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Registration No. 333-229465

PROSPECTUS

10,000,000 Common Shares

Auris Medical Holding AG
Common Shares

This prospectus relates to the resale, from time to time, of up to 10,000,000 common shares of Auris Medical Holding AG, a stock corporation organized under the laws of Switzerland, by the selling shareholder, LPC Capital Fund, LLC, or "LPC." The common shares to which this prospectus relates may be issued to LPC pursuant to a purchase agreement, dated as of May 2, 2018, between us and LPC, which we refer to as the "Purchase Agreement".

We are not selling any securities under this prospectus and will not receive any of the proceeds from the sale of common shares by the selling shareholder. However, we may receive proceeds of up to $8,989,225 from the issuance of our common shares to LPC under the Purchase Agreement, from time to time in our discretion after the date the registration statement of which this prospectus is a part is declared effective and the other conditions in the Purchase Agreement have been satisfied.

LPC is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act of 1933, as amended, or the "Securities Act". LPC may sell the common shares described in this prospectus in a number of different ways and at varying prices. See "Plan of Distribution" for more information about how LPC may sell the common shares being registered pursuant to this prospectus.

We will pay the expenses incurred in registering the common shares to which this prospectus relates, including legal and accounting fees. See "Plan of Distribution."

Currently, our common shares are traded on the Nasdaq Capital Market under the symbol "EARS". The closing price of our common shares on Nasdaq on February 12, 2019 was $0.36 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 page9.

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.

The date of this prospectus is February 15, 2019.

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Unless otherwise indicated or the context otherwise requires, all references in this prospectus to "Auris Medical Holding AG" or "Auris," the "Company," "we," "our," "ours," "us" or similar terms refer to Auris Medical Holding AG (formerly Auris Medical AG), together with its subsidiaries, prior to our corporate reorganization by way of the Merger (as defined below) on March 13, 2018 (i.e. to the transferring entity), and to Auris Medical Holding AG (formerly Auris Medical NewCo Holding AG), together with its subsidiaries after the Merger (i.e. to the surviving entity) and prior to the Redomestication (as defined below). The trademarks, trade names and service marks appearing in this prospectus are property of their respective owners. The term "Auris Medical (Bermuda)" refers to Auris Medical Holding Ltd., a Bermuda corporation whose shares our shareholders are expected to own after we change the corporate jurisdiction of the Company from Switzerland to Bermuda pursuant to the Redomestication.

On March 13, 2018, Auris NewCo Holding AG merged (the "Merger") with Auris Medical Holding AG ("Auris OldCo"), a corporation (Aktiengesellschaft) organized in accordance with Swiss law and domiciled in Switzerland. The Merger took place following Auris OldCo shareholder approval at an extraordinary general meeting of shareholders held on March 12, 2018. Auris NewCo Holding AG changed its name to Auris Medical Holding AG following consummation of the Merger.

Unless indicated or the context otherwise requires, all references in this prospectus to our common shares as of any date prior to March 13, 2018 refer to our common shares (having a nominal value of CHF 0.40 each) prior to the 10:1 "reverse share split" effected through the Merger and all references to our common shares as of, and after, March 13, 2018 refer to our common shares (having a nominal value of CHF 0.02 each) after the 10:1 "reverse share split" effected through the Merger.

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 have not authorized any other person to provide you with different or additional information. We are not 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 that address important unmet medical needs in neurotology and mental health supportive care. We are focusing on the development of intranasal betahistine for the treatment of vertigo (AM-125) and for the prevention of antipsychotic-induced weight gain and somnolence (AM-201). These programs have gone through two Phase 1 trials and will move into proof-of-concept studies in 2019. In addition, we have two Phase 3 programs under development: (i) Keyzilen® (AM-101), which is being developed for the treatment of acute inner ear tinnitus and (ii) Sonsuvi® (AM-111), which is being developed for the treatment of acute inner ear hearing loss. Sonsuvi® has been granted orphan drug status by the FDA and the EMA and has been granted fast track designation by the FDA.

Recent Developments

Acquisition of Orphan Drug Designation and Rights to In-License Patents Related to Betahistine

On December 6, 2018, we announced a strategic expansion for our intranasal betahistine development program. In two related transactions, we acquired an Orphan Drug Designation for betahistine in the treatment of obesity associated with Prader-Willi syndrome (PWS) and signed a binding letter of intent to in-license exclusive rights to two U.S. Patents relating to the use of betahistine for the treatment of depression and attention-deficit / hyperactivity disorder (ADHD), respectively. On January 15, 2019, we announced the closing of the acquisition of the Orphan Drug Designation and that the transfer of the designation to Auris Medical had been recorded by the FDA.

Positive Results from Second Phase 1 Clinical Trial with Intranasal Betahistine (AM-125)

On October 17, 2018, we announced positive results from the second Phase 1 trial evaluating intranasal betahistine in healthy volunteers. The study results demonstrated superior bioavailability over a range of four intranasal betahistine doses compared to oral betahistine, with plasma exposure being 6 to 29 times higher (p-value between 0.056 and p0.0001). Further, it confirmed the favorable safety profile of intranasal betahistine and showed that the treatment was well tolerated when administered three times daily for three days.

The randomized double blind placebo controlled Phase 1 trial with dose escalation enrolled a total of 72 healthy volunteers. One group of study participants received a single dose of intranasal betahistine or placebo and, following a wash-out period, three doses daily for three days. Single doses were escalated up to 60 mg, and repeated doses up to 40 mg. For the latter, the maximum tolerated dose based on local tolerability was determined at 40 mg. The other group of study participants received oral betahistine or placebo for reference. Pharmacokinetic parameters in blood plasma were determined for betahistine and its metabolites, and relative bioavailability for intranasal betahistine was calculated compared to oral betahistine 48 mg, which is the maximum approved daily dose as marketed worldwide (ex US). We plan to initiate two randomized double blind placebo controlled proof-of-concept studies with intranasal betahistine in the first quarter of 2019. In the planned TRAVERS, we plan to enroll patients suffering from acute vertigo following vestibular schwannoma resection.

We plan to initiate a Phase 2 randomized placebo-controlled clinical trial with AM-125 in the first quarter of 2019. The "TRAVERS" Phase 2 trial will enroll 138 patients suffering from acute vertigo following surgical removal of a vestibular schwannoma, a tumor growing behind the inner ear. It will be conducted in several European countries and potentially, Canada. The TRAVERS trial will have two parts:

In Part A, five ascending doses of AM-125 or placebo, administered three times daily over a total of four weeks, will be tested in a total of 50 patients. In addition, oral betahistine 48 mg will be tested in 16 patients under open-label conditions for reference. Based on an interim analysis, two doses will be selected and tested in an estimated 72 patients in Part B.

Launch of AM-201 Program

On May 15, 2018, we announced the expansion of our intranasal betahistine development program beyond the treatment of vertigo into mental health supportive care indications. Under project code AM-201, we intend to develop intranasal betahistine for the prevention of weight gain and drowsiness (somnolence), which are major side effects of many antipsychotic drugs. On November 20, 2018, we announced the results of our pre-Investigational New Drug ("IND") meeting on AM-201 with the FDA. In its written response, the FDA supported the planned conduct of a multiple dose Phase 1b proof-of-concept trial with AM-201 administered to healthy subjects in combination with olanzapine to evaluate the pharmacokinetics, pharmacodynamics and safety, and to establish proof-of-concept. Further, the FDA endorsed weight gain normalized to baseline body weight versus placebo as reasonable primary efficacy endpoint for a subsequent Phase 2 trial.

We expect to initiate the Phase 1b proof-of-concept trial in the first quarter of 2019. The trial will be conducted in Europe and will enroll 50 healthy volunteers who will receive either AM-201 or placebo concomitantly with olanzapine over four weeks.

Scientific Advice from the EMA on Development Plan and Regulatory Pathway for Sonsuvi®

On May 7, 2018, we announced that we had received positive Scientific Advice from the Committee for Medicinal Products for Human Use of the EMA related to the development plan and regulatory pathway for Sonsuvi®. The Scientific Advice (Protocol Assistance) had been requested by us following the results of the HEALOS Phase 3 trial. The EMA reviewed our proposed concept for a single pivotal trial with Sonsuvi® at a dose of 0.4 mg/mL in patients suffering from acute profound hearing loss, which builds to a large extent on the design and outcomes from HEALOS. The EMA endorsed the proposed trial design, choice of efficacy and safety endpoints, as well as the statistical methodology. In addition, the EMA provided important guidance on the regulatory path forward and the maintenance of Sonsuvi®'s orphan drug designation.

On August 30, 2018, we announced that we received feedback from a Type C meeting with the FDA related to the development plan and regulatory pathway for Sonsuvi®. The FDA reviewed our proposed concept for a placebo-controlled pivotal trial with Sonsuvi® at a dose of 0.4 mg/mL in patients suffering from acute profound hearing loss. The trial protocol builds to a large extent on the design and outcomes from HEALOS and also incorporates specific feedback provided by the EMA referenced above. In a written response, the FDA endorsed the proposed choice of primary and secondary efficacy endpoints, the safety endpoints, as well as the planned sample size and statistical methodology. In addition, the FDA provided important guidance on the regulatory path forward.

Identification of Potential Partners for Sonsuvi®

In early November 2018, we engaged JSB Partners LP, with offices in Boston, Munich and Zug, to identify potential partners for our Sonsuvi® program and to support us in negotiating potential partnering agreements.

Otonomy Ruling

On August 1, 2018, the United States Court of Appeals for the Federal Circuit reversed the USPTO Patent Trial and Appeal Board's determination of priority in our favor relating to the July 2015 USPTO declaration of patent interference (No. 106,030) involving our issued U.S. patent No. 9,066,865 and Otonomy's U.S. patent application No. 13/848,636. We believe that this ruling will not materially impact any of our development programs.

Redomestication

On January 29, 2019, we filed a registration statement on Form F-4 related to the redomestication of us from Switzerland to Bermuda (the "Redomestication"). On January 24, 2019, our board of directors determined that it would be in our best interest to change our legal seat and jurisdiction of incorporation, respectively, from Switzerland to Bermuda. We are proposing to change our legal seat and jurisdiction of incorporation by discontinuing from Switzerland and continuing as an exempted company limited by shares registered under the laws of Bermuda. To effect the Redomestication, we will, upon the approval of our shareholders, file an application with the Registrar of Companies in Bermuda.

The board of directors may not be able to implement the Redomestication if the relevant consents, rulings and approvals in connection with the Redomestication are not obtained, including approvals from our shareholders and the Swiss and Bermuda authorities.

Upon the issuance of a certificate of continuance by the Registrar of Companies in Bermuda, the Redomestication will be effected and we will have continued in Bermuda pursuant to Section 132C of the Companies Act as a Bermuda company, subject to the Companies Act and other laws of Bermuda, with a new name "Auris Medical Holding Ltd."

To effect the deletion of our company in the commercial register of the Canton of Zug, Switzerland, we will need, among other steps, to publish a notice to creditors three times in the Swiss Official Gazette of Commerce and our auditors will have to confirm that the claims of the creditors (if any) within the meaning of article 46 Swiss Merger Act have been secured or fulfilled or that the creditors agree to the deletion in the Swiss commercial register. The necessary filing of the documents with the commercial register will include, among other documents, the resolution of the board of directors, the minutes of the shareholders' resolution, a copy the certificate of continuance (issued by the Registrar of Companies in Bermuda), the legal opinion of Bermuda counsel and the auditors confirmation. Upon filing of the application to delete the Company in the commercial register of the Canton of Zug, the commercial register will involve the federal and cantonal tax authorities and request their consent to cancel our company. Such consent is only granted upon payment of all taxes by us (whether before or after the continuance of us in Bermuda).

The assets and liabilities as a Bermuda company immediately after the Redomestication will be identical to the assets and liabilities as a Swiss company immediately prior to the Redomestication. Our officers and directors immediately before the Redomestication becomes effective will be the officers and directors of the Bermuda company upon Redomestication. In addition, pursuant to Bermuda law, Auris Medical (Bermuda) will be required to appoint certain officers who are ordinarily resident in Bermuda, and therefore Auris Medical (Bermuda), upon effectiveness of the Redomestication, intends to appoint a secretary (or assistant secretary) and/or a resident representative who is ordinarily resident in Bermuda and maintain a registered office in Bermuda. The Redomestication will not result in any material change to our business and will not have any effect on the relative equity interests of our shareholders.

We believe that the Redomestication from Switzerland to Bermuda will provide us with additional corporate flexibility, result in cost savings and that Bermuda is a jurisdiction more familiar to most of our current and potential new investors ultimately resulting in improved access to capital markets.

Nasdaq Listing Requirements

We are currently not in compliance with the quantitative listing standards of the Nasdaq Capital Market, which require, among other things, that listed companies maintain a minimum closing bid price of $1.00 per share. We failed to satisfy this threshold for 30 consecutive trading days and on July 30, 2018, we received a letter from Nasdaq indicating that we had been provided a period of 180 calendar days, or until January 28, 2019, to regain compliance. We did not regain compliance within the 180 days.

On February 6, 2019, we received a letter from Nasdaq stating that due to our continued non-compliance with the minimum $1.00 bid price requirement, our common shares were subject to delisting unless we timely requested a hearing before the Nasdaq Hearings Panel. We timely requested such a hearing on February 8, 2019, which request has stayed any delisting or suspension action by Nasdaq pending the hearing and the expiration of any additional extension period granted following the hearing.

At the hearing, we intend to present our plan to regain compliance with the minimum $1.00 bid price requirement; however, there can be no assurance that the Nasdaq Hearings Panel will grant our request for continued listing or that we will be able to evidence compliance with the applicable listing criteria prior to the expiration of any additional extension period that may be granted to us.

At the hearing, we intend to commit that in the event that the Nasdaq Hearings Panel grants us an additional compliance period and the bid price of our common shares fails to increase above the $1.00 minimum during such additional compliance period, we will pursue a reverse share split by consolidating our common shares (together with a corresponding increase in the par value thereof) in a ratio determined by the board of directors in order to regain compliance with the $1.00 bid price requirement. In the event shareholders approve the Redomestication, Auris Medical (Bermuda)'s board of directors would have the ability, after the Redomestication, to effect a reverse share split without further shareholders approval, by consolidating our common shares (together with a corresponding increase in the par value thereof) in a ratio determined by the board of directors.

In addition to the minimum closing bid price requirement, we are required to comply with certain other Nasdaq continued listing requirements, including a series of financial tests relating to shareholder equity, market value of listed securities and number of market makers and shareholders. If we fail to maintain compliance with any of those requirements, our common shares could be delisted from Nasdaq's Capital Market. A delisting of our common shares is likely to reduce the liquidity of our common shares and may inhibit or preclude our ability to raise additional financing.

Repayment of Hercules Loan and Security Agreement

On April 5, 2018, we entered into an agreement with Hercules Capital, Inc. ("Hercules") whereby the terms of our Loan and Security Agreement (the "Loan and Security Agreement") with Hercules were amended to eliminate the $5 million liquidity covenant in exchange for a repayment of $5 million principal amount outstanding under the Loan and Security Agreement. As of September 30, 2018, CHF 2.1 million was the carrying amount under the Loan and Security Agreement. On January 31, 2019, we made the final payment to Hercules under the facility, comprising the last amortization rate as well as an end of term charge. With the final payment, all covenants and collaterals in favor of Hercules have been lifted. In addition, Hercules agreed to return the warrant held by Hercules exercisable for 15,673 common shares at an exercise price of $39.40 per common share for no consideration to us in exchange for our payment to Hercules. We will cancel the warrant upon receipt.

January 2018 Offering of Common Shares and Warrants

On January 26, 2018, we entered into a purchase agreement with certain investors providing for the issuance and sale by us of 12,499,999 of our common shares. The common shares were offered pursuant to an effective shelf registration statement on Form F-3, which was initially filed with the Securities and Exchange Commission (the "SEC," or the "Commission") on September 1, 2015 and declared effective on September 10, 2015 (File No. 333-206710).

In a concurrent private placement, we issued to the same investors warrants to purchase up to 7,499,999 of our common shares in the aggregate. The warrants became exercisable immediately upon their issuance on January 30, 2018, at an exercise price of $0.50 per common share, and expire on January 30, 2025. Following the consummation of the Merger, the warrants became exercisable for an aggregate of 750,002 of our common shares (assuming we decide to round up fractional common shares to the next whole common share), at an exercise price of $5.00 per common share. We refer to such warrants as the "January 2018 Warrants".

Committed Equity Financing

On May 2, 2018, we entered into a Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("LPC"). Pursuant to the Purchase Agreement, LPC has agreed to subscribe for up to $10,000,000 of our common shares over the 30-month term of the 2018 LPC Purchase Agreement.

Pursuant to the Purchase Agreement, so long as a registration statement covering the resale by LPC of the common shares that we issue to LPC pursuant to the Purchase Agreement is available for use, we have the right, from time to time at our sole discretion over the 30-month period from and after June 15, 2018, the date of the satisfaction of the conditions in the Purchase Agreement (the "Commencement"), to require LPC to subscribe for up to 250,000 of our common shares, subject to adjustments as set forth below (such maximum number of shares, as may be adjusted from time to time, the "Regular Purchase Share Limit"; each such purchase, a "Regular Purchase"); provided, however, that (i) the Regular Purchase Share Limit shall be increased to 300,000 of our common shares if the total number of outstanding common shares on the purchase date exceeds 10,000,000, (ii) the Regular Purchase Share Limit shall be increased to 350,000 of our common shares if the closing sale price of our common shares is not below $1.00 on the purchase date and the total number of outstanding common shares on the purchase date exceeds 12,500,000 and (iii) the Regular Purchase Share Limit shall be increased to 400,000 of our common shares if the closing sale price of our common shares is not below $1.00 on the purchase date and the total number of outstanding common shares on the purchase date exceeds 15,000,000. The Regular Purchase Share Limit is subject to proportionate adjustment in the event of a reorganization, recapitalization, non-cash dividend, stock split or other similar transaction; provided, that if after giving effect to such full proportionate adjustment, the adjusted Regular Purchase Share Limit would preclude us from requiring LPC to subscribe for common shares at an aggregate purchase price equal to or greater than $100,000 in any single Regular Purchase, then the Regular Purchase Share Limit for such Regular Purchase will not be fully adjusted, but rather the Regular Purchase Share Limit for such Regular Purchase shall be adjusted as specified in the Purchase Agreement, such that, after giving effect to such adjustment, the Regular Purchase Share Limit will be equal to (or as close as can be derived from such adjustment without exceeding) $100,000. We may not require LPC to purchase in any single Regular Purchase common shares having an aggregate purchase price greater than $1,000,000. We may not issue any of our common shares as a Regular Purchase on a date in which the closing sale price of our common shares is below $0.25 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction). The purchase price for Regular Purchases shall be equal to the lesser of (i) the lowest sale price of our common shares on the applicable purchase date and (ii) the average of the three lowest closing sale prices of our common shares during the 10 business days immediately prior to the applicable purchase date, as reported on the Nasdaq Capital Market.

We also have the right, at our sole discretion, to require LPC to make tranche purchases of up to $2,000,000 in separate tranches of not less than $100,000 and up to $500,000 for each purchase, at a purchase price equal to the lesser of (i) $5.00 per common share or (ii) 96% of the purchase price, provided that (a) the closing price of the common shares is not below $1.00 and (b) the total number of outstanding common shares exceeds 12,500,000. We can deliver notice for a tranche purchase at any time, so long as at least 15 business days have passed since a tranche purchase was completed.

In all instances, we may not issue common shares to LPC under the Purchase Agreement if it would result in LPC beneficially owning more than 4.99% of our outstanding common shares.

The Purchase Agreement contains customary representations, warranties and agreements of the parties, certain limitations and conditions to completing future sale transactions, indemnification rights of LPC and other obligations of the parties. LPC has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our common shares. We issued to LPC a cash commitment fee of $250,000 for entering into this commitment.

As of February 8, 2019, there were 37,495,859 of our common shares outstanding (approximately 31,222,679 of which common shares are held by non-affiliates), excluding the 10,000,000 common shares to which this prospectus relates that we may issue to LPC pursuant to the Purchase Agreement after the effective date. If all of the 10,000,000 common shares offered hereby were issued and outstanding as of February 8, 2019, such shares would represent approximately 21% of the total common shares outstanding, or approximately 24% of the common shares outstanding held by non-affiliates, as of February 8, 2019. The actual number of common shares offered for sale by LPC is dependent upon the number of common shares we ultimately elect to issue to LPC under the Purchase Agreement.

As of the date of this prospectus, we have sold 1,750,000 of our common shares for an aggregate offering price of $1,010,775 pursuant to the Purchase Agreement.

The remaining net proceeds under the Purchase Agreement will depend on the frequency and prices at which we issue our common shares to LPC. We expect that any proceeds received by us from such issuances to LPC will be used for working capital and general corporate purposes. We have the right to terminate the Purchase Agreement at any time for any reason upon one business day's written notice to LPC.

July 2018 Offering of Common Shares and Warrants

On June 28, 2018, an extraordinary general meeting of shareholders approved an ordinary share capital increase and certain changes to our articles of association to increase our authorized share capital and our conditional share capital for financing purposes (collectively, the "Capital Increase"). On July 17, 2018, we closed our registered offering of 17,948,717 common shares, Series A warrants to purchase 6,282,050 common shares and Series B warrants to purchase 4,487,179 common shares. We refer to such offering of common shares as the "July 2018 Registered Offering."

Since the July 2018 Registered Offering, certain Series A warrant holders exercised their warrant shares to purchase 2,904,518 of our common shares and certain Series B warrant holders exercised warrant shares to purchase 2,864,422 of our common shares.

2018 Registered Direct Offerings of Common Shares

On November 27, 2018 and December 11, 2018, we entered into purchase agreements with FiveT Capital AG, providing for the issuance and sale by us of an aggregate of 3,315,000 of our common shares for an aggregate purchase price of $1.6 million in two separate registered direct offerings.

"At-the-Market" Offering Program

On November 30, 2018, we entered into a Sales Agreement (the "A.G.P. Sales Agreement") with A.G.P./Alliance Global Partners ("A.G.P."). Pursuant to the terms of the A.G.P. Sales Agreement, we may offer and sell our common shares, from time to time through A.G.P. by any method deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) promulgated under the Securities Act. Pursuant to the A.G.P. Sales Agreement, we may sell common shares up to a maximum aggregate offering price of $25.0 million.

In the event that the Redomestication is effected, we will need to amend the A.G.P. Sales Agreement before we can sell additional common shares to A.G.P. We cannot be certain that we will be able to negotiate an amendment with the same terms and conditions, or at all.

As of the date of this prospectus, we have sold 2,595,814 of our common shares for an aggregate offering price of $1.3 million pursuant to the A.G.P. Sales Agreement.

Changes to Articles of Association to Allow Further Increases of the Share Capital Based Conditional and Authorized Share Capital

On January 17, 2019, an extraordinary general meeting of shareholders approved further changes to our articles of association to increase our authorized share capital, our conditional share capital for financing purposes and our conditional share capital for equity incentive plans.

Corporate Information

We are a stock corporation organized under the laws of Switzerland. We began our current operations in 2003. 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. On March 13, 2018, we effected a corporate reorganization through the Merger into a newly formed holding company for the purpose of effecting the equivalent of a 10-1 "reverse share split." Our principal office is located at Bahnhofstrasse 21, 6300 Zug, Switzerland, telephone number +41 (0)41 729 71 94.

We maintain a website at www.aurismedical.com where general information about us is available. Investors can obtain copies of our filings with the Securities and Exchange Commission, or SEC, from this site free of charge, as well as from the SEC website at www.sec.gov. We are not incorporating the contents of our website into 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.

We may take advantage of these provisions for up to five years from our initial public offering in 2014 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 $1.07 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.

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," our consolidated financial statements and the documents incorporated herein.

Common Shares offered by the selling shareholder	Up to 10,000,000 common shares.
Voting rights	Our common shares have one vote per common share.
Selling shareholder	Lincoln Park Capital Fund, LLC. See "Selling Shareholder."
Nasdaq Capital Market symbol	"EARS."
Use of proceeds	We will not receive any proceeds from the sales of our common shares by LPC. We may receive gross proceeds of up to $8,989,225 under the Purchase Agreement over the remaining portion of the 30-month period following the time we were first eligible to commence issuances to LPC under the Purchase Agreement, assuming that we issue all of the common shares committed to be purchased thereunder and excluding estimated offering fees and expenses. We intend to use the net proceeds from the issuance of common shares to LPC for working capital and 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."
Risk factors	An investment in our common shares involves a high degree of risk. Please refer to "Risk Factors" in this prospectus and other information included in this prospectus for a discussion of factors you should carefully consider before investing in our common shares.

The number of our common shares outstanding after this offering is based on 37,495,859 common shares outstanding as of January 25, 2019 and excludes:

- 1,630,613 of our common shares available for issuance pursuant to our conditional share capital for equity incentive plans pursuant to our amended and restated articles of association, including 1,068,848 of our common shares issuable upon the exercise of options outstanding as of January 25, 2019 at a weighted average exercise price of $1.00 per common share;
- 14,675,520 of our common shares available for issuance for financing purposes pursuant to our amended and restated articles of association, including 15,673 common shares issuable upon the exercise of a warrant issued to Hercules, at an exercise price of $39.40 per common share, 794,500 common shares issuable upon exercise of warrants issued on February 21, 2017 in a public offering at an exercise price of $12.00 per common share, 750,002 common shares issuable upon the exercise of the January 2018 Warrants at an exercise price of $5.00 per common share, and 3,377,533 common shares issuable upon the exercise of the warrants issued in the July 2018 Registered Offering; at an exercise price of CHF 0.39 per common share; and
- 14,327,059 common shares available for issuance pursuant to our authorized capital pursuant to our articles of association, including 1,622,356 common shares issuable upon the exercise of warrants issued the July 2018 Registered Offering at an exercise price of CHF 0.39 per common share.

RISK FACTORS

Any investment in our common shares involves a high degree of risk. You should carefully consider the risks described below and all of the information included in this prospectus before deciding whether to purchase our common shares. The risks and uncertainties described below are not the only risks and uncertainties we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. If any of the events or circumstances described in the following risk factors actually occur, our business, financial condition and results of operations would suffer. In that event, the price of our common shares could decline, and you may lose all or part of your investment. The risks discussed below also include forward-looking statements and our actual results may differ substantially from those discussed in these forward-looking statements. See "Forward-Looking Statements."

Risks Related to Our Business and Industry

We are in the process of evaluating potential next steps in the development of our lead product candidate, Keyzilen® following the failure of the Phase 3 trial. In addition, we have initiated a strategic partnering process for our second lead product candidate Sonsuvi®. We cannot give any assurance that these candidates will continue to be developed, receive regulatory approval or be successfully commercialized or partnered.

We do not have any products that have gained regulatory approval. We have two lead clinical-stage product candidates, (i) Keyzilen® (AM-101), which is being developed for the treatment of acute inner ear tinnitus and (ii) Sonsuvi® (AM-111), which is being developed for the treatment of acute inner ear hearing loss. On March 13, 2018, we announced that preliminary top-line data from the TACTT3 Phase 3 clinical trial with Keyzilen® indicated that the study did not meet its primary efficacy endpoint of a statistically significant improvement in the Tinnitus Functional Index, or TFI, score from baseline to Day 84 in the active treated group compared to placebo either in the overall population or in the otitis media subpopulation. This followed our announcement in August 2016 that, TACTT2, the previously conducted Phase 3 sister trial with Keyzilen®, did not meet its two co-primary efficacy endpoints of statistically significant changes in tinnitus loudness and tinnitus burden compared to placebo. We are in the process of evaluating our options for the Keyzilen® development program, including whether we will continue to seek the development, regulatory approval and commercialization of either Keyzilen® in the future, or pursue an alternative course of action. If we continue development of Keyzilen®, we would need to conduct additional studies and trials in the future, in order to pursue regulatory approval and would need to raise additional capital to fund any such additional study, and we may be unable to secure such capital. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of Keyzilen®.

On November 28, 2017, we announced that the HEALOS Phase 3 clinical trial that investigated our other lead product candidate, Sonsuvi®, in the treatment of acute inner ear hearing loss did not meet the primary efficacy endpoint of a statistically significant improvement in hearing from baseline to Day 28 compared to placebo for either active treatment groups in the overall study population. However, in post-hoc analyses a clinically meaningful and nominally significant improvement in hearing was observed in the subpopulation of patients with acute profound hearing loss at baseline. Based on these results, we submitted the design of a new pivotal trial with AM-111 0.4 mg/mL in patients suffering from acute profound hearing loss to the EMA and subsequently also to the FDA for review. Through a Protocol Assistance procedure the EMA endorsed the proposed trial design, choice of efficacy and safety endpoints, as well as the statistical methodology. In a Type C meeting with written responses, the proposed choice of primary and secondary efficacy endpoints, the safety endpoints, as well as the planned sample size and statistical methodology were also endorsed by the FDA. Following this feedback, we have mandated a transaction advisory firm to identify potential partners for the Sonsuvi® development program and provide support for partnering discussions and negotiations. If successful, this may result in one or several sale, out-licensing or co-development transaction(s) on a global or regional scale. However, there is no guarantee that we will be successful in any pursuit of such strategic options or if we do continue our efforts to develop and commercialize Sonsuvi® in the future, or that any alternative course of action will lead to the success of the program.

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 7.8 million for the nine months ended September 30, 2018, and CHF 24.4 million, CHF 30.7 million and CHF 29.7 million for the years ended December 31, 2017, 2016 and 2015, respectively. As of September 30, 2018, we had an accumulated deficit of CHF 142.5 million.

Our losses have resulted principally from expenses incurred in research and development of our product candidates, pre-clinical research and 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. In our financial year ended December 31, 2017, we incurred CHF 19.2 million in research and development costs, and we expect that our total operating expense in 2018 will be in the range of CHF 10.0 to 13.0 million.

To date, we have financed our operations through the initial public offering and a follow-on offering of our common shares, private placements of equity securities and short- and long-term loans. On July 19, 2016, we entered into a Loan and Security Agreement with Hercules Technology Growth Capital, Inc., or Hercules. The agreement provides us with a senior secured term loan facility for up to $20 million. As of September 30, 2018, the amount outstanding under the Loan and Security Agreement was CHF 2.1 million. On January 31, 2019, we made the final payment to Hercules under the facility, comprising the last amortization rate as well as an end of term charge. With the final payment, all covenants and collaterals in favor of Hercules have been lifted.

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. It may be several years, if ever, before we 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, Keyzilen®, Sonsuvi®, AM-125 or AM-201. 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;
- obtaining marketing approvals for our product candidates, including Keyzilen®, Sonsuvi®, AM-125 or AM-201, for which we will have to 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 FDA, 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 Keyzilen®, Sonsuvi®, AM-125 or AM-201 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 the 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 expect our research and development expenses to remain significant in connection with our ongoing clinical development activities, particularly as we continue our ongoing trials of AM-125, may initiate new trials of Keyzilen® and Sonsuvi® and initiate pre-clinical and clinical development of other product candidates. We expect that our total operating expense in 2019 will be in the range of CHF 10.0 to 13.0 million. As of September 30, 2018, our cash and cash equivalents were CHF 5.3 million. We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements at least until the second quarter of 2019. Our assumptions may prove to be wrong, and we may have to use our capital resources sooner than we currently expect. If we are unable to raise capital when needed, we could be forced to delay, suspend, reduce or terminate our product development programs or commercialization efforts. Also, should we fail to raise sufficient funds to cover our operating expenditures for at least a 12 month period, we may no longer be considered a “going concern.” The lack of a going concern assessment may negatively affect the valuation of the Company’s investments in its subsidiaries and result in a revaluation of these holdings. Under Swiss law, should the Company’s assets fall short of its liabilities as evidenced by the Company’s standalone Swiss GAAP accounts, the board of directors will have to immediately take steps to restructure the business or if it fails to do, file for bankruptcy. If the board of directors fails to take appropriate action, under Swiss law, in case of such over-indebtedness, the auditors may, according to Swiss law, file for bankruptcy on the Company’s behalf. Following the Redomestication, similar standards will apply under Bermuda law, and the board of directors will need to consider the interests of our creditors and take appropriate action to restructure the business if it appears that we are insolvent or likely to become insolvent. 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 funding to continue our ongoing clinical development activities and seek to obtain regulatory approval for, and commercialize, our product candidates. If we receive regulatory approval for any of our product candidates, 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, such as our term loan agreement with Hercules, 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 do not have a history of commercializing pharmaceutical products, which may make it difficult to evaluate the prospects for our future viability.

Our operations to date have been limited to financing and staffing the Company, developing our technology and developing our product candidates. We have not yet demonstrated an ability to successfully complete large-scale, pivotal clinical trials, obtain marketing approvals, 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 Keyzilen®, Sonsuvi®, and AM-125 and AM-201, which are still in clinical development. If our clinical trials are unsuccessful, we do not obtain regulatory approval or we are unable to commercialize Keyzilen®, Sonsuvi®, AM-125 and AM-201, 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201, which are still in

clinical development. Our ability to generate product revenues, which we do not expect will occur for at least the next few 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201 and our other product candidates 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 competent 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201, 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 pre-clinical 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 pre-clinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. For example, 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 pre-clinical 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 trials 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. Keyzilen® and Sonsuvi® are in Phase 3 clinical development and AM-125 is in Phase 2 and AM-201 is in Phase 1 clinical development.

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 pre-clinical 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;
- errors in survey design, data collection and translation;
- 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 pre-clinical 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. Product candidates that show positive pre-clinical 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 Keyzilen® achieved favorable results in our Phase 2 efficacy trial, in August 2016, we announced that the Phase 3 TACTT2 clinical trial of Keyzilen® did not meet its two co-primary efficacy endpoints of statistically significant changes in tinnitus loudness and tinnitus burden compared to placebo. On March 13, 2018, we announced preliminary top-line data from the TACTT3 trial which indicated that the study had not met its primary efficacy endpoint of a statistically significant improvement in the

Tinnitus Functional Score from baseline to Day 84 in the active treated group compared to placebo either in the overall population or in the otitis media subpopulation. On May 15, 2018, we announced that further investigation of the trial's outcomes confirmed these preliminary results.

Also, pre-clinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in pre-clinical 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 Keyzilen®, our endpoints in Phase 3 clinical trials are based on patient reported outcomes, or PROs, some of which were captured daily from trial participants with electronic diaries. Based on insights from our analysis of the TACTT2 and TACTT3 trials, we believe the high frequency of tinnitus loudness ratings over an extended period of time may have caused a number of patients to excessively focus on their tinnitus symptoms, thereby influencing the measured outcome. In addition, the daily reporting requirements may have led to rating fatigue and a loss of accuracy and reliability of the data that were entered. In the previous clinical trials with Keyzilen® we had collected these PROs only during study visits, i.e. much less frequently. Under the SPA with the FDA we agreed to increase the rating frequency.

In the case of Sonsuvi®, 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. In addition, we are dealing with a limited availability of detailed and reliable data relating to the natural history of acute hearing loss, which implies substantial uncertainty with regards to the design of clinical trials, e.g. for determining the number of patients required for statistical testing or the size of the expected treatment effect. For example, a Phase 2 clinical trial with Sonsuvi® showed a strong relationship between the level or severity of initial hearing loss and the size of the treatment effect for active-treated patients compared to placebo-treated patients. Whereas a high spontaneous recovery rate and no treatment effects were observed in patients with mild to moderate hearing loss at baseline, lower spontaneous recovery and meaningful treatment effects were observed in patients with severe to profound hearing loss. Accordingly, enrollment into the Phase 3 trials HEALOS and ASSENT was restricted to patients with severe-profound hearing loss at baseline. On November 28, 2017, we announced that the HEALOS Phase 3 clinical trial that investigated Sonsuvi® in the treatment of acute inner ear hearing loss did not meet the primary efficacy endpoint of a statistically significant improvement in hearing from baseline to Day 28 compared to placebo for either active treatment groups in the overall study population. However, a post-hoc analysis of the subpopulation with profound acute hearing loss (PTA ≥ 90 dB at baseline in accordance with a commonly used classification of hearing loss severity) revealed a clinically meaningful and nominally significant improvement in the Sonsuvi® 0.4 mg/mL treatment group. Accordingly, in HEALOS we found confirmation about the relationship between severity of hearing loss and the size of therapeutic effects; however, such therapeutic effects were not observed in the subgroup of patients with severe initial hearing loss but rather, unlike in the Phase 2 trial, only in the subgroup with profound initial hearing loss. We understand from animal studies that the pharmacological target for Sonsuvi® is only activated in case of severe acute cochlear injury; however, activation of this target cannot be determined in humans, and we have to rely on the measurement of hearing loss for assessing the severity of injury.

Based on the results from the HEALOS clinical trial, we submitted the design of a new pivotal trial with AM-111 0.4 mg/mL in patients suffering from acute profound hearing loss to the EMA and subsequently also to the FDA for review. Through a Protocol Assistance procedure the EMA endorsed the proposed trial design, choice of efficacy and safety endpoints, as well as the statistical methodology. In a

Type C meeting with written responses, the proposed choice of primary and secondary efficacy endpoints, the safety endpoints, as well as the planned sample size and statistical methodology were also endorsed by the FDA. 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 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 three of the 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 trials in the subgroup of ISSNHL, as is currently planned to gain the indication for ASNHL.

If we are required to conduct additional clinical trials or other testing of Keyzilen®, Sonsuvi®, AM-125, AM-201 or any other product candidate that we develop beyond the trials and testing that we currently 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 Keyzilen®, Sonsuvi® 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 or if we are required to conduct additional clinical trials or other testing of Keyzilen®, Sonsuvi®, AM-125 or AM-201 beyond the trials and testing that we currently contemplate and we may be required to obtain additional funds to complete such additional 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 Keyzilen®, Sonsuvi®, AM-125, AM-201 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 pre-clinical 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 Keyzilen® and Sonsuvi® 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 1.2 to 2.5% of patients enrolled in the Keyzilen® trials and in 2.7 to 4.5% of patients in the Sonsuvi® trials); all (Keyzilen®) or most (Sonsuvi®) were considered unrelated or unlikely related to the treatment. In the two Phase 1 trials

with intranasal betahistine, adverse events included transient and dose-dependent nasal congestion or discomfort. 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.

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 Sonsuvi® for the treatment of ASNHL from the FDA and the EMA, and we may rely on obtaining and maintaining orphan drug exclusivity for Sonsuvi®, 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 Sonsuvi®, we may be subject to earlier competition and our potential revenue will be reduced.

Sonsuvi® 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 Sonsuvi® 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.

The orphan drug designation for Sonsuvi® relates to ASNHL, an umbrella term comprising AAT, ISSNHL and surgery-induced trauma based on a common pathophysiologic pathway. Our Phase 3 late-stage program enrolled patients suffering from ISSNHL, which represent the largest of the three ASNHL subgroups.

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 have been primarily focused on the development of Keyzilen®, Sonsuvi®, AM-125 and AM-201 for the treatment of acute inner ear tinnitus, acute inner ear hearing loss, vertigo and antipsychotic-induced weight gain, 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 lead clinical-stage product candidates, (i) Keyzilen® (AM-101), which is being developed for the treatment of acute inner ear tinnitus and (ii) Sonsuvi® (AM-111), being developed for the treatment of acute inner ear hearing loss. Additionally, we have one product candidate, AM-125, in Phase II clinical development, and another, AM-201, in Phase I clinical development. 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, acute inner ear hearing loss or antipsychotic-induced weight gain 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 designed our Phase 3 trials for Keyzilen® and Sonsuvi® to include endpoints that we believe are clinically justified and meaningful. Specifically, with regard to Keyzilen®, 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.

With regard to Sonsuvi®, 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 Sonsuvi® will be approved even if it were to demonstrate such result in further Phase 3 trials.

Whereas various balance tests such as the tandem Romberg or standing on foam tests or other objective measures such as nystagmography or head impulse tests are widely used in the diagnosis and management of vertigo, there is no universally recognized definition of the clinical meaningfulness of outcomes, and regulatory authorities have not issued guidelines for demonstrating efficacy for drug-based treatments such as AM-125. Therefore we cannot be certain that AM-125 will be approved even if it were to show statistically significant improvements in these tests.

Some of our conclusions regarding the potential efficacy of Sonsuvi® in our completed HEALOS clinical trial for the treatment of ASNHL in the subgroup of patients with profound acute hearing loss is based on retrospective analyses of the results, which are generally considered less reliable indicators of efficacy than pre-specified analyses.

After determining that we did not achieve the primary efficacy endpoint in our completed HEALOS clinical trial of Sonsuvi® for the treatment of ASNHL, we performed retrospective analyses that we believe show treatment effects on the magnitude of hearing recovery in favor of Sonsuvi® in case of profound hearing loss at baseline. Although we believe that these additional analyses were warranted, a retrospective analysis performed after unblinding trial results can result in the introduction of bias if the analysis is inappropriately tailored or influenced by knowledge of the data and actual results. In particular, the analysis that resulted in a clinically meaningful effect being observed in active-treated patients who suffered from profound acute hearing loss poses greater risk of bias as such subgroup was not pre-specified in the trial design, notwithstanding that we applied a commonly used definition of profound hearing loss.

Because of these limitations, regulatory authorities typically give greatest weight to results from pre-specified analyses and less weight to results from post-hoc, retrospective analyses. According to discussions with the EMA and FDA, the therapeutic benefits that were observed in the HEALOS subgroup of profound acute hearing loss will need to be confirmed prospectively in one or more additional Phase 3 trials in order to gain regulatory market approval. However, there is no guarantee that we will ever receive such regulatory approval.

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 and betahistine, the active pharmaceutical ingredients, or APIs, of Keyzilen® and AM-125, may be affected by the safety of the drugs related to them. Although both APIs have been used successfully in patients for many years, newly observed toxicities or worsening of known toxicities, in pre-clinical studies of, or in patients receiving, Esketamine, the racemate Ketamine or betahistine, or reconsideration of known toxicities of these APIs in the setting of new indications, could result in increased regulatory scrutiny of Keyzilen® or AM-125. For example, Ketamine is regulated by the Drug Enforcement Administration, or DEA, under the Controlled Substances Act, or CSA, as a Schedule III drug. DEA scheduling is a separate process that can delay when a drug may become available to patients beyond a NDA approval date, and the timing and outcome of such DEA process is uncertain. Although we have observed no abuse liability associated with Keyzilen® to date, if Keyzilen® were to be scheduled under the CSA, such scheduling could negatively impact the ability or willingness of physicians to prescribe Keyzilen® and our ability to commercialize it.

Substantial additional data may need to be generated in order to obtain marketing approval for AM-125.

Oral betahistine has been in clinical use for several decades and is reported to be currently marketed in 115 countries world-wide. However, in the United States oral betahistine is not approved since the FDA revoked the drug product's marketing authorization in the early 1970s over issues with unsubstantiated information about some patients in the efficacy studies upon which approval had been based. Given the absence of an approved betahistine drug product in the United States and to the extent that existing data may not be deemed sufficient, the FDA may require a full development package for AM-125.

Furthermore, additional data will be required for the specific formulation of AM-125 and the intranasal administration route. Since intranasal delivery of betahistine has the potential to result in substantially higher systemic exposures as measured by concentrations in blood plasma compared to oral delivery, existing safety assessments conducted with or for the approved drug product may not be sufficient. In addition, some of these assessments were performed a long time ago and may not be in line with current regulations and guidelines. Therefore the scope of our development program for AM-125 may ultimately not be much smaller than one for new chemical entities.

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, cGDPs and cGCPs for any clinical trials that we conduct post-approval. In the European Union, the marketing authorization holder has to operate a pharmacovigilance system which conforms with and is equivalent to the respective Member State's pharmacovigilance system, requiring him to evaluate all information scientifically, to consider options for risk minimization and prevention and to take appropriate measures as necessary. As part of this system, we will have to, inter alia, have a qualified person responsible for pharmacovigilance, maintain a pharmacovigilance system master file, operate a risk management system for each medicinal product, monitor the outcome of risk minimization measures, and update continuously all pharmacovigilance data to update the risk assessment.

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 or any other regulatory authority'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.

For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law was enacted, 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 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 law imposed a significant annual fee on companies that manufacture or import branded prescription drug products, expanded eligibility criteria for Medicaid programs, and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. Substantial provisions affecting compliance were enacted, which may affect our business practices with health care practitioners. Continued pressure on pharmaceutical pricing is expected and may also increase our regulatory burdens and operating costs.

Other legislative changes have 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 2025 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, 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 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. Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing by requiring drug companies to notify insurers and government regulators of price increases and provide an explanation of the reasons for the increase, reduce the out-of-pocket cost of prescription drug, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Moreover, U.S. President Donald Trump has discussed the need for federal legislation, regulation or Executive Order to regulate the prices of medicines.

Because of the continued uncertainty about the implementation of the Health Care Reform Law, including the potential for further legal challenges or repeal of that legislation, we cannot quantify or predict with any certainty the likely impact of the Health Care Reform Law or its repeal on our business model, prospects, financial condition or results of operations, in particular on the pricing, coverage or reimbursement of any of our product candidates that may receive marketing approval. We also anticipate that Congress, state legislatures, and third-party payors may continue to review and assess alternative healthcare delivery and payment systems and may in the future propose and adopt legislation or policy changes or implementations effecting additional fundamental changes in the healthcare delivery system. We cannot assure you as to the ultimate content, timing, or effect of changes, nor is it possible at this time to estimate the impact of any such potential legislation.

In the European Union, a new clinical trial regulation centralizes clinical trial approval, which eliminates redundancy, but in some cases this may extend timelines for clinical trial approvals due to potentially longer wait times. The regulation requires specific consents for use of data in research which, among other measures, may increase the costs and timelines for our product development efforts. The

regulation also provides an obligation for clinical trial sponsors to make summaries of all trial results, accompanied by a summary understandable to laypersons, as well as the clinical trial report publicly available in a new database. Beyond this obligation, the EMA adopted a new "Agency policy on publication of clinical data" (in force since January 1, 2015) based on which the EMA makes available to the public all clinical trials submitted with the EMA as well as raw data results ("individual patient data"). These publication requirements can conflict with legitimate secrecy interests of the sponsors and may lead to valuable clinical trial data falling into the public domain.

On June 23, 2016, the UK public voted in a referendum to leave the European Union. The UK government subsequently announced its intention to serve notice of withdrawal from the European Union no later than March 2017. As a consequence of such withdrawal notice, EU law will cease to apply to the UK from the date of entry into force of a withdrawal agreement, or two years after UK's submission of the withdrawal notification. As a result, the UK is likely to remain within the European Union for at least the next two years, and, therefore there will likely be no major legal implications for the life sciences sector in the short term. In the long term, however, the effects may be more severe, in particular if the UK cannot agree the terms of a continued close association with the European Union and/or chooses not to incorporate existing EU rules into national law and/or to no longer align themselves with European law. The administrative burden for pharmaceutical companies could increase significantly because regulatory requirements, for example clinical trial authorizations and marketing authorization applications, may need to be fulfilled under a new and different legal framework for the UK. Existing marketing authorizations granted in the European Union under the centralized procedure prior to the exit may potentially not be recognized anymore by the UK.

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 may 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, among other penalties.

Healthcare providers, payors 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 U.S. 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, or HITECH, 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.

Similar laws exist in other jurisdictions.

In the European Union, there is currently no central European anti-bribery or similar legislation. However, more and more EU member states as well as life sciences industry associations are enacting increasingly specific anti-bribery rules for the healthcare sector which are as severe and sometimes even more severe than in the United States. Germany, for example, has recently adopted new criminal provisions dealing with granting benefits to healthcare professionals. This new law has increased the legal restrictions as well as the legal scrutiny for the collaboration and contractual relationships between the pharmaceutical industry and its customers.

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, Sound Pharmaceuticals, Inc., or Sound Pharma, and Sensorion SA, or Sensorion. In October 2013, Otonomy announced the launch of a development program for the treatment of tinnitus, OTO-311, which is based on the NMDA receptor antagonist gacyclidine and may directly compete with our Keyzilen® product candidate. According to a recent public filing, Otonomy intends to develop a polymer-based formulation of gacyclidine that will provide a full course of treatment from a single intratympanic injection. Following a Phase 1 trial, Otonomy made adjustments to the formulation, resulting in product candidate OTO-313, which the company plans to evaluate in a Phase 1/2 trial starting in 2019. OTO-313's competitive strength will ultimately depend on the demonstration of clinical efficacy and safety and its comparison with Keyzilen®. Otonomy is also developing OTO-104, which is a polymer-based formulation of dexamethasone for intratympanic treatment of vertigo in Ménière's disease. In Phase 3 of clinical development, OTO-104 showed no treatment effects in a North American study, but showed treatment effects in a European study, which had been terminated early. In March 2018 the company announced its intention to conduct another Phase 3 study with OTO-104. If Otonomy's drug product is approved prior to AM-125, we will have to compete against it in the treatment of vertigo in Ménière's disease. In addition, OTO-104 is being evaluated by Otonomy for the treatment of certain types of hearing loss and may compete against Sonsuvi®.

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 of temporary inner ear hearing loss from listening to loud music with a mobile digital media player. Although Sonsuvi® targets permanent rather than transient hearing loss, SPI-1005 may become competing products if Sound Pharma seeks and manages to demonstrate clinical efficacy also in the prevention and treatment of permanent inner ear hearing loss.

Sensorion is developing SENS-401, a 5-HT3 antagonist with anti-inflammatory properties, for the oral treatment of sudden sensorineural hearing loss. The company is initiating a Phase 2 clinical trial with SENS-401 in the treatment of sudden sensorineural hearing loss. Sensorion is also developing SENS-111, a histamine H4 receptor antagonist, for the oral treatment of acute vertigo crises and in 2017 initiated a Phase 2 trial to enroll patients with acute unilateral vestibulopathy. According to Sensorion, this trial will conclude in the second half of 2019. If successful, SENS-401 may compete against Sonsuvi®, and SENS-111 may compete against AM-125.

There are several companies developing treatments for hearing loss. Strekin AG, a privately held Swiss company, announced in April 2016 that it plans to develop STR001, an agonist of the peroxisome proliferator, for surgery induced hearing loss and that it commenced a Phase 2 program in Germany and France. Nordmark, a German company, is developing Ancrod, the biologically active substance from the venom of the Malayan Pit Viper (*Calloselasma rhodostoma*), for the treatment of sudden sensorineural hearing loss and has initiated Phase 2 program. Both, STR001 and Ancrod have the potential to compete with Sonsuvi®.

There exist a variety of drug products that are licensed or used off-label for the treatment of vestibular disorders and Ménière's disease, including steroids, diuretics, anti-emetics or anti-nausea medications. In many countries outside the United States, oral betahistine is the standard of care and licensed for the treatment of Ménière's disease and vestibular vertigo. Although, we expect that AM-125 will offer benefits over oral betahistine due to the ability to bypass the strong first-pass metabolism associated with oral intake and provide for a higher bioavailability and avoid gastric side effects, it may take time to change prescribing and usage patterns in favor of the newer product.

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 Keyzilen®, Sonsuvi®, AM-125, AM-201 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 Keyzilen®, Sonsuvi®, AM-125 or any other product candidate that we commercialize and, if available, that the reimbursement rates will be adequate.

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 Keyzilen®, Sonsuvi®, AM-125 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 Keyzilen®, Sonsuvi®, AM-125 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 Keyzilen® and Sonsuvi® have to be administered by an ear, nose, throat physician, and in case of Keyzilen® the procedure has to be repeated for a total of three times;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market, particularly as Keyzilen®, Sonsuvi® and AM-125, 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201 could be smaller than our estimates of the potential market opportunity. If the actual market for Keyzilen®, Sonsuvi®, AM-125 and AM-201 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 Keyzilen®, Sonsuvi®, AM-125 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 Sonsuvi® 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 Sonsuvi® 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. In the past, Xigen has also requested from us quantities of Sonsuvi® 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 certain quantities of the active substance of Sonsuvi® 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 Annual Report, 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 Sonsuvi®. 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 Sonsuvi® and our other product candidates and our financial condition. For a description of our agreement with Xigen. See "Business — Business overview — 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 Keyzilen®, 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 Keyzilen® and Sonsuvi®.

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 Keyzilen® and Sonsuvi® 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201. 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201, and others for the manufacturing and supply of pre-filled syringes and spray pumps. 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 time frame and at an acceptable cost or at all.

Our current and anticipated future dependence upon others for the manufacturing of Keyzilen®, Sonsuvi®, AM-125 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201. We currently have a relationship with one supplier each, for the supply of the API of Keyzilen®, Sonsuvi®, AM-125 and AM-201. 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201. 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long. In addition, upon issuance in the United States any patent term can be adjusted based on certain delays caused by the applicant(s) or the U.S. Patent and Trademark Office, or USPTO. For example, a patent term can be reduced based on certain delays caused by the patent applicant during patent prosecution.

While in the United States there is a possibility of obtaining market protection independent from any patent protection for up to 3 and 5 years from approval, and in the European Union one may obtain data exclusivity of eight years from approval with an additional two years of market exclusivity (which can potentially be extended by one year), there is no assurance that we can obtain such data exclusivity and market protection with respect to Keyzilen®, Sonsuvi®, AM-125, or any of our other product candidates. Our issued patents and pending patent applications are expected to expire for Keyzilen® between 2025 and 2028, for Sonsuvi® between 2020 and 2027, and for AM-125 and AM-201 between 2025 and 2037, 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 Keyzilen®, Sonsuvi®, AM-125 and AM-201 are approved, competitors could file ANDAs for generic versions of Keyzilen®, Sonsuvi®, AM-125 and AM-201, or 505(b)(2) NDAs that reference Keyzilen®, AM-111 and AM-125, respectively. If there are patents listed for Keyzilen®, Sonsuvi®, AM-125 and AM-201 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 Sonsuvi®. 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 Sonsuvi® 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 brimapitide (XG-102), the active substance of Sonsuvi®. 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 Keyzilen®, 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 Keyzilen®, 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 pre-clinical 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.

On July 20, 2015, the USPTO declared Patent Interference No. 106,030 involving our issued U.S. patent No. 9,066,865 (the "'865 Patent") and Otonomy's U.S. patent application No. 13/848,636 (the "'636 Application"). The patent interference identified claims 1-9 in the '865 Patent as interfering with claims 38, 43 and 46-50 of the '636 Application. The '865 Patent discloses methods of treating inner or middle ear diseases with intratympanic injections of poloxamer-based compositions. The claims of the '865 Patent are directed to the use of fluoroquinolone antibiotics in poloxamer 407 compositions under certain specifications. On January 26, 2017, the USPTO issued a decision on the interference granting Auris benefit of priority. As a result of the decision, judgment was entered against Otonomy and all claims in the '636 Application were refused. In addition, claims 1-8 of the '865 Patent were cancelled as the result of the USPTO's determination that the written description of the specification lacked full scope support for treating middle or inner ear disease with fluoroquinolone. However, claim 9, which is directed to a method of treating viral and bacterial infections with intratympanic injection of a fluoroquinolone antibiotic in a poloxamer 407 composition under certain specifications, was affirmed. On March 27, 2017, Otonomy submitted a notice of appeal to the United States Court of Appeals for the Federal Circuit. To preserve its rights, Auris filed a notice of cross-appeal on April 5, 2017. Otonomy subsequently filed its opening brief on July 20, 2017, and Auris filed its principal and response brief on October 27, 2017. On January 5, 2018, Otonomy filed its opposition and reply brief. Auris filed its reply brief on February 2, 2018. On August 1, 2018, the United States Court of Appeals for the Federal Circuit reversed the USPTO Patent Trial and Appeal Board's determination of priority in our favor relating to the July 2015 USPTO declaration of patent interference (No. 106,030) involving our issued '865 Patent and Otonomy's '636 Application. We believe that this ruling will not materially impact any of our development programs.

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 or know how, 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 and Hernan Levett, Chief Financial 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 Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel. If the Redomestication is not approved, we will remain impacted by legislation in Switzerland affecting public companies 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 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;
- our ability to maintain the listing of our common shares on Nasdaq; or
- other events and factors beyond our control.

Additionally, these factors may affect the liquidity of our common shares, which may hurt your ability to sell our common shares in the future. 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.

Our common shares may be involuntarily delisted from trading on The Nasdaq Capital Market if we fail to comply with the continued listing requirements. A delisting of our common shares is likely to reduce the liquidity of our common shares and may inhibit or preclude our ability to raise additional financing.

We are required to comply with certain Nasdaq continued listing requirements, including a series of financial tests relating to shareholder equity, market value of listed securities and number of market makers and shareholders. If we fail to maintain compliance with any of those requirements, our common shares could be delisted from The Nasdaq Capital Market.

We are currently not in compliance with the quantitative listing standards of the Nasdaq Capital Market, which require, among other things, that listed companies maintain a minimum closing bid price of $1.00 per share. We failed to satisfy this threshold for 30 consecutive trading days and on July 30, 2018, we received a letter from Nasdaq indicating that we had been provided a period of 180 calendar days, or until January 28, 2019, to regain compliance. We did not regain compliance within the 180 days.

On February 6, 2019, we received a letter from Nasdaq stating that due to our continued non-compliance with the minimum $1.00 bid price requirement, our common shares were subject to delisting unless we timely requested a hearing before the Nasdaq Hearings Panel. We timely requested such a hearing on February 8, 2019, which request has stayed any delisting or suspension action by Nasdaq pending the hearing and the expiration of any additional extension period granted following the hearing.

At the hearing, we intend to present our plan to regain compliance with the minimum $1.00 bid price requirement; however, there can be no assurance that the Nasdaq Hearings Panel will grant our request for continued listing or that we will be able to evidence compliance with the applicable listing criteria prior to the expiration of any additional extension period that may be granted to us.

At the hearing, we intend to commit that in the event that the Nasdaq Hearings Panel grants us an additional compliance period and the bid price of our common shares fails to increase above the $1.00 minimum during such additional compliance period, we will pursue a reverse share split by consolidating our common shares (together with a corresponding increase in the par value thereof) in a ratio determined by the board of directors in order to regain compliance with the $1.00 bid price requirement. In the event shareholders approve the Redomestication, Auris Medical (Bermuda)'s board of directors would have the ability, after the Redomestication, to effect a reverse share split without further shareholders approval, by consolidating our common shares (together with a corresponding increase in the par value thereof) in a ratio determined by the board of directors. However, there can be no assurance that we will be able to successfully resolve such noncompliance.

In 2017, we also failed to maintain compliance with the minimum bid price requirement. To address that non-compliance, on March 13, 2018, we effected the Merger, pursuant to which we effected a "reverse share split" at a ratio of 10-for-1. Additionally, on January 11, 2018, we received a letter from Nasdaq indicating that we were not in compliance with Nasdaq's market value of listed securities requirement. As a result of the July 2018 Registered Offering, we resolved the non-compliance with the market value of listed securities requirement by complying with Nasdaq's minimum equity standard. However, there can be no assurance that we will be able to successfully maintain compliance with the several Nasdaq continued listing requirements.

If, for any reason, Nasdaq should delist our common shares from trading on its exchange and we are unable to obtain listing on another national securities exchange or take action to restore our compliance with the Nasdaq continued listing requirements, a reduction in some or all of the following may occur, each of which could have a material adverse effect on our shareholders:

- the liquidity of our common shares;
- the market price of our common shares;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common shares;
- the number of investors in general that will consider investing in our common shares;
- the number of market makers in our common shares;
- the availability of information concerning the trading prices and volume of our common shares; and
- the number of broker-dealers willing to execute trades in shares of our common shares.

In the event that our common shares are delisted from Nasdaq, U.S. broker-dealers may be discouraged from effecting transactions in shares of our common shares because they may be considered penny stocks and thus be subject to the penny stock rules.

On February 6, 2019, we received a letter from Nasdaq stating that due to our continued non-compliance with the minimum $1.00 bid price requirement, our common shares were subject to delisting unless we timely requested a hearing before the Nasdaq Hearings Panel. We timely requested such a hearing on February 8, 2019, which request has stayed any delisting or suspension action by Nasdaq pending the hearing and the expiration of any additional extension period granted following the hearing. If the Nasdaq Hearings Panel does not grant our request for continued listing and our common shares are delisted from trading on Nasdaq, our common shares may be considered to be "penny stock."

The SEC has adopted a number of rules to regulate "penny stock" that restrict transactions involving stock which is deemed to be penny stock. Such rules include Rules 3a51-1, 15g-1, 15g-2, 15g-3, 15g-4, 15g-5, 15g-6, 15g-7, and 15g-9 under the Exchange Act. These rules may have the effect of reducing the liquidity of penny stocks. "Penny stocks" generally are equity securities with a price of less than $5.00 per share (other than securities registered on certain national securities exchanges or quoted on the Nasdaq Stock Market if current price and volume information with respect to transactions in such securities is provided

by the exchange or system). Our common shares have in the past constituted, and may again in the future constitute, "penny stock" within the meaning of the rules. The additional sales practice and disclosure requirements imposed upon U.S. broker-dealers may discourage such broker-dealers from effecting transactions in shares of our common shares, which could severely limit the market liquidity of such common shares and impede their sale in the secondary market.

A U.S. broker-dealer selling penny stock to anyone other than an established customer or "accredited investor" (generally, an individual with net worth in excess of $1,000,000 or an annual income exceeding $200,000, or $300,000 together with his or her spouse) must make a special suitability determination for the purchaser and must receive the purchaser's written consent to the transaction prior to sale, unless the broker-dealer or the transaction is otherwise exempt. In addition, the "penny stock" regulations require the U.S. broker-dealer to deliver, prior to any transaction involving a "penny stock", a disclosure schedule prepared in accordance with SEC standards relating to the "penny stock" market, unless the broker-dealer or the transaction is otherwise exempt. A U.S. broker-dealer is also required to disclose commissions payable to the U.S. broker-dealer and the registered representative and current quotations for the securities. Finally, a U.S. broker-dealer is required to submit monthly statements disclosing recent price information with respect to the "penny stock" held in a customer's account and information with respect to the limited market in "penny stocks."

Shareholders should be aware that, according to the SEC, the market for "penny stocks" has suffered in recent years from patterns of fraud and abuse. Such patterns include (i) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) "boiler room" practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and (v) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, resulting in investor losses. Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities.

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.

Certain principal shareholders and their affiliated entities as well as members of our executive team and board of directors own approximately 17% of our common shares. Depending on the level of attendance at our general meetings of shareholders, these shareholders may be in a position to determine the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the shares represented at our general meetings of shareholders may control any shareholder resolution requiring an absolute majority of the shares represented, including the election of members to the board of directors of the 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 17% 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. Additionally, as of the date of this prospectus we have warrants outstanding, which are exercisable for an aggregate of 6,544,791 common shares at a weighted average exercise price of $2.33 per share, an equity commitment to sell up to approximately $9.0 million of additional common shares to Lincoln Park Capital Fund, LLC ("LPC") pursuant to the commitment purchase agreement we entered into on May 2, 2018 with LPC (the "Purchase Agreement") and an at-the-market offering program pursuant to the sales agreement we entered into with A.G.P./Alliance Global Partners ("A.G.P.") on November 30, 2018 (the "A.G.P. Sales Agreement") for sales of up to $25.0 million of additional common shares. In connection with the Redomestication, we will be unable to raise capital through the A.G.P. Sales Agreement unless we successfully renegotiate such agreement with A.G.P. We cannot be certain that we will be able to negotiate the A.G.P. Sales Agreement with the same terms and conditions, or at all. 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 the resale of the common shares underlying the warrants that we have offered and sold in unregistered transactions, the common shares that are sold to LPC and the 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. In addition, we have filed a registration statement covering the issuance and sale by us of up to $100 million of common shares, debt securities, warrants, purchase contracts, units and common shares. We may issue such securities, including our common shares and warrants to purchase common shares, at any time and from time to time subject to the limitations set forth in General Instruction I.B.5 of Form F-3. If a large number of our common shares and/or warrants to purchase 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. Following the Redomestication, we intend to update all of our existing registration statements to the extent necessary to allow for their continued use.

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. Following the Redomestication, the proposal to pay future dividends to shareholders will in addition effectively be at the discretion of our board of directors after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitations pursuant to Swiss law or by our articles of association. If the Redomestication is effected, we will be subject to Bermuda law restrictions on the payment of dividends including that no dividends may be declared by our board of directors or paid by the Company if there are reasonable grounds for believing that: (i) we are, or would after the payment be, unable to pay our liabilities as they become due; or (ii) that the realizable value of our assets would thereby be less than our liabilities. 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.

Additionally, in connection with the Merger, the Swiss Federal Tax Administration took the position (on the basis of a tax ruling) that, as a result of the Merger, the existing Capital Contribution Reserves will be offset against the retained losses. This leads to a reduced amount of Capital Contribution Reserves. We do not intend to make distributions in the foreseeable future, but if the position of the tax authorities were to prevail, it is likely that any distributions exceeding the reduced amount of Capital Contributions Reserves would be treated as taxable dividends for Swiss tax purposes. If we ever decide to declare dividends, we expect to challenge the view under the tax ruling, but there can be no assurance that any such challenge would be successful.

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 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 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.

Neither Swiss law nor Bermuda law requires that a majority of our board of directors consists 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. We follow Swiss law requirements with respect to disclosure of compensation for our directors and executive officers. Neither Swiss law nor Bermuda law requires that we disclose information regarding third-party compensation of our directors or director nominee. As a result, our practice varies from the third-party compensation disclosure requirements of Nasdaq Listing Rule 5250(b)(3). After the Redomestication, we intend to follow the requirements of Bermuda law with respect to our compensation committee, disclosure of compensation of our directors and executive officers and information regarding third-party compensation of our directors or director nominee, each of which differ from the requirements of the Nasdaq Listing Rules.

In addition, as permitted by Swiss law and Bermuda law, we have opted not to implement a standalone 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 constitutive documents do not provide quorum requirements generally applicable to general meetings of shareholders. After the Redomestication, the quorum for a general meeting of shareholders will be as set out in the Bye-laws (as defined below), which will provide for a quorum of two or more persons present at the start of the meeting and representing in person or by proxy issued and outstanding voting shares in the company.

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 constitutive documents 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, neither Swiss law nor Bermuda law has a regulatory regime for the solicitation of proxies, 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.

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. 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. These criteria are tested on the last business day of our second fiscal quarter, each year. 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.

We believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for our 2018 taxable year, and we expect to be a PFIC for our current year and for the foreseeable future.

We believe that we were a "passive foreign investment company," or PFIC, for U.S. federal income tax purposes for our 2018 taxable year, and we expect to be a PFIC for our current year and for the foreseeable future. In addition, we may, directly or indirectly, hold equity interests in other PFICs. Under the Internal Revenue Code of 1986, as amended, we will be a PFIC for any taxable year in which (i) 75% or more of our gross income consists of passive income or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains.

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

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

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 August 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 the 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.

Risks Related to the Change in Our Jurisdiction of Incorporation

Currently, your rights as a shareholder of Auris Medical Holding AG arise under Swiss law as well as our existing Swiss articles of association. Upon Redomestication, your rights as a shareholder of Auris Medical (Bermuda) will arise under Bermuda law, the Memorandum of Continuance and the Bye-laws to be adopted in accordance with Bermuda law.

The Memorandum of Continuance (the "Memorandum of Continuance") and the Bye-laws (the "Bye-laws") of Auris Medical (Bermuda) will be the constitutive documents of Auris Medical (Bermuda) upon Redomestication, assuming shareholder approval of the Redomestication, the Memorandum of Continuance and the Bye-laws. These new constitutive documents and Bermuda law will contain provisions that differ from those in our current constitutive documents and Swiss law and, therefore, your rights as a shareholder of Auris Medical (Bermuda) could differ materially from the rights you currently possess as a shareholder of Auris Medical Holding AG. For instance, upon effectiveness of the Redomestication, the Swiss OaEC (*VegüV*) will no longer apply to the Company. The OaEC contains numerous provisions that serve to increase the transparency and provide shareholders with a right to voice their opinions on compensation matters. Pursuant to the OaEC, Swiss companies are, among others, obliged to have a framework in place according to which (i) the shareholders each year elect the members of the board of directors separately, (ii) the shareholders each year elect the chairman of the board of directors, (iii) the shareholders each year elect the members of the compensation committee and the independent proxy and (iv) the shareholders each year separately approve the compensation of the members of the board of directors, the management and the advisory board. The OaEC further contains provisions according to which the board of directors for each year has to prepare a written compensation report which has to be approved by the shareholders, detailing the compensations paid to each member of the board of directors, the management and the advisory board. In addition, companies that are subject to the OaEC are generally not allowed to make severance payments, advance compensations and to pay commissions for restructuring within the group. Under Bermuda law, directors are subject to election each year at the annual general meeting of the company, but there is no requirement that the chairman of the board of directors be elected by the shareholders. There is also no requirement under Bermuda law for shareholders to elect members of a company's compensation committee, or for shareholders to approve the compensation of the members of the board of directors or the company's management; the foregoing matters are typically determined by the company's board of directors. In addition, under Bermuda law there is no requirement to submit a written compensation report for approval to shareholders, and there are no general restrictions on severance payments, advance compensation or the payment of commissions for restructuring within the group. See "Risk Factors — Your rights as a shareholder of the Company will change as a result of the Redomestication. The Bye-laws grants certain powers to the board of directors that differs from our current articles of association. Such changes may adversely affect your rights as a shareholder of the Company."

Upon effectiveness of the Redomestication, we will be a Bermuda company and it may be difficult for you to enforce judgments against us or our directors and executive officers.

Upon our continuance in Bermuda, we will be a Bermuda exempted company. As a result, the rights of holders of our common shares will be governed by Bermuda law and our Memorandum of Continuance and Bye-laws. The rights of shareholders under Bermuda law may differ from the rights of shareholders of companies incorporated in other jurisdictions. Many of our directors and the named experts referred to in this prospectus are not residents of the United States, and a substantial portion of our assets are located outside the United States. As a result, it may be difficult for investors to effect service of process on those persons in the United States or to enforce in the United States judgments obtained in U.S. courts against us or those persons based on the civil liability provisions of the U.S. securities laws. It is doubtful whether courts in Bermuda will enforce judgments obtained in other jurisdictions, including the United States, against us or our directors or officers under the securities laws of those jurisdictions or entertain actions in Bermuda against us or our directors or officers under the securities laws of other jurisdictions.

Your rights as a shareholder of the Company will change as a result of the Redomestication. The Bye-laws grants certain powers to the board of directors that differs from our current articles of association. Such changes may adversely affect your rights as a shareholder of the Company.

Because of the differences between Swiss law and Bermuda law, your rights as a shareholder will change if the Redomestication is completed. The Bye-laws grant certain powers to the board of directors

that differ from our current articles of association. Generally, under Swiss law, shareholders are allowed to vote in matters related to an issuance of preferred shares or to alter the company's share capital by dividing, consolidating or sub-dividing the company's shares (including a reverse share split effected by consolidating our common shares (together with a corresponding increase in the par value thereof) in a ratio determined by the board of directors, while under Bermuda law, the board of directors have the power and authority to perform such acts without the shareholders' approval. Also, the presence and voting quorum requirements for certain shareholder resolutions under Swiss and Bermuda law differ in some instances. For example, the Bye-laws provide that, where certain business combination restrictions do not apply and the merger or amalgamation is approved by the board of directors, a merger or an amalgamation generally requires the approval of a majority of the votes cast at a general meeting at which the presence quorum is two or more persons present in person and representing in person or by proxy issued and outstanding voting shares. Whereas, under Swiss law, with certain exceptions, the approval of two thirds of the shares represented at the respective general meeting is required for a merger or an amalgamation. Additionally, under both Bermuda and Swiss law, shareholders may put proposals to the general meeting, but the exact framework and required shareholder and quorum requirements vary. Another matter that Bermuda and Swiss law differs is related to dividend payments. Under Swiss law, 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. Whereas, under Bermuda law, the board of directors may declare a dividend without shareholder approval, but a company may not declare or pay dividends if there are reasonable grounds for believing that: (i) the company is, or would after the payment be, unable to pay its liabilities as they become due; or (ii) that the realizable value of its assets would thereby be less than its liabilities. Also, the Bye-laws include anti-takeover provisions that our current articles of association do not contemplate. Such provisions give power and authority for the board of directors to require an increased majority for shareholder approval on a change of control. See "We have anti-takeover provisions in our proposed Bye-laws that may discourage a change of control." Such changes may adversely affect your rights as a shareholder of the Company.

Bermuda law differs from the laws in effect in the United States and may afford less protection to holders of our common shares.

Upon our continuance in Bermuda, we will be subject to the laws of Bermuda. As a result, our corporate affairs will be governed by the Companies Act, which differs in some material respects from laws typically applicable to U.S. corporations and shareholders, including the provisions relating to interested directors, amalgamations, mergers and acquisitions, takeovers, shareholder lawsuits and indemnification of directors. Generally, the duties of directors and officers of a Bermuda company are owed to the company only. Shareholders of Bermuda companies typically do not have rights to take action against directors or officers of the company and may only do so in limited circumstances. Class actions are not available under Bermuda law. The circumstances in which derivative actions may be available under Bermuda law are substantially more proscribed and less clear than they would be to shareholders of U.S. corporations. The Bermuda courts, however, would ordinarily be expected to permit a shareholder to commence an action in the name of a company to remedy a wrong to the company where the act complained of is alleged to be beyond the corporate power of the company or illegal, or would result in the violation of the company's memorandum of association or bye-laws. Furthermore, consideration would be given by a Bermuda court to acts that are alleged to constitute a fraud against the minority shareholders or, for instance, where an act requires the approval of a greater percentage of the company's shareholders than that which actually approved it.

When the affairs of a company are being conducted in a manner that is oppressive or prejudicial to the interests of some shareholders, one or more shareholders may apply to the Supreme Court of Bermuda, which may make such order as it sees fit, including an order regulating the conduct of the company's affairs in the future or ordering the purchase of the shares of any shareholders by other shareholders or by the company. Additionally, under our proposed Bye-laws and as permitted by Bermuda law, each shareholder has waived any claim or right of action against our directors or officers for any action taken by directors or officers in the performance of their duties, except for actions involving fraud or dishonesty. In addition, the rights of holders of our common shares and the fiduciary responsibilities of our directors under Bermuda

law are not as clearly established as under statutes or judicial precedent in existence in jurisdictions in the United States, particularly the State of Delaware. Therefore, holders of our common shares may have more difficulty protecting their interests than would shareholders of a corporation incorporated in a jurisdiction within the United States.

Our proposed Bye-laws restrict shareholders from bringing legal action against our officers and directors.

Our proposed Bye-laws contain a broad waiver by our shareholders of any claim or right of action, both individually and on our behalf, against any of our officers or directors. The waiver applies to any action taken by an officer or director, or the failure of an officer or director to take any action, in the performance of his or her duties, except with respect to any matter involving any fraud or dishonesty on the part of the officer or director. This waiver limits the right of shareholders to assert claims against our officers and directors unless the act or failure to act involves fraud or dishonesty.

We have anti-takeover provisions in our proposed Bye-laws that may discourage a change of control.

Our proposed Bye-laws contain provisions that could make it more difficult for a third party to acquire us without the consent of our board of directors. These provisions provide for:

- directors only to be removed for cause;
- restrictions on the time period in which directors may be nominated;
- our board of directors to determine the powers, preferences and rights of our preference shares and to issue the preference shares without shareholder approval; and
- an affirmative vote of 66⅔% of our voting shares for certain "business combination" transactions which have not been approved by our board of directors.

These provisions could make it more difficult for a third party to acquire us, even if the third party's offer may be considered beneficial by many shareholders. As a result, shareholders may be limited in their ability to obtain a premium for their shares.

If the Redomestication is effected, legislation enacted in Bermuda in response to the European Union's review of harmful tax competition could adversely affect our operations.

During 2017, the European Union ("EU") Economic and Financial Affairs Council ("ECOFIN") released a list of non-cooperative jurisdictions for tax purposes. The stated aim of this list, and accompanying report, was to promote good governance worldwide in order to maximize efforts to prevent tax fraud and tax evasion. Bermuda was not on the list of non-cooperative jurisdictions, but did feature in the report (along with approximately 40 other jurisdictions) as having committed to address concerns relating to economic substance by December 31, 2018. In accordance with that commitment, Bermuda has enacted legislation that requires certain entities in Bermuda engaged in "relevant activities" to maintain a substantial economic presence in Bermuda and to satisfy economic substance requirements. The list of "relevant activities" includes carrying on as a business any one or more of: banking, insurance, fund management, financing, leasing, headquarters, shipping, distribution and service center, intellectual property and holding entities. At present, it is unclear what (if anything) Auris Medical (Bermuda) would be required to do in order to satisfy economic substance requirements in Bermuda, but to the extent we are required to increase our substance in Bermuda to satisfy such requirements, it could result in additional costs that could adversely affect our financial condition or results of operations. If we were required to satisfy economic substance requirements in Bermuda but failed to do so, we could face automatic disclosure to competent authorities in the EU of the information filed by the entity with the Bermuda Registrar of Companies in connection with the economic substance requirements and may also face financial penalties, restriction or regulation of its business activities and/or may be struck off as a registered entity in Bermuda.

Risks Related to this Offering

We will have broad discretion in how we use the proceeds, and we may use the proceeds in ways in which you and other shareholders may disagree.

We intend to use the net proceeds we receive from the issuance of common shares to LPC pursuant to the Purchase Agreement for working capital and general corporate purposes. Our management will have broad discretion in the application of the proceeds from this offering and could spend the proceeds in ways that do not necessarily improve our operating results or enhance the value of our common shares.

You will experience immediate and substantial dilution in the net tangible book value per share of the common shares you purchase in this offering.

The assumed offering price of our common shares will be substantially higher than the as adjusted net tangible book value per common share. Therefore, investors purchasing our common shares in this offering 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 or warrants are exercised, such investors will incur further dilution. For example, LPC will incur immediate and substantial dilution of $0.33 per common share, after giving effect to the assumed issuance of an aggregate of 10,000,000 of our common shares at an assumed offering price of $0.36 per common share, the closing price of our common shares as listed on Nasdaq on February 12, 2019, and after deducting estimated offering expenses payable by us. See “Dilution”.

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.

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, including statements concerning our industry, our operations, our anticipated financial performance and financial condition, and our business plans and growth strategy and product development efforts. These statements constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Exchange Act. The words "may," "might," "will," "should," "estimate," "project," "plan," "anticipate," "expect," "intend," "outlook," "believe" and other similar expressions are intended to identify forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of their dates. These forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain and subject to a number of risks and uncertainties.

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:

- our operation as a development-stage company with limited operating history and a history of operating losses;
- our need for substantial additional funding to continue the development of our product candidates before we can expect to become profitable from sales of our products and the possibility that we may be unable to raise additional capital when needed;
- the outcome of our review of strategic options and of any action that we may pursue as a result of such review;
- our dependence on the success of AM-125, AM-201, Keyzilen® (AM-101) and Sonsuvi® (AM-111), which are still in clinical development, 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;
- the chance our clinical trials may not be completed on schedule, or at all, as a result of factors such as delayed enrollment or the identification of adverse effects;
- 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 product candidates 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 Sonsuvi®, 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 success or failure of strategic relationships, joint ventures or mergers and acquisitions transactions;
- 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;

- our ability to obtain, maintain and protect our intellectual property rights and operate our business without infringing or otherwise violating the intellectual property rights of others;
- our ability to comply with the requirements under our term loan facility with Hercules Capital, Inc., including repayment of amounts outstanding when due;
- our ability to meet the continuing listing requirements of Nasdaq and remain listed on The Nasdaq Capital Market;
- the chance that certain intangible assets related to our product candidates will be impaired; and
- other risk factors discussed under “Risk Factors.”

Our actual results or performance could differ materially from those expressed in, or implied by, any forward-looking statements relating to those matters. Accordingly, no assurances can be given that any of the events anticipated by the forward-looking statements will transpire or occur, or if any of them do so, what impact they will have on our results of operations, cash flows or financial condition. Except as required by law, we are under no obligation, and expressly disclaim any obligation, to update, alter or otherwise revise any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future events or otherwise.

MARKET FOR OUR COMMON SHARES

Our common shares are quoted on the Nasdaq Capital Market under the symbol “EARS.” The following table sets forth on a per share basis the low and high closing sale prices of our common shares as reported by the Nasdaq Capital Market for the periods presented.

	High	Low
Year Ended:		
December 31, 2015	6.38	3.02
December 31, 2016	7.79	0.89
December 31, 2017	1.27	0.39
Year Ended December 31, 2017:		
First Quarter	1.27	0.67
Second Quarter	0.92	0.61
Third Quarter	0.93	0.64
Fourth Quarter	0.95	0.39
Year Ended December 31, 2018:		
January 31, 2018	0.62	0.37
February 28, 2018	0.38	0.24
March 31, 2018 (through March 13, 2018*)	0.32	0.25
March 31, 2018 (from March 14, 2018 to March 31, 2018)	1.75	1.51
Second Quarter	1.98	0.77
Third Quarter	0.71	0.24
Fourth Quarter	1.48	0.31
Month Ended:		
January 31, 2019	0.49	0.40
February 28, 2019 (through February 12, 2019)	0.45	0.36

* On March 13, 2018, we effected the equivalent of a 10:1 “reverse share split” through the Merger.

As of February 8, 2019, we had 37,495,859 common shares issued and outstanding held by 7 registered holders, one of which is Cede & Co., a nominee for The Depository Trust Company (“DTC”). All of the common shares held by brokerage firms, banks and other financial institutions as nominees for beneficial owners are deposited into participant accounts at DTC and therefore are considered to be held of record by Cede & Co. as one shareholder.

USE OF PROCEEDS

We will not receive any proceeds from the sales of our common shares by LPC. We may receive gross proceeds of up to $8,989,225 under the Purchase Agreement over the remaining portion of the 30-month period following the Commencement, assuming that we issue all of the common shares available thereunder and excluding estimated offering fees and expenses. However, there can be no assurance we will issue any or all of the common shares to LPC or that they will resell such common shares offered hereby. Because there is no minimum offering amount required, we may issue less than all of the common shares offered hereby, which may significantly reduce the amount of proceeds received by us.

We estimate that the net proceeds to us from the issuance of our common shares to LPC pursuant to the Purchase Agreement will be up to approximately $8,989,225 over the remaining portion of the 30-month period following the Commencement, assuming that we issue the full amount of our common shares that we have the right, but not the obligation, to issue to LPC under that agreement and including estimated offering fees and expenses.

We intend to use the net proceeds from the issuance of the securities for working capital and general corporate purposes. Such purposes may include research and development expenditures and capital expenditures. Pending the use of the net proceeds, we intend to invest the net proceeds in interest-bearing, investment-grade securities. Accordingly, our management will have significant flexibility in applying any net proceeds that we receive pursuant to the Purchase Agreement.

SELLING SHAREHOLDER

We are filing the registration statement of which this prospectus forms a part pursuant to the provisions of the Registration Rights Agreement, which we entered into with LPC on May 2, 2018 concurrently with our execution of the Purchase Agreement, pursuant to which we agreed to provide certain registration rights with respect to sales by LPC of our common shares that may be issued to LPC under the Purchase Agreement. The selling shareholder may, from time to time, offer and sell pursuant to this prospectus any or all of the common shares that it holds or that may be acquired by it from the Company. The selling shareholder may sell some, all or none of its common shares. We do not know how long the selling shareholder will hold the common shares before selling them, and we currently have no agreements, arrangements or understandings with the selling shareholder regarding its resale of any of the common shares.

The following table presents information regarding the selling shareholder and the common shares that it may offer and sell from time to time under this prospectus. The table is prepared based on information supplied to us by the selling shareholder and reflects its beneficial ownership of our common shares as of February 8, 2019. Neither the selling shareholder nor any of its affiliates have held a position or office, or had any other material relationship, with us or any of our predecessors or affiliates. Beneficial ownership is determined in accordance with Rule 13d-3(d) promulgated by the SEC under the Exchange Act. The percentage of common shares beneficially owned prior to the offering is based on 37,495,859 common shares outstanding as of February 8, 2019.

Selling Shareholder	Shares Beneficially Owned Before this Offering[1]	Percentage of Outstanding Shares Beneficially Owned Before this Offering[1]	Shares to be Sold in this Offering	Number of Common Shares Beneficially Owned After this Offering[2]	Percentage of Outstanding Common Shares Beneficially Owned After this Offering[2]
Lincoln Park Capital Fund, LLC[3]	570,000	1.5%	10,000,000	570,000	1.2%

(1) Represents 570,000 of our common shares beneficially owned by LPC as of February 8, 2019. We have excluded from the number of common shares beneficially owned prior to the offering all of the common shares that LPC may be required to purchase under the Purchase Agreement, because the issuance and sale of such common shares to LPC is solely at our discretion and is subject to satisfaction of the conditions set forth in the Purchase Agreement that are outside of LPC's control, including the registration statement of which this prospectus is a part being declared effective by the SEC.

(2) Assumes the issuance and sale of all of the common shares offered by the selling shareholder pursuant to this prospectus.

(3) The selling shareholder is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act. Josh Scheinfeld and Jonathan Cope, the Managing Members of Lincoln Park Capital, LLC, the manager of the selling shareholder, are deemed to be beneficial owners of all of the common shares owned by the selling shareholder. Messrs. Cope and Scheinfeld have shared voting and investment power over the common shares being offered under this prospectus. Neither Lincoln Park Capital, LLC, nor the selling shareholder, is a licensed broker-dealer or an affiliate of a licensed broker-dealer.

THE LPC TRANSACTION

General

On May 2, 2018, we entered into the Purchase Agreement and the Registration Rights Agreement with LPC. Pursuant to the terms of the Purchase Agreement, LPC has agreed to subscribe for up to $10,000,000 of newly issued Company common shares (subject to certain limitations) from time to time over a 30-month period. Pursuant to the terms of the Registration Rights Agreement, we have filed with the SEC the registration statement that includes this prospectus to register for resale under the Securities Act the common shares that have been or may be issued to LPC under the Purchase Agreement.

Concurrently with the execution of the Purchase Agreement on May 2, 2018, we agreed to pay to LPC $250,000 in cash as a fee for its commitment to subscribe common shares under the Purchase Agreement. We have the right, from time to time at our sole discretion over the 30-month period from and after the Commencement, to require LPC to subscribe for up to 250,000 common shares in a Regular Purchase, which amount may be increased to up to 400,000 common shares, provided that certain thresholds on the closing price of our common shares and the number of our outstanding common shares set forth in the Purchase Agreement are satisfied; provided that LPC's maximum commitment obligation under any single Regular Purchase will not exceed $1,000,000. Additionally, we may direct LPC to subscribe for common shares in Additional Purchases under certain circumstances set forth in the Purchase Agreement.

As of the date of this prospectus, we have sold 1,750,000 of our common shares for an aggregate offering price of approximately $1.0 million pursuant to the Purchase Agreement, which represents the full number of shares registered under the Registration Statement on Form F-1 previously filed by us with the SEC under the terms of the Purchase Agreement and the Registration Rights Agreement and declared effective by the SEC.

Purchases of Common Shares Under the Purchase Agreement

The Purchase Agreement provides that, from time to time at our sole discretion over the 30-month period from and after the Commencement, so long as at least one business day has passed since the most recent prior Regular Purchase was completed in accordance with the Purchase Agreement, we may require LPC to subscribe for up to 250,000 of our common shares in a Regular Purchase. We may increase the amount of common shares we may issue to LPC pursuant to a Regular Purchase to up to (i) 300,000 of our common shares, provided that the total number of outstanding common shares on the purchase date exceeds 10,000,000, (ii) 350,000 of our common shares, provided that the closing sale price of our common shares is not below $1.00 on the purchase date and the total number of outstanding common shares on the purchase date exceeds 12,500,000 and (iii) 400,000 of our common shares, provided that the closing sale price of our common shares is not below $1.00 on the purchase date and the total number of outstanding common shares on the purchase date exceeds 15,000,000. The Regular Purchase Share Limit is subject to proportionate adjustment in the event of a reorganization, recapitalization, non-cash dividend, stock split or other similar transaction; provided, that if after giving effect to such full proportionate adjustment, the adjusted Regular Purchase Share Limit would preclude us from requiring LPC to subscribe for common shares at an aggregate purchase price equal to or greater than $100,000 in any single Regular Purchase, then the Regular Purchase Share Limit for such Regular Purchase will not be fully adjusted, but rather the Regular Purchase Share Limit for such Regular Purchase shall be adjusted as specified in the Purchase Agreement, such that, after giving effect to such adjustment, the Regular Purchase Share Limit will be equal to (or as close as can be derived from such adjustment without exceeding) $100,000. We may not require LPC to purchase in any single Regular Purchase common shares having an aggregate purchase price greater than $1,000,000. We may not issue any of our common shares as a Regular Purchase on a date in which the closing sale price of our common shares is below $0.25 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction). The purchase price for Regular Purchases shall be equal to the lesser of (i) the lowest sale price of our common shares on the applicable purchase date and (ii) the average of the three lowest closing sale prices of our common shares during the 10 business days immediately prior to the applicable purchase date, as reported on the Nasdaq Capital Market.

We also have the right, at our sole discretion, to require LPC to make Additional Purchases of our common shares, up to a maximum aggregate amount of $2,000,000, in individual purchases of not less than $100,000 and up to $500,000 each, at a purchase price equal to the lesser of (i) $5.00 per common share and (ii) 96% of the purchase price that would apply to a Regular Purchase made at such time, provided that (a) the closing price of the common shares is not below $1.00 on the applicable purchase date for the Additional Purchase, (b) the total number of outstanding common shares exceeds 12,500,000 and (c) at least 15 business days have passed since any prior Additional Purchase was completed.

There is no upper limit on the price per share that LPC could be obligated to pay for the common shares under any Regular Purchase under the Purchase Agreement. In the case of Regular Purchases and Additional Purchases, the purchase price per common share will be equitably adjusted for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction occurring during the business days used to compute the applicable purchase price.

In all instances, we may not issue common shares to LPC under the Purchase Agreement if it would result in LPC beneficially owning more than 4.99% of our outstanding common shares.

Other than as set forth above, there are no trading volume requirements or restrictions under the Purchase Agreement, and we will control the timing and amount of any issuances of our common shares to LPC.

Events of Default

Events of default under the Purchase Agreement include the following:

- the effectiveness of the registration statement of which this prospectus is a part, or any future registration statement relating to the resale of shares issuable pursuant to the Purchase Agreement, lapses for any reason (including, without limitation, the issuance of a stop order), or any required prospectus supplement and accompanying prospectus are unavailable for the resale by LPC of our common shares offered hereby, and such lapse or unavailability continues for a period of 10 consecutive business days or for more than an aggregate of 30 business days in any 365-day period;
- suspension by our principal market of our common shares from trading for a period of one full business day;
- the de-listing of our common shares from the NASDAQ Capital Market, provided our common shares are not immediately thereafter trading on The NASDAQ Global Market, The NASDAQ Global Select Market, the NYSE American, the NYSE Arca, the OTC Bulletin Board or OTC Markets (or nationally recognized successor to any of the foregoing);
- our transfer agent's failure for three business days to issue to LPC the common shares which LPC is entitled to receive under the Purchase Agreement;
- our breach of any representation, warranty, covenant or other term or condition contained in the Purchase Agreement or any related agreement which would reasonably be expected to have a material adverse effect on us, subject to a cure period of five business days;
- any voluntary or involuntary participation or threatened participation in insolvency or bankruptcy proceedings by or against us; or
- if at any time we are not eligible to transfer our common shares electronically.

LPC does not have the right to terminate the Purchase Agreement upon any of the events of default set forth above. During an event of default, all of which are outside of LPC's control, we cannot initiate any Regular Purchases or Additional Purchases under the Purchase Agreement.

Termination Rights

We have the right to terminate the Purchase Agreement, without any cost to us, at any time for any reason upon one business day's prior written notice to LPC. In the event of bankruptcy proceedings by or against us, the Purchase Agreement will automatically terminate without action of any party.

LPC may not assign or transfer its rights and obligations under the Purchase Agreement.

No Short-Selling or Hedging by LPC

LPC has represented to us that at no time prior to the Purchase Agreement has LPC or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common shares or any hedging transaction, which establishes a net short position with respect to our common shares. LPC agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

Prohibition of Certain Continuous Offerings

We agreed with Lincoln Park that we will not, for a period commencing on the date of the Purchase Agreement and ending on the later of: (i) the 30-month anniversary of the date of the Purchase Agreement and (ii) the 30-month anniversary of the date of Commencement, in either case irrespective of any earlier termination of the Purchase Agreement, enter into any agreement relating to or otherwise effect any issuance of our securities in certain types of continuous offerings in which we may issue securities at a future determined price.

Effect of Performance of the Purchase Agreement on Our Shareholders

All 10,000,000 shares registered in this offering are expected to be freely tradable. The sale by LPC of a significant amount of shares registered in this offering at any given time could cause the market price of our common shares to decline and to be highly volatile. LPC may ultimately purchase all, some or none of the 10,000,000 shares of common shares registered in this offering. If we issue these shares to LPC, LPC may issue all, some or none of such shares. Therefore, issuances to LPC by us under the Purchase Agreement may result in substantial dilution to the interests of other holders of our common shares. In addition, if we issue a substantial number of shares to LPC under the Purchase Agreement, or if investors expect that we will do so, the actual issuance of shares or the mere existence of our arrangement with LPC may make it more difficult for us to issue equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect such issuances. However, we have the right to control the timing and amount of any issuances of our shares to LPC and the Purchase Agreement may be terminated by us at any time at our discretion without any cost to us upon one business day's prior written notice to LPC.

Pursuant to the terms of the Purchase Agreement, we have the right, but not the obligation, to direct LPC to subscribe for up to $10,000,000 of our common shares, of which LPC has already purchased an aggregate of $1,010,775 of our common shares as of the date of this prospectus. Depending on the price per share at which we issue our common shares to LPC, we may be authorized to issue to LPC under the Purchase Agreement more shares of our common shares than are offered under this prospectus. If we choose to do so, we must first register for resale under the Securities Act any such additional shares, which could cause additional substantial dilution to our shareholders. The number of shares ultimately offered for resale by LPC under this prospectus is dependent upon the number of shares we direct LPC to purchase under the Purchase Agreement.

The following table sets forth the amount of gross proceeds we would receive from LPC from the issuance of a number of shares to LPC equal to the number of shares registered hereunder pursuant to the Purchase Agreement at varying purchase prices:

Assumed Average Purchase Price Per Common Share	Number of Registered Common Shares to be Issued if Full Purchase[1]	Percentage of Outstanding Common Shares After Giving Effect to the Issuance to LPC[2]	Proceeds from the Issuance of Shares to LPC Under the Purchase Agreement
$0.02[3]	10,000,000	21.05%	$ 200,000
$0.36[4]	10,000,000	21.05%	$ 3,600.000
$0.90	10,000,000	21.05%	$ 8,989,225[5]

(1) Although the Purchase Agreement provides that we may issue up to a remaining $8,989,225 of our common shares to LPC, we are only registering 10,000,000 common shares under this prospectus, which may or may not cover all of the common shares we ultimately issue to LPC under the Purchase Agreement, depending on the purchase price per common share. As a result, we have included in this column only the common shares that we are registering in this offering.

(2) The denominator is based on 37,495,859 common shares outstanding as of February 8, 2019, plus the number of shares set forth in the adjacent column which we would have sold to LPC at the applicable assumed average purchase price per share. The number of shares in such column does not include shares that may be issued to LPC under the Purchase Agreement which are not registered in this offering. The table does not give effect to the prohibition contained in the Purchase Agreement that prevents us from issuing to LPC shares such that, after giving effect to such issuance, LPC would beneficially own more than 4.99% of our common shares.

(3) The U.S. Dollar equivalent of the nominal value of a single Common Share translated at a rate of CHF 1.0000 to USD 1.00, the official exchange rate quoted as of February 8, 2019 by the U.S. Federal Reserve Bank.

(4) The closing sale price of our common shares on February 12, 2019.

(5) The maximum amount of gross proceeds remaining under the Purchase Agreement is $8,989,225.

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 association. 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 September 30, 2018:

- on an actual basis;
- on an as adjusted basis to give effect to the issuance of 10,000,000 common shares we are registering on behalf of the selling shareholder based upon an assumed offering price of $0.36 per common share, the closing price of our common shares as listed on Nasdaq on February 12, 2019 and after deducting approximately $78,651 in estimated offering expenses payable by us.

Investors should read this table in conjunction with our unaudited consolidated interim financial statements and related notes as of and for the three and nine months ended September 30, 2018 and management's discussion and analysis thereon, included elsewhere in this prospectus as well as "Use of Proceeds" in this prospectus.

U.S. dollar amounts have been translated into Swiss Francs at a rate of CHF 0.9758 to USD 1.00, the official exchange rate quoted as of September 28, 2018 by the U.S. Federal Reserve Bank (as no exchange rate is quoted for September 30, 2018). 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 on September 30, 2018 and have been provided solely for the convenience of the reader. On February 8, 2019, the exchange rate as reported by the U.S. Federal Reserve Bank was CHF 1.0000 to USD 1.00.

	September 30, 2018	
	Actual	As Adjusted
	(in thousands of CHF except share and per share data)	
Cash and cash equivalents[1]	5,258	8,704
Total debt[2]	2,144	2,144
Derivative Financial Instruments[3]	1,085	1,085
Shareholders' equity:		
Share capital[1]		
Common shares, nominal value CHF 0.02 per share; 24,066,105 common shares issued and outstanding on an actual basis, 34,066,105 common shares issued and outstanding on an as adjusted basis	481	681
Share premium	141,338	144,584
Foreign currency translation reserve	(46)	(46)
Accumulated deficit	(142,514)	(142,514)
Total shareholders' equity attributable to owners of the company	(741)	2,705
Total capitalization	2,488	5,934

(1) Since September 30, 2018, we have issued (i) an aggregate of 1,750,000 common shares for aggregate proceeds of $1,010,775 to LPC under the LPC Purchase Agreement, (ii) an aggregate of 5,768,940 common shares for aggregate proceeds of CHF 2,249,887 pursuant to exercises of warrants issued in the July 2018 Registered Offering, (iii) an aggregate of 3,315,000 common shares in the two registered direct offerings in November and December 2018 for aggregate proceeds of $1.6 million and (iv) an aggregate of 2,595,814 common shares for aggregate proceeds of $1,331,849 to A.G.P. pursuant to the A.G.P. Sales Agreement. These subsequent issuances and the proceeds therefrom are not reflected in the table as they occurred after September 30, 2018.

(2) Total debt is comprised of the $12.5 million drawn on July 19, 2016 under our secured term loan facility with Hercules as administrative agent. The loan was initially recognized at transaction value less the fair value of the warrant issued to Hercules in connection with the loan as of the transaction date and less directly attributable transactions costs. Following the initial recognition, the loan is

measured at amortized cost using the effective interest method. As of September 30, 2018, the loan has a carrying value of CHF 2,144,235 classified as current liability. The amortization payments, including the end of term charge, due within the 12 months after September 30, 2018, amount to CHF 2.5 million. As of January 28, 2018, the amount outstanding under our secured term loan facility with Hercules was $1.1 million. On January 31, 2019, we made the final payment to Hercules under the facility, comprising the last amortization rate as well as an end of term charge.

(3) The fair value calculation of the warrants is determined according to the Black-Scholes option pricing model. Assumptions are made regarding inputs such as volatility and the risk free rate in order to determine the fair value of the warrant. The fair value of the warrants is calculated based on assumptions made at September 30, 2018.

The above discussion and table are based on 24,066,105 common shares outstanding as of September 30, 2018 and excludes:

- 915,000 of our common shares available for issuance pursuant to our conditional share capital for equity incentive plans pursuant to our articles of association, including 438,050 of our common shares issuable upon the exercise of options outstanding as of September 30, 2018 at a weighted average exercise price of $1.62 per common share;

- 8,760,175 of our common shares available for issuance pursuant to our conditional share capital for warrants and convertible bonds pursuant to our articles of association, including 15,673 common shares issuable upon the exercise of a warrant issued to Hercules at an exercise price of $39.40 per common share, 794,500 common shares issuable upon exercise of warrants issued on February 21, 2017 in a public offering at an exercise price of US$12.00 per common share, 750,002 common shares issuable upon the exercise of the January 2018 Warrants at an exercise price of $5.00 per common share (each as adjusted, as a result of the “reverse share split” effected through the Merger) and 6,282,051 common shares issuable upon the exercise of the warrants issued in the July 2018 Registered Offering; at an exercise price of CHF 0.39 per common share; and

- 9,675,175 common shares available for issuance pursuant to our authorized capital pursuant to our articles of association, including 4,487,178 common shares issuable upon the exercise of warrants issued the July 2018 Registered Offering at an exercise price of CHF 0.39 per common share.

DILUTION

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

As of September 30, 2018, we had a net tangible book value of -$2.5 million, corresponding to a net tangible book value of -$0.10 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 24,066,105, the total number of our common shares outstanding as of September 30, 2018.

After giving effect to the issuance by us of 10,000,000 common shares to LPC at the assumed offering price of $0.36 per common share, the closing price of our common shares as listed on Nasdaq on February 12, 2019, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our as adjusted net tangible book value estimated as of September 30, 2018 would have been $1.1 million, representing $0.03 per common share. This represents an immediate increase in net tangible book value of $0.13 per common share to existing shareholders and an immediate dilution in net tangible book value of $0.33 per common share to LPC. Dilution for this purpose represents the difference between the price per common share paid by LPC and net tangible book value per common share immediately after the completion of the offering.

The following table illustrates this dilution to LPC.

Assumed offering price per common share	$ 0.36
Net tangible book value per common share as of September 30, 2018	$-0.10
Increase in net tangible book value per common share attributable to LPC	$ 0.13
As adjusted net tangible book value per common share after the offering	$ 0.03
Dilution per common share to LPC	$ 0.33
Percentage of dilution in net tangible book value per common share for LPC	92%

The above discussion and table are based on 24,066,105 common shares outstanding as of September 30, 2018 and excludes:

- 915,000 of our common shares available for issuance pursuant to our conditional share capital for equity incentive plans pursuant to our articles of association, including 438,050 of our common shares issuable upon the exercise of options outstanding as of September 30, 2018 at a weighted average exercise price of $1.62 per common share;
- 8,760,175 of our common shares available for issuance pursuant to our conditional share capital for warrants and convertible bonds pursuant to our articles of association, including 15,673 common shares issuable upon the exercise of a warrant issued to Hercules at an exercise price of $39.40 per common share, 794,500 common shares issuable upon exercise of warrants issued on February 21, 2017 in a public offering at an exercise price of US$12.00 per common share, 750,002 common shares issuable upon the exercise of the January 2018 Warrants at an exercise price of $5.00 per common share (each as adjusted, as a result of the “reverse share split” effected through the Merger) and 6,282,051 common shares issuable upon the exercise of the warrants issued in the July 2018 Registered Offering; at an exercise price of CHF 0.39 per common share; and
- 9,675,175 common shares available for issuance pursuant to our authorized capital pursuant to our articles of association, including 4,487,178 common shares issuable upon the exercise of warrants issued the July 2018 Registered Offering at an exercise price of CHF 0.39 per common share.

To the extent that outstanding options or warrants are exercised, you may 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.

Swiss Franc amounts have been translated into U.S. dollars at a rate of CHF 0.9758 to USD 1.00, the official exchange rate quoted as of September 28, 2018 by the U.S. Federal Reserve Bank (as no exchange rate is quoted for September 30, 2018). Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of Swiss Francs on September 30, 2018 and have been provided solely for the convenience of the reader.

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 February 8, 2019, the exchange rate as reported by the U.S. Federal Reserve Bank was CHF 1.0000 to $1.00.

	Period-End	Average for Period	Low	High
		(CHF per U.S. dollar)		
Year Ended December 31:				
2013	0.8904	0.9269	0.8856	0.9814
2014	0.9934	0.9147	0.8712	0.9934
2015	1.0017	0.9628	0.8488	1.0305
2016	1.0160	0.9848	0.9536	1.0334
2017	0.9738	0.9842	0.9456	1.0266
2018	0.9832	0.9784	0.9232	1.0083
Month Ended:				
January 31, 2019	0.9938	0.9897	0.9767	0.9988
February 28, 2019 (through February 18, 2019)	1.0000	0.9990	0.9940	1.0010

SELECTED CONSOLIDATED FINANCIAL AND OTHER INFORMATION

The following selected consolidated historical financial information should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations," our unaudited condensed consolidated interim financial statements as of September 30, 2018 and as of and for the three and nine months ended September 30, 2018 and 2017, and our consolidated financial statements dated as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017, including the notes thereto, included in this prospectus.

The numbers below have been derived from our unaudited condensed consolidated interim financial statements as of September 30, 2018 and as of and for the three and nine months ended September 30, 2018 and 2017, which have been prepared in accordance with International Accounting Standard (IAS) 34, and our consolidated financial statement as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017, which have been prepared in accordance with IFRS as issued by the IASB. The consolidated financial data as of December 31, 2015 and for the years ended December 31, 2014 and 2013 has been derived from our audited consolidated financial statements which have been prepared in accordance with IFRS as issued by the IASB and which have not been included herein.

We maintain our books and records in Swiss Francs. We have made rounding adjustments to some of the figures included in the table below. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them. Unless otherwise indicated, all references to currency amounts in this discussion and analysis are in Swiss Francs.

	For the years ended December 31,					Nine months ended September 30,	
	2017	2016	2015	2014	2013	2018	2017
	(in thousands of CHF except for share and per share data)						
Profit or Loss and Other Comprehensive Loss:							
Research and development	(19,211)	(24,777)	(26,536)	(17,705)	(13,254)	(6,655)	(14,926)
General and administrative	(5,150)	(5,447)	(4,342)	(4,489)	(1,362)	(3,630)	(3,997)
Operating loss	(24,361)	(30,224)	(30,878)	(22,194)	(14,616)	(10,285)	(18,923)
Interest income	54	68	37	52	74	—	54
Interest expense	(1,640)	(829)	(8)	(56)	(53)	(979)	(1,248)
Foreign currency exchange gain/ (loss), net	(825)	(100)	1,144	4,012	(104)	(180)	(929)
Revaluation gain from derivative financial instruments	3,372	291	—	—	—	4,132	1,705
Transaction costs	(1,027)	—	—	—	—	(520)	(506)
Loss before tax	(24,427)	(30,794)	(29,705)	(18,186)	(14,699)	(7,832)	(19,847)
Income tax gain	18	131	—	—	—	26	25
Income tax expense	—	—	—	(306)	—	—	—
Net loss attributable to owners of the Company	(24,409)	(30,663)	(29,705)	(18,492)	(14,699)	(7,806)	(19,822)

	For the years ended December 31,					Nine months ended September 30,	
	2017	2016	2015	2014	2013	2018	2017
	(in thousands of CHF except for share and per share data)						
Other comprehensive loss:							
Items that will never be reclassified to profit or loss:							
Remeasurements of defined benefits liability	272	(394)	(54)	(1,101)	(58)	1,295	378
Items that are or may be reclassified to profit or loss:							
Foreign currency translation differences	50	(20)	(13)	(105)	32	(13)	55
Other comprehensive income/ (loss)	322	(414)	(67)	(1,206)	(26)	1,282	433
Total comprehensive loss attributable to owners of the Company	(24,087)	(31,077)	(29,772)	(19,698)	(14,725)	(6,524)	(19,389)
Net loss per share[1]							
Net loss per share, basic and diluted[2]	(0.56)	(0.89)	(0.92)	(0.66)	(1.01)	(0.71)	(4.65)
Weighted-average number of shares used to compute net loss per common share, basic and diluted	43,741,870	34,329,280	32,299,166	27,692,494	14,917,064	10,987,582	4,260,176*

(1) For periods prior to the closing of our initial public offering, net loss per share includes preferred shares, which were converted on a one-for-one basis upon the closing of our initial public offering.

(2) Basic net loss per common share and diluted net loss per common share are the same. See Note 21 to our audited consolidated financial statements on page F-43.

* The basic and diluted loss per share for the nine months ended September 2017 is revised to reflect the reverse-split ratio of 10 to 1 following the Merger on March 13, 2018.

	As of December 31,					As of September 30,
	2017	2016	2015	2014	2013	2018
	(in thousands of CHF)					
Statement of Financial Position Data:						
Cash and cash equivalents	14,973	32,442	50,237	56,934	23,866	5,258
Total assets	17,826	35,658	52,812	59,493	26,252	8,051
Total liabilities	19,888	21,515	8,070	6,210	17,219	8,792
Share capital	19,350	13,732	13,722	11,604	6,487	481,322
Total shareholders' (deficit)/equity attributable to owners of the Company	(2,162)	14,143	44,741	53,283	9,034	(741,017)

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," our unaudited condensed consolidated interim financial statements as of September 30, 2018 and as of and for the three and nine months ended September 30, 2018 and 2017, and our consolidated financial statements dated as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017, including the notes thereto, included in this prospectus. Our unaudited condensed consolidated interim financial statements have been prepared in accordance with IAS 34, and on our consolidated financial statements have been prepared in accordance with IFRS 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.

We maintain our books and records in Swiss Francs. We have made rounding adjustments to some of the figures included in this management's discussion and analysis. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them. Unless otherwise indicated, all references to currency amounts in this discussion and analysis are in Swiss Francs.

Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel products that address important unmet medical needs in neurotology and mental health supportive care. We are focusing on the development of intranasal betahistine for the treatment of vertigo (AM-125) and for the treatment of antipsychotic-induced weight gain and somnolence (AM-201). These programs have gone through two Phase 1 trials and will move into proof-of-concept studies in 2019. In addition, we have two Phase 3 programs under development: (i) Keyzilen® (AM-101), which is being developed for the treatment of acute inner ear tinnitus and (ii) Sonsuvi® (AM-111), which is being developed for the treatment of acute inner ear hearing loss. Sonsuvi® has been granted orphan drug status by the FDA and the EMA and has been granted fast track designation by the FDA.

To date, we have financed our operations through public offerings of our common shares, private placements of equity securities, and short- and long-term loans. We have no products approved for commercialization and have never generated any revenues from royalties or product sales. As of September 30, 2018, we had cash and cash equivalents of CHF 5.3 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, Keyzilen®, Sonsuvi® or any of our other product candidates.

As of September 30, 2018, we had an accumulated deficit of CHF 142.5 million. We expect to continue incurring losses as we continue our clinical and pre-clinical 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.

INSERM

In 2006, we entered into a co-ownership/exploitation agreement with the 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 Keyzilen®. 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 Keyzilen®, 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 percentage 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 Keyzilen® 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, 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.

Otifex

On February 2, 2017, we entered into an asset purchase agreement with Otifex Therapeutics Pty Ltd ("Otifex"), pursuant to which we agreed to purchase and Otifex has agreed to sell us certain preclinical and clinical assets related to a formulation for the intranasal application of betahistine, which we refer to as AM-125, as well as associated intellectual property rights. We plan to develop the formulation for the treatment of vertigo. The Otifex transaction closed in July 2017.

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 pre-clinical compounds and drug substances by contract manufacturers;
- fees and other costs paid to contract research organizations in connection with additional pre-clinical 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 2018 will be in the range of CHF 10.0 to 13.0 million, the majority of which we expect to be research and development expense. Our research and development expense mainly relates to the following key programs:

- Keyzilen® *(AM-101).* We conducted a Phase 3 clinical development program with Keyzilen® comprising two Phase 3 trials and two open label follow-on trials. We completed enrollment of the last of these trials (TACTT3) in September 2017. On March 13, 2018, we announced preliminary top-line data from the TACTT3 trial which indicated that the study had not met its primary efficacy endpoint of a statistically significant improvement in the Tinnitus Functional Score from baseline to Day 84 in the active treated group compared to placebo either in the overall population or in the otitis media subpopulation. On May 15, 2018, we announced that further investigation of the trial's outcomes confirmed these preliminary results and that we believe that the lack of separation between the active- and placebo-treated groups may be due to certain elements of the study design and conduct. We anticipate that one or more additional clinical trials will be necessary to move the Keyzilen® program forward, which we will seek to fund through partnering or research grants. Pending such funding, we expect our research and development expenses in connection with the Keyzilen® program to remain minimal.

- *Sonsuvi® (AM-111).* We conducted a Phase 3 clinical development program with Sonsuvi® comprising two Phase 3 trials in the treatment of ISSNHL, titled HEALOS and ASSENT. On November 28, 2017, we announced that the HEALOS trial did not meet the primary efficacy endpoint of a statistically significant improvement in hearing from baseline to Day 28 compared to placebo for either active treatment groups in the overall study population. However, a post-hoc analysis of the subpopulation with profound acute hearing loss revealed a clinically meaningful and nominally significant improvement in the Sonsuvi® 0.4 mg/mL treatment group. We terminated the ASSENT trial as it was very similar in design to the HEALOS trial and, based on the new findings, was no longer adequate for testing Sonsuvi®. Based on the HEALOS results, we submitted the design of a new pivotal trial with AM-111 0.4 mg/mL in patients suffering from acute profound hearing loss to the EMA and subsequently also to the FDA for review. Through a Protocol Assistance procedure the EMA endorsed the proposed trial design, choice of efficacy and safety endpoints, as well as the statistical methodology. In a Type C meeting with written responses, the proposed choice of primary and secondary efficacy endpoints, the safety endpoints, as well as the planned sample size and statistical methodology were also endorsed by the FDA. Following this feedback, we have mandated a transaction advisory firm to identify potential partners for the SONSUVI® development program and provide support for partnering discussions and negotiations. If successful, this may result in one or several sale, outlicensing or co-development transaction(s) on a global or regional scale. For 2019, we expect our research and development expenses in connection with the Sonsuvi® program to be lower than in 2019, reflecting the completion of the Phase 3 trials.

- *AM-125*. In the first half of 2018, we initiated a second randomized placebo-controlled Phase 1 trial in 72 healthy volunteers to further test the safety and tolerability and the pharmacokinetics of AM-125. On October 17, 2018 we announced positive results from the trial as superior bioavailability over a range of four intranasal betahistine doses compared to oral betahistine observed, with plasma exposure being 6 to 29 times higher (p-value between 0.056 and $p < 0.0001$). Further, it confirmed the good safety profile of intranasal betahistine and showed that the treatment was well tolerated when administered three times daily for three days. In 2019 we plan to initiate a Phase 2 clinical study with AM-125 in the first quarter, which will result in higher research and development expense for the AM-125 program than in 2018. The "TRAVERS" Phase 2 trial will enroll 138 patients suffering from acute vertigo following surgical removal of a vestibular schwannoma, a tumor growing behind the inner ear. It will be conducted in several European countries and potentially, Canada.

- AM-201. On May 15, 2018, we announced the expansion of our intranasal betahistine development program beyond the treatment of vertigo into mental health supportive care indications. Under project code AM-201 we intend to develop intranasal betahistine for the prevention of antipsychotic-induced weight gain. We plan to initiate a randomized

placebo-controlled Phase 1b proof-of-concept trial with AM-201 in healthy volunteers in the first quarter of 2019. The trial will be conducted in Europe and will enroll 50 healthy volunteers who will receive either AM-201 or placebo concomitantly with olanzapine over four weeks.

Other research and development expenses mainly relate to our pre-clinical studies of AM-102 (second generation tinnitus treatment). The expenses mainly consist of costs for production of the pre-clinical compounds and costs paid to academic and other research institutions in conjunction with pre-clinical testing.

For the nine months ended September 30, 2018, we spent CHF 1.1 million on research and development for Keyzilen®, CHF 1.9 million on research and development for Sonsuvi® and CHF 3.5 million on research and development for intranasal Betahistine. For the years ended December 31, 2017, 2016 and 2015, we spent CHF 6.5 million, CHF 15.3 million and CHF 19.7 million, respectively, on research and development expenses related to Keyzilen®. For the same time periods, we spent CHF 11.4 million, CHF 9.4 million and CHF 6.4 million, respectively, on research and development expenses related to Sonsuvi®. In addition, we incurred research and development expenses related to our earlier stage products. Following a market reduction in research and development expenses related to the conclusion of the Phase 3 trials with Keyzilen® and Sonsuvi®, their level is expected to start increasing again from 2020 onward as we advance the clinical development with AM-125 and AM-201. 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 and payer discussions;
- 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-125, AM-201, Keyzilen® and Sonsuvi® 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 expenses 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.

Interest 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.

Interest expense

Our interest expense consists principally of bank charges and interest expenses due to the Loan and Security Agreement with Hercules.

Revaluation gain from derivative financial instruments

In connection with the Hercules Loan and Security Agreement, the Company issued Hercules a warrant to purchase up to 241,117 of its common shares at an exercise price of $3.94 per share. Revaluation gain/(loss) show the changes in fair value of the warrant issued to Hercules. As of March 13, 2018, following the consummation of the Merger, the Hercules warrant was exercisable for up to 15,673 common shares at an exercise price of $39.40 per common share.

On February 21, 2017, we issued 10,000,000 warrants, each warrant entitling its holder to purchase 0.70 of a common share at an exercise price of $1.20. Additionally, the underwriter was granted a 30-day option to purchase up to 1,500,000 additional common shares and/or 1,500,000 additional warrants. On February 15, 2017, the underwriter partially exercised its option for 1,350,000 warrants. Revaluation gain/(loss) show the changes in fair value of the warrant issued in connection with this offering. As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issued in the February 2017 offering were exercisable for up to 794,500 common shares at an exercise price of $12.00 per common share. As of September 30, 2018, the fair value of the warrants amounted to CHF 50,070. The revaluation gain of the derivative for the nine months ended September 30, 2018 amounted to CHF 1,763,343, which is an increase of CHF 63,221 when comparing to the same period in 2017. Since its initial recognition, the fair value decreased by CHF 5,040,393, resulting in a gain in the corresponding amount (fair value as of February 21, 2017: CHF 5,090,463).

Foreign currency exchange gain/(loss), net

Our foreign currency exchange gain/(loss), net, consists primarily of unrealized gains or losses on our USD and EUR denominated cash and cash equivalents.

Transaction costs

For the year ended December 31, 2017, transaction costs relates to the fees and transaction costs allocated to the warrants (derivative financial instrument) related to the public offering completed on February 21, 2017, and fees and transaction costs allocated to the Commitment Purchase Agreement entered in on October 10, 2017, representing LPC’s commitment to purchase shares at the option of the Company, subject to certain restrictions (derivative financial instrument).

For the nine months ended September 30, 2018, transaction costs relates to the fees and transaction costs allocated to the warrants (derivative financial instrument) related to the public offerings completed on January 2018 and July 2018, and the Purchase Agreement.

Other comprehensive loss

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 in other comprehensive loss.

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

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

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

Results of Operations

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

Comparison of the three months ended September 30, 2018 and 2017

	Three months ended September 30		
	2018	2017	Change
	(in thousands of CHF)		%
Research and development	(1,697)	(4,221)	(60)%
General and administrative	(1,170)	(1,336)	(12)%
Operating loss	**(2,867)**	**(5,557)**	**(48)%**
Interest income	—	8	n/a
Interest expense	(123)	(417)	(71)%
Foreign currency exchange (loss)/gain, net	(114)	2	(5,800)%
Revaluation gain/(loss) from derivative financial instruments	224	(56)	(500)%
Transaction costs	(109)	—	n/a
Loss before tax	**(2,989)**	**(6,020)**	**(50)%**
Income tax gain	9	8	13%
Net loss attributable to owners of the Company	**(2,980)**	**(6,012)**	**(50)%**
Other comprehensive income:			
Items that will never be reclassified to profit or loss			
Remeasurements of defined benefit liability	209	94	122%
Items that are or may be reclassified to profit and loss			
Foreign currency translation differences	6	(5)	(220)%
Other comprehensive income	**215**	**89**	**142%**
Total comprehensive loss attributable to owners of the Company	**(2,765)**	**(5,923)**	**(53)%**

Comparison of the nine months ended September 30, 2018 and 2017

	Nine months ended September 30		
	2018	2017	Change
	(in thousands of CHF)		%
Research and development	(6,655)	(14,926)	(55)%
General and administrative	(3,630)	(3,997)	(9)%
Operating loss	**(10,285)**	**(18,923)**	**(46)%**
Interest income	—	54	n/a
Interest expense	(979)	(1,248)	(22)%
Foreign currency exchange gain/(loss), net	(180)	(929)	(81)%
Revaluation gain from derivative financial instruments	4,132	1,705	142%
Transaction costs	(520)	(506)	3%
Loss before tax	**(7,832)**	**(19,847)**	**(61)%**
Income tax gain	26	25	4%
Net loss attributable to owners of the Company	**(7,806)**	**(19,822)**	**(61)%**
Other comprehensive income:			
Items that will never be reclassified to profit or loss			
Remeasurements of defined benefit liability	1,295	378	243%
Items that are or may be reclassified to profit or loss			
Foreign currency translation differences	(13)	55	(124)%
Other comprehensive income	**1,282**	**433**	**196%**
Total comprehensive loss attributable to the owners of the Company	**(6,524)**	**(19,389)**	**(66)%**

Research and development expense

	Three months ended September 30		
	2018	2017	Change
	(in thousands of CHF)		%
Clinical projects	(701)	(2,598)	(73)%
Pre-clinical projects	(370)	(124)	198%
Drug manufacturing and substance	45	(621)	(107)%
Employee benefits	(262)	(624)	(58)%
Other research and development expenses	(409)	(254)	61%
Total	**(1,697)**	**(4,221)**	**(60)%**

Research and development expenses amounted to CHF 1.7 million in the three months ended September 30, 2018. This represents a decrease of about CHF 2.5 million from research and development expenses of CHF 4.2 million for the three months ended September 30, 2017. Research and development expenses reflected the following:

- *Clinical projects.* In the three months ended September, 2018 clinical expenses were lower than in the three months ended September 30, 2017 by CHF 1.9 million due to lower service and milestone costs for our Keyzilen® and Sonsuvi® studies, mainly reflecting the completion of our late-stage clinical trials.

- *Pre-clinical projects*. In the three months ended September, 2018, pre-clinical expenses increased by CHF 0.2 million compared to the three months ended September, 2017, primarily due to higher expenses in our AM-125 program.

- *Drug manufacture and substance.* In the three months ended September 30, 2018, drug manufacture and substance related costs decreased by CHF 0.7 million compared to the three months ended September 30, 2017, due to lower Sonsuvi® project activities.

- *Employee benefits*. Employee expenses decreased by CHF 0.4 million in the three months ended September 30, 2018 compared to the same period in 2017 primarily due to a reduction in headcount.

- *Other research and development expenses*. Other research and development expenses increased by CHF 0.2 million in the three months ended September 30, 2018 compared to the same period in 2017 primarily due to intellectual property related activities.

	Nine months ended September 30		
	2018	2017	Change
	(in thousands of CHF)		%
Clinical projects	(2,689)	(9,741)	(72)%
Pre-clinical projects	(688)	(418)	65%
Drug manufacturing and substance	(1,058)	(1,675)	(37)%
Employee benefits	(1,300)	(2,118)	(39)%
Other research and development expenses	(920)	(974)	(6)%
Total	**(6,655)**	**(14,926)**	**(55)%**

Research and development expenses amounted to CHF 6.7 million in the nine months ended September 30, 2018. This represents a decrease of about CHF 8.2 million from research and development expenses of CHF 14.9 million for the nine months ended September 30, 2017. Research and development expenses reflected the following:

- *Clinical projects.* In the nine months ended September, 2018 clinical expenses were lower than in the nine months ended September 30, 2017 by CHF 7.1 million due to lower service and milestone costs for our Keyzilen® and Sonsuvi® studies, mainly reflecting the completion of our late-stage clinical trials.

- *Pre-clinical projects*. In the nine months ended September 30, 2018, pre-clinical expenses increased by CHF 0.3 million compared to the nine months ended September 30, 2017, primarily due to activities related to our AM-125 and AM-201 program.

- *Drug manufacture and substance.* In the nine months ended September 30, 2018, drug manufacture and substance related costs decreased by CHF 0.6 million compared to the nine months ended September 30, 2017, due to lower activities related to our AM-101 and Sonsuvi® project activities.

- *Employee benefits*. Employee expenses decreased by CHF 0.8 million in the nine months ended September 30, 2018 compared to the same period in 2017 primarily due to a reduction in headcount.

- *Other research and development expenses*. Other research and development expenses decreased by 54 thousand in the nine months ended September 30, 2018 compared to the same period in 2017 primarily due to a reduction in regulatory related activities.

General and administrative expense

	Three months ended September 30		
	2018	2017	Change
	(in thousands of CHF)		%
Employee benefits	(388)	(512)	(24)%
Lease expenses	(9)	(18)	(50)%
Business development	(1)	(68)	(99)%
Travel and representation	(25)	(31)	(19)%
Administration costs	(593)	(691)	(14)%
Depreciation tangible assets	(153)	(15)	920%
Capital tax expenses	(1)	—	n/a
Total	**(1,170)**	**(1,335)**	**(12)%**

General and administrative expense amounted to CHF 1.2 million in the three months ended September 30, 2018 compared to CHF 1.3 million in the same period in the previous year. Administration costs were lower mainly due to lower personnel cost expenses partly offset by higher depreciation of tangible assets.

	Nine months ended September 30		
	2018	2017	Change
	(in thousands of CHF)		%
Employee benefits	(1,137)	(1,642)	(31)%
Lease expenses	(45)	(62)	(27)%
Business development	(10)	(124)	(92)%
Travel and representation	(50)	(125)	(60)%
Administration costs	(2,202)	(1,987)	11%
Depreciation tangible assets	(183)	(52)	252%
Capital tax expenses	(3)	(5)	(40)%
Total	**(3,630)**	**(3,997)**	**(9)%**

General and administrative expense amounted to CHF 3.6 million in the nine months ended September 30, 2018 compared to CHF 4.0 million in the same period in the previous year. The decrease is related to lower employee benefits due to lower headcount and employee benefit-related expenses, partly offset by higher administration costs mainly due to higher legal fees related to the Merger.

Interest income

Interest income decreased by CHF 8 thousand in the three months ended September 30, 2018 compared to the three months ended September 30, 2017, due to the termination of short-term deposits.

Interest income decreased by CHF 54 thousand in the nine months ended September 30, 2018 compared to the nine months ended September 30, 2017, due to the termination of short-term deposits.

Interest expense

Interest expense decreased in the three months ended September 30, 2018 compared to the same prior year period by CHF 0.3 million. The decrease relates to a reduction in the outstanding balance of the loan under the Loan and Security Agreement, as we commenced repayment of the loan facility in July 2017 and made an extraordinary repayment of $5 million principal amount in April 2018.

Interest expense decreased in the nine months ended September 30, 2018 compared to the same prior year period by CHF 0.3 million. The decrease relates to a reduction in the outstanding balance of the loan under the Loan and Security Agreement, as we commenced repayment of the loan facility in July 2017.

Following the modification of the loan to repay $5 million, a loss of CHF 334,747 was recognized in connection with the modification of the loan and transaction costs. This loss is presented in the line interest expense in the condensed consolidated interim statement of profit or loss and other comprehensive income or loss.

Foreign currency exchange gain/(loss), net

For the three months ended September 30, 2018, foreign currency exchange loss was CHF 0.1 million higher than during the same period in the previous year, due to the impact of the appreciation of the US$ currency and the increased US$ cash and cash equivalents held by the Company from the July 2018 Registered Offering.

For the nine months ended September 30, 2018, foreign currency exchange loss was CHF 0.7 million lower than during the same period in the previous year, due to the impact of the appreciation of the US$ currency and the increased US$ cash and cash equivalents held by the Company from the January 2018 Registered Offering and the July 2018 Registered Offering.

Revaluation gain/(loss) from derivative financial instruments

In connection with the Hercules Loan and Security Agreement, we issued Hercules a warrant to purchase up to 241,117 of the Company's common shares at an exercise price of US$3.94 per share. As of March 13, 2018 following the consummation of the Merger, the warrant was exercisable for 15,673 common shares at an exercise price of $39.40 per common share. As of September 30, 2018 the fair value of the warrant amounted to CHF 1,065. The revaluation gain of the derivative for the nine months ended September, 2018 amounted to CHF 22,285, which is a decrease of CHF 39,384 when comparing to the same period in 2017. Since its initial recognition, the fair value decreased by CHF 407,115 resulting in a revaluation gain in the corresponding amount (fair value as of July 19, 2016: CHF 408,180).

On February 21, 2017 we issued 10,000,000 warrants in connection with the January 2018 Registered Offering, each warrant entitling its holder to purchase 0.70 of a common share at an exercise price of US$1.20 per common share. Additionally, the underwriter was granted a 30-day option to purchase up to 1,500,000 additional common shares and/or 1,500,000 additional warrants, of which the underwriter partially exercised its option for 1,350,000 warrants. As of March 13, 2018, following the consummation of the Merger, the warrants became exercisable for an aggregate of 794,000 of our common shares, at an exercise price of $12.00 per common share. As of September 30, 2018, the fair value of the warrants amounted to CHF 50,070. The revaluation gain of the derivative for the nine months ended September 30, 2018 amounted to CHF 1,763,343, which is an increase of CHF 63,221 when comparing to the same period in 2017. Since its initial recognition, the fair value decreased by CHF 5,040,393, resulting in a gain in the corresponding amount (fair value as of February 21, 2017: CHF 5,090,463).

On January 30, 2018 we issued 7,499,999 warrants in connection with a direct offering of 12,499,999 common shares, each warrant entitling its holder to purchase one common share at an exercise price of $0.50 per common share. As of March 13, 2018, following the consummation of the Merger, the warrants became exercisable for an aggregate of 750,002 of our common shares (assuming we decide to round up fractional common shares to the next whole common share), at an exercise price of $5.00 per common share. As of September 30, 2018 the fair value of the warrants amounted CHF 161,737. Since its initial recognition, the fair value of the warrants has decreased by CHF 2,322,010, resulting in a gain in the corresponding amount (fair value as of January 30, 2018: CHF 2,483,747).

On July 17, 2018 we issued 6,282,050 Series A warrants and 4,487,179 Series B warrants in connection with the July 2018 Registered Offering of 17,948,717 common shares, each warrant entitling its holder to purchase one common share at an exercise price of CHF 0.39 per common share. As of September 30, 2018 the fair value of the warrants amounted CHF 872,217. Since its initial recognition, the fair value of the warrants has decreased by CHF 24,224, resulting in a gain in the corresponding amount (fair value as of July 17, 2018: CHF 896,441).

Transaction costs

Transaction costs increased by CHF 0.1 million in the three months ended September 30, 2018 compared to the previous period, due to transaction costs related to the July 2018 Registered Offering.

Transaction costs increased by CHF 14 thousand in the nine months ended September 30, 2018 compared to the previous period, due to higher fees and transaction costs related to the equity offering in the first quarter of 2018 and the July 2018 Registered Offering compared to the equity offering in the first quarter of 2017.

Comparison of the years ended December 31, 2017 and 2016

	Year Ended December 31,		
	2017	2016	Change
	(in thousands of CHF)		%
Research and development	(19,211)	(24,777)	(22)%
General and administrative	(5,150)	(5,447)	(5)%
Operating loss	**(24,361)**	**(30,224)**	**(19)%**
Interest income	54	68	(21)%
Interest expense	(1,640)	(829)	98%
Foreign currency exchange gain/(loss), net	(825)	(100)	725%
Revaluation gain/(loss) from derivative financial instruments	3,372	291	1,059%
Transaction Costs	(1,027)	—	—%
Loss before tax	**(24,427)**	**(30,794)**	**(21)%**
Income tax gain	18	131	(86)%
Net loss attributable to owners of the Company	**(24,409)**	**(30,662)**	**(20)%**
Other comprehensive loss:			
Items that will never be reclassified to profit or loss			
Remeasurements of defined benefits liability	272	(394)	(169)%
Items that are or may be reclassified to profit or loss			
Foreign currency translation differences	50	(20)	(350)%
Other comprehensive income/(loss)	322	(414)	(178)%
Total comprehensive loss attributable to owners of the Company	**(24,087)**	**(31,076)**	**(22)%**

Research and development expense

	Year Ended December 31,		
	2017	2016	Change
	(in thousands of CHF)		%
Research and development expense			
Clinical projects	(12,366)	(16,639)	(26)%
Preclinical projects	(643)	(546)	18%
Drug manufacture and substance	(2,027)	(2,609)	(22)%
Employee benefits	(2,774)	(2,855)	(3)%
Other research and development expenses	(1,402)	(2,128)	(34)%
Total	**(19,211)**	**(24,777)**	**(22)%**

Research and development expense decreased by 22% from CHF 24.8 million in 2016 to CHF 19.2 million in 2017. Our research and development expense is dependent on the development phases of our research projects and may therefore fluctuate significantly from year to year. The variances in expense between 2016 and 2017 are mainly due to the following factors:

- *Clinical projects*. In 2017, we incurred lower service and milestone costs for our Keyzilen® studies, mainly reflecting the completion of TACTT2, AMPACT1 and AMPACT2 and progression towards completion of TACTT3 were partly offset by higher Sonsuvi® related expenses due to progression of our HEALOS and ASSENT trials.
- *Preclinical projects*. In 2017 preclinical expenses increased by 18% due to an increase in activities in our early stage program AM-102.
- *Drug manufacture and substance*. In 2017 costs related to raw material purchases and expenses decreased by 22% mainly due to lower costs for process validation related to Keyzilen®, which were partly offset by increases related to Sonsuvi®.
- *Employee benefits*. Employee benefit costs decreased in 2017 due to lower headcount and lower recruiting fees.

General and administrative expense

	Year Ended December 31,		
	2017	2016	Change
	(in thousands of CHF)		%
General and administrative expense			
Employee benefits	(2,098)	(2,175)	(4)%
Business development	(162)	(46)	255%
Travel expenses	(199)	(159)	26%
Administration expenses	(2,522)	(2,970)	(15)%
Lease expenses	(81)	(64)	28%
Depreciation tangible assets	(69)	(39)	75%
Capital tax (expenses)/income	(18)	5	(440)%
Total	**(5,150)**	**(5,447)**	**(5)%**

General and administrative expenses decreased by 5% from CHF 5.4 million in 2016 to CHF 5.2 million in 2017.

- *Employee benefits*. In 2017, headcount was similar to 2016 and in line with the planned organization of administrative staff and the management team. Employee benefits expenses decreased as a result of lower personnel cost due to certain positions temporarily being unfilled and lower recruiting fees.
- *Business development.* Business development expenses increased from CHF 0.05 million to CHF 0.2 million as a result of higher consulting fees.
- *Administration expenses.* The decrease of 15% from CHF 3.0 million in 2016 to CHF 2.5 million in 2017, primarily due to lower consultancy fees.

Interest income

Interest income decreased in 2017 compared to 2016 due to lower amounts earned on short-term deposits.

Interest expense

Interest expense increased substantially in 2017 to CHF 1.6 million compared to CHF 0.8 million in 2016, as a result of the Hercules Loan and Security Agreement. On June 19, 2016, we drew $12.5 million under the facility. The loan was initially recognized at transaction value less the fair value of the warrant as

of the transaction date and less directly attributable transactions costs. Following the initial recognition, the loan is measured at amortized cost using the effective interest method. Changes in amortized cost as well as interest paid to Hercules are recognized as interest expense. In addition, we recognized bank charges as interest expense.

Foreign currency exchange gain/(loss), net

Foreign currency exchange gains/(loss), net increased in 2017 mainly due to the depreciation of the U.S. dollar against the Swiss Franc which triggered a net foreign unrealized currency loss on U.S. dollar denominated cash and cash equivalents

Revaluation gain/(loss) from derivative financial instruments

In connection with the Hercules Loan and Security Agreement, the Company issued Hercules a warrant to purchase up to 241,117 of its common shares at an exercise price of $3.94 per share. As of March 13, 2018, following the consummation of the Merger, the warrant was exercisable for 15,673 common shares at an exercise price of $39.40 per common share. The fair value of the warrant on December 31, 2017 amounted to CHF 23,350. The revaluation gain of the derivative for 2017 amounted to CHF 93,782 (2016: revaluation gain of CHF 291,048).

On February 21, 2017, we issued 10,000,000 warrants, each warrant entitling its holder to purchase 0.70 of a common share at an exercise price of $1.20. Additionally, the underwriter was granted a 30-day option to purchase up to 1,500,000 additional common shares and/or 1,500,000 additional warrants. On February 15, 2017, the underwriter partially exercised its option for 1,350,000 warrants. As of December 31, 2017, the fair value of the warrants amounted CHF 1,813,412. Since its initial recognition, the fair value of the warrants have decreased by CHF 3,278,404, resulting in a gain in the corresponding amount (fair value as of February 21, 2017: CHF 5,090,463). As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issued in the February 2017 offering were exercisable for 794,500 common shares at an exercise price of $12.00 per common share.

Transaction costs

Transaction costs increased by CHF 1.0 million in 2017 compared to 2016. The increase relates to the fees and transaction costs related to the warrants issued as part of the public offering completed on February 21, 2017 and for obtaining the 2017 Commitment Purchase Agreement (as defined below), representing LPC's commitment to purchase shares at the option of the Company, subject to certain restrictions.

Income tax gain

Income tax gain reflects the reassessment of deferred tax assets and liabilities booked in the 2014 and 2015 fiscal years.

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), decreased by 169% from 2016 to 2017. The increase was due a change in the discount rate and a change in demographic assumptions.

Foreign currency translation differences

Foreign currency translation differences decreased by 350% from 2016 to 2017. The decrease was primarily related to changes in the opening and closing balance of the group's currency translation differences.

Comparison of the years ended December 31, 2016 and 2015

	Year Ended December 31,		
	2016	2015	Change
	(in thousands of CHF)		%
Research and development	(24,777)	(26,536)	(7)%
General and administrative	(5,447)	(4,342)	25%
Operating loss	**(30,224)**	**(30,878)**	**(2)%**
Interest income	68	37	84%
Interest expense	(829)	(8)	10,363%
Foreign currency exchange gain/(loss), net	(100)	1,144	(109)%
Revaluation gain from derivative financial instruments	291	—	—%
Loss before tax	**(30,794)**	**(29,705)**	**4%**
Income tax expense	131	—	—%
Net loss attributable to owners of the Company	**(30,662)**	**(29,705)**	**3%**
Other comprehensive loss:			
Items that will never be reclassified to profit or loss			
Remeasurements of defined benefits liability, net of taxes of CHF 0	(394)	(54)	630%
Items that are or may be reclassified to profit or loss			
Foreign currency translation differences, net of taxes of CHF 0	(20)	(13)	54%
Other comprehensive loss	**(414)**	**(67)**	**518%**
Total comprehensive loss attributable to owners of the Company	**(31,076)**	**(29,772)**	**4%**

Research and development expense

	Year Ended December 31,		
	2016	2015	Change
	(in thousands of CHF)		%
Research and development expense			
Clinical projects	(16,639)	(20,808)	(20)%
Preclinical projects	(546)	(468)	17%
Drug manufacture and substance	(2,609)	(1,866)	40%
Employee benefits	(2,855)	(2,140)	33%
Other research and development expenses	(2,128)	(1,253)	70%
Total	**(24,777)**	**(26,535)**	**(7)%**

Research and development expense decreased by 7% from CHF 26.5 million in 2015 to CHF 24.8 million in 2016. Our research and development expense is dependent on the development phases of our research projects and may therefore fluctuate significantly from year to year. The variances in expense between 2015 and 2016 are mainly due to the following factors:

- *Clinical projects*. In 2016 we incurred lower clinical expenses related to our Phase 3 clinical program with Keyzilen® than in 2015. Expenses decreased in 2016 primarily due to lower service and milestone costs charged by contracted service providers, reflecting the completion of the TACTT2 trial and progress in our open label follow-on studies AMPACT1 and AMPACT2. The decrease of Keyzilen® related expenses was partially offset by an increase of cost related to our Phase 3 clinical program with Sonsuvi® reflecting the progress in recruitment in HEALOS and the initiation of patient recruitment in the ASSENT trial.

- *Preclinical projects*. In 2016 preclinical expenses increased due to an increase in activities in our early stage program AM-102.

- *Drug manufacture and substance*. In 2016, drug manufacturing expenses increased due to the validation of the Keyzilen® drug product manufacturing process, work performed for the Sonsuvi® drug product validation as well as the production of clinical supplies for the Sonsuvi® trials.

- *Employee benefits*. Employee benefits increased in 2016 due to an increase in headcount and higher compensation expenses.

General and administrative expense

	Year Ended December 31,		
	2016	2015	Change
	(in thousands of CHF)		%
General and administrative expense			
Employee benefits	(2,175)	(1,503)	45%
Administration expenses	(2,970)	(2,387)	24%
Other	(302)	(452)	(33)%
Total	**(5,447)**	**(4,342)**	**25%**

General and administrative expenses increased by 25% from CHF 4.3 million in 2015 to CHF 5.4 million in 2016.

- *Employee benefits*. Headcount continued to increase in 2016 in line with the expansion of administrative staff and the management team. Employee benefits also reflect an increase in share-based payments and pension charges.

- *Administration expenses*. The increase reflects higher legal, consulting and auditing expenses associated with operating as a public company.

- *Other*. In 2016, these expenses, which comprise facility, business development and travel costs, decreased from previous year's level.

Interest income

Interest income increased due to higher interest rates on short-term deposits.

Interest expense

Interest expense increased substantially in 2016, as a result of the Hercules Loan and Security Agreement. On June 19, 2016, we drew $12.5 million under the facility. The loan was initially recognized at transaction value less the fair value of the warrant as of the transaction date and less directly attributable transactions costs. Following the initial recognition, the loan is measured at amortized cost using the effective interest method. Changes in amortized cost as well as interest paid to Hercules are recognized as interest expense. In addition, we recognized bank charges as interest expense.

Foreign currency exchange gains/(losses), net

Foreign currency exchange gains/(loss), net decrease in 2016 due to lower foreign exchange losses on the Company's U.S. dollar denominated cash and cash equivalents.

Revaluation gain/(loss) from derivative financial instruments

In connection with the Hercules Loan and Security Agreement, the Company issued Hercules a warrant to purchase up to 241,117 of its common shares at an exercise price of $3.94 per share. As of December 31, 2016, the warrant was exercisable for 156,726 common shares and the fair value of the

warrant amounted to CHF 117,132. Since its initial recognition, the fair value decreased by CHF 291,048 resulting in a gain in the corresponding amount (fair value as of July 19, 2016: CHF 408,180).

Income tax gain

Income tax gain reflects the reassessment of deferred tax assets and liabilities booked in the 2014 and 2015 fiscal years.

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 by 630% from 2015 to 2016. The increase was due a change in the discount rate and a change in demographic assumptions.

Foreign currency translation differences

Foreign currency translation differences increased by 54% from 2015 to 2016. The increase was primarily related to changes in the opening and closing balance of the group's currency translation differences.

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 public offerings of our common shares, private placements of equity securities and short-term loans.

Cash flows

Comparison of the three months ended September 30, 2018 and 2017

The table below summarizes our cash flows for the three months ended September 30, 2018 and 2017:

	Three months ended September 30	
	2018	2017
	(in thousands of CHF)	
Cash used in operating activities	(4,018)	(4,762)
Net cash from/(used in) investing activities	68	(63)
Net cash from/(used in) financing activities	4,917	(1,308)
Net effect of currency translation on cash	(131)	92
Cash and cash equivalents at beginning of the period	4,422	26,239
Cash and cash equivalents at end of the period	**5,258**	**20,198**

The decrease in net cash used in operating activities from CHF 4.8 million in the three months ended September 30, 2017 to CHF 4.0 million in the three months ended September 30, 2018 was mainly due to lower operating expenses compared to the same period in 2017. The increase in net cash used in financing activities is due to the July 2018 Registered Offering.

Comparison of the nine months ended September 30, 2018 and 2017

The table below summarizes our cash flows for the nine months ended September 30, 2018 and 2017:

	Nine months ended September 30	
	2018	2017
	(in thousands of CHF)	
Cash used in operating activities	(11,304)	(17,827)
Net cash from/(used in) investing activities	49	(93)
Net cash from financing activities	1,823	7,164
Net effect of currency translation on cash	(283)	(1,487)
Cash and cash equivalents at beginning of the period	14,973	32,442
Cash and cash equivalents at end of the period	**5,258**	**20,198**

The decrease in net cash used in operating activities from CHF 17.8 million in the nine months ended September 30, 2017 to CHF 11.3 million in the nine months ended September 30, 2018 was mainly due to lower operating expenses compared to the same period in 2017. Net cash from financing activities decreased as the net proceeds of the January 2018 Registered Offering of $4.9 million and the July 2018 Registered Offering of $6.2 million were partly used for the $5.0 million repayment and the regular monthly amortizations of $3.9 million on the Hercules loan.

Comparison of the years ended December 31, 2017 and 2016

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2017 and 2016:

	Year Ended December 31,	
	2017	2016
	(in thousands of CHF)	
Net cash used in operating activities	(24,276)	(29,454)
Net cash used in investing activities	(99)	(177)
Net cash from financing activities	8,221	11,439
Net effect of currency translation on cash	(1,315)	397
Cash and cash equivalents at the beginning of the period	32,422	50,237
Cash and cash equivalents at the end of the period	**14,973**	**32,442**

The decrease in cash used in operating activities from CHF 29.5 million in 2016 to CHF 24.3 million in 2017 reflects the impact of lower operating expenses primarily driven by lower research and development related expenses.

Cash used in investing activities reflects, in both 2017 and 2016, cash used in the purchase of property, plant and equipment (manufacturing equipment, leasehold improvements and office furniture) offset by interest received.

Cash from financing activities in 2017 includes the net proceeds of the February 2017 public offering of common shares and warrants to purchase common shares. The net proceeds to us from the offering were approximately CHF 9.1 million, after deducting underwriting discounts and other offering expenses payable by us. Cash from financing activities in 2017, also includes the principal amortization and interest payments due to the financing parties under the Hercules Loan and Security Agreement. In addition, cash from financing activities in 2017 includes the issuance of shares under the 2017 Commitment Purchase Agreement and a registration rights agreement with LPC which resulted in net proceeds of CHF 2.3 million.

Comparison of the years ended December 31, 2016 and 2015

The table below summarizes our consolidated statement of cash flows for the years ended December 31, 2016 and 2015:

	Year Ended December 31,	
	2016	2015
	(in thousands of CHF)	
Cash used in operating activities	(29,454)	(28,727)
Net cash used in investing activities	(177)	(43)
Net cash from financing activities	11,439	20,919
Net effect of currency translation on cash	397	1,155
Cash and cash equivalents at the beginning of the period	50,237	56,934
Cash and cash equivalents at the end of the period	**32,442**	**50,237**

The increase in cash used in operating activities from CHF 28.8 million in 2015 to CHF 29.5 million in 2016 reflects the change in working capital.

Cash used in investing activities reflects, in both 2016 and 2015, cash used in the purchase of property, plant and equipment (manufacturing equipment, leasehold improvements and office furniture) offset by interest received.

Cash from financing activities in 2016 reflects the net proceeds (CHF 12.0 million) from the drawdown of a $12.5 million tranche under the Loan and Security Agreement with Hercules and accounts for interest payments to Hercules as well as share issuance cost incurred in connection with restricted shares issued as a management bonus. Cash from financing activities in 2015 reflects the net proceeds (CHF 21.1 million) from our public offering of 5,275,000 common shares at a price of $4.75 per share. The proceeds were partially offset by issuance costs associated with the offering.

Cash and funding sources

The table below summarizes our sources of financing for the nine months ended September 30, 2018 and 2017 and the years ended December 31, 2017, 2016 and 2015.

	Equity Capital and Preferred Shares	Loans	Total
	(in thousands of CHF)		
Nine months ended September 30, 2018	12,286	—	12,286
Nine months ended September 30, 2017	9,321	—	9,321
Year ended December 31, 2017	11,491	—	11,491
Year ended December 31, 2016	—	11,987	11,987
Year ended December 31, 2015	21,071	—	21,071

On July 17, 2018, we completed a public offering of 17,948,717 common shares with a nominal value of CHF 0.02 each, 6,282,050 Series A warrants entitling its holder to purchase a common share and 4,487,179 Series B warrants entitling its holder to purchase a common share. The net proceeds to us from the July 2018 Registered Offering were approximately $6.2 million, after deducting underwriting discounts and other offering expenses payable by us. The outstanding Series A warrants issued in the July 2018 Registered Offering are exercisable for up to 6,282,051 common shares at an exercise price of CHF 0.39 per common share and the outstanding Series B warrants issued in the July 2018 Registered Offering are exercisable for up to 4,487,178 common shares at an exercise price of CHF 0.39 per common share.

On May 2, 2018, we entered into the Purchase Agreement and the registration rights agreement with LPC (the “Registration Rights Agreement”). Pursuant to the Purchase Agreement, LPC agreed to purchase common shares for up to $10,000,000 over the 30-month term of the Purchase Agreement. As of

November 15, 2018, we have issued an aggregate of 750,000 common shares for aggregate proceeds of $488,075 to LPC under the Purchase Agreement. The Purchase Agreement replaced the 2017 Commitment Purchase Agreement, dated October 10, 2017, between LPC and us (the "2017 Commitment Purchase Agreement"), which was terminated as a result of the Merger. Under the 2017 Commitment Purchase Agreement, LPC agreed to subscribe for up to $13,500,000 of our common shares and prior to its termination, we had issued an aggregate of 2,600,000 common shares for aggregate proceeds of $1.8 million to LPC under the 2017 Commitment Purchase Agreement.

On January 30, 2018, we completed a public offering of 12,499,999 common shares with a nominal value of CHF 0.40 each and a concurrent offering of 7,499,999 warrants, each warrant entitling its holder to purchase one common share. The net proceeds to the Company from the January 2018 Registered Offering were approximately $4.9 million, after deducting placement agent fees and other estimated offering expenses payable by the Company. As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issued in the January 2018 offering were exercisable for up to 750,002 common shares (assuming we decide to round up fractional common shares to the next whole common share) at an exercise price of $5.00 per common share.

On October 16, 2017, we issued 1,744,186 common shares to LPC for aggregate proceeds of $1,500,000.

On February 21, 2017, we completed a public offering of 10,000,000 common shares with a nominal value of CHF 0.40 each and 10,000,000 warrants, each warrant entitling its holder to purchase 0.70 of a common share. The net proceeds to us from the offering were approximately CHF 9.1 million, after deducting underwriting discounts and other offering expenses payable by us. The underwriter was granted a 30-day option to purchase up to 1,500,000 additional common shares and/or 1,500,000 additional warrants, of which the underwriter partially exercised its option in the amount of 1,350,000 warrants. As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issued in the February 2017 offering were exercisable for up to 794,500 common shares at an exercise price of $12.00 per common share.

On July 19, 2016, we entered into a Loan and Security Agreement with Hercules for a secured term loan facility of up to $20.0 million. An initial tranche of $12.5 million was drawn on July 19, 2016, concurrently with the execution of the loan agreement. The loan matures on January 2, 2020 and bears interest at a minimum rate of 9.55% per annum, and is subject to the variability of the prime interest rate. The loan is secured by a pledge of the shares of Auris Medical AG owned by us, all intercompany receivables owed to us by our Swiss subsidiaries and a security assignment of our bank accounts. In connection with the loan facility, we issued Hercules a warrant to purchase up to 241,117 of our common shares at an exercise price of $3.94 per share. As of March 13, 2018, following consummation of the Merger, the warrant is exercisable for 15,673 common shares at an exercise price of $39.40 per common share. On April 5, 2018 we entered into an agreement with Hercules whereby the terms of the Loan and Security Agreement were amended to eliminate the $5 million liquidity covenant in exchange for a repayment of $5 million principal amount outstanding under the Loan and Security Agreement. On January 31, 2019, we made the final payment to Hercules under the facility, comprising the last amortization rate as well as an end of term charge. With the final payment, all covenants and collaterals in favor of Hercules have been lifted. In addition, Hercules agreed to return the warrant held by Hercules exercisable for 15,673 common shares at an exercise price of $39.40 per common share for no consideration to us in exchange for our payment to Hercules. We will cancel the warrant upon receipt.

We have no other 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 expect that our operating expenses for 2019 will be in the range of CHF 10.0 to 13.0 million and that the existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2019. Additionally, as of the date of this prospectus we have warrants outstanding, which are exercisable for an aggregate of 6,544,791 common shares at a weighted average exercise price of $2.33 per share, an equity commitment to sell up to approximately

$9.0 million of additional common shares to LPC pursuant to the Purchase Agreement and an at-the-market offering program pursuant to the A.G.P. Sales Agreement for sales of up to $25.0 million of additional common shares. Following the Redomestication, we will be unable to raise capital through the A.G.P. Sales Agreement unless we successfully renegotiate such agreement with A.G.P. We cannot be certain that we will be able to renegotiate the A.G.P. Sales Agreement with the same terms and conditions or at all.

We anticipate that the issuance of our common shares under the Purchase Agreement will enable the Company to further fund its operations and capital requirements. 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 funding to continue our ongoing clinical development activities and seek to obtain regulatory approval for, and commercialize, our product candidates. If we receive regulatory approval for any of our product candidates, 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. Likewise, if we are unable to refinance amounts outstanding under our existing term loan facility before such amounts are due we may be unable to repay such amounts, which could result in foreclosure of the collateral pledged to secure such loan.

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.

Contractual Obligations and Commitments

The following table presents information relating to our contractual obligations as of September 30, 2018:

	Payments Due by Period			
	Less Than 1 Year	Between 1 and 3 Years	Between 3 and 5 Years	Total
	(in thousands of CHF)			
Operating lease obligations[1]	21	—	—	21
Long-term debt obligations[2]	2,144	—	—	2,144
Derivative Financial Instruments[3]	—	—	1,085	1,085
Total	**2,165**	**—**	**1,085**	**3,250**

(1) Operating lease obligations consist of payments pursuant to operating lease agreements relating to leases of our office space and are not accounted for on the balance sheet. The lease term is indefinite and can be terminated with a six month notice period.

(2) Long-term debt obligations consist of amortization payments and the end of term fee due under the Loan and Security Agreement converted to CHF at an exchange rate of CHF 0.9847 to US$1.00. The secured term loan under the Loan and Security Agreement has a maturity date of January 2, 2020, with an interest-only period through July 1, 2017, and amortized payments of principal and interest thereafter in equal monthly instalments until the maturity date. The loan bears interest at a minimum rate of 9.55% per annum, and is subject to the variability of the prime interest rate. Interest payments are not included in the table presented above.

(3) Derivative Financial instruments relate to the warrants issued in connection with the Loan and Security Agreement and the warrants issued in the public offering in February 2017, direct placement in January 2018 and the July 2018 Registered Offering.

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.

Under the terms of the asset purchase agreement with Otifex, we are obliged to make a development milestone payment of $200,000 subject to reaching certain development outcomes.

Off-Balance Sheet Arrangements

As of the date of this discussion and analysis, we do not have any, and during the periods presented we did not have any, off-balance sheet arrangements except for the operating lease agreement mentioned above under “Contractual Obligations and Commitments.”

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 have been 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 our annual report, 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 and Data rights

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 income/loss, or 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. Taxable profit differs from "loss before tax" as reported in the consolidated statement of profit or loss and other comprehensive loss because of items of income or expense that are taxable or deductible in other years and items that are never taxable or deductible.

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 employed in Switzerland through payments to an independent collective foundation. Under IFRS, the pension plan qualifies as a defined benefit 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 Company's equity incentive plan (the "Equity Incentive Plan" or "EIP") adopted in August 2014 and amended in April 2017 and assumed by Auris NewCo following the Merger, 50% of granted share options granted to employees 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. Share options granted to members of the board of directors in 2015 and 2016 vest after a period of one year after the grant date.

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 share options 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 share options as of each grant date.

In our historical 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 the Black Scholes option pricing model and assumptions are made for inputs such as volatility of our stock and the risk free rate.

Recent accounting pronouncements

See Note 4 to our audited financial statements included in this prospectus on page F-26 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 Exemption

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 not required to provide an auditor attestation report on our system of internal controls over financial reporting. This exemption will apply for a period of five years following the completion of our initial public offering (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 US$1.07 billion in annual revenue, have more than US$700 million in market value of our common shares held by non-affiliates or issue more than US$1.0 billion of non-convertible debt over a three-year period.

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. Only independent banks and financial institutions are used and banks with which we currently hold term deposits have a minimum S&P rating of "A". Receivables are not past due and not impaired and include only well-known counterparties.

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

Market Risk

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

Interest rate risk

Interest expense pursuant to borrowings under the loan and security agreement with Hercules Capital, Inc. is subject to the variability of the prime rate as reported by the Wall Street Journal. An increase or decrease of the prime rate reported effective September 30, 2018 by 50 basis points, with all other factors held constant, would have resulted in a CHF 3,672 increase or decrease of the net annual result (2017: CHF 4,682).

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

Currency Risk

We operate internationally and are exposed to foreign exchange risk arising from various exposures, primarily with respect to the U.S. Dollar and Euro. Foreign exchange risk arises from future commercial transactions, recognized assets and liabilities and net investments in foreign operations. To manage foreign exchange risk we maintain foreign currency cash balances to cover anticipated future purchases of materials and services in foreign currencies. We do not hedge our foreign exchange risk.

As of September 30, 2018, a 5% increase or decrease in the USD/CHF exchange rate with all other variables held constant would have resulted in a CHF 52,380 (December 31, 2017: CHF 832,032) 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 79,421 (December 31, 2017: CHF 89,403) increase or decrease in the net annual 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.

BUSINESS

Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel products that address important unmet medical needs in neurotology and mental health supportive care. We are focusing on the development of intranasal betahistine for the treatment of vertigo (AM-125) and for the prevention of antipsychotic-induced weight gain and somnolence (AM-201). These programs have gone through two Phase 1 trials and will move into proof-of-concept studies in 2019. In addition, we have two Phase 3 programs under development: (i) Keyzilen® (AM-101), which is being developed for the treatment of acute inner ear tinnitus and (ii) Sonsuvi® (AM-111), which is being developed for the treatment of acute inner ear hearing loss. Sonsuvi® has been granted orphan drug status by the FDA and the EMA and has been granted fast track designation by the FDA.

Recent Developments

Acquisition of orphan drug designation and rights to in-license patents related to betahistine

On December 6, 2018, we announced a strategic expansion for our intranasal betahistine development program. In two related transactions, we acquired an Orphan Drug Designation for betahistine in the treatment of obesity associated with Prader-Willi syndrome (PWS) and signed a binding letter of intent to in-license exclusive rights to two U.S. Patents relating to the use of betahistine for the treatment of depression and attention-deficit/hyperactivity disorder (ADHD), respectively. On January 15, 2019, we announced the closing of the acquisition of the Orphan Drug Designation and that the transfer of the designation to Auris Medical had been recorded by the FDA.

Positive Results From Second Phase 1 Clinical Trial With Intranasal Betahistine (AM-125)

On October 17, 2018, we announced positive results from the second Phase 1 trial evaluating intranasal betahistine in healthy volunteers. The study results demonstrated superior bioavailability over a range of four intranasal betahistine doses compared to oral betahistine, with plasma exposure being 6 to 29 times higher (p-value between 0.056 and $p < 0.0001$). Further, it confirmed the favorable safety profile of intranasal betahistine and showed that the treatment was well tolerated when administered three times daily for three days.

The randomized double blind placebo controlled Phase 1 trial with dose escalation enrolled a total of 72 healthy volunteers. One group of study participants received a single dose of intranasal betahistine or placebo and, following a wash-out period, three doses daily for three days. Single doses were escalated up to 60 mg, and repeated doses up to 40 mg. For the latter, the maximum tolerated dose based on local tolerability was determined at 40 mg. The other group of study participants received oral betahistine or placebo for reference. Pharmacokinetic parameters in blood plasma were determined for betahistine and its metabolites, and relative bioavailability for intranasal betahistine was calculated compared to oral betahistine 48 mg, which is the maximum approved daily dose as marketed worldwide (ex US). We plan to initiate two randomized double blind placebo controlled proof-of-concept studies with intranasal betahistine in the first quarter of 2019. In the planned TRAVERS, we plan to enroll patients suffering from acute vertigo following vestibular schwannoma resection.

We plan to initiate a Phase 2 randomized placebo-controlled clinical trial with AM-125 in the first quarter of 2019. The “TRAVERS” Phase 2 trial will enroll 138 patients suffering from acute vertigo following surgical removal of a vestibular schwannoma, a tumor growing behind the inner ear. It will be conducted in several European countries and potentially, Canada. The TRAVERS trial will have two parts: In Part A, five ascending doses of AM-125 or placebo, administered three times daily over a total of four weeks, will be tested in a total of 50 patients. In addition, oral betahistine 48 mg will be tested in 16 patients under open-label conditions for reference. Based on an interim analysis, two doses will be selected and tested in an estimated 72 patients in Part B.

Launch of AM-201 Program

On May 15, 2018, we announced the expansion of our intranasal betahistine development program beyond the treatment of vertigo into mental health supportive care indications. Under project code AM-201, we intend to develop intranasal betahistine for the prevention of weight gain and drowsiness (somnolence), which are major side effects of many antipsychotic drugs. On November 20, 2018, we announced the results of our pre-Investigational New Drug ("IND") meeting on AM-201 with the FDA. In its written response, the FDA supported the planned conduct of a multiple dose Phase 1b proof-of-concept trial with AM-201 administered to healthy subjects in combination with olanzapine to evaluate the pharmacokinetics, pharmacodynamics and safety, and to establish proof-of-concept. Further, the FDA endorsed weight gain normalized to baseline body weight versus placebo as reasonable primary efficacy endpoint for a subsequent Phase 2 trial.

We expect to initiate the Phase 1b proof-of-concept trial in the first quarter of 2019. The trial will be conducted in Europe and will enroll 50 healthy volunteers who will receive either AM-201 or placebo concomitantly with olanzapine over four weeks.

Scientific Advice from the EMA on Development Plan and Regulatory Pathway for Sonsuvi®

On May 7, 2018, we announced that we had received positive Scientific Advice from the Committee for Medicinal Products for Human Use of the EMA related to the development plan and regulatory pathway for Sonsuvi®. The Scientific Advice (Protocol Assistance) had been requested by us following the results of the HEALOS Phase 3 trial. The EMA reviewed our proposed concept for a single pivotal trial with Sonsuvi® at a dose of 0.4 mg/mL in patients suffering from acute profound hearing loss, which builds to a large extent on the design and outcomes from HEALOS. The EMA endorsed the proposed trial design, choice of efficacy and safety endpoints, as well as the statistical methodology. In addition, the EMA provided important guidance on the regulatory path forward and the maintenance of Sonsuvi®'s orphan drug designation.

On August 30, 2018, we announced that we received feedback from a Type C meeting with the FDA related to the development plan and regulatory pathway for Sonsuvi®. The FDA reviewed our proposed concept for a placebo-controlled pivotal trial with Sonsuvi® at a dose of 0.4 mg/mL in patients suffering from acute profound hearing loss. The trial protocol builds to a large extent on the design and outcomes from HEALOS and also incorporates specific feedback provided by the EMA referenced above. In a written response, the FDA endorsed the proposed choice of primary and secondary efficacy endpoints, the safety endpoints, as well as the planned sample size and statistical methodology. In addition, the FDA provided important guidance on the regulatory path forward.

Identification of Potential Partners for Sonsuvi®

In early November 2018, we engaged JSB Partners LP, with offices in Boston, Munich and Zug, to identify potential partners for our Sonsuvi® program and to support us in negotiating potential partnering agreements.

Otonomy Ruling

On August 1, 2018, the United States Court of Appeals for the Federal Circuit reversed the USPTO Patent Trial and Appeal Board's determination of priority in our favor relating to the July 2015 USPTO declaration of patent interference (No. 106,030) involving our issued U.S. patent No. 9,066,865 and Otonomy's U.S. patent application No. 13/848,636. We believe that this ruling will not materially impact any of our development programs.

Redomestication

On January 29, 2019, we filed a registration statement on Form F-4 related to the redomestication of us from Switzerland to Bermuda (the "Redomestication"). On January 24, 2019, our board of directors determined that it would be in our best interest to change our legal seat and jurisdiction of incorporation, respectively, from Switzerland to Bermuda. We are proposing to change our legal seat and jurisdiction of

incorporation by discontinuing from Switzerland and continuing as an exempted company limited by shares registered under the laws of Bermuda. To effect the Redomestication, we will, upon the approval of our shareholders, file an application with the Registrar of Companies in Bermuda.

The board of directors may not be able to implement the Redomestication if the relevant consents, rulings and approvals in connection with the Redomestication are not obtained, including approvals from our shareholders the Swiss and Bermuda authorities.

Upon the issuance of a certificate of continuance by the Registrar of Companies in Bermuda, the Redomestication will be effected and we will have continued in Bermuda pursuant to Section 132C of the Companies Act as a Bermuda company, subject to the Companies Act and other laws of Bermuda, with a new name "Auris Medical Holding Ltd."

To effect the deletion of our company in the commercial register of the Canton of Zug, Switzerland, we will need, among other steps, to publish a notice to creditors three times in the Swiss Official Gazette of Commerce and our auditors will have to confirm that the claims of the creditors (if any) within the meaning of article 46 Swiss Merger Act have been secured or fulfilled or that the creditors agree to the deletion in the Swiss commercial register. The necessary filing of the documents with the commercial register will include, among other documents, the resolution of the board of directors, the minutes of the shareholders' resolution, a copy the certificate of continuance (issued by the Registrar of Companies in Bermuda), the legal opinion of Bermuda counsel and the auditors confirmation. Upon filing of the application to delete the Company in the commercial register of the Canton of Zug, the commercial register will involve the federal and cantonal tax authorities and request their consent to cancel our company. Such consent is only granted upon payment of all taxes by us (whether before or after the continuance of us in Bermuda).

The assets and liabilities as a Bermuda company immediately after the Redomestication will be identical to the assets and liabilities as a Swiss company immediately prior to the Redomestication. Our officers and directors immediately before the Redomestication becomes effective will be the officers and directors of the Bermuda company upon Redomestication. In addition, pursuant to Bermuda law, Auris Medical (Bermuda) will be required to appoint certain officers who are ordinarily resident in Bermuda, and therefore Auris Medical (Bermuda), upon effectiveness of the Redomestication, intends to appoint a secretary (or assistant secretary) and/or a resident representative who is ordinarily resident in Bermuda and maintain a registered office in Bermuda. The Redomestication will not result in any material change to our business and will not have any effect on the relative equity interests of our shareholders.

We believe that the Redomestication from Switzerland to Bermuda will provide us with additional corporate flexibility, result in cost savings and that Bermuda is a jurisdiction more familiar to most of our current and potential new investors ultimately resulting in improved access to capital markets.

Nasdaq Listing Requirements

We are currently not in compliance with the quantitative listing standards of the Nasdaq Capital Market, which require, among other things, that listed companies maintain a minimum closing bid price of $1.00 per share. We failed to satisfy this threshold for 30 consecutive trading days and on July 30, 2018, we received a letter from Nasdaq indicating that we had been provided a period of 180 calendar days, or until January 28, 2019, to regain compliance. We did not regain compliance within the 180 days.

On February 6, 2019, we received a letter from Nasdaq stating that due to our continued non-compliance with the minimum $1.00 bid price requirement, our common shares were subject to delisting unless we timely requested a hearing before the Nasdaq Hearings Panel. We timely requested such a hearing on February 8, 2019, which request has stayed any delisting or suspension action by Nasdaq pending the hearing and the expiration of any additional extension period granted following the hearing.

At the hearing, we intend to present our plan to regain compliance with the minimum $1.00 bid price requirement; however, there can be no assurance that the Nasdaq Hearings Panel will grant our request for continued listing or that we will be able to evidence compliance with the applicable listing criteria prior to the expiration of any additional extension period that may be granted to us.

At the hearing, we intend to commit that in the event that the Nasdaq Hearings Panel grants us an additional compliance period and the bid price of our common shares fails to increase above the $1.00 minimum during such additional compliance period, we will pursue a reverse share split by consolidating our common shares (together with a corresponding increase in the par value thereof) in a ratio determined by the board of directors in order to regain compliance with the $1.00 bid price requirement. In the event shareholders approve the Redomestication, Auris Medical (Bermuda)'s board of directors would have the ability, after the Redomestication, to effect a reverse share split without further shareholders approval, by consolidating our common shares (together with a corresponding increase in the par value thereof) in a ratio determined by the board of directors.

In addition to the minimum closing bid price requirement, we are required to comply with certain other Nasdaq continued listing requirements, including a series of financial tests relating to shareholder equity, market value of listed securities and number of market makers and shareholders. If we fail to maintain compliance with any of those requirements, our common shares could be delisted from Nasdaq's Capital Market. A delisting of our common shares is likely to reduce the liquidity of our common shares and may inhibit or preclude our ability to raise additional financing.

Repayment of Hercules Loan and Security Agreement

On April 5, 2018, we entered into an agreement with Hercules Capital, Inc. ("Hercules") whereby the terms of our Loan and Security Agreement (the "Loan and Security Agreement") with Hercules were amended to eliminate the $5 million liquidity covenant in exchange for a repayment of $5 million principal amount outstanding under the Loan and Security Agreement. As of September 30, 2018, CHF 2.1 million was the carrying amount under the Loan and Security Agreement. On January 31, 2019, we made the final payment to Hercules under the facility, comprising the last amortization rate as well as an end of term charge. With the final payment, all covenants and collaterals in favor of Hercules have been lifted. In addition, Hercules agreed to return the warrant held by Hercules exercisable for 15,673 common shares at an exercise price of $39.40 per common share for no consideration to us in exchange for our payment to Hercules. We will cancel the warrant upon receipt.

January 2018 Offering of Common Shares and Warrants

On January 26, 2018, we entered into a purchase agreement with certain investors providing for the issuance and sale by us of 12,499,999 of our common shares. The common shares were offered pursuant to an effective shelf registration statement on Form F-3, which was initially filed with the Securities and Exchange Commission on September 1, 2015 and declared effective on September 10, 2015 (File No. 333-206710).

In a concurrent private placement, we issued to the same investors warrants to purchase up to 7,499,999 of our common shares in the aggregate. The warrants became exercisable immediately upon their issuance on January 30, 2018, at an exercise price of $0.50 per common share, and expire on January 30, 2025. Following the consummation of the Merger, the warrants became exercisable for an aggregate of 750,002 of our common shares (assuming we decide to round up fractional common shares to the next whole common share), at an exercise price of $5.00 per common share.

Committed Equity Financing

On May 2, 2018, we entered into a Purchase Agreement (the "Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("LPC"). Pursuant to the Purchase Agreement, LPC has agreed to subscribe for up to $10,000,000 of our common shares over the 30-month term of the Purchase Agreement.

Pursuant to the Purchase Agreement, so long as a registration statement covering the resale by LPC of the common shares that we issue to LPC pursuant to the Purchase Agreement is available for use, we have the right, from time to time at our sole discretion over the 30-month period from and after June 15, 2018, the date of the satisfaction of the conditions in the Purchase Agreement (the "Commencement"), to require LPC to subscribe for up to 250,000 of our common shares, subject to adjustments as set forth below (such maximum number of shares, as may be adjusted from time to time, the "Regular Purchase Share Limit";

each such purchase, a "Regular Purchase"); provided, however, that (i) the Regular Purchase Share Limit shall be increased to 300,000 of our common shares if the total number of outstanding common shares on the purchase date exceeds 10,000,000, (ii) the Regular Purchase Share Limit shall be increased to 350,000 of our common shares if the closing sale price of our common shares is not below $1.00 on the purchase date and the total number of outstanding common shares on the purchase date exceeds 12,500,000 and (iii) the Regular Purchase Share Limit shall be increased to 400,000 of our common shares if the closing sale price of our common shares is not below $1.00 on the purchase date and the total number of outstanding common shares on the purchase date exceeds 15,000,000. The Regular Purchase Share Limit is subject to proportionate adjustment in the event of a reorganization, recapitalization, non-cash dividend, stock split or other similar transaction; provided, that if after giving effect to such full proportionate adjustment, the adjusted Regular Purchase Share Limit would preclude us from requiring LPC to subscribe for common shares at an aggregate purchase price equal to or greater than $100,000 in any single Regular Purchase, then the Regular Purchase Share Limit for such Regular Purchase will not be fully adjusted, but rather the Regular Purchase Share Limit for such Regular Purchase shall be adjusted as specified in the Purchase Agreement, such that, after giving effect to such adjustment, the Regular Purchase Share Limit will be equal to (or as close as can be derived from such adjustment without exceeding) $100,000. We may not require LPC to purchase in any single Regular Purchase common shares having an aggregate purchase price greater than $1,000,000. We may not issue any of our common shares as a Regular Purchase on a date in which the closing sale price of our common shares is below $0.25 (subject to adjustment for any reorganization, recapitalization, non-cash dividend, stock split or other similar transaction). The purchase price for Regular Purchases shall be equal to the lesser of (i) the lowest sale price of our common shares on the applicable purchase date and (ii) the average of the three lowest closing sale prices of our common shares during the 10 business days immediately prior to the applicable purchase date, as reported on The Nasdaq Capital Market.

We also have the right, at our sole discretion, to require LPC to make tranche purchases of up to $2,000,000 in separate tranches of not less than $100,000 and up to $500,000 for each purchase, at a purchase price equal to the lesser of (i) $5.00 per common share or (ii) 96% of the purchase price, provided that (a) the closing price of the common shares is not below $1.00 and (b) the total number of outstanding common shares exceeds 12,500,000. We can deliver notice for a tranche purchase at any time, so long as at least 15 business days have passed since a tranche purchase was completed.

In all instances, we may not issue common shares to LPC under the Purchase Agreement if it would result in LPC beneficially owning more than 4.99% of our outstanding common shares.

The Purchase Agreement contains customary representations, warranties and agreements of the parties, certain limitations and conditions to completing future sale transactions, indemnification rights of LPC and other obligations of the parties. LPC has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our common shares. We issued to LPC a cash commitment fee of $250,000 for entering into this commitment.

As of February 8, 2019, there were 37,495,859 of our common shares outstanding (approximately 31,222,679 of which common shares are held by non-affiliates), excluding the 10,000,000 common shares to which this prospectus relates that we may issue to LPC pursuant to the Purchase Agreement after the effective date. If all of the 10,000,000 common shares offered hereby were issued and outstanding as of February 8, 2019, such shares would represent approximately 21% of the total common shares outstanding, or approximately 24% of the common shares outstanding held by non-affiliates, as of February 8, 2019. The actual number of common shares offered for sale by LPC is dependent upon the number of common shares we ultimately elect to issue to LPC under the Purchase Agreement.

As of the date of this prospectus, we have sold 1,750,000 of our common shares for an aggregate offering price of $1,010,775 pursuant to the Purchase Agreement.

The remaining net proceeds under the Purchase Agreement will depend on the frequency and prices at which we issue our common shares to LPC. We expect that any proceeds received by us from such issuances to LPC will be used for working capital and general corporate purposes. We have the right to terminate the Purchase Agreement at any time for any reason upon one business day's written notice to LPC.

July 2018 Offering of Common Shares and Warrants

On June 28, 2018, an extraordinary general meeting of shareholders approved an ordinary share capital increase and certain changes to our articles of association to increase our authorized share capital and our conditional share capital for financing purposes (collectively, the "Capital Increase"). On July 17, 2018, we closed our registered offering of 17,948,717 common shares, Series A warrants to purchase 6,282,050 common shares and Series B warrants to purchase 4,487,179 common shares. We refer to such offering of common shares as the "July 2018 Registered Offering."

Since the July 2018 Registered Offering, certain Series A warrant holders exercised their warrant shares to purchase 2,904,518 of our common shares and certain Series B warrant holders exercised warrant shares to purchase 2,864,422 of our common shares.

2018 Registered Direct Offerings of Common Shares

On November 27, 2018 and December 11, 2018, we entered into purchase agreements with FiveT Capital AG, providing for the issuance and sale by us of an aggregate of 3,315,000 of our common shares for an aggregate purchase price of $1.6 million in two separate registered direct offerings.

"At-the-Market" Offering Program

On November 30, 2018, we entered into the A.G.P. Sales Agreement with A.G.P. Pursuant to the terms of the A.G.P. Sales Agreement, we may offer and sell our common shares, from time to time through A.G.P. by any method deemed to be an "at-the-market" offering as defined in Rule 415(a)(4) promulgated under the Securities Act. Pursuant to the A.G.P. Sales Agreement, we may sell common shares up to a maximum aggregate offering price of $25.0 million.

In the event that the Redomestication is effected, we will need to amend the A.G.P. Sales Agreement before we can sell additional common shares to A.G.P. We cannot be certain that we will be able to negotiate an amendment with the same terms and conditions, or at all.

As of the date of this prospectus, we have sold 2,595,814 of our common shares for an aggregate offering price of $1.3 million pursuant to the A.G.P. Sales Agreement.

Changes to Articles of Association to Allow Further Increases of the Share Capital Based Conditional and Authorized Share Capital

On January 17, 2019, an extraordinary general meeting of shareholders approved further changes to our articles of association to increase our authorized share capital, our conditional share capital for financing purposes and our conditional share capital for equity incentive plans.

Corporate Information

We are a share corporation organized under the laws of Switzerland. We began our current operations in 2003. 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.

On March 13, 2018, in order to effect a 10:1 reverse share split, Auris Medical Holding AG merged into Auris Medical NewCo Holding AG (the "Merger"), a newly incorporated, wholly-owned Swiss subsidiary ("Auris NewCo") following shareholder approval at an extraordinary general meeting of shareholders held on March 12, 2018. Following the Merger, Auris NewCo, the surviving company had a share capital of CHF 122,347.76, divided into 6,117,388 common shares with a nominal value of CHF 0.02 each. Pursuant to the Merger, our shareholders received one common share with a nominal value of CHF 0.02 of Auris NewCo for every 10 common shares in Auris Medical Holding AG held prior to the Merger, effectively resulting in a "reverse share split" at a ratio of 10-for-1. Auris NewCo changed its name to "Auris Medical Holding AG" as part of the consummation of the Merger, effective March 13, 2018. On March 14, 2018, the common shares of Auris NewCo began trading on The Nasdaq Capital Market under the trading symbol "EARS."

Our principal office is located at Bahnhofstrasse 21, 6300 Zug, Switzerland, telephone number +41 (0)41 729 71 94. We maintain a website at www.aurismedical.com where general information about us is available. Investors can obtain copies of our filings with the SEC from this site free of charge, as well as from the SEC website at www.sec.gov. We are not incorporating the contents of our website into this prospectus.

Business overview

Strategy

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

- ***Target disorders that have a defined pathophysiology and that are amenable to treatment.*** We are focusing on disorders for which the pathophysiology is defined, 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 targeted administration.*** We are developing treatments for neurotology disorders based on targeted drug delivery. Where the target is inside the inner ear, such as in case of acute inner ear hearing loss or tinnitus, we employ intratympanic 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. Where the target is localized not only in the inner ear, but also in the brain, as in the case of vertigo, we are using a spray formulation for intranasal drug delivery to reach it more effectively than with oral administration.
- ***Leverage products into additional therapeutic indications.*** We consider our intranasal betahistine program as a platform on which various indications can be developed. The program started with project AM-125 for the treatment of acute vertigo and has been expanded with project AM-201 to address also the prevention of antipsychotic-induced weight gain. We see additional opportunities in other indications and seek to explore those for further indication expansions.
- ***Build an efficient commercial infrastructure to maximize the value of our product candidates.*** We intend to build commercial operations in select 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.

The Inner Ear

We have focused our drug discovery and development efforts on targeting the inner ear, which is comprised of the cochlea, the organ of hearing, and the vestibular system, the organ of balance. 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.

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 certain of our products via intratympanic 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.

The vestibular system communicates with the cochlea and consists of three semi-circular canals and the vestibule. It is responsible for the sensations of balance and motion. The vestibular system uses the same kinds of fluids and detection cells (hair cells) as the cochlea and sends information to the brain regarding the altitude, rotation, and linear motion of the head. The vestibular system works with the visual system to keep objects in view when the head is moved. Joint and muscle receptors are also important in maintaining balance. The brain receives, interprets, and processes the information from all these systems to create the sensation of balance.

When vestibular input from each ear is equal, the system is in balance, and there is no sense of movement. When inputs are unequal, the brain interprets this as movement. As a result, compensatory eye movements and postural adjustments occur to maintain balance. However, when some pathology (e.g., inflammation or trauma) disrupts signaling unilaterally, the result is an imbalance in vestibular input that can lead to vertigo.

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 the National Institute on Deafness and Other Communication Disorders, or NIDCD, approximately 10% of the U.S. adult population, or about 25 million Americans, have experienced tinnitus lasting at least five minutes in the past year. Additionally, according to a 2016 publication by Bhatt et al. in the journal JAMA Otolaryngology — Head and Neck Surgery, 21.4 million (9.6%) U.S. adults experienced tinnitus in the past 12 months.

The NIDCD also reports that 37.5 million Americans, or 15% of the adult U.S. population, report having some trouble hearing. Epidemiological studies reveal comparable prevalence rates for Europe. Additionally, according to a 2016 publication by Hoffman et al. in the journal JAMA Otolaryngology — Head and Neck Surgery, the annual prevalence of speech-frequency hearing loss among adults aged 20 to 69 years was 14.1% (27.7 million) in the 2011 – 2012 period. Furthermore, according to the NIDCD, more than four out of 10 Americans, at some point in their lives, experience an episode of dizziness significant enough to see a doctor. Approximately 615,000 individuals in the United States are currently diagnosed with Meniere's disease and 45,500 cases are newly diagnosed each year.

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.

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, tinnitus and vertigo 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. In case of vertigo, possible triggers include infection, inflammation, surgical trauma, disturbances of inner ear fluid balance or debris inside the inner ear. There has been a dearth of knowledge about the pathophysiology of tinnitus, hearing loss and vertigo, 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 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.
- ***Challenges with bioavailability.*** Betahistine, the active substance of AM-125 and also AM-201, has been used for decades for the treatment of vertigo. However, when administered orally, only small quantities of the drug actually reach the blood stream and can be distributed to the inner ear and the brain due to rapid and pronounced first pass metabolism. As a consequence of the low bioavailability, there has been significant variability in therapeutic outcomes.

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 targeted drug delivery to the inner ear reduces systemic exposure to our product candidates. We target specific types of tinnitus, hearing loss and vertigo that are addressable with drug-based therapies. We have worked with regulatory agencies to develop and validate acceptable clinical trial paradigms.

Our Localized Delivery Solution for the Inner Ear for the Treatment of Tinnitus and Hearing Loss

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 tinnitus or hearing loss 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 by intratympanic injection to maximize efficacy and minimize systemic side effects. With intratympanic 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 intratympanic 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 intratympanic delivery in mind.

One of the key shortcomings of current intratympanic 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 intratympanic injections we overcome this "draining off," facilitate contact with the RWM and achieve effective diffusion into the cochlea.

Both Keyzilen® and Sonsuvi® 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 physiologic or near-physiologic 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 Sonsuvi®, 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 intratympanic 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 intratympanic injection and it is well-accepted by patients. A billable procedure, intratympanic injection is routinely reimbursed under a broader reimbursement code. For the injection, patients lie on a stretcher or on a reclined exam chair, treated ear up; the injection is performed under local anesthesia of the eardrum by an ENT specialist using a microscope. Following the procedure, patients rest for 20 to 30 minutes to ensure maximum physical contact of the drug with the RWM. The tympanic membrane heals rapidly, usually within a few days, and the procedure may be performed several times. Often performed in children suffering from ear infections, the reversible opening of the eardrum is one of the most frequent ENT procedures.

Our Targeted Delivery Solution for the Treatment of Vestibular Disorders

In vestibular disorders, the target for pharmacologic intervention may not only be in the inner ear, but also in central parts of the vestibular system, i.e., the brain. In such case, a treatment may be best delivered systemically, provided that the active substance can reach these targets. Intranasal administration is a non-invasive route for drug delivery, which allows for drugs to be absorbed into the systemic circulation through the nasal mucosa. This route may be used in a range of acute or chronic conditions requiring considerable systemic exposure. It offers advantages such as ease of administration, rapid onset of action, and avoidance of first-pass metabolism.

Our Product Candidates

The following table summarizes our product development pipeline[(1)]:

Product	Indication	Preclin.	Phase 1	Phase 2	Phase 3	Next Key Milestones
AM-125 Betahistine	Vertigo					Start Phase 2 trial (Q1 2019)
AM-201 Betahistine	Antipsychotic-induced weight gain					Start PK/PD study (Q1 2019)
Sonsuvi® (AM-111) Brimapitide	ASNHL (sudden deafness)					Partnering
Keyzilen® (AM-101) Esketamine	Acute inner ear tinnitus					Reconfirming efficacy in Proof-of-concept study with objective tinnitus diagnostic
AM-102 Undisclosed	Tinnitus					Select lead compound

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

Keyzilen® in Tinnitus

Our clinical program with Keyzilen®, Esketamine gel for injection, is in Phase 3 clinical trials in acute inner ear tinnitus. Esketamine is a potent, small molecule non-competitive NMDA receptor antagonist. Keyzilen® is formulated in a biocompatible gel and delivered via intratympanic injection. It has demonstrated a favorable safety profile and positive effect on PROs associated with tinnitus in two Phase 2 clinical trials. The Phase 3 clinical development program comprised two pivotal clinical trials with highly similar design, one in North America (TACTT2) and one in Europe, which we refer to as TACTT3.

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 were 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 nerve fibers, 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 may become pathologically active, 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 — Keyzilen® (AM-101)

Therapeutic rationale for Keyzilen® in tinnitus

The API of Keyzilen® 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 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 Keyzilen® was able to suppress this type of tinnitus. Further pre-clinical work demonstrated that tinnitus could be suppressed even when drug was administered after the onset of tinnitus.

Toxicology and tolerability studies confirmed that Keyzilen® 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 Keyzilen® 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. 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 10 (“tinnitus extremely loud”). Among several tinnitus questionnaires, the 25 item TFI is one of 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, as described 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 Keyzilen® would 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 would serve as a co-primary efficacy endpoint in our TACTT2 trial in order to confirm the clinical meaningfulness of a reduction in tinnitus loudness.

Keyzilen® Clinical Development

Phase 1/2

We conducted the first clinical evaluation of Keyzilen® 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 (also called idiopathic sudden sensorineural hearing loss, or ISSNHL) and after unsuccessful steroid treatment. The primary objective of the trial was to evaluate the safety of intratympanically delivered Keyzilen®. This first clinical trial showed that single doses of intratympanically administered Keyzilen® 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, otitis media (OM), or ISSNHL, occurring not more than three months prior, and with a MML of at least 5 dB. Trial participants received three intratympanic administrations of Keyzilen® 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. Trial outcomes are described by van de Heyning and colleagues in a 2014 article in Otology & Neurotology.

In this trial, Keyzilen® 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 intratympanic injection procedure. These effects usually resolved with closure of the ear drum.

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, post-hoc efficacy analysis. based on PROs in the subgroup of patients with tinnitus caused by AAT or OM (n=118), that is, patients with well-established cochlear origin of tinnitus, demonstrated superiority of the high dose of Keyzilen® with respect to placebo for the change in the co-primary efficacy endpoint tinnitus loudness, sleep difficulties (e.g., falling asleep), and the THI-12 questionnaire from baseline to Day 90. When restricting the OM + AAT population to unilateral cases (71% of the subgroup), the treatment effects became more pronounced in these measures; in addition, the improvement in tinnitus annoyance also became nominally significant. 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 Keyzilen® 0.81 mg/mL group compared to 9% in the placebo group. 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. The improvements were dose dependent as the low-dose of Keyzilen® overall showed improvement between the high-dose and the placebo groups.

In case of ISSNHL related tinnitus, no treatment effects were evident as an unexpectedly high rate of spontaneous remission and substantial heterogeneity in outcomes were observed. 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, notably by evaluating efficacy trends with different treatment schemes and by obtaining additional data on concentrations of Esketamine and its primary metabolite in the bloodstream.

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 Keyzilen® at a dose level of 0.81 mg/mL or placebo. Unlike TACTT0, this trial allowed bilateral treatment where tinnitus was present in both ears. Subjective tinnitus loudness was selected as the primary efficacy measure, while the highly variable MML was monitored as a secondary read out.

As described by Staecker and colleagues in an article in Audiology & Neurotology in 2015, TACTT1 further confirmed the safety and tolerability outcomes observed in the preceding trials. It further demonstrated the gradual improvement in PROs in Keyzilen® treated groups that had already been observed in TACTT0. The primary efficacy analysis showed no statistically significant trend for improvement in subjective tinnitus loudness related to the number of injections.

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 observed differences suggest that repeated and concentrated application of Keyzilen® and hence concentrated inhibition of cochlear NMDA receptors provides superior treatment benefits. Over the two Phase 2 clinical trials, Keyzilen® 0.81 mg/mL showed a statistically significant improvement in the AAT and OM group of patients when compared against placebo.

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.

Keyzilen® Phase 3 Clinical Program

We have conducted two pivotal trials with Keyzilen® with highly similar designs, one in North America (TACTT2) and one in Europe (TACTT3). TACTT2 enrolled 343 patients, while TACTT3 Stratum A (Europe) has randomized 372 patients, both during the acute stage. Both trials were designed as a randomized, double-blind, placebo-controlled trial in acute inner ear tinnitus following traumatic cochlear injury or otitis media. Trial participants received three injections of Keyzilen® 0.87 mg/mL or placebo in a 3:2 ratio over three to five days and were followed for 84 days. The TACTT2 trial was conducted primarily in North America, the TACTT3 trial was conducted exclusively in Europe.

In addition, TACTT3 Stratum B explored the potential efficacy of Keyzilen® during the post-acute stage (tinnitus onset between three and 12 months) since data from our Phase 2 clinical program suggested that Keyzilen® might 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, TACTT3 Stratum B continued solely with enrollment of patients with tinnitus onset three to six months prior. In total, 369 patients were randomized in TACTT3 Stratum B pre- and post-interim analysis.

Two further trials, AMPACT1 and AMPACT2 (Keyzilen® in the Post-Acute Treatment of Peripheral Tinnitus) were nine-month open label extension trials conducted at the same sites as for TACTT2 and TACTT3. These extension trials were open to participants who completed the TACTT2 or the TACTT3

trial (the latter until summer 2016) and evaluated the safety and local tolerance of up to three treatment cycles, each with three repeated doses of Keyzilen® 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 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.

On August 18, 2016, we announced that the Phase 3 TACTT2 clinical trial did not meet the two co-primary efficacy endpoints of statistically significant changes in tinnitus loudness and the TFI questionnaire compared to placebo.

Baseline values for tinnitus loudness and TFI were 6.44 and 52.4 points in the Keyzilen® group, and 6.47 and 50.2 points in the placebo group. Treatment with Keyzilen® resulted in a reduction in tinnitus loudness of 0.63 points, compared to a reduction of 0.80 points for placebo (p-value of 0.321). With respect to tinnitus burden, treatment with Keyzilen® resulted in a 9.67 point reduction, as measured by the TFI, compared to a reduction of 10.63 points for placebo (p-value of 0.565). A reduction of 13 points as measured by the TFI was defined as clinically meaningful by the developers of the TFI. By convention, a p-value that is less than 0.05 is considered statistically significant.

Keyzilen® was well tolerated with no drug-related serious adverse events. The trial's primary safety endpoint, incidence of clinically meaningful hearing deterioration, was low with no statistically significant difference from the placebo group (p-value of 0.82), supporting the safety profile of Keyzilen®.

We believe we have identified two principal sources for the outcome: (i) the high frequency of tinnitus loudness ratings over an extended period of time and (ii) an unexpectedly high level of variability in outcomes among study sites. We believe the daily capture of tinnitus loudness and annoyance may have caused a number of patients to excessively focus on their tinnitus symptoms. With respect to variability, our analysis subsequent to the unblinding of the trial data has shown positive outcomes at numerous sites, including many of the high enrolling study centers, but inconclusive or contradictory outcomes at other sites.

However, the TACTT2 trial data show treatment effects on TFI in favor of Keyzilen® for specific subgroups. In the pre-specified subgroup of patients suffering from tinnitus following otitis media, treatment with Keyzilen® resulted in a reduction of 14.76 points in the TFI from baseline, as compared to 6.19 points for placebo (p-value of 0.048). In active-treated patients who suffered at baseline from severe or extreme tinnitus (a subgroup independent of tinnitus etiology that was not pre-specified), as determined by the Patient Global Impression of Severity, a 15.53 point reduction was observed, as compared to 11.48 points for placebo (p-value of 0.238).

Based on the outcomes from the TACTT2 trial, we amended our protocol for the TACTT3 Phase 3 clinical trial of Keyzilen® in two steps. Under the final, amended trial protocol, the change in TFI score was elevated from a key secondary endpoint to a primary efficacy endpoint, the trial size was increased to enhance statistical sensitivity to the effects of treatment, and the subgroup of patients with otitis media-related tinnitus was included in confirmatory statistical testing along with the overall study population. The change in tinnitus loudness was downgraded from a primary to a secondary efficacy endpoint. As in TACTT2, tinnitus loudness was initially rated on a daily basis; however, the rating frequency was subsequently reduced in between study visits in order to lighten the burden of patients and reduce the potential impact of the frequent measures. Enrollment into the TACTT3 trial was resumed in early 2017 and completed in September 2017.

On March 13, 2018, we announced that preliminary top-line data from the TACTT3 trial indicated that the study did not meet its primary efficacy endpoint of a statistically significant improvement in the Tinnitus Functional Score from baseline to Day 84 in the active treated group compared to placebo either in the overall population or in the otitis media subpopulation. This outcome was confirmed by further analyses. We consider that additional studies with Keyzilen® will be necessary to move the program forward, and that the way how outcomes are measured Keyzilen® will need to be improved in order to provide more robust efficacy data. We intend to fund further development of Keyzilen® either through partnerships or research grants.

Sonsuvi® (AM-111) in Hearing Loss

Sonsuvi® 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.

Sonsuvi® contains a synthetic D-form peptide (Brimapitide or D-JNKI-1) that protects sensorineural structures in the inner ear from stress-induced damage. Sonsuvi® has been granted orphan drug status by both EMA and FDA and has been granted fast track designation by the FDA for the treatment of sudden sensorineural hearing loss.

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. The latter is known as ISSNHL. Together they can be defined as 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.

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

Sensorineural 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 sensorineural 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 lists oral steroids and hyperbaric oxygen as treatment options, but refrains from recommending them in light of the low evidence level for their efficacy. Indeed, Nosrati-Zarenoe and Hultcrantz 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 — Sonsuvi® (AM-111)

We are developing Sonsuvi® as a treatment for acute inner ear hearing loss. Sonsuvi® 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 (Switzerland). Like Keyzilen®, Sonsuvi® is delivered in a biocompatible gel formulation via intratympanic injection. We have established the safety and preliminary efficacy of Sonsuvi® in a Phase 2 and in a Phase 3 clinical trial. The acute stage of hearing loss represents a window in time in which the inner ear can be protected from permanent hearing loss. Sonsuvi® received orphan drug designation by both EMA and FDA in 2005 and 2006, respectively, and was granted fast track designation by the FDA in 2017.

Therapeutic rationale for Sonsuvi® in hearing loss

The proprietary API of Sonsuvi® is brimapitide (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. Brimapitide comprises an active transporter sequence, or D-TAT, that enables Sonsuvi® 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. Sonsuvi® was shown to remain pharmacologically active for several days inside the cochlea. The D-form is necessary for Sonsuvi® to cross the RWM.

By attenuating inflammation and protecting cells from apoptosis, we believe that Sonsuvi® reinforces natural recovery processes and helps to prevent or minimize permanent damage respectively chronic hearing loss. Sonsuvi®'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 pre-clinical development program for Sonsuvi® in close collaboration with academic partners and various CROs. Brimapitide was invented by Xigen 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 pre-clinical 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.

Sonsuvi® Clinical Development

We have completed three clinical trials of Sonsuvi® that demonstrated its favorable safety profile and efficacy in treating more severe types of ASNHL. We have benefited several times from engaging in a protocol assistance procedure with the EMA and exchanges with the FDA. The design of our pivotal Phase 3 clinical trials was based on the outcomes from our Phase 2 clinical trial and our discussions with the EMA and FDA.

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 Sonsuvi® at either 0.4 mg/mL or 2 mg/mL in a biocompatible gel formulation by intratympanic injection into the most affected ear. The primary endpoint of the trial was the recovery of hearing thresholds from baseline to Day 30. Sonsuvi® was well tolerated by all trial participants, regardless of the dose. The Phase 1/2 trial provided the first indications of therapeutic benefit of Sonsuvi® in humans.

Phase 2 Clinical Trial

To further evaluate the efficacy and safety of Sonsuvi® we conducted a Phase 2b clinical trial between March 2009 and 2012. Since pre-clinical tests had demonstrated Sonsuvi®'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.

As described by Suckfuell and colleagues in an article in Otology & Neurotology in 2014, 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. Sonsuvi® 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 primary efficacy endpoint was hearing loss recovery from baseline to Day 7 at the three worst affected frequencies. The trial consisted of a baseline assessment and four follow-up visits on Days 3, 7, 30, and 90.

Sonsuvi® demonstrated a favorable safety profile 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 Sonsuvi® 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.

Overall, the trial did not meet its primary efficacy endpoint. Analysis of PTA improvement by hearing loss severity in accordance with a commonly used hearing loss classification revealed unexpectedly strong spontaneous recovery for lesser severities: by Day 7, placebo-treated patients enrolling with mild-to-moderate hearing loss (PTA < 60 dB) had recovered more than three quarters of their initial loss, whereas for patients with severe to profound hearing loss (PTA ≥ 60 dB), it was only about one quarter. Post-hoc analyses in the severe-to-profound hearing loss subgroup demonstrated superiority of Sonsuvi® 0.4 mg/mL over placebo for the primary endpoint, improvement in absolute PTA, as well as for co-primary efficacy endpoints, hearing improvement relative to the initial hearing loss and frequency of complete hearing recovery. Further, the improvement in word recognition scores was nominally significant as well as the frequency of complete tinnitus remission.

The Sonsuvi® 2.0 mg/mL group overall showed improvement between the Sonsuvi® 0.4 mg/mL and the placebo groups, without reaching statistical significance. However, differences between the two active treatment groups were nominally not significant.

Phase 3 Clinical Program

Based on Phase 2 clinical trial outcomes, we prepared and initiated a Phase 3 clinical program including confirmatory testing of Sonsuvi® 0.4 mg/mL as well as exploring potential incremental therapeutic benefits from a higher concentration (0.8 mg/mL) in ISSNHL patients. Since a “bell shaped” dose response curve was observed in animal studies, testing a concentration between 0.4 and 2.0 mg/mL was expected to shed further light on the dose effect relationship in humans. In view of the high spontaneous recovery in the mild to moderate hearing loss subgroup observed in Phase 2, recruitment was limited to patients experiencing severe or profound ISSNHL, i.e. patients with more pronounced medical need. Further, the time window for inclusion was extended from up to 48 hours to up to 72 hours from ISSNHL onset as the magnitude of the therapeutic effect in Phase 2 did not appear to decrease the later treatment was started. This enlargement also aligned the duration of the time window with the period over which ISSNHL can develop, which is defined, e.g. by the U.S. practice guideline for sudden sensorineural hearing loss, as 72 hours.

The first Phase 3 trial, called HEALOS, started enrollment in November 2015. The trial enrolled a total of 256 patients in several European and Asian countries. On November 28, 2017, we announced that the HEALOS Phase 3 clinical trial that investigated Sonsuvi® in the treatment of acute inner ear hearing loss did not meet the primary efficacy endpoint of a statistically significant improvement in hearing from baseline to Day 28 compared to placebo for either active treatment groups in the overall study population. However, a post-hoc analysis of the subpopulation with profound acute hearing loss (PTA ≥ 90 dB at baseline in accordance with a commonly used classification of hearing loss severity) revealed a clinically meaningful and nominally significant improvement in the Sonsuvi® 0.4 mg/mL treatment group. Further, patients treated with Sonsuvi® 0.4 mg/mL showed a nominally significantly lower incidence of no hearing improvement compared to placebo by Day 91 as well as a superior improvement in word recognition score. Outcomes with Sonsuvi® 0.8 mg/mL tended to be somewhat less pronounced than those observed for Sonsuvi® 0.4 mg/mL. Sonsuvi® was well tolerated and the primary safety endpoint was met.

Together with the outcomes of the HEALOS trial, we announced that ASSENT, the second Phase 3 clinical trial investigating Sonsuvi®, was terminated early in order to avoid the need for substantial protocol changes and interruptions of enrollment pending feedback from health authorities on the regulatory pathway. ASSENT was planned to enroll a total of 300 patients in the US, Canada and South Korea. In contrast to HEALOS and the Phase 2 trial, where patients with insufficient hearing recovery had the option of receiving a course of oral corticosteroids as reserve therapy, all patients in ASSENT would receive oral corticosteroids as a background therapy. At the time of early termination, the ASSENT trial had recruited 56 patients.

Based on the HEALOS results, we submitted the design of a new pivotal trial with AM-111 0.4 mg/mL in patients suffering from acute profound hearing loss to the EMA and subsequently also to the FDA for review. Through a Protocol Assistance procedure the EMA endorsed the proposed trial design, choice of efficacy and safety endpoints, as well as the statistical methodology. In a Type C meeting with written responses, the proposed choice of primary and secondary efficacy endpoints, the safety endpoints, as well as the planned sample size and statistical methodology were also endorsed by the FDA. Following this

feedback, we have mandated a transaction advisory firm to identify potential partners for the Sonsuvi® development program and provide support for partnering discussions and negotiations. If successful, this may result in one or several sale, out-licensing or co-development transaction(s) on a global or regional scale.

AM-125 in Vestibular Disorders

Vestibular Disorders

Balance disorders are medical conditions that evoke the sensation of unsteadiness, dizziness or vertigo. Patients suffering from balance disorders are often profoundly impacted in their daily activities. According to the NIDCD, more than four out of 10 Americans, at some point in their lives, experience an episode of dizziness significant enough to see a doctor. According to research by Saber Tehrani and colleagues published in the journal Academic Emergency Medicine in 2013 there are almost 4 million emergency room visits per year in the U.S. for problems of dizziness or vertigo. Balance problems can be caused by many different health conditions, medications or anything that affects certain areas of the brain or the inner ear labyrinth. Balance disorders originating from the inner ear labyrinth include benign paroxysmal positional vertigo, or positional vertigo, labyrinthitis, vestibular neuronitis and Meniere's disease, a chronic condition characterized by severe episodic vertigo, tinnitus, and fluctuating hearing loss.

In case of vertigo, patients experience a false sensation of movement of oneself or the environment. This can be a spinning or wheeling sensation, or they simply feel pulled to one side. This may lead to imbalance, nausea or vomiting. The cause of vertigo can be an imbalance between the left and right vestibular systems in signaling position and acceleration to the brain. The symptom of vertigo may partially or fully resolve thanks to spontaneous recovery of the peripheral vestibular function and/or through compensation of the imbalance at the brain level, which is known as vestibular compensation.

The imbalance between the left and right vestibular systems and thus the sensation of vertigo may be reduced by dampening the vestibular function in the unaffected, opposite inner ear through pharmacotherapy. This minimizes the extent of the imbalance falsely interpreted as movement. Most existing therapies rely on this strategy to minimize vertigo symptoms, but also have unintended sedative effects. Examples include meclizine, benzodiazepines, dimenhydrinate or amitriptyline.

Betahistine is widely used around the world for the treatment of vestibular disorders, notably Meniere's disease and vertigo. Its development goes back to the use of intravenous histamine, which provided symptomatic relief for these disorders. Betahistine is a structural analog of histamine. It acts as a partial histamine H1-receptor agonist and, more powerfully, as a histamine H3-receptor antagonist. Betahistine has been shown to increase cochlear, vestibular and cerebral blood flow, facilitate vestibular compensation and inhibit neuronal firing in the vestibular nuclei. Unlike other drugs, it has no sedating effect. Betahistine is typically taken orally with a recommended daily dose of 24 to 48 mg, divided in 2 or 3 single doses.

Betahistine is generally recognized as a safe drug and there exists a large body of data on the pharmacology, pharmacokinetics and toxicology of the compound. It is approved in about 115 countries world-wide for the treatment of Meniere's disease and vestibular vertigo, but not in the United States. In 1970, the Commissioner of FDA withdrew approval of the NDA after the discovery that the submission contained unsubstantiated information about some patients in the efficacy studies upon which approval was based. Today, betahistine is available in the United States only from compounding pharmacies or through importation. Despite limited availability, a survey by Clyde and colleagues published in Otology & Neurotology in 2017 revealed that 56% of U.S. neurotologists and 16% of generalists use betahistine and 20 – 30% of neurotologists use it often or always when treating patients with Meniere's disease.

Various studies and meta-analyses have demonstrated therapeutic benefits of betahistine in both the treatment of vertigo as well as in supporting vestibular rehabilitation. However, the evidence for therapeutic benefits is variable, and it has been suggested that efficacy could be increased with higher doses and/or longer treatment periods. It is well known that orally administered betahistine is rapidly and almost completely metabolized into 2-pyridylacetic acid, also known as 2-PAA, which lacks pharmacological activity. As a consequence the bioavailability of oral betahistine is estimated to be very low.

Our Solution — AM-125

On February 2, 2017, we entered into an asset purchase agreement with Otifex, pursuant to which we have purchased various assets related to betahistine dihydrochloride in a spray formulation, which we intend to develop for intranasal treatment of vertigo under the name AM-125.

The assets include data from a randomized placebo controlled dose escalating Phase 1 clinical trial in 40 healthy volunteers. The trial demonstrated good tolerability of intranasal betahistine and significantly higher betahistine concentrations in blood plasma than reported for oral betahistine administration. Comparing the betahistine concentrations in plasma with those from an independent Phase 1 clinical trial with oral betahistine showed a relative bioavailability (dose adjusted) for intranasal administration that was 20 – 40 times higher than with oral administration. In 2018, we conducted a second Phase 1 clinical trial with AM-125 in healthy volunteers. The trial showed superior bioavailability (unadjusted) over a range of four intranasal betahistine doses compared to oral betahistine observed, with plasma exposure being 6 to 29 times higher (p-value between 0.056 and $p < 0.0001$). Further, it confirmed the good safety profile of intranasal betahistine and showed that the treatment was well tolerated when administered three times daily for three days.

We have discussed the regulatory requirements for AM-125 during a Pre-IND meeting with the FDA and in the context of scientific advice meetings with the EMA and two European national health authorities to further define the development program. We believe that, if approved, AM-125 could become the first betahistine product for the treatment of vertigo in the United States.

In 2019, we plan to initiate a randomized placebo-controlled Phase 2 clinical study with AM-125 in the first quarter. The “TRAVERS” Phase 2 trial will enroll 138 patients suffering from acute vertigo following surgical removal of a vestibular schwannoma, a tumor growing behind the inner ear. It will be conducted in several European countries and potentially, Canada. The TRAVERS trial will have two parts: In Part A, five ascending doses of AM-125 or placebo, administered three times daily over a total of four weeks, will be tested in a total of 50 patients. In addition, oral betahistine 48 mg will be tested in 16 patients under open-label conditions for reference. Based on an interim analysis, two doses will be selected and tested in an estimated 72 patients in Part B.

AM-201 in Antipsychotic-Induced Weight Gain

Antipsychotic-induced weight gain

The use of second generation antipsychotic drugs such as olanzapine or clozapine can be associated with severe side effects such as weight gain, metabolic dysregulation and somnolence. These side effects not only have a negative effect on patients’ compliance with medication, but expose them to additional hazards: weight gain is strongly correlated with metabolic dysregulation leading to diabetes and cardiovascular disease; and somnolence may severely impact quality of life, affecting learning, social interactions or tasks such as driving or operating machinery. These adverse events are mainly attributed to the histamine H1 receptor antagonistic properties of these agents. Treatment with these antipsychotic drugs reduces the activity of the H1 receptor, which in turn causes increased eating and weight gain.

According to the U.S. prescription information for olanzapine, accumulated evidence shows that patients gain on average 2.6 kg over a treatment duration of 6 weeks. During long-term treatment (≥ 48 weeks) patients gain on average 5.6 kg as shown in a review published by Citrome and colleagues published in the journal Clinical Drug Investigations in 2011. Over that time period, 64%, 32%, and 12% of patients treated with olanzapine gain at least 7%, 15%, or 25% of their baseline body weight, respectively.

The concerns about antipsychotic-induced weight gain and consequent metabolic changes have led the FDA to highlight these risks as warnings in the prescribing information of certain antipsychotics and call for regular monitoring of glycemic control, lipid profile and weight. These concerns are also reflected in treatment guidelines, which do not recommend olanzapine or clozapine as first-line treatments, despite the fact that meta-analyses such as one by Leucht and colleagues published in 2013 in the journal Lancet show that they are among the most effective treatments for schizophrenia.

Our Solution — AM-201

On May 15, 2018, we announced the expansion of our intranasal betahistine development program beyond the treatment of vertigo into mental health supportive care indications. Under project code AM-201 we intend to develop intranasal betahistine for the prevention of antipsychotic-induced weight gain. Betahistine is thought to counteract the effects of antipsychotics such as olanzapine and to relieve the inhibitory effect on the H1 receptor by binding to and activating the H1 receptor to normalize/reduce the food take and consequently lead to reduced weight gain. We believe the weight-attenuating effect is intensified by betahistine's property as antagonist at the H3 receptor. We have discussed our development plan for AM-201 with the FDA during a Pre-IND meeting. In its written response, the FDA supported the planned conduct of a multiple dose Phase 1 trial with AM-201 administered to healthy subjects in combination with olanzapine to evaluate the pharmacokinetics, pharmacodynamics, and safety, and to establish proof-of-concept. Further, the FDA endorsed weight gain normalized to baseline body weight versus placebo as reasonable primary efficacy endpoint for a subsequent Phase 2 trial.

We expect to initiate the Phase 1b proof-of-concept trial with AM-201 in the first quarter of 2019. The randomized double blind placebo controlled trial will be conducted in a European country and enroll 50 healthy volunteers who will receive either AM-201 or placebo concomitantly with olanzapine over four weeks. Doses will be escalated in five steps. We expect to conclude the study and obtain results during 2019.

Competition

We may face competition from different sources with respect to our product candidates Keyzilen® (AM-101), Sonsuvi® (AM-111), AM-125 and AM-201 and our other 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 Keyzilen® and Sonsuvi® 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. A variety of drug products that are licensed or used off-label for the treatment of vestibular disorders and Meniere's disease exist, including steroids, diuretics, anti-emetics or anti-nausea medications. In many countries outside the United States, oral betahistine is the standard of care and licensed for the treatment of Meniere's disease and vestibular vertigo.

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 hearing loss or vertigo. 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 pre-clinical 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 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 the following drug product candidates that are currently in clinical development:

- 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. Following an interim analysis, Autifony announced in October 2015 that it would halt enrollment in its Phase 2 trial due to a lack of efficacy.
- Otonomy Inc. acquired an early stage NMDA receptor antagonist product candidate (NST-001, gacyclidine) from Neurosystec Inc. in October 2013. According to public information, Otonomy intends to develop a polymer-based formulation of gacyclidine for the treatment of tinnitus that will provide a full course of treatment from a single intratympanic injection. OTO-311 has been evaluated in a Phase 1 trial. Following a change in formulation, Otonomy is planning to initiate a Phase 1/2 trial with the modified drug product OTO-313 in 2019.

Based on publicly available information, OTO-313 will target a similar group of tinnitus patients. Its competitive strength will ultimately depend on the demonstration of clinical efficacy and safety and its comparison with Keyzilen®. Progress in the development of Keyzilen® 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.

Acute inner ear hearing loss

There are a number of product candidates in pre-clinical 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 the following drug product candidates that are currently in clinical development:

- Autifony Therapeutics Ltd. has a Kv3 potassium channel agonist product candidate (AUT00063) that is designed for oral administration. Autifony conducted a Phase 2 trial with AUT00063 in the treatment of speech-in-noise deficits in elderly patients. Autifony announced in August 2016 that the study showed no treatment benefit for AUT00063. In July 2016, the company announced a pilot trial with AUT00063 in adult cochlear implant users in the United Kingdom.
- GenVec, Inc. is developing CGF166, E1-, E3-, E4-deleted human adenovector serotype 5 (Ad5) backbone in collaboration with Novartis and has initiated a Phase 1/2 study for the treatment of hearing loss and vestibular dysfunction. The first patient was treated in October 2014.
- Nordmark, a German company, is developing Ancrod, the biologically active substance from the venom of the Malayan Pit Viper (Calloselasma rhodostoma), for the treatment of sudden sensorineural hearing loss and has initiated a Phase 2 program.
- Sound Pharma has a product candidate (SPI-1005, ebselen), that mimics and prompts production of the enzyme glutathione peroxidase and is designed for oral administration. In a Phase 2 clinical trial SP-1005 was tested for the prevention of noise-induced hearing loss in young adults. The study showed a reduction in the temporary hearing threshold that in one dose was better by 2.75 dB than in the placebo group.
- 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 completed in December 2015. A Phase 2 clinical trial is under preparation.
- Sensorion, a French company, is developing SENS-401 (R-azasetron besylate) for the treatment of sudden sensorineural hearing loss by way of oral administration. The company plans to initiate a Phase 2 trial in 2019. Sensorion has received orphan drug designation by the EMA for sudden sensorineural hearing loss.

- 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.

- Strekin AG, a privately held Swiss company, has an agonist of the peroxisome proliferator (STR001) that it plans to develop for surgery induced haring loss. A Phase 2 trial was initiated in 2016. Strekin has received orphan drug designation by the EMA for sudden sensorineural hearing loss.

We believe that Sonsuvi® is the only product candidate administered after an incidence of acute hearing loss that so far has demonstrated in a randomized, placebo controlled clinical trial a clinically relevant and significant improvement in hearing. 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 the United States. 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.

Vestibular Disorders

There are a number of product candidates in clinical development by third parties that aim to prevent or treat vertigo. Based on publicly available information, we have identified the following drug product candidates that are currently in clinical development:

- Otonomy is developing a polymer-based formulation for the steroid dexamethasone (Otividex; OTO-104) for patients with Meniere's disease. In August 2017 Otonomy announced that a Phase 3 clinical trial conducted in the United States had failed to show a treatment effect of OTO-104 against placebo and that a European Phase 3 clinical trial was terminated early. In November 2017 the company announced that the European study showed a statistically significant reduction in the count of definitive vertigo days.

- Sensorion is developing SENS-111, a histamine H_4 receptor antagonist, for the oral treatment of acute vertigo crises. A Phase 2 trial started enrolling patients with acute unilateral vestibulopathy in 2017. Results are expected in the second half of 2019.

- Sound Pharma has a product candidate (SPI-1005, ebselen), that mimics and prompts production of the enzyme glutathione peroxidase and is designed for oral administration. In October 2017 Sound Pharmaceuticals announced a Phase 2 clinical trial with SP-1005 to treat patients with Meniere's disease.

The aforementioned developments have the potential to compete with AM-125. Likewise, AM-125, if approved, will compete with products that are licensed or used off-label for the treatment of vestibular disorders and Meniere's disease, including steroids, diuretics, anti-emetics or anti-nausea medications as well as oral betahistine, the standard of care for treatment of Meniere's disease and vestibular vertigo outside the United States. Although we expect that AM-125 will offer benefits over oral betahistine due to the ability to bypass the strong first-pass metabolism associated with oral intake and provide for a higher bioavailability and avoid gastric side effects, it may take time to change prescribing and usage patterns in favor of the newer product.

Antipsychotic-induced weight gain

There are a number of product candidates in clinical development by third parties that aim to prevent or treat antipsychotic-induced weight gain. Based on publicly available information, we have identified the following drug product candidates that are currently in clinical development:

- ALKS-3831 is a fixed-dose combination of olanzapine and samidorphan, a novel opioid system modulator, which is being developed by Alkermes Inc. with the specific aim of providing the therapeutic benefits of olanzapine with less weight gain than olanzapine monotherapy. On November 29, 2018 Alkermes announced that the ENLIGHTEN-2 phase 3 trial with ALKS-3831

had met its coprimary endpoints of mean % body weight change from baseline and % of patients with ≥10% weight gain. The reported reduction in weight gain over 6 months was 37% versus olanzapine monotherapy. and that the company expects to file for an NDA in mid-2019.

If approved, ALKS-3831 will reach the market well before AM-201. We believe that our product may provide various benefits over ALKS-3831, notably that it does not come in a fixed dose combination, allowing for dosing flexibility, and that it may be used with other antipsychotic drugs than olanzapine.

As weight gain is associated with immediate metabolic side effects it is advisable to prevent antipsychotic-induced weight gain rather than seek to treat the overweight once it has developed. Weight monitoring, dietary and lifestyle changes as well as behavioral and cognitive counseling present the most effective non-pharmacologic ways to prevent and also treat antipsychotic weight gain. Pharmacologic approaches include the switch to an alternative antipsychotic treatment strategy, which however can be associated with a loss of efficacy or the appearance of other side effects. Limited evidence for efficacy with metformin as an exploratory adjuvant to prevent antipsychotic-induced weight gain has been demonstrated.

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.

As of December 31, 2018, we own five issued U.S. patents and five pending U.S. patent applications along with foreign counterparts of particular patents and applications in various jurisdictions. We co-own four 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 one of our pending applications with Xigen pursuant to the terms of our collaboration and license agreement.

In addition, as of December 31, 2018, we have exclusively licensed from Xigen eleven issued U.S. patents and two 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 ASNHL.

With respect to our issued patents in the United States, 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.

Keyzilen®

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 four issued U.S. patents and

one 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 Keyzilen® are expected to expire between 2024 and 2028, prior to any patent term extensions to which we may be entitled under applicable laws.

Sonsuvi®

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 twelve issued U.S. patents and three 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 Sonsuvi® 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 Sonsuvi® 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 December 31, 2018, any resulting litigation could result in substantial legal expenses and potentially the loss of our right to commercialize Sonsuvi®.

Intranasal Betahistine

We have acquired one patent from Otifex directed to intranasal application of betahistine for Eustachian tube dysfunction that is issued in the United States. In addition, we purchased from Otifex a patent application on the composition and use of intranasal betahistine. Further, we acquired in 2018 two U.S. patents relating to the use of betahistine for the prevention and treatment of olanzapine induced weight gain, and we entered into a binding letter of intent to acquire the right to in-license two U.S. patents relating to the use of betahistine for the treatment of attention deficit/hyperactivity disorder and atypical depression.

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 U.S.

Janssen, a subsidiary of Johnson & Johnson, has been testing Esketamine in a spray formulation for intranasal treatment of treatment-resistant depression in several clinical trials to date, and completed a Phase 3 program. In November 2014, the FDA designated Esketamine a 'breakthrough therapy' for this indication. In the event that Janssen receives marketing authorization prior to us receiving marketing authorization for Keyzilen®, we would lose the potential benefit of a five year market exclusivity period that we would otherwise expect to obtain.

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 Sonsuvi® 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. In addition, we have acquired a U.S. orphan drug designation for betahistine for the treatment of obesity associated with Prader-Willi syndrome.

We have obtained U.S. trademark registrations for Auris, Auris Medical, Auris Medical Cochlear Therapies (and Design), Keyzilen® and Sonsuvi®. Further, we have obtained several U.S. trademark registrations for betahistine.

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 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 Keyzilen®. 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 Keyzilen®, 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 Keyzilen® 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, 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 API for Sonsuvi® 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 Sonsuvi®. 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.

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 Keyzilen®, Sonsuvi®, AM-125 and AM-201. 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 and neurology, 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 FDA, under the Federal Food, Drug, and Cosmetic Act, 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 pre-clinical laboratory tests and animal tests conducted under GLP regulations;
- the submission to the FDA of an 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 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.

Pre-clinical 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 pre-clinical 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 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 pre-clinical 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 pre-clinical, 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, 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, pre-clinical 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.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to a drug intended to treat a rare disease or condition, which is a disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000, there is no reasonable expectation that sales of the drug in the United States will be sufficient to offset the costs of developing and making the drug available in the United States. Orphan drug designation must be requested before submitting an NDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

If the FDA approves a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition for which it was designated, the sponsor is eligible for a seven-year period of marketing exclusivity, during which the FDA may not approve another sponsor's marketing application for a drug with the same active moiety and intended for the same use or indication as the approved orphan drug, except in limited circumstances, such as if a subsequent sponsor demonstrates its product is clinically superior. During a sponsor's orphan drug exclusivity period, competitors, however, may receive approval for drugs with different active moieties for the same indication as the approved orphan drug, or for drugs with the same active moiety as the approved orphan drug, but for different indications. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for a drug with the same active moiety intended for the same indication before we do, unless we are able to

demonstrate that grounds for withdrawal of the orphan drug exclusivity exist, such as that our product is clinically superior. Further, if a designated orphan drug receives marketing approval for an indication broader than the rare disease or condition for which it received orphan drug designation, it may not be entitled to exclusivity.

Special FDA Expedited Review and Approval Programs

The FDA has various programs, including rare pediatric disease and breakthrough therapy designations, which are intended to expedite or simplify the process for the development and FDA review of drugs that are intended for the treatment of serious or life threatening diseases or conditions and demonstrate the potential to address unmet medical needs. The purpose of these programs is to provide important new drugs to patients earlier than under standard FDA review procedures.

Rare pediatric disease, or RPD, designation by the FDA enables priority review voucher, or PRV, eligibility upon U.S. market approval of a designated drug for rare pediatric diseases. The RPD-PRV program is intended to encourage development of therapies to prevent and treat rare pediatric diseases. The voucher, which is awarded upon NDA or Biologics License Application, or BLA, approval to the sponsor of a designated RPD can be sold or transferred to another entity and used by the holder to receive priority review for a future NDA or BLA submission, which reduces the FDA review time of such future submission from ten to six months.

Breakthrough therapy designation is for a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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 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.

The federal Drug Supply Chain Security Act imposes obligations on manufacturers of pharmaceutical products, among others, related to product tracking and tracing. 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.

Organizational structure

The registrant corporation, Auris Medical Holding AG, has four wholly-owned subsidiaries which are each listed in Exhibit 21.1 to the registration statement of which this prospectus forms a part. We primarily operate our business out of our operating subsidiary Auris Medical AG.

Property, plants and equipment

Our headquarters are in Zug, Switzerland. We also lease approximately 5,900 square feet of office space in Basel, Switzerland. This property serves as the corporate headquarters of our principal operating subsidiary.

Employees

As of January 25, 2019, we had 11 employees (9.6 full time equivalents). None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We consider our relations with our employees to be good.

Legal Proceedings

From time to time we may become involved in legal proceedings that arise in the ordinary course of business. During the period covered by the financial statements contained herein, we have not been a party to or paid any damages in connection with litigation that has had a material adverse effect on our financial position.

On July 20, 2015, the USPTO declared Patent Interference No. 106,030 involving our issued U.S. patent No. 9,066,865 (the "'865 Patent") and Otonomy's U.S. patent application No. 13/848,636 (the "'636 Application"). The patent interference identified claims 1-9 in the '865 Patent as interfering with claims 38, 43 and 46-50 of the '636 Application. The '865 Patent discloses methods of treating inner or middle ear diseases with intratympanic injections of poloxamer-based compositions. The claims of the '865 Patent are directed to the use of fluoroquinolone antibiotics in poloxamer 407 compositions under certain specifications. On January 26, 2017, the USPTO issued a decision on the interference granting Auris benefit of priority. As a result of the decision, judgment was entered against Otonomy and all claims in the '636 Application were refused. In addition, claims 1-8 of the '865 Patent were cancelled as the result of the USPTO's determination that the written description of the specification lacked full scope support for treating middle or inner ear disease with fluoroquinolone. However, claim 9, which is directed to a method of treating viral and bacterial infections with intratympanic injection of a fluoroquinolone antibiotic in a poloxamer 407 composition under certain specifications, was affirmed. On March 27, 2017, Otonomy submitted a notice of appeal to the United States Court of Appeals for the Federal Circuit. To preserve its rights, Auris filed a notice of cross-appeal on April 5, 2017. Otonomy subsequently filed its opening brief on July 20, 2017, and Auris filed its principal and response brief on October 27, 2017. On January 5, 2018, Otonomy filed its opposition and reply brief. Auris filed its reply brief on February 2, 2018. On August 1, 2018, the United States Court of Appeals for the Federal Circuit reversed the USPTO Patent Trial and Appeal Board's determination of priority in our favor relating to the July 2015 USPTO declaration of patent interference (No. 106,030) involving our issued '865 Patent and the '636 Application. We believe that this ruling will not materially impact any of our development programs.

MANAGEMENT

No Change in Management or Our Board of Directors

Our executive officers and board of directors (including the membership of the committees of our board of directors) will remain the same upon effectiveness of the Redomestication. Our directors have been elected for a one year term and, accordingly, the term will expire at the time of our 2019 annual general meeting. The following table presents information about our executive officers and directors.

Name	Position	Age	Initial Year of Appointment
Executive Officers			
Thomas Meyer	Chairman, Director and Chief Executive Officer	51	2003
Hernan Levett	Chief Financial Officer	43	2017
Non-Executive Directors			
Armando Anido	Director	61	2016
Mats Blom	Director	53	2017
Alain Munoz	Director	68	2018
Calvin W. Roberts	Director	66	2015

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 of the Board of Directors 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.

Hernan Levett, Chief Financial Officer: Mr. Levett joined the Company on January 1, 2017 as Chief Financial Officer. Prior to joining Auris Medical, Mr. Levett served as Head of Group Controlling at Acino Pharma AG. Prior to Acino, he served as Vice President of Finance and Administration Europe at InterMune International AG and spent 10 years at Novartis, most recently as Chief Financial Officer of Novartis Chile SA. Mr. Levett is a certified public accountant and holds an accounting degree from the University of Buenos Aires, Argentina.

Non-Executive Directors

Armando Anido, Director, Chairman of the Compensation Committee: Mr. Anido has been a member of our board of directors since April 2016. Mr. Anido has more than 30 years of executive, operational and commercial leadership experience in the biopharmaceutical industry. He serves as Chairman and Chief Executive Officer of Zynerba Pharmaceuticals, Inc., since October 2014. Prior to Zynerba, Mr. Anido served as Chief Executive Officer of NuPathe, Inc., and Auxilium Pharmaceuticals, Inc. Prior to Auxilium, Mr. Anido held commercial leadership roles at MedImmune, Glaxo Wellcome and Lederle Labs. He was a member of the board of directors and Chairman of the Compensation Committee of Aviragen Therapeutics (until it merged with Vaxart). He was a member of the board of directors of Adolor Corporation until it was sold to Cubist Pharmaceuticals. Mr. Anido holds a BS in Pharmacy and an MBA from West Virginia University.

Mats Blom, Director: Mats Blom has been a member of our board of directors since April 2017. Mr. Blom is Executive Vice President and Chief Financial Officer (CFO) of Zealand Pharma A/S. Prior to joining Zealand, he served as CFO of Swedish Orphan International, an orphan drug company acquired by BioVitrum in 2009. In addition, Mr. Blom has extensive managerial experience and has held CFO positions at Active Biotech AB and Anoto Group AB. Previously, he served as a management consultant at Gemini Consulting and Ernst & Young. Mats Blom holds a BA in Business Administration and Economics from the University of Lund and an MBA from IESE University of Navarra, Barcelona.

Alain Munoz, Director: Mr. Munoz, MD, has been a member of our board of directors since March 2018 and previously served on our board of directors between 2007 and 2015. Mr. Munoz is an entrepreneur and independent management consultant in the pharmaceutical and biotechnology industry. From 1990 to 2000, Dr. Munoz worked with the Fournier Group, as Research and Development Director and then Senior Vice President of the Pharmaceutical Division. He joined Fournier from Sanofi Research, where he started as Director in the cardiovascular and anti-thrombotic products department and then as Vice President international development. Dr. Munoz is qualified in cardiology and anesthesiology from the University Hospital of Montpellier, France where he was head of the clinical cardiology department. He has been a member of the Scientific Committee of the French drug agency. He is advisor to Kurma partners and serves on the Board of Valneva SA (VLA.PA), Hybrigenics S.A. (ALHYG.PA) and Zealand Pharma A/S. (ZEAL.CO).

Calvin W. Roberts, Director: Mr. Roberts, MD, has been a member of our board of directors since April 2015. Mr. Roberts is Chief Medical Officer at Bausch + Lomb and Senior Vice President and Chief Medical Officer, Eye Care of Valeant Pharmaceuticals. He joined Bausch + Lomb in 2011. Dr. Roberts is a specialist in cataract and refractive surgery and has been a pioneer in the use of ophthalmic non-steroidals. Since 1982 he has been a Clinical Professor of Ophthalmology at Weill Medical College of Cornell University. In addition, he had a private ophthalmology practice in New York City between 1998 and 2008 and is the author of over 50 peer-reviewed articles. Dr. Roberts has been a member of the board of directors and the Audit Committee of Alimera Sciences, Inc., since it was founded in 2003.

Board Composition and Election of Directors

Our board of directors is currently composed of five members. 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 March 12, 2018 for a one-year term ending at the next general meeting of shareholders. The election of directors at the extraordinary meeting of shareholders prior to the Merger were implemented by the surviving company on March 13, 2018, following the consummation of the Merger.

We are a foreign private issuer. As a result, in accordance with the Nasdaq stock exchange listing requirements, we comply with country governance requirements and certain exemptions thereunder rather than the Nasdaq stock exchange corporate governance requirements.

Committees of the Board of Directors

Audit Committee

The audit committee, which consists of Mats Blom, Alain Munoz 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. Blom serves as chairman of the committee. The audit committee consists exclusively of members of our board of directors who are financially literate, and Mr. Blom is considered an “audit committee financial expert” as defined by the SEC. Our board of directors has determined that Mr. Blom, Mr. Munoz 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 Armando Anido and Alain Munoz, assists our board of directors in overseeing our cash compensation and equity award recommendations for our executive officers along with the rationale for such recommendations, as well as summary information regarding the aggregate compensation provided to our 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

For the year ended December 31, 2017, 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 2,310,786 (2016: CHF 2,235,682).

For the year ended December 31, 2017, 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 94,839 (2016: CHF 88,838).

Compensation awarded to the board of directors in 2017

The total compensation of the members of the board of directors in 2017 is outlined below:

(in CHF)	Cash Compensation	Social Contributions	Stock Options[4]	Total
Thomas Meyer, PhD, Chairman[1]	—	—	—	**—**
Armando Anido, MBA	50,105	3,119	11,371	**64,595**
Mats Blom, MBA[2]	34,336	—	11,371	**45,707**
Alain Munoz, MD[3]	n/a	n/a	n/a	**n/a**
Calvin W. Roberts, MD	48,018	2,989	11,371	**62,378**
Total	**132,459**	**6,108**	**34,113**	**172,680**

(1) Disclosed under "Compensation Awarded to Our Executive Officers" below. The Chief Executive Officer does not receive any additional compensation for the exercise of the office of the Chairman.

(2) Elected on April 13, 2017.

(3) Mr. Munoz was elected on March 12, 2018.

(4) In 2017, 53,140 options were granted to each eligible member of the board of directors. The fair value calculation of the options was based on the Black-Scholes option pricing model. Assumptions were made regarding inputs such as volatility and the risk-free rate in order to determine the fair value of the options.

Compensation awarded to our executive officers in 2017

The total compensation and the highest individual compensation to our executive officers in 2017 are outlined below:

(in CHF)	Fixed Cash Compensation	Variable Compensation[3]	Social contributions and fringe benefits	Stock Options[4]	Total
Thomas Meyer, PhD, Chief Executive Officer[1]	363,600	—	60,490	127,895	551,958
Executive Officers Total[2]	**1,277,638**	**155,118**	**238,948**	**301,463**	**1,973,167**

(1) Highest paid executive.

(2) On December 31, 2017, we had three executive officers. Dr. Zoller and Dr. Jung retired from their functions as executive officers effective as of April 30, 2017 and December 31, 2017, respectively. Mr. Levett was appointed an executive officer effective as of January 1, 2017. The compensation to the retired executive officers for their services in 2017 is included in the executive officer total compensation.

(3) The variable compensation is paid in cash. Dr. Meyer waived his short-term incentive for 2017.

(4) 2017 option grants. The fair value calculation of the options was based on the Black-Scholes option pricing model. Assumptions were made regarding inputs such as volatility and the risk-free rate in order to determine the fair value of the options.

Employment Agreements

We have entered into employment agreements with our executive officers Thomas Meyer and Hernan Levett. 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 seven days 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 and a 12 month non-compete period following the end of employment in our agreement with Mr. Levett.

None of our directors has 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

Equity Incentive Plan

In August 2014, as amended in April 2017, we established an equity incentive plan (the "Equity Incentive Plan" or "EIP") 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. As of March 13, 2018, following the consummation of the Merger, the maximum number of shares available for issuance under the EIP was 915,000 common shares. The option exercise price for options under the EIP 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. The EIP was assumed by Auris NewCo following the Merger.

Plan administration. The EIP is administered by our compensation committee. Approval of the committee is required for all grants of awards under the EIP. 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 director, 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 EIP.

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 EIP provides that upon a change of control of the Company (as defined in the EIP) 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 EIP). 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 EIP subject, in certain circumstances, to required shareholder approval or the consent of an affected participant.

Indemnification

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. We also have entered into indemnification agreements with each of the members of our board of directors and executive officers in the form filed as Exhibit 4.3 to this Annual Report.

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.

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, 2017, there were 50,000 common shares underlying outstanding Options granted pursuant to Plan A and 121,250 common shares underlying outstanding Options granted pursuant to Plan C. There are no outstanding Options under Plan B, which was abolished in 2015. Following our initial public offering, we ceased issuing any new grants under 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. Plan A and Plan C were assumed by Auris NewCo following the Merger.

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.

Option Exercise Price. The exercise price of each Option is set forth in the applicable option agreement. As of March 13, 2018, following the consummation of the Merger, the exercise prices for currently granted and unexercised Options range from USD 8.20 to USD 59.80.

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. Options granted under Plan A vested and became immediately exercisable upon the closing of our initial public offering. Under Plan C, Options vest four years after grant.

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 February 8, 2019 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 February 8, 2019 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 February 8, 2019 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 February 8, 2019, 31,294,920 common shares, or approximately 83.46%, were 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 37,495,859 common shares issued and outstanding as of February 8, 2019. The number of outstanding common shares reflect the 10:1 “reverse share split” effected through the Merger. Each common share confers the right on the holder to cast one vote at a general meeting of shareholders and no shareholder has different voting rights.

	Shares Beneficially Owned	
Shareholder	**Number**	**Percent**
5% Shareholders		
Rosalind Advisors, Inc.[1]	2,050,489	5.54%
Executive Officers and Directors		
Thomas Meyer, Ph.D.[2]	8,986,219	23.97%
Armando Anido, M.B.A[3]	6,064	*
Mats Blom, M.B.A.[4]	5,314	*
Alain Munoz[5]	2,082	*
Calvin W. Roberts, M.D.[6]	12,589	*
Hernan Levett, CPA	—	—

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

(1) Based on a Schedule 13G filed with the SEC on August 10, 2018 by Rosalind Advisors, Inc., Rosalind Master Fund L.P. and Steven Salamon. Consists of 2,050,489 common shares held by Rosalind Advisors, Inc., Rosalind Master Fund L.P. and Steven Salamon. The address for Rosalind Advisors, Inc. and Steven Salamon is 175 Bloor Street East Suite 1316, North Tower Toronto, Ontario M4W 3R8, Canada and the address for Rosalind Master Fund L.P. is P.O. Box 309 Ugland House, Grand Cayman KY1-1104, Cayman Islands.

(2) Consists of 6,205,438 common shares, warrants to purchase 2,761,928 common shares, options to purchase 6,000 common shares under the Company's Plan C, and options to purchase 12,853 common shares under the Company's Long Term Equity Incentive Plan (the "EIP").

(3) Consists of options to purchase common shares under the Company's EIP.

(4) Consists of options to purchase common shares under the Company's EIP.

(5) Consists of 1,250 common shares owned by Alain Munoz, options to purchase an additional 50 common shares under the Company's Plan C, and 782 options to purchase common shares under the Company's EIP.

(6) Consists of 1,525 common shares jointly owned by Calvin W. Roberts and Andrea Colvin Roberts. Also, consists of 2,000 common shares held by Calvin W. Roberts, MD PC Pension Plan, 1,000 common shares held by The David Roberts Trust and 1,000 common 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 and The Joanna Roberts Trust. Also, consists of options to purchase an additional 7,064 common shares under the Company's EIP.

Holders

As of February 8, 2019, we had seven shareholders of record of our common shares.

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 public offerings. 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%), the ZKB Funds (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. In May 2015, we completed a public offering of 5,275,000 common shares. In February 2017, we completed a public offering of 10,000,000 common shares and warrants to purchase 7,000,000 common shares. In January 2018, we completed a public offering of 12,499,999 common shares and a concurrent offering of warrants to purchase 7,499,000 common shares. While none of our existing shareholders sold common shares in the public offerings, certain shareholders purchased common shares in certain of the public offerings. The percentage ownership held by certain shareholders decreased as a result of the issuance of the common shares sold by us in the public offerings.

Additionally, in February/March 2018 (prior to the Merger), Sofinnova Capital VII FCPR sold 2,000,000 of our common shares and in April/May 2018 Sofinnova Venture Partners VIII, L.P. sold all of our common shares beneficially held by it.

Related Party Transactions

The following is a description of related party transactions we have entered into since January 1, 2017 with any of our members of our board of directors or management and the holders of more than 5% of our common shares.

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

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.

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. 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.

Controlled Equity Offering^{SM}

Thomas Meyer, our Chief Executive Officer, or the Share Lender, entered into a share lending agreement with Cantor to facilitate the timely settlement of common shares sold under the Controlled Equity Offering Sales Agreement with Cantor. Pursuant to the terms of the share lending agreement, the Share Lender would lend common shares to Cantor so that those common shares could be delivered by Cantor to purchasers of common shares sold in any offering under the Controlled Equity Offering Sales Agreement. Cantor would return common shares to the Share Lender upon the issuance of new common shares by us to Cantor. Neither we nor the Share Lender received any compensation for this arrangement. In the year ended December 31, 2017, we did not offer or sell any common shares under the Controlled Equity Offering Sales Agreement. The Controlled Equity Offering program terminated upon consummation of the Merger on March 13, 2018.

Merger

Thomas Meyer, our Chief Executive Officer, entered into a shares transfer agreement with us to facilitate the rounding up of fractional shares resulting from the exchange ratio used in the Merger. Pursuant to the terms of the share transfer agreement, Mr. Meyer committed to transfer, at no consideration, a common share to any shareholder entitled to a fraction of a common share as part of the Merger. Pursuant to the share transfer agreement, neither we nor Mr. Meyer received any compensation for this arrangement. Any expenses incurred by Mr. Meyer in connection with the transfers under such agreement were borne by us.

EXPENSES OF THE OFFERING

We estimate that our expenses in connection with this offering will be as follows:

EXPENSES	AMOUNT
U.S. Securities and Exchange Commission registration fee	$ 524
Stamp Duty	$34,853
Legal fees and expenses	$30,000
Accounting fees and expenses	$10,000
Total	$75,377

All amounts in the table are estimates except the U.S. Securities and Exchange Commission registration fee. The Company will pay all of the expenses of this offering.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

The Company

We are registered with the commercial register of the canton of Zug, Switzerland, under the company number CHE-474.294.374. We and our subsidiaries are together referred to as the "Group." Our purpose as stated in article 2 of our articles of association is to participate in business organizations of all kinds in Switzerland and abroad, particularly in relation to pharmaceutical products and services. Moreover, the Company may transact any business conducive to developing the Company or furthering the Company's purpose.

The Company may also arrange financing for its own or third party account, in particular it may grant loans to companies of the Group or to third parties, as well as guarantees or surety bonds of any sort for obligations towards companies of the Group. These loans or guarantees may also be granted without any remuneration or compensation. The Company may in addition participate in cash-pooling operations within the Group.

Share Capital

As of January 25, 2019, our issued fully paid-in share capital consists of CHF 749,917.19, divided into 37,495,859 common shares with a nominal value of CHF 0.02 each and no preferred shares.

Articles of Association

Unless otherwise indicated or the context otherwise requires, when we refer to our amended and restated articles of association dated as of January 24, 2019.

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. 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.

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 loans, warrants, convertible bonds or other financial market instruments issued by 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 Swiss Code of Obligations, or 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 a purpose set forth in our articles of association.

Our Authorized Share Capital

The relevant provision of the articles of association was adopted on January 17, 2019 (article 3a of the articles of association) and reads as follows (translation of the binding original German version):

"*The Board of Directors is authorized at any time until 16 January 2021 to increase the share capital by a maximum aggregate amount of CHF 326,122.66 through the issuance of not more than 16,306,133 registered shares, which will have to be fully paid-in, with a nominal value of CHF 0.02 each.*

Increases in partial amounts are permitted. The Board of Directors may issue new shares also by means of underwriting or in any other manner by one or more banks and subsequent offer to shareholders or third parties. The Board of Directors determines the type of contributions, the issue price, the time of the issue, the conditions for the exercise of the pre-emptive rights, the allocation of pre-emptive rights which have not been exercised, and the date on which the dividend entitlement starts. The Board of Directors is authorized to permit, to restrict or to deny the trade with pre-emptive rights.

If pre-emptive rights are granted, but not exercised, the Board of Directors may use the respective shares in the interest of the Corporation.

The Board of Directors is authorized to restrict or to exclude the pre-emptive rights of the shareholders, and to allocate them to third parties or to the Corporation, in the event of use of the shares for the purpose of: a) 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; b) granting an over-allotment option ("greenshoe") to one or several underwriters in connection with a placement of shares; c) share placements, provided the issue price is determined by reference to the market price; d) the participation of employees, Members of the Board of Directors or consultants of the Corporation or of one of its Group companies according to one or several equity incentive plans issued by the Board of Directors; e) the acquisition of companies, company assets, participations, the acquisition of products, intellectual property rights, licenses or new investment projects or for public or private share placements for the financing and/or refinancing of such transactions; f) for raising equity capital in a fast and flexible manner as such transaction would be difficult to carry out, or could be carried out only at less favorable terms, without the exclusion of the pre-emptive rights of the existing shareholders; or g) the acquisition of a participation in the Corporation by a strategic partner (including in the case of a public takeover offer)."

Within the limits of Swiss law, the general meeting of shareholders may increase or alter the authorization granted to the board of directors. See "— Ordinary Capital Increase, Authorized and Conditional Share Capital."

To effect any capital increase based on our authorized share capital in connection with any subscription by LPC, the Company will have to follow the relevant procedures under Swiss law. In particular, the Company's board of directors will have to approve a general authorization resolution

(*Ermächtigungsbeschluss*), issue a capital increase report (*Kapitalerhöhungsbericht*), approve a notarized confirmation resolution (*Feststellungsbeschluss*) on the capital increase and the articles of association, and obtain (i) duly executed subscription form(s) covering the subscription of the relevant number of new shares, (ii) a report of an audit firm relating to the withdrawal of the pre-emptive rights, as well as (iii) a banking confirmation confirming the payment of the aggregate nominal value of the respective number of new shares to a special Swiss bank account, all in accordance with Swiss law. The Company's board of directors will subsequently have to file the relevant documentation accompanied by an application form with the competent commercial register. Any issuance of common shares based on such filing(s) is subject to the recording of the respective capital increase(s) in the commercial register in accordance with Swiss law.

Our Conditional Share Capital

Conditional Share Capital for Financing Purposes

The relevant provision of the articles of association was adopted on January 17, 2019 (article 3b of the articles of association) reads as follows (translation of the binding original German version):

"The Corporation's share capital shall be increased by a maximum aggregate amount of CHF 293,510.40 through the issuance of not more than 14,675,520 registered shares, which will have to be fully paid-in, with a nominal value of CHF 0.02 each, by the exercise of option and conversion rights which are granted in connection with bonds, similar obligations, loans or other financial market instruments or contractual obligations of the Corporation or one of its Group companies, and/or by the exercise of option rights issued by the Corporation or one of its Group companies ("Financial Instruments"). The pre-emptive rights of shareholders are excluded. The holders of Financial Instruments are entitled to the new shares. The conditions of the Financial Instruments shall be determined by the Board of Directors.

When issuing Financial Instruments the Board of Directors is authorized to limit or exclude the advance subscription rights of shareholders:

a) for the purpose of financing or refinancing the acquisition of enterprises, divisions thereof, or of participations, products, intellectual property rights, licenses, cooperations or of newly planned investments of the Corporation;

b) if the issue occurs on domestic or international capital markets including private placements; or

c) for purposes of an underwriting of the Financial Instruments by a banking institution or a consortium of banks with subsequent offering to the public.

To the extent that the advance subscription rights are excluded, i) the Financial Instruments are to be placed at market conditions; ii) the exercise period, the conversion period or the exchange period of the Financial Instruments may not exceed 10 years as of the date of the issue; and iii) the conversion price, the exchange price or other exercise price of the Financial Instruments must be determined by reference to the market price."

Conditional Share Capital for Equity Incentive Plans

The relevant provision of the Articles of Association was adopted on January 17, 2019 (last paragraph of article 3b of the articles of association) and reads as follows (translation of the binding original German version):

"The Corporation's share capital shall, to the exclusion of the pre-emptive rights and advance subscription rights of shareholders, be increased by a maximum aggregate amount of CHF 32,612.26 through the issuance of not more than 1,630,613 registered shares, which shall be fully paid-in, with a nominal value of CHF 0.02 each, by issuance of shares upon the exercise of options or pre-emptive rights thereof, which have been issued or granted to employees, Members of the Board of Directors or consultants of the Corporation or of one of its Group companies according to one or several equity incentive plans or regulations issued by the Board of Directors. The details shall be determined 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. If registered in our 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.

Participation Certificates and Profit Sharing Certificates

The Company has not issued any non-voting equity securities, such as participation certificates (*Partizipationsscheine*) or profit sharing certificates (*Genussscheine*), nor has it issued any preference shares (*Vorzugsaktien*).

No Additional Capital Contributions

Under Swiss law, shareholders are not obliged to make any capital contribution in excess of the subscription amount.

General Meeting of Shareholders

Ordinary/Extraordinary Meetings and 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; and
- 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 registered 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; and
- 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 presence 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 presence 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. The notice period for a general meeting of shareholders may be waived if all shareholders are present or represented at such 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 are 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. The Board of Directors issues the regulations on the determination of shareholder status, on proxies and voting instructions, and on the issue of voting cards.

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.

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 usufructuary 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 usufructuary 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. Any acquirer of our shares who is not registered in our share register as a shareholder with voting rights will still be entitled to dividends and other rights with financial value with respect to such shares.

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 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.

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). 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.

In addition, under Swiss law, the sale of "all or substantially all of our assets" by us may require the approval of two-thirds of the number of shares represented at a general meeting shareholders and the absolute majority of the nominal value of the shares represented. Whether a shareholder resolution is required depends on the particular transaction, including whether the following test is satisfied:

- a core part of the Company's business is sold without which it is economically impracticable or unreasonable to continue to operate the remaining business;
- the Company's assets, after the divestment, are not invested in accordance with the Company's statutory business purpose; and
- the proceeds of the divestment are not earmarked for reinvestment in accordance with the Company's business purpose but, instead, are intended for distribution to the Company's shareholders or for financial investments unrelated to the Company's business.

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. Under Swiss law, a member of the Board of Directors is not required to be a shareholder.

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, to the extent required for the governance of the Company;
- 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;
- 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; and
- 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 13 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 into indemnification agreements with each of the members of our board of directors and executive management. The indemnification agreements and our articles of association require us to indemnify our directors and executive officers to the fullest extent permitted by law.

Conflict of Interest, Management Transactions

Swiss law does not provide for 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 has adopted a Code of Business Conduct and Ethics that covers 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, our shareholders must annually resolve on the approval of 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 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; and

- 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.

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; and

- 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 and Other Limitations on the Rights to Own Securities

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.

Swiss law and/or our articles of association do not impose any restrictions on the exercise of voting or any other shareholder right by shareholders resident outside Switzerland.

Notification and Disclosure of Substantial Share Interests

The disclosure obligations generally applicable to shareholders of Swiss corporations under the Swiss Financial Market Infrastructure Act 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 Capital Market under the symbol “EARS.”

The Depository Trust Company

Initial settlement of any common shares to be issued pursuant to this prospectus will take place 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.

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

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
	shareholder whose claim has been dismissed to recover attorneys' fees incurred to the extent he acted in good faith.
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 of 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 shareholders 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 (including the chairman) and the members of the compensation committee individually for a term of office of one year. Re-election is possible.
Indemnification of directors and executive management and limitation of liability	
The Delaware General Corporation Law provides that a certificate of incorporation may contain a provision eliminating or limiting the personal liability of directors (but not other controlling persons) of the corporation for monetary damages for breach of a fiduciary duty as a director, except no provision in the certificate of incorporation may eliminate or limit the liability of a director for: • any breach of a director's duty of loyalty to the corporation or its shareholders; • acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; • statutory liability for unlawful payment of dividends or unlawful stock purchase or redemption; or • 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	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
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. 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	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 interest of the corporation. He must not use his corporate position for personal gain or advantage.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
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 a breach of one of the fiduciary duties. 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.	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.
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 (directly or through a proxy) and may not act by written consent.
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: • 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 • 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),

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
	(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 (including the chairman) for a term of office of one year (i.e. until the following annual general meeting) is mandatory for listed Swiss corporations.
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. The articles of association may provide for a qualified majority 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 (but only by way of a resolution with the majority stipulated by law).

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
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.	By way of a public deed, the articles of association of a Swiss corporation may be amended with a resolution passed by an absolute majority of the shares represented at such meeting, unless otherwise provided in the articles of association. There are a number of resolutions, such as an amendment of the stated purpose of the corporation and the introduction of authorized and conditional capital, that require the approval by two-thirds of the votes and an absolute majority of the nominal value of the shares represented at a shareholders' meeting. The articles of association may increase the voting thresholds.
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. The inspection right is limited in scope and only extends to information required for the exercise of shareholder rights and does not extend to confidential information. 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: • out of its surplus, or • in case there is no such surplus, out of its net profits for the fiscal year in which the	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

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
dividend is declared and/or the preceding fiscal year. Shareholder approval is required to authorize capital stock in excess of that provided in the charter. Directors may issue authorized shares without shareholder approval.	dividends are not allowed and 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 requires a shareholders' resolution documented by way of a public deed. 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.

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 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 Auris Medical Holding AG

Auris Medical Holding AG is a Swiss based company, taxed as a holding company in the Canton of Zug. The company is taxed at a current effective income tax rate of 7.83% (including direct federal as well as cantonal/communal taxes), whereby a participation relief applies to dividend income from qualifying participations, and a current annual capital tax rate of 0.003% which is levied on the net equity of the Company.

Switzerland is currently in the process of reforming certain elements of its corporate tax law which may impact the taxation of Auris Medical Holding AG (including the abolition of the holding privilege at cantonal/communal level). Whether and when such new rules will enter into force is not known.

Swiss Federal Withholding Tax on Dividends and Other 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 redemption of common shares in the Company may under certain circumstances (in particular, if the common shares in the Company are redeemed for subsequent cancellation) be taxed as a partial liquidation for Swiss federal withholding tax purposes, with the consequence that the difference between the repurchase price and the nominal value of the shares (*Nennwertprinzip*) plus capital contribution reserves (*Reserven aus Kapitaleinlagen*) is subject to Swiss federal withholding tax.

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 Swiss 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, on January 1, 2017 Switzerland implemented the agreement with the European Community regarding the Automatic Exchange of Information in Tax Matters. This agreement contains in its Article 19 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.

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 share capital of the Company. All Swiss cantons 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 share capital of the Company. All cantons 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 participation 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 nominal 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 neither are 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 or warrants 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 or warrants 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 or warrants 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 or warrants 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 or Warrants

Swiss resident individuals who sell or otherwise dispose of the common shares or warrants realize a tax-free capital gain, or a non-deductible capital loss, as the case may be, provided that they hold the common shares or warrants, as applicable, as part of their private assets. Under certain circumstances, the sale proceeds may be requalified into taxable investment income (e.g., if the taxpayer is deemed to be a professional securities dealer).

Capital gains realized on the sale of the common shares or warrants held by Swiss resident individuals, Swiss resident corporate taxpayers as well as non-Swiss resident individuals and corporate taxpayers holding the common shares or warrants 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 share capital of the Company).

Swiss resident corporate taxpayers as well as non-Swiss resident corporate taxpayers holding the common shares or warrants 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

represent at least 10% of the Company's share capital or if the common shares sold give entitlement to 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 acquisition costs of the participation (*Gestehungskosten*).

Individuals and corporations not resident in Switzerland for tax purposes and not holding the common shares or warrants 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 or warrants.

Gift and Inheritance Tax

Transfers of common shares or warrants 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 is subject to paying to the Swiss Federal Tax Administration a 1% Swiss federal issuance stamp tax (*Emissionsabgabe*) on any increase of the nominal share capital of the Company (with or without issuance of shares) or any other equity contributions received by the Company (regardless of whether or not any compensation is paid to the shareholder in connection with the contribution). Certain costs incurred in connection with the issuance of shares (if any) may be deductible. There are several exemptions from issuance stamp tax that may apply under certain circumstances (e.g., certain intercompany reorganizations).

Swiss Securities Transfer Tax

The purchase or sale (or other financial transfer) 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%, 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.

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to 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 the 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 a 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 straddle, wash sale, or conversion 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 the vote or value of our 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 non-U.S. 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 2018 taxable year, and we expect to be a PFIC for our current taxable year and for the foreseeable future. In addition, we may, directly or indirectly, hold equity interests in other PFICs, or Lower-tier PFICs. In general, a non-U.S. corporation will be considered a PFIC for any taxable year in which (i) 75% or more of its gross income consists of passive income or (ii) 50% or more of the average quarterly value of its assets consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains.

Under attribution rules, assuming 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 if the U.S. Holder has not received the proceeds of those distributions or dispositions.

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 U.S. 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, if any, 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 U.S. 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 our common shares are "regularly traded" on a "qualified exchange," a U.S. Holder may make a mark-to-market election with respect to the shares that would result in tax treatment different from the general tax treatment for PFICs described above. Our 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 and the consequences to them if the common shares are delisted from Nasdaq (see "Risk Factors"). 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 U.S. 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 U.S. Holder's tax basis in the common shares will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on a sale or other disposition of common shares in a year in which 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 U.S. 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 its 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 that 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 U.S. 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 U.S. Holder's income under the QEF Election will not be taxable to the U.S. 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 its 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 its 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 with respect to a particular U.S. Holder we are 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 will not apply.

If we are a PFIC for any taxable year during which a U.S. Holder holds common shares, such U.S. Holder will 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 on Common Shares

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 PFIC 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 U.S. dollar amount of any 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.

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 withholding 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 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.

PLAN OF DISTRIBUTION

The common shares offered by this prospectus is being offered by the selling shareholder. The common shares may be sold or distributed from time to time by the selling shareholder directly to one or more purchasers or through brokers, dealers, or underwriters who may act solely as agents at market prices prevailing at the time of sale, at prices related to the prevailing market prices, at negotiated prices, or at fixed prices, which may be changed. The sale of the common shares offered by this prospectus could be effected in one or more of the following methods:

- ordinary brokers' transactions;
- transactions involving cross or block trades;
- through brokers, dealers, or underwriters who may act solely as agents;
- "at the market" into an existing market for the common shares;
- in other ways not involving market makers or established business markets, including direct sales to purchasers or sales effected through agents;
- in privately negotiated transactions; or
- any combination of the foregoing.

In order to comply with the securities laws of certain states, if applicable, the common shares may be sold only through registered or licensed brokers or dealers. In addition, in certain states, the common shares may not be sold unless they have been registered or qualified for sale in the state or an exemption from the state's registration or qualification requirement is available and complied with.

LPC is an "underwriter" within the meaning of Section 2(a)(11) of the Securities Act.

LPC has informed us that it intends to use an unaffiliated broker-dealer to effectuate all sales, if any, of the common shares that it may purchase from us pursuant to the Purchase Agreement. Such sales will be made at prices and at terms then prevailing or at prices related to the then current market price. Each such unaffiliated broker-dealer will be an underwriter within the meaning of Section 2(a)(11) of the Securities Act. LPC has informed us that each such broker-dealer will receive commissions from LPC that will not exceed customary brokerage commissions.

Brokers, dealers, underwriters or agents participating in the distribution of the common shares as agents may receive compensation in the form of commissions, discounts, or concessions from the selling shareholder and/or purchasers of the common shares for whom the broker-dealers may act as agent. The compensation paid to a particular broker-dealer may be less than or in excess of customary commissions. Neither we nor LPC can presently estimate the amount of compensation that any agent will receive.

We know of no existing arrangements between LPC and any other shareholder, broker, dealer, underwriter or agent relating to the sale or distribution of the common shares offered by this prospectus. At the time a particular offer of shares is made, a prospectus supplement, if required, will be distributed that will set forth the names of any agents, underwriters or dealers and any compensation from the selling shareholder, and any other required information.

We will pay the expenses incident to the registration, offering, and issuance of the common shares to LPC. We have agreed to indemnify LPC and certain other persons against certain liabilities in connection with the offering of shares of common shares offered hereby, including liabilities arising under the Securities Act or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities. LPC has agreed to indemnify us against liabilities under the Securities Act that may arise from certain written information furnished to us by LPC specifically for use in this prospectus or, if such indemnity is unavailable, to contribute amounts required to be paid in respect of such liabilities.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers, and controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is therefore, unenforceable.

LPC has represented to us that at no time prior to the Purchase Agreement has LPC or its agents, representatives or affiliates engaged in or effected, in any manner whatsoever, directly or indirectly, any short sale (as such term is defined in Rule 200 of Regulation SHO of the Exchange Act) of our common shares or any hedging transaction, which establishes a net short position with respect to our common shares. LPC agreed that during the term of the Purchase Agreement, it, its agents, representatives or affiliates will not enter into or effect, directly or indirectly, any of the foregoing transactions.

We have advised LPC that it is required to comply with Regulation M promulgated under the Exchange Act. With certain exceptions, Regulation M precludes the selling shareholder, any affiliated purchasers, and any broker-dealer or other person who participates in the distribution from bidding for or purchasing, or attempting to induce any person to bid for or purchase any security which is the subject of the distribution until the entire distribution is complete. Regulation M also prohibits any bids or purchases made in order to stabilize the price of a security in connection with the distribution of that security. All of the foregoing may affect the marketability of the securities offered by this prospectus.

Our common shares are listed on the Nasdaq Capital Market under the symbol “EARS.”

LEGAL MATTERS

The validity of the common shares and certain other matters of Swiss law will be passed upon for us by Walder Wyss Ltd., Zurich, Switzerland. Certain matters of U.S. federal and New York State law will be passed upon for us by Lowenstein Sandler LLP, New York, New York.

EXPERTS

The consolidated financial statements as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017 included in this Prospectus, have been audited by Deloitte AG, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements have been so 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.

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 directors, executive officers and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

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Condensed Consolidated Interim Statement of Profit or Loss and Other Comprehensive Income or Loss (unaudited)

For the Three and Nine Months Ended September 30, 2018 and 2017 (in CHF)

	Note	Three months ended September 30		Nine months ended September 30	
		2018	2017	2018	2017
			(in CHF)		
Research and development		(1,697,045)	(4,221,324)	(6,654,666)	(14,925,642)
General and administrative		(1,170,244)	(1,336,217)	(3,629,665)	(3,997,373)
Operating loss		**(2,867,289)**	**(5,557,541)**	**(10,284,331)**	**(18,923,015)**
Interest income		—	7,788	—	53,563
Interest expense	4	(123,038)	(416,956)	(979,195)	(1,248,400)
Foreign currency exchange (loss)/gain, net		(114,011)	1,650	(179,925)	(929,386)
Revaluation gain/loss from derivative financial instruments	4, 5	223,904	(55,613)	4,131,862	1,705,018
Transaction costs	5	(108,809)	—	(520,125)	(506,234)
Loss before tax		**(2,989,243)**	**(6,020,672)**	**(7,831,714)**	**(19,848,454)**
Income tax gain	3	8,726	8,191	26,179	24,573
Net loss attributable to owners of the Company		**(2,980,517)**	**(6,012,481)**	**(7,805,535)**	**(19,823,881)**
Other comprehensive income:					
Items that will never be reclassified to profit or loss					
Remeasurement of defined benefit liability, net of taxes of CHF 0.00		209,760	94,463	1,294,862	378,100
Items that are or may be reclassified to profit or loss					
Foreign currency translation differences, net of taxes of CHF 0.00		5,913	(4,594)	(13,116)	55,316
Other comprehensive income, net of taxes of CHF 0.00		**215,673**	**89,869**	**1,281,746**	**433,416**
Total comprehensive loss attributable to owners of the Company		**(2,764,844)**	**(5,922,612)**	**(6,523,789)**	**(19,390,465)**
Basic and diluted loss per share	8	(0.14)	(1.36)	(0.71)	(4.65)

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

Condensed Consolidated Interim Statement of Financial Position (unaudited)

As of September 30, 2018 and December 31, 2017

	Note	September 30, 2018	December 31, 2017
		(in CHF)	
ASSETS			
Non-current assets			
Property and equipment		44,948	252,899
Intangible assets		1,663,763	1,629,100
Derivative financial instruments		252,351	—
Other non-current financial assets		15,996	76,710
Total non-current assets		**1,977,058**	**1,958,709**
Current assets			
Other receivables		309,143	241,281
Prepayments		507,329	652,913
Cash and cash equivalents		5,257,881	14,973,369
Total current assets		**6,074,353**	**15,867,563**
Total assets		**8,051,411**	**17,826,272**
EQUITY AND LIABILITIES			
Equity			
Share capital	5	481,322	19,349,556
Share premium		141,338,018	114,648,228
Foreign currency translation reserve		(46,163)	(33,047)
Accumulated deficit		(142,514,194)	(136,126,946)
Total shareholders' equity attributable to owners of the Company		**(741,017)**	**(2,162,209)**
Non-current liabilities			
Loan	4	—	5,584,297
Derivative financial instruments	4, 5	1,085,089	1,836,763
Employees benefits		850,746	1,962,970
Deferred tax liabilities	3	152,630	178,809
Total non-current liabilities		**2,088,465**	**9,562,839**
Current liabilities			
Loan	4	2,144,235	4,542,109
Trade and other payables		1,115,102	1,200,820
Accrued expenses		3,444,626	4,682,713
Total current liabilities		**6,703,963**	**10,425,642**
Total liabilities		**8,792,428**	**19,988,481**
Total equity and liabilities		**8,051,411**	**17,826,272**

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

Condensed Consolidated Interim Statement of Changes in Equity (unaudited)

As of September 30, 2018 and 2017 (in CHF)

	Note	Attributable to Owners of the Company				
		Share Capital	Share Premium	FX Translation Reserve	Accumulated Deficit	Total Equity
				(in CHF)		
As of January 1, 2017		**13,731,881**	**112,838,815**	**(83,544)**	**(112,344,303)**	**14,142,849**
Total comprehensive loss						
Net loss		—	—	—	(19,823,881)	**(19,823,881)**
Other comprehensive income		—	—	55,316	378,100	**433,416**
Total comprehensive income		**—**	**—**	**55,316**	**19,445,781**	**19,390,465**
Transactions with owners of the Company						
Transaction costs		—	(397,685)	—	—	**(397,685)**
Share based payments	7	—	—	—	259,561	**259,561**
Capital increase		4,000,000	907,841	—	—	**4,907,841**
Balance at September 30, 2017	**5**	**17,731,881**	**113,348,971**	**(28,228)**	**(131,530,523)**	**(477,899)**
As of January 1, 2018		**19,349,556**	**114,648,228**	**(33,047)**	**(136,126,946)**	**(2,162,209)**
Total comprehensive loss						
Net loss		—	—	—	(7,805,535)	**(7,805,535)**
Other comprehensive (loss)/income		—	—	(13,116)	1,294,862	**1,281,746**
Total comprehensive (loss)/income		**—**	**—**	**(13,116)**	**(6,510,673)**	**(6,523,789)**
Transactions with owners of the Company						
Reorganization of group structure	5	(24,347,208)	24,347,208	—	—	**—**
Transaction costs	5	—	(1,084,109)	—	—	**(1,084,109)**
Share based payments	7	—	—	—	123,425	**123,425**
Capital increase	5	5,478,974	3,426,691	—	—	**8,905,665**
Balance at September 30, 2018	**5**	**481,322**	**141,338,018**	**(46,163)**	**(142,514,194)**	**(741,017)**

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

Condensed Consolidated Interim Statement of Cash Flows (unaudited)

For the Nine Months Ended September 30, 2018 and 2017 (in CHF)

	Note	Nine months ended September 30, 2018	Nine months ended September 30, 2017
		(in CHF)	
Cash flows from operating activities			
Net loss		**(7,805,535)**	**(19,823,881)**
Adjustments for:			
Depreciation		61,661	96,011
Unrealized foreign currency exchange (gain)/loss, net		(70,673)	906,191
Net interest expense		965,096	1,181,897
Loss on disposal of property and equipment		78,133	—
Share based payments	7	108,399	259,561
Transaction costs		520,125	506,234
Employee benefits		182,638	100,995
Fair value derivative financial instruments		(4,131,862)	(1,705,018)
Deferred tax gain	3	(26,179)	(24,573)
		(10,118,197)	**(18,502,583)**
Changes in:			
Other receivables		(7,148)	34,644
Prepayments		145,584	505,140
Trade and other payables		(85,718)	(687,671)
Accrued expenses		(1,238,087)	823,109
Net cash used in operating activities		**(11,303,566)**	**(17,827,361)**
Cash flows from investing activities			
Proceeds from disposal of property and equipment		68,160	—
Purchase of intangibles		(19,638)	(146,580)
Interest received		—	53,563
Net cash used in/from investing activities		**48,522**	**(93,017)**
Cash flows from financing activities			
Proceeds from public offering	5	12,285,854	9,321,807
Transaction costs		(1,856,585)	(227,422)
Repayment of loan	4	(8,204,072)	(1,025,042)
Interest paid		(402,847)	(905,353)
Net cash from financing activities		**1,822,350**	**7,163,990**
Net (decrease) in cash and cash equivalents		**(9,432,694)**	**(10,756,388)**
Cash and cash equivalents at beginning of the period		14,973,369	32,442,222
Net effect of currency translation on cash		(282,794)	(1,487,419)
Cash and cash equivalents at end of the period		**5,257,881**	**20,198,415**

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

AURIS MEDICAL HOLDING AG

Notes to the Condensed Consolidated Interim Financial Statements
As of September 30, 2018 and December 31, 2017 and for the Three and Nine Months Ended September 30, 2018 and 2017 (in CHF)

1. Reporting entity

Auris Medical Holding AG, previously named Auris NewCo Holding AG, (the "Company" or "Auris NewCo") is a corporation (Aktiengesellschaft) organized in accordance with Swiss law and domiciled in Switzerland and was established on March 13, 2018. On March 13, 2018, Auris NewCo Holding AG merged (the "Merger") with Auris Medical Holding AG ("Auris OldCo"), a corporation (Aktiengesellschaft) organized in accordance with Swiss law and domiciled in Switzerland. The Merger took place following Auris OldCo shareholder approval at an extraordinary general meeting of shareholders held on March 12, 2018. Auris NewCo Holding AG changed its name to Auris Medical Holding AG following consummation of the Merger. Following the Merger, the Company had a share capital of CHF 122,347.76, divided into 6,117,388 common shares with a nominal value of CHF 0.02 each. Pursuant to the Merger, the Auris OldCo's shareholders received one common share with a nominal value of CHF 0.02 of the Company for every 10 of our common shares held prior to the Merger, effectively resulting in a "reverse stock split" at a ratio of 10-for-1. On March 14, 2018 the common shares of Auris NewCo began trading on the Nasdaq Capital Market under the trading symbol "EARS".

The Company's registered address is Bahnhofstrasse 21, 6300 Zug. These condensed consolidated interim financial statements comprise the Company and its subsidiaries (together referred to as the "Group" and individually as "Group entities"). These condensed consolidated interim financial statements also include financial information of Auris OldCo prior to the Merger as discussed below. The Company is the ultimate parent of the following Group entities:

- Auris Medical AG, Basel, Switzerland (100%) with a nominal share capital of CHF 2,500,000
- Otolanum AG, Zug, Switzerland (100%) with a nominal share capital of CHF 100,000
- Auris Medical Inc., Chicago, United States (100%) with a nominal share capital of USD 15,000
- Auris Medical Ltd., Dublin, Ireland (100%) with a nominal share capital of EUR 100

The Group is primarily involved in the development of novel products that address important unmet medical needs in neurotology and mental health supportive care. The Group is primarily focusing on the development of intranasal betahistine for the treatment of vertigo (AM-125) and for the treatment of antipsychotic-induced weight gain and somnolence (AM-201). These projects have gone through two Phase 1 trials and the Company expects to move into proof-of-concept studies in 2019.

2. Basis of preparation

Statement of compliance

These condensed consolidated interim financial statements as of September 30, 2018 and December 31, 2017 and for the three and nine months ended September 30, 2018 have been prepared in accordance with International Accounting Standard 34 Interim Financial Reporting ("IAS 34") and should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2017.

These condensed consolidated interim financial statements include all adjustments that are necessary to fairly state the results of the interim period. The Group believes that the disclosures are adequate to make the information presented not misleading. Interim results are not necessarily indicative of results to be expected for the full year. Management does not consider the business to be seasonal or cyclical.

Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with International Financial Reporting Standards ("IFRS"), as issued by the International Accounting Standards Board, have been condensed or omitted as permitted by IAS 34. The condensed consolidated statement of financial position as of December 31, 2017 was derived from the audited consolidated financial statements.

The interim condensed consolidated financial statements were authorized for issuance by the Company's Audit Committee on November 13, 2018.

Functional and reporting currency

These interim condensed consolidated financial statements are presented in Swiss Francs ("CHF"), which is the Company's functional currency ("functional currency") and the Group's reporting currency.

Considering reorganization/Merger

The Merger is not a business combination and is accounted for as a reorganization. Therefore, the condensed consolidated interim financial statements of the Company are a continuation of the financial information of Auris OldCo except that the condensed consolidated interim financial statements reflect a reclassification between share capital and share premium in order to reflect the share capital of Auris NewCo. For the periods prior to the Merger, in calculating loss per share, the weighted average number of shares outstanding is calculated based on the number of weighted average shares issued by Auris OldCo, adjusted for the reverse stock split ratio of 10-for-1.

Related Party Transaction

On February 9, 2018, Thomas Meyer, our Chief Executive Officer, entered into a share transfer agreement with the Company to facilitate the rounding up of fractional shares resulting from the exchange ratio used in the Merger. Pursuant to the terms of the share transfer agreement, Mr. Meyer committed to transfer, at no consideration, a common share to any shareholder entitled to a fraction of a common share as part of the Merger. Pursuant to the share transfer agreement, neither the Company nor Mr. Meyer received any compensation for this arrangement. Any expenses incurred by Mr. Meyer in connection with the transfers under such agreement were borne by the Company.

Significant accounting policies

The accounting policies applied by the Group in these condensed consolidated interim financial statements are the same as those applied by the Group in its audited consolidated financial statements as of and for the year ended December 31, 2017 and have been applied consistently to all periods presented in these condensed consolidated interim financial statements, unless otherwise indicated.

New standards, amendments and interpretations adopted by the Group

The Group has not early adopted any standard, interpretation or amendment that was issued, but is not yet effective.

A number of new standards, amendments to standards and interpretations are effective for the Group's 2018 reporting year. The application of these new standards, amendments to standards and interpretations does not have material impact on the financial statements of the Group.

Asset Purchase

On April 24, 2018, one of our subsidiaries entered into an agreement to purchase patents related to compositions for weight management and methods of reducing weight gain associated with olanzapine treatment.

3. Taxation

The Group's income tax expense recognized in the condensed interim consolidated statement of profit or loss is presented as follows:

	Nine months ended	
	September 30, 2018	**September 30, 2017**
Deferred income tax expense	—	—
Deferred income tax gain	26,179	24,573
Total income tax gain	**26,179**	**24,573**

The tax effect of taxable temporary differences that give rise to deferred income tax liabilities or to deferred income tax assets as of September 30, 2018 and 2017 is presented as follows:

	September 30, 2018	**September 30, 2017**
Deferred Tax liabilities		
Intangible assets	(354,117)	(349,052)
Hercules Loan & Warrant	(5,202)	(53,309)
Derivatives financial instrument	(19,759)	—
Total	**(379,078)**	**(402,361)**
Deferred Tax asset		
Net operating loss (NOL)	226,448	230,352
Total	**226,448**	**230,352**
Deferred Tax, net	**(152,630)**	**(172,009)**

4. Loan and Warrant

On July 19, 2016 the Company entered into a Loan and Security Agreement (the "Hercules Loan and Security Agreement") for a secured term loan facility of up to $20.0 million with Hercules Capital, Inc. as administrative agent ("Hercules") and the lenders party thereto. An initial tranche of $12.5 million was drawn on July 19, 2016, concurrently with the execution of the Hercules Loan and Security Agreement. The loan matures on January 2, 2020 and bears interest at a minimum rate of 9.55% per annum, and is subject to the variability of the prime interest rate. The loan is secured by a pledge of the shares of Auris Medical AG owned by the Company, all intercompany receivables owed to the Company by its Swiss subsidiaries and a security assignment of the Company's bank accounts.

On April 5, 2018 the Company entered into an agreement with Hercules whereby the terms of the Hercules Loan and Security Agreement were amended to eliminate the $5 million liquidity covenant in exchange for a repayment of $5 million principal amount outstanding under the Hercules Loan and Security Agreement. The Company shall maintain a blocked cash account denominated in United States Dollars as a blocked account (the "Blocked Account") as collateral for the remaining principal balance of the Secured Obligations and the End of Term Charge. The carrying value of the cash serving as collateral is USD 2,120,257. The Blocked Account will be reduced on a dollar for dollar basis by the amount of such principal payments or end of term charge when such payments are received by Lender.

Following the modification of the loan to repay $5 million, a loss of CHF 334,747 was recognized in connection with the modification of the loan and transaction costs. This loss is presented in the line interest expense in the condensed consolidated interim statement of profit or loss and other comprehensive income or loss.

The loan was initially recognized at transaction value with deductions of the fair value of the warrant at transaction date and directly attributable transactions costs.

Subsequent to initial recognition, the loan is measured at amortized cost using the effective interest method. Applying this method, the calculated value of the loan as of September 30, 2018 is CHF 2,144,235. Of the CHF 2,144,235 amortization payments due within the next 12 months, the entirety is classified as current liabilities.

In connection with the loan facility, the Company issued Hercules a warrant to purchase up to 241,117 of its common shares at an exercise price of $3.94 per share. As of March 13, 2018, following consummation of the Merger, the warrant is exercisable for 15,673 common shares at an exercise price of $39.40 per common share. Upon Hercules making the second advance under the loan facility, the warrant shall become exercisable for the additional 8,440 common shares (assuming the Company rounds up fractional common shares to the next whole common share). The warrant expires on July 19, 2023. The fair value calculation of the warrant is based on the Black-Scholes option price model. Assumptions are made regarding inputs such as volatility and the risk free rate in order to determine the fair value of the warrant. As the warrant is part of the loan transaction, its fair value was deducted from the loan proceeds and accounted for separately as non-current financial liability. Following the initial recognition, the warrant is measured at fair value and the changes in fair value are shown as profit or loss.

On September 30, 2018, the fair value of the warrant amounts to CHF 1,065. Therefore, the fair value decreased by the total amount of CHF 22,285 in the current year (fair value as of December 31, 2017: CHF 23,350).

5. Capital and reserves

Share capital

The issued share capital of the Company consisted of:

	Common Shares Number	
	2018	**2017**
As of January 1	48,373,890	34,329,704
Common shares issued for capital increase with a nominal value of CHF 0.40 each	12,800,000	10,000,000
Adjustment during the Merger:		
Issuance of Auris NewCo Shares	6,117,388	—
Cancellation of Auris OldCo Shares	(61,173,890)	—
Common shares issued for capital increase with a nominal value of CHF 0.02 each	17,948,717	—
Shares outstanding after Merger on March 13, 2018	24,066,105	—
Total, as of September 30, 2018	**24,066,105**	**44,329,704**

All shares have a nominal value of CHF 0.02 after the Merger (respective CHF 0.40 before the Merger) and are fully paid in. As of September 30, 2018, the nominal value of the 24,066,105 issued shares amounted to CHF 481,322.10 (as of September, 2017, the nominal value of 44,329,704 issued shares amounted to CHF 17,731,881.60).

As of March 13, 2018, following consummation of the Merger, the number of shares were reduced by the ratio of 10 to 1 (resulting in a “reverse share split”) and the nominal value per share was reduced from CHF 0.40 to CHF 0.02. This resulted in a reduction of share capital and in a concurrent increase in share premium, totaling to CHF 24,347,208, presented in the statement of changes in equity in the line reorganization of group structure.

Equity Offerings

On July 17, 2018 the Company completed a public offering of 17,948,717 common shares with a nominal value of CHF 0.02 each, Series A warrants each entitling its holder to purchase 0.35 of a common share and for an aggregate of 6,282,050 common shares, and Series B warrants entitling its holder to purchase 0.25 of a common share for an aggregate of 4,487,179 common shares (the "July 2018 Registered Offering"). The exercise price for both series Warrants is CHF 0.39 per common share. The net proceeds to us from the July 2018 Registered Offering were approximately $6.2 million, after deducting underwriting discounts and other offering expenses payable by us.

The Company had transaction costs amounting to CHF 851,692. The transactions costs were recorded as CHF 742,833 in equity for the issuance of the common shares and CHF 108,809 to finance expense in the statement of profit or loss and comprehensive loss for the issuance of the warrants.

As of September 30, 2018 the fair value of the warrants issued in the July 2018 Registered Offering amounted CHF 872,217. Since its initial recognition, the fair value of the warrants issued in the July 2018 Registered Offering has decreased by CHF 24,224, resulting in a gain in the corresponding amount (fair value as of July 17, 2018: CHF 896,441).

On May 2, 2018 the Company entered into the 2018 Commitment Purchase Agreement and the 2018 Registration Rights Agreement with LPC. Pursuant to the 2018 Commitment Purchase Agreement, LPC agreed to purchase common shares for up to $10,000,000 over the 30-month term of the 2018 Commitment Purchase Agreement. As of November 15, 2018, the Company has issued an aggregate of 750,00 common shares for aggregate proceeds of $488,075 to LPC under the 2018 Commitment Purchase Agreement. The 2018 Commitment Purchase Agreement replaces the 2017 Commitment Purchase Agreement, which was terminated as a result of the Merger. Under the 2017 Commitment Purchase Agreement, LPC agreed to subscribe for up to $13,500,000 common shares and prior to its termination, the Company had issued an aggregate of 2,600,000 common shares for aggregate proceeds of $1.8 million to LPC under the 2017 Commitment Purchase Agreement.

The Company had transaction costs amounting to CHF 349,907. The payment of CHF 252,351 was recorded as a derivative financial instrument and classified as a non-current asset and CHF 97,556 to finance expense in the statement of profit or loss and comprehensive loss.

On January 30, 2018, the Company completed a public offering of 12,499,999 common shares with a nominal value of CHF 0.40 each and concurrent offering of 7,499,999 warrants, each warrant entitling its holder to purchase one common share (the "January 2018 Registered Offering"). The net proceeds to the Company from the January 2018 Registered Offering were approximately $4.9 million, after deducting placement agent fees and other estimated offering expenses payable by the Company. As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issued in the January 2018 Registered Offering were exercisable for up to 750,002 common shares (assuming the Company rounds up fractional common shares to the next whole common share) at an exercise price of $5.00 per common share.

The Company had transaction costs amounting to CHF 654,985. The transaction costs were recorded as CHF 341,226 in equity for the issuance of the common shares and CHF 313,760 to finance expense in the statement of profit or loss and comprehensive loss for the issuance of the warrants.

As of September 30, 2018 the fair value of the warrants issued in the January 2018 Registered Offering amounted to CHF 161,737. Since its initial recognition, the fair value of these warrants has decreased by CHF 2,322,010 resulting in a gain in the corresponding amount (fair value as of January 30, 2018: CHF 2,483,747).

On October 10, 2017 the Company entered into a purchase agreement and a registration rights agreement with Lincoln Park Capital Fund, LLC. Pursuant to the purchase agreement, LPC agreed to subscribe for up to $13,500,000 of our common shares over the 30-month term of the purchase agreement. On January 23, 2018, the Company issued 300,000 of our common shares to LCP for an aggregate amount of CHF 136,077 under the purchase agreement.

On February 21, 2017, in connection with a public offering of 12,499,000 common shares, the Company issued 10,000,000 warrants, each warrant entitling its holder to purchase 0.70 of a common share at an exercise price of $1.20 per common share. Additionally, the underwriter was granted a 30-day option to purchase up to 1,500,000 additional common shares and/or 1,500,000 additional warrants, of which the underwriter partially exercised its option for 1,350,000 warrants. As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issuable in the 2017 offering were exercisable for an aggregate of 794,000 common shares, at an exercise price of $12.00 per common share. As of September 30, 2018 the fair value of the warrants amounted to CHF 50,070. The revaluation gain of the derivative for the nine months ended September 30, 2018 amounted to CHF 1,763,342, which is an increase of CHF 63,220 when comparing to the same period in 2017. Since its initial recognition, the fair value decreased by CHF 5,040,393 resulting in a gain in the corresponding amount (fair value as of February 21, 2017: CHF 5,090,463).

Issue of common shares upon exercise of options

During the nine months ended September 30, 2018, no options were exercised.

Controlled Equity Offering

On June 1, 2016, the Company entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald, pursuant to which we might have offered and sold from time to time common shares, with a nominal value of CHF 0.40 per common share, having an aggregate offering price of up to $35 million through Cantor. In the first quarter of 2018, we did not offer or sell any common shares under the Controlled Equity Offering Sales Agreement. The Controlled Equity Offering program terminated upon consummation of the Merger on March 13, 2018.

6. Employee benefits

	Nine months ended	
	September 30, 2018	**September 30, 2017**
Salaries	2,119,880	2,971,707
Pension costs	302,748	277,554
Share based compensation expense	108,399	259,561
Other employee costs and social benefits	91,225	251,000
Total employee benefits	**2,622,252**	**3,759,822**

7. Share based payments

Share based compensation net loss of CHF 123,425 was recognized for the nine months ended September 30, 2018. Share based compensation loss related to employee stock options amounted to CHF 108,399 for the nine months ended September 30, 2018 (for the nine months ended September 30, 2017 a loss of CHF 259,561).

Share based compensation expense of CHF 15,024 related to the purchase of intangibles was capitalized for the nine months ended September 30, 2018. A total of 371,893 options were granted in the nine months ended September 30, 2018. The exercise price of the options granted is US$1.579 per share. The methodology for computation of share based compensation expense for the period is consistent with the methodology used in 2017.

8. Loss per share

	Three months ended		Nine months ended	
	September 30, 2018	**September 30, 2017**	**September 30, 2018**	**September 30, 2017**
Loss attributable to owners of the Company	(2,980,517)	(6,012,481)	(7,805,535)	(19,823,881)
Weighted average number of shares outstanding	20,944,590	4,432,970	10,987,582	4,260,176
Basic and diluted loss per share	**(0.14)**	**(1.36)***	**(0.71)**	**(4.65)***

* The basic and diluted loss per share for the three and nine months ended September 30, 2017 is revised to reflect the reverse-split ratio of 10 to 1 following the Merger on March 13, 2018.

For the three and nine months ended September 30, 2018 and September 30, 2017 basic and diluted loss per share are calculated based on the weighted average number of shares issued and outstanding and excludes shares to be issued under the stock option plans, as they would be anti-dilutive. As of the date hereof, the Company had 438,050 options outstanding under its stock option plans. The average number of options outstanding between January 1, 2018 and September 30, 2018 was 332,998 (139,065 for the period between January 1, 2017 and September 30, 2017).

9. Events after the Reporting Period

Subsequent to September 30, 2018, certain holders of Series A warrant issued in the July 2018 Registered Offering exercised their warrant shares to purchase 2,904,518 common shares of the Company for a total amount of CHF 1,132,762.02 and certain holders of Series B warrant issued in the July 2018 Registered Offering exercised warrant shares to purchase 2,864,422 common shares for a total amount of CHF 1,117,124.58.

As of November 15, 2018, the Company's issued fully paid-in share capital consists of CHF 611,700.90, divided into 30,585,045 common shares with a nominal value of CHF 0.02 each.

As of November 15, 2018, the Company has issued an aggregate of 750,000 common shares for aggregate proceeds of $488,075 to LPC pursuant to the Commitment Purchase Agreement.

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Auris Medical Holding AG

Opinion on the Financial Statements

We have audited the accompanying consolidated statements of financial position of Auris Medical Holding AG and its subsidiaries (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of profit or loss and other comprehensive income/(loss), changes in equity, and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Auris Medical Holding AG and its subsidiaries as of December 31, 2017 and 2016, and the results of their operations, and their cash flows for each of the three years in the period ended December 31, 2017, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Deloitte AG
DELOITTE AG

By: /s/ Matthias Gschwend	By: /s/ Adrian Kaeppeli
Name: Matthias Gschwend	Name:
Title: Auditor in Charge	Title:

Zurich Switzerland
March 22, 2018

We have served as the Company's auditor since 2014.

AURIS MEDICAL HOLDING AG

Consolidated Statement of Profit or Loss and Other Comprehensive Income/(Loss)

	Note	For the Years ended December 31, 2017	2016	2015
			(in CHF)	
Research and development	16	(19,210,842)	(24,776,763)	(26,536,176)
General and administrative	17	(5,150,409)	(5,446,512)	(4,341,570)
Operating loss		**(24,361,251)**	**(30,223,275)**	**(30,877,746)**
Interest income	19	53,570	67,565	36,562
Interest expense	19	(1,640,394)	(828,547)	(7,985)
Foreign currency exchange (loss)/gain, net		(824,592)	(100,097)	1,144,106
Revaluation gain from derivative financial instruments	19, 24, 25	3,372,186	291,048	—
Transaction costs		(1,026,766)	—	—
Loss before tax		**(24,427,247)**	**(30,793,306)**	**(29,705,063)**
Income tax gain	20	17,773	131,055	—
Net loss attributable to owners of the Company		**(24,409,474)**	**(30,662,251)**	**(29,705,063)**
Other comprehensive income/(loss):				
Items that will never be reclassified to profit or loss				
Remeasurement of defined benefit liability, net of taxes of CHF 0	18	271,980	(394,102)	(53,916)
Items that are or may be reclassified to profit or loss				
Foreign currency translation differences, net of taxes of CHF 0		50,497	(19,723)	(12,712)
Other comprehensive income/(loss), net of taxes of CHF 0		**322,477**	**(413,825)**	**(66,628)**
Total comprehensive loss attributable to owners of the Company		**(24,086,997)**	**(31,076,076)**	**(29,771,691)**
Basic and diluted loss per share	21	(0.56)	(0.89)	(0.92)

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

AURIS MEDICAL HOLDING AG

Consolidated Statement of Financial Position
As of December 31, 2017 and 2016

	Note	December 31, 2017	December 31, 2016
		(in CHF)	
ASSETS			
Non-current assets			
Property and equipment	7	252,899	369,294
Intangible assets	8	1,629,100	1,482,520
Other non-current receivables		76,710	114,778
Total non-current assets		**1,958,709**	**1,966,592**
Current assets			
Other receivables	9	241,281	296,531
Prepayments	10	652,913	952,595
Cash and cash equivalents	11	14,973,369	32,442,222
Total current assets		**15,867,563**	**33,691,348**
Total assets		**17,826,272**	**35,657,940**
EQUITY AND LIABILITIES			
Equity			
Share capital	12	19,349,556	13,731,881
Share premium		114,648,228	112,838,815
Foreign currency translation reserve		(33,047)	(83,544)
Accumulated deficit		(136,126,946)	(112,344,303)
Total shareholders' (deficit)/equity attributable to owners of the Company		**(2,162,209)**	**14,142,849**
Non-current liabilities			
Loan	24	5,584,297	10,151,498
Derivative financial instruments	24,25	1,836,763	117,132
Employees benefit liability	18	1,962,970	2,092,434
Deferred tax liabilities	20	178,809	196,582
Total non-current liabilities		**9,562,839**	**12,557,646**
Current liabilities			
Loan	24	4,542,109	2,212,706
Trade and other payables	14	1,200,820	1,837,997
Accrued expenses	15	4,682,713	4,906,742
Total current liabilities		**10,425,642**	**8,957,445**
Total liabilities		**19,988,481**	**21,515,091**
Total equity and liabilities		**17,826,272**	**35,657,940**

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

AURIS MEDICAL HOLDING AG

Consolidated Statement of Changes in Equity

As of December 31, 2017, 2016 and 2015

	Note	Share Capital	Share Premium	Foreign Currency Translation Reserve	Accumulated Deficit	Total Equity/ (Deficit)
				(in CHF)		
As of January 1, 2015		**11,604,156**	**93,861,171**	**(51,109)**	**(52,131,426)**	**53,282,793**
Total comprehensive loss						
Net loss		—	—	—	(29,705,063)	(29,705,063)
Other comprehensive loss		—	—	(12,712)	(53,916)	(66,628)
Total comprehensive loss		**—**	**—**	**(12,712)**	**(29,758,979)**	**(29,771,691)**
Transactions with owners of the Company						
Capital increase from follow-on offering		2,110,000	19,604,877	—	—	21,714,877
Transaction costs	12	—	(643,796)	—	—	(643,796)
Share issuance costs		—	(211,142)	—	—	(211,142)
Share based payments	13	—	—	—	311,671	311,671
Share options exercised	13	7,400	51,800	—	—	59,200
Balance at December 31, 2015		**13,721,556**	**112,662,910**	**(63,821)**	**(81,578,733)**	**44,741,912**
As of January 1, 2016		**13,721,556**	**112,662,910**	**(63,821)**	**(81,578,733)**	**44,741,912**
Total comprehensive loss						
Net loss		—	—	—	(30,662,251)	(30,662,251)
Other comprehensive loss		—	—	(19,723)	(394,102)	(413,825)
Total comprehensive loss		**—**	**—**	**(19,723)**	**(31,056,353)**	**(31,076,076)**
Transactions with owners of the Company						
Issue of bonus shares	13	10,325	177,767	—	—	188,092
Share issuance costs	13	—	(1,862)	—	—	(1,862)
Share based payments	13	—	—	—	290,783	290,783
Balance at December 31, 2016		**13,731,881**	**112,838,815**	**(83,544)**	**(112,344,303)**	**14,142,849**
As of January 1, 2017		**13,731,881**	**112,838,815**	**(83,544)**	**(112,344,303)**	**14,142,849**
Total comprehensive loss						
Net loss		—	—	—	(24,409,474)	(24,409,474)
Other comprehensive income		—	—	50,497	271,980	322,477
Total comprehensive income/(loss)		**—**	**—**	**50,497**	**(24,137,494)**	**(24,086,997)**
Transactions with owners of the Company						
Capital increase		5,617,675	2,330,928	—	—	7,948,603
Transaction costs		—	(521,515)	—	—	(521,515)
Share based payments	13	—	—	—	354,851	354,851
Balance at December 31, 2017		**19,349,556**	**114,648,228**	**(33,047)**	**(136,126,946)**	**(2,162,209)**

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

AURIS MEDICAL HOLDING AG

Consolidated Statement of Cash Flows

	Note	For the Years ended December 31, 2017	2016	2015
			(in CHF)	
Cash flows from operating activities				
Net loss		**(24,409,474)**	**(30,662,251)**	**(29,705,063)**
Adjustments for:				
Depreciation	16, 17	122,784	97,600	92,777
Unrealized foreign currency exchange loss/(gain), net		776,165	99,091	(1,167,227)
Net interest expense/(income)	19	1,568,781	748,840	(36,390)
Share based payments	13	354,851	290,783	311,671
Transaction costs		1,026,766	—	—
Employee benefits		142,514	122,501	111,321
Revaluation gain derivative financial instruments	24, 25	(3,372,186)	(291,048)	—
Income tax gain	20	(17,773)	(131,055)	—
		(23,807,572)	**(29,725,539)**	**(30,392,911)**
Changes in:				
Other receivables		93,328	277,483	(146,244)
Prepayments		299,684	(771,551)	84,126
Trade and other payables		(637,177)	632,474	(2,028,862)
Accrued expenses		(224,028)	133,522	3,756,744
Net cash used in operating activities		**(24,275,765)**	**(29,453,611)**	**(28,727,147)**
Cash flows from investing activities				
Purchase of property and equipment	7	(6,389)	(244,324)	(79,920)
Purchase of intangibles	8	(146,580)	—	—
Interest received	19	53,570	67,553	36,562
Net cash used in investing activities		**(99,399)**	**(176,771)**	**(43,358)**
Cash flows from financing activities				
Proceeds from exercise of options	12	—	—	59,200
Share issuance costs	12	—	(1,862)	(211,142)
Proceeds from issue of loan with warrant	24	—	11,986,671	—
Proceeds from follow-on offering	12, 25	13,039,066	—	21,071,081
Transaction costs	12	(1,548,281)	—	—
Repayment of loan		(2,087,076)	—	—
Interest paid	19, 24	(1,182,369)	(546,170)	(172)
Net cash from financing activities		**8,221,340**	**11,438,639**	**20,918,967**
Net decrease in cash and cash equivalents		**(16,153,824)**	**(18,191,743)**	**(7,851,538)**
Cash and cash equivalents at beginning of the period		32,442,222	50,237,300	56,934,325
Net effect of currency translation on cash		(1,315,029)	396,665	1,154,513
Cash and cash equivalents at end of the period		**14,973,369**	**32,442,222**	**50,237,300**

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

AURIS MEDICAL HOLDING AG

1. Reporting entity

Auris Medical Holding AG (the "Company") is a corporation (*Aktiengesellschaft*) organized in accordance with Swiss law and 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%) with a nominal share capital of CHF 2,500,000
- Otolanum AG, Zug, Switzerland (100%) with a nominal share capital of CHF 100,000
- Auris Medical Inc., Chicago, United States (100%) with a nominal share capital of USD 15,000
- Auris Medical Ltd., Dublin, Ireland (100%) with a nominal share capital of EUR 100

On April 22, 2014, the Company changed its 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. On March 13, 2018, the Company merged (the "Merger") into Auris Medical NewCo Holding AG ("Auris NewCo"), a newly incorporated, wholly-owned Swiss subsidiary following shareholder approval at an extraordinary general meeting of shareholders held on March 12, 2018. Following the Merger, Auris NewCo, the surviving company, had a share capital of CHF 122,347.76, divided into 6,117,388 common shares with a nominal value of CHF 0.02 each. Pursuant to the Merger, the Company's shareholders received one common share with a nominal value of CHF 0.02 of Auris NewCo for every 10 of our common shares held prior to the Merger, effectively resulting in a "reverse stock split" at a ratio of 10-for-1. Auris NewCo changed its name to "Auris Medical Holding AG" following consummation of the Merger. On March 14, 2018 the common shares of Auris NewCo began trading on the Nasdaq Capital Market under the trading symbol "EARS."

The Group is primarily involved in the development of pharmaceutical products for the treatment of inner ear and vestibular 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 20, 2018.

Basis of measurement

The consolidated financial statements are prepared on the historical cost basis, except for the revaluation to fair value of certain financial liabilities. 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.

In addition, for financial reporting purposes, fair value measurements are categorized into Level 1, 2 or 3 based on the degree to which the inputs to the fair value measurements are observable and the significance of the inputs to the fair value measurement in its entirety, which are described as follows:

- Level 1 inputs are quoted prices (unadjusted) in active markets for identical assets or liabilities that the entity can access at the measurement date

- Level 2 inputs are inputs, other than quoted prices included within Level 1, that are observable for the asset or liability, either directly or indirectly; and
- Level 3 inputs are unobservable inputs for the asset or liability.

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 20 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. Tax losses may be used within 7 years from the year the losses arose.

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 state law.

Other than a tax asset in the amount of CHF 217,720, 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. Income tax gain reflects the reassessment of deferred tax assets and liabilities booked in the 2017 fiscal year.

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 and vestibular disorders. Financial information is only available for the Group as a whole. Therefore, management considers there is only one operating segment under the requirements of IFRS 8, Operating Segments.

Foreign currency

Foreign currency transactions

Items included in the financial statements of Group entities are measured using the currency of the primary economic environment in which the entity operates. Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in profit or loss. Non-monetary items that are measured based on historical cost in a foreign currency are not re-translated.

Foreign operations

Assets and liabilities of Group entities whose functional currency is other than CHF are included in the consolidation by translating the assets and liabilities into the reporting currency at the exchange rates applicable at the end of the reporting period. Income and expenses are translated at average exchange rates (unless this average is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the dates of the transaction).

These foreign currency translation 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 relative to CHF:

Currency		Geographical area	Reporting entities	December 31, 2017	December 31, 2016	December 31, 2015
CHF	Swiss Franc	Switzerland	3	1.0000	1.0000	1.0000
USD	Dollar	United States	1	0.9725	1.0196	1.0014
EUR	Europe	Europe	1	1.1713	1.0723	1.0875

Average exchange rates for the year for the most significant foreign currencies relative to CHF:

Currency		Geographical area	Reporting entities	2017	2016	2015
CHF	Swiss Franc	Switzerland	3	1.0000	1.0000	1.0000
USD	Dollar	United States	1	0.9849	0.9855	0.9613
EUR	Europe	Europe	1	1.1116	1.0901	1.0659

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 (other than certain milestone payments) have been capitalized in 2014 and 2015. 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 and data rights

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 which will be the case after regulatory approvals are obtained and the related products 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.

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, cancelled, or expired.

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 receivable

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.

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.

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 warrants are classified as a financial liability at fair value through profit or loss and the cost allocated to the liability component will be immediately expensed to the income statement.

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.

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.

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.

Derivative Financial Instruments

Derivative financial instruments are accounted at fair value and changes in fair value are shown as profit or loss. The fair value calculation of the derivative financial instruments is based on the Black-Scholes option pricing model. Assumptions are made for volatility and the risk free rate in order to estimate the fair value of the instrument. Transaction cost related to derivative financial instruments are recorded through profit and 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 Other Comprehensive Income.

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 Other Comprehensive Income. 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 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 Stock Option Plans A and C. Under the Auris

Medical Holding AG Long Term Equity Incentive Plan (the "Equity Incentive Plan" or "EIP"), 50% of granted share options granted to employees 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. Share options granted to members of the Board of Directors in 2017, 2016 and in 2015 vest after a period of one year after the grant date. 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 has been abolished in 2015.

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

Following the completion of our initial public offering, option pricing and values are determined based on the Black Scholes option pricing model and assumptions are made for inputs such as volatility of our stock and the risk free rate.

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.

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.

IAS 7 amendments	Statement of Cash Flows, Disclosure Initiative
IAS 12 amendments	Income taxes, Recognition of Deferred Tax Assets for Unrealized Losses

A number of new standards, amendments to standards and interpretations are effective for annual periods beginning after January 1, 2018, 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				
IFRS 9	Financial instruments	(2)	January 1, 2018	FY 2018
IFRS 15	Revenue from Contracts with Customers and the related clarifications	(3)	January 1, 2018	FY 2018
IFRS 16	Leases	(4)	January 1, 2019	FY 2019
IFRS 2	Amendment to IFRS 2, Classification and Measurement of Share-based Payment Transaction	(1)	January 1, 2018	FY 2018
IFRS 1/IAS 28	Amendment to IFRS 1 and IAS 28, Investment in Associates and Joint Ventures and First-time Adoption of International Reporting Standards	(1)	January 1, 2018	FY 2018
IAS 40	Amendment to IAS 40, Transfers of Investment Property	(1)	January 1, 2018	FY 2018
IFRIC 22	Foreign Currency Transactions and Advance Consideration	(1)	January 1, 2018	FY 2018

(1) The impact on the consolidated financial statements of the Group cannot yet be determined with sufficient reliability.

(2) IFRS 9, Financial Instruments

IFRS 9 introduces a single approach for the classification and measurement of financial assets according to their cash flow characteristics and the business model they are managed in, and provides a new impairment model based on expected credit losses. IFRS 9 also includes new regulations regarding the application of hedge accounting to better reflect an entity's risk management activities especially with regard to managing non-financial risks. The Group plans to adopt the new standard on the required effective date and will not restate comparative information. During 2017, the Group has performed an impact assessment of all three aspects of IFRS 9. This assessment is based on currently available information and may be subject to changes arising from further reasonable and supportable information being made available to the Group in 2018 when the Group will adopt IFRS 9. The Group does not expect a significant impact on its balance sheet or equity on applying the classification and measurement requirements of IFRS 9. Further, the Group does not apply hedge accounting. IFRS 9 requires the Group to record expected credit losses on all of its loans and trade receivables, either on a 12-month or lifetime basis. The Group will apply the simplified approach and record lifetime expected losses. Due to the nature of its receivables, the Group does not expect a significant impact on its balance sheet or equity on applying the impairment model under the IFRS 9 standard.

(3) IFRS 15, Revenue from Contracts with Customers

According to the new standard, revenue is recognized to depict the transfer of promised goods or services to a customer in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. Revenue is recognized when, or as, the customer obtains control of the goods or services. The new revenue standard will supersede all current revenue recognition requirements under IFRS. The Group is focused on the development of pharmaceutical products for the treatment of inner ear disorders. As a clinical stage company it currently has no revenue from contracts with customers. The adoption of IFRS 15 is not expected to have any impact on the Group's revenue and profit or loss.

(4) IFRS 16, Leases

The new standard eliminates the current classification model for lessee's lease contracts as either operating or finance leases and, instead, introduces a single lessee accounting model requiring lessees to recognize right-of-use assets and lease liabilities for leases with a term of more than twelve months. This brings the previous off-balance leases on the balance sheet in a manner largely comparable to current finance lease accounting. A lessee can choose to apply the standard using either a full retrospective or a modified retrospective approach. Adoption of IFRS 16 will result in the Group recognizing right of use assets and lease liabilities for all contracts that are, or contain, a lease. For leases currently classified as operating leases, under current accounting requirements the Group does not recognize related assets or liabilities, and instead spreads the lease payments on a straight-line basis over the lease term, disclosing in its annual financial statements the operating lease commitment. The Group is expecting that current leasing arrangements relating to office space will be capitalized under IFRS 16. In 2018, the Group will continue to assess the potential effect of IFRS 16 on its consolidated financial statements.

5. Financial instruments and risk management

The following table shows the carrying amounts of financial assets and financial liabilities:

	December 31, 2017	December 31, 2016
Financial assets		
Cash and cash equivalents	**14,973,369**	**32,422,222**
Loans and receivables		
Other receivables	79,840	134,900
Total financial assets	**15,053,209**	**32,557,122**
Financial liabilities		
At amortized cost		
Trade and other payables	1,200,820	1,837,997
Accrued expenses	4,395,609	4,652,033
Loan	10,126,406	12,364,204
At fair value through profit and loss		
Derivative financial instruments	1,836,763	117,132
Total financial liabilities	**17,559,598**	**18,971,366**

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. In respect of the Company's loan which has floating rates of interest, the fair value approximates carrying value.

Financial risk factors

The Group's activities expose it to a variety of financial risks: market risk, credit risk, interest rate 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 2017 and 2016 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.

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 of December 31, 2017 and 2016. 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, 2017					
Trade and other payables	1,200,820	1,200,820	—	—	1,200,820
Accrued expenses	4,395,609	4,395,609	—	—	4,395,609
Loan and borrowings	10,126,406	1,349,531	9,446,716	1,166,225	11,962,472
Derivative financial instruments	1,836,763	—	—	1,836,763	1,836,763
Total	**17,559,598**	**6,945,960**	**9,446,716**	**3,002,988**	**19,395,664**

	Carrying amount	Less than 3 months	Between 3 months and 2 years	2 years and later	Total
December 31, 2016					
Trade and other payables	1,837,997	1,837,997	—	—	1,837,997
Accrued expenses	4,652,033	3,632,752	1,019,281	—	4,652,033
Loan and borrowings	12,364,204	311,013	8,725,772	6,834,249	15,871,034
Derivative financial instruments	117,132	—	—	117,132	117,132
Total	**18,971,366**	**5,781,762**	**9,745,053**	**6,951,381**	**22,478,196**

Fair value measurement

	Fair values as at			
Financial assets/liabilities	**December 31, 2017**	**December 31, 2016**	**Fair value hierarchy**	**Valuation technique(s) and key input(s)**
Derivative financial liabilities	Liability 1,836,763	Liability 117,132	Level 2	Black-Scholes option pricing model. The share price is determined by our NASDAQ quoted-price. The strike price and maturity are coming from the contract. The volatility assumption is driven by our historic quoted share price and the risk free rate is estimated based on observable yield curves at the end of each reporting period.

	01.01.2017	Financing Cash Flows[1]	Non-cash changes: Fair value revaluation	Non-cash changes: Other changes[2]	31.12.2017
Derivative financial instrument	117,132	5,091,817	(3,372,186)	—	1,836,763
Loans	12,364,204	(2,087,076)	—	(150,722)	10,126,406
Total	**12,481,336**	**3,004,741**	**(3,372,186)**	**(150,722)**	**11,963,169**

(1) The financing cash flows are from loan repayment and from issuance of new derivative

(2) Internal rate of return changes and fx-difference

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. Other receivables were current as of December 31, 2017 and December 31, 2016, 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, 2017	December 31, 2016
Financial assets		
Cash and cash equivalents	14,973,369	32,442,222
Other receivables	79,840	134,900
Total	15,053,209	32,577,122

As of December 31, 2017 and December 31, 2016 other receivables consisted of other non-current receivables from third party and deposits for rent.

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. The summary of quantitative data about the exposure of the Group's financial assets and liabilities to currency risk was as follows:

	2017		2016	
	USD	EUR	USD	EUR
	(in CHF)			
Cash and cash equivalent	13,901,698	116,942	31,124,874	444,075
Trade and other payables	(365,999)	(426,050)	(501,249)	(847,892)
Accrued expenses	(1,750,752)	(1,692,946)	(1,031,096)	(2,964,552)
Loan and borrowings	(10,126,406)	—	(12,364,204)	—
Derivative financial instruments	(1,836,763)	—	(117,132)	—
Net statement of financial position exposure-asset/ (liability)	**(178,222)**	**(2,002,054)**	**17,111,193**	**(3,368,369)**

As of December 31, 2017, a 5% increase or decrease in the USD/CHF exchange rate with all other variables held constant would have resulted in a CHF 8,662 (2016: CHF 872,443) 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 117,320 (2016: CHF 180,595) 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

On July 19, 2016, the Company entered into a Loan and Security Agreement for a secured term loan facility of up to $20.0 million with Hercules Capital, Inc. as administrative agent ("Hercules") and the lenders party thereto. An initial tranche of $12.5 million was drawn on July 19, 2016, concurrently with the execution of the loan agreement. The loan matures on January 2, 2020 and bears interest at a minimum rate of 9.55% per annum, and is subject to the variability of the prime interest rate. The Company's exposure to interest rates on financial assets and financial liabilities is resulting from loan and cash at banks. As of December 31, 2017 an increase or decrease in interest rates on financial obligations by 50 basis points with all other variables held constant would have resulted in a CHF 62,500 (2016: 28,276) 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, 2017	December 31, 2016
Switzerland	1,958,709	1,966,592
Total	**1,958,709**	**1,966,592**

Non-current assets exclude financial instruments.

7. Property and Equipment

	Production equipment	Office furniture and EDP	Leasehold improvements	Total
At cost				
As of January 1, 2016	**283,499**	**208,712**	**17,132**	**509,343**
Additions	—	24,994	219,330	244,324
As of December 31, 2016	**283,499**	**233,706**	**236,462**	**753,667**
Additions	6,389	—	—	6,389
As of December 31, 2017	**289,888**	**233,706**	**236,462**	**760,056**
Accumulated depreciation				
As of January 1, 2016	**(127,629)**	**(149,873)**	**(9,271)**	**(286,773)**
Charge for the year	(56,700)	(33,837)	(7,063)	(97,600)
As of December 31, 2016	**(184,329)**	**(183,710)**	**(16,334)**	**(384,373)**
Charge for the year	(53,594)	(21,918)	(47,272)	(122,784)
As of December 31, 2017	**(237,923)**	**(205,628)**	**(63,606)**	**(507,157)**
Net book value				
As of December 31, 2016	**99,170**	**49,996**	**220,128**	**369,294**
As of December 31, 2017	**51,965**	**28,078**	**172,856**	**252,899**

As of December 31, 2017, and 2016 no items of property and equipment were pledged. Refer to note 24 for security provided to Hercules Capital, Inc under the Loan and Security Agreement.

8. Intangible assets

	Licenses	IP & Data rights	Total
At cost			
As of January 1, 2016	1,482,520	—	1,482,520
As of December 31, 2016	1,482,520	—	1,482,520
As of December 31, 2017	1,482,520	146,580	1,629,100
Accumulated amortization and impairment losses			
As of December 31, 2016	—	—	—
As of December 31, 2017	—	—	—
Net book value			
As of December 31, 2016	1,482,520	—	1,482,520
As of December 31, 2017	1,482,520	146,580	1,629,100

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.

On February 2, 2017, the Company entered into an asset purchase agreement with Otifex Therapeutics Pty Ltd (“Otifex”), pursuant to which the Company agreed to purchase and Otifex has agreed to sell to the Company certain pre-clinical and clinical assets related to a formulation for the intranasal application of Betahistine, which the Company refers to as AM-125, as well as intellectual property rights. The Otifex transaction closed in July 2017 and the Company recorded CHF 146,580 as intangibles related to this transaction.

No amortization or impairment was recorded in 2017 and 2016.

9. Other receivables

	December 31, 2017	December 31, 2016
Value added tax receivable	63,452	132,570
Withholding tax receivable	18,115	23,644
Deposit credit cards	79,840	79,900
Other	79,874	60,417
Total other receivables	**241,281**	**296,531**

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

10. Prepayments

	December 31, 2017	December 31, 2016
Advance payments to supplier	442,828	759,716
Clinical projects and related activities	—	41,681
Insurance	200,246	151,198
Other	9,839	—
Total prepayments	**652,913**	**952,595**

11. Cash and cash equivalents

	December 31, 2017	December 31, 2016
Cash in bank accounts	14,972,761	32,441,968
Cash on hand	608	254
Total cash and cash equivalents	**14,973,369**	**32,442,222**

12. Capital and reserves

Share capital

The issued share capital of the Company at December 31 consisted of:

	December 31, 2017		December 31, 2016	
	Number	CHF	Number	CHF
Common shares with a nominal value of CHF 0.40 each	48,373,890	19,349,556	34,329,704	13,731,881
Total	**48,373,890**	**19,349,556**	**34,329,704**	**13,731,881**

	Common Shares (Number)	
	2017	2016
As of January 1	34,329,704	34,303,891
Common shares issued or for stock options exercises with a nominal value of CHF 0.40 each		
Common shares issued for the follow-on offering with a nominal value of CHF 0.40 each	14,044,186	
Restricted shares issue for bonus purposes nominal value of CHF 0.40 each	—	25,813
Total, as of December 31	**48,373,890**	**34,329,704**

All shares have a nominal value of CHF 0.40 and are fully paid in. As of December 31, 2017, the nominal value of the 48,373,890 issued shares amounted to CHF 19,349,556.00 (as of December 31, 2016, the nominal value of 34,329,704 issued shares amounted to CHF 13,731,881.60).

On October 10, 2017, the Company entered into a purchase agreement (the "Commitment Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("LPC"). Pursuant to the Commitment Purchase Agreement, LPC has agreed to subscribe for up to $13,500,000 of our common shares over the 30-month term of the Commitment Purchase Agreement. Regular purchases may be made from time to time under the Commitment Purchase Agreement subject to certain amount limitations. As of December 31, 2017, the Company has issued an aggregate of 2,300,000 common shares for aggregate proceeds of CHF 1,594,611 ($1,630,415) to LPC pursuant to the Commitment Purchase Agreement. The related transaction cost of CHF 25,701 were recorded in equity.

The transaction costs for obtaining the Commitment Purchase Agreement were recorded as CHF 265,205 in transaction costs in the statement of profit or loss and comprehensive income/(loss). The commitment fee of CHF 290,400 (US$300,000) represents the fair value of the right to require LPC to purchase common shares within the Commitment Purchase Agreement. The proportion of the commitment fee CHF 35,073 related to cash received from common shares issued pursuant to the Commitment Purchase Agreement as a percentage of the total contract value of US$13.5 million is recognized in equity as if this proportion of the commitment fee was incorporated into the strike price of the option. The remaining portion of the commitment fee of CHF 255,327 was derecognized through transaction costs in the statement of profit and loss and comprehensive income/(loss) as the Commitment Purchase Agreement did not have any significant future value as of December 31, 2017 due the fact that the Commitment Purchase Agreement terminated upon consumption of Merger on March 13, 2018.

Additionally, on October 16, 2017, the Company issued 1,744,186 of its common shares to LPC for aggregate proceeds of CHF 1,446,150 ($1,500,000) pursuant to our effective shelf registration statement on Form F-3. The related transaction cost of CHF 63,056 were recorded in equity.

On February 21, 2017, the Company completed a public offering (the "February 2017 Offering") of 10,000,000 common shares with a nominal value of CHF 0.40 each and 10,000,000 warrants, each warrant entitling its holder to purchase 0.70 of a common share. The gross proceeds to the Company from the February 2017 Offering were CHF 9,998,305 (US$10,000,000). The Company had transaction costs amounting to CHF 903,919. The transactions costs were recorded as CHF 397,685 in equity for the issuance of the common shares and CHF 506,234 to finance expense in the statement of profit or loss and comprehensive loss for the issuance of the warrants.

On May 20, 2015, the Company completed a public offering of 5,275,000 shares, yielding net proceeds after underwriting discounts of USD 23.6 million (CHF 21.7 million). Offering costs associated with the follow-on amounted to CHF 643,796. Following the offering (and settlement of the employee options mentioned below) there were 34,329,704 common shares of the Company outstanding as of December 31, 2016.

Issuance of common shares with restrictions

For the business year 2015, 25,813 restricted common shares with a nominal value of CHF 0.40 were awarded and issued on January 7, 2016 under the Equity Incentive Plan for the purpose of share based bonus payments. The shares are fully vested on the grant date but remain subject to transfer restrictions for a period until January 7, 2019. The Company recorded a payroll charge of CHF 188,092 in 2015.

Controlled Equity Offering

On June 1, 2016, we entered into a Controlled Equity Offering^{SM} Sales Agreement (the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which we may offer and sell, from time to time common shares, with a nominal value of CHF 0.40 per share, having an aggregate offering price of up to $35 million through Cantor. In 2017, we did not offer or sell any common shares under the Sales Agreement. The Controlled Equity Offering program terminated upon consummation of the Merger on March 13, 2018.

Authorized share capital

On April 13, 2017, the annual general meeting of shareholders revised the provisions related to authorized and contingent capital of the Company and approved an increase and extension of the authorized share capital. As of December 31, 2017, the Company's authorized capital amounted to CHF 8,860,000 and allowed to Board of Directors, subject to the terms and conditions set forth in the Articles of Association, to issue up to 22,150,000 fully paid registered shares with a nominal value of CHF 0.40 each.

Conditional share capital

The share capital may be increased by the issuance of up to 6,500,000 fully paid registered Common Shares with a nominal value of CHF 0.40 per share and to the maximum amount of CHF 2,600,000 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).

The Company's share capital may be further increased by the issuance of up to 15,650,000 fully paid registered Common Shares with a nominal value of CHF 0.40 per share and to the maximum amount of CHF 6,260,000 in execution of conversion rights in connection with warrants and convertible bonds of the Company. For the terms of the warrant issued to Hercules, refer to Note 24.

13. Share based compensation

Description

On November 21, 2008, the Company 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 Stock Option 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 Stock Option Plan B were made in 2008, 2009 and 2014 only. Stock Option Plan B was abolished in 2015 and no grants under Stock Option Plan B were made in 2015. In 2014, the Group introduced a further equity incentive plan, the EIP. The Company granted 1,918,100 options in 2017 (2016: 555,660) under the EIP.

Holders of vested options are entitled to purchase common shares of the Company. For the stock option plans that were in place before the IPO, the exercise price corresponded to the value per share at the most recent financing round. Under the Equity Incentive Plan, the Board of Directors defined the exercise price as the average daily closing price of the Company's shares during the 30 days preceding the date 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 at December 31, 2017 as follows:

Plan	Number of options outstanding	Vesting conditions	Contractual life of option
Stock option Plan A	50,000	3 years' service from grant date	5 years
Stock option Plan C	121,250	4 years' service from grant date	6 years
Equity Incentive Plan Board	368,200	1 year service from grant date	8 years
Equity Incentive Plan Employees/ Board*	856,045	2 years' service from grant date (50%)	8 years
Equity Incentive Plan Employees/ Board*	856,045	3 years' service from grant date (50%)	8 years

* 25,000 options issued to Bettina Stubinski, the former Chief Medical Officer of the Company, have vested early, on December 29, 2016 and expired on March 29, 2017.

Measurement of fair values

The fair value of the options was measured based on the Black-Scholes formula.

	Stock Option Plan			
	Equity Incentive Plan 2017	Equity Incentive Plan 2017	Equity Incentive Plan 2016	Equity Incentive Plan 2016
Fair value at grant date	USD 0.198 (1 year vesting)[1]	USD 0.233 (1 year vesting)[2]	USD 0.308 (1 year vesting)[1]	USD 1.094 (1 year vesting)[2]
	USD 0.287 (2 year vesting)[1]	USD 0.335 (2 year vesting)[2]	USD 0.472 (2 year vesting)[1]	USD 1.560 (2 year vesting)[2]
	USD 0.352 (3 year vesting)[1]	USD 0.406 (3 year vesting)[2]	USD 0.583 (3 year vesting)[1]	USD 1.888 (3 year vesting)[2]
Share price at grant date	USD 0.76	USD 0.72	USD 1.03	USD 3.66
Exercise price	USD 0.82	USD 0.82	USD 1.39	USD 3.92
Expected volatility	72.85%	93.01%	100.93%	82.00%
Expected life	1, 2 and 3 years	1, 2 and 3 years	1, 2 and 3 years	1, 2 and 3 years
Expected dividends	—	—	—	—
Risk free interest rate	2.38%	2.19%	1.84%	1.83%

(1) October grants for the respective year

(2) April grants for the respective year

The Company uses its own historic volatility to calculate expected volatility. 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 354,851 in 2017 (2016: CHF 290,783, 2015: 311,671).

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

	2017			2016		
	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	1,038,140	3.36	6.14	629,010	4.92	5.42
Expired during the year	(67,500)	—	—	(17,500)	—	—
Forfeited during the year	(637,200)	—	—	(129,030)	—	—
Exercised during the year	—	—	—	—	—	—
Granted during the year	1,918,100	0.82	7.70	555,660	1.99	7.81
Outstanding at December 31	**2,251,540**	**1.74**	**6.88**	**1,038,140**	**3.36**	**6.14**
Exercisable at December 31	326,510	4.48	4.24	199,005	4.56	3.11

The range of exercise prices for outstanding options was CHF 0.8 to CHF 5.81 as of December 31, 2017 and CHF 1.35 to CHF 6.01 as of December 31, 2016.

14. Trade and other payables

	December 31, 2017	December 31, 2016
Trade accounts payable – third parties	1,032,557	1,733,319
Other	168,263	104,678
Total trade and other payables	**1,200,820**	**1,837,997**

15. Accrued expenses

	December 31, 2017	December 31, 2016
Accrued research and development costs including milestone payments	4,060,048	4,307,089
Professional fees	227,363	316,470
Accrued vacation & overtime	69,455	115,749
Employee benefits incl. share based payments	217,649	138,960
Board of Directors fees	—	1,529
Other	108,198	26,945
Total accrued expenses	**4,682,713**	**4,906,742**

16. Research and development expense

	December 31, 2017	December 31, 2016	December 31, 2015
Pre-clinical projects	642,821	546,429	468,326
Clinical projects	12,365,768	16,639,304	20,808,025
Drug manufacturing and substance	2,027,184	2,608,814	1,866,148
Employee benefits and expenses	2,773,516	2,854,624	2,140,664
Lease expenses	111,680	84,344	42,953
Patents and trademarks	603,892	941,836	824,201
Regulatory projects	632,387	1,043,287	331,822
Depreciation tangible assets	53,594	58,125	54,037
Total research and development expense	**19,210,842**	**24,776,763**	**26,536,176**

17. General and administrative expense

	December 31, 2017	December 31, 2016	December 31, 2015
Employee benefits and expenses	2,097,853	2,174,543	1,502,900
Business development	161,985	45,649	72,562
Travel expenses	199,484	158,774	257,454
Administration expenses	2,522,217	2,969,796	2,386,791
Lease expenses	81,277	63,695	59,665
Depreciation tangible assets	69,190	39,475	38,740
Capital tax expenses	18,403	(5,420)	23,458
Total general and administrative expenses	**5,150,409**	**5,446,512**	**4,341,570**

18. Employee benefits

	December 31, 2017	December 31, 2016	December 31, 2015
Salaries	3,761,171	3,662,180	2,833,741
Pension costs	378,588	342,805	282,517
Other social benefits	277,468	301,537	191,079
Share based payments costs	354,851	290,783	311,671
Recruitment costs	125,731	391,035	—
Other personnel expenditures	(26,439)	40,827	24,557
Total employee benefits	**4,871,370**	**5,029,167**	**3,643,565**

Benefit plans

The Company participates in a retirement plan (the “Plan”) organized as 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 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 the determination of 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. The rate was 1.75% in 2015, 1.25% in 2016 and 1.00% in 2017.

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

	2017	2016
Defined benefit obligation at January 1	7,122,841	5,427,776
Service costs	348,172	319,173
Plan participants' contribution	236,074	218,275
Interest cost	50,494	62,916
Actuarial losses	60,781	417,937
Transfer-out amounts	(440,950)	(1,276,315)
Transfer-in amounts of new employees	622,205	1,953,079
Defined benefit obligation at December 31	**7,999,617**	**7,122,841**

The defined benefit obligation includes only liabilities for active employees. The weighted average modified duration of the defined benefit obligation at December 31, 2017 is 20.9 years (2016: 21.7 years).

Change in fair value of plan assets

	2017	2016
Fair value of plan assets at January 1	5,030,407	3,851,943
Interest income	37,500	47,994
Return on plan assets excluding interest income	332,759	23,835
Employer contributions	236,074	220,306
Plan participants' contributions	236,074	218,275
Transfer-out amounts	(440,950)	(1,276,315)
Transfer-in amounts of new employees	622,205	1,953,079
Administration expense	(17,422)	(8,710)
Fair value of plan assets at December 31	**6,036,647**	**5,030,407**

Net defined benefit liability recognized in the statement of financial position

	December 31, 2017	December 31, 2016
Present value of funded defined benefit obligation	7,999,617	7,122,841
Fair value of plan assets	(6,036,647)	(5,030,407)
Net defined benefit liability	**1,962,970**	**2,092,434**

Defined Benefit Cost

	2017	2016	2015
Service cost	348,172	319,173	261,778
Net interest expense	12,994	14,922	14,873
Administration expense	17,422	8,710	5,866
Total defined costs for the year recognized in profit or loss	**378,588**	**342,805**	**282,517**

Remeasurement of the Defined Benefit Liability

	2017	2016	2015
Actuarial loss (gain) arising from changes in financial assumption	(150,552)	412,396	(167,623)
Actuarial loss arising from experience adjustments	211,331	264,417	175,375
Actuarial gain arising from demographic assumptions	—	(258,876)	—
Return on plan assets excluding interest income	(332,759)	(23,835)	46,164
Total defined benefit cost for the year recognized in the other comprehensive loss	**(271,980)**	**394,102**	**53,916**

Assumptions

	2017	2016	2015
At December 31			
Discount rate	0.80%	0.70%	1.10%
Future salary increase	1.10%	1.10%	1.10%
Pension indexation	0.00%	0.00%	0.00%
Mortality and disability rates	BVG2015G	BVG2015G	BVG2010G

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,	
	2017	2016
Change in assumption	0.25% increase	0.25% increase
Discount rate	(354,477)	(324,057)
Salary increase	49,707	42,181
Pension indexation	189,965	201,221
Change in assumption	+1 year	+1 year
Life expectancy	182,977	167,161

19. Finance income and finance expense

	2017	2016	2015
Interest income	53,570	67,565	36,562
Net foreign currency exchange gain	1,912,681	843,950	1,806,206
Revaluation gain from derivative financial instruments	3,372,186	291,048	—
Total finance income	**5,338,437**	**1,202,563**	**1,842,768**
Interest expense (incl. Bank charges)	1,640,394	828,547	7,985
Net foreign currency exchange loss	2,737,273	944,047	662,100
Total finance expense	**4,377,667**	**1,772,594**	**670,085**
Finance income/(expense), net	**960,770**	**(570,031)**	**1,172,683**

In 2017, net foreign currency exchange gains contain translation gains of CHF 1,315,029 (2016: CHF 396,665; 2015: CHF 1,154,513) which arose on the Company's USD and EUR denominated cash and cash equivalents. In 2017, interest expenses include interest paid to Hercules Capital, Inc. under the Loan and Security Agreement in an amount of CHF 1,182,369 (2016: CHF 546,170; 2015: CHF 0).

20. Taxation

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

	2017	2016	2015
Deferred income tax expense	(21,415)	—	(32,761)
Deferred income tax gain	39,188	131,055	32,761
	17,773	**131,055**	**—**

The Group's effective income tax expense differed from the expected theoretical amount computed by applying the Group's applicable weighted average tax rate of 21.7% in 2017 (2016: 21.5%, 2015: 21.9%) as summarized in the following table:

	2017	2016	2015
Reconciliation			
Loss before income tax	(24,427,247)	(30,793,306)	(29,705,063)
Income tax at statutory tax rates applicable to results in the respective countries	5,311,030	6,629,237	6,493,569
Effect of unrecognized temporary differences	193,598	(27,072)	(105,395)
Effect of unrecognized taxable losses	(5,429,935)	(6,360,837)	(6,438,609)
Effect of previously unrecognized deferred tax asset	39,189	131,055	—
Effect of expenses deductible for tax purposes	9,696	2,505	—
Effect of expenses not considerable for tax purposes	—	23,716	—
Effect of impact from application of different tax rates	(105,805)	(267,695)	—
Effect of unrecognized taxable losses in equity	—	146	50,435
Income tax gain	**17,773**	**131,055**	**—**

The tax effect of taxable temporary differences that give rise to deferred income tax liabilities or to deferred income tax assets as of December 31 is presented below:

	December 31, 2017	December 31, 2016
Deferred Tax Liabilities		
Intangible assets	(349,052)	(327,637)
Hercules Loan Facility	(47,477)	(76,390)
Total	**(396,529)**	**(404,027)**

	December 31, 2017	December 31, 2016
Deferred Tax Assets		
Net operating loss (NOL)	217,720	207,445
Total	**217,720**	**207,445**
Deferred Tax, net	**(178,809)**	**(196,582)**

AURIS MEDICAL HOLDING AG

Deferred Tax 2017	Opening Balance	Recognized in Profit or Loss	Recognized in Equity	Closing Balance
Intangible assets	(327,637)	(21,415)	—	(349,052)
Hercules Loan Facility	(76,390)	28,913	—	(47,477)
Net operating loss (NOL)	207,445	10,275	—	217,720
Total	**(196,582)**	**17,773**	**—**	**(178,809)**

Deferred Tax 2016	Opening Balance	Recognized in Profit or Loss	Recognized in Equity	Closing Balance
Intangible assets	(327,637)	—	—	(327,637)
Hercules Loan Facility	—	(76,390)	—	(76,390)
Net operating loss (NOL)	—	207,445	—	207,445
Total	**(327,637)**	**131,055**	**—**	**(196,582)**

As of December 31, 2017, the Group had total gross tax loss carry forwards amounting to CHF 142 million (2016: CHF 115.4 million), of which CHF 140.9 million related to Auris Medical AG, Auris Medical Holding AG and Otolanum AG in Switzerland and CHF 1.1 million to Auris Medical Inc. in the United States (2016: CHF 114.3 million for Auris Medical AG and Otolanum AG and CHF 1.1 million for Auris Medical Inc.).

The Group's tax loss carry-forwards with their expiry dates are as follows:

	December 31, 2017	December 31, 2016
Within 1 year	1,754,398	1,859,601
Between 1 and 3 years	31,089,191	9,928,391
Between 3 and 7 years	108,055,089	102,542,641
More than 7 years	1,072,260	1,087,543
Total	**141,970,938**	**115,418,176**

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

	December 31, 2017	December 31, 2016
Deductible temporary differences		
Employee benefit plan	433,816	450,227
Stock option plans	400,764	—
Total potential tax assets	**834,580**	**450,227**
Taxable unrecognized temporary differences		
Property and equipment	—	—
Total unrecognized potential tax liabilities	—	—
Offsetting potential tax liabilities with potential tax assets	—	—
Net potential tax assets from temporary differences not recognized	834,580	450,227
Potential tax assets from loss carry-forwards not recognized	29,959,963	25,082,968
Total potential tax assets from loss carry-forwards and temporary differences not recognized	**30,794,543**	**25,533,195**

21. Loss per share

	December 31, 2017	December 31, 2016	December 31, 2015
Loss attributable to owners of the Company	(24,409,474)	(30,662,251)	(29,705,063)
Weighted average number of shares outstanding	43,741,870	34,329,280	32,299,166
Basic and diluted loss per share	**(0.56)**	**(0.89)**	**(0.92)**

For the years ended December 31, 2017 and 2016 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 the warrant issued to Hercules (Note 24) as they would be anti-dilutive. As of December 31, 2017, the Company has 2,251,540 options outstanding under its stock option plans. The average number of options outstanding between January 1, 2017 and December 31, 2017 was 1,676,526 (769,529 for the period between January 1, 2016 and December 31, 2016). As of December 31, 2017, the Company issued warrants to purchase up to 8,186,117 of its common shares outstanding.

22. Commitments and contingencies

Operating lease commitments

On October 1, 2016, the Group entered into a lease for a new office space under an operating lease agreement. The lease has a five year fixed term, subject to a one-time cancellation option effective as per September 30, 2019. Effective December 31, 2017, the Group entered into a termination agreement related to a lease entered into on April 1, 2013.

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, 2017	December 31, 2016
Within one year	161,110	161,110
Between one and five years	446,051	607,161
Total	**607,161**	**768,271**

Office lease expenses of CHF 192,957, CHF 148,039 and CHF 107,450 were booked in 2017, 2016 and 2015, respectively, in the consolidated statement of profit or loss and other comprehensive loss.

23. 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 2017, the total compensation paid to management amounted to CHF 1,973,167 (2016: CHF 1,871,406; 2015: CHF 1,619,208). The fees paid to members of the Board of Directors in 2017 for their activities as board members totaled CHF 337,619 (2016: CHF 364,276; 2015: CHF 329,827).

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.

	Executive Management			Board of Directors			Total		
	2017	2016	2015	2017	2016	2015	2017	2016	2015
Short term benefits	1,576,864	1,554,850	1,363,796	280,762	325,493	268,810	1,857,626	1,880,343	1,632,606
Post-employee benefits years	94,839	88,838	78,721	—	—	—	94,839	88,838	78,721
Share-based payment charge	190,659	217,981	176,691	72,647	103,380	61,017	263,306	321,361	237,708
Total	**1,862,362**	**1,861,669**	**1,619,208**	**353,409**	**428,873**	**329,827**	**2,215,771**	**2,290,542**	**1,949,035**

In 2017, CHF 263,306 (2016: CHF 321,361; 2015: CHF 237,708) was expensed for grants of stock options to members of the Board of Directors and management. The 2017 share based payment charge shown above excludes adjustments for instruments forfeited in 2017 due to termination of service. Contributions to pension schemes amounted to CHF 94,839, CHF 88,838 and CHF 78,721 during the years 2017, 2016 and 2015, respectively. No termination benefits or other long term benefits were paid.

Members of the Board of Directors and management held 1,782,605, 656,355 and 457,510 stock options as of December 31, 2017, 2016, and 2015, respectively.

For the business year 2015, the Company granted 25,813 restricted shares to employees under the Equity Incentive Plan. The grant price for the 2015 awards was the closing price of our shares on January 7, 2016 (USD 7.08) and resulted in a total payroll charge of CHF 188,092 in 2015. These shares vest upon grant and have a sale restriction for a period of 3 years. For the 2017 and 2016 business year, no restricted shares were issued.

Controlled Equity Offering℠

Thomas Meyer, our Chief Executive Officer, or the Share Lender, has entered into a share lending agreement with Cantor to facilitate the timely settlement of common shares sold under the Controlled Equity Offering Sales Agreement with Cantor. Pursuant to the terms of the share lending agreement, the Share Lender will lend common shares to Cantor so that those common shares may be delivered by Cantor to purchasers of common shares sold in the offering. Cantor will return common shares to the Share Lender upon the issuance of new common shares by the Company to Cantor. Neither the Company nor the Share Lender received any compensation for this arrangement. In the year ended December 31, 2017, we did not offer or sell any common shares under the Controlled Equity Offering Sales Agreement. The Controlled Equity Offering program terminated upon consummation of the Merger on March 13, 2018.

24. Loan and Warrant

On July 19, 2016, the Company entered into a Loan and Security Agreement (the “Hercules Loan and Security Agreement”) for a secured term loan facility of up to $20.0 million with Hercules Capital, Inc. as administrative agent (“Hercules”) and the lenders party thereto. An initial tranche of $12.5 million was drawn on July 19, 2016, concurrently with the execution of the Hercules Loan and Security Agreement. The loan matures on January 2, 2020 and bears interest at a minimum rate of 9.55% per annum, and is subject to the variability of the prime interest rate. The loan is secured by a pledge of the shares of Auris Medical AG owned by the Company, all intercompany receivables owed to the Company by its Swiss subsidiaries and a security assignment of the Company’s bank accounts.

The loan was initially recognized at transaction value with deductions of the fair value of the warrant at transaction date and directly attributable transactions costs. Subsequent to initial recognition, the loan is measured at amortized cost using the effective interest method. Applying this method, the calculated value of the loan as of December 31, 2017 is CHF 10,126,406. Of the CHF 10,126,406 amortization payments due within the next 12 months in an amount of CHF 4,542,109 are reclassified as current liabilities.

In connection with the loan facility, the Company issued Hercules a warrant to purchase up to 241,117 of its common shares at an exercise price of $3.94 per share. As of July 19, 2016, the warrant was exercisable for 156,726 common shares. Upon Hercules making the second advance under the loan facility, the warrant shall become exercisable for the additional 84,391 common shares. The warrant expires on July 19, 2023. The fair value calculation of the warrant is based on the Black-Scholes option price model. Assumptions are made regarding inputs such as volatility and the risk free rate in order to determine the fair value of the warrant. As the warrant is part of the loan transaction, its fair value was deducted from the loan proceeds and accounted for separately as non-current financial liability. Following the initial recognition, the warrant is measured at fair value and the changes in fair value are shown as profit or loss.

As of December 31, 2017 the fair value of the warrant amounts to CHF 23,350. Therefore, the fair value decreased by the total amount of CHF 93,782 in the current year (2016: CHF 291,048).

As of March 13, 2018, following the consummation of the Merger, the warrant was exercisable for 15,673 common shares at an exercise price of $39.40 per common share.

25. Warrants from Public Offering

On February 21, 2017, the Company completed a public offering (the “February 2017 Offering”) of 10,000,000 common shares with a nominal value of CHF 0.40 each and 10,000,000 warrants, each warrant entitling its holder to purchase 0.70 of a common share. The net proceeds to the Company from the February 2017 Offering were approximately CHF 9.1 million (US$9.1 million), after deducting underwriting discounts and other estimated offering expenses payable by us. The Company had transaction costs amounting to CHF 903,919. The transactions costs were recorded as CHF 397,685 in equity for the issuance of the common shares and CHF 506,234 to finance expense in the statement of profit or loss and comprehensive loss for the issuance of the warrants.

The underwriter was granted a 30-day option to purchase up to 1,500,000 additional common shares and/or 1,500,000 additional warrants. On February 15, 2017, the underwriter partially exercised its 30-day option to purchase additional common shares and/or warrants in the amount of 1,350,000 warrants.

Consequently, the Company issued warrants to purchase up to 7,945,000 of its common shares at an exercise price of US$1.2 per share. The warrants are exercisable during a five-year period beginning on date of issuance. The fair value calculation of the warrants is based on the Black-Scholes option price model. Assumptions are made regarding inputs such as volatility and the risk free rate in order to determine the fair value of the warrant. If a warrant is exercised, the Company will receive variable proceeds because the Company’s functional currency is CHF and the exercise price is in USD, which results in the warrants being considered liability instruments. Therefore, the warrants were assigned fair values using the Black-Scholes model. The residual value was assigned to the common share sold along with each warrant in accordance with IAS 32 Financial instruments. The gross proceeds from the February 2017 offering were CHF 9,998,305 of which CHF 5,091,817 (fair value as of February 21, 2017) was assigned to the warrants and CHF 4,906,488 was assigned to equity.

As of December 31, 2017, the fair value of the warrants amounted to CHF 1,813,413. The fair value decreased by CHF 3,278,404 since the initial recognition.

As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issued in the February 2017 Offering are excisable for up to 794,500 common shares at an exercise price of $12.00 per common share.

26. Events after the balance sheet date

Interference Proceedings

On July 20, 2015, the USPTO declared Patent Interference No. 106,030 involving our issued U.S. patent No. 9,066,865 (the “‘865 Patent”) and Otonomy’s U.S. patent application No. 13/848,636 (the “‘636 Application”). The patent interference identified claims 1-9 in the ‘865 Patent as interfering with

claims 38, 43 and 46-50 of the ‘636 Application. The ‘865 Patent discloses methods of treating inner or middle ear diseases with intratympanic injections of poloxamer-based compositions. The claims of the ‘865 Patent are directed to the use of fluoroquinolone antibiotics in poloxamer 407 compositions under certain specifications. On January 26, 2017, the USPTO issued a decision on the interference granting Auris benefit of priority. As a result of the decision, judgment was entered against Otonomy and all claims in the ‘636 Application were refused. In addition, claims 1-8 of the ‘865 Patent were cancelled as the result of the USPTO’s determination that the written description of the specification lacked full scope support for treating middle or inner ear disease with fluoroquinolone. However, claim 9, which is directed to a method of treating viral and bacterial infections with intratympanic injection of a fluoroquinolone antibiotic in a poloxamer 407 composition under certain specifications, was affirmed. On March 27, 2017, Otonomy submitted a notice of appeal to the United States Court of Appeals for the Federal Circuit. To preserve its rights, Auris filed a notice of cross-appeal on April 5, 2017. Otonomy subsequently filed its opening brief on July 20, 2017, and Auris filed its principal and response brief on October 27, 2017. On January 5, 2018, Otonomy filed its opposition and reply brief. Auris filed its reply brief on February 2, 2018.

Equity Offering

As of March 12, 2018, we had issued an aggregate of 300,000 common shares to LPC pursuant to the Commitment Purchase Agreement.

On January 30, 2018, we completed a public offering of 12,499,999 common shares with a nominal value of CHF 0.40 each and concurrent offering of 7,499,999 warrants, each warrant entitling its holder to purchase one common share. The net proceeds to the Company from the offering were approximately $4.9 million, after deducting placement agent fees and other estimated offering expenses payable by the Company. As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issued in the January 2018 offering were exercisable for up to 749,999.9 common shares at an exercise price of $5.00 per common share.

Merger

On March 13, 2018, the Company merged into Auris NewCo AG, a newly incorporated, wholly-owned Swiss subsidiary following shareholder approval at an extraordinary general meeting of shareholders held on March 12, 2018. Following the Merger, Auris NewCo, the surviving company, had a share capital of CHF 122,347.76, divided into 6,117,388 common shares with a nominal value of CHF 0.02 each. Pursuant to the Merger, shareholders received one common share with a nominal value of CHF 0.02 of Auris NewCo for every 10 of the Company’s common shares held prior to the Merger, effectively resulting in a “reverse stock split” at a ratio of 10-for-1. Auris NewCo changed its name to “Auris Medical Holding AG” following consummation of the Merger. On March 14, 2018 the common shares of Auris NewCo began trading on the Nasdaq Capital Market under the trading symbol “EARS.”

Related Party Transaction

On February 9, 2018, Thomas Meyer, our Chief Executive Officer, entered into a shares transfer agreement with the Company to facilitate the rounding up of fractional shares resulting from the exchange ratio used in the Merger. Pursuant to the terms of the share transfer agreement, Mr. Meyer committed to transfer, at no consideration, a common share to any shareholder entitled to a fraction of a common share as part of the Merger. Pursuant to the share transfer agreement, the Company nor the Mr. Meyer received any compensation for this arrangement. Any expenses incurred by Mr. Meyer in connection with the transfers under such agreement were borne by the Company.

TACTT3 Data read-out

On March 13, 2018, the Company announced that preliminary top-line data from the TACTT3 trial indicated that the study did not meet its primary efficacy endpoint of a statistically significant improvement in the Tinnitus Functional Score from baseline to Day 84 in the active treated group compared to placebo either in the overall population or in the otitis media subpopulation. The Company is currently investigating the outcomes, including those in TACTT2, the previously conducted sister trial. Following this analysis, the Company will assess if the intangible asset recorded in our financial statements for a total amount of CHF 157,520 related to the acquisition of the technical file will need to be impaired or not.