111 D-JNKI-1	*Acute inner ear hearing loss*					Start HEALOS Start ASSENT Start REACH	Q3 2015 Q1 2016 Q3 2016
	Menière's disease					Trial application	Fall 2015
AM-102 Undisclosed	*Tinnitus*					Lead compound selected	Fall 2015
AM-123 Undisclosed	*Rhinology*					Lead compound selected	Fall 2015

(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. According to the American Tinnitus Association, approximately 16 million patients in the United States have tinnitus symptoms severe enough to seek medical attention and about two million patients cannot function on a normal day-to-day basis. In addition, tinnitus is now the number one service-connected disability for all veterans, before hearing loss, and annual service-connected disability payments for tinnitus to veterans from all periods of service are expected to exceed $2.75 billion by the end of 2016.

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.

Market Potential for AM-101

In order to assess the market potential of AM-101 in the United States, we commissioned MEDACorp, Inc., or MedaCorp, to conduct a primary market research survey of U.S. ENT doctors. The survey was conducted online in April 2014 and included 53 ENT doctors (41 general ENTs, 12 otologists) who responded to an invitation to participate. Participants indicated that they see an average of 43.5 tinnitus patients in an average month (median: 30 patients), of which 38% were seen within the first three months following onset, during the acute stage. When presented with phase 2 clinical trial safety and efficacy data, surveyed physicians would consider 42.6% of their tinnitus patients as candidates for the profiled product. Under the assumption that there was an approved i.t. treatment for acute tinnitus, 74% of survey participants expected their monthly tinnitus patient volume to increase.

The results from the survey should be interpreted with caution since they may or may not be representative of the entire population of ENT doctors. For example, we assume respondents were ENT doctors with a particular interest in tinnitus who may see more tinnitus patients than the average ENT doctor. Also, acceptance of AM-101 will not only depend on ENT doctors’ acceptance, but also other factors such as reimbursement levels, the actual labeling and patient acceptance. Please refer to the “Risk Factors” section of this prospectus for a discussion of the potential risks related to the commercialization of AM-101.

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.

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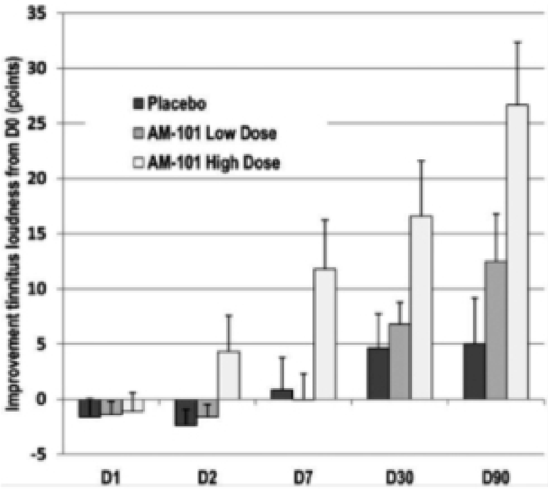
Improvement in tinnitus PROs

	PLACEBO	AM-101 LOW DOSE	AM-101 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.

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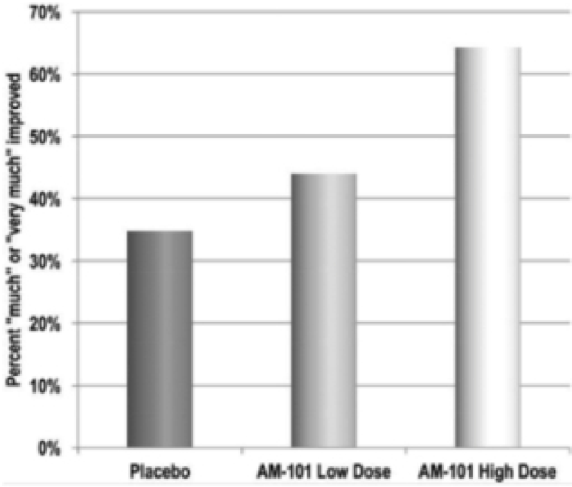
64% of patients in the high dose group rated their tinnitus severity at Day 90 compared to baseline as “much improved” or “very much improved”, compared with 34% of patients in the placebo group. The majority of placebo treated patients reported only “somewhat improved” tinnitus severity.

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 read out.

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).

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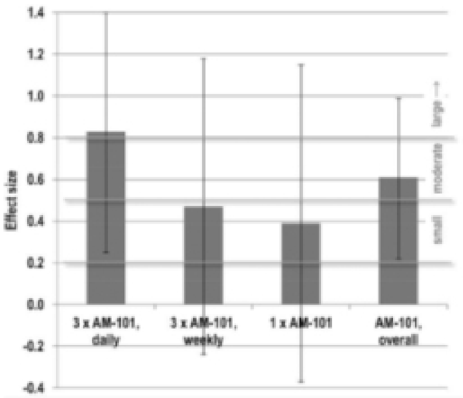
When comparing the improvement in tinnitus loudness in patients with unilateral tinnitus following traumatic injury to the cochlea or OM, treatment effects in TACTT1 were smaller than in TACTT0. The effect size was 0.83 where AM-101 had been administered three times over three consecutive days in TACTT0, 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 designs, 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. 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. Enrollment of patients in the acute stage is expected to be completed in fall 2015, and no interim analysis is planned.

In addition, TACTT3 is exploring the potential efficacy of AM-101 during the post-acute stage (tinnitus onset between three and 12 months) since data from our Phase 2 clinical program suggest that AM-101 may be effective beyond the three month acute stage. An Independent Data Review Committee conducted an interim analysis after enrollment of 150 patients. The interim analysis showed positive efficacy signals, with higher activity levels observed in the early post-acute stage (three to six months) compared to the late post-acute stage (six to 12 months). Based on recommendations from the Independent Data Review Committee, this part of TACTT 3 will continue solely with enrollment of patients with tinnitus onset three to six months prior. In total, approximately 330 patients will be enrolled in the stratum pre- and post-interim analysis.

The same, well-defined patient population we used in Phase 2 (acute inner ear tinnitus following traumatic injury to the cochlea or OM) is selected in our Phase 3 clinical trials. Furthermore, based on the data we have gathered on the various subjective clinical read outs, 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 the first quarter of 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 Alexander and Harris published in Otology & Neurotology in 2013, the average annual incidence of sudden deafness is 66,954 new cases among the U.S. insured population. There are no currently approved treatments for this patient population.

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 are preparing for the late stage clinical development of AM-111 in acute inner ear hearing loss. 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 received orphan drug designation 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.

Market Potential for AM-111

In order to assess the market potential of AM-111 in the United States, we commissioned MEDACorp, to conduct a primary market research survey of U.S. ENT doctors. The survey was conducted online in April 2014 and included 53 ENT doctors (41 general ENTs, 12 otologists) who responded to an invitation to participate. Participants indicated that they see an average of 11.2 patients suffering from idiopathic sudden sensorineural hearing loss and 6.3 patients suffering from acute acoustic trauma in an average month (median: six and three patients, respectively), of which 40% were seen within the first three days following onset. On average, 43% of ISSNHL and AAT patients suffered from severe to profound hearing loss (^{3} 60 dB hearing threshold). When presented with phase 2 clinical trial safety and efficacy data, surveyed doctors considered 59.9% of their acute hearing loss patients as candidates for the profiled product. Under the assumption that there was an approved i.t. treatment for ASNHL, 64% of survey participants expected their monthly acute inner ear hearing loss patient volume to increase.

The results from the survey should be interpreted with caution since they may or may not be representative of the entire population of ENT doctors. For example, we assume respondents were ENT doctors with a particular interest in acute inner ear hearing loss who may see more ISSNHL or AAT patients than the average ENT doctor. Also, acceptance of AM-111 will not only depend on ENT doctors' acceptance, but also other factors such as reimbursement levels, the actual labeling and patient acceptance. Please refer to the "Risk Factors" section of this prospectus for a discussion of the potential risks related to the commercialization of AM-111.

AM-111 Clinical Development

We have successfully completed two clinical trials of AM-111 that demonstrated its safety and efficacy. We have benefited several times from engaging in a protocol assistance procedure with the EMA, most recently for the design of HEALOS. The FDA held a pre-IND meeting with us in September 2014 and also provided formal feedback and guidance on HEALOS. We are preparing two pivotal clinical trials in the treatment of idiopathic sudden sensorineural hearing loss, or ISSNHL, titled HEALOS and ASSENT. We expect to start enrollment in HEALOS in the third quarter of 2015 and in ASSENT in the first quarter of 2016. In addition, we are preparing a Phase 2 trial titled REACH in order to test AM-111 in the treatment of surgery-induced hearing loss following cochlear implantation. We expect to start enrollment in REACH in the third quarter of 2016.

Our pivotal Phase 3 clinical trial design is based on the outcomes from our Phase 2 clinical trial and our discussions with the EMA and FDA. We have 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.

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.

Improvement in hearing and speech discrimination

		AM-111	
	PLACEBO	LOW DOSE	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.

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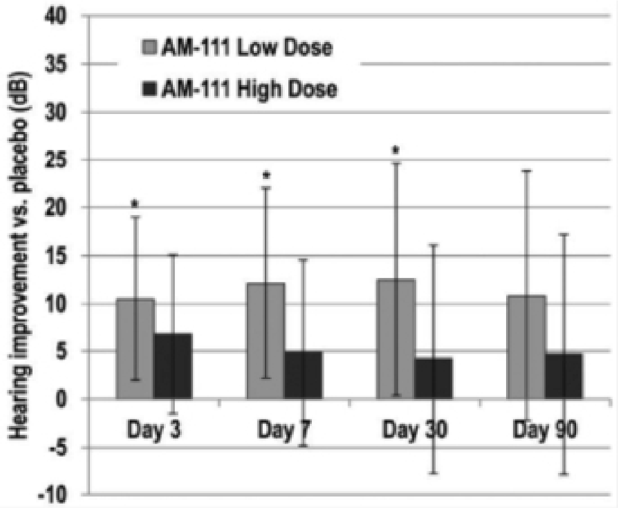
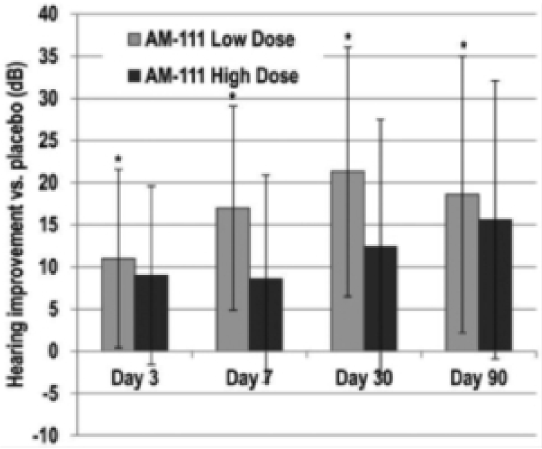
Improvement in hearing over time



*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.

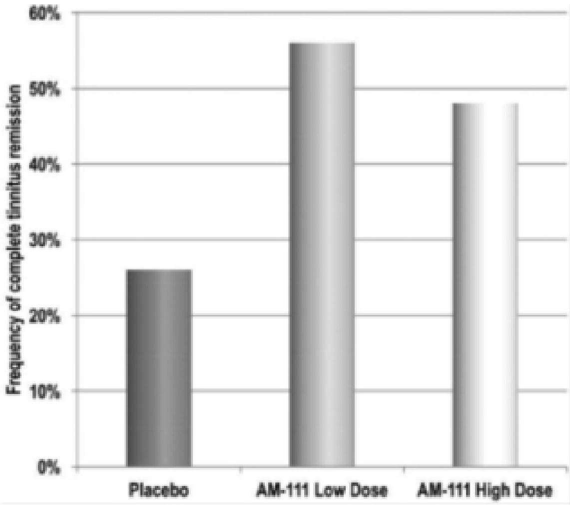
Improvement in hearing over time – ASNHL onset 24 to 48 hours before



*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 Program

Based on Phase 2 clinical trial outcomes and after obtaining guidance from the EMA and FDA, we have been preparing a late stage clinical program. We are planning to conduct confirmatory testing of AM-111 0.4 mg/mL as well as to explore potential incremental therapeutic benefits from the use of AM-111 0.8 mg/mL. 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. In addition, we are planning to test AM-111 for protection against surgery-induced hearing loss in cochlear implant surgery.

We have been preparing for a pivotal Phase 3 trial called HEALOS (Efficacy and Safety of AM-111 in the treatment of Acute Inner Ear Hearing Loss) in European and Asian countries with approximately 255 patients. A single dose of either 0.4 mg/mL or 0.8 mg/mL of AM-111 will be compared to placebo in patients suffering from acute severe to profound hearing loss with ISSNHL as the onset factor and an enrollment time window that is extended from 48 to 72 hours. The FDA held a pre-IND meeting with us in September 2014 and provided formal feedback and guidance on our pre-clinical and Chemistry, Manufacturing and Control, or CMC, development and specifically on HEALOS. In response to this feedback and further Protocol Assistance from the EMA, we finalized the design of HEALOS.

We are also preparing for a second pivotal Phase 3 trial called ASSENT in the United States in order to test AM-111 in the treatment of acute sudden sensorineural hearing loss, with a similar number of patients as for HEALOS. The principal enrollment criteria will be identical to HEALOS, and patients will also be randomized to receive a single dose of either AM-111 0.4 mg/mL, AM-111 0.8 mg/mL or placebo by i.t. injection. Unlike HEALOS, in which patients receive AM-111 or placebo alone, patients in ASSENT may receive a course of oral corticosteroid, which is the de facto standard of care in the United States despite equivocal evidence of efficacy, as background therapy in the active and placebo arms. We plan to discuss certain aspects of the study protocol with the FDA and expect ASSENT to start enrolling patients in the first quarter of 2016.

In addition to ISSNHL, we also intend to test AM-111 in the treatment of surgery-induced hearing loss with REACH. We plan to administer AM-111 intraoperatively in patients with residual hearing who are undergoing cochlear implant surgery and who are at risk of losing residual hearing. We submitted an IND for REACH that has become effective, and plan to seek grant funding in support of the trial. We expect to start enrollment into REACH in the third quarter of 2016.

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.
- Autifony Therapeutics Ltd. has a Kv3 potassium channel agonist product candidate (AUT00063) that is designed for oral administration. In 2014 Autifony initiated a Phase 2 study with AUT00063 in patients with post-acute tinnitus. The trial is expected to complete enrollment in summer 2015.

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. Otonomy is expected to submit an IND and initiate a Phase 1 clinical trial for OTO-311 in 2015.

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. Autifony is expected to initiate a Phase 2 trial with AUT00063 in the treatment of speech-in-noise deficits in elderly patients.
- 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 (HPN-07) designed for treatment of acute hearing loss by way of oral administration. A Phase 1 trial was initiated 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 is a micronized dexamethasone formulated in a poloxamer gel designed for single dose i.t. injection for which results of a Phase 2b clinical trial in the United States and Canada are expected to be reported in the second quarter of 2015. If successful, Otonomy is expected to initiate a second pivotal trial for OTO-104 in 2015.
- 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. For example, we have broad disclosures in our patent applications and can pursue patent claims directed to our own leading product candidates as well as claims directed to certain potentially competing products. In addition, our earlier filed patent applications are prior art to others including certain of our competitors who filed their patent applications later than ours. 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 rights 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 April 15, 2015, we own two (2) issued U.S. patents and nine (9) 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, we co-own two of our pending applications with Xigen pursuant to the terms of our collaboration and license agreement.

In addition, as of April 15, 2015, we have exclusively licensed from Xigen eleven (11) issued U.S. patents and three (3) pending U.S. patent applications, along with their foreign counterparts in various jurisdictions that cover the composition of matter or method of use of 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 April 15, 2015 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, Eurasia, Australia, Canada, Japan, Brazil, China, South Korea, Israel, India, Mexico, Philippines, Russia, South Africa 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 eleven (11) issued U.S. patents and three (3) pending U.S. applications along with their foreign counterparts in various jurisdictions including, Europe, Australia, Brazil, Canada, Eurasia, South Korea, Israel, India, Mexico, Ukraine 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 2027, prior to any patent term extensions to which we may be entitled under applicable laws. In addition, we co-own two patent families with Xigen related to use of JNK ligand peptides for the treatment of Meniere’s disease or tinnitus.

We have several areas of disagreement with Xigen, including (i) our interpretation of the scope of the exclusive worldwide license granted to us by Xigen, (ii) the assignment by Xigen of certain of the patents covered by the license and (iii) Xigen’s refusal to grant its consent for the disclosure of certain provisions of our agreement in the prospectus associated with our initial public offering and the filing of a redacted version of the agreement with the SEC. Although the difference in interpretation over the scope of the license has no impact on our current or planned use of AM-111 and we have been assured by Xigen and its assignee that the assignment of patents is without prejudice to our license, these areas of disagreement could adversely affect our relationship with Xigen and our business, commercialization prospects and financial conditions. Although Xigen has not taken any action as of the date of this prospectus, any resulting litigation could result in substantial legal expenses and potentially the loss of our right to commercialize AM-111. 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 may be adversely affected, we could potentially lose our right to commercialize AM-111 and our business, commercialization prospects and financial condition may be adversely affected.”

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 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. 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 our initial public 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 may be adversely affected, we could potentially lose our right to commercialize AM-111 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, the Health Care Reform Law, 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, 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 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 Health Care Reform Law 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, the Health Care Reform Law was signed into law. The Health Care Reform Law has the potential to substantially change the way healthcare is financed by both governmental and private insurers. The Health Care Reform Law, 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

Our headquarters are in Zug, Switzerland. We also 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 April 20, 2015, we had 16 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 our consolidated 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.

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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 at the time of our 2016 annual shareholder meeting.

NAME	POSITION	AGE	INITIAL YEAR OF APPOINTMENT
Executive Officers			
Thomas Meyer	Chairman and Chief Executive Officer	47	2003
Bettina Stubinski	Chief Medical Officer	48	2013
Sven Zimmermann	Chief Financial Officer	44	2014
Non-Executive Directors			
Wolfgang Arnold	Director	73	2007
James I. Healy	Director	50	2013
Oliver Kubli	Director	42	2010
Antoine Papiernik	Director	48	2013
Berndt A. E. Modig	Director	57	2015
Calvin W. Roberts	Director	63	2015

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. (Dr.rer.pol.) 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 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 Zurich 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 1981 to 1992, he served as Head of the Department of Otorhinolaryngology, Head and Neck Surgery of the Cantonal Hospital Lucerne, Switzerland. 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, Vice-Chairman: 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 Hyperion Therapeutics, Inc., Amarin Corporation, plc., Ascendis Pharma A/S, Coherus Bioscience, Inc. and several private companies. Previously, he served as a board member of CoTherix, Inc., Durata Therapeutics, Inc., InterMune, Inc. 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, Director: Mr. Kubli has been a member of our board of directors since June 2010. He is a Managing Director and Head of the Portfolio Management of Adamant Biomedical Investments AG, a life science asset management boutique, which is currently being merged with Bellevue Asset Management AG. 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, Zurich/Winterthur, Switzerland.

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.

Berndt A. E. Modig, Director: Mr. Modig has been a member of our board of directors since April 2015. He was the Chief Financial Officer of Prosensa Holding N.V. from March 2010 to January 2015, when Prosensa was acquired by Biomarin Pharmaceutical Inc. From October 2003 to November 2008, he was the Chief Financial Officer of Jerini AG, and held various management positions in its industry, finance and private equity groups. He started his professional career in the auditing practice of Price WaterhouseCoopers. Mr. Modig is a member of the board of directors and the audit committee of Affimed N.V., member of the board of directors and chairman of the audit committee of Axovant Sciences, Ltd., and member of the board of directors of OncobioTek. Mr. Modig is a Certified Public Accountant and holds a B.A. in Business Administration, Economics and German from the University of Lund and an MBA from INSEAD.

Calvin W. Roberts, Director: Dr. Roberts has been a member of our board of directors since April 2015. He is Chief Medical Officer at Bausch + Lomb, which he joined in 2011 and Senior Vice President and Chief Medical Officer, Eye Care at Valeant Pharmaceuticals. He has been a Clinical Professor of Ophthalmology at Weill Medical College of Cornell University since 1982. From 1998 to 2008, he had a private ophthalmology practice in New York City. Dr. Roberts has been a member of the board of directors of Alimera Sciences, Inc. since its foundation in 2003, and served on its audit committee from 2008 to 2012. He is a specialist in cataract and refractive surgery and is a pioneer in the use of ophthalmic non-steroidals. He has authored over 50 peer-reviewed articles.

Board Composition and Election of Directors

Our board of directors is currently composed of seven members, see "Management—Directors and senior management." Each director is elected for a one year term. Our articles of association 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, 2015 to serve until their successors are duly elected and qualified.

We are 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 "Corporate governance."

Committees of the Board of Directors

Audit Committee

The audit committee, which consists of Oliver Kubli, Berndt A. E. Modig and Calvin W. Roberts, assists our board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. In addition, the audit committee is directly responsible for the appointment, compensation, retention and oversight of the work of our independent registered public accounting firm. Mr. Kubli serves as Chairman of the committee. The audit committee consists exclusively of members of our supervisory board who are financially literate, and Mr. Kubli and Mr. Modig are each considered an "audit committee financial expert" as defined by the SEC. Our board of directors has determined that Mr. Kubli, Mr. Modig and Mr. Roberts satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act.

The audit committee is governed by a charter that complies with Nasdaq rules. The audit committee is responsible for, among other things:

- the appointment, compensation, retention and oversight of any auditor or accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit, review or attest services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- reviewing and discussing with the independent auditor its responsibilities under generally accepted auditing standards, the planned scope and timing of the independent auditor's annual audit plan(s) and significant findings from the audit;
- obtaining and reviewing a report from the independent auditor describing all relationships between the independent auditor and the Company consistent with the applicable PCAOB requirements regarding the independent auditor's communications with the audit committee concerning independence;
- confirming and evaluating the rotation of the audit partners on the audit engagement team as required by law;
- reviewing with management and the independent auditor, in separate meetings whenever the Audit Committee deems appropriate, any analyses or other written communications prepared by the Management and/or the independent auditor setting forth significant financial reporting issues and judgments made in connection with the preparation of the financial statements, including analyses of the effects of alternative IFRS methods on the financial statements; and other critical accounting policies and practices of the Company;
- reviewing, in conjunction with the Chief Executive Officer and Chief Financial Officer of the Company, the Company's disclosure controls and procedures and internal control over financial reporting;
- establishing procedures for the receipt, retention and treatment of complaints received by the Company regarding accounting, internal accounting controls or auditing matters, and the confidential, anonymous submission by employees of the Company of concerns regarding questionable accounting or auditing matters;
- approving or ratifying any related person transaction (as defined in our related person transaction policy) in accordance with our related person transaction policy.

The audit committee meets at least four times per year.

Compensation Committee

The compensation committee, which consists of Antoine Papiernik, Wolfgang Arnold and James I. Healy assists our board of directors in overseeing our cash compensation and equity award recommendations for our directors and executive officers along with the rationale for such recommendations, as well as summary information regarding the aggregate compensation provided to our directors and executive officers. Swiss law requires that we adopt a compensation committee, so in accordance with Nasdaq Listing Rule 5615(a)(3), we follow home country requirements with respect to the compensation committee. As a result, our practice varies 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, 2014, 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 1,008,817.

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 63,386 in the year ended December 31, 2014.

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. 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 our initial public offering, we ceased issuing any new grants under Stock Option Plan C and adopted a new omnibus equity incentive plan under which we have the discretion to grant a broad range of equity-based awards to eligible participants.

Equity Incentive Plan

In August 2014, we established the 2014 Plan with the purpose of motivating and rewarding those employees and other individuals who are expected to contribute significantly to our success, and advancing the interests of our shareholders by enhancing our ability to attract, retain and motivate individuals. The maximum number of shares available for issuance under the 2014 Plan (and, if any, under the Prior Plans as described hereinafter) is 1,444,119 common shares as provided in our articles of incorporation. The option exercise price for options under the 2014 Plan is determined by the compensation committee at the time of grant, but shall not be less than the nominal value of a common share on the grant date.

Plan administration. The 2014 Plan is administered by our compensation committee. Approval of the committee is required for all grants of awards under the 2014 Plan. The committee may delegate to one or more officers the authority to grant options and stock appreciation rights, and the committee may delegate to another committee (which may consist of solely one director) the authority to grant all types of awards.

Eligibility. Any employee, consultant or any other individual who provides services to us or any of our affiliates is eligible to be selected to receive an award under the 2014 Plan.

Awards. Awards include options, stock appreciation rights, restricted stock, restricted stock units, performance awards and other stock-based awards.

Vesting period. The committee determines the time or times at which an option becomes vested and exercisable, provided that the minimum vesting period is 12 months. The committee may specify in an award agreement that an "in-the-money" option be automatically exercised on its expiration date. For restricted stock and restricted stock units, the award agreement will specify the vesting schedule and, with respect to restricted stock units, the delivery schedule.

Accelerated vesting. Subject to any additional vesting conditions that may be specified in an individual award agreement, the 2014 Plan provides that upon a change of control of the Company (as defined in the 2014 Plan) the committee may cause options and stock appreciation rights to be cancelled in consideration of full acceleration of the award or a substitute award with equal intrinsic value (as defined in the 2014 Plan). It also provides that the committee may decide, or include in any award agreement, the circumstances in which, and the extent to which, an award may be exercised, settled, vested, paid or forfeited in the event of a participant's termination of service prior to exercise or settlement of an award.

Amendment. Our board of directors has the authority to amend the 2014 Plan subject, in certain circumstances, to required shareholder approval or the consent of an affected participant.

Prior Plans

In 2013 we established Stock Option Plan C, or Plan C, and in 2008 we established Stock Option Plan A, or Plan A and Stock Option Plan B, or 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 December 31, 2014, there were 146,000 common shares underlying outstanding Options granted pursuant to Plan A and 173,750 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 vested and became immediately exercisable upon the closing of our initial public offering.

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

PRINCIPAL SHAREHOLDERS

The following table presents information relating to the beneficial ownership of our common shares as of April 27, 2015, 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 April 27, 2015 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 April 27, 2015 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 April 27, 2015, 14,133,210 common shares, or approximately 48.7%, are held by two holders in the United States. Unless otherwise indicated below, the address for each beneficial owner is Auris Medical Holding AG, Bahnhofstrasse 21, 6300 Zug, Switzerland.

The percentage of common shares beneficially owned is based on 29,018,891 common shares issued and outstanding as of April 27, 2015, which includes 8,500 common shares issued upon exercise of options since December 31, 2014, but excludes 1,435,619 of our common shares covered by additional awards available for future issuance under our amended and restated articles of association. The percentage of common shares beneficially owned after this offering is based on 35,018,891 common shares that will be issued and outstanding upon the completion of this offering, including 8,500 common shares issued upon exercise of options since December 31, 2014.

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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 Venture Partners VIII, L.P. (1)	5,818,175	20.0%	5,818,175	16.6%	16.2%
Sofinnova Capital VII FCPR(2)	5,384,450	18.6%	5,384,450	15.4%	15.0%
Entities affiliated with ZKB(3)	2,169,625	7.5%	2,169,625	6.2%	6.0%
Entities affiliated with Idinvest Partners (4)	2,065,233	7.1%	2,065,233	5.9%	5.7%
Clifton Park Capital Management, LLC (5)	1,666,667	5.7%	1,666,667	4.8%	4.6%
FMR LLC (6)	1,666,667	5.7%	1,666,667	4.8%	4.6%
Executive Officers and Directors					
Thomas Meyer, Ph.D. (11)	6,742,500	23.2%	6,742,500	19.3%	18.8%
Wolfgang Arnold, M.D. (11)	12,500	*	12,500	*	*
James I. Healy, M.D., Ph.D. (7)	5,818,175	20.0%	5,818,175	16.6%	16.2%
Oliver Kubli (8)(11)	2,188,375	7.5%	2,188,375	6.2%	6.1%
Antoine Papiernik (9)	5,384,450	18.6%	5,384,450	15.4%	15.0%
Berndt A. E. Modig	—	—	—	—	—
Calvin W. Roberts (10)	65,242	*	65,242	*	*
Bettina Stubinski, M.D.	25,862	*	25,862	*	*
Sven Zimmermann, Ph.D.	29,019	*	29,019	*	*

* 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 Venture 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 5,384,450 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 Fondsleitung AG, Peter Merian-Strasse 47, 4002 Basel, Switzerland. The address for the AG Funds is c/o Adamant Biomedical Investments AG, Freischützgasse 3, 8004 Zurich, Switzerland. The address for ZKB Pharma Vision Funds is c/o Zurcher Kantonalbank, Bahnhofstrasse 9, 8001 Zurich, Switzerland.

(4) Consists of 805,481 common shares held by Allianz Innovation 8 FCPI; 578,257 common shares held by Idinvest Croissance 2005 FCPI; 454,360 shares held by Allianz Innovation 7 FCPI and 227,135 shares held by La Banque Postale Innovation 3 FCPI. These entities are collectively referred to as the “Idinvest Funds.” Idinvest Partners is the investment management company to 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) Based on a Schedule 13G filed with the SEC on February 13, 2015 by FMR LLC. Members of the family of Edward C. Johnson 3d, Director and Chairman of FMR LLC, including Abigail P. Johnson, Vice Chairman, Chief Executive Officer and President of FMR LLC, are the predominant owners, directly or through trusts, of 49% of the voting power of FMR LLC. FMR LLC reports that members of the Johnson family may be deemed, under the Investment Company Act of 1940, to form a controlling group with respect to FMR LLC. FMR LLC reports that neither FMR LLC nor Edward C. Johnson 3d nor Abigail P. Johnson has the sole power to vote or direct the voting of the shares owned directly by the various investment companies registered under the Investment Company Act (“Fidelity Funds”) advised by Fidelity Management & Research Company (“Fidelity”), a wholly owned subsidiary of FMR LLC, which power resides with the Fidelity Funds’ Boards of Trustees. Fidelity carries out the voting of the shares under written guidelines established

by the Fidelity Funds' Boards of Trustees. FMR LLC reports that the shares it beneficially owns do not reflect securities, if any, beneficially owned by certain other companies whose beneficial ownership of securities is disaggregated from that of its subsidiaries, affiliates and other companies in accordance with Securities and Exchange Commission Release No. 34-39538 (January 12, 1998). The address of FMR LLC and Fidelity is 245 Summer Street, Boston, Massachusetts 02210.

(6) Based on a Schedule 13G filed with the SEC on February 13, 2015 by Clifton Park Capital Management, LLC. The address of Clifton Park Capital Management, LLC is 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808-1645.

(7) Consists of 5,818,175 common shares held by Sofinnova Venture 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.

(8) 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 Fonds Aktien Gesundheit. He disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. Also consists of 18,750 common shares acquired by Mr. Kubli pursuant to the exercise of Plan A options.

(9) Consists of 5,384,450 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.

(10) Consists of 15,242 shares jointly owned by Calvin W. Roberts and Andrea Colvin Roberts. Also consists of 20,000 shares held by Calvin W. Roberts, MD PC Pension Plan, 10,000 shares held by The David Roberts Trust, 10,000 shares held by The Lindsay Roberts Trust and 10,000 shares held by The Joanna Roberts Trust. Calvin Roberts is a trustee for each of Calvin W. Roberts, MD PC Pension Plan, The David Roberts Trust, The Lindsay Roberts Trust and The Joanna Roberts Trust.

(11) Upon the closing of our initial public offering, all 181,000 options outstanding under our Stock Option Plan A vested and became immediately exercisable. Mr. Meyer, Dr. Arnold and Mr. Kubli own 50,000, 18,750 and 6,250 Stock Option Plan A options, respectively.

Significant Changes in Ownership by Major Shareholders

We have experienced significant changes in the percentage ownership held by major shareholders as a result of our initial public offering. Prior to our initial public offering in August 2014, our principal shareholders were Thomas Meyer (34.9%), Sofinnova Venture Partners VIII, L.P. (19.3%), Sofinnova Capital VII FCPR (18.6%), entities affiliated with Zurcher Kantonalbank, Bahnhofstrasse (ZKB) (11.4%) and entities affiliated with Idinvest Partners (9.1%).

In August 2014, we completed our initial public offering and listed our common shares on the Nasdaq Global Market. In the initial public offering, we issued and sold 10,113,325 common shares, including 713,235 common shares sold to the underwriters pursuant to the underwriters' over-allotment option. While none of our existing shareholders sold common shares in the initial public offering, the percentage ownership held by certain shareholders decreased as a result of the issuance of the common shares sold by us in the initial public offering.

RELATED PARTY TRANSACTIONS

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 were converted into 4,636,375 Series C preferred shares, and in connection with our initial public offering, such Series C shares were converted into common 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 to effect the Third Closing was waived by the Company and the Series C investors.

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 Venture 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.

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, which were subsequently converted into common shares in connection with our initial public offering at a one-for-one conversion rate.

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

We have entered into a registration rights agreement with certain of our existing shareholders pursuant to which granted them customary registration rights for the resale of the common shares held by certain of our existing shareholders.

Demand registration rights. Certain of our shareholders that are party to the Registration Rights Agreement (the "RRA Shareholders") are entitled to request that we effect up to an aggregate of two demand registrations under the Registration Rights Agreement, covering the RRA Shareholders' ordinary shares that are subject to transfer restrictions under Rule 144 ("registrable securities"). The demand registration rights are subject to certain customary conditions and limitations, including customary underwriter cutback rights and deferral rights. No demand registration rights exist while a shelf registration is in effect.

Piggyback registration rights. If we propose to register any ordinary shares (other than in a shelf registration or on a registration statement on Form F-4, S-4 or S-8), the RRA Shareholders are entitled to notice of such registration and to include their registrable securities in that registration. The registration of RRA Shareholders' registrable securities pursuant to a piggyback registration does not relieve us of the obligation to effect a demand registration. The managing underwriter has the right to limit the number of registrable securities included in a piggyback registration if the managing underwriter believes it would interfere with the successful marketing of the ordinary shares.

Form F-3 registration rights. When we are eligible to use Form F-3, one or more RRA Shareholders have the right to request that we file a registration statement on Form F-3. RRA Shareholders will have the right to cause us to undertake underwritten offerings from the shelf registration, but no more than one underwritten offering in a six-month period. Each underwritten takedown constitutes a demand registration for purposes of the maximum number of demand registrations we are obligated to effectuate.

Subject to limited exceptions, the Registration Rights Agreement provides that we must pay all registration expenses in connection with a demand, piggyback or shelf registration. The Registration Rights Agreement contains customary indemnification and contribution provisions.

Related Person Transaction Policy

Prior to our initial public offering, we entered into a new related person transaction policy under which any such transaction must be approved or ratified by the audit committee.

Indemnification Agreements

We have entered 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—Compensation—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

Upon the closing of this offering, giving effect to the issuance of the common shares to be sold in this offering, our issued fully paid-in share capital will consist of CHF 14,007,556, divided into common shares with a nominal value of CHF 0.40 each and no preferred shares.

Articles of Association

When we refer to our articles of association in this prospectus, we refer to our amended and restated articles of association adopted on April 8, 2015.

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); and/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; or
- the acquisition of a participation in us by a strategic partner.

Our Authorized Share Capital

Under our articles of association, our board of directors is authorized at any time until June 30, 2016 to increase our share capital by a maximum aggregate amount of CHF 3,314,706 through the issuance of not more than 8,286,765 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 CHF 2,400,000 (or by a larger amount to the extent that any over-allotment shares will be issued).

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 statutory 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 577,647.60 through the issuance of not more than 1,444,119 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 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

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- 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.

Our board of directors have adopted 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 annually votes 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

Our common shares are listed on the Nasdaq Global 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 is currently 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
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
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. 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. Reelection 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: n any breach of a director's duty of loyalty to the corporation or its shareholders; n acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; n statutory liability for unlawful payment of dividends or unlawful stock purchase or redemption; or n any transaction from which the director derived an improper personal benefit. 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. 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
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: - by a majority vote of the directors who are not parties to the proceeding, even though less than a quorum; - by a committee of directors designated by a majority vote of the eligible directors, even though less than a quorum; - by independent legal counsel in a written opinion if there are no eligible directors, or if the eligible directors so direct; or - by the shareholders. 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: - the duty of care; and - the duty of loyalty. 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: - the duty of care; and - the duty of loyalty. 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. 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. The burden of proof for a violation of these duties is with the corporation or with the shareholder bringing a suit against the director. Directors also have an obligation to treat shareholders equally proportionate to their share ownership.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
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.	
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: 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 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. Any shareholder can propose candidates for election as directors without prior written notice. 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
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

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
	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.
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: n out of its surplus, or 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. 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. 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 shareholders' 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

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, we will have 35,018,891 common shares outstanding assuming no exercise of the underwriters' option to purchase additional common shares. Of these shares, 16,177,616 common shares, or 17,077,616 common shares if the underwriters exercise their option in full to purchase additional common shares, 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 18,841,275 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. After the expiration of the contractual lock-up periods described below, these common shares may be sold in the public market only if registered or pursuant to an exemption under Rules 144 or 701, which are summarized below.

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, and in compliance with certain of, 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 350,189 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 Nasdaq Global Market 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, and in compliance with certain of, the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales must 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 have entered into a registration rights agreement with certain of our existing shareholders pursuant to which we agreed 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 certain other holders of our common shares 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 90 days (in the case of our directors and executive officers) and 60 days (in the case of the other holders of our common shares that have agreed to enter into lock-up agreements) after the date of this prospectus, subject to certain exceptions, without the prior written consent of 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. In the treaty with Austria, the flat-rate tax withheld substitutes the ordinary capital gains tax and income tax on the relevant capital gains and income items, so far as the Austrian income tax law foresees such substitutive effect. Under the treaty with the UK, the flat-rate tax withheld substitutes the ordinary capital gains tax and income tax on the relevant capital gains and income items, 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. Alternatively, instead of paying the flat-rate tax, such individuals may opt for a disclosure of 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 recognize 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 recognize 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 CHF 1 million or 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 U.S. federal income 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, as amended, 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 and 2014 taxable years, 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, 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 preferential 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

As discussed above under "Dividend Policy," we do not currently expect to make distributions on our common shares. In the event that we do make distributions of cash or other property, 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). 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.

As discussed above under "Passive Foreign Investment Company Rules," we expect to be a PFIC, and, as a result, the preferential dividend rate with respect to dividends paid to certain non-corporate U.S. Holders 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 may 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 PFIC 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.

UNDERWRITING

Leerink Partners LLC is acting as representative of each of the underwriters named below and as sole bookrunning manager for this offering. Subject to the terms and conditions set forth in the underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of common shares set forth opposite its name below.

UNDERWRITER	NUMBER OF SHARES
Leerink Partners LLC	
JMP Securities LLC	
Needham & Company, LLC	
LifeSci Capital LLC	
Total	6,000,000

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of the shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officers' certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representative has advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering of the shares, the public offering price, concession or any other term of the offering may be changed by the representative.

The following table shows the public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their over-allotment option.

		TOTAL	
	PER SHARE	WITHOUT OVER-ALLOTMENT OPTION	WITH OVER-ALLOTMENT OPTION
Public offering price	$	$	$
Underwriting discounts and commissions	$	$	$
Proceeds, before expenses, to us	$	$	$

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately $0.7 million. We also have agreed to reimburse the underwriters for up to $30,000 for their FINRA counsel fee. In accordance with FINRA Rule 5110, this reimbursed fee is deemed underwriting compensation for this offering.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 900,000 additional shares at the public offering price, less the underwriting discounts and commissions cover

over-allotments, if any. If the underwriters exercise this option, each underwriter will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

No Sales of Similar Securities

Subject to certain exceptions, we, our executive officers and directors have agreed not to sell or transfer any common shares or securities convertible into or exchangeable or exercisable for common shares, for 90 days after the date of this prospectus and certain of our other existing shareholders have agreed not to sell or transfer any common shares or securities convertible into or exchangeable or exerciseable for common shares, for 60 days after the date of this prospectus, in each case without first obtaining the written consent of Leerink Partners LLC on behalf of the underwriters. Specifically, we and these other persons have agreed, with certain limited exceptions, not to directly or indirectly:

- offer, pledge, sell or contract to sell any common shares;
- sell any option or contract to purchase any common shares;
- purchase any option or contract to sell any common shares;
- grant any option, right or warrant for the sale of any common shares;
- otherwise dispose of or transfer any common shares;
- request or demand that we file a registration statement related to the common shares; or
- enter into any swap or other agreement or any transaction that transfers, in whole or in part, the economic consequence of ownership of any common shares, whether any such swap, agreement or transaction is to be settled by delivery of shares or other securities, in cash or otherwise.

This lock-up provision applies to common shares and to securities convertible into or exchangeable or exercisable for common shares. It also applies to common shares owned now or acquired later by the person executing the agreement or for which the person executing the agreement later acquires the power of disposition. The foregoing restrictions, however, will not apply to the filing by us of any registration statement that we are required to file pursuant to our registration rights agreement with certain of our shareholders.

NASDAQ Global Market Listing

Our common shares are listed on The NASDAQ Global Market under the symbol "EARS."

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common shares. However, the representative may engage in transactions that stabilize the price of the common shares, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common shares in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option described above. The underwriters may close out any covered short position by either exercising their option or purchasing 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 granted to them. "Naked" short sales are sales in excess of such option. 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 our common shares in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common shares made by the underwriters in the open market prior to the closing of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representative has repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' 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. The underwriters may conduct these transactions on The NASDAQ Global Market, in the over-the-counter market or otherwise.

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. In addition, neither we nor any of the underwriters make any representation that the representative will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

The underwriters may also engage in passive market making transactions in our common shares on The NASDAQ Global Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers of sales 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

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and certain of their 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. Some of the underwriters and certain of their affiliates may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us and our affiliates, for which they may in the future receive customary fees, commissions and expenses. An affiliate of LifeSci Capital LLC, an underwriter in this offering, has provided in the past, and will continue to provide in the future, consulting services to us and has received, and will receive, customary fees for its services.

In addition, in the ordinary course of their business activities, the underwriters and their 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.

Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may 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.

Canada

The offering of the common shares in Canada is being made on a private placement basis in reliance on exemptions from the prospectus requirements under the securities laws of each applicable Canadian province and territory where the common shares may be offered and sold, and therein may only be made with investors that are purchasing as principal and that qualify as both an “accredited investor” as such term is defined in National Instrument 45-106 Prospectus and Registration Exemptions and as a “permitted client” as such term is defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligation. Any offer and sale of the common shares in any province or territory of Canada may only be made through a dealer that is properly registered under the securities legislation of the applicable province or territory wherein the common shares are offered and/or sold or, alternatively, by a dealer that qualifies under and is relying upon an exemption from the registration requirements therein.

Any resale of the common shares by an investor resident in Canada must be made in accordance with applicable Canadian securities laws, which may require resales to be made in accordance with prospectus and registration requirements, statutory exemptions from the prospectus and registration requirements or under a discretionary exemption from the prospectus and registration requirements granted by the applicable Canadian securities regulatory authority. These resale restrictions may under certain circumstances apply to resales of the common shares outside of Canada.

Upon receipt of this document, each Canadian investor hereby confirms that it has expressly requested that all documents evidencing or relating in any way to the sale of the securities described herein (including for greater certainty any purchase confirmation or any notice) be drawn up in the English language only. *Par la réception de ce document, chaque investisseur canadien confirme par les présentes qu’il a expressément exigé que tous les documents faisant foi ou se rapportant de quelque mani’ ere que ce soit à la vente des valeurs mobilières décrites aux présentes (incluant, pour plus de certitude, toute confirmation d’achat ou tout avis) soient rédigés en anglais seulement.*

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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	$ 4,067
Nasdaq listing fee	7,500
FINRA filing fee	5,750
Printing and engraving expenses	150,000
Legal fees and expenses	310,400
Accounting fees and expenses	196,300
Total	$674,017

All amounts in the table are estimates except the U.S. Securities and Exchange Commission registration fee, the Nasdaq 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.

EXPERTS

The consolidated financial statements of Auris Medical Holding AG as of and for the year ended December 31, 2014, included in this prospectus and the registration statement, have been audited by Deloitte AG, an independent registered public accounting firm, as stated in their report appearing herein. Such consolidated financial statements have been included in reliance upon the report of such firm, given upon their authority as experts in accounting and auditing.

The current address of Deloitte AG is General Guisan-Quai 38, 8002 Zurich, Switzerland, phone number + (41) 58 279 60 00.

The consolidated financial statements of Auris Medical Holding AG (formerly Auris Medical AG) as of December 31, 2013 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.

References to the market research survey prepared by MEDACorp, Inc. have been included in this prospectus in reliance on the survey, given on the authority of MEDACorp. Inc.

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.

We are subject to the informational requirements of the Exchange Act. Accordingly, we are 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 are not 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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Audited Consolidated Financial Statements—Auris Medical Holding AG (formerly Auris Medical AG)

As at December 31, 2014 and 2013 and for the years ended December 31, 2014, 2013, and 2012

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Auris Medical Holding AG (formerly: Auris Medical AG)

We have audited the accompanying consolidated statement of financial position of Auris Medical Holding AG and its subsidiaries (the "Company") as of December 31, 2014, and the related consolidated statements of profit or loss and other comprehensive loss, changes in equity, cash flows, and notes for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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 Holding AG and its subsidiaries as of December 31, 2014, and the results of its operations, cash flows, and notes for the year ended, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Deloitte AG

/s/ James D. Horiguchi
Partner
Auditor in Charge

/s/ Matthias Gschwend
Director

Zurich, Switzerland
March 30, 2015

Report of Independent Registered Public Accounting Firm

The Board of Directors
Auris Medical AG:

We have audited the accompanying consolidated statement of financial position of Auris Medical AG and subsidiaries (the "Company") as of December 31, 2013, and the related consolidated statements of profit or loss and other comprehensive loss, 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, 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 HOLDING AG (formerly Auris Medical AG)

Consolidated Statement of Profit or Loss and Other Comprehensive Loss
For the Years Ended December 31, 2014, 2013 and 2012
(in CHF)

	NOTE	2014	2013	2012
Research and development	17	-17,704,461	-13,253,638	-3,986,691
General and administrative	18	-4,489,051	-1,362,211	-623,812
Operating loss		**-22,193,512**	**-14,615,849**	**-4,610,503**
Finance expense	20	-207,825	-158,641	-1,800
Finance income	20	4,216,322	75,747	9,894
Loss before tax		**-18,185,015**	**-14,698,743**	**-4,602,409**
Income tax expense	21	—	-305,750	—
Net loss attributable to owners of the Company		**-18,185,015**	**-15,004,493**	**-4,602,409**
Other comprehensive loss:				
Items that will never be reclassified to profit or loss*				
Remeasurements of defined benefit liability, net of taxes of CHF 0	19	-1,101,468	-57,716	-54,577
Items that are or may be reclassified to profit or loss				
Foreign currency translation differences, net of taxes of CHF 0		-105,104	31,720	22,275
Other comprehensive loss, net of taxes of CHF 0*		**-1,206,572**	**-25,996**	**-32,302**
Total comprehensive loss attributable to owners of the Company		**-19,391,587**	**-15,030,489**	**-4,634,711**
Basic and diluted loss per share	22	-0.66	-1.01	-0.40

* the net effect of taxes was CHF 0 for 2013 and 2012

The accompanying notes form an integral part of these consolidated financial statements.

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AURIS MEDICAL HOLDING AG (formerly Auris Medical AG)

Consolidated Statement of Financial Position
As of December 31, 2014 and 2013
(in CHF)

	NOTE	DECEMBER 31, 2014	DECEMBER 31, 2013
ASSETS			
Non-current assets			
Property and equipment	7	235,427	195,915
Intangible assets	8	1,482,520	1,482,520
Deferred Tax Asset	21	32,761	—
Total non-current assets		**1,750,708**	**1,678,435**
Current assets			
Other receivables	9	542,538	524,786
Prepayments	10	265,170	183,137
Cash and cash equivalents	11	56,934,325	23,865,842
Total current assets		**57,742,033**	**24,573,765**
Total assets		**59,492,741**	**26,252,200**
EQUITY AND LIABILITIES			
Equity			
Share capital	12	11,604,156	6,487,130
Share premium		93,861,171	35,608,210
Foreign currency translation reserve		-51,108	53,995
Accumulated deficit		-52,131,426	-33,115,689
Total shareholders' equity attributable to owners of the Company		**53,282,793**	**9,033,646**
Non-current liabilities			
Employee benefits	19	1,410,598	328,342
Deferred tax liabilities	21	360,398	327,637
Total non-current liabilities		**1,770,996**	**655,979**
Current liabilities			
Convertible loans	14	—	13,711,200
Trade and other payables	15	3,234,384	954,257
Accrued expenses	16	1,204,568	1,897,118
Total current liabilities		**4,438,952**	**16,562,575**
Total liabilities		**6,209,948**	**17,218,554**
Total equity and liabilities		**59,492,741**	**26,252,200**

The accompanying notes form an integral part of these consolidated financial statements.

AURIS MEDICAL HOLDING AG (formerly Auris Medical AG)

Consolidated Statement of Changes in Equity
For the Years Ended December 31, 2014, 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		—	3,335,763	—	—	—	3,335,763
Share based payments		—	—	—	—	56,013	56,013
Treasury shares sold		—	—	526,320	—	—	526,320
Balance at December 31, 2012		**4,632,580**	**13,341,942**	**—**	**22,275**	**-18,240,831**	**-244,034**
As of January 1, 2013		**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		1,854,550	22,625,510	—	—	—	24,480,060
Share issuance costs		—	-359,242	—	—	—	-359,242
Convertible loans - equity component	14	—	—	—	—	99,038	99,038
Convertible loans - deferred tax	14	—	—	—	—	-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**
As of January 1, 2014		**6,487,130**	**35,608,210**	**—**	**53,995**	**-33,115,689**	**9,033,646**
Total comprehensive loss							
Net loss		—	—	—	—	-18,185,015	-18,185,015
Other comprehensive loss		—	—	—	-105,104	-1,101,468	-1,206,572
Total comprehensive loss		**—**	**—**	**—**	**-105,104**	**-19,286,483**	**-19,391,587**
Transactions with owners of the Company							
Issue of ordinary shares associated with Initial Public Offering ("IPO")	12	4,045,294	47,261,446	—	—	—	51,306,740
Issuance costs associated with IPO	12	—	-1,815,056	—	—	—	-1,815,056
Conversion of convertible loan	14	1,043,180	12,717,655	—	—	—	13,760,835
Share issuance costs		—	-136,697	—	—	—	-136,697
Share based payments	13	—	—	—	—	270,747	270,747
Share options exercised	13	28,552	225,613	—	—	—	254,165
Balance at December 31, 2014		**11,604,156**	**93,861,171**	**—**	**-51,109**	**-52,131,426**	**53,282,793**

The accompanying notes form an integral part of these consolidated financial statements.

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AURIS MEDICAL HOLDING AG (formerly Auris Medical AG)

Consolidated Statement of Cash Flows
For the Years Ended December 31, 2014, 2013 and 2012
(in CHF)

	NOTE	2014	2013	2012
Cash flows from operating activities				
Net loss		**-18,185,015**	**-15,004,493**	**-4,602,409**
Adjustments for:				
Depreciation	17,18	73,984	37,517	9,242
Unrealized Net foreign currency exchange (gains) loss		-4,066,452	32,076	20,920
Net interest income	20	-2,498	-23,859	-5,825
Share option costs	13	270,747	110,198	56,013
Employee benefits		-19,211	27,980	9,545
Income tax expense	21	—	305,750	0
		-21,928,445	-14,514,831	-4,512,514
Changes in:				
Other receivables		-17,634	-288,765	-125,782
Prepayments		-82,033	-98,812	-15,659
Trade and other payables		2,279,626	530,080	254,063
Accrued expenses		432,449	328,719	-98,575
Cash used in operating activities		**-19,316,037**	**-14,043,609**	**-4,498,467**
Cash flows from investing activities				
Purchase of property and equipment	7	-113,496	-108,936	-131,751
Purchase of intangibles		-1,125,000	—	—
Sale of financial asset		—	—	72,850
Interest received	20	52,133	74,036	5,825
Net cash used in investing activities		**-1,186,363**	**-34,900**	**-53,076**
Cash flows from financing activities				
Proceeds from share capital increase	13	—	24,120,818	3,335,762
Proceeds from exercise of options	13	254,165	—	—
Share issuance costs		-136,697	—	—
Proceeds from issue of convertible loans	14	—	13,769,976	—
Proceeds from IPO, net (net of underwriting fees and IPO costs)	12	50,037,847	—	—
Share issuance costs IPO	12	-546,163	—	—
Sale of treasury shares		—	—	526,320
Interest paid	20	—	-9,915	—
Net cash from financing activities		**49,609,152**	**37,880,879**	**3,862,082**
Net increase in cash and cash equivalents		**29,106,752**	**23,802,370**	**-689,461**
Cash and cash equivalents at beginning of the period		23,865,842	63,967	752,874
Net effect of currency translation on cash		3,961,731	-495	554
Cash and cash equivalents at end of the period		**56,934,325**	**23,865,842**	**63,967**

The accompanying notes form an integral part of these consolidated financial statements.

AURIS MEDICAL HOLDING AG (FORMERLY AURIS MEDICAL AG)

Notes to the Consolidated Financial Statements
as of December 31, 2014, 2013
and for the Years Ended December 31, 2014, 2013 and 2012 (in CHF)

1. Reporting entity

Auris Medical Holding AG (the "Company") is domiciled in Switzerland. The Company's registered address is Bahnhofstrasse 21, 6300 Zug. 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 AG, Basel, Switzerland (100%)
- Otolanum AG, Zug, Switzerland (100%)
- Auris Medical Inc., Chicago, United States (100%)
- Auris Medical Ltd., Dublin, Ireland (100%)

On April 22, 2014, we changed our name from Auris Medical AG to Auris Medical Holding AG. On May 21, 2014 the domicile of Auris Medical Holding AG was transferred from Basel to Zug.

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 consolidated financial statements were approved by the Board of Directors of the Company on March 30, 2015.

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. Historical cost is generally based on the fair value of the consideration given in exchange for goods and services. The principal accounting policies adopted are set out below.

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 IFRS 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 prior to expiry of such losses. The Group also has tax losses in the United States which may be used within 20 years of the end of the year in which losses arose, or 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 as to whether costs incurred for the Group's development projects can be capitalized. 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. Given the current stage of the Group's 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.

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 Company makes relevant actuarial assumptions with regard to the discount rate, future salary increases and life expectancy.

3. Significant accounting policies

The accounting policies set out below have been applied consistently to all periods presented in these consolidated financial statements, unless otherwise indicated.

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"). The CODM 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.

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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 Loss 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, 2014	DECEMBER 31, 2013	DECEMBER 31, 2012
CHF	Swiss Franc	Switzerland	3/1*	1.0000	1.0000	1.0000
USD	Dollar	United States	1	0.9895	0.8894	0.9154
EUR	Euro	Europe	1	1.2027	1.2255	1.2068

* There were three operating entities in 2014 and one operating entity in each of 2013 and 2012.

Average exchange rates for the year for the most significant foreign currencies:

CURRENCY		GEOGRAPHICAL AREA	REPORTING ENTITIES	2014	2013	2012
CHF	Swiss Franc	Switzerland	3/1*	1.0000	1.0000	1.0000
USD	Dollar	United States	1*	0.9150	0.9391	0.9481
EUR	Euro	Europe	1*	1.2144	1.2414	1.2196

* There were three operating entities in 2014 and one operating entity in each of 2013 and 2012.

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 Group's research programs 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 in 2013 and 2014. Intellectual property-related costs for patents are part of the expenditure for 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 commence once the Group's intangible assets are 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 statement of financial position 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 classification depends on the nature and purpose of the financial assets and is determined at the time of initial recognition.

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 other comprehensive loss. 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 component parts of convertible loans issued by the Company are classified separately as financial liabilities and equity in accordance with the substance of the contractual arrangement. At the date of issue, the fair value of the liability component is estimated using the prevailing market interest rate for a similar non-convertible instrument. This amount is recorded as a liability on an amortized cost basis using the effective interest method until extinguished upon conversion or at the instrument's maturity date. The equity component is determined by deducting the amount of the liability component from the fair value of the compound instrument as a whole. This is recognized and included in equity, net of income tax effects, and is not subsequently remeasured.

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, the Group assesses at the end of each reporting period whether there is objective evidence of impairment including a significant or prolonged decline in its fair value below its cost. An equity security is impaired and impairment losses are incurred only if there is objective evidence of impairment as a result of one or more events that occurred after the initial recognition of the asset (a "loss event") and that loss event (or events) has an impact on the estimated future cash flows of the financial asset or group of financial assets that can be reliably estimated.

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 reporting 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 when there is a legally enforceable right to set off tax assets against tax liabilities and when they relate to income taxes levied by the same taxation authority and the Group intends to settle its tax assets and liabilities on a net basis.

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 Group's 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 as well as two and three years for 50% of an option award under the Company's Equity Incentive Plan. Stock Option Plan B was created to provide shares for share based compensation plans; it was used in the years 2008, 2009 and 2014 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. 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.

Following the completion of our initial public offering, option pricing and values are determined based on quoted market prices of our common shares.

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 owners of the 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 owners of the Company by the weighted average number of shares outstanding during the period adjusted for the conversion of all dilutive potential ordinary shares.

4. New standards, amendments and interpretations adopted by the group

In the current year, the following revised standards have been adopted in these financial statements. Adoption has not had a significant impact on the amounts reported in these financial statements but may impact the accounting for future transactions and arrangements.

Amendments to IAS 32 (December 2011) Offsetting financial assets and financial liabilities

Amendments to IAS 36 (May 2013) Recoverable Amount Disclosures for Non-Financial Assets

Amendments to IAS 39 (Jun 2013) Novation of Derivatives and Continuation of Hedge Accounting

Amendments to IFRS 10, IFRS 12 and IAS 27 (Oct 2012) Investment Entities

IFRIC 21 Levies (May 2013)

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A number of new standards, amendments to standards and interpretations are effective for annual periods beginning after January 1, 2015, 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 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, 2016	To be determined
IFRS 14	Regulatory Deferral Accounts	2)	January 1, 2016	To be determined
IFRS 15	Revenue from contract with customers	2)	January 1, 2017	To be determined
IFRS 11 amendment	Joint Arrangement	2)	January 1, 2016	To be determined
IAS 16 & 38	Property Plant and Equipment, Intangible Assets	2)	January 1, 2016	To be determined
IAS 16 & 41 amendments	Property Plant and Equipment, Agriculture	2)	January 1 2016	To be determined
IAS 27 amendments	Consolidated and Separate Financial Statements	2)	January 1 2016	To be determined
Various	Annual Improvements to IFRSs:2012-2014 Cycle	2)	January 1 2016	To be determined
IFRS 10,12, & 28 amendments	Consolidated Financial Statements, Disclosure of Interests in Other Entities	2)	January 1 2016	To be determined
IAS 1 amendments	Presentation of Financial Statements	2)	January 1 2016	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, 2014	DECEMBER 31, 2013
Financial assets		
Available for sale		
Current financial assets	—	—
Loans and receivables		
Cash and cash equivalents	56,934,325	23,865,842
Other receivables	451,355	451,206
Total financial assets	**57,385,680**	**24,317,048**
Financial liabilities		
At amortized cost		
Convertible loans from shareholders	—	13,711,200
Trade and other accounts payable	3,234,383	954,257
Accrued expenses	1,162,988	1,871,598
Total financial liabilities	**4,397,371**	**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 due to the short term nature of these instruments.

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 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 2014 and 2013 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 issuance 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 December 31, 2014 and 2013. 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, 2014					
Convertible loans from shareholders	—	—	—	—	—
Trade and other accounts payable	3,234,383	3,234,383	—	—	3,234,383
Accrued expenses	1,162,988	1,162,988	—	—	1,162,988
Total	**4,397,371**	**4,397,371**	**—**	**—**	**4,397,371**

	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**

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. Other receivables were current as of December 31, 2014 and December 31, 2013, 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, 2014	DECEMBER 31, 2013
Financial assets		
Cash and cash equivalents	56,934,325	23,865,842
Other receivables	451,355	451,206
Total	**57,385,680**	**24,317,048**

As of December 31, 2014 and December 31, 2013 other receivables consisted of advance payments to suppliers, and deposits for rent (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:

	2014		2013	
in CHF	**USD**	**EUR**	**USD**	**EUR**
Prepayments	183,779	11,489	11,321	112,133
Other receivables	145,636	267,533	145,636	273,438
Cash and cash equivalents	46,433,371	1,949,684	4,267,768	2,309,318
Trade and other accounts payable	-1,686,733	-1,238,171	-334,896	-502,645
Accrued expenses	-354,397	-590,001	-219,304	-435,046
Net statement of financial position exposure - asset/(liability)	**44,721,656**	**400,534**	**3,870,525**	**1,757,198**

As at December 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 2,212,604 (2013: CHF 175,115) 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 24,086 (2013: CHF 107,672) 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, 2014 an increase or decrease in interest rates by 50 basis points with all other variables held constant would have resulted in a CHF 169,455 (2013: CHF 119,329) increase or decrease in the net result.

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, 2014	DECEMBER 31, 2013
Switzerland	1,750,708	1,678,435
Total	**1,750,708**	**1,678,435**

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, 2013	**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**
Additions	63,499	49,997	—	113,496
As at December 31, 2014	**230,249**	**182,042**	**17,132**	**429,423**
Accumulated depreciation				
As at January 1, 2013	**-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**
Charge for the year	-42,230	-28,251	-3,503	-73,984
As at December 31, 2014	**-73,592**	**-114,539**	**-5,865**	**-193,996**
Net book value				
As at December 31, 2013	**135,388**	**45,757**	**14,770**	**195,915**
As at December 31, 2014	**156,657**	**67,502**	**11,267**	**235,427**

As at December 31, 2014, and 2013 no items of property and equipment were pledged.

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8. Intangible assets

	LICENSES
At cost	
As at January 1, 2013	**357,520**
Additions	1,125,000
As at December 31, 2013	**1,482,520**
As at December 31, 2014	**1,482,520**
Accumulated amortization and impairment losses	
As at December 31, 2013	**—**
As at December 31, 2014	**—**
Net book value	
As at December 31, 2013	**1,482,520**
As at December 31, 2014	**1,482,520**

Intangible assets comprise upfront and milestone payments related to licenses. In 2013 a milestone of CHF 1,125,000 related to the AM-111 program was recorded. Amortization will commence once the intangible assets are available for use, which will be the case after regulatory approvals are obtained and the related products are available for use.

No amortization or impairment was recorded in 2014, 2013 and 2012.

9. Other receivables

	DECEMBER 31, 2014	DECEMBER 31, 2013
Advance payments to suppliers	413,169	413,169
Value added tax receivable	74,065	47,714
Withholding tax receivable	17,118	25,866
Deposit for rent	38,066	38,037
Other	120	—
Total other receivables	**542,538**	**524,786**

Other receivables were not considered impaired in the years under review.

10. Prepayments

	DECEMBER 31, 2014	DECEMBER 31, 2013
Clinical projects and related activities	85,299	114,076
Insurance	179,871	4,323
Social charges	—	22,450
Capital taxes	—	32,910
Other	—	9,378
Total prepayments	**265,170**	**183,137**

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11. Cash and cash equivalents

	DECEMBER 31, 2014	DECEMBER 31, 2013
Cash in bank accounts	56,932,993	23,865,165
Petty cash	1,332	677
Total cash and cash equivalents	**56,934,325**	**23,865,842**

12. Capital and reserves

Share capital

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 25:1 stock split. All shares are fully paid in.

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 the Company at December 31 consisted of:

	DECEMBER 31, 2014		DECEMBER 31, 2013	
	NUMBER	CHF	NUMBER	CHF
Common shares with a nominal value of CHF 0.40 each	29,010,391	11,604,156	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	**29,010,391**	**11,604,156**	**16,217,825**	**6,487,130**

	COMMON SHARES (NUMBER)		PREFERRED SHARES (NUMBER)	
	2014	2013	2014	2013
As of January 1	72,600	72,600	16,145,225	11,508,850
Common share stock options with a nominal value of CHF 0.40 each	71,381	—	—	—
Shares issued for cash	—	—	—	4,636,375
Preferred shares C issued for conversion of convertible loans with a nominal value of CHF 0.40 each	—	—	2,607,950	—
Common share issued for the IPO with a nominal value of CHF 0.40 each cash	10,113,235	—	—	—
Common share issued with a nominal value of CHF 0.40 each resulting from conversion of preference shares at the IPO	18,753,175	—	-18,753,175	—
Total, as at December 31	**29,010,391**	**72,600**	**—**	**16,145,225**

IPO on NASDAQ Global Market

In August, 2014, the Company completed its IPO issuing 10,113,235 shares, including the underwriter's overallotment option, yielding total net proceeds of CHF 51.3 million (USD 56.4 million). Offering costs associated with the IPO were CHF 2,091,259. As of March 31, 2014, management determined that successful completion of the IPO was not deemed to be more likely than not, thus CHF 822,367 was expensed in the first quarter of 2014.

Following the IPO there were 28,954,510 common shares of the Company outstanding. At December 31, 2014 there were 29,010,391 shares outstanding due to exercise of options.

Pursuant to the agreements related to the preferred shares, all preferred shares outstanding at the time of the IPO converted automatically into common shares at the ratio of 1:1 upon consummation of the IPO.

Issuance of common shares upon exercise of options

In 2014, a total of 50,500 stock options were exercised under Stock Option Plan A at an exercise price of CHF 3.20 per common share with a nominal value of CHF 0.40. This resulted in an increase in the share capital of CHF 20,200. Total proceeds from the exercise to the Company were CHF 161,600.

Issuance of common shares with restrictions

In 2014, 20,881 restricted common shares with a nominal value of CHF 0.40 each were issued under Stock Option Plan B for the purpose of share based bonus payments. This resulted in a further increase in share capital of CHF 8,352 and proceeds to the Company of CHF 92,565. The shares will vest December 31, 2017.

Issuance of preferred shares

In April 2013, 4,636,375 preferred shares Series C with a nominal value of CHF 0.40 each were issued at CHF 5.28 per share.

In January 2014, a convertible loan was converted into 2,607,950 preferred shares Series C with a nominal value of CHF 0.40 at a conversion price of CHF 5.28 each. See Note 14.

Authorized share capital

Prior to the IPO, the Company's authorized share capital consisted of common shares and preferred shares. Preferred shares (Series A, B, and C) had the same voting rights and dividend rights as common shares but enjoyed a liquidation preference.

In April 2013, the shareholders approved an extension and increase of the authorized capital of the Company. The Board was authorized to increase the share capital at any time until April 5, 2015, by the maximum amount of CHF 1,715,450 by issuing no more than 4,288,625 registered preferred shares Series C with a nominal value of CHF 0.40 each. These shares had to be fully paid-in and had the same preference rights as Series C shares.

In August 2014, 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 June 30, 2016 by the maximum amount of CHF 3,314,706 by issuing not more than 8,286,765 registered shares with a nominal value of CHF 0.40 each. The shares will have to be fully paid-in.

Conditional share capital

The share capital may be increased by the issuance of up to 1,500,000 fully paid registered Common Shares with a nominal value of CHF 0.40 per share and to the maximum amount of CHF 600,000 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). As of December 31, 2014, 55,881 share options had been exercised to reduce the available share capital.

The Company's share capital may be further increased by the issuance of up to 5,000,000 fully paid registered Common Shares with a nominal value of CHF 0.40 per share and to the maximum amount of CHF 2,000,000 in execution of conversion rights in connection with warrants and convertible bonds of the Company

13. Share based compensation

Description

On November 21, 2008, one of the Company's subsidiaries established share option programs ("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. Stock Option 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 Stock Option Plan A and subsequently under Stock Option Plan C were offered in each year with vesting periods of three and four years; grants under Plan B were made in 2008, 2009 and 2014 only. In 2014, the Group introduced a further stock option plan, the Equity Incentive Plan.

The Company granted 20,881 shares (2013 & 2012: 0) to employees under Stock Option Plan B in 2014. The options were exercised on the grant date. There were no Stock Option Plan B options outstanding as of December 31, 2014, or December 31, 2013. The exercise price for the 2014 awards was CHF 4.43 per share and resulted in a total payroll charge of CHF 92,565 (2013 & 2012: 0).These shares vested immediately and have sale restriction for a period of 3 years. The fair value of the shares was defined in the pre-IPO Phase based on DCF-valuation and historical shares transactions and discounted for the fact the shares cannot be sold during the restriction period of three years.

In accordance with all of these programs, holders of vested options are entitled to purchase common shares of the Company at an exercise price equal to the value per share at the most recent financing round or the publicly quoted market price of the Company shares at the day of grant. 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:

PLAN	NUMBER OF INSTRUMENTS AWARDED (1)	VESTING CONDITIONS	CONTRACTUAL LIFE OF OPTIONS
Stock option plan A	236,500	3 years' service from grant date	5 years
Stock option plan B	93,231	Immediately	3 months
Stock option plan C	173,750	4 years' service from grant date	6 years
Equity Incentive Plan	99,260	2 years' service from grant date (50%), 3 years' service from grant date (50%)	8 years

(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		
	EQUITY INCENTIVE PLAN 2014	PLAN C 2014 (CHF)	PLAN C 2013 (CHF)	PLAN A 2013 (CHF)
Fair value at grant date	USD 1.572 (2 years vesting); USD 1.902 (3 year vesting)	3.03	3.03	2.43
Share price at grant date	USD 3.92	5.28	5.28	4.80
Exercise price	USD 4.05	5.28	5.28	4.80
Expected volatility	74%	74%	78%	78%
Expected life	2 and 3 years	4 years	4 years	3 years
Expected dividends	—	—	—	—
Risk-free interest rate	2.22%	0.96%	1.0%	1.0%

The Company has historically been a private company and only recently started trading publicly. Therefore the Company lacks significant Company-specific historical and implied volatility information. The Company estimates our expected volatility based on comparable public company data. The expected life of all options is assumed to correspond to the vesting period.

The total expense recognized for equity-settled share-based payment transactions were CHF 56,013 in 2012, CHF 110,198 in 2013 and CHF 270,747 in 2014.

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The number and weighted average exercise prices (in CHF) of options under the share option programs for Plan A, Plan C and the Equity Incentive Plan are as follows:

	2014			2013			2012		
	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING TERM	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING TERM	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED AVERAGE REMAINING TERM
Outstanding at January 1	272,750	4.32	3.64	146,500	3.66	3.29	109,000	3.20	3.70
Forfeited during the year	—	—	—	—	—	—	-10,000	4.00	—
Exercised during the year	50,500	3.20		—	—	—	—	—	—
Granted during the year	196,760	4.64	6.71	126,250	5.09	5.24	47,500	4.80	4.77
Outstanding at December 31	**419,010**	**4.61**	**4.86**	**272,750**	**4.32**	**3.64**	**146,500**	**3.66**	**3.29**
Exercisable at December 31	146,000	4.21	2.33	69,000	3.20	1.12	38,000	3.20	1.60

The range of exercise prices for outstanding options was CHF 3.20 to CHF 5.28 as of December 31, 2014, CHF 3.20 to CHF 5.28 as of December 2013, and CHF 3.20 to CHF 4.80 as of December 2012.

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 had the right to convert the loans into new registered preferred shares Series C with a nominal value of CHF 0.40 each for CHF 5.28 per share. In case of non-conversion, the Company had the right to repay the convertible loans any time after February 1, 2014, and the obligation to repay by 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, was included in shareholders’ equity as a transaction with a shareholder in its capacity as shareholder. Subsequent to initial recognition, the convertible loan was measured at amortized cost using the effective interest method.

Convertible loan notes recognized in the December 31, 2013 statement of financial position were calculated as follows:

	DECEMBER 31, 2013
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**

On January 27, 2014, the loans were converted into new preferred shares Series C with a nominal value of CHF 0.40 each for CHF 5.28 per share. The Company issued 2,607,950 preferred shares Series C associated with this conversion.

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.

	DECEMBER 31, 2014
Convertible loans balance at January 1, 2014	13,711,200
Loss on de-recognition	9,141
Imputed interest expense	49,635
De-recognition of liability at conversion into equity	13,769,976
Convertible loans at December 31	**—**

15. Trade and other payables

	DECEMBER 31, 2014	DECEMBER 31, 2013
Trade accounts payable - third parties	3,141,194	946,215
Other	93,190	8,042
Total trade and other payables	**3,234,384**	**954,257**

16. Accrued expenses

	DECEMBER 31, 2014	DECEMBER 31, 2013
Accrued research and development costs including milestone payments	949,561	1,791,638
Professional fees	178,000	57,950
Accrued vacation & overtime	41,580	25,520
Board of Directors fees	32,056	9,836
Social security	—	10,700
Other	3,371	1,474
Total accrued expenses	**1,204,568**	**1,897,118**

17. Research and development expense

	2014	2013	2012
Pre-clinical projects	1,160,058	2,078,407	297,960
Clinical projects	12,141,571	8,753,398	1,687,368
Drug manufacturing and substance	1,383,581	1,036,152	915,368
Employee benefits	1,718,212	1,074,398	770,124
Lease expenses	68,082	74,065	35,556
Patents and trademarks	665,023	100,702	53,473
Regulatory projects	519,104	106,325	219,106
Depreciation tangible assets	48,830	30,191	7,736
Total research and development expense	**17,704,461**	**13,253,638**	**3,986,691**

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18. General and administrative expense

	2014	2013	2012
Employee benefits	1,136,677	195,739	116,251
Business development	237,720	479,027	86,231
Travel expenses	169,602	77,616	9,551
Administration costs	2,014,178	556,445	375,155
IPO costs, expensed	822,367	—	—
Lease expenses	35,072	3,968	2,340
Depreciation tangible assets	25,153	7,326	1,506
Capital tax expenses	48,281	42,090	32,778
Total general and administrative expenses	**4,489,051**	**1,362,211**	**623,812**

As of March 31, 2014, management determined that successful completion of the IPO was not deemed to be more likely than not thus CHF 822,367 was expensed in the first quarter of 2014.

19. Employee benefits

	2014	2013	2012
Salaries	2,259,112	836,686	711,883
Pension costs	118,755	78,917	50,046
Other social benefits	131,939	71,878	39,921
Share option costs	270,748	110,198	56,013
Other	74,334	172,458	28,512
Total employee benefits	**2,854,888**	**1,270,137**	**886,375**

Benefit plans

The Company participates in a retirement plan (the “Plan”) organized through enrollment in an independent collective foundation, that covers all of its employees in Switzerland, including management. The collective foundation is governed by a 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 interest allocated on 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, coupled with annual retirement credits and interest (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 plan 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, retirement savings are 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 the rate was 1.5% and in 2014 it was 1.75%.

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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

	2014	2013
Defined benefit obligation at January 1	1,626,241	1,030,145
Service cost	111,513	72,803
Plan participants' contribution	137,966	50,937
Interest cost	52,097	23,133
Actuarial losses	1,484,222	136,933
Benefits paid	-539,920	-107,303
Transfer-in amounts of new employees	2,023,548	419,593
Defined benefit obligation at December 31	**4,895,667**	**1,626,241**

The defined benefit obligation includes only liabilities for active employees. The weighted average modified duration of the defined benefit obligation at December 31, 2014 is 22.6 years (2013: 19.9 years).

Change in fair value of plan assets

	2014	2013
Fair value of plan assets at January 1	1,297,899	787,499
Interest income	47,909	19,394
Return on plan assets excluding interest income	382,755	79,217
Employer contributions	137,966	50,937
Plan participants' contributions	137,966	50,937
Benefits paid	-539,920	-107,303
Transfer-in amounts of new employees	2,023,548	419,593
Administration expense	-3,054	-2,375
Fair value of plan assets at December 31	**3,485,069**	**1,297,899**

Net defined benefit liability recognized in the statement of financial position

	DECEMBER 31, 2014	DECEMBER 31, 2013
Present value of funded defined benefit obligation	4,895,667	1,626,241
Fair value of plan assets	-3,485,069	-1,297,899
Net defined benefit liability	**1,410,598**	**328,342**

Defined Benefit Cost

	2014	2013	2012
Service cost	111,513	72,803	45,036
Net interest expense	4,188	3,739	3,313
Administration expense	3,054	2,375	1,697
Total defined benefit cost for the year recognized in profit or loss	**118,755**	**78,917**	**50,046**

Remeasurement of the Defined Benefit Liability

	2014	2013	2012
Actuarial loss (gain) arising from changes in financial assumptions	699,456	-44,737	49,754
Actuarial loss arising from experience adjustments	784,766	181,670	57,684
Return on plan assets excluding interest income	-382,755	-79,217	-52,861
Total defined benefit cost for the year recognized in other comprehensive loss	**1,101,467**	**57,716**	**54,577**

In 2015, the Group anticipates to contribute CHF 164,040 to the Plan.

Assumptions

AT DECEMBER 31	2014	2013	2012
Discount rate	1.20%	2.20%	1.95%
Future salary increase	1.50%	1.50%	1.50%
Pension indexation	0.00%	0.00%	0.00%
Mortality and disability rates	BVG 2010G	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, 2014		
Change in assumption	0.25% increase	0.25% decrease
Discount rate	-228,394	249,899
Salary increase	29,192	-33,212
Pension indexation	135,368	N/A
Change in assumption	+1 year	-1 year
Life expectancy	99,859	-101,889

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20. Finance income and finance expense

	2014	2013	2012
Interest income	52,133	74,036	5,825
Investment income	—	—	1,216
Net foreign exchange gain	4,164,189	1,711	2,853
Total finance income	**4,216,322**	**75,747**	**9,894**
Interest expense related parties	49,635	50,177	—
Bank charges	6,175	2,454	1,800
Net foreign exchange loss	152,015	106,010	—
Total finance expense	**207,825**	**158,641**	**1,800**
Finance income/(expense), net	**4,008,497**	**-82,894**	**8,094**

Interest expense on convertible loans of CHF 49,635 (2013: CHF 40,262; 2012: 0) was not cash relevant. In 2014, net foreign exchange gains contains gains of CHF 3,961,731 which arose on the Company's cash and cash equivalents, which are held in USD.

21. Taxation

The Group's income tax expense recognized in the consolidated statement of profit or loss and other comprehensive loss was as follows:

	2014	2013
Deferred income tax expense	-32,761	-305,750
Deferred income tax gain	32,761	—
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 23.0% (2013: 23.7%; 2012: 23.3%) as summarized in the following table:

RECONCILIATION	2014	2013	2012
Loss before income tax	-18,185,015	-14,698,743	-4,602,409
Income tax at statutory tax rates applicable to results in the respective countries	4,177,780	3,488,916	1,071,976
Effect of unrecognized temporary differences	-273,073	1,343,556	823,403
Effect of unrecognized taxable losses	-4,160,118	-5,160,108	-1,895,379
Effect of unrecognized taxable losses in equity	-99,406		—
Effect on unrecognized deferred tax due to change in income tax rate	156,005	—	—
Deferred tax recognized 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 or to deferred income tax assets as at December 31 is presented below:

DEFERRED TAX LIABILITIES	DECEMBER 31, 2014	DECEMBER 31, 2013
Intangible assets	-327,637	-327,637
Provisions	-32,761	—
Total	**-360,398**	**-327,637**
Deferred Tax Asset		
Net operating loss (NOL)	32,761	—
Total	**32,761**	**—**
Deferred Tax, net	**-327,637**	**-327,637**

DEFERRED TAX 2014	OPENING BALANCE	RECOGNIZED IN PROFIT OR LOSS	RECOGNIZED IN EQUITY	CLOSING BALANCE
Intangible assets	-327,637	—	—	-327,637
Provisions	—	-32,761	—	-32,761
Net operating loss (NOL)	—	32,761		32,761
Total	**-327,637**	**—**	**—**	**-327,637**

DEFERRED TAX 2013	OPENING BALANCE	RECOGNIZED IN PROFIT OR LOSS	RECOGNIZED IN EQUITY	CLOSING BALANCE
Intangible assets/Convertible Loan	—	-305,751	-21,886	-327,637
Total	**—**	**-305,751**	**-21,886**	**-327,637**

As of December 31, 2014, the Group had total gross tax loss carry forwards amounting to CHF 58.6 million (2013: 38.9 million), of which CHF 57.5 million related to Auris Medical AG and Otolanum AG in Switzerland and CHF 1.1 million (2013: 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, 2014	DECEMBER 31, 2013	DECEMBER 31, 2012
Within 1 year	2,068,441	18,568	32,654
Between 1 and 3 years	3,456,587	3,755,427	2,087,009
Between 3 and 7 years	51,963,606	34,194,937	13,474,978
More than 7 years	1,056,556	938,560	785,439
Total	**58,635,190**	**38,907,492**	**16,380,080**

The tax effect of the major unrecognized temporary differences and loss carry-forwards is presented in the table below:

	DECEMBER 31, 2014	DECEMBER 31, 2013
Deductible temporary differences		
Employee benefit plan	311,742	75,174
Stock option plans	114,145	56,262
Accrued expenses	—	26,097
Total potential tax assets	**425,887**	**157,533**
Taxable unrecognized temporary differences		
Property and equipment	—	4,719
Total unrecognized potential tax liabilities	**—**	**4,719**
Offsetting potential tax liabilities with potential tax assets	—	4,719
Net potential tax assets from temporary differences not recognized	425,887	152,814
Potential tax assets from loss carry-forwards not recognized	13,067,988	8,907,870
Total potential tax assets from loss carry-forwards and temporary differences not recognized	**13,493,874**	**9,060,684**

22. Loss per share

	DECEMBER 31, 2014	DECEMBER 31, 2013
Loss attributable to owners of the Company	-18,185,015	-15,004,493
Weighted average number of shares outstanding	27,692,494	14,917,064
Basic and diluted loss per share	**-0.66**	**-1.01**

For the years ended December 31, 2014, 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.

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 expires in March 31, 2018 with an option to extend it for a further 5 years.

The future minimum lease payments under non-cancellable operating leases that are not accounted for in the statement of financial position were as follows:

	DECEMBER 31, 2014	DECEMBER 31, 2013
Within one year	103,572	91,572
Between one and five years	58,893	122,096
Total	**162,465**	**213,668**

Office lease expense of CHF 99,072 were booked in 2014 and of CHF 78,033 and CHF 37,896 in 2013 and 2012, respectively, in the consolidated statement of profit or loss and other comprehensive loss.

24. Related party transactions

For 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.

Compensation of the members of the Board of Directors and Management

In 2014 total compensation paid to directors and management was CHF 1,008,817 (2013: CHF 418,332, 2012: 287,320).

The fees paid to members of the Board of Directors in 2014 for their activities as board members totaled CHF 81,567 (2013: recorded CHF 10,500; 2012: 8,750).

Up to the Company's IPO, 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. Following the IPO, the Board's remuneration policy was modified in that all non-executive directors received remuneration for their work as members of the Board as well as of the newly constituted Compensation Committee and Audit Committee.

The Chief Executive Officer was compensated in 2013 by means of a management agreement between Auris Medical AG and Altamira Pharma GmbH, a company fully owned by the CEO. During 2013, the Group paid CHF 248,000 (2012: 247,200), for the management services rendered.

In 2014, CHF 210,554 (2013: CHF 74,145; 2012: 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 63,386 and CHF 6,836 during the years 2014 and 2013. No termination benefits or other long term benefits were paid.

Members of the Board of Directors and management held 287,510, 187,500 and 87,500 stock options as of December 31, 2014, 2013 and 2012, respectively.

In January 2013 Auris Medical AG obtained 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 was repaid by the Company on 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, 2014	DECEMBER 31, 2013
Convertible loans from shareholders	—	13,711,200
Trade and other payables	—	22
Total liabilities to related parties	**—**	**13,711,222**

The convertible loans from shareholders with a nominal value of CHF 13,769,976 were subordinated to any other indebtedness of the Company; they bore no interest (see Note 14).

	2014	2013
Interest expense related parties	-49,635	-50,177
Net interest expense—related parties	**-49,635**	**-50,177**

In 2014 and 2013, interest expense to related parties includes the calculated effective interest on the convertible loans from shareholders. In 2013, interest expense also includes the interest on a bridge loan from a related party.

There were no significant subsequent events after the date of the statement of financial position.

25. Events after the balance sheet date

No events that would require adjustments to or disclosure in the consolidated financial statements occurred between the date of the statement of financial position and the date the consolidated financial statements were approved by the Board of Directors of the Company.

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Through and including   , 2015 (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 AG

PROSPECTUS

Leerink Partners

JMP Securities

Needham & Company

LifeSci Capital

, 2015

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 have entered 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.

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 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, at the time of our initial public offering, all of our outstanding preferred shares converted 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.

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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 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
Plan B		
December 31, 2014	20,881	4.43
Equity Incentive Plan		
December 29, 2014	99,260	4.01
March 17, 2015	95,750	6.01

Item 8. Exhibits

(a) The following documents are filed as part of this registration statement:

1.1	Form of Underwriting Agreement
3.1	Articles of Association (incorporated by reference to exhibit 1.1 of the Auris Medical Holding AG Annual Report on Form 20-F for the year ended December 31, 2014, filed with the Commission on March 31, 2015)
4.1	Registration Rights Agreement between Auris Medical Holding AG and the shareholders listed therein (incorporated by reference to exhibit 4.1 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on July 21, 2014)
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 (incorporated by reference to exhibit 10.1 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
10.2†	Co-Ownership and Exploitation Agreement, dated September 29, 2003, between Auris Medical AG and INSERM (incorporated by reference to exhibit 10.2 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
10.3	Series C Investment Agreement, dated April 5, 2013 (incorporated by reference to exhibit 10.3 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
10.4	Series C Shareholders' Agreement, dated April 5, 2013 (incorporated by reference to exhibit 10.4 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
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10.6	Service Agreement, dated January 2011 between Auris Medical AG and Altamira Pharma GmbH (incorporated by reference to exhibit 10.6 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
10.7	Termination of Service Agreement, dated February 2014 between Auris Medical AG and Altamira Pharma GmbH (incorporated by reference to exhibit 10.7 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
10.8	Loan Agreement, dated January 2013 between Auris Medical AG and Altamira Pharma GmbH (incorporated by reference to exhibit 10.8 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
10.9	Form of Indemnification Agreement (incorporated by reference to exhibit 10.9 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on July 21, 2014)
10.10	English language translation of Lease Agreement between Auris Medical AG and Privera AG (incorporated by reference to exhibit 10.10 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)

10.11	Stock Option Plan A (incorporated by reference to exhibit 10.11 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
10.12	Stock Option Plan C (incorporated by reference to exhibit 10.12 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
21.1	List of subsidiaries (incorporated by reference to exhibit 2.1 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
23.1	Consent of Deloitte AG
23.2	Consent of KPMG AG
23.3	Consent of Froriep, Swiss counsel of Auris Medical Holding AG (included in Exhibit 5.1)
23.4	Consent of Froriep, Swiss counsel of Auris Medical Holding AG (included in Exhibit 8.1)
23.5	Consent of Davis Polk & Wardwell LLP (included in Exhibit 8.2)
23.6	Consent of MEDACorp, Inc.
24.1	Powers of attorney (included on signature page to the registration statement)

† 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.

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 May 4, 2015.

Auris Medical Holding AG

By: /s/ Thomas Meyer
Name: Thomas Meyer
Title: Chief Executive Officer

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 May 4, 2015 in the capacities indicated:

NAME	TITLE
/s/ Thomas Meyer Thomas Meyer	Chief Executive Officer and Director (principal executive officer)
/s/ Sven Zimmermann Sven Zimmermann	Chief Financial Officer (principal financial officer and principal accounting officer)
* Wolfgang Arnold	Director
* James I. Healy	Director
* Oliver Kubli	Director
* Antoine Papiernik	Director
/s/ Berndt Modig Berndt Modig	Director
/s/ Calvin Roberts Calvin Roberts	Director
* Colleen A. DeVries SVP of National Corporate Research, Ltd.	Authorized Representative in the United States

*By: /s/ Thomas Meyer
Thomas Meyer
As Attorney-in-Fact

EXHIBIT INDEX

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† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

Exhibit 1.1

[●] Common Shares

Auris Medical Holding AG

UNDERWRITING AGREEMENT

[●], 2015

LEERINK PARTNERS LLC
As Representative of the several Underwriters
255 California Street, 12th Floor
San Francisco, CA 94111

Ladies and Gentlemen:

Introductory. Auris Medical Holding AG, a company established in Switzerland (the "**Company**"), proposes to issue and sell to the several underwriters named in Schedule A (the "**Underwriters**") an aggregate of [●] common shares, nominal value CHF 0.40 per share (the "**Shares**"). The [●] Shares to be sold by the Company are called the "**Firm Shares**." In addition, the Company has granted to the Underwriters an option to purchase up to an additional [●] Shares as provided in Section 2. The additional [●] Shares to be sold by the Company pursuant to such option are collectively called the "**Optional Shares**." The Firm Shares and, if and to the extent such option is exercised, the Optional Shares are collectively called the "**Offered Shares**." Leerink Partners LLC ("**Leerink**") has agreed to act as representative of the several Underwriters (in such capacity, the "**Representative**") in connection with the offering and sale of the Offered Shares.

The Company has prepared and filed with the Securities and Exchange Commission (the "**Commission**") a registration statement on Form F-1, File No. 333-203554 which contains a form of prospectus to be used in connection with the public offering and sale of the Offered Shares. Such registration statement, as amended, including the financial statements, exhibits and schedules thereto, in the form in which it became effective under the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder (collectively, the "**Securities Act**"), including any information deemed to be a part thereof at the time of effectiveness pursuant to Rule 430A under the Securities Act, is called the "**Registration Statement**." Any registration statement filed by the Company pursuant to Rule 462(b) under the Securities Act in connection with the offer and sale of the Offered Shares is called the "**Rule 462(b) Registration Statement**," and from and after the date and time of filing of any such Rule 462(b) Registration Statement the term "Registration Statement" shall include the Rule 462(b) Registration Statement. The prospectus, in the form first used by the Underwriters to confirm sales of the Offered Shares or in the form first made available to the Underwriters by the Company to meet requests of purchasers pursuant to Rule 173 under the Securities Act, is called the "**Prospectus**." The preliminary prospectus dated [●], 2015 describing the Offered Shares and the offering thereof is called the "**Preliminary Prospectus**," and the Preliminary Prospectus and any other prospectus in preliminary form that describes the Offered Shares and the offering thereof and is used prior to the filing of the Prospectus is called a "**preliminary prospectus**." As used herein, "**Applicable Time**" is [●] p.m. (New York City time) on [●], 2015. As used herein, "**free writing prospectus**" has the meaning set forth in Rule 405 under the Securities Act, and "**Time of Sale Prospectus**" means the Preliminary Prospectus together with the free writing prospectuses, if any, identified in Schedule B hereto and the pricing information identified on Schedule D hereto. As used herein, **"Road Show"** means a "road show" (as defined in Rule 433 under the Securities Act) relating to the offering of the Offered Shares contemplated hereby that is a "written communication" (as defined in Rule 405 under the Securities Act). As used herein, "**Section 5(d) Written**

Communication" means each written communication (within the meaning of Rule 405 under the Securities Act) that is made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company to one or more potential investors that are qualified institutional buyers ("**QIBs**") and/or institutions that are accredited investors ("**IAIs**"), as such terms are respectively defined in Rule 144A and Rule 501(a) under the Securities Act, to determine whether such investors might have an interest in the offering of the Offered Shares; "**Section 5(d) Oral Communication**" means each oral communication, if any, made in reliance on Section 5(d) of the Securities Act by the Company or any person authorized to act on behalf of the Company made to one or more QIBs and/or one or more IAIs to determine whether such investors might have an interest in the offering of the Offered Shares; "**Marketing Materials**" means any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the offering of the Offered Shares, including any roadshow or investor presentations made to investors by the Company (whether in person or electronically); and "**Permitted Section 5(d) Communication**" means the Section 5(d) Written Communication(s) and Marketing Materials listed on Schedule C attached hereto.

All references in this Agreement to (i) the Registration Statement, any preliminary prospectus (including the Preliminary Prospectus), or the Prospectus, or any amendments or supplements to any of the foregoing, or any free writing prospectus, shall include any copy thereof filed with the Commission pursuant to its Electronic Data Gathering, Analysis and Retrieval System ("**EDGAR**") and (ii) the Prospectus shall be deemed to include any "electronic Prospectus" provided for use in connection with the offering of the Offered Shares as contemplated by Section 5(m) of this Agreement.

The Company hereby confirms its agreements with the Underwriters as follows:

Section 1. Representations and Warranties of the Company.

The Company hereby represents, warrants and covenants to each Underwriter, as of the date of this Agreement, as of the First Closing Date (as hereinafter defined) and as of each Option Closing Date (as hereinafter defined), if any, as follows:

(a) ***Compliance with Registration Requirements.*** The Registration Statement has become effective under the Securities Act. The Company has complied, to the Commission's satisfaction with all requests of the Commission for additional or supplemental information, if any. No stop order suspending the effectiveness of the Registration Statement is in effect and, to the knowledge of the Company, no proceedings for such purpose have been instituted or are pending or are contemplated or threatened by the Commission.

(b) ***Disclosure.*** Each preliminary prospectus and the Prospectus when filed complied in all material respects with the Securities Act and, if filed by electronic transmission pursuant to EDGAR, was identical (except as may be permitted by Regulation S-T under the Securities Act) to the copy thereof delivered to the Underwriters for use in connection with the offer and sale of the Offered Shares. Each of the Registration Statement and any post-effective amendment thereto, at the time it became or becomes effective, complied and will comply in all material respects with the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. As of the Applicable Time, the Time of Sale Prospectus (including any preliminary prospectus wrapper) did not, and at the First Closing Date (as defined in Section 2) and at each applicable Option Closing Date (as defined in Section 2), will not, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading. The Prospectus (including any Prospectus wrapper), as of its date, did not, and at the First Closing Date and at each applicable Option Closing Date, will not, contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the three immediately preceding sentences do not apply to statements in or omissions from the Registration Statement or any post-effective amendment thereto, or the Prospectus or the Time of Sale Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with written information relating to any Underwriter furnished to the Company in writing by the Representative expressly for use therein, it being understood and agreed that the only such information consists of the information described in Section 11(b) below. There are no contracts or other documents required to be described in the Time of Sale Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which have not been described or filed as required.

(c) ***Free Writing Prospectuses; Road Show*****.** As of the determination date referenced in Rule 164(h) under the Securities Act, the Company was not, is not or will not be (as applicable) an "ineligible issuer" in connection with the offering of the Offered Shares pursuant to Rules 164, 405 and 433 under the Securities Act. Each free writing prospectus that the Company is required to file pursuant to Rule 433(d) under the Securities Act has been, or will be, filed with the Commission in accordance with the requirements of the Securities Act. Each free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) under the Securities Act or that was prepared by or on behalf of or used or referred to by the Company complies or will comply in all material respects with the requirements of Rule 433 under the Securities Act, including timely filing with the Commission or retention where required and legending, and each such free writing prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Offered Shares did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Prospectus or any preliminary prospectus and not superseded or modified. Except for the free writing prospectuses, if any, identified in Schedule B, and electronic road shows, if any, furnished to you before first use, the Company has not prepared, used or referred to, and will not, without your prior written consent, prepare, use or refer to, any free writing prospectus. Each Road Show, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(d) ***Distribution of Offering Material By the Company*****.** Prior to the later of (i) the expiration or termination of the option granted to the several Underwriters in Section 2 and (ii) the completion of the Underwriters' distribution of the Offered Shares, the Company has not distributed and will not distribute any offering material in connection with the offering and sale of the Offered Shares other than the Registration Statement, the Time of Sale Prospectus, the Prospectus or any free writing prospectus reviewed and consented to by the Representative, the free writing prospectuses, if any, identified on Schedule B and any Permitted Section 5(d) Communications.

(e) ***The Underwriting Agreement*****.** This Agreement has been duly authorized, executed and delivered by the Company.

(f) ***Authorization of the Offered Shares*****.** The Offered Shares have been duly authorized for issuance and sale pursuant to this Agreement and, when issued and delivered by the Company against payment therefor pursuant to this Agreement, will be validly issued, fully paid and nonassessable, and the issuance and sale of the Offered Shares is not subject to any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase the Offered Shares which have not been duly withdrawn waived or satisfied. Upon the sale and delivery to the Underwriters of the Offered Shares, and payment therefor, the Underwriters will acquire good, marketable and valid title to such Offered Shares, free and clear of all pledges, liens, security interests, charges, claims or encumbrances.

(g) ***No Applicable Registration or Other Similar Rights*****.** Except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, there are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly withdrawn or waived.

(h) ***No Material Adverse Change*****.** Except as otherwise disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, subsequent to the respective dates as of which information is given in the Registration Statement, the Time of Sale Prospectus and the Prospectus: (i) there has been no material adverse change, or any development that could be expected to result in a material adverse change, in the condition, financial or otherwise, or in the earnings, business, properties, operations, assets, liabilities or prospects, whether or not arising from transactions in the ordinary course of business, of the Company and its subsidiaries, considered as one entity (any such change being referred to herein as a "**Material Adverse Change**"); (ii) the Company and its subsidiaries, considered as one entity, have not incurred any material liability or obligation, indirect, direct or contingent, including without limitation any losses or interference with its business from fire, explosion, flood, earthquakes, accident or other calamity, whether or not covered by insurance, or from any strike, labor dispute or court or governmental action, order or decree, that are material, individually or in the aggregate, to the Company and its subsidiaries, considered as one entity, or have entered into any transactions not in the ordinary course of business; and (iii) there has not been any material decrease in the capital stock or any material increase in any short-term or long-term indebtedness of the Company or its subsidiaries and there has been no dividend or distribution of any kind declared, paid or made by the Company or, except for dividends paid to the Company or other subsidiaries, by any of the Company's subsidiaries on any class of capital stock, or any repurchase or redemption by the Company or any of its subsidiaries of any class of capital stock.

(i) ***No Overindebtedness.*** Except for Auris Medical AG, whose overindebtedness is covered by subordination of claims of the Company, neither the Company nor its Swiss subsidiaries are overindebted or suffering from capital loss within the meaning of article 725 CO.

(j) ***Independent Accountants*****.** Deloitte AG and KPMG AG, which have expressed their respective opinions with respect to the financial statements (which term as used in this Agreement includes the related notes thereto) filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus, are each (i) an independent registered public accounting firm as required by the Securities Act, the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (collectively, the "**Exchange Act**"), and the rules of the Public Company Accounting Oversight Board ("**PCAOB**"), (ii) in compliance with the applicable requirements relating to the qualification of accountants under Rule 2-01 of Regulation S-X under the Securities Act, (iii) a registered public accounting firm as defined by the PCAOB whose registration has not been suspended or revoked and who has not requested such registration to be withdrawn and (iv) an independent qualified public accountant qualified under the applicable provisions of the Swiss Code of Obligations (the "**CO**"), the Swiss Audit Supervision Act (*Revisionsaufsichtsgesetz*) and any ordinances promulgated thereunder.

(k) ***Financial Statements*****.** The financial statements filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus present fairly, in all material respects, the consolidated financial position of the Company and its subsidiaries as of the dates indicated and the results of their operations, changes in stockholders' equity and cash flows for the periods specified. Such financial statements have been prepared in conformity with International Financial Reporting Standards ("**IFRS**") as issued by the International Accounting Standards Board (the "**IASB**") applied on a consistent basis throughout the periods involved, except as may be expressly stated in the related notes thereto or as otherwise disclosed therein, and, in the case of interim financial statements, subject to normal year-end audit adjustments and the exclusion of certain footnotes. No other financial statements or supporting schedules are required to be included in the Registration Statement, the Time of Sale Prospectus or the Prospectus. The financial data set forth in each of the Registration Statement, the Time of Sale Prospectus and the Prospectus under the captions "Prospectus Summary—Summary Selected Financial Data," "Selected Financial Data" and "Capitalization" present fairly, in all material respects, the information set forth therein on a basis consistent with that of the audited financial statements contained in the Registration Statement, the Time of Sale Prospectus and the Prospectus. To the Company's knowledge, no person who has been suspended or barred from being associated with a registered public accounting firm, or who has failed to comply with any sanction pursuant to Rule 5300 promulgated by the PCAOB, has participated in or otherwise aided the preparation of, or audited, the financial statements, supporting schedules or other financial data filed with the Commission as a part of the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(l) *Company's Accounting System*. The Company and each of its subsidiaries make and keep accurate books and records and maintain a system of internal accounting controls designed to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with IFRS as issued by IASB and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(m) *Disclosure Controls and Procedures; Deficiencies in or Changes to Internal Control Over Financial Reporting*. The Company has established and maintains disclosure controls and procedures (as defined in Rules 13a-15 and 15d-15 under the Exchange Act), which are designed to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to the Company's principal executive officer and its principal financial officer by others within those entities and are effective in all material respects to perform the functions for which they were established. Since the end of the Company's most recent audited fiscal year, there has been no material weakness in the Company's internal control over financial reporting (whether or not remediated) and no change in the Company's internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. The Company is not aware of any change in its internal control over financial reporting that has occurred that has materially and adversely affected, or is reasonably likely to materially and adversely affect, the Company's internal control over financial reporting.

(n) *Incorporation of the Company*. The Company has been duly incorporated and is validly existing under the laws of Switzerland and has the corporate power and authority to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and to enter into and perform its obligations under this Agreement. The Company is duly qualified as a foreign corporation to transact business in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business.

(o) *Subsidiaries*. Each of the Company's "subsidiaries" (for purposes of this Agreement, as defined in Rule 405 under the Securities Act) has been duly incorporated or organized, as the case may be, and is validly existing as a corporation, partnership or limited liability company, as applicable, in good standing (where such concept exists) under the laws of the jurisdiction of its incorporation or organization and has the power and authority (corporate or other) to own, lease and operate its properties and to conduct its business as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

Each of the Company's subsidiaries is duly qualified as a foreign corporation, partnership or limited liability company, as applicable, to transact business and is in good standing in each jurisdiction in which such qualification is required, whether by reason of the ownership or leasing of property or the conduct of business, except where the failure to be so qualified or in good standing (where such concept exists) would not, individually or in the aggregate, result in a Material Adverse Effect. All of the issued and outstanding capital stock or other equity or ownership interests of each of the Company's subsidiaries have been duly authorized and validly issued, are fully paid and nonassessable and are owned by the Company, directly or through subsidiaries, free and clear of any security interest, mortgage, pledge, lien, encumbrance or adverse claim. The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21 to the Registration Statement.

(p) ***Capitalization and Other Capital Stock Matters*****.** The authorized, issued and outstanding share capital of the Company is as set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Capitalization" (other than for subsequent issuances, if any, pursuant to employee benefit plans, or upon the exercise of outstanding options or conversion rights, in each case described in the Registration Statement, the Time of Sale Prospectus and the Prospectus). The share capital of the Company, including the Offered Shares, conforms in all material respects to the description thereof contained in the Time of Sale Prospectus. All of the issued and outstanding Shares have been duly authorized and validly issued, are fully paid and nonassessable and have been issued in compliance with all applicable securities laws. Except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, none of the outstanding Shares was issued in violation of any preemptive rights, rights of first refusal or other similar rights to subscribe for or purchase securities of the Company. The Shares conform to the law of the jurisdiction of the Company's incorporation and to any requirements of the Company's organizational documents. There are no authorized or outstanding options, warrants, preemptive rights, rights of first refusal or other rights to purchase, or equity or debt securities convertible into or exchangeable or exercisable for, any capital stock of the Company or any of its subsidiaries other than those described in the Registration Statement, the Time of Sale Prospectus and the Prospectus. The descriptions of the Company's stock option, stock bonus and other stock plans or arrangements, and the options or other rights granted thereunder, set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus accurately and fairly presents the information required to be shown with respect to such plans, arrangements, options and rights.

(q) ***Stock Exchange Listing*****.** The Offered Shares have been approved for listing on The NASDAQ Global Market (the "**NASDAQ**").

(r) ***Non-Contravention of Existing Instruments; No Further Authorizations or Approvals Required*****.** Neither the Company nor any of its subsidiaries is in violation of its articles of association or operating agreement or similar organizational documents, as applicable, or is in default (or, with the giving of notice or lapse of time, would be in default) ("**Default**") under any indenture, loan, credit agreement, note, lease, license agreement, contract, franchise or other instrument (including, without limitation, any pledge agreement, security agreement, mortgage or other instrument or agreement evidencing, guaranteeing, securing or relating to indebtedness) to which the Company or any of its subsidiaries is a party or by which it or any of them may be bound, or to which any of their respective properties or assets are subject (each, an "**Existing Instrument**"), except for such Defaults as would not be expected, individually or in the aggregate, to have a material adverse effect on the condition (financial or other), earnings, business, properties, operations, assets, liabilities or prospects of the Company and its subsidiaries, considered as one entity (a "**Material Adverse Effect**"). The Company's execution, delivery and performance of this Agreement, consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus and the issuance and sale of the Offered Shares (including the use of proceeds from the sale of the Offered Shares as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus under the caption "Use of

Proceeds") (i) have been duly authorized by all necessary corporate action and will not result in any violation of the provisions of the articles of association or operating agreement or similar organizational documents, as applicable, of the Company or any subsidiary (ii) will not conflict with or constitute a breach of, or Default or a Debt Repayment Triggering Event (as defined below) under, or result in the creation or imposition of any lien, charge or encumbrance upon any property or assets of the Company or any of its subsidiaries pursuant to, or require the consent of any other party to, any Existing Instrument and (iii) will not result in any violation of any law, administrative regulation or administrative or court decree applicable to the Company or any of its subsidiaries except, as to clauses (ii) and (iii), as would not be expected, individually or in the aggregate, to have a Material Adverse Effect. No consent, approval, authorization or other order of, or registration or filing with, any court or other governmental or regulatory authority or agency, is required for the Company's execution, delivery and performance of this Agreement and consummation of the transactions contemplated hereby and by the Registration Statement, the Time of Sale Prospectus and the Prospectus, except such as have been obtained or made by the Company and are in full force and effect under the Securities Act and such as may be required under applicable state securities or blue sky laws, the Financial Industry Regulatory Authority ("**FINRA**") or the NASDAQ. As used herein, a "**Debt Repayment Triggering Event**" means any event or condition which gives, or with the giving of notice or lapse of time would give, the holder of any note, debenture or other evidence of indebtedness (or any person acting on such holder's behalf) the right to require the repurchase, redemption or repayment of all or a portion of such indebtedness by the Company or any of its subsidiaries.

(s) ***Compliance with Laws.*** The Company and its subsidiaries have been and are in compliance with all applicable laws, rules and regulations, except where failure to be so in compliance would not be expected, individually or in the aggregate, to have a Material Adverse Effect.

(t) ***No Material Actions or Proceedings*.** There is no action, suit, proceeding, inquiry or investigation brought by or before any governmental entity now pending or, to the knowledge of the Company, threatened, against or affecting the Company or any of its subsidiaries, which would be expected, individually or in the aggregate, to have a Material Adverse Effect or materially and adversely affect the consummation of the transactions contemplated by this Agreement or the performance by the Company of its obligations hereunder; and the aggregate of all pending legal or governmental proceedings to which the Company or any such subsidiary is a party or of which any of their respective properties or assets is the subject, including ordinary routine litigation incidental to the business, if determined adversely to the Company, would not be expected to have a Material Adverse Effect. No material labor dispute with the employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is threatened or imminent.

(u) ***Intellectual Property Rights*.** Except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, the Company, to the best of its knowledge, owns or has valid, binding and enforceable licenses or other enforceable rights under the patents and patent applications, copyrights, trademarks, trademark registrations, service marks, service mark registrations, trade names, service names and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and used in the conduct, or the proposed conduct, of the business of the Company in the manner described in the Registration Statement, the Time of Sale Prospectus and the Prospectus (collectively, the "**Company Intellectual Property**"); except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, to the knowledge of the Company, the patents, trademarks, and copyrights included within the Company Intellectual Property are valid, enforceable, and subsisting, and there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity, enforceability or scope of any Company Intellectual Property; other than as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, (i) the Company has not received any notice of any claim of infringement, misappropriation or conflict with any asserted rights of others with respect to any of the Company's products, proposed products or processes, (ii) to the knowledge of the Company, neither the sale nor use of any of products, proposed products or processes of the Company referred to in the Registration Statement, the Time of Sale Prospectus or the Prospectus do or will, to the knowledge of the Company, infringe, any valid patent claim of any third party or violate any valid right of any third party, and (iii) to the knowledge of the Company, no third party has any ownership right in or to any Company Intellectual Property that is owned by the Company, other than any co-owner of any patent or pending patent application constituting Company Intellectual Property who is listed on the records of the U.S. Patent and Trademark Office (the "**USPTO**") , and, to the knowledge of the Company, no third party has any ownership right in or to any Company Intellectual Property in any field of use that is exclusively licensed to the Company, other than any licensor to the Company of such Company Intellectual Property; except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, none of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company except as would not be expected, individually or in the aggregate, to have a Material Adverse Effect, or, to the Company's knowledge, upon any of its officers, directors or employees; except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, to the knowledge of the Company all patents and patent applications owned by and licensed to the Company or under which the Company has rights have been duly and properly filed and maintained; to the knowledge of the Company, the parties prosecuting such applications have complied with their duty of candor and disclosure to the USPTO in connection with such applications; and the Company is not aware of any facts required to be disclosed to the USPTO that were not disclosed to the USPTO and which would preclude the grant of a patent in connection with any such application or could form the basis of a finding of invalidity with respect to any patents that have issued with respect to such applications.

(v) ***All Necessary Permits, etc*****.** The Company and its subsidiaries possess such valid and current certificates, authorizations, exemptions, approvals, clearances or permits required by state, federal or foreign regulatory agencies or bodies to conduct their respective businesses as currently conducted and as described in the Registration Statement, the Time of Sale Prospectus or the Prospectus ("Permits"). Neither the Company nor any of its subsidiaries is in violation of, or in default under, any of the Permits or has received any notice of proceedings relating to the revocation or modification of, or non-compliance with, any such certificate, authorization or permit except where such revocation or modification would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(w) ***Title to Properties*****.** The Company and its subsidiaries have good and marketable title to all of the real and personal property and other assets reflected as owned in the financial statements referred to in Section 1(k) above (or elsewhere in the Registration Statement, the Time of Sale Prospectus or the Prospectus), in each case free and clear of any security interests, mortgages, liens, encumbrances, equities, adverse claims and other defects, except as otherwise disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus or as would not reasonably be expected to have a Material Adverse Effect. The real property, improvements, equipment and personal property held under lease by the Company or any of its subsidiaries are held under valid and enforceable leases, with such exceptions as are not material and do not materially interfere with the use made or proposed to be made of such real property, improvements, equipment or personal property by the Company or such subsidiary.

(x) ***Tax Law Compliance*****.** Except where the failure to do so would not constitute a Material Adverse Effect, (a) all tax returns (including tax refund requests) required to be filed pursuant to applicable law by or with respect to the Company and any of its subsidiaries have been timely filed, or proper request of extension thereof has been filed, and (b) all tax returns filed are complete and correct, and all taxes, fines or penalties due including any interest and penalties, except tax deficiencies that the Company or any of its subsidiaries are contesting in good faith subject to applicable reserves, have been timely paid and fully reserved against in the applicable financial statements referred to in Section 1(k). Except as disclosed in the Registration Statement, the Time of Sale Prospectus and the Prospectus, no stamp or other issuance or transfer taxes or duties and no capital gains, income, withholding, value added, capital or other taxes (but excluding any income tax, capital gains tax or similar resulting from the sale of the Offered Shares and any tax on or determined by reference to the income of any Underwriter that is subject to tax on a net income basis) are payable by or on behalf of the Underwriters to any Swiss tax authorities or any political subdivisions or taxing authority thereof or therein in connection with (i) the issuance of the Offered Shares, (ii) the execution and delivery of this Agreement or any other document to be furnished hereunder, and (iii) the sale, delivery and resale of the Offered Shares in the manner contemplated in the Registration Statement, the Time of Sale Prospectus, the Prospectus and this Agreement.

(y) *Insurance*. Except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, each of the Company and its subsidiaries are insured with policies in such amounts and with such deductibles and covering such risks as the Company believes are adequate and customary for their businesses including, but not limited to, policies covering real and personal property owned or leased by the Company and its subsidiaries against theft, damage, destruction, acts of vandalism and earthquakes and policies covering the Company and its subsidiaries for product liability claims and clinical trial liability claims. The Company has no reason to believe that it or any of its subsidiaries will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not be expected to have a Material Adverse Effect. Neither the Company nor any of its subsidiaries has been denied any insurance coverage which it has sought or for which it has applied.

(z) *Compliance with Environmental Laws*. Except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus and except as would not be expected, individually or in the aggregate, to have a Material Adverse Effect: (i) neither the Company nor any of its subsidiaries is in violation of any federal, state, local or foreign statute, law, rule, regulation, ordinance, code, policy or rule of common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products (collectively, "**Hazardous Materials**") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "**Environmental Laws**"); (ii) the Company and its subsidiaries have all permits, authorizations and approvals required under any applicable Environmental Laws and are each in compliance with their requirements; (iii) there are no pending or, to the Company's knowledge, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of noncompliance or violation, investigation or proceedings relating to any Environmental Law against the Company or any of its subsidiaries; and (iv) to the Company's knowledge there are no events or circumstances that might reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any of its subsidiaries relating to Hazardous Materials or any Environmental Laws.

(aa) *ERISA Compliance*. The "employee benefit plans" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "***ERISA***")) sponsored or maintained by the Company or its subsidiaries are operated in compliance in all material respects with ERISA to the extent applicable, except where the failure to be in compliance would not be expected to have a Material Adverse Effect. "***ERISA Affiliate***" means, with respect to the Company or any of its subsidiaries, any entity that is treated as a single employer with the Company or any of its subsidiaries under Sections 414(b), (c), (m) or (o) of the Internal

Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "Code"). Neither the Company, its subsidiaries nor any of their ERISA Affiliates has incurred or reasonably expects to incur any liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code that would reasonably be expected to be a material liability of the Company. Neither the Company nor any of its subsidiaries (i) sponsors or maintains any plan that is subject to Title IV of ERISA or is intended to be qualified under Section 401(a) of the Code or (ii) reasonably expects to incur any material liability under Title IV of ERISA.

(bb) ***Company Not an "Investment Company"*** The Company is not, and will not be, either after receipt of payment for the Offered Shares or after the application of the proceeds therefrom as described under "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus or the Prospectus, required to register as an "investment company" under the Investment Company Act of 1940, as amended (the **"Investment Company Act"**).

(cc) ***No Price Stabilization or Manipulation; Compliance with Regulation M*****.** Neither the Company nor any of its subsidiaries has taken, directly or indirectly (without giving any effect to the activities of the Underwriters), any action designed to or that might cause or result in stabilization or manipulation of the price of the Shares or of any "reference security" (as defined in Rule 100 of Regulation M under the Exchange Act (**"Regulation M"**)) with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and has taken no action which would directly or indirectly violate Regulation M.

(dd) ***Related-Party Transactions*****.** There are no business relationships or related-party transactions involving the Company or any of its subsidiaries or any other person required to be described in the Registration Statement, the Time of Sale Prospectus or the Prospectus that have not been described as required.

(ee) ***FINRA Matters*****.** All of the information provided to the Underwriters or to counsel for the Underwriters by the Company, its counsel, its officers and directors and, to the Company's knowledge, the holders of any securities (debt or equity) or options to acquire any securities of the Company in connection with the offering of the Offered Shares is true, complete, correct and compliant with FINRA's rules in all material respects and any letters, filings or other supplemental information provided to FINRA pursuant to FINRA Rules or NASD Conduct Rules is true, complete and correct in all material respects.

(ff) ***Parties to Lock-Up Agreements*****.** The Company has furnished to the Underwriters a letter agreement in the form attached hereto as Exhibit A (the "**Lock-up Agreement**") from each of the persons listed on Exhibit B. Such Exhibit B lists under an appropriate caption the directors and officers of the Company. If any additional persons shall become directors or officers of the Company prior to the end of the Company Lock-up Period (as defined below), the Company shall cause each such person, prior to or contemporaneously with their appointment or election as a director or officer of the Company, to execute and deliver to the Representative a Lock-up Agreement.

(gg) ***Statistical and Market-Related Data*****.** All statistical, demographic and market-related data included in the Registration Statement, the Time of Sale Prospectus or the Prospectus are based on or derived from sources that the Company believes, to be reliable and accurate in all material respects. To the extent required, the Company has obtained the written consent to the use of such data from such sources.

(hh) ***No Unlawful Contributions or Other Payments*****.** Neither the Company nor any of its subsidiaries nor, to the Company's knowledge, any employee or agent of the Company or any subsidiary, has made any contribution or other payment to any official of, or candidate for, any federal, state or foreign office in violation of any law or of the character required to be disclosed in the Registration Statement, the Time of Sale Prospectus or the Prospectus.

(ii) ***Foreign Corrupt Practices Act*****.** Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or other person acting on behalf of the Company or any of its subsidiaries has, in the course of its actions for, or on behalf of, the Company or any of its subsidiaries (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expenses relating to political activity; (ii) made any direct or indirect unlawful payment to any domestic government official, "foreign official" (as defined in the U.S. Foreign Corrupt Practices Act of 1977, as amended, and the rules and regulations thereunder (collectively, the "**FCPA**") or employee from corporate funds; (iii) violated or is in violation of any provision of the FCPA or any applicable non-U.S. anti-bribery statute or regulation; or (iv) made any unlawful bribe, rebate, payoff, influence payment, kickback or other unlawful payment to any domestic government official, such foreign official or employee; and the Company and its subsidiaries and, to the knowledge of the Company, the Company's affiliates have conducted their respective businesses in compliance with the FCPA and have instituted policies and procedures designed to ensure, and which are reasonably expected to continue to ensure, continued compliance therewith.

(jj) ***Money Laundering Laws*****.** The operations of the Company and its subsidiaries are, and have been conducted at all times, in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all applicable jurisdictions, the rules and regulations thereunder and any related or similar applicable rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

(kk) ***OFAC*****.** Neither the Company nor any of its subsidiaries nor, to the knowledge of the Company, any director, officer, agent, employee, affiliate or person acting on behalf of the Company or any of its subsidiaries is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("**OFAC**"); and the Company will not directly or indirectly use the proceeds of this offering, or lend, contribute or otherwise make available such proceeds to any subsidiary, or any joint venture partner or other person or entity, for the purpose of financing the activities of or business with any person, or impermissibly in any country or territory, that currently is the subject to any U.S. sanctions administered by OFAC or in any other manner that will result in a violation by any person (including any person participating in the transaction whether as underwriter, advisor, investor or otherwise) of U.S. sanctions administered by OFAC.

(ll) ***Brokers*****.** Except pursuant to this Agreement, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(mm) ***Submission to Jurisdiction.*** The Company has the power to submit, and pursuant to Section 21 of this Agreement, has legally, validly, effectively and irrevocably submitted, to the personal jurisdiction of each United States federal court and New York state court located in the Borough of Manhattan, in the City of New York, New York, U.S.A. (each, a "**New York Court**"), and the Company has the power to designate, appoint and authorize, and pursuant to Section 21 of this Agreement, has legally, validly, effectively and irrevocably designated, appointed and authorized an agent for service of process in any action arising out of or relating to this Agreement or the Offered Shares in any New York Court, and service of process effected on such authorized agent will be effective to confer valid personal jurisdiction over the Company as provided in Section 21 hereof.

(nn) ***No Rights of Immunity.*** Except as provided by laws or statutes generally applicable to transactions of the type described in this Agreement, neither the Company nor any of its respective properties, assets or revenues has any right of immunity under Swiss, New York or United States law, from any legal action, suit or proceeding, from the giving of any relief in any such legal action, suit or proceeding, from set-off or counterclaim, from the jurisdiction of any Swiss, New York or United States federal court, from service of process, attachment upon or prior judgment, or attachment in aid of execution of judgment, or from execution of a judgment, or other legal process or proceeding for the giving of any relief or for the enforcement of a judgment, in any such court, with respect to its obligations, liabilities or any other matter under or arising out of or in connection with this Agreement or the Deposit Agreement. To the extent that the Company or any of its respective properties, assets or revenues may have or may hereafter become entitled to any such right of immunity in any such court in which proceedings may at any time be commenced, the Company waives or will waive such right to the extent permitted by law and has consented to such relief and enforcement as provided in Section 21 of this Agreement.

(oo) ***Forward-Looking Statements.*** Each financial or operational projection or other "forward-looking statement" (as defined by Section 27A of the Securities Act or Section 21E of the Exchange Act) contained in the Registration Statement, the Time of Sale Prospectus or the Prospectus (i) was so included by the Company in good faith and with reasonable basis after due consideration by the Company of the underlying assumptions, estimates and other applicable facts and circumstances and (ii) is accompanied by meaningful cautionary statements identifying those factors that could cause actual results to differ materially from those in such forward-looking statement. No such statement was made with the knowledge of an executive officer or director of the Company that is was false or misleading.

(pp) ***Foreign Private Issuer***. The Company is a "foreign private issuer" within the meaning of Rule 405 under the Securities Act.

(qq) ***Emerging Growth Company Status***. From the time of initial filing of the Registration Statement with the Commission (or, if earlier, the first date on which the Company engaged in any Section 5(d) Written Communication or any Section 5(d) Oral Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a)(19) of the Securities Act (an "**Emerging Growth Company**").

(rr) ***Communications***. The Company (i) has not alone engaged in communications with potential investors in reliance on Section 5(d) of the Securities Act other than Permitted Section 5(d) Communications with the consent of the Representative with entities that are QIBs or IAIs and (ii) has not authorized anyone other than the Representative to engage in such communications; the Company reconfirms that the Representative has been authorized to act on its behalf in undertaking Marketing Materials, Section 5(d) Oral Communications and Section 5(d) Written Communications; as of the Applicable Time, each Permitted Section 5(d) Communication, when considered together with the Time of Sale Prospectus, did not, as of the Applicable Time, include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each Permitted Section 5(d) Communication, if any, does not, as of the date hereof, conflict with the information contained in the Registration Statement, the Preliminary Prospectus and the Prospectus; provided that the Company makes no representation or warrant with respect to any statements or omissions made in each such Permitted Section 5(d) Communication in reliance upon and in conformity with written information furnished to the Company in writing by an Underwriter through the Representative expressly for use in such Permitted Section 5(d) Communication, it being understood and agreed that the only such information furnished by any Underwriter consists of the information described as such in Section 11(b) hereof.

(ss) ***Clinical Data and Regulatory Compliance.*** The preclinical tests and clinical trials conducted by the Company, and to the knowledge of the Company, the preclinical tests and clinical trials conducted on behalf of or sponsored by the Company, that are described in, or the results of which are referred to in, the Registration Statement, the Time of Sale Prospectus or the Prospectus were and, if still pending, are being conducted in all material respects in accordance with the protocols, procedures and controls designed and approved for such studies and with standard medical and scientific research procedures and all applicable laws and regulations, including, without limitation, 21 C.F.R. Parts 50, 54, 56, 58, and 312; each description of the results of such studies is accurate and complete in all material respects and fairly presents the data derived from such studies, and the Company and its subsidiaries have no knowledge of any other studies the results of which are inconsistent with, or otherwise call into question, the results described or referred to in the Registration Statement, the Time of Sale Prospectuses or the Prospectus; the Company and its subsidiaries have made all such filings and obtained all such Permits as may be required by the Food and Drug Administration of the U.S. Department of Health and Human Services or any committee thereof or from any other U.S. or foreign government or drug or medical device regulatory agency, or health care facility Institutional Review Board (collectively, the "**Regulatory Agencies**") for the operation of the Company's business as currently conducted, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; neither the Company nor any of its subsidiaries has received any notice of, or correspondence from, any Regulatory Agency requiring the termination, suspension or modification of any clinical trials that are described or referred to in the Registration Statement, the Time of Sale Prospectus or the Prospectus; and the Company and its subsidiaries have each operated and currently are in compliance in all material respects with all applicable rules and regulations of the Regulatory Agencies except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(tt) ***Compliance with Health Care Laws***. Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, each of the Company and its subsidiaries is, and at all times has been, in compliance with all applicable Health Care Laws, and has not engaged in activities which are, as applicable, cause for false claims liability, civil penalties, or mandatory or permissive exclusion from Medicare, Medicaid, or any other state health care program or federal health care program. For purposes of this Agreement, "**Health Care Laws**" means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; (ii) all applicable federal, state, local and all applicable foreign health care related fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the Anti-Inducement Law (42 U.S.C. § 1320a-7a(a)(5)), the U.S. Physician Payment Sunshine Act (42 U.S.C. § 1320a-7h), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Claims Law (42 U.S.C. § 1320a-7b(a)), all criminal laws relating to health care fraud and abuse, including but not limited to 18 U.S.C. Sections 286 and 287, and the health care fraud criminal provisions under the U.S. Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**") (42 U.S.C. Section 1320d et seq.), the exclusion laws (42 U.S.C. § 1320a-7), the civil monetary penalties law (42 U.S.C. § 1320a-7a), HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (42 U.S.C. Section 17921 et seq.), and the regulations promulgated pursuant to such statutes; (iii) Medicare (Title XVIII of the Social Security Act); (iv) Medicaid (Title XIX of the Social Security Act); and (v) any and all other applicable health care laws and regulations. Neither the Company nor, to the knowledge of the Company, its subsidiary has received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Health Care Laws, and, to the Company's knowledge, no such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action is threatened. Neither the Company nor, to the knowledge of the Company, its subsidiary is a party to or has any ongoing reporting obligations pursuant to any corporate integrity agreements, deferred prosecution agreements, monitoring agreements, consent decrees, settlement orders, plans of correction or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company, its subsidiaries nor any of its respective employees, officers or directors has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that could reasonably be expected to result in debarment, suspension, or exclusion.

(uu) ***No Contract Terminations.*** Neither the Company nor any of its subsidiaries has sent or received any communication regarding termination of, or intent not to renew, any of the contracts or agreements referred to or described in any preliminary prospectus, the Prospectus or any free writing prospectus, or referred to or described in, or filed as an exhibit to, the Registration Statement, and no such termination or non-renewal has been threatened by the Company or any of its subsidiaries or, to the Company's knowledge, any other party to any such contract or agreement, which threat of termination or non-renewal has not been rescinded as of the date hereof, except where such termination or non-renewal would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(vv) ***Dividend Restrictions*****.** Except as described in the Registration Statement, the Time of Sale Prospectus and the Prospectus, no subsidiary of the Company is prohibited or restricted, directly or indirectly, from paying dividends to the Company, or from making any other distribution with respect to such subsidiary's equity securities or from repaying to the Company or any other subsidiary of the Company any amounts that may from time to time become due under any loans or advances to such subsidiary from the Company or from transferring any property or assets to the Company or to any other subsidiary.

Any certificate signed by any officer of the Company or any of its subsidiaries and delivered to any Underwriter or to counsel for the Underwriters in connection with the offering, or the purchase and sale, of the Offered Shares shall be deemed a representation and warranty by the Company to each Underwriter as to the matters covered thereby.

The Company has a reasonable basis for making each of the representations set forth in this Section 1. The Company acknowledges that the Underwriters and, for purposes of the opinions to be delivered pursuant to Section 8 hereof, counsel to the Company and counsel to the Underwriters, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

Section 2. Purchase, Sale and Delivery of the Offered Shares.

(a) ***The Firm Shares*****.** Upon the terms herein set forth, the Company agrees to issue and sell to the several Underwriters an aggregate of [●] Firm Shares. On the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Underwriters agree, severally and not jointly, to purchase from the Company the respective number of Firm Shares set forth opposite their names on Schedule A. The purchase price per Firm Share to be paid by the several Underwriters to the Company shall be $[●] per share. For the avoidance of doubt, the several Underwriters will deduct the Firm Capital Increase Amount (as defined in Section 3(b)(ii)) from the aggregate purchase price for the Firm Shares payable by the several Underwriters to the Company.

(b) ***The First Closing Date*****.** Delivery of the Firm Shares to be purchased by the Underwriters and payment therefor shall be made at the offices of Latham & Watkins LLP (or such other place as may be agreed to by the Company and the Representative) at [●] a.m. New York City time, on [●], 2015, or such other time and date not later than [●] p.m. New York City time, on [●], 2015 as the Representative shall designate by notice to the Company (the time and date of such closing are called the "**First Closing Date**"). The Company hereby acknowledges that circumstances under which the Representative may provide notice to postpone the First Closing Date as originally scheduled include, but are not limited to, any determination by the Company or the Representative to recirculate to the public copies of an amended or supplemented Prospectus or a delay as contemplated by the provisions of Section 13.

(c) *The Optional Shares; Option Closing Date*. In addition, on the basis of the representations, warranties and agreements herein contained, and upon the terms but subject to the conditions herein set forth, the Company hereby grants an option to the several Underwriters to purchase, severally and not jointly, up to an aggregate of [●] Optional Shares from the Company at the purchase price per share to be paid by the Underwriters for the Firm Shares. For the avoidance of doubt, the several Underwriters will deduct the Over-Allotment Capital Increase Amount (as defined in Section 4(a)(ii)) from the aggregate purchase price for any Applicable Optional Shares (as defined in Section 4(a)(i)) payable by the several Underwriters to the Company. The option granted hereunder may be exercised at any time and from time to time in whole or in part upon notice by the Representative to the Company, which notice may be given at any time within 30 days from the date of this Agreement (the date of any such exercise, an "**Option Exercise Date**"). Such notice shall set forth (i) the aggregate number of Optional Shares as to which the Underwriters are exercising the option and (ii) the time, date and place at which the Optional Shares will be delivered (which time and date may be simultaneous with, but not earlier than, the First Closing Date; and in the event that such time and date are simultaneous with the First Closing Date, the term "**First Closing Date**" shall refer to the time and date of delivery of the Firm Shares and such Optional Shares). Any such time and date of delivery, if subsequent to the First Closing Date, is called an "**Option Closing Date**," shall be determined by the Representative and shall not be earlier than three or later than five full business days after delivery of such notice of exercise. If any Optional Shares are to be purchased, each Underwriter agrees, severally and not jointly, to purchase the number of Optional Shares (subject to such adjustments to eliminate fractional shares as the Representative may determine) that bears the same proportion to the total number of Optional Shares to be purchased as the number of Firm Shares set forth on Schedule A opposite the name of such Underwriter bears to the total number of Firm Shares. The Representative may cancel the option at any time prior to its expiration by giving written notice of such cancellation to the Company.

(d) *Public Offering of the Offered Shares*. The Representative hereby advises the Company that the Underwriters intend to offer for sale to the public, initially on the terms set forth in the Registration Statement, the Time of Sale Prospectus and the Prospectus, their respective portions of the Offered Shares as soon after this Agreement has been executed and the Registration Statement has been declared effective as the Representative, in its sole judgment, have determined is advisable and practicable.

(e) *Payment for the Offered Shares*. (i) Payment for the Offered Shares shall be made at the First Closing Date (and, if applicable, at each Option Closing Date) by wire transfer of immediately available funds to the order of the Company.

(ii) It is understood that the Representative has been authorized, for their own account and the accounts of the several Underwriters, to accept delivery of and receipt for, and make payment of the purchase price for, the Firm Shares and any Optional Shares the Underwriters have agreed to purchase. Leerink, individually and not as the Representative of the Underwriters, may (but shall not be obligated to) make payment for any Offered Shares to be purchased by any Underwriter whose funds shall not have been received by the Representative by the First Closing Date or the applicable Option Closing Date, as the case may be, for the account of such Underwriter, but any such payment shall not relieve such Underwriter from any of its obligations under this Agreement.

(f) *Delivery of the Offered Shares*. The Company shall deliver, or cause to be delivered to the Representative for the accounts of the several Underwriters the Firm Shares at the First Closing Date, against release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The Company shall also deliver, or cause to be delivered to the Representative for the accounts of the several Underwriters, the Optional Shares the Underwriters have agreed to purchase at the First Closing Date or the applicable Option Closing Date, as the case may be, against the release of a wire transfer of immediately available funds for the amount of the purchase price therefor. The Offered Shares shall be registered in such names and denominations as the Representative shall have requested at least two full business days prior to the First Closing Date (or the applicable Option Closing Date, as the case may be). Time shall be of the essence, and delivery at the time and place specified in this Agreement is a further condition to the obligations of the Underwriters.

Section 3. Capital Increase and Initial Subscription.

(a) *Shareholder's Resolution on Capital Increase*. The Company confirms that:

(i) pursuant to the articles of association, the Board of Directors of the Company (the "**Board**") may effect an increase of the Company's share capital in a maximum amount of CHF 3,314,706 by issuing up to 8,286,765 Shares out of the Company's authorized share capital, such authorization having been granted by resolution of the shareholders meeting of July 14, 2014 (*Ermächtigungsbeschluss*); and

(ii) all statutory pre-emptive rights to which the existing shareholders of the Company are entitled under Swiss law with respect to the capital increase described in Section 3(a)(i) have been validly set aside or waived.

(b) *Subscription of Firm Capital Increase*. The Representative, acting in its own name but for the accounts of the several Underwriters, agrees, on the basis of the representations, warranties and agreements herein contained, to:

(i) subscribe, on or by 12:00 p.m. (CEST) three business days prior to the First Closing Date, or such other time and date as agreed between the Company and Representative, for all of the Firm Shares at the issue price (*Ausgabebetrag*) of CHF 0.40 per Firm Share corresponding to the nominal value for each Firm Share and to deliver the corresponding subscription form (*Zeichnungsschein*) to the Company in the form of Exhibit C; and

(ii) deposit or cause to be deposited, not later than 1:30 p.m. (CEST) two business days prior to the First Closing Date, or such other time and date as agreed between the Company and Representative, same-day funds for value in the amount of CHF 0.40 (corresponding to the aggregate nominal value of the Firm Shares) (the "**Firm Capital Increase Amount**") with UBS AG, bank clearing no. 235 (the "**Capital Increase Bank**"), in a blocked account for such capital increase (*Kapitaleinzahlungskonto*), IBAN CH63 0023 5235 1683 93D7 U, made out to the Company's name (the "**Firm Capital Increase Account**"), and to cause the Capital Increase Bank to issue and deliver a written confirmation of payment of the Firm Capital Increase Amount to the Company no later than 6:00 p.m. (CEST) two business days prior to the First Closing Date (or such other time and date as agreed between the Company and the Representative).

(c) *Board Resolution and Registration of Firm Capital Increase*. Upon receipt of the documents referred to in Section 3(b) and before 8:30 a.m. (CEST) on the business day prior to the First Closing Date, or such other time and date as agreed between the Company and the Representative, the Board (or a committee or a Board member duly authorized by the Board) will:

(i) pass a capital increase resolution (*Erhöhungsbeschluss*) regarding the issuance of the Firm Shares subscribed for pursuant to Section 3(b)(i) (the "**Firm Capital Increase**");

(ii) adopt a report on the Firm Capital Increase (*Kapitalerhöhungsbericht*) and take note of the auditors' report (*Prüfungsbestätigung*), all in accordance with Swiss statutory law;

(iii) resolve on the Firm Capital Increase and making all amendments to the articles of association of the Company necessary in connection with the Firm Capital Increase (*Feststellungs- und Statutenänderungsbeschluss*); and

(iv) promptly thereafter, no later than 9:30 a.m. (CEST) on the business day prior to the First Closing Date, file the documents necessary for the registration of the Firm Capital Increase with the Commercial Register of the Canton of Zug;

provided, *however*, that if this Agreement is terminated pursuant to Section 14 prior to the Company filing the relevant resolutions with the Commercial Register of the Canton of Zug, (A) the Company undertakes not to resolve on the Firm Capital Increase (if it has not already done so) or to file the relevant resolutions with the Commercial Register of the Canton of Zug, and (B) the Company shall immediately cause the Capital Increase Bank to release the Firm Capital Increase Amount in full to the Representative, acting for the accounts of the several Underwriters, as soon as practicable; and the Underwriters understand that the Capital Increase Bank may require confirmation, including from the Underwriters, to release the Firm Capital Increase Amount and the Underwriters agree to deliver such confirmation.

(d) ***Issue of Firm Shares***. Immediately after the registration of the Firm Capital Increase in the Commercial Register of the Canton of Zug pursuant to Section 3(c), but in no event later than 5:00 p.m. (CEST) on the business day prior to the First Closing Date, the Company will:

(i) deliver to each of the Representative and the Capital Increase Bank, (A) a copy of the certified excerpt of the journal entry (*Tagebuch*) or a copy of the certified excerpt from the Commercial Register of the Canton of Zug evidencing the Firm Capital Increase, (B) a copy of the certified updated articles of association of the Company evidencing the Firm Capital Increase, (C) a copy of the Company's book of uncertificated securities (*Wertrechtebuch*) evidencing the Underwriters as first holders of the Firm Shares, and (D) a copy of the share register (*Aktienbuch*) of the Company evidencing the Underwriters as shareholders with respect to the Firm Shares; and

(ii) take all steps necessary to ensure that the Firm Shares will be (A) duly recorded in an account of the Underwriters at the Depository Trust Company ("**DTC**") on the First Closing Date; and (B) freely transferable (subject to any applicable restrictions set forth in the articles of association of the Company) on the First Closing Date.

(e) ***Use of Firm Capital Increase Amount.*** The funds deposited in the Firm Capital Increase Account shall, upon registration of the Firm Capital Increase pursuant to Section 3(c) and upon request by the Representative, be transferred to a separate account of the Company with UBS AG and shall, in such case, remain so deposited for the account of the Company until the earlier of:

(i) the issuance of the Firm Shares to the Underwriters as set forth in Section 3(d) on the First Closing Date; and

(ii) the date of receipt by the Representative on behalf of the several Underwriters of the proceeds of (A) the sale of the Firm Shares as set forth in Sections 15(b), 15(c) or 15(e) or (B) the Capital Reduction as set forth in Section 15(d), as the case may be.

Any fees payable to the Capital Increase Bank for any transfer of the funds deposited in the Firm Capital Increase Account pursuant to this Section 3(e) shall be payable directly to the Capital Increase Bank by the Company.

Section 4. Subscription and Issuance of Optional Shares.

(a) ***Subscription of Over-Allotment Capital Increase*****.** If the Representative exercises the option granted to it under Section 2(c) of this Agreement, the Representative, acting in its own name but for the accounts of the several Underwriters, agrees, on the basis of the representations, warranties and agreements herein contained, and subject to the conditions stated below and to this Agreement having not been terminated, to:

(i) subscribe for the number of Optional Shares for which the option to purchase has been exercised pursuant to Section 2(c) (the "**Applicable Optional Shares**") at the issue price (*Ausgabebetrag*) of CHF 0.40 for each Applicable Optional Share corresponding to the nominal value of each Applicable Optional Share, and to deliver the corresponding subscription form (*Zeichnungsschein*) in the form of Exhibit C to the Company by not later than 12:00 p.m. (CEST) two business days prior to the Option Closing Date (or such other date set forth in the relevant option exercise notice delivered by the Representative pursuant to Section 2(c)); and

(ii) deposit or cause to be deposited, not later than 1:30 p.m. (CEST) two business days prior to the Option Closing Date (or such other date set forth in the relevant option exercise notice delivered by the Representative pursuant to Section 2(c)), same day funds for value on such date, in the amount of CHF 0.40 multiplied by the number of Applicable Optional Shares (the "**Over-Allotment Capital Increase Amount**") with the Capital Increase Bank, in a blocked account for the Over-Allotment Capital Increase (*Kapitaleinzahlungskonto*), IBAN CH63 0023 5235 1683 93D7 U, made out to the Company's name (the "**Over-Allotment Capital Increase Account**"), and to cause the Capital Increase Bank to issue and deliver a written confirmation of payment of the Over-Allotment Capital Increase Amount to the Company no later than 6:00 p.m. (CEST) two business days prior to the Option Closing Date (or at a later date, as set forth in the option exercise notice delivered by the Representative pursuant to Section 2(c)).

(b) ***Board Resolution and Registration of Over-Allotment Capital Increase*****.** Upon receipt of the documents referred to under Section 4(a) in relation to any Applicable Optional Shares and before 9:30 a.m. (CEST) on the business day prior to the Option Closing Date (or at a later date, as set forth in the relevant option exercise notice delivered by the Representative pursuant to Section 2(c)), the Board (or a committee or Board member duly authorized by the Board) will:

(i) pass a capital increase resolution (*Erhöhungsbeschluss*) regarding the issuance of the Applicable Optional Shares subscribed for pursuant to Section 4(a)(i) (the "**Over-Allotment Capital Increase**");

(ii) adopt a report on the Over-Allotment Capital Increase (*Kapitalerhöhungsbericht*) and take note of the auditors' report (*Prüfungsbestätigung*), all in accordance with Swiss statutory law;

(iii) resolve on the Over-Allotment Capital Increase and making all amendments to the articles of association of the Company necessary in connection with the Over-Allotment Capital Increase (*Feststellungs- und Statutenänderungsbeschluss*); and

(iv) promptly thereafter, no later than 9:30 a.m. (CEST) on the business day prior to the Option Closing Date (or at a later date, as set forth in the relevant option exercise notice delivered by the Representative pursuant to Section 2(c)) file the documents necessary for the registration of the Over-Allotment Capital Increase with the Commercial Register of the Canton of Zug *provided*, *however*, that if this Agreement is terminated pursuant to Section 14 prior to the Company filing the relevant resolutions with the Commercial Register of the Canton of Zug, (A) the Company undertakes not to resolve on the Over-Allotment Capital Increase (if it has not already done so) or to file the relevant resolutions with the Commercial Register of the Canton of Zug, and (B) the Company shall immediately cause the Capital Increase Bank to release the Capital Increase Amount in full to the Representative, acting for the accounts of the several Underwriters, as soon as practicable; and the Underwriters understand that the Capital Increase Bank may require confirmation, including from the Underwriters, to release the Firm Capital Increase Amount and the Underwriters agree to deliver such confirmation.

(c) ***Issue of Applicable Optional Shares***. Immediately after the registration of the Over-Allotment Capital Increase in the Commercial Register of the Canton of Zug pursuant to Section 4(b) in relation to any Applicable Optional Shares, but in no event later than 3:00 p.m. (CEST) on the business day prior to the Option Closing Date (or such other date set forth in the relevant option exercise notice delivered by the Representative pursuant to Section 2(c)), the Company will:

(i) deliver to each of the Representative, the Capital Increase Bank and the share registrar of the Company, (A) a copy of the certified excerpt of the journal entry (*Tagebuch*) or a copy of the certified excerpt from the Commercial Register of the Canton of Zug evidencing the Over-Allotment Capital Increase, (B) a copy of the certified updated articles of association of the Company evidencing the Over-Allotment Capital Increase, (C) a copy of the Company's book of uncertificated securities (*Wertrechtebuch*) evidencing the Underwriters as first holders of the Applicable Optional Shares, and (D) a copy of the share register (*Aktienbuch*) of the Company evidencing the Underwriters as shareholders with respect to the Applicable Optional Shares; and

(ii) take all steps necessary to ensure that the Applicable Optional Shares will be (A) issued to the Underwriters, (B) duly recorded in an account of the Underwriters at DTC on the relevant Option Closing Date, and (C) freely transferable (subject to any applicable restrictions set forth in the articles of association of the Company) on the relevant Option Closing Date.

(d) ***Use of Over-Allotment Capital Increase Amount.*** The funds deposited in the Over-Allotment Capital Increase Account shall, upon registration of the Over-Allotment Capital Increase pursuant to Section 4(b) and upon request by the Representative, be transferred to a separate account of the Company with UBS AG and shall, in such case, remain so deposited, without interest, for the account of the Company until the earlier of:

(i) the issuance of the Applicable Optional Shares to the Underwriters as set forth in Section 4(c) on the relevant Option Closing Date; and

(ii) the date of receipt by the Representative on behalf of the several Underwriters of the proceeds of (A) the sale of the Applicable Optional Shares as set forth in Sections 15(b), or 15(c) or 15(e) or (B) the Capital Reduction as set forth in Section 15(d), as the case may be.

Any fees payable to the Capital Increase Bank for any transfer of the funds deposited in the Over-Allotment Capital Increase Account pursuant to this Section 4(d) shall be payable directly to the Capital Increase Bank by the Company.

Section 5. Additional Covenants of the Company.

The Company further covenants and agrees with each Underwriter as follows:

(a) ***Delivery of Registration Statement, Time of Sale Prospectus and Prospectus.*** The Company shall furnish to you in New York City, without charge, prior to 10:00 a.m. New York City time on the business day next succeeding the date of this Agreement and during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares, as many copies of the Time of Sale Prospectus, the Prospectus and any supplements and amendments thereto or to the Registration Statement as you may reasonably request.

(b) ***Representative's Review of Proposed Amendments and Supplements.*** During the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), the Company (i) will furnish to the Representative for review, a reasonable period of time prior to the proposed time of filing of any proposed amendment or supplement to the Registration Statement, a copy of each such amendment or supplement and (ii) will not amend or supplement the Registration Statement without the Representative's prior written consent, which shall not be unreasonably withheld. Prior to amending or supplementing any preliminary prospectus, the Time of Sale Prospectus or the Prospectus, the Company shall furnish to the Representative for review, a reasonable amount of time prior to the time of filing or use of the proposed amendment or supplement, a copy of each such proposed amendment or supplement. The Company shall not file or use any such proposed amendment or supplement without the Representative's prior written consent, which shall not be unreasonably withheld. The Company shall file with the Commission within the applicable period specified in Rule 424(b) under the Securities Act any prospectus required to be filed pursuant to such Rule.

(c) ***Free Writing Prospectuses.*** The Company shall furnish to the Representative for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of each proposed free writing prospectus or any amendment or supplement thereto prepared by or on behalf of, used by, or referred to by the Company, and the Company shall not file, use or refer to any proposed free writing prospectus or any amendment or supplement thereto without the Representative's prior written consent, which shall not be unreasonably withheld. The Company shall furnish to each Underwriter, without charge, as many copies of any free writing prospectus prepared by or on behalf of, used by or referred to by the Company as such Underwriter may reasonably request. If at any time when a prospectus is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) in connection with sales of the Offered Shares (but in any event if at any time through and including the First Closing Date) there occurred or occurs an event or development as a result of which any free writing prospectus prepared by or on behalf of, used by, or referred to by the Company conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, the Company shall promptly amend or supplement such free writing prospectus to eliminate or correct such conflict so that the statements in such free writing prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances prevailing at such time, not misleading, as the case may be; *provided, however*, that prior to amending or supplementing any such free writing prospectus, the Company shall furnish to the Representative for review, a reasonable amount of time prior to the proposed time of filing or use thereof, a copy of such proposed amended or supplemented free writing prospectus, and the Company shall not file, use or refer to any such amended or supplemented free writing prospectus without the Representative's prior written consent, which shall not be unreasonably withheld.

(d) *Filing of Underwriter Free Writing Prospectuses.* The Company shall not take any action that would result in an Underwriter or the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that such Underwriter otherwise would not have been required to file thereunder.

(e) *Amendments and Supplements to Time of Sale Prospectus.* If the Time of Sale Prospectus is being used to solicit offers to buy the Offered Shares at a time when the Prospectus is not yet available to prospective purchasers, and any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Time of Sale Prospectus so that the Time of Sale Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading, or if any event shall occur or condition exist as a result of which the Time of Sale Prospectus conflicts with the information contained in the Registration Statement, or if, in the opinion of counsel for the Underwriters, it is necessary to amend or supplement the Time of Sale Prospectus to comply with applicable law, the Company shall (subject to Section 5(b) and Section 5(c) hereof) promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, either amendments or supplements to the Time of Sale Prospectus so that the statements in the Time of Sale Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when delivered to a prospective purchaser, not misleading or so that the Time of Sale Prospectus, as amended or supplemented, will no longer conflict with the information contained in the Registration Statement, or so that the Time of Sale Prospectus, as amended or supplemented, will comply with applicable law.

(f) *Certain Notifications and Required Actions*. After the date of this Agreement, the Company shall promptly advise the Representative in writing of: (i) the receipt of any comments of, or requests for additional or supplemental information from, the Commission; (ii) the time and date of any filing of any post-effective amendment to the Registration Statement or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus; (iii) the time and date that any post-effective amendment to the Registration Statement becomes effective; and (iv) the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto or any amendment or supplement to any preliminary prospectus, the Time of Sale Prospectus or the Prospectus or of any order preventing or suspending the use of any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus or the Prospectus, or of any proceedings to remove, suspend or terminate from listing or quotation the Shares from any securities exchange upon which they are listed for trading or included or designated for quotation, or, to the Company's knowledge, of the threatening or initiation of any proceedings for any of such purposes. If the Commission shall enter any such stop order at any time, the Company will use its best efforts to obtain the lifting of such order at the earliest possible moment. Additionally, the Company agrees that it shall comply with all applicable provisions of Rule 424(b), Rule 433 and Rule 430A under the Securities Act and will use its reasonable efforts to confirm that any filings made by the Company under Rule 424(b) or Rule 433 were received in a timely manner by the Commission.

(g) *Amendments and Supplements to the Prospectus and Other Securities Act Matters.* If any event shall occur or condition exist as a result of which it is necessary to amend or supplement the Prospectus so that the Prospectus does not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading, or if in the opinion of the Representative or counsel for the Underwriters it is otherwise necessary to amend or supplement the Prospectus to comply with applicable law, the Company agrees (subject to Section 5(b) and Section 5(c)) hereof to promptly prepare, file with the Commission and furnish, at its own expense, to the Underwriters and to any dealer upon request, amendments or supplements to the Prospectus so that the statements in the Prospectus as so amended or supplemented will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances when the Prospectus is delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) to a purchaser, not misleading or so that the Prospectus, as amended or supplemented, will comply with applicable law. Neither the Representative's consent to, nor delivery of, any such amendment or supplement shall constitute a waiver of any of the Company's obligations under Section 5(b) or Section 5(c).

(h) ***Blue Sky Compliance*.** The Company shall cooperate with the Representative and counsel for the Underwriters to qualify or register the Offered Shares for sale under (or obtain exemptions from the application of) the state securities or blue sky laws or Canadian provincial securities laws (or other foreign laws) of those jurisdictions reasonably designated by the Representative, shall comply with such laws and shall continue such qualifications, registrations and exemptions in effect so long as required for the distribution of the Offered Shares. The Company shall not be required to qualify as a foreign corporation or to take any action that would subject it to general service of process in any such jurisdiction where it is not presently qualified or where it would be subject to taxation as a foreign corporation. The Company will advise the Representative promptly of the suspension of the qualification or registration of (or any such exemption relating to) the Offered Shares for offering, sale or trading in any jurisdiction or any initiation or threat of any proceeding for any such purpose, and in the event of the issuance of any order suspending such qualification, registration or exemption, the Company shall use its best efforts to obtain the withdrawal thereof at the earliest possible moment.

(i) ***Use of Proceeds*.** The Company shall apply the net proceeds from the sale of the Offered Shares sold by it in all material respects as described under the caption "Use of Proceeds" in the Registration Statement, the Time of Sale Prospectus and the Prospectus.

(j) ***Earnings Statement*.** The Company will make generally available to its security holders and to the Representative as soon as practicable an earnings statement (which need not be audited) covering a period of at least twelve months beginning with the first fiscal quarter of the Company commencing after the date of this Agreement that will satisfy the provisions of Section 11(a) of the Securities Act and the rules and regulations of the Commission thereunder.

(k) ***Continued Compliance with Securities Laws*.** The Company will comply with the Securities Act and the Exchange Act so as to permit the completion of the distribution of the Offered Shares as contemplated by this Agreement**,** the Registration Statement, the Time of Sale Prospectus and the Prospectus. Without limiting the generality of the foregoing, the Company will, during the period when a prospectus relating to the Offered Shares is required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule), file on a timely basis with the Commission and the NASDAQ all reports and documents required to be filed under the Exchange Act.

(l) ***Listing*.** The Company will use its best efforts to list the Offered Shares on the NASDAQ.

(m) ***Company to Provide Copy of the Prospectus in Form That May be Downloaded from the Internet*.** If requested by the Representative, the Company shall cause to be prepared and delivered, at its expense, within two business days from the effective date of this Agreement, to the Representative an “**electronic Prospectus**” to be used by the Underwriters in connection with the offering and sale of the Offered Shares. As used herein, the term “**electronic Prospectus**” means a form of Time of Sale Prospectus, and any amendment or supplement thereto, that meets each of the following conditions: (i) it shall be encoded in an electronic format, reasonably satisfactory to the Representative, that may be transmitted electronically by the Representative and the other Underwriters to offerees and purchasers of the Offered Shares; (ii) it shall disclose the same information as the paper Time of Sale Prospectus, except to the extent that graphic and image material cannot be disseminated electronically, in which case such graphic and image material shall be replaced in the electronic Prospectus with a fair and accurate narrative description or tabular representation of such material, as appropriate; and (iii) it shall be in or convertible into a paper format or an electronic format, reasonably satisfactory to the Representative, that will allow investors to store and have continuously ready access to the Time of Sale Prospectus at any future time, without charge to investors (other than any fee charged for subscription to the Internet as a whole and for on-line time). The Company hereby confirms that it has included or will include in the Prospectus filed pursuant to EDGAR or otherwise with the Commission and in the Registration Statement at the time it was declared effective an undertaking that, upon receipt of a request by an investor or his or her representative, the Company shall transmit or cause to be transmitted promptly, without charge, a paper copy of the Time of Sale Prospectus.

(n) ***Agreement Not to Offer or Sell Additional Shares*****.** During the period commencing on and including the date hereof and continuing through and including the 90th day following the date of the Prospectus (such period being referred to herein as the “**Lock-up Period**”), the Company will not, without the prior written consent of the Representative (which consent may be withheld in its sole discretion), directly or indirectly: (i) sell, offer to sell, contract to sell or lend any Shares or Related Securities (as defined below); (ii) effect any short sale, or establish or increase any “put equivalent position” (as defined in Rule 16a-1(h) under the Exchange Act) or liquidate or decrease any “call equivalent position” (as defined in Rule 16a-1(b) under the Exchange Act) of any Shares or Related Securities; (iii) pledge, hypothecate or grant any security interest in any Shares or Related Securities; (iv) in any other way transfer or dispose of any Shares or Related Securities; (v) enter into any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of any Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise; (vi) announce the offering of any Shares or Related Securities; (vii) file any registration statement under the Securities Act in respect of any Shares or Related Securities (other than as contemplated by this Agreement with respect to the Offered Shares); or (viii) publicly announce the intention to do any of the foregoing; *provided*, *however*, that the Company may (A) effect the transactions contemplated hereby (B) issue Shares, rights to receive Shares, phantom equity settleable into Shares or options to purchase Shares, or issue Shares upon settlement of phantom equity or vesting of rights to receive Shares or exercise of options, pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Registration Statement, the Time of Sale Prospectus and the Prospectus or any compensatory equity plan, but only if the holders of such Shares, phantom equity, rights to receive Shares or options agree in writing with the Underwriters not to sell, offer, dispose of or otherwise transfer any such Shares, rights to receive Shares, phantom equity or options during such Lock-up Period without the prior written consent of the Representative (which consent may be withheld in its sole discretion), except as allowed pursuant to the form of Lock-up Agreement on Exhibit A, (C) file any registration statement on Form S-8 or a successor form thereto, (D) file any registration statement that the Company is required to file pursuant to the Registration Rights Agreement dated as of August 11, 2014, among the Company and the Shareholders party thereto and (E) issue Shares or other securities issued in connection with a transaction that includes a commercial relationship (including joint ventures, marketing or distribution arrangements, collaboration agreements or intellectual property license agreements) or any acquisition of assets or not less than a majority or controlling portion of the equity of another entity, provided that (x) the aggregate number of shares issued pursuant to this clause (E) shall not exceed 5.0% of the total number of outstanding Shares immediately following the issuance and sale of the Offered

Shares pursuant hereto and (y) the recipient of any such Shares and securities issued pursuant to this clause (E) during the 90th-day restricted period described above shall enter into an agreement in writing with the Underwriters not to sell, offer, dispose of or otherwise transfer any such Shares or securities during such Lock-up Period without the prior written consent of the Representative (which consent may be withheld in its sole discretion). For purposes of the foregoing, "**Related Securities**" shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for, or convertible into, Shares.

(o) ***Future Reports to the Representative.*** During the period of two years hereafter, the Company will furnish to the Representative, c/o Leerink, at 255 California Street, 12th Floor, San Francisco, CA 94111, Attention: [●]: (i) as soon as practicable after the end of each fiscal year, copies of the Annual Report of the Company containing the consolidated statement of financial position of the Company as of the close of such fiscal year and consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for the year then ended and the opinion thereon of the Company's independent public or certified public accountants; (ii) as soon as practicable after the filing thereof, copies of each Annual Report on Form 20-F, Report on Form 6-K or other report filed by the Company with the Commission or any securities exchange; and (iii) as soon as available, copies of any report or communication of the Company furnished or made available generally to holders of its capital stock; *provided, however*, that the requirements of this Section 5(o) shall be satisfied to the extent that such reports, statement, communications, financial statements or other documents are available on EDGAR.

(p) ***Investment Limitation*****.** The Company shall not invest or otherwise use the proceeds received by the Company from its sale of the Offered Shares in such a manner as would require the Company or any of its subsidiaries to register as an investment company under the Investment Company Act.

(q) ***No Stabilization or Manipulation; Compliance with Regulation M*****.** The Company will not take, and will ensure that no affiliate of the Company will take, directly or indirectly, any action designed to or that might cause or result in stabilization or manipulation of the price of the Shares or any reference security with respect to the Shares, whether to facilitate the sale or resale of the Offered Shares or otherwise, and the Company will, and shall cause each of its affiliates to, comply with all applicable provisions of Regulation M (it being understood that the Company makes no statement as to the activities of the Underwriters in connection with the offering).

(r) ***Enforce Lock-Up Agreements*****.** During the Lock-up Period, the Company will use commercially reasonable efforts to enforce all agreements between the Company and any of its security holders that restrict or prohibit, expressly or in operation, the offer, sale or transfer of Shares or Related Securities or any of the other actions restricted or prohibited under the terms of the form of Lock-up Agreement. In addition, the Company will direct the transfer agent to place stop transfer restrictions upon any such securities of the Company that are bound by such "lock-up" agreements for the duration of the periods contemplated in such agreements, including, without limitation, "lock-up" agreements entered into by the Company's officers and directors pursuant to Section 8(m) hereof.

(s) ***Company to Provide Interim Financial Statements*****.** Prior to the First Closing Date and each applicable Option Closing Date, the Company will furnish the Underwriters, as soon as practicable after they have been prepared by or are available to the Company, a copy of any unaudited interim quarterly financial statements of the Company for any period subsequent to the period covered by the most recent financial statements appearing in the Registration Statement and the Prospectus; *provided, however,* that the requirements of this Section 5(s) shall be satisfied to the extent that such financial statements are available on EDGAR.

(t) *Tax Indemnity.* The Company will indemnify and hold harmless the Underwriters against all issue, transfer and other stamp taxes, in connection with the issuance and sale of the Offered Shares to the Underwriters, but excluding any brokerage and resale fee or security transfer tax including, without limitation, any Swiss Federal stamp duty on the transfer of securities (*Umsatzabgabe*) — should the Underwriters be Swiss security dealers in the meaning of the Swiss law on stamp duty — and any income tax, capital gains tax or similar resulting from the sale of the Offered Shares and any tax on or determined by reference to the income of any Underwriter that is subject to tax on a net income basis.

(u) *Transfer Agent.* The Company agrees to maintain a transfer agent and, if necessary under the jurisdiction of incorporation of the Company, a registrar for the Shares.

(v) *Amendments and Supplements to Permitted Section 5(d)Communications*. If at any time following the distribution of any Permitted Section 5(d) Communication, there occurred or occurs an event or development as a result of which such Permitted Section 5(d) Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Representative and will promptly amend or supplement, at its own expense, such Permitted Section 5(d) Communication to eliminate or correct such untrue statement or omission.

(w) *Emerging Growth Company Status*. The Company will promptly notify the Representative if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) the time when a prospectus relating to the Offered Shares is not required by the Securities Act to be delivered (whether physically or through compliance with Rule 172 under the Securities Act or any similar rule) and (ii) the expiration of the Lock-Up Period (as defined herein).

Section 6. Payment of Expenses. The Company agrees to pay all costs, fees and expenses incurred in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including without limitation (i) all expenses incident to the issuance and delivery of the Offered Shares (including all printing and engraving costs), (ii) all fees and expenses of the registrar and transfer agent of the Shares, (iii) all issue, transfer and other stamp taxes in connection with the issuance and sale of the Offered Shares to the Underwriters, (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors, (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Time of Sale Prospectus, the Prospectus, each free writing prospectus prepared by or on behalf of, used by, or referred to by the Company, and each preliminary prospectus, each Permitted Section 5(d) Communication, and all amendments and supplements thereto, and this Agreement, (vi) all filing fees, attorneys' fees and expenses incurred by the Company or the Underwriters in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Offered Shares for offer and sale under the state securities or blue sky laws or the provincial securities laws of Canada, and, if requested by the Representative, preparing and printing a "Blue Sky Survey" or memorandum (such "Blue Sky Survey" or memorandum, fees and expenses of counsel not to exceed $10,000) and a "Canadian wrapper", and any supplements thereto, advising the Underwriters of such qualifications, registrations and exemptions, (vii) the costs, fees and expenses incurred by the Underwriters in connection with determining their compliance with the rules and regulations of FINRA related to the Underwriters' participation in the offering and distribution of the Offered Shares, including any related filing fees and the legal fees of, and disbursements by, counsel to the Underwriters (such counsel fees not to exceed $30,000), (viii) the costs and expenses of the Company relating to investor presentations on any "road show", any Permitted Section 5(d) Communication or any Section 5(d) Oral Communication undertaken in connection with the offering of the Offered Shares, including, without limitation, expenses associated with the preparation or dissemination of any electronic road show, expenses associated with the production of road show slides and graphics, fees and expenses of any consultants engaged in connection with the road show presentations with the prior approval of the Company, and travel and lodging expenses of the representatives, employees and officers of the Company and any such consultants, (ix) the fees and expenses associated with listing the Offered Shares on the NASDAQ and (x) all other fees, costs and expenses of the nature referred to in Item 13 of Part II of the Registration Statement. Except as provided in this Section 6 or in Section 9, Section 11 or Section 12 hereof, the Underwriters shall pay their own expenses, including the fees and disbursements of their counsel, stock transfer taxes payable on the sale and delivery by the Underwriters of the Offered Shares to the initial purchasers thereof, including, without limitation, any Swiss federal stamp duty on the issuance of securities (*Emissionsabgabe*) and Swiss federal stamp duty on the transfer of securities (*Umsatzabgabe*), any advertising expenses connected with any offers they may make and the travel expenses of their own representatives in connection with any road show presentation to potential investors. Further, the Underwriters and the Company will each pay 50% of the costs of any jointly used chartered aircraft in the road show.

Section 7. Covenant of the Underwriters. Each Underwriter severally and not jointly covenants with the Company not to take any action that would result in the Company being required to file with the Commission pursuant to Rule 433(d) under the Securities Act a free writing prospectus prepared by or on behalf of such Underwriter that otherwise would not, but for such actions, be required to be filed by the Company under Rule 433(d).

Section 8. Conditions of the Obligations of the Underwriters. The respective obligations of the several Underwriters hereunder to purchase and pay for the Offered Shares as provided herein on the First Closing Date and, with respect to the Optional Shares, each Option Closing Date, shall be subject to the accuracy of the representations and warranties on the part of the Company set forth in Section 1 hereof as of the date hereof and as of the First Closing Date as though then made and, with respect to the Optional Shares, as of each Option Closing Date as though then made, to the timely performance by the Company of its covenants and other obligations hereunder, and to each of the following additional conditions:

(a) ***Comfort Letter of Deloitte AG.*** On the date hereof, the Representative shall have received from Deloitte AG, independent registered public accountants for the Company for the 2014 financial year, a letter dated the date hereof addressed to Leerink Partners LLC, as representative of the several underwriters, in form and substance satisfactory to the Representative, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus, and each free writing prospectus, if any.

(b) ***Comfort Letter of KPMG AG.*** On the date hereof, the Representative shall have received from KPMG AG, independent registered public accountants for the Company for the 2013 and 2012 financial years, a letter dated the date hereof addressed to Leerink Partners LLC, as representative of the several underwriters, in form and substance satisfactory to the Representative, containing statements and information of the type ordinarily included in accountant's "comfort letters" to underwriters, delivered according to Statement of Auditing Standards No. 72 (or any successor bulletin), with respect to the audited financial statements and certain financial information contained in the Registration Statement, the Time of Sale Prospectus, and each free writing prospectus, if any.

(c) ***Compliance with Registration Requirements; No Stop Order; No Objection from FINRA.***

(i) The Company shall have filed the Prospectus with the Commission (including the information required by Rule 430A under the Securities Act) in the manner and within the time period required by Rule 424(b) under the Securities Act; or the Company shall have filed a post-effective amendment to the Registration Statement containing the information required by such Rule 430A, and such post-effective amendment shall have become effective.

(ii) No stop order suspending the effectiveness of the Registration Statement or any post-effective amendment to the Registration Statement shall be in effect, and, to the knowledge of the Company, no proceedings for such purpose shall have been instituted or threatened by the Commission.

(iii) FINRA shall have raised no objection to the fairness and reasonableness of the underwriting terms and arrangements.

(d) ***No Material Adverse Change or Ratings Agency Change*****.** For the period from and after the date of this Agreement and through and including the First Closing Date and, with respect to any Optional Shares purchased after the First Closing Date, each Option Closing Date:

(i) in the judgment of the Representative there shall not have occurred any Material Adverse Change; and

(ii) there shall not have occurred any downgrading, nor shall any notice have been given of any intended or potential downgrading or of any review for a possible change that does not indicate the direction of the possible change, in the rating accorded any securities of the Company or any of its subsidiaries by any “nationally recognized statistical rating organization” as that term is used in Rule 15c3-1(c)(2)(vi)(F) under the Exchange Act.

(e) ***Opinion of U.S. Counsel for the Company*****.** On each of the First Closing Date and each Option Closing Date the Representative shall have received the opinion and 10b-5 statement of Davis Polk & Wardwell LLP, U.S. counsel for the Company, dated as of such date, in the form and substance previously agreed to by, and satisfactory to, the Representative.

(f) ***Opinion of Swiss Counsel for the Company.*** On each of the First Closing Date and each Option Closing Date, the Representative shall have received the opinion of Froriep, counsel for the Company with respect to the laws of Switzerland, dated as of such date, in the form and substance previously agreed to by, and satisfactory to, the Representative.

(g) ***Opinion of Cooley LLP.*** On each of the First Closing Date and each Option Closing Date, the Representative shall have received the opinion of Cooley LLP, counsel for the Company with respect to intellectual property and regulatory matters, dated as of such date, in the form and substance previously agreed to by, and satisfactory to, the Representative.

(h) ***Opinion of U.S. Counsel for the Underwriters*****.** On each of the First Closing Date and each Option Closing Date the Representative shall have received the opinion and 10b-5 statement of Latham & Watkins LLP, counsel for the Underwriters in connection with the offer and sale of the Offered Shares, in form and substance satisfactory to the Underwriters, dated as of such date with executed copies for each of the other Underwriters named on the Prospectus cover page.

(i) ***Opinion of Swiss Counsel for the Underwriters.*** On each of the First Closing Date and each Option Closing Date, the Representative shall have received the opinion of Homburger, counsel for the Underwriters with respect to the laws of Switzerland, in form and substance satisfactory to the Underwriters, dated as of such date, with executed copies for each of the other Underwriters named on the Prospectus cover page.

(j) ***Officers' Certificate*****.** On each of the First Closing Date and each Option Closing Date, the Representative shall have received a certificate, on behalf of the Company, executed by the Chief Executive Officer of the Company and the Chief Financial Officer of the Company, dated as of such date, to the effect set forth in Section 8(c)(ii) and further to the effect that:

(i) for the period from and including the date of this Agreement through and including such date, there has not occurred any Material Adverse Change;

(ii) the representations, warranties and covenants of the Company set forth in Section 1 of this Agreement are true and correct with the same force and effect as though expressly made on and as of such date; and

(iii) the Company has complied, in all material respects, with all the agreements hereunder and satisfied all the conditions on its part to be performed or satisfied hereunder at or prior to such date.

(k) ***Bring-down Comfort Letter of Deloitte AG*****.** On each of the First Closing Date and each Option Closing Date the Representative shall have received from Deloitte AG, independent registered public accountants for the Company for the 2014 financial year, a letter dated such date, in form and substance satisfactory to the Representative, which letter shall: (i) reaffirm the statements made in the letter furnished by them pursuant to Section 8(a), except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the First Closing Date or the applicable Option Closing Date, as the case may be; and (ii) cover certain financial information contained in the Prospectus.

(l) ***Bring-down Comfort Letter of KPMG AG*****.** On each of the First Closing Date and each Option Closing Date the Representative shall have received from KPMG AG, independent registered public accountants for the Company for the 2013 and 2012 financial years, a letter dated such date, in form and substance satisfactory to the Representative, which letter shall: (i) reaffirm the statements made in the letter furnished by them pursuant to Section 8(b), except that the specified date referred to therein for the carrying out of procedures shall be no more than three business days prior to the First Closing Date or the applicable Option Closing Date, as the case may be; and (ii) cover certain financial information contained in the Prospectus.

(m) ***Lock-Up Agreements.*** On or prior to the date hereof, the Company shall have furnished to the Representative an agreement in the form of Exhibit A hereto from each of the persons listed on Exhibit B hereto, and each such agreement shall be in full force and effect on each of the First Closing Date and each Option Closing Date.

(n) ***Rule 462(b) Registration Statement*****.** In the event that a Rule 462(b) Registration Statement is filed in connection with the offering contemplated by this Agreement, such Rule 462(b) Registration Statement shall have been filed with the Commission on the date of this Agreement and shall have become effective automatically upon such filing.

(o) ***Approval of Listing***. At the First Closing Date, the Offered Shares shall have been approved for listing on the NASDAQ, subject only to official notice of issuance.

(p) ***Additional Documents***. On or before each of the First Closing Date and each Option Closing Date, the Representative and counsel for the Underwriters shall have received such information, documents and opinions as they may reasonably request for the purposes of enabling them to pass upon the issuance and sale of the Offered Shares as contemplated herein, or in order to evidence the accuracy of any of the representations and warranties, or the satisfaction of any of the conditions or agreements, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Offered Shares as contemplated herein and in connection with the other transactions contemplated by this Agreement shall be reasonably satisfactory in form and substance to the Representative and counsel for the Underwriters.

If any condition specified in this Section 8 is not satisfied when and as required to be satisfied, this Agreement may be terminated by the Representative by notice from the Representative to the Company at any time on or prior to the First Closing Date and, with respect to the Optional Shares, at any time on or prior to the applicable Option Closing Date, which termination shall be without liability on the part of any party to any other party, except that Section 6, Section 9, Section 11 and Section 12 shall at all times be effective and shall survive such termination.

Section 9. Reimbursement of Underwriters' Expenses. If this Agreement is terminated by the Representative pursuant to Section 8, Section 13 (in such case, only such Underwriters as have so terminated this Agreement with respect to themselves severally and not in default hereunder) or Section 14, or if the sale to the Underwriters of the Offered Shares on the First Closing Date is not consummated because of any refusal, inability or failure on the part of the Company to perform any agreement herein or to comply with any provision hereof, the Company agrees to reimburse the Representative and the other Underwriters (or such Underwriters as have terminated this Agreement with respect to themselves), severally, upon demand for all documented out-of-pocket expenses that shall have been reasonably incurred by the Representative and the Underwriters in connection with the proposed purchase and the offering and sale of the Offered Shares, including, but not limited to, fees and disbursements of counsel, printing expenses, travel expenses, postage, facsimile and telephone charges.

Section 10. Effectiveness of this Agreement. This Agreement shall become effective upon the execution and delivery hereof by the parties hereto.

Section 11. Indemnification.

(a) ***Indemnification of the Underwriters*****.** The Company agrees to indemnify and hold harmless each Underwriter, its affiliates, directors, officers, employees and agents, and each person, if any, who controls any Underwriter within the meaning of the Securities Act or the Exchange Act against any loss, claim, damage, liability or expense, as incurred, to which such Underwriter or such affiliate, director, officer, employee, agent or controlling person may become subject, under the Securities Act, the Exchange Act, other federal or state statutory law or regulation, or the laws or regulations of foreign jurisdictions where Offered Shares have been offered or sold or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of the Company), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (A) (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing), or the omission or alleged omission to state therein a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading; or (iii) any act or failure to act or any alleged act or failure to act by any Underwriter in connection with, or relating in any manner to, the Shares or the offering contemplated hereby, and which is included as part of or referred to in any loss, claim, damage, liability or action arising out of or based upon any matter covered by clause (i) or (ii) above, or (B) the violation of any laws or regulations of foreign jurisdictions where Offered Shares have been offered or sold; and to reimburse each Underwriter and each such affiliate, director, officer, employee, agent and controlling person for any and all reasonable expenses (including the reasonable fees and disbursements of counsel) as such expenses are incurred by such Underwriter or such affiliate, director, officer, employee, agent or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action; *provided*, *however*, that the foregoing indemnity agreement shall not apply to any loss, claim, damage, liability or expense to the extent, but only to the extent, arising out of or based upon any untrue statement or alleged untrue statement or omission or alleged omission made in reliance upon and in conformity with information relating to any Underwriter furnished to the Company by the Representative or its counsel in writing expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any such free writing prospectus, any Marketing Material, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement thereto), it being understood and agreed that the only such information consists of the information described in Section 11(b) below. The indemnity agreement set forth in this Section 11(a) shall be in addition to any liabilities that the Company may otherwise have.

(b) ***Indemnification of the Company, its Directors and Officers***. Each Underwriter agrees, severally and not jointly, to indemnify and hold harmless the Company, each of its directors, each of its officers who signed the Registration Statement and each person, if any, who controls the Company within the meaning of the Securities Act or the Exchange Act, against any loss, claim, damage, liability or expense, as incurred, to which the Company, or any such director, officer or controlling person may become subject, under the Securities Act, the Exchange Act, or other federal or state statutory law or regulation, or at common law or otherwise (including in settlement of any litigation, if such settlement is effected with the written consent of such Underwriter), insofar as such loss, claim, damage, liability or expense (or actions in respect thereof as contemplated below) arises out of or is based upon (i) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement, or any amendment thereto, or any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading or (ii) any untrue statement or alleged untrue statement of a material fact included in any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus, that the Company has used, referred to or filed, or is required to file, pursuant to Rule 433 of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement) or the omission or alleged omission to state therein a material fact necessary in order to make the statements, in the light of the circumstances under which they were made, not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in the Registration Statement, such preliminary prospectus, the Time of Sale Prospectus, such free writing prospectus, such Section 5(d) Written Communication or the Prospectus (or any such amendment or supplement), in reliance upon and in conformity with information relating to such Underwriter furnished to the Company by the Representative or its counsel in writing expressly for use therein; and to reimburse the Company, or any such director, officer or controlling person for any and all expenses (including the fees and disbursements of counsel) as such expenses are incurred by the Company, or any such director, officer or controlling person in connection with investigating, defending, settling, compromising or paying any such loss, claim, damage, liability, expense or action. The Company hereby acknowledges that the only information that the

Representative or its counsel have furnished to the Company expressly for use in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, any free writing prospectus that the Company has filed, or is required to file, pursuant to Rule 433(d) of the Securities Act, any Section 5(d) Written Communication or the Prospectus (or any amendment or supplement to the foregoing) are the statements regarding delivery of the Shares by the Underwriters set forth on the cover page, the concession figure appearing under the sub-caption "Commission and Expenses" under the caption "Underwriting," the information regarding stabilizing transactions and passive market making contained under the sub-caption "Stabilization" under the caption "Underwriting" and the information regarding internet distribution contained under the sub-caption "Electronic Distribution" under the caption "Underwriting," each in the Preliminary Prospectus and the Prospectus. The indemnity agreement set forth in this Section 11(b) shall be in addition to any liabilities that each Underwriter may otherwise have.

(c) ***Notifications and Other Indemnification Procedures*****.** Promptly after receipt by an indemnified party under this Section 11 of notice of the commencement of any action, such indemnified party will, if a claim in respect thereof is to be made against an indemnifying party under this Section 11, notify the indemnifying party in writing of the commencement thereof, but the omission so to notify the indemnifying party will not relieve the indemnifying party from any liability which it may have to any indemnified party to the extent the indemnifying party is not materially prejudiced as a proximate result of such failure and shall not in any event relieve the indemnifying party from any liability that it may have otherwise than on account of this indemnity agreement. In case any such action is brought against any indemnified party and such indemnified party seeks or intends to seek indemnity from an indemnifying party, the indemnifying party will be entitled to participate in, and, to the extent that it shall elect, jointly with all other indemnifying parties similarly notified, by written notice delivered to the indemnified party promptly after receiving the aforesaid notice from such indemnified party, to assume the defense thereof with counsel reasonably satisfactory to such indemnified party; *provided*, *however*, that if the defendants in any such action include both the indemnified party and the indemnifying party and the indemnified party shall have reasonably concluded that a conflict may arise between the positions of the indemnifying party and the indemnified party in conducting the defense of any such action or that there may be legal defenses available to it and/or other indemnified parties which are different from or additional to those available to the indemnifying party, the indemnified party or parties shall have the right to select separate counsel to assume such legal defenses and to otherwise participate in the defense of such action on behalf of such indemnified party or parties. Upon receipt of notice from the indemnifying party to such indemnified party of such indemnifying party's election so to assume the defense of such action and approval by the indemnified party of counsel, the indemnifying party will not be liable to such indemnified party under this Section 11 for any legal or other expenses subsequently incurred by such indemnified party in connection with the defense thereof unless (i) the indemnified party shall have employed separate counsel in accordance with the proviso to the preceding sentence (it being understood, however, that the indemnifying party shall not be liable for the fees and expenses of more than one separate counsel (together with local counsel), representing the indemnified parties who are parties to such action), which counsel (together with any local counsel) for the indemnified parties shall be selected by Leerink (in the case of counsel for the indemnified parties referred to in Section 11(a) above) or by the Company (in the case of counsel for the indemnified parties referred to in Section 11(b) above)) or (ii) the indemnifying party shall not have employed counsel satisfactory to the indemnified party to represent the indemnified party within a reasonable time after notice of commencement of the action or (iii) the indemnifying party has authorized in writing the employment of counsel for the indemnified party at the expense of the indemnifying party, in each of which cases the reasonable fees and expenses of counsel shall be at the expense of the indemnifying party and shall be paid as they are incurred upon receipt from the indemnified party of a written request for payment thereof accompanied by a written statement with reasonable supporting detail of such reasonable fees and expenses.

(d) *Settlements*. The indemnifying party under this Section 11 shall not be liable for any settlement of any proceeding effected without its written consent, but if settled with such consent or if there be a final judgment for the plaintiff, the indemnifying party agrees to indemnify the indemnified party against any loss, claim, damage, liability or expense by reason of such settlement or judgment. Notwithstanding the foregoing sentence, if at any time an indemnified party shall have requested an indemnifying party to reimburse the indemnified party for reasonable fees and expenses of counsel as contemplated by Section 11(c) hereof, the indemnifying party shall be liable for any settlement of any proceeding effected without its written consent if (i) such settlement is entered into more than 30 days after receipt by such indemnifying party of the aforesaid request and (ii) such indemnifying party shall not have reimbursed the indemnified party in accordance with such request prior to the date of such settlement. No indemnifying party shall, without the prior written consent of the indemnified party, effect any settlement, compromise or consent to the entry of judgment in any pending or threatened action, suit or proceeding in respect of which any indemnified party is or could have been a party and indemnity was or could have been sought hereunder by such indemnified party, unless such settlement, compromise or consent includes an unconditional release of such indemnified party from all liability on claims that are the subject matter of such action, suit or proceeding and does not include an admission of fault or culpability or a failure to act by or on behalf of such indemnified party.

Section 12. Contribution. If the indemnification provided for in Section 11 is for any reason held to be unavailable to or otherwise insufficient to hold harmless an indemnified party in respect of any losses, claims, damages, liabilities or expenses referred to therein, then each indemnifying party shall contribute to the aggregate amount paid or payable by such indemnified party, as incurred, as a result of any losses, claims, damages, liabilities or expenses referred to therein (i) in such proportion as is appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, from the offering of the Offered Shares pursuant to this Agreement or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other hand, in connection with the statements or omissions which resulted in such losses, claims, damages, liabilities or expenses, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other hand, in connection with the offering of the Offered Shares pursuant to this Agreement shall be deemed to be in the same respective proportions as the total proceeds from the offering of the Offered Shares pursuant to this Agreement (before deducting expenses) received by the Company, and the total underwriting discounts and commissions received by the Underwriters, in each case as set forth on the front cover page of the Prospectus, bear to the aggregate initial public offering price of the Offered Shares as set forth on such cover. The relative fault of the Company, on the one hand, and the Underwriters, on the other hand, shall be determined by reference to, among other things, whether any such untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company, on the one hand, or the Underwriters, on the other hand, and the parties' relative intent, knowledge, access to information and opportunity to correct or prevent such statement or omission.

The amount paid or payable by a party as a result of the losses, claims, damages, liabilities and expenses referred to above shall be deemed to include, subject to the limitations set forth in Section 11(c), any legal or other fees or expenses reasonably incurred by such party in connection with investigating or defending any action or claim. The provisions set forth in Section 11(c) with respect to notice of commencement of any action shall apply if a claim for contribution is to be made under this Section 12; *provided*, *however*, that no additional notice shall be required with respect to any action for which notice has been given under Section 11(c) for purposes of indemnification.

The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 12 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to in this Section 12.

Notwithstanding the provisions of this Section 12, no Underwriter shall be required to contribute any amount in excess of the underwriting discounts and commissions received by such Underwriter in connection with the Offered Shares underwritten by it and distributed to the public. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. The Underwriters' obligations to contribute pursuant to this Section 12 are several, and not joint, in proportion to their respective underwriting commitments as set forth opposite their respective names on Schedule A. For purposes of this Section 12, each affiliate, director, officer, employee and agent of an Underwriter and each person, if any, who controls an Underwriter within the meaning of the Securities Act or the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Securities Act and the Exchange Act shall have the same rights to contribution as the Company.

Section 13. Default of One or More of the Several Underwriters. If, on the First Closing Date or any Option Closing Date any one or more of the several Underwriters shall fail or refuse to purchase Offered Shares that it or they have agreed to purchase hereunder on such date, and the aggregate number of Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase does not exceed 10% of the aggregate number of the Offered Shares to be purchased on such date, the Representative may make arrangements satisfactory to the Company for the purchase of such Offered Shares by other persons, including any of the Underwriters, but if no such arrangements are made by such date, the other Underwriters shall be obligated, severally and not jointly, in the proportions that the number of Firm Shares set forth opposite their respective names on Schedule A bears to the aggregate number of Firm Shares set forth opposite the names of all such non-defaulting Underwriters, or in such other proportions as may be specified by the Representative with the consent of the non-defaulting Underwriters, to purchase the Offered Shares which such defaulting Underwriter or Underwriters agreed but failed or refused to purchase on such date. If, on the First Closing Date or any Option Closing Date any one or more of the Underwriters shall fail or refuse to purchase Offered Shares and the aggregate number of Offered Shares with respect to which such default occurs exceeds 10% of the aggregate number of Offered Shares to be purchased on such date, and arrangements satisfactory to the Representative and the Company for the purchase of such Offered Shares are not made within 48 hours after such default, this Agreement shall terminate without liability of any party to any other party except that the provisions of Section 6, Section 9, Section 11 and Section 12 shall at all times be effective and shall survive such termination. In any such case either the Representative or the Company shall have the right to postpone the First Closing Date or the applicable Option Closing Date, as the case may be, but in no event for longer than seven days in order that the required changes, if any, to the Registration Statement and the Prospectus or any other documents or arrangements may be effected.

As used in this Agreement, the term "**Underwriter**" shall be deemed to include any person substituted for a defaulting Underwriter under this Section 13. Any action taken under this Section 13 shall not relieve any defaulting Underwriter from liability in respect of any default of such Underwriter under this Agreement.

Section 14. Termination of this Agreement. Prior to the purchase of the Firm Shares by the Underwriters on the First Closing Date, this Agreement may be terminated by the Representative by notice given to the Company if at any time: (i) trading or quotation in any of the

Company's securities shall have been suspended or limited by the Commission or by the NASDAQ, or trading in securities generally on either the NASDAQ or the New York Stock Exchange shall have been suspended or limited, or minimum or maximum prices shall have been generally established on any of such stock exchanges; (ii) a general banking moratorium shall have been declared by any of federal, New York or Swiss authorities; (iii) there shall have occurred any outbreak or escalation of national or international hostilities or any crisis or calamity, or any change in the United States or international financial markets, or any substantial change or development involving a prospective substantial change in United States' or international political, financial or economic conditions, as in the judgment of the Representative is material and adverse and makes it impracticable to market the Offered Shares in the manner and on the terms described in the Time of Sale Prospectus or the Prospectus or to enforce contracts for the sale of securities; (iv) in the judgment of the Representative there shall have occurred any Material Adverse Change; or (v) the Company shall have sustained a loss by strike, fire, flood, earthquake, accident or other calamity of such character as in the judgment of the Representative may interfere materially with the conduct of the business and operations of the Company regardless of whether or not such loss shall have been insured. Any termination pursuant to this Section 14 shall be without liability on the part of (a) the Company to any Underwriter, except that the Company shall be obligated to reimburse the expenses of the Representative and the Underwriters pursuant to Section 6 or Section 9 hereof or (b) any Underwriter to the Company; *provided, however,* that the provisions of Section 11 and Section 12 shall at all times be effective and shall survive such termination.

Section 15. ***Effects of Termination on Offered Shares****.*

(a) If, after application and registration of the Firm Capital Increase and/or any Over-Allotment Capital Increase with the Commercial Register of the Canton of Zug pursuant to Section 3(c) or Section 4(b), prior to the First Closing Date or the relevant Option Closing Date, as the case may be, this Agreement is terminated pursuant to Section 14, or if the delivery of the Firm Shares or Applicable Optional Shares to the Representative for the account of the several Underwriters is not completed on the First Closing Date or the relevant Option Closing Date, as the case may be (each, an "**Event of Non-Completion**"), and unless the Company and the Representative, acting on behalf of the several Underwriters, otherwise agree within ten calendar days after the Event of Non-Completion, then:

(i) the Company shall have a call option against the Underwriters pursuant to Section 15(b);

(ii) if the call option is not exercised, the Representative acting on behalf of the several Underwriters shall have a put option against the Company pursuant to Section 15(c);

(iii) if the put option is not possible for legal reasons or insufficient to dispose of the Firm Shares or Applicable Optional Shares, as applicable, or if such put option is not exercised within the deadline set forth in Section 15(c), the Company shall effect a capital reduction pursuant to Section 15(d); and

(iv) if the capital reduction is not effected in accordance with Section 15(d), the Underwriters may sell the Firm Shares or Applicable Optional Shares, as applicable, in the market as provided in Section 15(e).

(b) ***Call Option***.

(i) The Company, acting on its own behalf or on behalf of third parties, shall have the right (the "**Call Option**") to request in writing that the Representative, acting on behalf of the several Underwriters, deliver the Firm Shares or Applicable Optional Shares, as applicable, to an account specified by the Company against payment of an amount representing the aggregate nominal value of the respective Firm Shares or Applicable Optional Shares, as applicable, plus expenses of the Representative as set out in Section 15(f). The Call Option shall expire on the tenth calendar day after the Event of Non-Completion.

(ii) An acquisition of the Firm Shares or Applicable Optional Shares, as applicable, by the Company for its own account shall only be permitted if the Company has delivered evidence to the Representative reasonably satisfactory to the Representative that the Company has sufficient freely available reserves to acquire the Firm Shares or Applicable Optional Shares, as applicable, under this Section 15(b) or, alternatively, that the Company has entered into arrangements with a third party other than any of the Company's subsidiaries ensuring for the immediate re-sale of the Firm Shares or Applicable Optional Shares, as applicable, to such third party, at no less than their nominal value, on the date of acquisition of the Firm Shares or Applicable Optional Shares, as applicable, by the Company.

(c) ***Put Option***.

(i) Following the expiry of the Call Option pursuant to Section 15(b), the Representative, acting on behalf of the several Underwriters, shall have an option (the "**Put Option**") to require the Company, subject to article 659 CO, to purchase all Firm Shares or Applicable Optional Shares, as applicable, entered in the Commercial Register of the Canton of Zug at their nominal value, plus expenses of the Representative as set out in Section 15(f), within ten calendar days after receipt of a notice in writing addressed to the Company from the Representative, stating that the Representative exercises the Put Option. The Put Option shall expire on the twentieth calendar day after the Event of Non-Completion.

(ii) The notice in which the Representative, acting on behalf of the several Underwriters, exercises the Put Option shall specify the date on which the Representative will deliver the Firm Shares or Applicable Optional Shares, as applicable, to the Company against direct payment therefore, and shall contain detailed instructions regarding payment, delivery of the Firm Shares or Applicable Optional Shares, as applicable, and amount payable (including satisfactory details regarding the costs claimed according to Section 15(f)).

(d) ***Capital Reduction***.

(i) If the Put Option is not exercised within the deadline set forth in Section 15(c) or it is not possible for legal reasons or insufficient to dispose of the Firm Shares or Applicable Optional Shares, as applicable, including due to non-availability of sufficient freely disposable reserves, the Company shall immediately call a shareholders' meeting and table the reduction of the share capital. Such shareholders' meeting shall take place no later than fifty days after the Event of Non-Completion. The Representative will vote in favor of a reduction of the issued and outstanding share capital of the Company (the "**Capital Reduction**") by cancellation of the Firm Shares or Applicable Optional Shares, as applicable, entered in the Commercial Register of the Canton of Zug against repayment of the aggregate nominal value of such securities to the Representative, acting on behalf of the several Underwriters. Prior to such shareholders' meeting, the Company shall use its best efforts to cause its auditors to confirm in writing, pursuant to article 732 para. 2 CO, that the claims of the Company's creditors are fully covered notwithstanding the Capital Reduction, provided that if such confirmation is not made by the auditors prior to such meeting, the meeting shall be cancelled. The Company shall use its best efforts to cause its shareholders to vote in favor of the Capital Reduction.

(ii) At the earliest possible date, and subject to statutory law, the Capital Reduction shall be consummated by registration in the Commercial Register of the Canton of Zug. The proceeds of the Capital Reduction, being an amount representing the aggregate nominal value of the Firm Shares or Applicable Optional Shares, as applicable, shall be paid (for value on the date of the entry in the Commercial Register of the Canton of Zug) in cash to the Representative, acting on behalf of the several Underwriters.

(iii) Upon consummation of the Capital Reduction, the Company shall deregister the Firm Shares or Applicable Optional Shares, as applicable, in its book of uncertificated securities (*Wertrechtebuch*) to reflect the number of Shares registered with the Commercial Register of the Canton of Zug.

(e) ***Sale of Firm Shares or Applicable Optional Shares***. In addition, if an Event of Non-Completion occurs and,

(i) the Company fails to acquire or cause a third party to acquire the Firm Shares or Applicable Optional Shares, as applicable, in accordance with Section 15(b) within ten calendar days after the Event of Non-Completion; and

(ii) in the event and to the extent the Put Option is not possible for legal reasons or insufficient to dispose of the Firm Shares or Applicable Optional Shares, as applicable, including due to insufficient freely disposable reserves, or if the Put Option is not exercised within the deadline set forth in Section 15(c); and

(iii) the Capital Reduction has not been resolved by the shareholders' meeting of the Company within sixty days after the Event of Non-Completion, the Representative, acting on behalf of the several Underwriters, are entitled to sell any or all Firm Shares or Applicable Optional Shares on terms which the Representative deem fit under the circumstances. The difference between the proceeds of such sale and the nominal amount of such Firm Shares or Applicable Optional Shares, as applicable, sold, less the costs and expenses pursuant to Section 15(f) reasonably incurred by the Representative in connection with the sale, if any, shall be transferred to the Company.

(f) ***Costs; Indemnity***.

(i) The Company shall bear (a) all costs directly incidental to the Capital Reduction, including but not limited to notarization costs, costs of the Commercial Register and costs of publication of the Capital Reduction and (b) the costs of the Representative reasonably incurred in connection with the Call Option, the Put Option or the Capital Reduction, as applicable (including but not limited to (x) taxes, (y) interest at a rate of the 3-month CHF LIBOR, calculated on a 30/360 basis, following the Event of Non-Completion until the payment of proceeds to the Representative, acting on behalf of the several Underwriters, and (z) reasonable out of pocket expenses of the Representative and its counsel).

(ii) The Company further undertakes to indemnify the Representative for, and to hold the Representative harmless from, any reasonable costs, expenses, third party claims and liabilities, actual or contingent, that may be incurred by or made against the Representative in connection with the Capital Reduction.

Section 16. No Advisory or Fiduciary Relationship. The Company acknowledges and agrees that (a) the purchase and sale of the Offered Shares pursuant to this Agreement, including the determination of the public offering price of the Offered Shares and any related discounts and commissions, is an arm's-length commercial transaction between the Company, on the one hand, and the several Underwriters, on the other hand, (b) in connection with the offering contemplated hereby and the process leading to such transaction, each Underwriter is and has been acting solely as a principal and is not the agent or fiduciary of the Company, or its stockholders, creditors, employees or any other party, (c) no Underwriter has assumed or will assume an advisory or fiduciary responsibility in favor of the Company with respect to the offering contemplated hereby or the process leading thereto (irrespective of whether such Underwriter has advised or is currently advising the Company on other matters) and no Underwriter has any obligation to the Company with respect to the offering contemplated hereby except the obligations expressly set forth in this Agreement, (d) the Underwriters and their respective affiliates may be engaged in a broad range of transactions that involve interests that differ from those of the Company, and (e) the Underwriters have not provided any legal, accounting, regulatory or tax advice with respect to the offering contemplated hereby and the Company has consulted its own legal, accounting, regulatory and tax advisors to the extent it deemed appropriate.

Section 17. Representations and Indemnities to Survive Delivery. The respective indemnities, agreements, representations, warranties and other statements of the Company, of its officers and of the several Underwriters set forth in or made pursuant to this Agreement will remain in full force and effect, regardless of any investigation made by or on behalf of any Underwriter or the Company or any of its or their partners, officers or directors or any controlling person, as the case may be, and, anything herein to the contrary notwithstanding, will survive delivery of and payment for the Offered Shares sold hereunder and any termination of this Agreement.

Section 18. Notices. All communications hereunder shall be in writing and shall be mailed, hand delivered or telecopied and confirmed to the parties hereto as follows:

If to the Representative:	Leerink Partners LLC 1 Federal Street, 37th Floor Boston, MA 02110 Facsimile: (415) 905-7400 Attention: General Counsel
with a copy to:	Latham & Watkins LLP 555 11th Street NW, Suite 1000 Washington, DC 20004 Facsimile: (202) 637-2201 Attention: Rachel Sheridan
If to the Company:	Auris Medical Holding AG Bahnhofstrasse 21 6300 Zug Switzerland Facsimile: +41 61 201 13 51 Attention: Thomas Meyer
with a copy to:	Davis Polk & Wardwell LLP 450 Lexington Avenue New York, NY 10017 Facsimile: (212) 701-5762 Attention: Sophia Hudson

Any party hereto may change the address for receipt of communications by giving written notice to the others.

Section 19. Successors. This Agreement will inure to the benefit of and be binding upon the parties hereto, including any substitute Underwriters pursuant to Section 13 hereof, and to the benefit of the affiliates, directors, officers, employees, agents and controlling persons referred to in Section 11 and Section 12, and in each case their respective successors, and no other person will have any right or obligation hereunder. The term "**successors**" shall not include any purchaser of the Offered Shares as such from any of the Underwriters merely by reason of such purchase.

Section 20. Partial Unenforceability. The invalidity or unenforceability of any section, paragraph or provision of this Agreement shall not affect the validity or enforceability of any other section, paragraph or provision hereof. If any section, paragraph or provision of this Agreement is for any reason determined to be invalid or unenforceable, there shall be deemed to be made such minor changes (and only such minor changes) as are necessary to make it valid and enforceable.

Section 21. Governing Law Provisions; Currency Provisions. This Agreement shall be governed by and construed in accordance with the internal laws of the State of New York applicable to agreements made and to be performed in such state. Any legal suit, action or proceeding arising out of or based upon this Agreement or the transactions contemplated hereby ("**Related Proceedings**") may be instituted in the federal courts of the United States of America located in the Borough of Manhattan in the City of New York or the courts of the State of New York in each case located in the Borough of Manhattan in the City of New York (collectively, the "**Specified Courts**"), and each party irrevocably submits to the exclusive jurisdiction (except for proceedings instituted in regard to the enforcement of a judgment of any such court (a "**Related Judgment**"), as to which such jurisdiction is non-exclusive) of such courts in any such suit, action or proceeding. Service of any process, summons, notice or document by mail to such party's address set forth above shall be effective service of process for any suit, action or other proceeding brought in any such court. The parties irrevocably and unconditionally waive any objection to the laying of venue of any suit, action or other proceeding in the Specified Courts and irrevocably and unconditionally waive and agree not to plead or claim in any such court that any such suit, action or other proceeding brought in any such court has been brought in an inconvenient forum. The Company and each other party not located in the United States has irrevocably appointed National Corporate Research, Ltd., which currently maintains a New York City office at 10 East 40th Street, New York, New York 10016, United States of America, as its agent to receive service of process or other legal summons for purposes of any such suit, action or proceeding that may be instituted in any state or federal court in the Borough of Manhattan in the City of New York, United States of America.

With respect to any Related Proceeding, each party irrevocably waives, to the fullest extent permitted by applicable law, all immunity (whether on the basis of sovereignty or otherwise) from jurisdiction, service of process, attachment (both before and after judgment) and execution to which it might otherwise be entitled in the Specified Courts, and with respect to any Related Judgment, each party waives any such immunity in the Specified Courts or any other court of competent jurisdiction, and will not raise or claim or cause to be pleaded any such immunity at or in respect of any such Related Proceeding or Related Judgment, including, without limitation, any immunity pursuant to the United States Foreign Sovereign Immunities Act of 1976, as amended.

The obligations of the Company pursuant to this Agreement in respect of any sum due to any Underwriter shall, notwithstanding any judgment in a currency other than United States dollars, not be discharged until the first business day, following receipt by any Underwriter of any sum adjudged to be so due in such other currency, on which such Underwriter may in accordance with normal banking procedures purchase United States dollars with such other currency. If the United States dollars so purchased are less than the sum originally due to such Underwriter in United States dollars hereunder, the Company agrees as a separate obligation and notwithstanding any such judgment, to indemnify such Underwriter against such loss. If the United States dollars so purchased are greater than the sum originally due to such Underwriter hereunder, such Underwriter agrees to pay to the Company an amount equal to the excess of the dollars so purchased over the sum originally due to such Underwriter hereunder.

All payments made by the Company under this Agreement, if any, will be made without withholding or deduction for or on account of any present or future taxes, duties, assessments or governmental charges of whatever nature (other than taxes on net income) imposed or levied by or on behalf of Switzerland, any other jurisdiction from or through which payment is made, or, in each case, any political subdivision or any taxing authority thereof or therein unless the Company is or becomes required by law to withhold or deduct such taxes, duties, assessments or other governmental charges. In such event, the Company will pay such additional amounts as will result, after such withholding or deduction, in the receipt by each Underwriter and each person controlling any Underwriter, as the case may be, of the amounts that would otherwise have been receivable in respect thereof.

Section 22. General Provisions. This Agreement constitutes the entire agreement of the parties to this Agreement and supersedes all prior written or oral and all contemporaneous oral agreements, understandings and negotiations with respect to the subject matter hereof. This Agreement may be executed in two or more counterparts, each one of which shall be an original, and delivered by electronic means, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement may not be amended or modified unless in writing by all of the parties hereto, and no condition herein (express or implied) may be waived unless waived in writing by each party whom the condition is meant to benefit. The section headings herein are for the convenience of the parties only and shall not affect the construction or interpretation of this Agreement.

Each of the parties hereto acknowledges that it is a sophisticated business person who was adequately represented by counsel during negotiations regarding the provisions hereof, including, without limitation, the indemnification provisions of Section 11 and the contribution provisions of Section 12, and is fully informed regarding said provisions. Each of the parties hereto further acknowledges that the provisions of Section 11 and Section 12 hereof fairly allocate the risks in light of the ability of the parties to investigate the Company, its affairs and its business in order to assure that adequate disclosure has been made in the Registration Statement, any preliminary prospectus, the Time of Sale Prospectus, each free writing prospectus and the Prospectus (and any amendments and supplements to the foregoing), as contemplated by the Securities Act and the Exchange Act.

If the foregoing is in accordance with your understanding of our agreement, kindly sign and return to the Company the enclosed copies hereof, whereupon this instrument, along with all counterparts hereof, shall become a binding agreement in accordance with its terms.

Very truly yours,

AURIS MEDICAL HOLDING AG

By: ____________________________
Name:
Title:

By: ____________________________
Name:
Title:

The foregoing Underwriting Agreement is hereby confirmed and accepted by the Representative in New York, New York as of the date first above written.

LEERINK PARTNERS LLC

Acting individually and as Representative of the several
Underwriters named in the attached Schedule A.

LEERINK PARTNERS LLC

By: ____

Name:

Title:

Schedule A

Underwriters	Number of Firm Shares to be Purchased
Leerink Partners LLC	[●]
JMP Securities LLC	[●]
Needham & Company, LLC	[●]
LifeSci Capital LLC	[●]
Total	[●]

Free Writing Prospectuses Included in the Time of Sale Prospectus

[●]

Schedule C

<u>Permitted Section 5(d) Communications</u>

None.

Schedule D

Pricing Information

Exhibit A

Form of Lock-up Agreement

[●], 2015

Leerink Partners LLC
As Representative of the Several Underwriters

255 California Street, 12th Floor
San Francisco, California 94111

RE: Auris Medical Holding AG (the "**Company**")

Ladies & Gentlemen:

The undersigned is an owner of common shares, nominal value CHF 0.40 per common share, of the Company ("**Shares**") or of securities convertible into or exchangeable or exercisable for Shares. The Company proposes to conduct a public offering of Shares (the "**Offering**") for which Leerink Partners LLC ("**Leerink**") will act as the representative of the underwriters. The undersigned recognizes that the Offering will benefit each of the Company and the undersigned. The undersigned acknowledges that the underwriters are relying on the representations and agreements of the undersigned contained in this letter agreement in conducting the Offering and, at a subsequent date, in entering into an underwriting agreement (the "**Underwriting Agreement**") and other underwriting arrangements with the Company with respect to the Offering.

Annex A sets forth definitions for capitalized terms used in this letter agreement that are not defined in the body of this agreement. Those definitions are a part of this agreement.

In consideration of the foregoing, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned hereby agrees that, during the Lock-up Period, the undersigned will not (and will cause any Family Member not to), without the prior written consent of Leerink, which may withhold its consent in its sole discretion:

- Sell or Offer to Sell any Shares or Related Securities currently or hereafter owned either of record or beneficially (as defined in Rule 13d-3 under the Exchange Act) by the undersigned or such Family Member,
- enter into any Swap,
- make any demand for, or exercise any right with respect to, the registration under the Securities Act of the offer and sale of any Shares or Related Securities, or cause to be filed a registration statement, prospectus or prospectus supplement (or an amendment or supplement thereto) with respect to any such registration, or
- publicly announce any intention to do any of the foregoing.

The foregoing will not apply to the registration of the offer and sale of the Shares, and the sale of the Shares to the underwriters, in each case as contemplated by the Underwriting Agreement. In addition, the foregoing restrictions shall not apply to (A) the transfer of Shares or Related Securities as a bona fide gift or gifts or by testate succession or intestate distribution to the legal representative, heir, beneficiary or a member of the immediate family of the undersigned, (B) any Shares acquired by the undersigned in the open market or in the Offering (other than any Company directed Shares purchased in the Offering by an officer or director of the Company), (C) the exercise of stock options or other similar awards or the settlement or conversion of any Related Security granted pursuant to the Company's equity incentive plans; provided that such restriction shall apply to any of the undersigned's Shares or Related Securities issued upon such exercise, settlement or conversion except to the extent necessary (i) to satisfy withholding taxes and (ii) to satisfy the exercise price, in each case, for any of the undersigned's Shares or Related Securities issued pursuant to the Company's Stock Option Plan A, (D) any Shares or Related Securities that are used for the primary purpose of satisfying any withholding tax or other governmental withholding or payment obligation or any exercise price, through cashless surrender or otherwise, with respect to any award of equity-based compensation or in connection with tax or other obligations as a result of testate succession or intestate distribution, (E) the establishment of any contract, instruction or plan (a "Plan") that satisfies all of the requirements of Rule 10b5-1(c)(1)(i)(B) under the Exchange Act provided that no sales of the undersigned's Shares shall be made pursuant to such a Plan prior to the expiration of the Lock-up Period, (F) transfers to a Family Member or to a trust whose beneficiaries consist exclusively of one or more of the undersigned and/or a Family Member, (G) distributions of Shares or Related Securities to members or stockholders of the undersigned or to any corporation, partnership or other person or entity that is a direct or indirect affiliate of the undersigned and (H) the transfer of the undersigned's Shares or Related Securities to the Company pursuant to any contractual arrangement in effect on the date of this letter agreement that provides for the repurchase of the undersigned's Shares or Related Securities by the Company or in connection with the termination of the undersigned's employment with the Company or the undersigned's failure to meet certain conditions set out upon receipt of such Shares or Related Securities; provided that in the case of any transfer or distribution pursuant to clauses (A), (F) or (G), each donee, distributee or transferee shall execute and deliver to Leerink an agreement in form and substance satisfactory to Leerink stating that such transferee is receiving and holding such Shares and/or Related Securities subject to the provisions of this letter agreement and agrees not to Sell or Offer to Sell such Shares and/or Related Securities, engage in any Swap or engage in any other activities restricted under this letter agreement except in accordance with this letter agreement (as if such transferee had been an original signatory hereto); and provided, further, that in the case of any transfer or distribution pursuant to clause (A), (B) or (E) through (G), no filing by any party (donor, donee, transferor or transferee) under the Exchange Act, or other public announcement shall be required or shall be made voluntarily in connection with such transfer or distribution (other than a filing on a Form 5 made after the expiration of the Lock-up Period).

If the undersigned is an officer or director of the Company, the undersigned further agrees that the foregoing provisions shall be equally applicable to any Company directed Shares the undersigned may purchase or otherwise receive in the Offering (including pursuant to a directed share program).

In the event that any percentage of the Shares or Related Securities held by any person or entity other than the undersigned that is subject to a lock-up agreement related to the Offering similar in form to this agreement, is released from any restrictions set forth in such lock-up agreement, the same percentage of the Shares or Related Securities held by the undersigned shall be immediately and fully released from any remaining restrictions on transfer set forth in this agreement concurrently therewith; provided, however, that Leerink will not be obligated to release the undersigned from the restrictions on transfer set forth in this agreement in connection with any release described in this paragraph unless and until Leerink has first released from such restrictions Shares or Related Securities belonging to such person or entity valued at more than $250,000. In the event that the undersigned is released from any of its obligations under this agreement or, by virtue of this agreement, becomes entitled to offer, pledge, sell, contract to sell, or otherwise transfer or dispose of any Shares or Related Securities prior to the end of the Lock-Up Period, Leerink shall use its commercially reasonable efforts to notify the undersigned within three business days; provided that the failure to give such notice shall not give rise to any claim or liability against Leerink.

With respect to the Offering only, the undersigned waives any registration rights relating to registration under the Securities Act of the offer and sale of any Shares and/or any Related Securities owned either of record or beneficially by the undersigned, including any rights to receive notice of the Offering.

The undersigned confirms that the undersigned has not, and has no knowledge that any Family Member has, directly or indirectly, taken any action designed to or that might reasonably be expected to cause or result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale of the Shares. The undersigned will not, and will cause any Family Member not to take, directly or indirectly, any such action.

Whether or not the Offering occurs as currently contemplated or at all depends on market conditions and other factors. The Offering will only be made pursuant to the Underwriting Agreement, the terms of which are subject to negotiation between the Company and the underwriters. The undersigned understands that, if (i) the Underwriting Agreement does not become effective on or before June 30, 2015, (ii) the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Shares to be sold thereunder, (iii) Leerink, on the one hand, or the Company, on the other hand, informs the other, prior to the execution of the Underwriting Agreement, that it has determined not to proceed with the Offering or (iv) the registration statement related to the Offering has been withdrawn, the undersigned shall be released from all obligations under this letter agreement.

The undersigned hereby represents and warrants that the undersigned has full power, capacity and authority to enter into this letter agreement. This letter agreement is irrevocable and will be binding on the undersigned and the successors, heirs, personal representatives and assigns of the undersigned.

This letter agreement shall be governed by, and construed in accordance with, the laws of the State of New York.

Signature

Printed Name of Person Signing

(Indicate capacity of person signing if signing as custodian or trustee, or on behalf of an entity)

Certain Defined Terms
Used in Lock-up Agreement

For purposes of the letter agreement to which this Annex A is attached and of which it is made a part:

- "**Call Equivalent Position**" shall have the meaning set forth in Rule 16a-1(b) under the Exchange Act.
- "**Exchange Act**" shall mean the Securities Exchange Act of 1934, as amended.
- "**Family Member**" shall mean the spouse of the undersigned, an immediate family member of the undersigned or an immediate family member of the undersigned's spouse, in each case living in the undersigned's household or whose principal residence is the undersigned's household (regardless of whether such spouse or family member may at the time be living elsewhere due to educational activities, health care treatment, military service, temporary internship or employment or otherwise). "**Immediate family member**" as used above shall have the meaning set forth in Rule 16a-1(e) under the Exchange Act.
- "**Lock-up Period**" shall mean the period beginning on the date hereof and continuing through the close of trading on the date that is [90/60] days after the date of the Prospectus (as defined in the Underwriting Agreement.
- "**Put Equivalent Position**" shall have the meaning set forth in Rule 16a-1(h) under the Exchange Act.
- "**Related Securities**" shall mean any options or warrants or other rights to acquire Shares or any securities exchangeable or exercisable for or convertible into Shares, or to acquire other securities or rights ultimately exchangeable or exercisable for or convertible into Shares, which shall include, for the avoidance of doubt, any restricted stock unit whether time- or performance-vested.
- "**Securities Act**" shall mean the Securities Act of 1933, as amended.
- "**Sell or Offer to Sell**" shall mean to:
    - sell, offer to sell, contract to sell or lend,
    - effect any short sale or establish or increase a Put Equivalent Position or liquidate or decrease any Call Equivalent Position
    - pledge, hypothecate or grant any security interest in, or
    - in any other way transfer or dispose of,

  in each case whether effected directly or indirectly.
- "**Swap**" shall mean any swap, hedge or similar arrangement or agreement that transfers, in whole or in part, the economic risk of ownership of Shares or Related Securities, regardless of whether any such transaction is to be settled in securities, in cash or otherwise.

Capitalized terms not defined in this Annex A shall have the meanings given to them in the body of this lock-up agreement

Exhibit B

Directors, Officers and Others
<u>Signing Lock-up Agreement</u>

Directors:	Wolfgang Arnold
	James I. Healy
	Oliver Kubli
	Antoine Papiernik
	Berndt Modig
	Calvin Roberts
Officers:	Thomas Meyer
	Bettina Stubinski
	Sven Zimmerman
Others:	Sofinnova Capital VII
	Sofinnova Venture Partners VIII, L.P.
	ZKB Adamant Fund

Exhibit C

Zeichnungsschein / *Subscription form*

zur genehmigten Kapitalerhöhung der Auris Medical Holding AG, mit Sitz in Zug

with regard to the authorised capital increase of Auris Medical Holding AG, having its registered office in Zug

---

Mit Bezugnahme auf:

With reference to:

- die uns bekannten Statuten der Auris Medical Holding AG, Zug;

  the articles of association of Auris Medical Holding AG, Zug, which are known to us;

- die Generalversammlungsbeschlüsse vom 14. Juli 2014 der Auris Medical Holding AG, Zug, und die darin beschlossene und am 7. August 2014 in Kraft getretene Ermächtigung des Verwaltungsrat zur Erhöhung des Aktienkapitals um maximal CHF 3,600,000, welches nach der Kapitalerhöhung vom 18. August 2014 neu CHF 3’314’706 beträgt, sowie im Hinblick auf die Beschlüsse des Verwaltungsrates, das Kapital entsprechend zu erhöhen;

  the resolutions of the shareholders’ meeting dated 14 July 2014 of Auris Medical Holding AG, Zug regarding the authorization of the board of directors to increase the share capital by a maximum of CHF 3,600,000, whereby such authorization entered into force on 7 August 2014 and which upon the capital increase dated 18 August 2014 newly amounts to CHF 3’314’706, and in view of the resolutions of the board of directors to increase the share capital in the relevant amount;

zeichnet die Unterzeichnende

the undersigned

[company name/name], [domicile]

bedingungslos und unwiderruflich [Anzahl] Namenaktien der Auris Medical Holding AG, Zug, von je CHF 0.40 Nennwert zum Ausgabebetrag von CHF 0.40 je Aktie, insgesamt CHF [Betrag]. Gemäss Underwriting Agreement vom [Datum] verpflichtet sich die Unterzeichnende, CHF [Betrag] auf das Kapitaleinzahlungskonto der Auris Medical Holding AG zu überweisen.

herewith unconditionally and irreversibly subscribes for [number] registered shares in Auris Medical Holding AG, Zug, with a par value of CHF 0.40 each at the issue price of CHF 0.40 per share, CHF [amount] in total. In accordance with the Underwriting Agreement dated [date] the undersigned hereby commits to transfer CHF [amount] to the capital contribution account of Auris Medical Holding AG.

Die Unterzeichnende verpflichtet sich hiermit bedingungslos, eine dem Ausgabebetrag entsprechende Einlage der gezeichneten Aktien zu leisten.

The undersigned herewith unconditionally commits to make a contribution equal to the issue price.

Diese Zeichnung ist verbindlich bis zum [Datum].

This subscription shall be binding until [date].

Dieser Zeichnungsschein ist ein Zeichnungsschein im Sinne des schweizerischen Obligationenrechts Auf diesen Zeichnungsschein ist ausschliesslich Schweizerisches Recht anwendbar. Für sämtliche Streitigkeiten aus oder im Zusammenhang mit diesem Zeichnungsschein sind die ordentlichen Gerichte des Kantons Zug zuständig.

This Subscription Form is a subscription form within the meaning of the Swiss Code of Obligations. The Subscription Form shall be subject to and exclusively governed by Swiss Law. All disputes arising out of or in connection with this Subscription Form shall be settled by the ordinary courts of the Canton of Zug.

[company name/name]
represented by:

Ort, Datum *Place, date*	[name, function]
Ort, Datum *Place, date*	[name, function]

ZURICH
GENEVA
ZUG
LAUSANNE
LONDON
MADRID

To:
Auris Medical Holding AG
Bahnhofstrasse 21
6300 Zug
Switzerland

Zurich, May 4, 2015
10031170/486423

Marco A. Rizzi | Partner
mrizzi@froriep.ch

Auris Medical Holding AG – Registration Statement on Form F-1

Ladies and Gentlemen:

We have acted as Swiss counsel to Auris Medical Holding AG (the "**Company**") in connection with the filing of a registration statement on Form F-1, as amended (Registration No. 333-203554), including the prospectus set forth therein (the "**Registration Statement**") for the purpose of registering under the United States Securities Act of 1933, as amended (the "**Securities Act**") 6,000,000 common shares of CHF 0.40 par value each of the Company and any additional shares with a nominal value of CHF 0.40 sold or, if and to the extent such option is exercised, to be sold to the underwriters pursuant to the over-allotment option granted by the Company to the underwriters (the "**Shares**"). As such counsel, we have been requested to render an opinion as to certain matters of Swiss law.

1. Basis of Opinion

This opinion is confined to and given on the basis of the laws of Switzerland in force at the date hereof and as currently applied by the Swiss courts. In the absence of statutory or established case law, we base our opinion on our independent professional judgement.

This opinion is also confined to the matters stated herein and is not to be read as extending, by implication or otherwise, to any other matter.

For the purpose of giving this opinion, we have only examined the following documents (the "**Documents**"):

(i) a pdf copy of the Registration Statement;

(ii) a pdf copy of the notarially certified articles of incorporation of the Company in their version of March 27, 2015 (the "**Articles**"); and

(iii) the original of a certified excerpt from the Commercial Register of the Canton of Zug dated April 30, 2015 relating to the Company (the "**Excerpt**").

No documents have been reviewed by ourselves in connection with this opinion other than those listed above. Accordingly, our opinion is limited to the above Documents and their legal implications under Swiss law.

All terms used in this opinion in uppercase form shall have the meaning ascribed to them in the Registration Statement, unless otherwise defined herein. In this opinion, Swiss legal concepts are expressed in English language terms and not in their original language. These concepts may not be identical to the concepts described by the same English language terms as they exist under the laws of other jurisdictions.

2. Assumptions

In rendering the opinion below, we have assumed:

a) the conformity to the Documents of all documents produced to us as copies, fax copies or via e-mail, and that the original was executed in the manner appearing on the copy of the draft;

b) the genuineness and authenticity of the signatures on all copies of the original Documents thereof which we have examined, and the accuracy of all factual information contained in, or material statements given in connection with, the Documents;

c) the Registration Statement has been duly filed by the Company;

d) the Articles and the Excerpt are unchanged and correct as of the date hereof and no changes have been made which should have been or should be reflected in the Articles or the Excerpt as of the date hereof;

e) to the extent relevant for purposes of this opinion, all factual information contained in, or material statements given in connection with, the Documents are true, complete and accurate;

f) (i) a sufficient number of Shares will be available for issuance, (ii) the Registration Statement is effective and will continue to be effective, (iii) the offering and sale of and payment for the Shares will be in accordance with the Registrations Statement, (iv) the consideration received for the issuance and sale of the Shares will not be less than the nominal value of the Shares,

(v) to the extent applicable, the Shares will be issued in accordance with articles 647, 651-652h, 931a – 937 and 973c of the Swiss Code of Obligations as well as the relevant commercial register regulations, and (vi) the issuance and sale of the Shares will not violate the articles of incorporation or organizational regulations of the Company, any applicable law or any requirement or restriction imposed by any court or governmental body having jurisdiction of the Company.

3. Opinion

Based upon the foregoing and subject to the qualifications set out below, we are of the opinion that the Shares, when sold, will be validly issued, fully paid-in (up to their nominal amount) and non-assessable (which term means when used herein that no further contributions have to be made by the holders of the Shares).

4. Qualifications

The above opinions are subject to the following qualifications:

a) The lawyers of our firm are members of the Swiss bar and do not hold themselves to be experts in any laws other than the laws of Switzerland. Accordingly, we are opining herein as to Swiss law only and we express no opinion with respect to the applicability thereto, or the effect thereon, of the laws of any other jurisdiction.

b) This opinion is based on the current provisions of the laws of Switzerland and the regulations thereunder in effect on the date hereof and only as currently interpreted in Switzerland. Such laws and their interpretation are subject to change.

c) We express no opinion as to the accuracy or completeness of the information contained in the Registration Statement.

d) We express no opinion as to any commercial, calculating, auditing or other non-legal matters. Further, we express no opinion as to tax law.

* * *

We have rendered this opinion as of the date hereof and we assume no obligation to advise you of changes that may thereafter be brought to our attention.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the references to us under the heading “Legal Matters” contained in the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act.

This opinion shall be governed by and construed in accordance with the laws of Switzerland.

Sincerely yours,

/s/ FRORIEP

FRORIEP

Marco A. Rizzi

Exhibit 8.1

ZURICH
GENEVA
ZUG
LAUSANNE
LONDON
MADRID

To:
Auris Medical Holding AG
Bahnhofstrasse 21
6300 Zug
Switzerland

Zurich, May 4, 2015
10031170/486426

Marco A. Rizzi | Partner
mrizzi@froriep.ch

Auris Medical Holding AG – Registration Statement on Form F-1

Ladies and Gentlemen:

We have acted as Swiss counsel to Auris Medical Holding AG (the "**Company**") in connection with the filing of a registration statement on Form F-1, as amended (Registration No. 333-203554), including the prospectus set forth therein (the "**Registration Statement**") for the purpose of registering under the United States Securities Act of 1933, as amended (the "**Securities Act**") 6,000,000 common shares of CHF 0.40 par value each of the Company and any additional shares with a nominal value of CHF 0.40 sold or, if and to the extent such option is exercised, to be sold to the underwriters pursuant to the over-allotment option granted by the Company to the underwriters (the "**Shares**"). As such counsel, we have been requested to render an opinion as to certain matters of Swiss law.

1. Basis of Opinion

This opinion is confined to and given on the basis of the laws of Switzerland in force at the date hereof and as currently applied by the Swiss courts. In the absence of statutory or established case law, we base our opinion on our independent professional judgement.

This opinion is also confined to the matters stated herein and is not to be read as extending, by implication or otherwise, to any other matter.

For the purpose of giving this opinion, we have only examined a pdf copy of the Registration Statement.

No documents have been reviewed by ourselves in connection with this opinion other than the Registration Statement. Accordingly, our opinion is limited to the Registration Statement and its legal implications under Swiss law.

All terms used in this opinion in uppercase form shall have the meaning ascribed to them in the Registration Statement, unless otherwise defined herein. In this opinion, Swiss legal concepts are expressed in English language terms and not in their original language. These concepts may not be identical to the concepts described by the same English language terms as they exist under the laws of other jurisdictions.

2. Assumptions

In rendering the opinion below, we have assumed that:

a) the offering and sale of the Shares will be conducted in the manner as described in the Registration Statement;

b) the Registration Statement has been duly filed by the Company; and

c) to the extent relevant for purposes of this opinion, all factual information contained in, or material statements given in connection with, the Registration Statement are true, complete and accurate.

3. Opinion

Based upon the foregoing and subject to the qualifications set out below, we are of the opinion that as of the date hereof the discussion in the Registration Statement contained under the heading "Swiss Tax Considerations" is as it addresses matters of Swiss tax law or considerations, an accurate summary in all material respects of the tax matters purported to be described therein.

4. Qualifications

The above opinion is subject to the following qualifications:

a) The lawyers of our firm are members of the Swiss bar and do not hold themselves to be experts in any laws other than the laws of Switzerland. Accordingly, we are opining herein as to Swiss law only and we express no opinion with respect to the applicability thereto, or the effect thereon, of the laws of any other jurisdiction.

b) This opinion is based on the current provisions of the laws of Switzerland and the regulations thereunder in effect on the date hereof and only as currently interpreted in Switzerland. Such laws and their interpretation are subject to change.

c) Except as expressly stated herein, we express no opinion as to the accuracy of the information contained in the Registration Statement.

d) Except as expressly stated herein, we express no opinion as to any other legal matters. We express no opinion as to any non-legal matters.

* * *

We have rendered this opinion as of the date hereof and we assume no obligation to advise you of changes that may thereafter be brought to our attention.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the references to us under the heading "Legal Matters" contained in the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act.

This opinion shall be governed by and construed in accordance with the laws of Switzerland.

Sincerely yours,

/s/ FRORIEP

FRORIEP

Marco A. Rizzi

Exhibit 8.2

New York
Menlo Park
Washington DC
São Paulo
London
Paris
Madrid
Tokyo
Beijing
Hong Kong

Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, NY 10017

212 450 4000 tel
212 701 5800 fax

May 4, 2015

Re: Auris Medical Holding AG Common Shares Offering

Auris Medical Holding AG
Bahnhofstrasse 21
6300 Zug
Switzerland

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 preparation of the Registration Statement on Form F-1 (the "**Registration Statement**") and the related Prospectus (the "**Prospectus**") filed with the United States Securities and Exchange Commission (File No. 333-203554) by the Company for the purpose of registering under the United States Securities Act of 1933 (the "**Act**") 6,000,000 of its Common Shares (nominal value CHF 0.40 per Common Share).

We, as your counsel, have examined originals or copies of such documents, corporate records, certificates of public officials and other instruments as we have deemed necessary or advisable for the purpose of rendering 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 the foregoing opinion is limited to 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 captions "Taxation" and "Legal Matters" in the Prospectus included in the Registration Statement and to the filing, as an exhibit to the Registration, of this letter. In giving this consent we do not admit that we come within the category of persons whose consent is required under Section 7 of the Act.

Very truly yours,

/s/ Davis Polk & Wardwell LLP

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the use in this Registration Statement on Form F-1 of our report dated March 30, 2015 relating to the consolidated financial statements of Auris Medical Holding AG as of and for the year-end December 31, 2014 appearing in the Prospectus, which is part of this Registration Statement.

We also consent to the reference to us under the headings “Summary Consolidated Historical And Other Financial Information”, “Selected Consolidated Financial and Other Information” and “Experts” in such Prospectus.

Deloitte AG

/s/ James D. Horiguchi	/s/ Matthias Gschwend
James D. Horiguchi	Matthias Gschwend

Zurich, Switzerland
May 4, 2015

EXHIBIT 23.2

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 statement of financial position of Auris Medical AG and subsidiaries as of December 31, 2013, and the related consolidated statements of profit or loss and other comprehensive loss, 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
May 4, 2015

Exhibit 23.6

CONSENT TO USE OF NAME IN REGISTRATION STATEMENT

This Consent to Use of Name in Registration Statement is executed as of May 4, 2015, by a duly authorized representative of MEDACorp, Inc (the "Company").

The Company hereby consents to the use of the Company's name and data from the independent report the Company published on behalf of Auris Medical Holding AG ("Auris Medical") in Auris Medical's Registration Statement on Form F-1 and any amendments thereto (collectively, the "Registration Statement"), including references to the Company under the heading "Experts." The Company understands that the Registration Statement is a public document.

MEDACORP, INC.

By: /s/ Anthony Gibney
Name: Anthony Gibney
Title: Managing Director