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

FORM 20-F

(Mark One)

o **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 for the fiscal year ended December 31, 2017**

OR

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

OR

o **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
Date of event requiring this shell company report

Commission file number: 000-55917

AURIS MEDICAL HOLDING AG

(Exact name of Registrant as specified in its charter)

Switzerland
(Jurisdiction of incorporation)

Bahnhofstrasse 21
6300 Zug
Switzerland
(Address of principal executive offices)

Thomas Meyer
Tel: +41 (0)41 729 71 94
Bahnhofstrasse 21
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Switzerland
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

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450 Lexington Avenue
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Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Shares, nominal value CHF 0.02 per share	The Nasdaq Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act:

None
(Title of Class)

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act:

None
(Title of Class)

Indicate the number of outstanding shares of each of the issuer's classes of capital stock or common stock as of the close of the period covered by the annual report.

Common shares: 48,373,890*

* 4,837,389 shares if adjusted to reflect the 10:1 "reverse stock split" effected through a statutory merger in connection with our corporate reorganization on March 13, 2018.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

o Yes x No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934.

o Yes x No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

x Yes o No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

o Yes x No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer o	Non-accelerated filer x
		Emerging Growth Company x

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. o

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP o	International Financial Reporting Standards as issued by the International Accounting Standards Board x	Other o

If "Other" has been checked in response to the previous question indicate by check mark which financial statement item the registrant has elected to follow.

o Item 17 o Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

o Yes x No

AURIS MEDICAL HOLDING AG

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Unless otherwise indicated or the context otherwise requires, all references in this annual report on Form 20-F (the "Annual Report") 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). The trademarks, trade names and service marks appearing in this Annual Report are property of their respective owners.

Unless indicated or the context otherwise requires, all references in this Annual Report 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 stock 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 stock 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.

FORWARD-LOOKING STATEMENTS

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

Forward-looking statements appear in a number of places in this Annual Report and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section “Item 3. Key Information—D. Risk factors” in this Annual Report. These risks and uncertainties include factors relating to:

- our operation as a development-stage company with limited operating history and a history of operating losses;
- our need for substantial additional funding to continue the development of our product candidates before we can expect to become profitable from sales of our products;
- 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 Keyzilen® (AM-101), AM-111 and AM-125, which are still in clinical development and may eventually prove to be unsuccessful, or that the post-hoc analysis in the subpopulation of profound acute hearing loss patients in the HEALOS trial may not be considered acceptable for regulatory filing purposes by relevant health authorities, which may impair our ability to raise additional funding to continue the development of our product candidates;
- 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 being subject to expensive, ongoing obligations and continued regulatory overview;
- enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval and commercialization;
- the chance that we do not obtain orphan drug exclusivity for AM-111, which would allow our competitors to sell products that treat the same conditions;
- dependence on governmental authorities and health insurers establishing adequate reimbursement levels and pricing policies;
- our products may not gain market acceptance, in which case we may not be able to generate product revenues;
- our reliance on our current strategic relationships with INSERM or Xigen and the potential 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, 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 “Item 3. Key Information—D. 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.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. Directors and senior management

Not applicable.

B. Advisers

Not applicable.

C. Auditors

Not applicable.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMETABLE

A. Offer statistics

Not applicable.

B. Method and expected timetable

Not applicable.

ITEM 3. KEY INFORMATION

A. Selected Financial Data

The following tables summarize our consolidated financial data as of the dates and for the periods indicated. The consolidated financial statement data as of December 31, 2017 and 2016 and for each of the years in the three-year period ended December 31, 2017 has been derived from our consolidated financial statements presented elsewhere in this Annual Report, which have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). The consolidated financial data 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 and which have not been included herein.

This financial information should be read in conjunction with "Item 5—Operating and Financial Review and Prospects" and our consolidated audited financial statements, including the notes thereto, included in this Annual Report.

	For the years ended December 31,				
	2017	2016	2015	2014	2013
	(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)
General and administrative	(5,150)	(5,447)	(4,342)	(4,489)	(1,362)
Operating loss	**(24,361)**	**(30,224)**	**(30,878)**	**(22,194)**	**(14,616)**
Interest income	54	68	37	52	74
Interest expense	(1,640)	(829)	(8)	(56)	(53)
Foreign currency exchange gain/(loss), net	(825)	(100)	1,144	4,012	(104)
Revaluation gain from derivative financial instruments	3,372	291	—	—	—
Transaction costs	(1,027)				
Loss before tax	**(24,427)**	**(30,794)**	**(29,705)**	**(18,186)**	**(14,699)**
Income tax gain	18	131	—	—	—
Income tax expense	—	—	—	(306)	—
Net loss attributable to owners of the Company	**(24,409)**	**(30,663)**	**(29,705)**	**(18,492)**	**(14,699)**
Other comprehensive loss:					
Items that will never be reclassified to profit or loss:					
Remeasurements of defined benefits liability	272	(394)	(54)	(1,101)	(58)
Items that are or may be reclassified to profit or loss:					
Foreign currency translation differences	50	(20)	(13)	(105)	32
Other comprehensive income/(loss)	**322**	**(414)**	**(67)**	**(1,206)**	**(26)**
Total comprehensive loss attributable to owners of the Company	**(24,087)**	**(31,077)**	**(29,772)**	**(19,698)**	**(14,725)**
Net loss per share(1)					
Net loss per share, basic and diluted(2)	(0.56)	(0.89)	(0.92)	(0.66)	(1.01)
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

(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 included elsewhere in this Annual Report.

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

Exchange Rate Information

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 rates were derived from the U.S. Federal Reserve Bank's reported exchange rates. On March 16, 2018, the exchange rate as reported by the U.S. Federal Reserve Bank was CHF 0.9532 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
Month Ended:				
September 30, 2017	0.9688	0.9625	0.9456	0.9745
October 31, 2017	0.9968	0.9821	0.9732	0.9990
November 30, 2017	0.9838	0.9915	0.9788	1.0014
December 31, 2017	0.9738	0.9870	0.9738	0.9928
January 31, 2018	0.9738	0.9604	0.9321	0.9832
February 28, 2018	0.9430	0.9355	0.9232	0.9438
March, 2018 (through March 16, 2018)	0.9532	0.9455	0.9378	0.9532

B. Capitalization and indebtedness

Not applicable.

C. Reasons for the offer and use of proceeds

Not applicable.

D. Risk factors

You should carefully consider the risks and uncertainties described below and the other information in this Annual Report. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common shares could decline. This Annual Report also contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.

Risks Related to Our Business and Industry

We are in the process of evaluating our clinical trial data following the failure of the Phase 3 trial for our lead product candidate, Keyzilen®. In addition, we are preparing discussions with key health authorities on the regulatory pathway for our second lead product candidate AM-111, which did not meet the primary efficacy endpoint in a Phase 3 trial, but showed in post-hoc analyses clinically meaningful and nominally significant treatment effects in a subpopulation. We cannot give any assurance that these candidates will continue to be developed, receive regulatory approval or be successfully commercialized, and we are assessing strategic options focused on enhancing shareholder value.

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) 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 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. In addition, on November 28, 2017, we announced that the HEALOS Phase 3 clinical trial that investigated our other lead product candidate, AM-111, 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.

As a result, we are in the process of evaluating strategic options for the Company focused on enhancing shareholder value. The review will include a thorough evaluation of the Company's current development plan, including a review of the relevant Keyzilen® clinical trial data, the regulatory pathway for developing AM-111 for the indication of treating profound acute hearing loss and the Company's future direction, including whether we will continue to seek the development, regulatory approval and commercialization of either Keyzilen® or AM-111 in the future, or pursue an alternative course of action. There is no guarantee that we will be successful in any pursuit of strategic options or if we do continue our efforts to develop and commercialize either Keyzilen® or AM-111 in the future, or that any alternative course of action will lead to the success of our business.

If we continue development of our product candidates, we would need to conduct additional studies and trials in the future, in order to pursue regulatory approval. We will 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 our product candidates. In addition, we may be forced to refinance our existing indebtedness or ramp down our business activity. If we are not able to raise additional capital when needed, there would be substantial doubt as to our ability to continue as a going concern. See "-We expect that we will need substantial additional funding before we can expect to become profitable from sales of our products. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts."

We are 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 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 December 31, 2017, we had an accumulated deficit of CHF 136.1 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 CHF 12.0 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 December 31, 2017, we have drawn $12.5 million under the facility of which we have repaid $2.2 million.

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®, AM-111 or AM-125. 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®, AM-111 or AM-125, 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 U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory agencies, domestic or foreign, to change our manufacturing processes, or to perform clinical, nonclinical, or other types of trials in addition to those that we currently anticipate. In cases where we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain coverage and reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Additionally, if we are not able to generate sufficient revenue from the sale of any approved products, we may never become profitable.

We may be unable to develop and commercialize Keyzilen®, AM-111, AM-125 or any other product candidate and, even if we do, may never achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business or continue our operations.

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

We 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 AM-111 and initiate pre-clinical and clinical development of other product candidates. We expect that our total operating expense in 2018 will be in the range of CHF 10.0 to 12.0 million. As of December 31, 2017, our cash and cash equivalents were CHF 15.0 million. We believe that our existing cash and cash equivalents (including the net proceeds from the equity offering completed in January 2018) will enable us to fund our operating expenses and capital expenditure requirements at least until the fourth quarter of 2018. 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. 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. 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 our 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®, AM-111 and AM-125, 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®, AM-111 and AM-125, 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®,AM-111 and AM-125, 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®, AM-111, AM-125 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®, AM-111 or AM-125, 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 AM-111 are in Phase 3 clinical development and AM-125 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. Additionally, 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. We are currently investigating the outcomes, including those in TACTT2, the previously conducted sister trial.

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, some of which are captured daily from trial participants with electronic diaries. Based on insights from our analysis of the TACTT2 trial, 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, low compliance with daily reporting requirements may impact the trials' validity or statistical power.

Under the SPA with the FDA, we agreed to use the Tinnitus Functional Index, or TFI, as a co-primary efficacy endpoint in the TACTT2 trial and a secondary efficacy endpoint in the TACTT3 trial. 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. We used a different tinnitus questionnaire in the previous clinical trials with Keyzilen® (Tinnitus Handicap Inventory 12, THI-12, a 12-item short version of the 25-item Tinnitus Handicap Inventory, or THI). Unlike the THI-12, the TFI was developed and validated broadly in accordance with the FDA's guidance for patient-reported outcome measures and with the explicit aim of measuring treatment-related changes in tinnitus. In addition, the TFI covers all important domains of negative tinnitus impact including sleep difficulties, whereas the THI-12 does not include any sleep-related item. In spite of the methodological superiority of the TFI and a 2011 study by Meikle et al. showing a high correlation between THI and TFI scores with higher responsiveness to change of the latter, there is no assurance that outcomes with the TFI will be qualitatively and quantitatively similar or the same as those that would result with the THI-12. In the TACTT2 trial, treatment with Keyzilen® did not result in a clinically meaningful change in TFI in the overall trial population. The preliminary top-line data from the TACTT3 trial also 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.

For calculating the statistical power of the extended TACTT3 trial, we made certain hypotheses regarding the size of the true treatment effect of Keyzilen® over placebo and the related standard deviations. For the TFI, those were based on actual outcomes for the subpopulation of otitis media-related tinnitus in the TACTT2 trial, whereas the standard deviation was taken at the 80% confidence level (meaning that the probability is 80% that the true standard deviation is not higher). The statistical power for detecting a true treatment effect of at least 5 TFI points in the overall trial population or of at least 7 TFI points in the subpopulation with otitis media related tinnitus was calculated at about 90%. 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. We are currently investigating the outcomes, including those in TACTT2, the previously conducted sister trial.

In the case of AM-111, we are evaluating the safety and efficacy in an idiopathic condition which implies a considerable heterogeneity in the etiology and natural history of the condition. 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 AM-111 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 AM-111 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 AM-111 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 AM-111 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.

We plan to obtain guidance from the FDA and EMA on the regulatory path forward in light of the results from HEALOS. We expect that we will need to conduct at least one more trial in order to confirm the therapeutic effects of AM-111 in patients with acute profound hearing loss.

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.

Based on our analysis of the TACTT2 clinical trial results, we amended our TACTT3 Phase 3 clinical trial of Keyzilen® and enrolled additional patients, which caused our product development costs to increase. If we are required to conduct additional clinical trials or other testing of Keyzilen®, AM-111, AM-125 or any other product candidate that we develop beyond the trials and testing that we contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with Keyzilen®, AM-111 or our other product candidates, we may:

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

Our product development costs will also increase if we experience delays in testing or marketing approvals or if we are required to conduct additional clinical trials or other testing of Keyzilen®, AM-111 or AM-125 and we may be required to obtain additional funds to complete clinical trials. We cannot assure you that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our trials after they have begun. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates, which may harm our business and results of operations. In addition, some of the factors that cause, or lead to, clinical trial delays may ultimately lead to the denial of regulatory approval of Keyzilen®, AM-111, AM-125 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 AM-111 to date, adverse events have included procedure-related transient changes in tinnitus loudness, muffled hearing, ear discomfort or pain, incision site complications and middle ear infections. A limited number of serious adverse events were observed (in 1.2 to 2.5% of patients enrolled in the Keyzilen® trials and in 2.7 to 4.5% of patients in the AM-111 trials); all (Keyzilen®) or most (AM-111) were considered unrelated or unlikely related to the treatment. Occurrence of serious procedure- or treatment-related side effects could impede clinical trial enrollment and receipt of marketing approval from the FDA, the EMA and comparable foreign regulatory authorities. They could also adversely affect physician or patient acceptance of our product candidates.

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

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

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

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

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies.

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

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

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

their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

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

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

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

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

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

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

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

The orphan drug designation for AM-111 relates to ASNHL, an umbrella term comprising acute acoustic trauma, 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®, AM-111 and AM-125 for the treatment of acute inner ear tinnitus, acute inner ear hearing loss and vertigo, 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) AM-111, being developed for the treatment of acute inner ear hearing loss. Additionally, we have one product candidate, AM-125, 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 or acute inner ear hearing loss has been approved by the FDA or the EMA. Accordingly, our current product candidates or any of our other future product candidates could take a significantly longer time to gain regulatory approval than expected or may never gain regulatory approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our product candidates.

We generally plan to seek regulatory approval to commercialize our product candidates in the United States, the European Union and in additional foreign countries where we have commercial rights. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing, and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. Failure to obtain marketing authorization for our product candidates will result in our being unable to market and sell such products, which would materially adversely affect our business, financial conditional and results of operations. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited. Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

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

There are currently no drugs with proven efficacy for acute inner ear tinnitus or acute inner ear hearing loss. In addition, there has been limited historical clinical trial experience generally for the development of drugs to treat these conditions. Regulatory authorities in the United States and European Union have not issued definitive guidance as to how to measure the efficacy of treatments for acute inner ear tinnitus or acute inner ear hearing loss, and regulators have not yet established what is required to be demonstrated in a clinical trial in order to signify a clinically meaningful result and/or obtain marketing approval. We designed our Phase 3 trials for Keyzilen® and AM-111 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. The TACTT2 clinical trial with Keyzilen® did not meet the two co-primary efficacy endpoints of statistically significant changes in tinnitus loudness and tinnitus burden compared to placebo. Further, the 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.

With regard to AM-111, the FDA and EMA have indicated that a 10 dB improvement in hearing thresholds is clinically significant, in line with clinical practice. However, no product has been approved for marketing based upon such guidance and we cannot be certain that AM-111 will be approved even if it were to demonstrate such results in Phase 3 trials.

Some of our conclusions regarding the potential efficacy of AM-111 in our completed HEALOS clinical trial for the treatment of acute sensorineural hearing loss 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 AM-111 for the treatment of acute sensorineural hearing loss, we performed retrospective analyses that we believe show treatment effects on the magnitude of hearing recovery in favor of AM-111 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. As a result, even if the ASSENT trial provided further evidence of AM-111's therapeutic benefits in the subgroup of profound acute hearing loss, the HEALOS results and the retrospective analysis could negatively impact the evaluation by the EMA or the FDA, and we expect that such outcome may need to be confirmed prospectively in one or more additional Phase 3 trials in order to gain regulatory market 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, the active pharmaceutical ingredient of Keyzilen®, is an isomer of Ketamine, and may be affected by the safety of the drugs related to them. Although Ketamine has been used successfully in patients for many years, newly observed toxicities or worsening of known toxicities, in pre-clinical studies of, or in patients receiving, Ketamine, or reconsideration of known toxicities of Ketamine in the setting of new indications, could result in increased regulatory scrutiny of Keyzilen®. For example, Ketamine is regulated by the Drug Enforcement Administration, or DEA, under the Controlled Substances Act as a Schedule III drug. DEA scheduling is a separate process that can delay when a drug may become available to patients beyond a New Drug Application, or 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 Controlled Substances Act, 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.

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.

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, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Health Care Reform Law, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. The Health Care Reform Law, among other things, increased rebates a manufacturer must pay to the Medicaid program, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, established a 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. On January 2, 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These 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.

Furthermore, it is possible that following the inauguration of President Trump on January 20, 2017, legislation will be introduced and passed by the Republican-controlled Congress repealing the Health Care Reform Law in whole or in part and signed into law by President Trump, consistent with statements made by him during his presidential campaign and subsequently indicating his intention to do so within a short time following his inauguration. In May 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act, which, if enacted, would have amended and repealed significant portions of the Health Care Reform Law. The U.S. Senate considered but did not adopt other legislation to amend and/or replace elements of the Health Care Reform Law and authority to act under the fiscal year 2017 budget resolution expired on September 30, 2017.

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, 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, and Sound Pharmaceuticals, Inc., or Sound Pharma, both U.S. companies developing pharmaceutical treatments for ear disorders. In October 2013, Otonomy announced the launch of a development program for the treatment of tinnitus, OTO-311, which 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®. Further, we intend to rely on our patent applications with broad disclosures to pursue claims relating to the use of polymers with NMDA antagonists in controlled-release topical compositions for the treatment of tinnitus. Otonomy is also developing OTO-104, which is a polymer-based formulation of dexamethasone for intratympanic treatment of 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 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 AM-111.

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 AM-111 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 project completed Phase 1 of clinical development and obtained orphan drug designation from the EMA. The company announced its intention to initiate 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. If successful, SENS-401 may compete against AM-111, 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 AM-111.

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. In December 2016, Castle Creek Pharmaceuticals, LLC announced the in-licensing of Arlevert, a fixed-dose combination of cinnarizine, a calcium channel antagonist, and dimenhydrinate, an antihistamine, from Hennig Arzneimittel GmbH & Co. KG, a German company, and its intention to develop it as a treatment for vertigo in the United States market. Arlevert is approved and has been marketed for a long time in various countries outside the US.

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®, AM-111, AM-125 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®, AM-111, 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®, AM-111, 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®, AM-111, 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 AM-111 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®, AM-111 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®, AM-111 and AM-125 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®, AM-111 and AM-125 could be smaller than our estimates of the potential market opportunity. If the actual market for Keyzilen®, AM-111 and AM-125 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®, AM-111, 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 AM-111 and our business, commercialization prospects and financial condition may be adversely affected.

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

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

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

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

We cannot predict the result of these disagreements with Xigen and any litigation that may result. While Xigen has taken no action as of the date of this 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 AM-111. No assurance can be given that these disagreements and any resulting litigation will not have a material adverse effect on our business, commercialization prospects for AM-111 and our other product candidates and our financial condition. For a description of our agreement with Xigen, please see "Item 4. Information on the Company—B. 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 AM-111.

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

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

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

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. We may also be restricted under existing and future collaboration agreements from entering into strategic partnerships or collaboration agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all, for any of our existing or future product candidates and programs because the potential partner may consider that our research and development pipeline is insufficiently developed to justify a collaborative effort, or that our product candidates and programs do not have the requisite potential to demonstrate safety and efficacy in the target population. If we are unsuccessful in establishing and maintaining a collaboration with respect to a particular product candidate, we may have to curtail the development of that product candidate, reduce the scope of or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our

own expense for which we have not budgeted. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue. Even if we are successful in establishing a new strategic partnership or entering into a collaboration agreement, we cannot be certain that, following such a strategic transaction or license, we will be able to progress the development and commercialization of the applicable product candidates as envisaged, or that we will achieve the revenues that would justify such transaction, and we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

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

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

We have relied upon and plan to continue to rely upon third-party CROs to monitor and manage data for our ongoing nonclinical and clinical programs, including the clinical trials of Keyzilen®, AM-111 and AM-125. 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®, AM-111 and AM-125, and others for the manufacturing and supply of pre-filled syringes. For the foreseeable future, we expect to continue to rely on such third parties for the manufacture of any of our product candidates on a clinical or commercial scale, if any of our product candidates receives regulatory approval. Reliance on third-party providers may expose us to different risks than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable marketing application to the FDA or other regulatory authority. Although we have auditing rights with all our manufacturing counterparties, we do not have control over a supplier's or manufacturer's compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

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

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

Our current and anticipated future dependence upon others for the manufacturing of Keyzilen®, AM-111, 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®, AM-111 and AM-125. We currently have a relationship with one supplier each, for the supply of the active pharmaceutical ingredients and the hyaluronic acid component of Keyzilen®, AM-111 and AM-125. 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®, AM-111 and AM-125. 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®, AM-111 and AM-125, we cannot

provide any assurances that any such patent term extension will be obtained and, if so, for how long. Specifically, Xigen is concurrently developing other indications for XG-102, the active substance of AM-111. Since for each product only a single patent can be selected for patent term extension, there may be a conflict of interest with respect to patent selection for extending patent terms covering two different indications of XG-102. It is possible that Xigen may select a patent that does not provide the longest patent term for the AM-111 indication developed by us. In addition, upon issuance in the United States any patent term can be adjusted based on certain delays caused by the applicant(s) or 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®, AM-111, 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 and for AM-111 between 2020 and 2027 and 2035, prior to any patent term extensions to which we may be entitled under applicable laws.

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, with a Phase 3 program expected to complete in early 2018. In November 2014, the FDA designated Esketamine a ‘breakthrough therapy’ for this indication. In the event that Janssen’s confirmatory trials are successful and the company receives marketing authorization prior to us receiving marketing authorization for Keyzilen®, we would lose the potential benefit of a five-year marketing exclusivity period that we would otherwise expect to obtain.

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 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®, AM-111 and AM-125 are approved, competitors could file ANDAs for generic versions of Keyzilen®, AM-111 and AM-125, or 505(b)(2) NDAs that reference Keyzilen®, AM-111 and AM-125, respectively. If there are patents listed for Keyzilen®, AM-111 and AM-125 in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict whether any patents issuing from our pending patent applications will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

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

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

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

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

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents relating to our product candidates are controlled by our licensors. This is the case under our agreement with Xigen, where Xigen is entirely responsible for the prosecution and maintenance of the licensed patents and patent applications directed to AM-111. Xigen has no obligation to provide us any information with respect to such prosecution and we will not have access to any patent prosecution or maintenance information that is not publicly available. Although we monitor Xigen's ongoing prosecution and maintenance

of the licensed patents, if Xigen or any of our future licensing partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering AM-111 or any of our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products. Specifically, Xigen is concurrently developing another indication for brimapitide (XG-102), the active substance of AM-111. This may cause a conflict of interest and adversely affect Xigen's ability to prosecute the patent portfolio licensed to us in the best interest of our business. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties including with respect to the patents and applications licensed to us under our co-ownership and exploitation agreement with INSERM for 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.

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, Andrea Braun-Scherhag, Head Regulatory & Quality Affairs 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 our home country, Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel. In Switzerland, new legislation affecting public companies has been passed that, among other things, (a) imposes an annual binding shareholders' "say on pay" vote with respect to the compensation of executive management, including executive officers and the board of directors, (b) prohibits severance, advances, transaction premiums and similar payments to executive officers and directors and (c) requires companies to specify various compensation-related matters in their articles of association, thus requiring them to be approved by a shareholders' vote. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. We face

competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement business strategy, which could have a material adverse effect on our business.

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

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

Risks Related to Our Common Shares

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

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

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

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.

We have received a delisting notice from Nasdaq. Our common shares may be involuntarily delisted from trading on The Nasdaq Capital Market if we fail to regain compliance with the minimum closing bid price requirement of $1.00 per share and other 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.

The quantitative listing standards of the Nasdaq Capital Market 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 March 30, 2017, we received a letter from Nasdaq indicating that we have been provided an initial period of 180 calendar days, or until September 26, 2017, in which to regain compliance. On September 27, 2017 we received an additional 180-day

compliance period that will end on March 26, 2018. If we do not regain compliance by March 26, 2018, the Nasdaq staff will provide written notice that our common shares are subject to delisting.

To address the non-compliance, on March 13, 2018, 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.

In connection with the Merger, the Swiss Federal Tax Administration has taken 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 on the level of the surviving company . 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.

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”. There is no guarantee that the Merger or any other corporate action that we may attempt will solve the non-compliance with the minimum bid price requirement or that the price of our common shares will not fall below the minimum bid price requirement in the future in the event that we regain compliance.

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. On January 11, 2018, we received a letter from Nasdaq indicating that we have been provided an initial period of 180 calendar days, or until July 10, 2018 to regain compliance with Nasdaq’s market value of listed securities requirement.

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.

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 Securities and Exchange Act of 1934, as amended (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".

Stockholders 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 62.9% of our common shares. Depending on the level of attendance at our general meetings of shareholders, these shareholders may be in a position to determine the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the shares represented at our general meetings of shareholders may control any shareholder resolution requiring an absolute majority of the shares represented, including the election of members to the board of directors of our company, certain decisions relating to our capital structure, the approval of certain significant corporate transactions and certain amendments to our articles of association. To the extent that the interests of these shareholders may differ from the interests of the Company's other shareholders, the latter may be disadvantaged by any action that these shareholders may seek to pursue. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our common shares.

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

Future sales of a substantial number of our common shares, or the perception that such sales will occur, could cause a decline in the market price of our common shares. Approximately 28% of our common shares outstanding are held by affiliates. If these shareholders sell substantial amounts of common shares in the public market, or the market perceives that such sales may occur, the market price of our common shares and our ability to raise capital through an issue of equity securities could be adversely affected. We have also entered into a registration rights agreement pursuant to which we have agreed under certain circumstances to file a registration statement to register the resale of common shares held by certain of our shareholders, as well as to cooperate in certain public offerings of such common shares. We have also filed registration statements to register all common shares and other equity securities that we have issued under our prior equity incentive plans or may issue under our new omnibus equity compensation plan. These common shares may be freely sold in the public market upon issuance, subject

to certain limitations applicable to affiliates. If a large number of our common shares are sold in the public market, the sales could reduce the trading price of our common shares and impede our ability to raise future capital.

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

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

We are a holding company with no material direct operations.

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

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

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

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

We are organized under the laws of Switzerland. There can be no assurance that Swiss law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the U.S., which could adversely affect the rights of investors.

U.S. shareholders may not be able to obtain judgments or enforce civil liabilities against us or our executive officers or members of our board of directors.

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

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

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

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

Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, the payment of dividends and cancellation of treasury shares must be approved by shareholders. Swiss law also requires that our shareholders themselves resolve to, or authorize our board of directors to, increase our share capital. While our shareholders may authorize share capital that can be issued by our board of directors without additional shareholder approval, Swiss law limits this authorization to 50% of the issued share capital at the time of the shareholders' authorization. The authorization, furthermore, has a limited duration of up to two years and must be renewed by the shareholders from time to time thereafter in order to be available for raising capital. Additionally, Swiss law grants pre-emptive rights to existing shareholders to subscribe for new issuances of shares. In certain circumstances, including those explicitly described in our articles of association, our board of directors may withdraw such pre-emptive rights. Shareholders who believe pre-emptive rights were improperly withdrawn may sue us for damages or may attempt to block the registration of the issuance of new shares in the commercial register which may delay or exclude the share issuance. Swiss law also does not provide as much flexibility in the various rights and regulations that can attach to different categories of shares as do the laws of some other jurisdictions. These Swiss law requirements relating to our capital management may limit our flexibility, and situations may arise where greater flexibility would have provided benefits to our shareholders.

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

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

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

We are a foreign private issuer. As a result, in accordance with Nasdaq Listing Rule 5615(a)(3), we comply with home country governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of Nasdaq.

Swiss law does not require that a majority of our board of directors 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. Swiss law does not require 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).

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

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 2017 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 2017 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, or the Code, we will be a PFIC for any taxable year in which (i) 75% or more of our gross income consists of passive income or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets of the other corporation and received directly its proportionate share of the income of the other corporation. Passive income generally includes dividends, interest, rents, royalties and capital gains.

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

For further discussion of the adverse U.S. federal income tax consequences of our classification as a PFIC, see "Item 10. 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 2019. An independent assessment of the effectiveness of our internal controls could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

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

The trading market for our common shares depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We cannot assure you that analysts will cover us or provide favorable coverage. If one or more of the analysts who cover us downgrade our common shares or publish inaccurate or unfavorable research about our business, the price of our common shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common shares could decrease, which might cause the price of our common shares and trading volume to decline.

ITEM 4. INFORMATION ON THE COMPANY

A. History and development of the Company

We are a clinical-stage biopharmaceutical company focused on the development of novel products for the treatment of inner ear disorders. 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) AM-111, being developed for the treatment of acute inner ear hearing loss and has been granted orphan drug status by the FDA and the EMA and has been granted fast track designation by the FDA. AM-125 is being developed for the treatment of vestibular disorders. In addition, we are pursuing early stage projects for the treatment of tinnitus.

Our product candidates Keyzilen® and AM-111 are injected under local anesthesia into the middle ear by a technique called intratympanic injection. Once injected into the middle ear, the active substance, which is formulated in a biocompatible gel, diffuses into the inner ear. The procedure is short, safe, has a long history of use and allows for highly targeted drug delivery with minimal systemic exposure. It is performed by an ear, nose and throat, or ENT, specialist on an outpatient basis over one or more visits.

Our product candidate AM-125 is administered with a metered spray into the nose. Intranasal application allows for the active substance to reach the blood stream rapidly while avoiding the substantial “first-pass” metabolism associated with the current standard oral intake of betahistine.

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

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

Possible causes of acute inner ear tinnitus include traumatic insult such as exposure to excessive noise, or middle ear infection (otitis media, or OM). We have conducted Phase 2 trials in this specific tinnitus population with Keyzilen®, which demonstrated a favorable safety profile. Furthermore, in our Phase 2 clinical trials, Keyzilen® showed a dose dependent, persistent and clinically relevant improvement, as compared to the placebo, in subjective tinnitus loudness as well as other patient reported outcomes, such as tinnitus annoyance, tinnitus severity, sleep difficulties and general tinnitus impact. In August 2016, we announced that the trial Efficacy and Safety of Keyzilen® (AM-101) in the Treatment of Acute Peripheral Tinnitus 2, or TACTT2, the first of two pivotal Phase 3 clinical trials with Keyzilen®, did not meet the two co-primary endpoints of statistically significant changes in tinnitus loudness and tinnitus burden as measured by the TFI compared to placebo. However, the TACTT2 trial data showed treatment effects on TFI in favor of Keyzilen® for certain subgroups and support the positive safety profile established in the Phase 2 trials.

In the second quarter of 2017 we announced results from AMPACT1 and AMPACT2 (AM-101 in the Post-Acute Treatment of Peripheral Tinnitus 1 and 2), two open-label extension studies of the Phase 3 TACTT2 and TACTT3 clinical trials, respectively. The AMPACT studies were conducted at the request of the US Food and Drug Administration (FDA) to generate safety data from chronic intermittent use of Keyzilen® for up to 12 months. Both AMPACT1 and AMPACT2 confirmed the good safety profile of Keyzilen®.

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.

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. We are currently investigating the outcomes, including those in TACTT2, the previously conducted sister trial. See “Item 4. Information on the Company – Business Overview – Keyzilen® Phase 3 Clinical Program.”

We are also developing AM-111 for acute inner ear hearing loss. In our Phase 2 clinical trial, AM-111 showed a favorable safety profile. Furthermore, in patients with severe to profound ASNHL, we observed a clinically relevant improvement in hearing threshold, speech discrimination and a higher rate of complete tinnitus remission compared with placebo. On November 28, 2017, we announced that the HEALOS Phase 3 clinical trial that investigated AM-111 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 revealed a clinically meaningful and nominally significant improvement in the AM-111 0.4 mg/mL treatment group. At the same time, we announced that ASSENT, the second Phase 3 clinical trial investigating AM-111, 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.

On March 13, 2018, we merged into 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, our 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” 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.”

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 41 729 71 94.

On August 11, 2014, we completed our initial public offering of common shares, selling an aggregate of 10,113,235 common shares, which included 713,235 common shares sold on August 19, 2014 pursuant to an over-allotment option granted to the underwriters. All of these common shares were sold at a price to the public of $6.00 per share, yielding gross proceeds of $60.7 million. On May 18, 2015, we completed an underwritten offering of 5,275,000 shares at an offering price of $4.75 per share, yielding gross proceeds of $25.1 million.

On June 1, 2016, we entered into a Controlled Equity Offering Sales Agreement with Cantor Fitzgerald & Co., or Cantor, pursuant to which we may offer and sell, from time to time, having an aggregate offering price of up to $35 million through Cantor. 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 program terminated upon consummation of the Merger on March 13, 2018.

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. 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 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 warrant expires on July 19, 2023. The loan is secured by a pledge of the shares of Auris Medical AG, our principal operating subsidiary, all intercompany receivables owed to us by our Swiss subsidiaries and a security assignment of our bank accounts.

On February 2, 2017, we entered into an asset purchase agreement with Otifex Therapeutics Pty. Ltd, or Otifex, an Australian company, under which we purchased certain preclinical and clinical assets related to a formulation for the intranasal application of Betahistine, which we refer to as AM-125. See “Item 4. Information on the Company - Business Overview - AM-125 in Vestibular Disorders.”

On February 21, 2017, we completed a public offering of 10,000,000 common shares and 11,350,000 warrants, which included 1,350,000 warrants issued pursuant to an over-allotment option granted to the underwriter. Each warrant entitles its holder to purchase 0.70 of a common share. The net proceeds to the Company from the Offering were approximately $9.1 million, after deducting underwriting discounts and other estimated offering expenses payable by us. As of March 13, 2018, following the consummation of the Merger, the outstanding warrants issued in connection with the February 2017 offering were exercisable for an aggregate of 794,500 common shares at an exercise price of $12.00 per common share.

On October 10, 2017, we 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 agreed to subscribe for up to $13,500,000 of our common shares over the 30-month term of the Commitment Purchase Agreement. Pursuant to the Registration Rights Agreement, we agreed to file registration statements with the SEC to register the resale of the common shares purchased by LPC. As of March 12, 2018, we had issued an aggregate of 2,600,000 common shares to LPC pursuant to the Commitment Purchase Agreement. The Commitment Purchase Agreement terminated upon consummation of the Merger on March 13, 2018. Additionally, on October 16, 2017, we issued 1,744,186 of our common shares to LPC for an aggregate price of $1,500,000.

On January 30, 2018, we completed a public offering of 12,499,999 common shares, 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 offerings were approximately $4.9 million, after deducting placement agent fees and other estimated offering expenses payable by us. As of March 13, 2018, following consummation of the Merger, the outstanding warrants issued in the January 2018 offering were exercisable for an aggregate of 749,999.9 common shares at an exercise price of $5.00 per common share.

B. Business overview

Strategy

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

- ***Target inner ear disorders that have a defined pathophysiology and that are amenable to treatment.*** We are focusing on inner ear disorders for which the pathophysiology is 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 inner ear 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.

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

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

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

We are addressing each of these issues with our approach to developing therapeutics targeting the inner ear. Using 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 AM-111 are formulated in a viscous gel of sodium hyaluronate that is biocompatible, biodegradable, and isotonic (that is, having the same salt concentration and therefore not causing any pressure build up on either side of the RWM). The gel has a 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 AM-111, we are employing D-TAT, a peptidic active transporter technology that allows the transport of a large molecule to the inner ear that would normally be blocked by the RWM. This novel use of D-TAT brings

peptides not only behind the RWM but inside cells in the inner ear. To our knowledge, we are the first company to be delivering intracellular peptides to the inner ear using an active transporter such as D-TAT.

The 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-111 Brimapitide	*ASNHL (sudden deafness)*					Discussion regulatory pathway with agencies	Q2 2018
Keyzilen® (AM-101) Esketamine	*Acute inner ear tinnitus*					Data TACTT3 (A)	Under review
	Post-acute inner ear tinnitus					Data TACTT3 (B)	
AM-125 Betahistine	*Vertigo*					Initiate second Phase 1	Q1 2018
AM-102 Undisclosed	*Tinnitus*					Select lead compound	Q2 2018

(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 patient reported outcomes associated with tinnitus in two Phase 2 clinical trials. The Phase 3 clinical development program comprises 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 active pharmaceutical ingredient 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 acute acoustic trauma, or AAT. Unlike salicylate-induced tinnitus, AAT triggers glutamate excitotoxicity and may lead to irreversible damage to sensory cells. It does not result in tinnitus in all cases, but where it sets in, it may be permanent. In our pre-clinical trials, we demonstrated that 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. Patient reported outcomes, or PROs, such as the visual or numerical rating of tinnitus loudness or tinnitus questionnaires provide direct subjective measures of tinnitus and its impact on sleep, relaxation, communication, emotions, social interactions and other factors. For example, patients are asked a single question to rate the loudness of their tinnitus “right now” on a scale from 0 (“no tinnitus heard”) to 10 (“tinnitus extremely loud”). Among several tinnitus questionnaires, the 25 item Tinnitus Functional Index (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 acute acoustic trauma (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 approximately 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 new drug application, or NDA, filing. Although we do not have any plans to seek a label for such use, the FDA considered such unintended use likely to occur.

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. We are currently investigating the outcomes, including those in TACTT2, the previously conducted sister trial. Following such review, we intend to reassess our development plans for Keyzilen® and make appropriate adjustments as needed.

AM-111 in Hearing Loss

AM-111 is being developed for the treatment of ASNHL. In sensorineural hearing loss, there is damage to the sensory cells of the inner ear or the auditory nerve. Sensorineural hearing loss is also called “inner ear hearing loss”. Hearing loss is a heterogeneous disorder of many forms with a variety of causes. ASNHL may be triggered by a variety of insults, such as exposure to excessively loud sound, infection, inflammation or certain ototoxic drugs. These insults may also result in tinnitus. According to an article by Alexander and Harris published in Otology & Neurotology in 2013, the average annual incidence of sudden deafness is 66,954 new cases among the U.S. insured population. There are no currently approved treatments for this patient population.

AM-111 contains a synthetic D-form peptide (Brimapitide or D-JNKI-1) that protects sensorineural structures in the inner ear from stress-induced damage. AM-111 has been granted orphan drug status by both EMA and FDA 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 for acute acoustic trauma. The latter is known as ISSNHL for idiopathic sudden sensorineural hearing loss. Together they can be defined as acute sensorineural hearing loss or ASNHL. In both cases, the onset is sudden. And in both cases, part of the initial hearing loss tends to recover naturally in the days and weeks following the loss; however, some of the loss may remain and, over time, become chronic in nature and less amenable to therapeutic intervention.

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

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

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 – AM-111

We are developing AM-111 as a treatment for acute inner ear hearing loss. AM-111 contains a synthetic D-form peptide (D-JNKI-1) that acts as a c-Jun N-terminal Kinase (JNK) ligand, thereby protecting sensorineural structures in the inner ear from stress-induced damage. We are developing D-JNKI-1 under a worldwide exclusive license for the treatment of ear disorders from Xigen S.A. (Switzerland). Like Keyzilen®, AM-111 is delivered in a biocompatible gel formulation via intratympanic injection. We have established the safety and preliminary efficacy of AM-111 in a Phase 2 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. AM-111 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 AM-111 in hearing loss

The proprietary active pharmaceutical ingredient of AM-111 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 AM-111 to cross the round window membrane quickly, diffuse widely throughout the cochlea, transfect sensorineural cells effectively and reach its target inside the cell nucleus. The D-form of the peptide provides for protease resistance and hence enhanced stability. AM-111 was shown to remain pharmacologically active for several days inside the cochlea. The D-form is necessary for AM-111 to cross the RWM.

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

We conducted our pre-clinical development program for AM-111 in close collaboration with academic partners and various contract research organizations, or CROs. Brimapitide was invented by Xigen S.A. in Lausanne, Switzerland. In 2003, we signed a Collaboration and License Agreement with Xigen, under which we in-licensed worldwide exclusive rights for use of D-JNKI-1 in the treatment of ear disorders. Under the agreement with Xigen, we have exchanged various 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.

AM-111 Clinical Development

We have successfully completed two clinical trials of AM-111 that demonstrated its favorable safety profile and efficacy in treating 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. We initiated two pivotal Phase 3 trials in the treatment of idiopathic sudden sensorineural hearing loss, titled HEALOS and ASSENT. HEALOS enrolled patients in Europe and Asia and ASSENT has enrolled patients in the U.S., Canada and South Korea.

Phase 1/2 Clinical Trial

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

Trial participants received a single dose of AM-111 at either 0.4 mg/mL or 2 mg/mL in a biocompatible gel formulation by intratympanic injection into the most affected ear. The primary endpoint of the trial was the recovery of hearing thresholds from baseline to Day 30. AM-111 was well tolerated by all trial participants, regardless of the dose. The Phase 1/2 trial provided the first indications of therapeutic benefit of AM-111 in humans.

Phase 2 Clinical Trial

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

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. AM-111 was dosed at 0 mg/mL (placebo), 0.4 mg/mL (Low Dose) and 2.0 mg/mL (High Dose). All patients without a clinically relevant hearing recovery on Day 7 were given the option to take a course of oral prednisolone as a reserve therapy. The 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.

AM-111 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 AM-111 treated patients at any time points, no systemic side effects and no negative impact on balance or tinnitus. There were transient procedure related effects such as ear discomfort or pain, incision site complications or middle ear infection in less than 5% of cases.

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 AM-111 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 AM-111 2.0 mg/mL group overall showed improvement between the AM-111 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 AM-111 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 US 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 AM-111 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 AM-111 0.4 mg/mL treatment group. Further, patients treated with AM-111 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 AM-111 0.8 mg/mL tended to be somewhat less pronounced than those observed for AM-111 0.4 mg/mL. AM-111 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 AM-111, 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 of which 32 belonged to the subgroup of profound acute hearing loss. We expect to obtain outcomes from the trial in late March or early April 2018 and expect to meet with the FDA and EMA during the second quarter 2018 for a discussion of the regulatory path forward.

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 US 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 BPPV, 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 US 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 for intranasal administration that was 20-40 times higher than with oral administration.

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 two European health authorities to further define the development program. In 2018, we intend to conduct a second Phase 1 clinical trial with AM-125 in order to determine the maximum tolerated dose with single and repeated dosing and to generate additional data on the relative bioavailability compared to oral betahistine. The trial will take place in Europe. We will also generate additional toxicology data specifically with intranasal delivery in animals. Later in 2018 we intend to file an Investigational New Drug application with the FDA; in addition we plan to initiate a Phase 2 clinical trial in

late 2018. We believe that, if approved, AM-125 could become the first betahistine product for the treatment of vertigo in the United States.

Competition

We may face competition from different sources with respect to our product candidates Keyzilen® (AM-101), AM-111 and AM-125 and our pipeline products or any product candidates that we may seek to develop or commercialize in the future. Because there are a variety of means to block the activity of NMDA receptors or the JNK pathway, our patents and other proprietary protections for Keyzilen® and AM-111 may not prevent development or commercialization of all viable product candidates that are different from our lead product candidates.

Any product candidates that we successfully develop and commercialize will compete with existing therapies, even if they are not licensed specifically for use in our target therapeutic indications or if they lack clear proof of efficacy.

There exist no FDA or EMA approved products for the treatment of acute inner ear tinnitus or acute inner ear hearing loss; however, some drug products such as pentoxifylline, gingko biloba, corticosteroids, betahistine, trimetazidine or piracetam are frequently prescribed off-label. Some of them are even licensed as tinnitus or hearing loss treatments in certain countries of the European Union. 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 Tinnitus Retraining Therapy (TRT) or tinnitus maskers as well as more recent approaches like transcranial magnetic stimulation, vagus nerve stimulation, or customized sound therapy. Based on publicly available information, we have further identified 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 and, according to public information, is planning to develop it as OTO-311 for intratympanic injection. 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-311 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®. Further, we intend to rely on our patent applications with broad disclosures to pursue claims relating to the use of polymers with NMDA antagonists in controlled-release topical compositions for the treatment of tinnitus. Further 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 Pharmaceuticals, Inc. has a product candidate (SPI-1005, ebselen), that mimics and prompts production of the enzyme glutathione peroxidase and is designed for oral administration. 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 2018. 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 AM-111 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.

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

- Castle Creek Pharmaceuticals, LLC, a U.S. company, announced in December 2016 the in-licensing of Arlevert, a fixed-dose combination of cinnarizine, a calcium channel antagonist, and dimenhydrinate, an antihistamine, from Hennig Arzneimittel GmbH & Co. KG, a German company, and its intention to develop it as a treatment for vertigo for the U.S. market. Arlevert is approved and has been marketed for a long time in various countries outside the U.S. The current status of the program, which no longer appears on Castle Creek's website, is unclear.

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.

Intellectual Property

Patents

We seek regulatory approval for our products in disease areas with high unmet medical need, great market potential and where we have a proprietary position through patents covering various aspects of our products, e.g., composition, dosage, formulation, and use, etc. Our success depends on an intellectual property portfolio that supports our future revenue streams as well as erects barriers to our competitors. For example, we have broad disclosures in our patent applications and can pursue patent claims directed to our own leading product candidates as well as claims directed to certain potentially competing products. In addition, our earlier filed patent applications are prior art to others including certain of our competitors who filed their patent applications later than ours. We are maintaining and building our patent portfolio through: filing new patent applications; prosecuting existing applications and licensing and acquiring new patents and patent applications.

Despite these measures, any of our intellectual property and proprietary rights could be challenged, invalidated, circumvented, infringed or misappropriated, or such intellectual property and proprietary rights may not be sufficient to permit us to take advantage of current market trends or otherwise to provide competitive advantages. For more information, please see "Item 3. Key Information—D. Risk factors—Risks Related to Intellectual Property."

As of December 31, 2017, we own five issued U.S. patents and nine pending U.S. patent applications along with foreign counterparts of such 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 two of our pending applications with Xigen pursuant to the terms of our collaboration and license agreement.

In addition, as of December 31, 2017, we have exclusively licensed from Xigen twelve issued U.S. patents and three pending U.S. patent applications, along with their foreign counterparts in various jurisdictions that cover the composition of matter or method of use of JNK ligand peptides in a limited field including the intratympanic treatment of acute sensorineural hearing loss.

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

The patent portfolios for our two leading product candidates as well as other related filings as of December 31, 2017 are summarized below.

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.

AM-111

We are the exclusive licensee under our agreement with Xigen of a portfolio of patents and patent applications that relate, among other things, to JNK ligand peptides or their use in hearing loss. This portfolio includes 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 AM-111 are expected to expire between 2020 and 2027, prior to any patent term extensions to which we may be entitled under applicable laws. In addition, we co-own two patent families with Xigen related to use of JNK ligand peptides for the treatment of Meniere's disease or tinnitus.

We have several areas of disagreement with Xigen, including (i) our interpretation of the scope of the exclusive worldwide license granted to us by Xigen, (ii) the assignment by Xigen of certain of the patents covered by the license and (iii) Xigen's refusal to grant its consent for the disclosure of certain provisions of our agreement in the prospectus associated with our initial public offering and the filing of a redacted version of the agreement with the SEC. Although the difference in interpretation over the scope of the license has no impact on our current or planned use of AM-111 and we have been assured by Xigen and its assignee that the assignment of patents is without prejudice to our license, these areas of disagreement could adversely affect our relationship with Xigen and our business, commercialization prospects and financial conditions. Although Xigen has not taken any action as of the date of this Annual Report, any resulting litigation could result in substantial legal expenses and potentially the loss of our right to commercialize AM-111. For a discussion of these issues, please refer to "Item 3. Key Information—D. Risk factors —Risks Related to our Reliance on Third Parties—We have several areas of disagreement with Xigen, and consequently our relationship with Xigen may be adversely affected, we could potentially lose our right to commercialize AM-111 and our business, commercialization prospects and financial condition may be adversely affected."

Additional Patents and Applications

In addition to the Keyzilen® and AM-111 patent portfolios, we own one issued and four U.S. patent applications directed to poloxamer-based compositions with actives including fluoroquinolone antibiotics, steroids, or gacyclidine. Although these applications are not directed to our Keyzilen® or AM-111 products, they can provide a competitive advantage in the relevant market.

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. See "Item 3. Key Information—D. Risk factors—Risks Related to Intellectual Property.

We have acquired one United States patent from Otifex directed to intranasal application of betahistine for eustachian tube dysfunction and we have filed a patent application directed at the application of the formulation for vestibular disorders.

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, with a Phase 3 program starting in 2015. In November 2014, the FDA designated Esketamine a 'breakthrough therapy' for this indication. In the event that Janssen's confirmatory trials are successful and the company 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 AM-111 for the treatment of ASNHL in the United States and Europe. Orphan drug protection has been or may be sought where available if such protection also grants 7 years of market exclusivity.

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

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

Collaboration and License Agreements

INSERM

In 2006, we entered into a co-ownership/exploitation agreement with the Institut National de la Santé et de la Recherche Médicale, or INSERM, a publicly funded government science and technology agency in France. Pursuant to the terms of the agreement, we were granted the exclusive right to exploit any products derived from patents that resulted from our joint research program with INSERM that was conducted in 2003 to 2005 and led to the development of 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 S.A., or Xigen, pursuant to which Xigen granted us an exclusive worldwide license to use specified compounds to develop, manufacture and commercialize "pharmaceutical products as well as drug delivery devices and formulations for local administration of therapeutic substances to the inner ear for the treatment of ear disorders" (the Area). We also have a right of first refusal to license certain additional compounds developed by Xigen which may be used for the Area, specifically any cell permeable inhibitors to effectively block certain signal pathways in apoptotic processes.

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

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

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

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

There have been several areas of disagreement with Xigen, primarily related to interpreting the definition of the Area, the transfer of patents to Xigen Inflammation Ltd. and to the disclosure of certain provisions of the agreement in the context of our initial public offering. For a discussion of these issues, please refer to "Item 3. Key Information—D. Risk factors —Risks Related to our Reliance on Third Parties—We have several areas of disagreement with Xigen, and consequently our relationship with Xigen may be adversely affected, we could potentially lose our right to commercialize AM-111 and our business, commercialization prospects and financial condition may be adversely affected."

Manufacturing

We currently rely on and expect to continue to rely on third parties for the supply of raw materials and to manufacture drug supplies for clinical trials of our product candidates, including Keyzilen®, AM-111 and AM-125. For the foreseeable future, we expect to continue to rely on such third parties for the manufacture of any of our product candidates on a clinical or commercial scale, if any of our product candidates receives regulatory approval. Reliance on third-party providers may expose us to more risk than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after we submit our NDA or comparable marketing application to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we

have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us. If we were unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

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

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

Commercialization Strategy

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

Government Regulation

Product Approval Process

The clinical testing, manufacturing, labeling, storage, distribution, record keeping, advertising, promotion, import, export and marketing, among other things, of our product candidates are subject to extensive regulation by governmental authorities in the United States and other countries. The U.S. Food and Drug Administration, or FDA, under the Federal Food, Drug, and Cosmetic Act, or FDCA, regulates pharmaceutical products in the United States. The steps required before a drug may be approved for marketing in the United States generally include:

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

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

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 institutional review board, or IRB, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries. The FDA, the IRB or the clinical trial sponsor may suspend or terminate clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk. Additionally, some clinical trials are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides authorization for whether or not a trial may move forward at designated check points based on access to certain data from the study. We may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

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

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

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

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

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

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

After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its Active Pharmaceutical Ingredient, or 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.

Special Protocol Assessment

The FDA and an IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of a claim of effectiveness in an NDA. This process is known as a special protocol assessment, or SPA. Upon a specific request for an SPA by an IND sponsor, the FDA will evaluate the protocol. If an SPA agreement is reached, however, it is not a guarantee of product approval by the FDA or approval of any permissible claims about the product. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. In particular, the SPA agreement is not binding on the FDA if previously unrecognized public health concerns later come to light, other new scientific concerns regarding product safety or efficacy arise, the IND sponsor fails to comply with the protocol agreed upon, or the relevant data, assumptions, or information provided by the IND sponsor when requesting an SPA agreement change, are found to be false statements or misstatements, or are found to omit relevant facts. An SPA agreement may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA, or if the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the drug was identified after the testing began.

Orphan Drug Designation

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

If a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug or biological product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. The designation of such drug also entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor

obtains approval of the same drug or biological product as defined by the FDA or if our drug candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity. Orphan drug status in the European Union has similar but not identical benefits in that jurisdiction.

DEA Regulation

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

Post-Approval Requirements

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

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

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

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

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

Foreign Regulation

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

Other Healthcare Laws

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

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, facility, item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term “remuneration” has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and our practices may not in all cases meet all of the criteria for a statutory exception or safe harbor protection. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute’s intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated. A person or entity does not need to have actual knowledge of the statute or the specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act (discussed below). Further, the civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

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

In addition, we may be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, imposes certain requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. In addition, certain state laws

govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

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

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

Pharmaceutical Coverage, Pricing and Reimbursement

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

In addition, significant uncertainty exists as to the coverage and reimbursement status of newly approved healthcare product candidates. The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or other alternative is available. Furthermore, third-party payor reimbursement to providers for our product candidates may be subject to a bundled payment that also includes the procedure administering our products. To the extent there is no separate payment for our product candidates, there may be further uncertainty as to the adequacy of reimbursement amounts.

Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. We cannot be certain that our product candidates will be considered cost-effective. Because coverage and reimbursement determinations are made on a payor-by-payor basis, obtaining acceptable coverage and reimbursement from one payor does not guarantee the Company will obtain similar acceptable coverage or reimbursement from another payor. If we are unable to obtain coverage of, and adequate reimbursement and payment levels for, our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition and future success.

Furthermore, in many foreign countries, particularly the countries of the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the Company placing the medicinal product on the market. We may face competition for our product candidates from lower-priced products in foreign countries that have placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with our own products, which could negatively impact our profitability.

Healthcare Reform

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

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

In 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.

C. Organizational structure

The registrant corporation, Auris Medical Holding AG, has four wholly-owned subsidiaries which are each listed in Exhibit 8.1 filed hereto. We primarily operate our business out of our operating subsidiary Auris Medical AG.

D. 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.

ITEM 4A. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with the information under “Item 3. Key Information—A. Selected Financial Data” and our audited consolidated financial statements, including the notes thereto, included in this Annual Report. The following discussion is based on our financial information 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 “Item 3. Key Information—D. Risk factors” and elsewhere in this Annual Report.

A. Operating results

Overview

We are a clinical-stage biopharmaceutical company focused on the development of novel products for the treatment of inner ear and vestibular disorders. 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) AM-111, being developed for the treatment of acute inner ear hearing loss. Keyzilen® (AM-101) is being developed for the treatment of acute inner ear tinnitus and has received fast track designation from the FDA. In two Phase 2 clinical trials, Keyzilen® demonstrated a favorable safety profile and statistically significant improvement in tinnitus loudness and other patient reported outcomes. In August 2016, we announced that the trial Efficacy and Safety of AM-101 in the Treatment of Acute Peripheral Tinnitus 2 (TACTT2), the first of two pivotal Phase 3 clinical trials with Keyzilen® , did not meet the two co-primary endpoints of statistically significant changes in tinnitus loudness and tinnitus burden as measured by the Tinnitus Functional Index (TFI), compared to placebo.

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. We are currently investigating the outcomes, including those in TACTT2, the previously conducted sister trial.

We are also developing AM-111 for acute inner ear hearing loss. In November 2015 and in June 2016 we initiated two pivotal Phase 3 trials in the treatment of idiopathic sudden sensorineural hearing loss (ISSNHL; aka sudden deafness), titled HEALOS and ASSENT.

HEALOS enrolled 256 patients in Europe and Asia. 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 and statistically significant improvement in the AM-111 0.4 mg/mL treatment group. We plan to discuss the HEALOS results and the regulatory pathway with health authorities. In addition, we terminated the ASSENT trial as it is very similar in design to the HEALOS trial and, based on the new findings, is no longer adequate for testing AM-111.

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 December 31, 2017, we had cash and cash equivalents of CHF 15.0 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®, AM-111 or any of our other product candidates.

As of December 31, 2017, we had an accumulated deficit of CHF 136.1 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.

Collaboration and License Agreements

INSERM

In 2006, we entered into a co-ownership/exploitation agreement with the Institut National de la Santé et de la Recherche Médicale, or INSERM, a publicly funded government science and technology agency in France. Pursuant to the terms of the agreement, we were granted the exclusive right to exploit any products derived from patents that resulted from our joint research program with INSERM that was conducted in 2003 to 2005 and led to the development of 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 S.A., or Xigen, pursuant to which Xigen granted us an exclusive worldwide license to use specified compounds to develop, manufacture and commercialize “pharmaceutical products as well as drug delivery devices and formulations for local administration of therapeutic substances to the inner ear for the treatment of ear disorders” (the Area). We also have a right of first refusal to license certain additional compounds developed by Xigen which may be used for the Area, specifically any cell permeable inhibitors to effectively block certain signal pathways in apoptotic processes.

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

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. We plan to initiate a second Phase 1 clinical trial with AM-125 in the first half of 2018.

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 12.0 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 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. We are currently investigating the outcomes, including those in TACTT2, the previously conducted sister trial. We anticipate that our research and development expenses in connection with the Keyzilen® trials will be lower in 2018 than in 2017, reflecting the completion of trials.
- *AM-111*. We conducted a Phase 3 clinical development program with AM-111 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 and statistically significant improvement in the AM-111 0.4 mg/mL treatment group. We plan to discuss the HEALOS results and the regulatory pathway with health authorities. In addition, we terminated the ASSENT trial as it is very similar in design to the HEALOS trial and, based on the new findings, is no longer adequate for testing AM-111.
- *AM-125*. In the first half of 2018, we plan to initiate a second Phase 1 trial in healthy volunteers to further test the safety and tolerability and the pharmacokinetics of AM-125. We expect to obtain the results of the study in summer 2018.

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 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 spend CHF 11.4 million, CHF 9.4 million and CHF 6.4 million, respectively, on research and development expenses related to AM-111. In addition, we incurred research and development expenses related to our earlier stage products. These expenses exclude the milestone payment to Xigen for AM-111 as it was capitalized. Research and development expenses are expected to remain at significant levels as we advance the clinical development of Keyzilen®, AM-111 and AM-125. 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 Keyzilen®, AM-111 or any other product candidate that we may develop could mean a significant change in the costs and timing associated with the development of such product candidate. For example, if the FDA or other regulatory authority were to require us to conduct preclinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of the clinical development.

General and administrative expense

Our general and administrative expense consists principally of:

- salaries for general and administrative staff and related expenses, including employee benefits;
- business development expenses, including travel expenses;
- administration 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.

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

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).

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 consolidated financial statements included elsewhere herein. The discussion below should be read along with these consolidated financial statements and it is qualified in its entirety by reference to them.

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 AM-111 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 AM-111.

- *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 Commitment Purchase Agreement entered in October 10, 2017 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 AM-111 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 AM-111 drug product validation as well as the production of clinical supplies for the AM-111 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.

B. 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 flow

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 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 years ended December 31, 2017, 2016 and 2015.

	Equity Capital and Preferred Shares	Loans	Total
		(in thousands of CHF)	
2017	11,491	—	11,491
2016	—	11,987	11,987
2015	21,071	—	21,071
Total	32,562	11,987	44,549

On October 10, 2017, we entered into the Commitment Purchase Agreement and a Registration Rights Agreement with LPC. Pursuant to the Commitment Purchase Agreement, LPC agreed to subscribe for up to $13,500,000 of our common shares over the 30-month term of the Commitment Purchase Agreement. As of March 12, 2018, we had issued an aggregate of 2,600,000 common shares for an aggregate proceeds of $1,774,655 to LPC pursuant to the Commitment Purchase Agreement. The Commitment Purchase Agreement terminated upon consummation of the Merger on March 13, 2018.

On October 16, 2017, we issued 1,744,186 common shares to LPC for an 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 estimated 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. On February 15, 2017, 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, the Company entered into a Loan and Security Agreement for a secured term loan facility of up to $20.0 million with Hercules as administrative agent 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 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. 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 $3.94 per common share.

On June 1, 2016, we entered into a Controlled Equity Offering Sales Agreement with 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 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.

On May 20, 2015, we completed a public offering of 5,275,000 common shares at a price to the public of $4.75 per share. The net proceeds of the public offering were CHF 21.1 million.

In addition, subsequent to December 31, 2017, 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 January 2018 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.

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 existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the fourth quarter of 2018. 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 complete our development programs with Keyzilen®, AM-111 and AM-125, obtain regulatory approval for them and to commercialize our product candidates Keyzilen® , AM-111, AM-125 or any other product candidate. If we receive regulatory approval for Keyzilen®, AM-111 or AM-125, 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. We may also seek to refinance out outstanding indebtedness.

For more information as to the risks associated with our future funding needs, see “Item 3. Key Information—D. Risk factors.”

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 this 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 elsewhere in this Annual Report for a full description of recent accounting pronouncements, including the expected dates of adoption and effects on the Company's financial condition, results of operations and cash flows.

JOBS Act exemptions

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

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

These exemptions will apply until 2019 or until we no longer meet the requirements of being an "emerging growth company," whichever is earlier. We would cease to be an emerging growth company if we have more than $1.07 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.

C. Research and development, patents and licenses, etc.

See "Item 4. Information on the Company—A. History and Development of the Company," "Item 4. Information on the Company—B. Business Overview" and Item 5. Operating and Financial Review and Prospects—A. Operating Results—Results of Operations."

D. Trend information

See "Item 5. Operating and Financial Review and Prospects."

E. Off-balance sheet arrangements

As of the date of this Annual Report, we do not have any, and during the periods presented we did not have any, off-balance sheet arrangements except for the operating lease mentioned below.

F. Tabular disclosure of contractual obligations

The following table presents information relating to our contractual obligations as of December 31, 2017:

	Payments Due by Period				
	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years	Total
			(in thousands of CHF)		
Operating lease obligations (1)	161	322	124	—	607
Loan and Borrowings (2)	4,542	6,213	—	—	10,755
Derivative Financial Instruments (3)			1,837	—	1,837
Total	**4,703**	**6,535**	**1,961**	**—**	**13,199**

(1) Operating lease obligations consist of payments pursuant to an operating lease agreements relating to our lease of office space and are not accounted for on the balance sheet. The lease term of our lease in Basel, Switzerland, is 5 years and expires on September 30, 2021, with an option to extend for another five years.

(2) Loan obligations consist of amortization payments and the end of term fee due under the Hercules Loan and Security Agreement converted to CHF at an exchange rate of CHF 0.9725 to US$1.00. The secured term loan under the Hercules 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 Hercules Loan and Security Agreement and the warrants issued in the public offering in February 2017.

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 Therapeutics Pty Ltd, we are obliged to make a development milestone payment of $200,000 if use of the purchased formulation is supported by the results from toxicology studies over three to six months.

G. Safe harbor

See “Forward-Looking Statements.”

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and senior management

From the 2017 annual general meeting to our extraordinary meeting of shareholders held on March, 12, 2018, our board of directors was composed of Thomas Meyer (Chairman), Armando Anido, Mats Blom, Oliver Kubli, Berndt A.E. Modig and Calvin W. Roberts (Antoine Papiernik was elected at the 2017 annual meeting and resigned effective as of September 26, 2017). Mr. Kubli and Mr. Modig did not stand for re-election at the March 12, 2018 meeting. All other directors were re-elected and Alain Munoz was elected as new director at the March 12, 2018 meeting. 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. 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 as of March 13, 2018, following the consummation of the Merger.

Name	Position	Age	Initial Year of Appointment
Executive Officers(1)			
Thomas Meyer	Chairman, Director and Chief Executive Officer	50	2003
Andrea Braun-Scherhag	Head Regulatory & Quality Affairs	51	2016
Hernan Levett	Chief Financial Officer	42	2017
Non-Executive Directors(2)(3)			
Armando Anido	Director	60	2016
Mats Blom	Director	53	2017
Alain Munoz	Director	68	2018
Calvin W. Roberts	Director	65	2015

(1)Effective April 30, 2017, Anne Sabine Zoller resigned from her position as General Counsel of the Company and, effective December 31, 2017, Thomas Jung resigned from his position as Chief Development Officer of the Company.

(2)Effective September 26, 2017, Antoine Papiernik resigned from the board of directors of the Company.

(3)Mr. Kubli and Mr. Modig did not stand for re-election at the General Meeting held on March 12, 2018.

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

Executive Officers

Thomas Meyer, Founder, Chairman 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.

Andrea Braun-Scherhag, Head Regulatory & Quality Affairs: Ms. Braun leads the Company's regulatory affairs, quality and pharmacovigilance departments. Prior to joining the Company, Ms. Braun was Head of Global Regulatory Affairs and Vice President at Alvotech. Prior to Alvotech, she spent 15 years in various regulatory affairs functions at Roche, most recently as Head of EU Regulatory Affairs, and five years in regulatory affairs at DSM Nutritional Products. Ms. Braun received her state examination in pharmacy from the University of Heidelberg, Germany, and holds a Ph.D. in immunology from the University of Basel, 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.

B. 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(6)	Total
Thomas Meyer, PhD, Chairman(1)	—	—	—	**—**
James I. Healy, MD, PhD, Vice-Chairman(2)	10,636	662	0	**11,298**
Armando Anido, MBA	50,105	3,119	11,371	**64,595**
Wolfgang Arnold, MD(2)	10,010	362	0	**10,372**
Mats Blom, MBA(3)	34,336	—	11,371	**45,707**
Oliver Kubli, CFA	41,700	2,596	11,371	**55,667**
Berndt A.E. Modig, MBA	55,904	—	11,371	**67,275**
Antoine Papiernik, MBA(4)(5)	20,327	0	0	**20,327**
Calvin W. Roberts, MD	48,018	2,989	11,371	**62,378**
Total	**271,036**	**9,728**	**56,855**	**337,619**

(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)Dr. Healy and Dr. Arnold did not stand for re-election at the 2017 Annual shareholders’ meeting and their terms therefore ended on April 13, 2017.

(3)Elected on April 13, 2017.

(4)As the internal regulations applicable to Sofinnova Capital VII FCPR did not allow for payment of a compensation or the grant of equity instruments to fund managers, the compensation payable to Mr. Papiernik was paid to Sofinnova Capital VII FCPR. Instead of an option grant, the grant date fair value of the options (less applicable taxes and charges) was paid to Sofinnova Capital VII FCPR in cash.

(5)Resigned effective as of September 26, 2017.

(6)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(1)	Social contributions and fringe benefits	Stock Options(2)	Total
Thomas Meyer, PhD Chief Executive Officer(3)	363,600	—	60,490	127,895	551,985
Executive Officers Total(4)	**1,277,638**	**155,118**	**238,948**	**301,463**	**1,973,167**

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

(2)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.

(3)Highest paid executive.

(4)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.

Employment Agreements

We have entered into employment agreements with our executive officers Thomas Meyer, Andrea Braun-Scherhag 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 share of common stock 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.

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 Stock Option Plan C and adopted a new omnibus equity incentive plan under which we have the discretion to grant a broad range of equity-based awards to eligible participants. 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.

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.

C. Board practices

Board Composition and Election of Directors

Our board of directors is currently composed of five members, see “Item 6. Directors, Senior Management and Employees—A. Directors and senior management.” Each director is elected for a one year term.

Our articles of association require our directors to retire once they have reached 75 years of age, subject to a special exception being granted by the general meeting of shareholders for up to two additional terms of office. The current members of our board of directors were appointed at a shareholders meeting held on 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. For an overview of our corporate governance principles, see “Item 16G. Corporate governance.”

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.

D. Employees

As of December 31, 2017, we had 24 employees (20.9 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.

E. Share ownership

See “Item 7. Major Shareholders and Related Party Transactions—A. Major shareholders.”

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major shareholders

The following table presents information relating to the beneficial ownership of our common shares as of March 20, 2018, following the consummation of the Merger, 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 March 20, 2018 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 March 20, 2018 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 March 20, 2018, 5,090,525 common shares, or approximately 83.2%, are held by three 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 6,117,388 common shares issued and outstanding as of March 20, 2018. The number of outstanding common shares reflect the 10:1 “reverse stock 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.

Shareholder	Shares Beneficially Owned	
	Number	Percent
5% Shareholders		
Sofinnova Venture Partners VIII, L.P. (1)	921,818	14.73%
Sofinnova Capital VII FCPR (2)	338,445	5.53%
Lincoln Park Capital Fund, LLC (3)	360,763	5.76%
Anson Investments Master Fund LP (4)	333,950	5.33%
Sabby Volatility Warrant Master Fund, Ltd. (5)	399,740	6.38%
Empery Asset Management, LP (6)	474,429	7.69%
Executive Officers and Directors		
Thomas Meyer, Ph.D. (7)	772,895	12.56%
Armando Anido, M.B.A (8)	3,296	*
Mats Blom, M.B.A. (9)	2,546	*
Oliver Kubli, C.F.A.(10)	222,244	3.63%
Berndt A.E. Modig, M.B.A. (11)	4,296	*
Alain Munoz (12)	2,657	*
Calvin W. Roberts, M.D.(12)	9,821	*
Andrea Braun-Scherhag, Ph.D. (13)	1,042	*
Hernan Levett, CPA	—	—

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

(1) Based on 9,218,175 common shares reported on a Form 13D/A filed with the SEC on March 9, 2017 (prior to the Merger) by Sofinnova Venture Partners VIII, L.P., a Delaware limited partnership (“SVP VIII”), Sofinnova Management VIII, L.L.C., a Delaware limited liability company (“SM VIII”), Dr. Srinivas Akkaraju , Dr. Michael F. Powell , Dr. James I. Healy , and Dr. Anand Mehra. Consists of 7,818,175 common shares and warrants to purchase an additional 1,400,000 common shares. Drs. Powell, Healy and Mehra, the managing members of SM VIII, which is the general partner of SVP VIII, share the power to vote or dispose of these shares and therefore may be deemed to have voting and investment power with respect to such shares. Dr. Akkaraju is no longer a managing member of SM VIII. Each of the managing members of SM VIII disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein, if any. The address for Sofinnova Venture Partners VIII, L.P. and Sofinnova Management VIII, L.L.C. is 2800 Sand Hill Road, Suite 150, Menlo Park, California 94025, USA. The number of common shares shown in the table reflect the 10-1 “reverse stock split” effected through the Merger.

(2) Based on 3,384,450 common shares reported on a Form 13D/A filed with the SEC on March 5, 2018 (prior to the Merger) by Sofinnova Capital VII FCPR. Consists of 3,384,450 common shares held by Sofinnova Capital VII FCPR ("SC VII"), Sofinnova Partners SAS, a French corporation ("SP SAS"), and Denis Lucquin, Antoine Papiernik and Monique Saulnier, the managing partners of SP SAS. Rafaèle Tordjman ceased to be a managing partner of SP SAS on February 28, 2017. All of the managing partners of SP SAS disclaim beneficial ownership of such shares except to the extent of their pecuniary interest therein. The address for Sofinnova Capital VII FCPR is 16-18 Rue du Quatre Septembre, 75002 Paris, France. The number of common shares shown in the table reflect the 10-1 “reverse stock split” effected through the Merger.

(3) Based on 3,607,630 common shares information provided to the Company in connection with the registration statement on Form F-1 filed with the SEC on February 9, 2018 by the Company. Joshua Scheinfeld and Jonathan Cope, the principals of Lincoln Park are deemed to be beneficial owners of all the common shares owned by Lincoln Park. Messrs. Scheinfeld and Cope have shared voting and disposition power over such shares. The address of Lincoln Park Capital Fund, LLC is 440 N. Wells Street, Suite 410, Chicago, Illinois 60654.

(4) Based on 3,339,499 common shares information provided to the Company in connection with the registration statement on Form F-1 filed with the SEC on February 9, 2018 by the Company. Anson Advisors Inc and Anson Funds Management LP, the Co-Investment Advisers of Anson Investments Master Fund LP (“Anson”), hold voting and dispositive power over the common shares held by Anson. Bruce Winson is the managing member of Anson Management GP LLC, which is the general partner of Anson Funds Management LP. Moez Kassam and Adam Spears are directors of Anson Advisors Inc. Mr.

Winson, Mr. Kassam and Mr. Spears each disclaim beneficial ownership of such common shares except to the extent of their pecuniary interest therein. The principal business address of Anson is 190 Elgin Ave; George Town, Grand Cayman.

(5) Based on 3,997,399 common shares information provided to the Company in connection with the registration statement on Form F-1 filed with the SEC on February 9, 2018 by the Company. The address of Sabby Volatility Warrant Master Fund, Ltd. is c/o Ogier Fiduciary Services (Cayman) Limited, 89 Nexus Way, Camana Bay, Grand Cayman KY1-9007, Cayman Islands. This shareholder has indicated that Hal Mintz has voting and investment power over the shares held by it. This shareholder has indicated that Sabby Management, LLC serves as its investment manager, that Hal Mintz is the manager of Sabby Management, LLC and that each of Sabby Management, LLC and Hal Mintz disclaims beneficial ownership over such shares except to the extent of any pecuniary interest therein.

(6) Based on 4,744,290 common shares information provided to the Company in connection with the registration statement on Form F-1 filed with the SEC on February 9, 2018 by the Company. Consists of 2,109,624 common shares beneficially held by Empery Asset Master Ltd ("EAM"), 887,447 common shares beneficially held by Empery Tax Efficient, LP ("ETE") and 1,747,669 common shares beneficially held by Empery Tax Efficient II, LP ("ETE II"). Empery Asset Management LP, the authorized agent of EAM, ETE and ETE II, has discretionary authority to vote and dispose of the shares held by EAM, ETE and ETE II and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM, ETE and ETE II, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares. The address of EAM, ETE and ETE II is c/o Empery Asset Management, LP, 1 Rockefeller Plaza, Suite 1205, New York, New York 10020.

(7) Consists of 724,250 common shares, warrants to purchase 35,000 common shares, options to purchase 6,000 common shares under the Company’s Stock Option Plan C, and options to purchase 7,645 common shares under the Company’s EIP.

(8) Consists of options to purchase common shares under the Company’s EIP.

(9) Consists of options to purchase common shares under the Company’s EIP.

(10) Based on 2,169,625 common shares reported on a Schedule 13G/A filed with the SEC on February 12, 2018 (prior to the Merger) by Swisscanto Fondsleitung AG, Swisscanto Holding AG and Zurcher Kantonalbank. Swisscanto Fondsleitung AG, Swisscanto Holding AG and Zurcher Kantonalbank sponsor BB Adamant Global Biotech, BB Adamant Global Generika, BB Adamant Global Medtech and Services and Swisscanto (CH) Equity Fund Global Health Care (collectively, the “ZKB Funds”). Investment power over the 216,963 common shares held by the ZKB Funds is exercised by Bellevue Asset Management AG, an independent manager. The address of Swisscanto Fondsleitung AG, Swisscanto Holding AG and Zurcher Kantonalbank is Bahnhofstrasse 9, 8001 Zurich, Switzerland. The number of common shares shown in the table reflect the 10-1 “reverse stock split” effected through the Merger.

Oliver Kubli is a Senior Portfolio manager for the ZKB Funds. He disclaims beneficial ownership of such shares except to the extent of his pecuniary interest therein. Also consists of 1,875 common shares acquired by Mr. Kubli pursuant to the exercise of Plan A options, options to purchase an additional 625 common shares under the Company’s Stock Option Plan C, and options to purchase an additional 2,782 common shares under the Company’s Equity Incentive Plan held by Mr. Kubli.

(11) Consists of options to purchase common shares under the Company’s EIP.

(12) Consists of 1,250 common shares owned by Alain Munoz, options to purchase an additional 625 common shares under the Company's Stock Option Plan C, and 782 options to purchase common shares under the Company's EIP.

(13) 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 4,296 common shares under the Company’s EIP.

(14) Consists of 430 common shares owned by Andrea Braun-Scherhag and 612 options to purchase common shares under the Company’s EIP.

Holders

As of March 20, 2018, we had eight shareholders of record of our common stock.

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.

B. 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.

Related Person Transaction Policy

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

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. See "Item 6. Directors, Senior Management and Employees—B. Compensation—Employment Agreements."

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, 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 any offering under the Controlled Equity Offering Sales Agreement. 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.

Merger

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 has 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 will receive any compensation for this arrangement. Any expenses incurred by Mr. Meyer in connection with the transfers under such agreement were borne by the Company.

C. Interests of experts and counsel

Not applicable.

ITEM 8. FINANCIAL INFORMATION

A. Consolidated statements and other financial information

Financial Statements

See "Item 18. Financial Statements," which contains our financial statements prepared in accordance with IFRS. The standalone financial statements of the Company have been prepared in accordance in Swiss law and have been filed as Exhibit 99.8 to our predecessor's report on Form 6-K filed with the SEC on February 2, 2017.

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.

No assurance can be given that future litigation will not have a material adverse effect on our financial position. See “Item 3. Key Information—D. Risk factors.”

Dividends and 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. Any future determination related to our dividend policy will be made at the discretion of our board of directors and any payment of dividends will, amongst other requirements, require the approval of the annual general meeting of shareholders.

B. Significant changes

A discussion of the significant changes in our business can be found under “Item 4. Information on the Company—A. History and development of the Company” and “Item 4. Information on the Company—B. Business Overview.”

ITEM 9. THE OFFER AND LISTING

A. Offering and listing details

The following table sets forth the high and low closing prices as reported in USD by Nasdaq for the periods presented:

	High	Low
Year Ended December 31:		
2015	6.38	3.02
2016	7.79	0.90
2017	1.39	0.38
Year Ended December 31, 2016:		
First Quarter	7.96	3.20
Second Quarter	4.42	3.10
Third Quarter	5.45	1.55
Fourth Quarter	1.77	0.84
Year Ended December 31, 2017:		
First Quarter	1.39	0.66
Second Quarter	0.93	0.60
Third Quarter	0.97	0.62
Fourth Quarter	0.95	0.38
Month Ended:		
September 30, 2017	0.83	0.64
October 31, 2017	0.95	0.74
November 30, 2017	0.95	0.38
December 31, 2017	0.66	0.38
January 31, 2018	0.65	0.37
February 28, 2018	0.38	0.24
March, 2018 (through March 13, 2018)	0.32	0.25

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

B. Plan of distribution

Not applicable.

C. Markets

Our common shares began trading on the Nasdaq Global Market on August 11, 2014 under the symbol “EARS”. On September 28, 2017, we transferred our common shares from the Nasdaq Global Market to the Nasdaq Capital Market under the same symbol ("EARS"). On March 14, 2018, our post-Merger common shares began trading on the Nasdaq Capital Market.

D. Selling shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the issue

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. Share capital

Not applicable.

B. Memorandum and articles of association

When we refer to our articles of association in this annual report on Form 20-F, we refer to Auris Newco's articles of association dated as of March 12, 2018, which became our articles of association following the Merger.

We are registered with the commercial register of the canton of Zug, Switzerland, under the company number CHE-108.297.413. Our purpose as stated in article 2 of our articles of association is to hold investments of all kinds in Switzerland and abroad, particularly in relation to pharmaceutical products and services. Moreover, our corporation may transact any business conducive to developing the corporation or furthering the corporation's purpose. We may also arrange financing for our own or third-party account, in particular we may grant loans to Group companies, as well as provide guarantees or surety bonds of any sort of such financing.

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 of the Group 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 the Company, 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 provision adopted on January 30, 2018, (article 3a of the articles of association) reads as follows (translation of the binding original German version):

"The Board of Directors is authorized at any time until 29 January 2020 to increase the share capital by a maximum aggregate amount of CHF 61,000.00 through the issuance of not more than 3,050,000 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."

Our Conditional Share Capital

Conditional Share Capital for Warrants and Convertible Bonds

The provision adopted on January 30, 2018 (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 42,700.00 through the issuance of not more than 2,135,000 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. 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. b) if the issue occurs on domestic or international capital markets including private placements; or

c. 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 provision adopted on January 30, 2018 (last paragraph of article 3b of the articles of association) 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 18,300.00 through the issuance of not more than 915,000 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;
- 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;
- dissolving or liquidating the Company.

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

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

Notice

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

concerning items included in the agenda or for debates that do not result in a vote. 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.

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;
- 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.

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.

C. Material contracts

Except as otherwise disclosed in this annual report on Form 20-F (including the Exhibits), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange controls

There are no Swiss governmental laws, decrees or regulations that restrict, in a manner material to us, the export or import of capital, including any foreign exchange controls, or that generally affect the remittance of dividends or other payments to non-residents or non-citizens of Switzerland who hold our common shares.

E. **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 subsidiaries, 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.

Taxation of Common Shares: Swiss Federal Withholding Tax on Dividends and Distributions

Dividend payments and similar cash or in-kind distributions on the common shares (including dividends on liquidation proceeds and stock dividends) that the Company makes to shareholders are subject to Swiss federal withholding tax (*Verrechnungssteuer*) at a rate of 35% on the gross amount of the dividend. The Company is required to withhold the Swiss federal withholding tax from the dividend and remit it to the Swiss Federal Tax Administration. Distributions based upon a capital reduction (*Nennwertrückzahlungen*) and reserves paid out of capital contributions (*Reserven aus Kapitaleinlagen*) are not subject to Swiss federal withholding tax.

The Swiss federal withholding tax may also apply to gains realized upon a repurchase of shares by the Company, on the difference between the repurchase price and the nominal value of the shares (*Nennwertprinzip*); a different basis of taxation may apply under the capital contribution principle (*Kapitaleinlageprinzip*).

The Swiss federal withholding tax is refundable or creditable in full to a Swiss tax resident corporate and individual shareholder as well as to a non-Swiss tax resident corporate or individual shareholder who holds the common shares as part of a trade or business carried on in Switzerland through a permanent establishment or fixed place of business situated for tax purposes in Switzerland, if such person is the beneficial owner of the distribution and, in the case of a Swiss tax resident individual who holds the common shares as part of his private assets, duly reports the gross distribution received in his individual income tax return or, in the case of a person who holds the common shares as part of a trade or business carried on in Switzerland through a permanent establishment or fixed place of business situated for tax purposes in Switzerland, recognizes the gross dividend distribution for tax purposes as earnings in the income statements and reports the annual profit in the 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.

On 27 May 2015, Switzerland signed an agreement with the European Union (EU) to meet the Organisation for Economic Co-operation and Development's (OECD) global standard for the automatic exchange of financial account information. The agreement came into force on January 1, 2017 and exempts intercompany payments of dividends, interest and royalties from any withholding tax in the source state.

Individual and Corporate Income Tax on Dividends

Swiss resident individuals holding the common shares as part of their private assets who receive dividends and similar distributions (including stock dividends and liquidation proceeds), which are not repayments of the nominal value (*Nennwertrückzahlungen*) of the common shares or reserves paid out of capital contributions (*Reserven aus Kapitaleinlagen*) are required to report such payments in their individual income tax returns and are liable to Swiss federal, cantonal and communal income taxes on any net taxable income for the relevant tax period. Furthermore, for the purpose of the Direct Federal Tax, dividends, shares in profits, liquidation proceeds and pecuniary benefits from shares (including bonus shares) are included in the tax base for only 60% of their value (*Teilbesteuerung*), if the investment amounts to at least 10% of nominal capital of the Company. Most 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 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 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 in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to report their common shares as part of their wealth and will be subject to cantonal and communal wealth tax to the extent the aggregate taxable net wealth is allocable to Switzerland.

Swiss resident corporate taxpayers and non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, will be subject to cantonal and communal annual capital tax on the taxable capital to the extent the aggregate taxable capital is allocable to Switzerland.

Individuals and corporate taxpayers not resident in Switzerland for tax purposes and not holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are not subject to wealth or annual capital tax in Switzerland because of the mere holding of the common shares.

Capital Gains on Disposal of Common Shares

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

Capital gains realized on the sale of the common shares held by Swiss resident individuals who do not hold the common shares as part of their private assets and Swiss resident corporate taxpayers, as well as non-Swiss resident individuals and corporate taxpayers holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, will be subject to Swiss federal, cantonal and communal individual or corporate income tax, as the case may be. This also applies to Swiss resident individuals who, for individual income tax purposes, are deemed to be professional securities dealers for reasons of, inter alia, frequent dealing and debt-financed purchases. Capital gains realized by resident individuals who hold the common shares as business assets might be entitled to reductions or partial taxations similar to those mentioned above for dividends (*Teilbesteuerung*) if certain conditions are met (e.g., holding period of at least one year and participation of at least 10% of nominal capital of the Company).

Swiss resident corporate taxpayers as well as non-Swiss resident corporate taxpayers holding the common shares in connection with the conduct of a trade or business, through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to recognize such capital gain in their income statements for the relevant tax period. Corporate taxpayers may qualify for participation relief on capital gains (*Beteiligungsabzug*), if the common shares sold during the tax period 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 initial costs of the participation (*Gestehungskosten*).

Individuals and corporations not resident in Switzerland for tax purposes and not holding the common shares in connection with the conduct of a trade or business in Switzerland through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are not subject to Swiss federal, cantonal and communal individual income or corporate income tax, as the case may be, on capital gains realized on the sale of the common shares.

Gift and Inheritance Tax

Transfers of common shares may be subject to cantonal and/or communal inheritance or gift taxes if the deceased or the donor or the recipient were resident in a Canton levying such taxes and, in international circumstances where residency requirements are satisfied, if the applicable tax treaty were to allocate the right to tax to Switzerland.

Swiss Issuance Stamp Duty

The Company is subject to paying to the Swiss Federal Tax Administration a 1% Swiss federal issuance stamp tax (*Emissionsabgabe*) on any increase of the nominal 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 the U.S. Holders described below of owning and disposing of common shares, but it does not purport to be a comprehensive description of all tax considerations that may be relevant to a particular person's decision to hold the common shares. This discussion applies only to a U.S. Holder that holds common shares as capital assets for U.S. federal

income tax purposes. In addition, it does not describe all of the tax consequences that may be relevant in light of the U.S. Holder's particular circumstances, including alternative minimum tax consequences, the potential application of the provisions of the 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, 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 our stock by vote or value;
- persons who acquired our common shares pursuant to the exercise of an employee stock option or otherwise as compensation; 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 PFIC for U.S. federal income tax purposes for our 2017 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 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 currently 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 "Risks Related to Our Business and Industry--We have received a delisting notice from

Nasdaq" above). 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 which we control to provide such information with respect to such Lower-tier PFIC. However, no assurance can be given that such QEF information will be available for any Lower-tier PFIC.

If a U.S. Holder makes a QEF Election with respect to a PFIC, the 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 we were a PFIC or, with respect to a particular U.S. Holder, were treated as a PFIC for the taxable year in which we paid a dividend or the prior taxable year, the preferential dividend rate with respect to dividends paid to certain non-corporate U.S. Holders will not apply.

If we were a PFIC for any taxable year during which a U.S. Holder held common shares, such U.S. Holder would be required to file an annual information report with such U.S. Holder's U.S. Federal income tax return on IRS Form 8621.

U.S. Holders should consult their tax advisers concerning our PFIC status and the tax considerations relevant to an investment in a PFIC.

Taxation of Distributions

As discussed above under "Item 8. Dividends and 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 Reporting 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 whether or not they are obligated to report information relating to their ownership and disposition of the common shares.

F. Dividends and paying agents

Not applicable.

G. Statement by experts

Not applicable.

H. Documents on display

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.

Additionally, pursuant to Swiss law, any shareholder of record has the right to receive a free copy of this Annual Report and to inspect this Annual Report at any time at our registered offices in Zug.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be

required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

I. Subsidiary information

Not applicable.

ITEM 11. 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 December 31, 2017 by 50 basis points, with all other factors held constant, would have resulted in a CHF 52,185 increase or decrease of the net annual result (2016: CHF 28,276).

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 US Dollar and Euro. Foreign exchange risk arises from future commercial transactions, recognized assets and liabilities and net investments in foreign operations. To manage foreign exchange risk we maintain foreign currency cash balances to cover anticipated future purchases of materials and services in foreign currencies. We do not hedge our foreign exchange risk.

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 832,032 (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 89,403 (2016: CHF 180,595) 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.

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt securities

Not applicable.

B. Warrants and rights

Not applicable.

C. Other securities

Not applicable.

D. American Depositary Shares

Not applicable.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

A. Defaults

No matters to report.

B. Arrears and delinquencies

No matters to report.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

E. Use of Proceeds

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

A. Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, our principal executive officer and principal financial officer, respectively. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives.

Based on the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective, as of the end of the period covered by this Annual Report, in providing a reasonable level of assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods in SEC rules and forms, including providing a reasonable level of assurance that information required to be disclosed by us in such reports is accumulated and communicated to our management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

B. Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) of the Exchange Act. Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based upon criteria established in *Internal Control – Integrated Framework* (2013) by the Committee of Sponsoring Organizations of the Treadway Commission. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our internal control over financial reporting was effective as of December 31, 2017.

C. Attestation Report of the Registered Public Accounting Firm

This Annual Report does not include an attestation report of our registered public accounting firm due to an exemption provided to emerging growth companies under the JOBS Act.

D. Changes in Internal Control over Financial Reporting

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) that occurred during the period covered by this Annual Report that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

ITEM 16. [RESERVED]

ITEM 16A. Audit committee financial expert

Our board of directors has determined that Mats Blom is the audit committee financial expert, as that term is defined by the SEC, and is independent for the purposes of SEC and Nasdaq rules.

ITEM 16B. Code of ethics

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics which covers a broad range of matters including the handling of conflicts of interest, compliance issues and other corporate policies such as insider trading and equal opportunity and non-discrimination standards. Our Code of Business Conduct applies to all of our directors, executive officers and employees. We have published our Code of Business Conduct and Ethics on our website, *www.aurismedical.com*. The information contained on our website is not a part of this Annual Report.

ITEM 16C. Principal Accountant Fees and Services

	2017	2016
Audit fees	191	231
Audit-related fees	153	117
Total fees	**344**	**348**

At the ordinary annual general meeting on April 22, 2014, the shareholders appointed Deloitte AG as the Company's auditor for the year ended December 31, 2014. Deloitte AG's was reelected at the ordinary annual general meeting on April 22, 2015, April 8, 2016, April 13, 2017 and the extraordinary meeting of shareholders on March 12, 2018. On March 13, 2018 following the consummation of the Merger, the successor company implemented the election of Deloitte AG.

In 2017, we were billed CHF 190,550, by Deloitte AG in connection with our annual filing as well as interim reviews, group audit, and statutory audits plus CHF 153,446 in connection with audit related services in the context of registration statement fillings and issuance of shares and other statutory required audit reports. In 2016, we were billed CHF 182,304, by Deloitte AG in connection with audit services for our annual filing as well as interim reviews, group audit, and statutory audits plus CHF 123,696 in connection with audit-related services for work in connection with our controlled equity offering program Further, we were billed CHF 42,000 by KPMG AG in connection with our annual filing.

Pre-Approval Policies and Procedures

To ensure the independence and objectivity of the Company's external auditors, the provision of all non-audit services by the external auditors are pre- approved by the Audit Committee.

Pre-Approval Policies and Procedures

To ensure the independence and objectivity of the Company's external auditors, the provision of all non-audit services by the external auditors are pre- approved by the Audit Committee.

ITEM 16D. Exemptions from the listing standards for audit committees

Not applicable.

ITEM 16E. Purchases of equity securities by the issuer and affiliated purchasers

In 2017, no purchases of our equity securities were made by or on behalf of Auris Medical Holding AG or any affiliated purchaser.

ITEM 16F. Change in registrant's certifying accountant

Not applicable.

ITEM 16G. Corporate governance

Summary of Significant Corporate Governance Differences From Nasdaq Listing Standards

Our common shares are listed on the Nasdaq Capital Market, or Nasdaq. We are therefore required to comply with certain of the Nasdaq's corporate governance listing standards, or the Nasdaq Standards. As a foreign private issuer, we may follow our home country's corporate governance practices in lieu of certain of the Nasdaq Standards. Our corporate governance practices differ in certain respects from those that U.S. companies must adopt in order to maintain a Nasdaq listing. A brief, general summary of those differences is provided as follows.

Independent Directors

Swiss law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we will not be subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present.

Audit Committee

We relied on the phase-in rules of the SEC and Nasdaq with respect to the independence of our audit committee. These rules require all members of our audit committee must meet the independence standard for audit committee members within one year of our initial public offering. All current members of our audit committee meet the independence requirements.

Compensation Committee

Although Swiss law also requires that we have a compensation committee, we will follow home country requirements with respect to such committee. As a result, our practice will vary from the requirements of Nasdaq Listing Rule 5605(d), which sets forth certain requirements as to the responsibilities, composition and independence of compensation committees.

Nominating and Corporate Governance Committee

As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(e), which requires an issuer to have independent director oversight of director nominations.

Quorum requirements

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

Solicitation of proxies

Our articles of association provide for an independent proxy holder elected by our shareholders, who may represent our shareholders at a general meeting of shareholders, and we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders. However, Swiss law does not have a regulatory regime for the solicitation of proxies and company solicitation of proxies is prohibited for public companies in Switzerland, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies.

Shareholder approval

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.

Third Party Compensation

We follow Swiss law requirements with respect to disclosure of compensation for our directors and executive officers. Swiss law does not require that we disclose information regarding third party compensation of our directors or director nominees. As a result, our practice varies from the third-party compensation disclosure requirements of Nasdaq Listing Rule 5250(b)(3).

ITEM 16H. Mine safety disclosure

Not applicable.

PART III

ITEM 17. Financial statements

We have responded to Item 18 in lieu of this item.

ITEM 18. Financial statements

Financial Statements are filed as part of this Annual Report, see page F-1.

ITEM 19. Exhibits

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

1.1*	Articles of Association of Auris Medical Holding AG
2.1	Form of Registration Rights Agreement between Auris Medical Holding AG and the shareholders listed therein (incorporated by reference to exhibit 4.1 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on July 21, 2014)
2.2*	Warrant Agreement, dated as of March 13, 2018, between Auris Medical Holding AG and Hercules Capital, Inc.
2.3	Registration Rights Agreement, dated as of October 10, 2017 between Auris Medical Holding AG and Lincoln Park Capital Fund, LLC (incorporated by reference to exhibit 10.3 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on October 11, 2017)
4.1†	Collaboration and License Agreement, dated October 21, 2003, between Auris Medical AG and Xigen SA (incorporated by reference to exhibit 10.1 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
4.2†	Co-Ownership and Exploitation Agreement, dated September 29, 2003, between Auris Medical AG and INSERM (incorporated by reference to exhibit 10.2 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
4.3	Form of Indemnification Agreement (incorporated by reference to exhibit 99.4 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on May 11, 2016)
4.5	Stock Option Plan A (incorporated by reference to exhibit 10.11 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
4.6	Stock Option Plan C (incorporated by reference to exhibit 10.12 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
4.7	Equity Incentive Plan, as amended (incorporated by reference to exhibit 99.1 to the Auris Medical Holding AG registration statement on Form S-8 (Registration no. 333-217306) filed with the Commission on April 14, 2017)
4.8	English language translation of Lease Agreement between Auris Medical AG and PSP Management AG (incorporated by reference to exhibit 4.8 of the Auris Medical Holding AG and report on Form 20-F for the year ended December 31, 2016 filed with the Commission on March 14, 2017)
4.9	Controlled Equity Offering℠ Sales Agreement, dated as of June 1, 2016, between Auris Medical Holding AG and Cantor Fitzgerald & Co. (incorporated by reference to exhibit 1.1 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on June 1, 2016)
4.10	Share Lending Agreement, dated as of June 1, 2016, between Thomas Meyer and Cantor Fitzgerald & Co. (incorporated by reference to exhibit 10.1 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on June 1, 2016)
4.11	Loan and Security Agreement, dated as of July 19, 2016, between Auris Medical Holding AG, the several banks and other financial institutions or entities from time to time parties to the agreement and Hercules Capital, Inc. (incorporated by reference to exhibit 10.1 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on July 19, 2016)
4.12*	Consent and Waiver, dated as of March 8, 2018, between Auris Medical Holding AG, the several banks and other financial institutions or entities from time to time parties to the agreement and Hercules Capital, Inc.
4.13*	Joinder Agreement dated as of March 13, 2018 to the Loan and Security Agreement, dated as of July 19, 2016, between Auris Medical Holding AG, the several banks and other financial institutions or entities from time to time parties to the agreement and Hercules Capital, Inc.
4.14	Share Pledge Agreement, dated July 19, 2016, between Auris Medical Holding AG and Hercules Capital, Inc. (incorporated by reference to exhibit 10.3 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on July 19, 2016)

4.15	Claims Security Assignment Agreement, dated July 19, 2016, between Auris Medical Holding AG and Hercules Capital, Inc. (incorporated by reference to exhibit 10.4 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on July 19, 2016)
4.16	Bank Account Claims Security Assignment Agreement, dated July 19, 2016, between Auris Medical Holding AG and Hercules Capital, Inc. (incorporated by reference to exhibit 10.5 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on July 19, 2016)
4.17	Purchase Agreement, dated as of October 10, 2017 between Auris Medical Holding AG and Lincoln Park Capital Fund, LLC (incorporated by reference to exhibit 10.1 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on October 11, 2017)
4.18	Purchase Agreement, dated as of October 10, 2017 between Auris Medical Holding AG and Lincoln Park Capital Fund, LLC (incorporated by reference to exhibit 10.2 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on October 11, 2017)
4.19	Placement Agency Agreement, dated as of January 28, 2018, between Auris Medical Holding AG and Ladenburg Thalmann & Co. Inc. (incorporated by reference to exhibit 1.1 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on January 30, 2018)
4.20	Securities Purchase Agreement, dated as of January 26, 2018 by and among Auris Medical Holding AG and the investors named therein (incorporated by reference to exhibit 10.1 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on January 30, 2018)
4.21	Agreement and Plan of Merger, dated as of February 9, 2018 by and among Auris Medical Holding AG and Auris Medical NewCo Holding AG (incorporated by reference to exhibit 99.3 of the Auris Medical Holding AG report on Form 6-K filed with the Commission on February 9, 2018)
4.22*	Share Transfer Agreement, dated as of February 9, 2018 by and between Thomas Meyer and Auris Medical Holding AG
8.1	List of subsidiaries (incorporated by reference to exhibit 21.1 of the Auris Medical Holding AG registration statement on Form F-1 (Registration no. 333-197105) filed with the Commission on June 27, 2014)
12.1*	Certification of Thomas Meyer pursuant to 17 CFR 240.13a-14(a)
12.2*	Certification of Hernan Levett pursuant to 17 CFR 240.13a-14(a)
13.1*	Certification of Thomas Meyer pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C.1350
13.2*	Certification of Hernan Levett pursuant to 17 CFR 240.13a-14(b) and 18 U.S.C. 1350

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* Filed herewith

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

(b) Financial Statement Schedules

None.

Signatures

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this Annual Report on its behalf.

AURIS MEDICAL HOLDING AG

By: /s/ Thomas Meyer

Name: Thomas Meyer

Title: Chief Executive Officer

Date: March 22, 2018

Index to Consolidated Financial Statements

Audited Consolidated Financial Statements — Auris Medical Holding AG

As of December 31, 2017 and 2016 and for the years ended December 31, 2017, 2016, and 2015

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

/s/ Matthias Gschwend
Auditor in Charge

/s/ Adrian Kaeppeli

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)
For the Years Ended December 31, 2017, 2016 and 2015
(in CHF)

	Note	2017	2016	2015
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				
Remeasurements 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 consolidated financial statements.

AURIS MEDICAL HOLDING AG

Consolidated Statement of Financial Position
As of December 31, 2017 and 2016
(in CHF)

	Note	December 31, 2017	December 31, 2016
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
Employee 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 consolidated financial statements.

AURIS MEDICAL HOLDING AG

Consolidated Statement of Changes in Equity
As of December 31, 2017, 2016 and 2015
(in CHF)

	Note	Share Capital	Share Premium	Foreign Currency Translation Reserve	Accumulated Deficit	Total Equity / (Deficit)
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 consolidated financial statements.

AURIS MEDICAL HOLDING AG

Consolidated Statement of Cash Flows
For the Years Ended December 31, 2017, 2016, and 2015
(in CHF)

	Note	2017	2016	2015
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 consolidated financial statements.

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:

Financial assets		
	December 31, 2017	**December 31, 2016**
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

Financial assets / liabilities	Fair values as at		Fair value hierarchy	Valuation technique(s) and key input(s)
	December 31, 2017	December 31, 2016		
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.

		Non-cash changes			
	01.01.2017	**Financing Cash Flows [1)]**	**Fair value revaluation**	**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	
in CHF	**USD**	**EUR**	**USD**	**EUR**
Cash and cash equivalents	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

	Licences	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℠ 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 options
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 0.287 (2 year vesting) [1] USD 0.352 (3 year vesting) [1]	USD 0.233 (1 year vesting) [2] USD 0.335 (2 year vesting) [2] USD 0.406 (3 year vesting) [2]	USD 0.308 (1 year vesting) [1] USD 0.472 (2 year vesting) [1] USD 0.583 (3 year vesting) [1]	USD 1.094 (1 year vesting) [2] USD 1.560 (2 year vesting) [2] 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 assumptions	(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

At December 31	**2017**	**2016**	**2015**
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	BVG 2010G

Sensitivity analysis

Reasonably possible changes at the reporting date to one of the relevant actuarial assumptions, holding other assumptions constant, would have affected the defined benefit obligation by the amounts shown below.

December 31,	**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:

Reconciliation	**2017**	**2016**	**2015**
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 unrecognised 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:

Deferred Tax Liabilities	**December 31, 2017**	**December 31, 2016**
Intangible assets	(349,052)	(327,637)
Hercules Loan Facility	(47,477)	(76,390)
Total	**(396,529)**	**(404,027)**

Deferred Tax Asset	**December 31, 2017**	**December 31, 2016**
Net operating loss (NOL)	217,720	207,445
Total	**217,720**	**207,445**
Deferred Tax, net	**(178,809)**	**(196,582)**

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 has 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 will receive 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.

Statuten

Articles of Association

Auris Medical Holding AG

I Firma, Sitz, Dauer, Zweck		I Corporate Name, Domicile, Duration, Purpose	
	Art. 1	Art. 1	
Firma	Unter der Firma	Incorporated under the name	*Corporate name*
	Auris Medical Holding AG	Auris Medical Holding AG	
	Auris Médical Holding SA	Auris Médical Holding SA	
	Auris Medical Holding Ltd.	Auris Medical Holding Ltd.	
Dauer, Sitz	besteht auf unbestimmte Zeit eine Aktiengesellschaft mit Sitz in Zug.	is a stock corporation, formed for an indefinite duration and domiciled in Zug.	*Duration, domicile*
Zweigniederlassungen	Die Gesellschaft kann im In- und Ausland Zweigniederlassungen und Vertretungen errichten.	The Corporation may establish branches and representative agencies in Switzerland and abroad.	*Branch establishments*
	Art. 2	Art. 2	
Zweck	Zweck der Gesellschaft ist die Beteiligung an Unternehmungen aller Art im In- und Ausland, die insbesondere in Beziehung zu pharmazeutischen Produkten und Dienstleistungen stehen. Die Gesellschaft kann im Übrigen alle Geschäfte betreiben, die bestimmt oder geeignet sind, das Unternehmen zu entwickeln oder den Gesellschaftszweck zu fördern. Die Gesellschaft kann auch Finanzierungen für eigene oder fremde Rechnung vornehmen, insbesondere Darlehen an Konzerngesellschaften oder an Dritte gewähren sowie Garantien oder Bürgschaften aller Art für Verbindlichkeiten gegenüber Konzerngesellschaften ausrichten. Diese Darlehen, Garantien oder Bürgschaften können auch ohne Vergütung oder Entschädigung gewährt werden. Die Gesellschaft kann zudem an Cash-Pooling-Operationen innerhalb des Konzerns teilnehmen.	The Corporation's purpose is to participate in business organizations of all kinds in Switzerland and abroad, particularly in relation to pharmaceutical products and services. Moreover, the Corporation may transact any business conducive to developing the Corporation or furthering the Corporation's purpose. The Corporation 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 Corporation may in addition participate in cash-pooling operations within the Group.	*Purpose*

II Aktienkapital		II Share Capital	
	Art. 3	Art. 3	
Aktienkapital, Stückelung	Das Aktienkapital beträgt CHF 122‘347.76 und ist eingeteilt in 6‘117‘388 Namenaktien zu je CHF 0.02 Nennwert. Die Aktien sind vollständig liberiert.	The share capital totals CHF 122,347.76 and is divided into 6,117,388 registered shares with a nominal value of CHF 0.02 each. The shares are fully paid-in.	*Share capital, denominations*
	Art. 3a	Art. 3a	
Genehmigtes Aktienkapital	Der Verwaltungsrat ist ermächtigt, jederzeit bis zum 29. Januar 2020 das Aktienkapital im Maximalbetrag von CHF 61‘000.00 durch Ausgabe von höchstens 3‘050‘000 vollständig zu liberierenden Namenaktien mit einem Nennwert von je CHF 0.02 zu erhöhen.	The Board of Directors is authorized at any time until 29 January 2020 to increase the share capital by a maximum aggregate amount of CHF 61,000.00 through the issuance of not more than 3,050,000 registered shares, which will have to be fully paid-in, with a nominal value of CHF 0.02 each.	*Authorized share capital*
	Erhöhungen in Teilbeträgen sind gestattet. Der Verwaltungsrat kann neue Aktien auch mittels Festübernahme oder auf eine andere Weise durch eine oder mehrere Banken und anschliessendem Angebot an Aktionäre oder Dritte ausgeben. Der Verwaltungsrat legt die Art der Einlagen, den Ausgabebetrag, den Zeitpunkt der Ausgabe, die Bedingungen für die Ausübung der Bezugsrechte sowie die Zuteilung der Bezugsrechte, welche nicht ausgeübt wurden, und den Beginn der Dividendenberechtigung fest. Der Verwaltungsrat ist ermächtigt, den Handel mit Bezugsrechten zu ermöglichen, zu beschränken oder auszuschliessen.	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.	
	Aktien, für welche Bezugsrechte eingeräumt, aber nicht ausgeübt werden, können vom Verwaltungsrat anderweitig im Interesse der Gesellschaft verwendet werden.	If pre-emptive rights are granted, but not exercised, the Board of Directors may use the respective shares in the interest of the Corporation.	

	Der Verwaltungsrat ist berechtigt, das Bezugsrecht der Aktionäre zu beschränken oder aufzuheben und Dritten, oder der Gesellschaft, zuzuweisen im Fall der Verwendung der Aktien: a) für Zwecke der Erweiterung des Aktionärskreises in bestimmten Investorenmärkten oder im Rahmen der Kotierung, Handelszulassung oder Registrierung der Aktien an inländischen oder ausländischen Börsen; b) im Zusammenhang mit einem Aktienangebot, um die einer oder mehreren Banken gewährte Mehrzuteilungsoption (Over-Allotment Option) abzudecken; c) für Aktienplatzierungen, wenn der Ausgabebetrag der neuen Aktien unter Berücksichtigung des Marktpreises festgesetzt wird; d) für die Beteiligung von Mitarbeitern, Mitgliedern des Verwaltungsrats und Beratern der Gesellschaft oder ihrer Tochtergesellschaften nach Massgabe eines oder mehrerer vom Verwaltungsrat erlassenen Reglemente; e) für die Übernahme von Unternehmen, Unternehmensteilen oder Beteiligungen, den Erwerb von Produkten, Immaterialgüterrechten, Lizenzen oder neue Investitionsvorhaben oder im Falle einer privaten oder öffentlichen Aktienplatzierung für die Finanzierung und/oder Refinanzierung solcher Transaktionen; f) für die rasche und flexible Beschaffung von Eigenkapital, welche ohne Entzug des Bezugsrechts nur schwer oder zu schlechteren Bedingungen möglich wäre, oder g) für den Erwerb einer Beteiligung an der Gesellschaft durch einen strategischen Partner (einschliesslich im Falle eines öffentlichen Übernahmeangebots).	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).	
	Art. 3b	Art. 3b	
Bedingtes Kapital zu Finanzierungszwecken	Das Aktienkapital wird im Maximalbetrag von CHF 42‘700.00 durch Ausgabe von höchstens 2‘135‘000 vollständig zu liberierenden Namenaktien mit einem Nennwert von je CHF 0.02 erhöht durch Ausübung von Options- und Wandelrechten, welche in Verbindung mit Anleihensobligationen, ähnlichen Obligationen, Darlehen oder anderen Finanzmarktinstrumenten oder vertraglichen Verpflichtungen der Gesellschaft oder einer ihrer Konzerngesellschaften ausgegeben werden, und/oder durch Ausübung von Optionsrechten, welche von der Gesellschaft oder einer ihrer Konzerngesellschaften ausgegeben werden („Finanzinstrumente“). Das Bezugsrecht der Aktionäre ist ausgeschlossen. Zum Bezug der neuen Aktien sind die jeweiligen Inhaber von Finanzinstrumenten berechtigt. Die Bedingungen der Finanzinstrumente sind durch den Verwaltungsrat festzulegen.	The Corporation’s share capital shall be increased by a maximum aggregate amount of CHF 42,700.00 through the issuance of not more than 2,135,000 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.	*Conditional share capital for financing purposes*
	Der Verwaltungsrat kann bei der Ausgabe von Finanzinstrumenten das Vorwegzeichnungsrecht der Aktionäre ganz oder teilweise ausschliessen:	When issuing Financial Instruments the Board of Directors is authorized to limit or exclude the advance subscription rights of shareholders:	

	a) zur Finanzierung und Refinanzierung des Erwerbs von Unternehmen, Unternehmensteilen oder Beteiligungen, Produkten, Immaterialgüterrechten, Lizenzen, Kooperationen oder von neuen Investitionsvorhaben der Gesellschaft; b) wenn die Ausgabe auf nationalen oder internationalen Kapitalmärkten einschliesslich Privatplatzierungen erfolgt, oder c) zum Zwecke einer Festübernahme der Finanzinstrumente durch eine Bank oder ein Bankkonsortium mit anschliessendem öffentlichem Angebot. Soweit das Vorwegzeichnungsrecht ausgeschlossen ist, sind i) die Finanzinstrumente zu Marktbedingungen zu platzieren; ist ii) die Ausübungs-, Wandel- oder Tauschfrist der Finanzinstrumente auf höchstens 10 Jahre ab dem Zeitpunkt der Emission anzusetzen und ist iii) der Umwandlungs-, Tausch- oder sonstige Ausübungspreis der Finanzinstrumente unter Berücksichtigung des Marktpreises festzulegen.	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.	
Bedingtes Kapital für Beteiligungspläne	Das Aktienkapital wird unter Ausschluss des Bezugs- und Vorwegzeichnungsrechts im Maximalbetrag von CHF 18‘300.00 durch Ausgabe von höchstens 915‘000 vollständig zu liberierenden Namenaktien mit einem Nennwert von je CHF 0.02 erhöht durch Ausgabe von Aktien infolge Ausübung von Optionen oder diesbezüglichen Bezugsrechten, welche Mitarbeiterinnen und Mitarbeitern, Mitgliedern des Verwaltungsrates oder Beratern der Gesellschaft oder einer ihrer Konzerngesellschaften im Rahmen eines oder mehrerer durch den Verwaltungsrat erlassenen Aktienbeteiligungsprogramme oder Reglemente ausgegeben bzw. eingeräumt werden. Der Verwaltungsrat regelt die Einzelheiten.	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 18,300.00 through the issuance of not more than 915,000 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.	*Conditional share capital for equity incentive plans*
	Art. 4	Art. 4	
Aktienbuch, Aktienzertifikate und Bucheffekten	Die Gesellschaft oder von ihr beauftragte Dritte führen ein Aktienbuch. Darin werden die Eigentümer (inklusive, falls anwendbar, Nominees) und Nutzniesser der Aktien mit Namen und Vornamen, Wohnort und Adresse (bei juristischen Personen mit Firma und Sitz), der Anzahl und Beschreibung der gehaltenen Aktien, dem Datum, zu welchem eine Person ins Aktienbuch eingetragen wurde wie auch das Datum, an welchem eine Person ihre Aktionärseigenschaft aufgegeben hat, eingetragen. Jeder Aktionär hat der Gesellschaft allfällige Adressänderungen zur Eintragung ins Aktienbuch zu melden.	The Corporation shall maintain, itself or through a third party, a share register. The share register shall list the name, first name and address (in the case of legal entities, the company name and registered offices) of the owners (including, if applicable, nominees) and usufructuaries of the shares, the number and description of the shares held, the date on which each person was entered in the register and the date on which any person ceased to be a shareholder. The shareholders shall notify the Corporation of any change of their address.	*Share register, share certificates and intermediated securities*

	Als Aktionär gilt, wer im Aktienbuch als Aktionär eingetragen ist. Ist die Eintragung eines Erwerbers aufgrund falscher Angaben erfolgt, kann dieser nach Anhörung vom Verwaltungsrat aus dem Aktienbuch gestrichen werden.	Whoever is registered in the share register as shareholder is deemed to be a shareholder of the Corporation. The Board of Directors may, after having heard the concerned owner of the shares, cancel entries which were based on untrue information.	
	Die Gesellschaft gibt ihre Namenaktien in Form von Einzelurkunden, Globalurkunden oder Wertrechten aus. Der Gesellschaft steht es im Rahmen der gesetzlichen Vorgaben frei, ihre in einer dieser Formen ausgegebenen Namenaktien jederzeit und ohne Zustimmung der Aktionäre in eine andere Form umzuwandeln. Die Gesellschaft trägt dafür die Kosten.	The Corporation may issue its registered shares in the form of single certificates, global certificates or uncertificated securities. Under the conditions set forth by statutory law, the Corporation may convert its registered shares from one form into another form at any time and without the approval of the shareholders. The Corporation shall bear the cost of any such conversion.	
	Falls Namenaktien in der Form von Einzelurkunden oder Globalurkunden ausgegeben werden, tragen sie die Unterschrift von zwei Mitgliedern des Verwaltungsrates. Beide Unterschriften können Faksimile Unterschriften sein.	If registered shares are issued in the form of single certificates or global certificates, they shall be signed by two members of the Board of Directors. Both signatures may be affixed in facsimile.	
	Der Aktionär hat keinen Anspruch auf Umwandlung von in bestimmter Form ausgegebenen Namenaktien in eine andere Form. Jeder Aktionär kann jedoch von der Gesellschaft jederzeit die Ausstellung einer Bescheinigung über die von ihm gemäss Aktienbuch gehaltenen Namenaktien verlangen.	The shareholder has no right to request a conversion of the form of the registered shares. Each shareholder may, however, at any time request a written confirmation from the Corporation of the registered shares held by such shareholder, as reflected in the share register.	
	Werden Bucheffekten im Auftrag der Gesellschaft oder des Aktionärs von einer Verwahrungsstelle, einem Registrar, Transfer Agenten, einer Trust Gesellschaft, Bank oder einer ähnlichen Gesellschaft verwaltet (die Verwahrungsstelle), so setzt Wirksamkeit gegenüber der Gesellschaft voraus, dass diese Bucheffekten und die damit verbundenen Rechte unter Mitwirkung der Verwahrungsstelle übertragen oder daran Sicherheiten bestellt werden.	If intermediated securities are administered on behalf of the Corporation or a shareholder by an intermediary, registrar, transfer agent, trust company, bank or similar entity (“Intermediary”), any transfer or grant of a security interest in such intermediated securities and the appurtenant rights associated therewith, in order for such transfer or grant of a security interest to be valid against the Corporation, requires the cooperation of the Intermediary.	
	Art. 5	Art. 5	
Bezugsrecht	[aufgehoben]	[annulled]	*Pre-emptive rights*
III Organisation der Gesellschaft		III Organization of the Corporation	
	i) Generalversammlung	i) General Meeting of Shareholders	
	Art. 6	Art. 6	

Arten der Generalversammlung	Die ordentliche Generalversammlung findet jedes Jahr innerhalb von sechs Monaten nach Schluss des Geschäftsjahres statt.	The ordinary General Meeting of shareholders shall be held annually within six months of the close of the financial year.	*Types of General Meetings*
	Ausserordentliche Generalversammlungen finden nach Bedarf statt, insbesondere	Extraordinary General Meetings of shareholders shall be held as required, in particular:	
	a) auf Beschluss der Generalversammlung oder des Verwaltungsrats,	a) by resolution of the General Meeting of shareholders or the Board of Directors,	
	b) auf Begehren der Revisionsstelle,	b) at the request of the auditors,	
	c) wenn es von einem oder mehreren Aktionären, die zusammen mindestens 10 % des Aktienkapitals vertreten, schriftlich verlangt wird. Der schriftliche Antrag soll die Verhandlungsgegenstände, die gestellten Anträge sowie die weiteren Angaben, die gemäss anwendbaren Gesetzes- oder Kotierungsvorschriften notwendig sind, enthalten.	c) if requested by one or more shareholders who together represent at least 10 % of the issued share capital, by application in writing. The application shall contain an agenda, the respective motions as well as any other information required under the applicable laws and stock exchange rules.	
	d) wenn es Gesetz oder Statuten vorsehen.	d) if required by law or by these Articles of Association.	
	Art. 7	Art. 7	
Einberufung	Die Einberufung der Generalversammlung erfolgt durch den Verwaltungsrat oder, wenn die gesetzlichen oder statutarischen Voraussetzungen gegeben sind, durch die Revisionsstelle, die Liquidatoren oder die Vertreter der Anleihensgläubiger.	The General Meeting of shareholders shall be called by the Board of Directors or, if required under statutory or articled provisions, by the auditors, liquidators or the representatives of the Bond owners.	*Calling of General Meeting*
Bekanntmachung	Die Generalversammlung ist unter Bekanntgabe von Ort, Zeit, Verhandlungsgegenständen, Anträgen des Verwaltungsrates zu den Verhandlungsgegenständen, Anträgen auf Änderung der Statuten und Art des Ausweises über den Aktienbesitz mindestens 20 Tage vor dem Versammlungstag durch einmalige Bekanntmachung im Schweizerischen Handelsamtsblatt einzuberufen. In der Einberufung sind zudem die Anträge der Aktionäre bekanntzugeben, welche die Durchführung der Generalversammlung oder die Traktandierung eines Verhandlungsgegenstandes nach den Bestimmungen von Art. 8 verlangt haben, sowie bei Wahlgeschäften die Namen des oder der zur Wahl vorgeschlagenen Kandidaten anzugeben.	The General Meeting of shareholders is to be called at least twenty days before the day appointed for the Meeting by a notice published once in the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt), stating time, place, agenda, resolutions put forward by the Board of Directors for the agenda items, any resolutions to amend these Articles and method of proving shareholder status. The announcement is to include the motions put forward by those shareholders who have requested the General Meeting of shareholders to be held or that an item be included in the Agenda in accordance with Article 8 and, in the event of elections, the name(s) of the candidate(s) that has or have been put on the ballot for election.	*Announcement*
	Die Einladung der Aktionäre kann zudem schriftlich an deren im Aktienbuch eingetragene Adresse erfolgen, wobei der Fristenlauf mit dem Tag beginnt, welcher der Postaufgabe folgt.	An invitation may also be sent to the shareholders at their address registered in the share register; whereby the convocation period begins at the day following the date of posting.	

Universalversammlung	Über Gegenstände, die nicht in dieser Weise angekündigt sind, kann, unter Vorbehalt der gesetzlichen Bestimmungen über die Universalversammlung, kein Beschluss gefasst werden, es sei denn über die Einberufung einer ausserordentlichen Generalversammlung oder die Durchführung einer Sonderprüfung.	Subject to the statutory provisions on the universal meeting of all shareholders, matters not announced in this way shall not be eligible for resolution except the calling of an extraordinary General Meeting of shareholders or the carrying out of a special audit.	*Universal meeting of all shareholders*
	Art. 8	Art. 8	
Traktandierung	An einer Generalversammlung darf nur über die Gegenstände abgestimmt werden, die	At any General Meeting of shareholders only such business shall be conducted as shall have been brought before the meeting	*Agenda*
	a) vom Verwaltungsrat oder im Auftrag des Verwaltungsrates oder	a) by the Board of Directors or at its direction, or	
	b) von einem oder von mehreren Aktionären im Verfahren gemäss diesem Art. 8 traktandiert werden.	b) by any shareholder of the Corporation in accordance with the procedure set forth in this Article 8.	
	Das Traktandierungsbegehren eines Aktionärs für die ordentliche Generalversammlung muss mindestens 45 Kalendertage vor der Versammlung bei der Gesellschaft eingereicht werden. Das Traktandierungsbegehren muss in schriftlicher Form gestellt werden und bezüglich jedem vorgebrachten Traktandum die nachfolgenden Informationen enthalten:	To be timely for consideration at the ordinary General Meeting of shareholders, a shareholder's application must be received by the Corporation at least 45 calendar days in advance of the meeting. The application must be made in writing and contain, for each of the agenda items, the following information:	
	a) eine kurze Beschreibung des gewünschten Traktandums sowie der Gründe, weshalb dieses Traktandum von der Generalversammlung behandelt werden soll;	a) 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;	
	b) der Name und die Adresse des traktandierenden Aktionärs, wie sie im Aktienbuch registriert sind; und	b) the name and address, as they appear in the share register, of the shareholder proposing such business; and	
	c) sämtliche weiteren Informationen, welche unter den anwendbaren Gesetzes- und Kotierungsbestimmungen verlangt werden.	c) all other information required under the applicable laws and stock exchange rules.	
	Art. 9	Art. 9	
Vorsitz	Die Generalversammlung steht unter der Leitung des Präsidenten des Verwaltungsrates oder, wenn er verhindert ist, eines andern vom Verwaltungsrat bezeichneten Mitgliedes.	The General Meeting of shareholders shall be chaired by the Chairman of the Board of Directors, or, in the event of his/her incapacity, by another Board Member designated by the Board.	*Chair*
Protokollführer, Stimmenzähler	Der Vorsitzende bezeichnet den Protokollführer und die nötigen Stimmzähler, welche nicht Aktionäre zu sein brauchen.	The Chairman shall appoint a secretary to take the minutes and any necessary scrutineers, who need not be shareholders.	*Secretary, scrutineers*
Protokoll	Über die Verhandlungen wird ein Protokoll geführt, das vom Vorsitzenden und vom Protokollführer zu unterzeichnen ist.	The proceedings shall be recorded in the minutes, which shall be signed by the Chairman and the secretary.	*Minutes*
	Art. 10	Art. 10	

Stimmrecht	Jede Aktie verfügt, unabhängig von ihrem Nennwert, über eine Stimme. Die Rechte an den Aktien sind unteilbar. Das Stimmrecht und die übrigen Mitgliedschaftsrechte können nur von den im Aktienbuch eingetragenen Aktionären, Nutzniessern oder Nominees geltend gemacht werden. Vorbehalten bleiben die gesetzliche Vertretung sowie nach Massgabe der Statuten die rechtsgeschäftliche Stellvertretung. Stimmberechtigt in der Generalversammlung sind diejenigen Aktionäre, Nutzniesser und Nominees, die an dem vom Verwaltungsrat bezeichneten Stichtag im Aktienbuch eingetragen sind.	Each share entitles to one vote, regardless of its nominal value. The shares are not divisible. The right to vote and the other member rights may only be exercised by shareholders, beneficiaries or nominees who are registered in the share register. Reserved are the legal representation and power of attorneys in accordance with the provision of these Articles of Association. Those entitled to vote in the General Meeting of shareholders are the shareholders, beneficiaries and nominees who are entered in the share register at such cut-off date as shall be determined by the Board of Directors.	*Voting rights*
Stellvertretung	Jeder Aktionär kann seine Aktien an der Generalversammlung durch den unabhängigen Stimmrechtsvertreter, durch einen anderen Aktionär oder eine Drittperson mittels schriftlicher Vollmacht oder durch seinen gesetzlichen Vertreter vertreten lassen. Über die Anerkennung der Vollmacht entscheidet der Vorsitzende.	Any shareholder may appoint the independent proxy, another registered shareholder or third person with written authorization or his legal representative to act as proxy to represent his shares at the General Meeting of shareholders. The Chairman decides whether to recognize the power of attorney.	*Representation*
Unabhängiger Stimmrechtsvertreter	Der unabhängige Stimmrechtsvertreter wird von der Generalversammlung für eine Amtsdauer bis zum Abschluss der nächsten ordentlichen Generalversammlung gewählt und kann wiedergewählt werden. Hat die Gesellschaft keinen unabhängigen Stimmrechtsvertreter, bezeichnet der Verwaltungsrat den unabhängigen Stimmrechtsvertreter für die nächste Generalversammlung.	The independent proxy shall be elected for a term of office until completion of the next ordinary General Meeting of shareholders by the General Meeting of shareholders and shall be eligible for re-election. If the Corporation does not have an independent proxy the Board of Directors shall appoint the independent proxy for the next General Meeting of shareholders.	*Independent proxy*
Bestimmungen	Der Verwaltungsrat erlässt die Bestimmungen betreffend Ausweis über Aktienbesitz, Vollmachten und Stimminstruktionen sowie die Ausgabe von Stimmkarten.	The Board of Directors shall issue the regulations on the method of proving shareholder status, on proxies and voting instructions, and on the issue of voting cards.	*Regulations*
	Art. 11	Art. 11	
Beschlüsse, Wahlen	Die Generalversammlung fasst ihre Beschlüsse und vollzieht ihre Wahlen mit der absoluten Mehrheit der vertretenen Aktienstimmen, soweit das Gesetz nicht zwingend etwas anderes bestimmt.	Resolutions and elections made by the General Meeting of shareholders shall require the absolute majority of the share votes represented, unless otherwise stipulated by law.	*Resolutions, elections*

Spezialquorum

Ein Beschluss der Generalversammlung, der mindestens zwei Drittel der vertretenen Stimmen und die absolute Mehrheit der Aktiennennwerte der vertretenen Stimmen auf sich vereinigt, ist erforderlich für:

a) die Änderung des Gesellschaftszwecks,

b) Einführung oder Aufhebung von Vorzugsaktien oder die Änderung von Vorzugsrechten solcher Aktien,

c) die Aufhebung oder Änderung der Beschränkungen der Übertragbarkeit von Namenaktien,

d) eine genehmigte oder bedingte Kapitalerhöhung,

e) die Kapitalerhöhung aus Eigenkapital, gegen Sacheinlage oder zwecks Sachübernahme und die Gewährung von besonderen Vorteilen,

f) die Einschränkung oder Aufhebung des Bezugsrechtes,

g) die Verlegung des Sitzes der Gesellschaft,

h) die Auflösung der Gesellschaft mit oder ohne Liquidation.

A resolution of the General Meeting of the shareholders passed by at least two thirds of the share present or represented, and the absolute majority of the nominal value of the share present or represented is required for:

a) amending the Corporation's purpose,

b) creating or cancelling shares with preference rights or amending rights attached to such shares,

c) cancelling or amending the transfer restrictions of registered shares,

d) creating authorized or conditional share capital,

e) increasing the share capital out of equity, against contributions in kind or for the purpose of acquiring specific assets and granting specific benefits,

f) limiting or suppressing shareholder's pre-emptive rights,

g) changing of the Company's domicile,

h) dissolving or liquidating the Company.

Special quorum

Abstimmung

Abstimmungen und Wahlen erfolgen offen durch Handerheben, wenn der Vorsitzende nichts anderes anordnet. Der Vorsitzende kann bestimmen, dass Abstimmungen oder Wahlen elektronisch oder schriftlich durchgeführt werden.

Bei schriftlichen Abstimmungen und Wahlen kann der Vorsitzende anordnen, dass zur Beschleunigung der Stimmenauszählung nur die Stimmzettel derjenigen Aktionäre eingesammelt werden, die sich der Stimme enthalten oder eine Nein-Stimme abgeben wollen, und dass alle übrigen im Zeitpunkt der Abstimmung in der Generalversammlung vertretenen Aktien als Ja-Stimmen gewertet werden.

Voting and elections shall be by show of hands unless otherwise ordered by the Chairman. The Chairman may decide that voting or elections shall be conducted electronically or by written ballots.

In the case of written ballots, the Chairman may rule that only the ballots of those shareholders shall be collected who choose to abstain or to cast a negative vote, and that all other shares represented at the General Meeting at the time of vote shall be counted in favor, in order to expedite the counting of votes.

Voting

Stimmen-gleichheit

Bei Stimmengleichheit entscheidet die Stimme des Vorsitzenden.

In the event of an equality of votes, the Chairman shall have the casting vote.

Equality of votes

Art. 12

Art. 12

Befugnisse	Der Generalversammlung stehen folgende unübertragbare Befugnisse zu:	The General Meeting of shareholders shall have the following powers which shall not be delegated:	*Powers*
	a) Festsetzung und Änderung der Statuten,	a) issuing and amending the Articles of Association,	
	b) Wahl der Mitglieder des Verwaltungsrates, des Präsidenten des Verwaltungsrats, der Mitglieder des Vergütungsausschusses und der Revisionsstelle,	b) 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,	
	c) Genehmigung des Jahresberichtes, der Jahresrechnung und der Konzernrechnung sowie Beschlussfassung über die Verwendung des Bilanzgewinnes, insbesondere die Festsetzung der Dividenden,	c) approving the annual report, the annual 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,	
	d) Genehmigung der Vergütung des Verwaltungsrats und der Geschäftsleitung gemäss Artikel 22 dieser Statuten,	d) approving the compensation of the Board of Directors and of the executive management pursuant to Article 22 of these Articles of Association,	
	e) Entlastung der Mitglieder des Verwaltungsrates und der Geschäftsleitung,	e) discharging the Members of the Board of Directors and of the executive management,	
	f) Auflösung der Gesellschaft mit oder ohne Liquidation,	f) dissolving the Corporation with or without liquidation,	
	g) Beschlussfassung über die Gegenstände, die der Generalversammlung durch das Gesetz oder die Statuten vorbehalten sind oder ihr durch den Verwaltungsrat vorgelegt werden.	g) deciding matters reserved to the General Meeting of shareholders by law or by these Articles of Association or which are presented to it by the Board of Directors.	
	ii) Verwaltungsrat	ii) Board of Directors	
	Art. 13	Art. 13	
Mitgliederzahl	Der Verwaltungsrat besteht aus mindestens drei, maximal neun Mitgliedern.	The Board of Directors shall consist of at least three and not exceed nine members.	*Number*
Konstituierung	Vorbehältlich der Wahl des Präsidenten des Verwaltungsrats und der Mitglieder des Vergütungsausschusses durch die Generalversammlung konstituiert sich der Verwaltungsrat selbst. Er bezeichnet den Sekretär, der dem Verwaltungsrat nicht angehören muss. Ist das Präsidium des Verwaltungsrats vakant, bezeichnet der Verwaltungsrat aus seiner Mitte einen Präsidenten für die verbleibende Amtsdauer.	Except for the election of the Chairman of the Board of Directors and the members of the Compensation Committee by the General Meeting of shareholders, the Board of Directors shall constitute itself. It shall appoint the secretary, who does not need to be a Board member. If the office of the Chairman of the Board of Directors is vacant, the Board of Directors shall appoint a new Chairman from among its members for the remaining term of office.	*Constitution*
Reglement	Der Verwaltungsrat erlässt ein Organisationsreglement.	The Board of Directors shall issue organizational rules.	*Regulations*
	Art. 14	Art. 14	

Amtsdauer

Die Mitglieder des Verwaltungsrats und der Präsident des Verwaltungsrats werden von der Generalversammlung jährlich für die Dauer bis zum Abschluss der nächsten ordentlichen Generalversammlung gewählt und sind wieder wählbar. Die Wahl erfolgt für jedes Mitglied einzeln.

Wählbar sind nur Personen, die im Zeitpunkt der Wahl das fünfundsiebzigste Lebensjahr noch nicht vollendet haben. Die Generalversammlung kann in besonderen Fällen Ausnahmen von dieser Regelung vorsehen und ein Mitglied des Verwaltungsrats für eine oder mehrere Amtsperioden, höchstens aber insgesamt für zwei weitere Amtsjahre wählen.

Ersatzwahlen erfolgen in der Regel an der nächsten ordentlichen Generalversammlung.

The Members of the Board of Directors and the Chairman of the Board of Directors shall be elected annually by the General Meeting of shareholders for a period until the completion of the next General Meeting of shareholders and shall be eligible for re-election. Each Member of the Board of Directors shall be elected individually.

Only persons who have not completed their seventy-fifth year of age on the election date are eligible for election. The General Meeting of shareholders may, under special circumstances, grant an exception from this rule and may elect a Member of the Board of Directors for one or several terms of office provided that the total number of these additional terms of office does not exceed two.

Elections to fill vacancies shall be generally held at the next ordinary General Meeting of shareholders.

Term of office

Art. 15

Befugnisse

Der Verwaltungsrat vertritt die Gesellschaft nach aussen und fasst diejenigen Beschlüsse, die nicht nach Gesetz, Statuten oder Reglement einem anderen Organ der Gesellschaft übertragen sind.

Art. 15

The Board of Directors represents the Corporation externally and shall pass those resolutions which, according to law, these Articles of Association or regulations of the Corporation, are not covered by another executive body.

Powers

Unübertragbare Aufgaben

Er hat insbesondere folgende unübertragbare und unentziehbare Aufgaben:

a) Oberleitung der Gesellschaft und Erteilung der nötigen Weisungen,

b) Festlegung der Organisation,

c) Ausgestaltung des Rechnungswesens, der Finanzkontrolle sowie der Finanzplanung,

d) Ernennung und Abberufung der mit der Geschäftsführung und der Vertretung betrauten Personen und Regelung der Zeichnungsberechtigung,

e) Oberaufsicht über die mit der Geschäftsführung betrauten Personen, namentlich im Hinblick auf die Befolgung der Gesetze, Statuten, Reglemente und Weisungen,

f) Erstellen des Geschäftsberichtes und des Vergütungsberichtes sowie Vorbereitung der Generalversammlung und Ausführung ihrer Beschlüsse,

g) Benachrichtigung des Richters im Falle der Überschuldung.

Delegation

Der Verwaltungsrat kann, unter Vorbehalt der unübertragbaren Aufgaben, einen Teil seiner Befugnisse, vor allem die unmittelbare Geschäftsführung, an einzelne oder mehrere seiner Mitglieder (Delegierte, Ausschüsse) oder an Dritte, die nicht Mitglieder des Verwaltungsrats oder Aktionäre sein müssen, übertragen. Die Einzelheiten der Delegation werden im Organisationsreglement geregelt.

The Board of Directors has the following non-delegable and inalienable duties: *Exclusive powers*

a) the ultimate direction of the business of the Corporation and issuing of the relevant directives,

b) laying down the organization of the Corporation,

c) formulating accounting procedures, financial controls and financial planning,

d) nominating and removing persons entrusted with the management and representation of the Corporation and regulating the power to sign for the Corporation,

e) the ultimate supervision of those persons entrusted with management of the Corporation, with particular regard to adherence to law, these Articles of Association, and regulations and directives of the Corporation,

f) issuing the annual report and the compensation report, and preparing for the General Meeting of shareholders and carrying out its resolutions,

g) informing the court in case of indebtedness.

The Board of Directors may, while retaining its exclusive powers, 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. Details of the delegation shall be determined in the organizational rules. *Delegation*

	Art. 16	Art. 16	
Einberufung	Der Verwaltungsrat versammelt sich auf Einladung seines Präsidenten, so oft die Geschäfte es erfordern, oder auf Verlangen eines seiner Mitglieder.	The Board of Directors shall meet at the Chairman's invitation whenever business so requires or if requested by one of its members.	*Calling of Board Meetings*
Vorsitz	Den Vorsitz des Verwaltungsrates führt der Präsident oder, wenn er verhindert ist, der Vizepräsident oder ein anderes Mitglied.	The Board of Directors shall be chaired by the Chairman or, in the event of his/her incapacity, by the Vice Chairman or another Member of the Board of Directors.	*Chair*
Beschluss-fähigkeit und Beschluss-fassung	Beschlussfähigkeit (Präsenz) und Beschlussfassung des Verwaltungsrats richten sich nach dem Organisationsreglement. Bei Stimmengleichheit entscheidet die Stimme des Vorsitzenden.	The number of members who must be present to constitute a quorum and the modalities for the passing of resolutions by the Board of Directors shall be laid down in the organizational rules. In the event of an equality of votes, the chairman of the meeting shall have the casting vote.	*Quorum*
Zirkulations-beschluss	Beschlüsse können auf dem Zirkularweg schriftlich oder per Telefax oder E-Mail gefasst werden, wenn kein Mitglied mündliche Beratung verlangt. Zirkulationsbeschlüsse bedürfen der Zustimmung der absoluten Mehrheit der Mitglieder des Verwaltungsrats.	Board resolutions may be passed by circular, i.e. in writing or by facsimile or email, unless a member requests oral debate. Resolutions passed by circular require the agreement of the absolute majority of the Members of the Board of Directors.	*Circulatory resolutions*
Protokoll	Über Verhandlungen, Beschlüsse und Wahlen des Verwaltungsrats ist ein Protokoll zu führen, das vom Vorsitzenden und vom Sekretär zu unterzeichnen ist.	Proceedings, resolutions and elections at Board Meetings shall be recorded in the minutes, which shall be signed by the chairman of the meeting and the secretary.	*Minutes*
	Art. 17	Art. 17	

Schadlos-haltung, Versicherungs-leistungen

Soweit gesetzlich zulässig, hält die Gesellschaft aktuelle und ehemalige Mitglieder des Verwaltungsrats und der Geschäftsleitung sowie deren Erben, Konkurs- oder Nachlassmassen aus Gesellschaftsmitteln für Schäden, Verluste und Kosten aus drohenden, hängigen oder abgeschlossenen Klagen, Verfahren oder Untersuchungen zivil-, straf-, verwaltungsrechtlicher oder anderer Natur (beispielsweise und nicht ausschliesslich Verantwortlichkeiten gestützt auf Vertragsrecht, Haftpflichtrecht und anderes anwendbares ausländisches Recht und alle angemessenen Anwalts-, Prozess- und anderen Kosten und Auslagen) schadlos, welche ihnen oder ihren Erben, Konkurs- oder Nachlassmassen entstehen oder entstehen können aufgrund a) von tatsächlichen oder behaupteten Handlungen, Zustimmungen oder Unterlassungen im Zusammenhang mit der Ausübung ihrer Pflichten oder behaupteten Pflichten; b) ihrer Tätigkeit als Mitglied des Verwaltungsrats oder der Geschäftsleitung; oder c) ihrer Tätigkeit im Auftrag der Gesellschaft als Mitglied des Verwaltungsrats oder der Geschäftsleitung, Arbeitnehmer oder Agent einer anderen Kapitalgesellschaft, Personengesellschaft, eines Trusts oder anderer Gesellschaftsformen. Diese Pflicht zur Schadloshaltung besteht nicht, soweit in einem endgültigen und rechtskräftigen Entscheid eines zuständigen Gerichts, Schiedsgerichts oder einer zuständigen Verwaltungsbehörde entschieden worden ist, dass eine der genannten Personen ihre Pflichten als Mitglied des Verwaltungsrats oder der Geschäftsleitung absichtlich oder grobfahrlässig verletzt hat.

The Corporation shall indemnify and hold harmless, to the fullest extent permitted by law, the current and former Members of the Board of Directors, the executive management, and their heirs, executors and administrators out of the assets of the Corporation from against all damages, losses, liabilities and expenses in connection with threatened, pending or completed actions, proceedings or investigations, whether civil, criminal, administrative or other (including, but not limited to, liabilities under contract, tort and statute or any applicable foreign law or regulation and all reasonable legal and other costs and expenses properly payable) which they or any of them, their heirs, executors or administrators, shall or may incur or sustain by or reason of a) any act done or alleged to be done, concurred or alleged to be concurred in or omitted or alleged to be omitted in or about the execution of their duty, or alleged duty; or b) serving as a Member of the Board of Directors or member of the executive management of the Corporation; or c) serving at the request of the Corporation as director, officer, or employee or agent of another corporation, partnership, trust or other enterprise. This indemnity shall not extend to any matter in which any of the said persons is found, in a final judgment or decree of a court, arbitral tribunal or governmental or administrative authority of competent jurisdiction not subject to appeal, to have committed an intentional or grossly negligent breach of said person's duties as Member of the Board of Directors or member of the executive management.

Indemnification, insurance coverage

Ohne den vorstehenden Absatz einzuschränken, schiesst die Gesellschaft aktuellen und ehemaligen Mitgliedern des Verwaltungsrates und der Geschäftsleitung die Gerichts- und Anwaltskosten vor, die im Zusammenhang mit zivil-, straf- oder verwaltungsrechtlichen Verfahren oder im Zusammenhang mit Untersuchungen, wie im vorstehenden Absatz beschrieben, anfallen. Die Gesellschaft kann solche Kostenvorschüsse ablehnen oder zurückfordern, sofern ein zuständiges Gericht oder eine zuständige Verwaltungsbehörde rechtskräftig feststellt, dass das entsprechende Mitglied des Verwaltungsrats oder der Geschäftsleitung eine vorsätzliche oder grobfahrlässige Verletzung seiner Pflichten als Mitglied des Verwaltungsrats oder der Geschäftsleitung begangen hat.	Without limiting the foregoing, the Corporation shall advance to existing and former Members of the Board of Directors and executive management court costs and attorney fees in connection with civil, criminal, administrative or investigative proceedings as described in the preceding paragraph. The Corporation may reject and/or recover such advanced costs if a court or governmental or administrative authority of competent jurisdiction not subject to appeal holds that the Member of the Board of Directors or member of the executive management in question has committed an intentional or grossly negligent breach of his statutory duties as a Member of the Board of Directors or member of the executive management.
Die Gesellschaft kann Haftpflichtversicherungen für die Mitglieder des Verwaltungsrates oder der Geschäftsleitung abschliessen. Die Bezahlung der Versicherungsprämien wird von der Gesellschaft oder ihren Tochtergesellschaften übernommen.	The Corporation may procure directors' and officers' liability insurance for Members of the Board of Directors and members of the executive management of the Corporation. The insurance premiums shall be charged to and paid by the Corporation or its subsidiaries.

	iii) Vergütungsausschuss	iii) Compensation Committee	
	Art. 18	Art. 18	
Mitgliederzahl	Der Vergütungsausschuss besteht aus mindestens zwei und höchstens drei Mitgliedern des Verwaltungsrats.	The Compensation Committee shall consist of at least two and not more than three members of the Board of Directors.	*Composition*
Konstituierung	Der Verwaltungsrat bezeichnet einen Vorsitzenden.	The Board of Directors shall appoint a chairman.	*Constitution*
Amtsdauer	Die Mitglieder des Vergütungsausschusses werden von der Generalversammlung jährlich für die Dauer bis zum Abschluss der nächsten ordentlichen Generalversammlung gewählt und sind wieder wählbar. Die Wahl erfolgt für jedes Mitglied des Vergütungsausschusses einzeln. Bei Vakanzen im Vergütungsausschuss, die zu einer Unterschreitung der Mindestanzahl von zwei Mitgliedern führen, bezeichnet der Verwaltungsrat fehlende Mitglieder aus seiner Mitte für die verbleibende Amtsdauer.	The members of the Compensation Committee shall be elected by the General Meeting of shareholders annually for a period until completion of the next ordinary General Meeting of shareholders and shall be eligible for re-election. Each Member of the Compensation Committee shall be elected individually. If there are vacancies on the Compensation Committee and the number of members falls below the minimum of two, the Board of Directors shall appoint the missing members from among its members for the remaining term of office.	*Term of office*
	Art. 19	Art. 19	
Befugnisse	Der Vergütungsausschuss unterstützt den Verwaltungsrat bei der Festsetzung und Überprüfung der Vergütungsstrategie der Gesellschaft und der Leistungsziele und bei der Vorbereitung der Anträge zuhanden der Generalversammlung betreffend die Vergütung des Verwaltungsrats und der Geschäftsleitung, und kann dem Verwaltungsrat Vorschläge zu weiteren Vergütungsfragen unterbreiten.	The Compensation Committee shall support the Board of Directors in establishing and reviewing the Corporation's compensation strategy and in preparing the proposals to the General Meeting of shareholders regarding compensation of the Members of the Board of Directors and the members of the executive management, and may submit proposals to the Board of Directors in other compensation-related issues.	*Powers*
	Der Verwaltungsrat kann dem Vergütungsausschuss weitere Aufgaben und Befugnisse zuweisen.	The Board of Directors may delegate further tasks and powers to the Compensation Committee.	
Regelung der Leistungsziele, Zielwerte und Vergütungen	Der Verwaltungsrat kann in einem Reglement festlegen, für welche Funktionen des Verwaltungsrats und der Geschäftsleitung der Vergütungsausschuss, gemeinsam mit dem Präsidenten des Verwaltungsrats oder alleine, Vorschläge für die Leistungsziele, Zielwerte und Vergütungen der Mitglieder des Verwaltungsrats und der Geschäftsleitung unterbreitet, und für welche Funktionen er im Rahmen dieser Statuten und der vom Verwaltungsrat erlassenen Vergütungsrichtlinien die Leistungsziele, Zielwerte und Vergütungen festsetzt.	The Board of Directors may determine in a charter for which positions of the Board of Directors and of the executive management the Compensation Committee shall, together with the Chairman of the Board of Directors or on its own, submit proposals for the performance metrics, target levels and compensation of Members of the Board of Directors and members of the executive management, and for which positions it shall determine, in accordance with these Articles of Association and the compensation guidelines established by the Board of Directors, the performance metrics, target levels and compensation.	*Determination of performance targets, target levels and compensation*
	iv) Revisionsstelle	iv) Auditors	

	Art. 20	Art. 20	
Zusammensetzung, Amtsdauer	Die Generalversammlung wählt jedes Jahr die Revisionsstelle im Sinne von Art. 727 ff. OR. Die Revisionsstelle muss von der Gesellschaft unabhängig sein und die vom Gesetz geforderten besonderen fachlichen Voraussetzungen erfüllen.	The ordinary General Meeting of shareholders shall each year appoint the auditors as defined in Art. 727 et seq. Swiss Code of Obligations. The auditors shall be independent from the Corporation and meet the special professional standards required by law.	*Composition, term of office*
Befugnisse	Die Revisionsstelle prüft die Jahresrechnung der Gesellschaft, die Konzernrechnung sowie den Vergütungsbericht, und erstattet dem Verwaltungsrat und der Generalversammlung schriftlich Bericht. Sie hat die im Gesetz festgehaltenen Befugnisse und Pflichten.	The auditors shall audit the annual financial statements of the Corporation, the consolidated financial statements and the compensation report, and prepare a written report to the Board of Directors and to the General Meeting of shareholders. It disposes of the duties and entitlements laid down in the law.	*Powers*
IV Vergütung des Verwaltungsrats und der Geschäftsleitung		IV Compensation of the Board of Directors and the Executive Management	
	Art. 21	Art. 21	
Genehmigung der Vergütung	Die Generalversammlung genehmigt jährlich die Anträge des Verwaltungsrats in Bezug auf:	The General Meeting of shareholders shall approve annually the proposals of the Board of Directors in relation to:	*Approval of compensation*
	a) den maximalen Gesamtbetrag der Vergütung des Verwaltungsrats für die folgende Amtsperiode,	a) the maximum aggregate amount of compensation of the Board of Directors for the following term of office;	
	b) den maximalen Gesamtbetrag der Vergütung der Geschäftsleitung für das folgende Geschäftsjahr.	b) the maximum aggregate amount of the compensation of the executive management for the following financial year.	
	Der Verwaltungsrat kann der Generalversammlung abweichende und zusätzliche Anträge in Bezug auf die gleichen oder andere Zeitperioden zur Genehmigung vorlegen.	The Board of Directors may submit for approval by the General Meeting of shareholders deviating or additional proposals relating to the same or different periods.	

Weiteres Verfahren im Falle eines ablehnenden Aktionärsentscheids	Lehnt die Generalversammlung einen Antrag des Verwaltungsrats ab, setzt der Verwaltungsrat den entsprechenden (maximalen) Gesamtbetrag oder (maximale) Teilbeträge unter Berücksichtigung aller relevanten Faktoren fest, und unterbreitet den oder die so festgesetzten Beträge derselben Generalversammlung, einer nachfolgenden ausserordentlichen Generalversammlung oder der nächsten ordentlichen Generalversammlung zur Genehmigung.	In the event the General Meeting of shareholders does not approve a proposal of the Board of Directors, the Board of Directors shall determine, taking into account all relevant factors, the respective (maximum) aggregate amount or partial (maximum) amounts, and submit the amount(s) so determined for approval by the same General Meeting of shareholders, a subsequent extraordinary General Meeting or the next ordinary General Meeting of shareholders.	*Further procedure in the event of a negative shareholder vote*
Ausrichtung von Vergütung vor Genehmigung	Die Gesellschaft oder von ihr kontrollierte Gesellschaften können Vergütungen vor der Genehmigung durch die Generalversammlung unter Vorbehalt der nachträglichen Genehmigung durch die Generalversammlung ausrichten.	The Corporation or any company controlled by it may pay out compensation prior to approval by the General Meeting of shareholders subject to subsequent approval by the General Meeting of shareholders.	*Payment of compensation prior to approval*
Zusatzbetrag bei Wechseln in der Geschäftsleitung	Die Gesellschaft oder von ihr kontrollierte Gesellschaften sind ermächtigt, jedem Mitglied, das während einer von der Generalversammlung bereits genehmigten Vergütungsperiode in die Geschäftsleitung eintritt, während der Dauer der bereits genehmigten Vergütungsperiode(n) einen Zusatzbetrag auszurichten. Der Zusatzbetrag darf 40% der zuletzt von der Generalversammlung genehmigten Gesamtbeträge der fixen und variablen Vergütungen der Geschäftsleitung je Vergütungsperiode nicht übersteigen.	The Corporation or any company controlled by it shall be authorized to pay to any executive who becomes a member during a compensation period for which the General Meeting of shareholders has already approved the compensation of the executive management a supplementary amount during the compensation period(s) already approved. The supplementary amount shall not exceed 40% of the aggregate amounts of fixed and variable compensation of the executive management last approved by the General Meeting of shareholders per compensation period.	*Supplementary amount for changes to the executive management*
	Art. 22	Art. 22	
Allgemeine Vergütungsgrundsätze	Zusätzlich zu einer fixen Vergütung kann den Mitgliedern des Verwaltungsrats und der Geschäftsleitung eine variable Vergütung, die sich nach der Erreichung bestimmter Leistungsziele richtet, ausgerichtet werden.	In addition to a fixed compensation, Members of the Board of Directors and members of the executive management may be paid a variable compensation, depending on the achievement of certain performance criteria.	*General compensation principles*
Leistungsziele	Die Leistungsziele können persönliche Ziele, Ziele der Gesellschaft oder bereichsspezifische Ziele und im Vergleich zum Markt, anderen Unternehmen oder vergleichbaren Richtgrössen berechnete Ziele umfassen, unter Berücksichtigung von Funktion und Verantwortungsstufe des Empfängers der variablen Vergütung. Der Verwaltungsrat oder, soweit an ihn delegiert, der Vergütungsausschuss legen die Gewichtung der Leistungsziele und die jeweiligen Zielwerte fest.	The performance criteria may include individual targets, targets of the Corporation or parts thereof and targets in relation to the market, other companies or comparable benchmarks, taking into account 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.	*Performance targets*

Arten der Vergütung

Die Vergütung kann in Form von Geld, Aktien, Finanzinstrumenten oder Sach- oder Dienstleistungen ausgerichtet werden. Der Verwaltungsrat oder, soweit an ihn delegiert, der Vergütungsausschuss legen Zuteilungs-, Ausübungs- und Verfallsbedingungen sowie Wartefristen fest. Sie können vorsehen, dass aufgrund des Eintritts im Voraus bestimmter Ereignisse wie einem Kontrollwechsel oder der Beendigung eines Arbeits- oder Mandatsverhältnisses Wartefristen oder Ausübungsbedingungen weitergelten, verkürzt oder aufgehoben werden, Vergütungen unter Annahme der Erreichung der Zielwerte ausgerichtet werden oder Vergütungen verfallen.

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; they may provide for continuation, acceleration or removal of vesting and exercise conditions, for payment or grant of compensation assuming target achievement or for forfeiture in the event of pre-determined events such as a change-of-control or termination of an employment or mandate agreement.

Types of compensation

Zuteilung von Optionsrechten und anderen aktienbasierten Vergütungen

Der Verwaltungsrat oder der Vergütungsausschuss kann im Rahmen eines Aktienbeteiligungsprogramms sowie eines hierzu von ihm erlassenen Reglements über die Zuteilung von Optionsrechten oder andere aktienbasierte Vergütungen an Mitglieder des Verwaltungsrates und der Geschäftsleitung grundsätzlich nach freiem Ermessen entscheiden.

Zuteilungen erfolgen individuell und ohne irgendwelche Ansprüche der Empfänger auf wiederkehrende Leistung zu begründen. Sie haben im Rahmen folgender Vorgaben zu erfolgen:

a) Zuteilungen sind ausschliesslich möglich an Mitglieder des Verwaltungsrates, welche noch im Amt sind, oder an Mitglieder der Geschäftsleitung in ungekündigtem Arbeitsverhältnis und nach Ablauf der Probezeit,

b) der Ausgabepreis oder die Regeln zu seiner Bestimmung werden festgelegt, wobei Zuteilungen auch gratis erfolgen können,

c) der Ausübungspreis entspricht mindestens dem Nennwert der zugrundeliegenden Aktien,

d) die Wartefrist für die Ausübung von Optionsrechten beläuft sich auf mindestens zwölf Monate,

e) nach Ablauf der Wartefrist können Optionsrechte bis längstens 10 Jahre ab Zuteilung ausgeübt werden; nicht ausgeübte Optionsrechte verfallen ersatzlos.

Der Verwaltungsragt oder der Vergütungsausschuss bestimmt die Bedingungen und Voraussetzungen, einschliesslich einer allfälligen Beschleunigung, Verkürzung oder Aufhebung der Sperrfrist im Fall bestimmter Ereignisse wie einem Kontrollwechsel sowie allfällige Rückforderungsmechanismen.

Ausrichtung

Die Vergütung kann durch die Gesellschaft oder durch von ihr kontrollierte Gesellschaften ausgerichtet werden.

V Verträge mit Mitgliedern des Verwaltungsrats und der Geschäftsleitung

Art. 23

Grant of option rights and other share based compensation

The Board of Directors or the Compensation Committee may under an equity incentive plan and based on the regulations issued by it for this purpose determine at its own discretion to grant option rights or other share based compensations to Members of the Board of Directors or members of the executive management.

Grants are made individually and do not constitute any claim whatsoever by beneficiaries for recurring awards. They shall be made pursuant to the following principles:

a) grants are awarded only to Members of the Board of Directors whose term has not expired or to members of the executive management in a non-terminated employment agreement and after conclusion of the probation period;

b) the issue price or the principles for the determination of the issue price shall be set out, whereby grants may be made free of charge;

c) the exercise price shall at least be equal to the nominal value of the underlying shares;

d) exercise shall be subject to a vesting period of at least twelve months;

e) vested option rights shall be exercised within a maximum of ten years after the grant date; unexercised option rights shall lapse without compensation.

The Board of Directors or the Compensation Committee shall determine more detailed terms and requirements, including any acceleration, curtailing or waiving of the vesting period in specific circumstances such as a change of control, as well as any claw-back provisions.

Payment

Compensation may be paid by the Corporation or companies controlled by it.

V Agreements with Members of the Board of Directors and the Executive Management

Art. 23

Verträge mit Mitgliedern des Verwaltungsrats	Die Gesellschaft oder von ihr kontrollierte Gesellschaften können mit Mitgliedern des Verwaltungsrats unbefristete oder befristete Verträge über deren Vergütung abschliessen. Die Dauer und Beendigung richten sich nach Amtsdauer und Gesetz.	The Corporation or companies controlled by it may enter into agreements for a fixed term or for an indefinite term with members of the Board of Directors relating to their compensation. Duration and termination shall comply with the term of office and the law.	*Agreements with Members of the Board of Directors*
Verträge mit Mitgliedern der Geschäftsleitung	Die Gesellschaft oder von ihr kontrollierte Gesellschaften können mit Mitgliedern der Geschäftsleitung unbefristete oder befristete Arbeitsverträge abschliessen. Befristete Arbeitsverträge haben eine Höchstdauer von einem Jahr. Eine Erneuerung ist zulässig. Unbefristete Arbeitsverträge haben eine Kündigungsfrist von maximal zwölf Monaten.	The Corporation or companies controlled by it may enter into employment agreements with members of the executive management for a fixed term or for an indefinite term. Employment agreements for a fixed term may have a maximum duration of 1 year. Renewal is possible. Employment agreements for an indefinite term may have a termination notice period of not more than 12 months.	*Agreements with members of the executive management*
Beendigung	Mitglieder der Geschäftsleitung, die einer Kündigungsfrist unterliegen, können von ihrer Arbeitspflicht befreit werden. Die Gesellschaft oder von ihr kontrollierte Gesellschaften können Aufhebungsvereinbarungen abschliessen.	Members of executive management who are subject to a termination notice may be released from their obligation of work. The Corporation or companies controlled by it may enter into termination agreements.	*Termination*
Konkurrenzverbote	Die Gesellschaft oder von ihr kontrollierte Gesellschaften können Konkurrenzverbote für die Zeit nach Beendigung eines Arbeitsvertrags für eine Dauer von bis zu einem Jahr vereinbaren. Ein solches Konkurrenzverbot wird grundsätzlich nicht abgegolten.	The Corporation or companies controlled by it may enter into non-compete agreements for the time after termination of the employment agreement for a duration of up to one year. Such non-compete agreement shall not be compensated in principle.	*Non-compete agreements*
	Art. 24	Art. 24	
Darlehen, Kredite	Darlehen oder Kredite an ein Mitglied des Verwaltungsrates oder der Geschäftsleitung dürfen nur zu Marktbedingungen gewährt werden und zum Zeitpunkt ihrer Gewährung den Betrag der letzten dem betreffenden Mitglied ausgerichteten gesamten Jahresvergütung nicht übersteigen.	Loans or credits to a Member of the Board of Directors or member of the executive management may only be granted at market conditions and may, at the time of grant, not exceed the respective member's most recent total annual compensation.	*Loans , credits*
VI Mandate ausserhalb der Gesellschaft		VI Mandates Outside the Corporation	
	Art. 25	Art. 25	
Höchstzahl an Mandaten	Kein Mitglied des Verwaltungsrats oder der Geschäftsleitung kann mehr als sechs zusätzliche Mandate in börsenkotierten Gesellschaften und zehn zusätzliche in nicht-kotierten Gesellschaften wahrnehmen.	No Member of the Board of Directors or of the executive management may hold more than six additional mandates in listed companies and ten additional mandates in non-listed companies.	*Maximum number of mandates*

Ausgenommene Mandate	Die folgenden Mandate fallen nicht unter diese Beschränkung: a) Mandate in Unternehmen, die durch die Gesellschaft kontrolliert werden oder die Gesellschaft kontrollieren; b) Mandate in Vereinen, gemeinnützigen Organisationen, Stiftungen, Trusts sowie Personalfürsorgestiftungen. Kein Mitglied des Verwaltungsrats oder der Geschäftsleitung kann mehr als zehn solche Mandate wahrnehmen.	The following mandates are not subject to these limitations: a) mandates in companies which are controlled by the Corporation or which control the Corporation; b) mandates in associations, charitable organizations, foundations, trusts and employee welfare foundations. No Member of the Board of Directors or of the executive management shall hold more than ten such mandates.	*Exempt mandates*
VII Jahresrechnung und Gewinnverwendung		VII Annual Financial Statements and Profit Allocation	
	Art. 26	Art. 26	
Geschäftsjahr	Das Geschäftsjahr beginnt mit dem 1. Januar und endet am 31. Dezember.	The financial year shall commence on 1 January and shall end on 31 December.	*Financial year*

	Art. 27	Art. 27	
Jahresrechnung	Die Jahresrechnung, bestehend aus der Erfolgsrechnung, der Bilanz und dem Anhang, sowie die Konzernrechnung werden nach den gesetzlichen Vorschriften und nach allgemein anerkannten kaufmännischen und branchenüblichen Grundsätzen aufgestellt.	The annual financial statements, consisting of income statement, balance sheet and the notes, as well as the consolidated financial statements, shall be prepared according to law and generally recognized commercial and accounting principles.	*Annual financial statements*
	Art. 28	Art. 28	
Gewinnverwendung	Über den ausgewiesenen Bilanzgewinn verfügt die Generalversammlung im Rahmen der gesetzlichen Vorschriften, insbesondere Art. 671 ff OR.	The allocation of the net profit disclosed shall fall to the General Meeting of shareholders within the limits of the statutory provisions, in particular Article 671 et seq. Swiss Code of Obligations.	*Allocation of profits*
VIII Auflösung, Liquidation		VIII Dissolution, Liquidation	
	Art. 29	Art. 29	
Auflösung, Liquidation, Fusion	Die Generalversammlung kann jederzeit Auflösung und Liquidation oder Fusion mit einer anderen Gesellschaft nach den gesetzlichen Vorschriften beschliessen.	The General Meeting of shareholders may at any time decide to dissolve and liquidate the Corporation or merge it with another company pursuant to the relevant statutory provisions.	*Dissolution, liquidation, merger*
	Unter Vorbehalt abweichender Anordnung der Generalversammlung besorgt der Verwaltungsrat die Liquidation; er kann dabei Aktiven freihändig veräussern.	Unless otherwise ordered by the General Meeting of share- holders, the Board shall perform the liquidation, with power for the sale of assets on the open market.	
IX Bekanntmachungen		IX Notices	
	Art. 30	Art. 30	
Publikations-organ	Publikationsorgan für Bekanntmachungen der Gesellschaft ist das Schweiz. Handelsamtsblatt; der Verwaltungsrat kann weitere Publikationsorgane bezeichnen.	The publishing medium for notices of the Corporation is the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt); the Board of Directors may select additional publishing mediums.	*Publishing medium*

Im Falle von Abweichungen zwischen der deutschen und englischen Version dieser Statuten hat die deutsche Fassung Vorrang. Die englische Version ist eine Übersetzung der deutschen Fassung.

In the event of discrepancies between the German and English version of these Articles of Association, the German text shall prevail. The English version is a translation of the German text.

THIS WARRANT AND THE SHARES ISSUABLE UPON EXERCISE HEREOF HAVE NOT BEEN REGISTERED UNDER THE US SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), ANY US STATE SECURITIES LAWS, OR UNDER THE SECURITIES LAWS OF ANY OTHER JURISDICTION, AND MAY NOT BE SOLD, OFFERED FOR SALE, PLEDGED, OR HYPOTHECATED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT UNDER THE ACT AND SUCH OTHER LAWS AS MAY BE APPLICABLE OR, SUBJECT TO SECTION 11 HEREOF, AN OPINION OF COUNSEL (WHICH MAY BE COMPANY COUNSEL) REASONABLY SATISFACTORY TO THE COMPANY THAT SUCH REGISTRATION IS NOT REQUIRED.

WARRANT AGREEMENT

To Purchase the Common Shares of

AURIS MEDICAL HOLDING AG

(reg. no. CHE-474.294.374)

Dated as of March 13, 2018 (the "Effective Date")

WHEREAS, effective as of March 13, 2018 the former Auris Medical Holding AG ("Old Auris") merged into Auris Medical NewCo Holding AG (the "Company"), a corporation organized under the laws of Switzerland and registered in the commercial register of the canton of Zug under registration number CHE-474.294.374 (the "Merger"); and

WHEREAS, the Company changed its name to Auris Medical Holding AG upon effectiveness of the Merger; and

WHEREAS, the Company, as successor-in-interest to Old Auris, is party to a certain Loan and Security Agreement dated July 19, 2016 (as amended and in effect from time to time, the "Loan Agreement") with Hercules Capital, Inc., a Maryland USA corporation, as administrative agent, Hercules Capital, Inc. as a lender (the "Warrantholder"), and the other lender parties thereto; and

WHEREAS, pursuant to the Loan Agreement and as additional consideration to the Warrantholder for, among other things, its agreements therein, Old Auris entered into a certain Warrant Agreement with the Warrantholder dated July 19, 2016, providing for the Warrantholder's right to purchase certain Common Shares of Old Auris (the "Old Auris Warrant"); and

WHEREAS, the Company, as successor-by-merger to Old Auris, has assumed the Old Auris Warrant and the obligations of Old Auris thereunder, which Old Auris Warrant is now exercisable for certain Common Shares of the Company; and

WHEREAS, the parties desire to exchange the Old Auris Warrant for, and replace it with, this Warrant Agreement (this "Warrant", "Warrant Agreement", or "Agreement");

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and Warrantholder agree as follows:

SECTION 1. GRANT OF THE RIGHT TO PURCHASE COMMON SHARES.

(a) For value received, the Company hereby grants to the Warrantholder, and the Warrantholder is entitled, upon the terms and subject to the conditions hereinafter set forth, to subscribe for and

purchase, from the Company, up to the number of fully paid and non-assessable Common Shares (as defined below) as determined pursuant to Section 1(b) below, at a purchase price per share equal to the Exercise Price (as defined below). The number and Exercise Price of such shares are subject to adjustment as provided in Section 8. As used herein, the following terms shall have the following meanings:

"Act" means the US Securities Act of 1933, as amended.

"Charter" means the Company's Articles of Association, or other constitutional document, as may be amended and in effect from time to time.

"CHF" means Swiss Francs.

"Common Shares" means the Company's common shares with a nominal value of CHF 0.02 each, as presently constituted under the Charter, and any class, series or other designation of Company share capital for or into which such common shares may be converted or exchanged in a reorganization, recapitalization or similar transaction.

"Dollars" or "$" means United States Dollars.

"Exercise Price" means $39.40, subject to adjustment from time to time in accordance with the provisions of this Warrant; provided that notwithstanding anything herein to the contrary, the Exercise Price shall not be adjusted below the nominal value of the Common Shares subject hereto (currently CHF 0.02).

"Liquid Sale" means the closing of a Merger Event in which the consideration received by the Company and/or its shareholders, as applicable, consists solely of cash and/or Marketable Securities.

"Marketable Securities" in connection with a Merger Event means securities meeting all of the following requirements: (i) the issuer thereof is then subject to the reporting requirements of Section 13 or Section 15(d) of the US Securities Exchange Act of 1934, as amended (the "Exchange Act"), or any comparable applicable law(s) of any other jurisdiction, and is then current in its filing of all required reports and other information under the Act and the Exchange Act or such comparable law(s); (ii) the class and series, or other designation, of shares or other security of the issuer that would be received by the Warrantholder in connection with the Merger Event were the Warrantholder to exercise this Warrant on or prior to the closing thereof is then traded on a national securities exchange or over-the-counter market in the US or other jurisdiction, and (iii) following the closing of such Merger Event, Warrantholder would not be restricted from publicly re-selling all of the issuer's shares and/or other securities that would be received by Warrantholder in such Merger Event were Warrantholder to exercise this Warrant in full on or prior to the closing of such Merger Event, except to the extent that any such restriction (x) arises solely under US federal or state securities laws, rules or regulations, or the securities laws of any other jurisdiction, and (y) does not extend beyond six (6) months from the closing of such Merger Event.

"Merger Event" means any of the following: (i) a sale, lease or other transfer of all or substantially all assets of the Company, (ii) any merger or consolidation involving the Company in which the Company is not the surviving entity or in which the outstanding Common Shares of the Company are otherwise converted into or exchanged for share capital or other securities or property of another entity and in which the holders of a majority of the outstanding Common Shares of the Company immediately prior to such merger or consolidation do not hold a majority of the voting power of the surviving entity or other entity immediately following such merger or consolidation, or (iii) any sale by holders of the outstanding voting equity securities of the Company in a single transaction or series of related transactions of shares constituting a majority of the outstanding combined voting power of the Company.

"Purchase Price" means, with respect to any exercise of this Warrant, an amount equal to the then-effective Exercise Price multiplied by the number of Common Shares as to which this Warrant is then exercised.

"Rule 144" means Rule 144 promulgated under the Act, as amended.

"US" means the United States of America.

(b) Number of Shares. This Warrant shall be exercisable for such number of Common Shares as shall equal (x) $617,500.00, divided by (y) the Exercise Price, subject to adjustment from time to time in accordance with the provisions of this Warrant.

SECTION 2. TERM OF THE AGREEMENT.

The term of this Agreement and the right to purchase Common Shares as granted herein shall commence on the Effective Date and, subject to Section 8(a) below, shall be exercisable for a period ending upon July 19, 2023.

SECTION 3. EXERCISE OF THE PURCHASE RIGHTS.

(a) Exercise. The purchase rights set forth in this Agreement are exercisable by the Warrantholder, in whole or in part, at any time, or from time to time, prior to the expiration of the term set forth in Section 2, by tendering to the Company at its principal office a notice of exercise in the form attached hereto as Exhibit I (the "Notice of Exercise"), duly completed and executed; provided, that any single exercise shall be for no less than $300,000 of Common Shares (or if, on account of one or more prior exercises of this Warrant, the Warrantholder's purchase rights hereunder shall then be for less than $300,000 of Common Shares, such exercise shall be for all Common Shares then subject to purchase hereunder). Promptly upon receipt of the Notice of Exercise and the payment of the Purchase Price in accordance with the terms set forth below, and in no event later than three business (3) days thereafter, the Company shall issue to the Warrantholder the number of Common Shares purchased either by delivering a certificate to the Warrantholder or its designee evidencing such Common Shares or by causing its transfer agent to establish book entries evidencing such Common Shares, and in any case shall execute the acknowledgment of exercise in the form attached hereto as Exhibit II (the "Acknowledgment of Exercise") indicating the number of shares which remain subject to future purchases under this Warrant, if any.

The Purchase Price shall be paid in cash by wire transfer (in Dollars or Swiss francs) to a bank account in Switzerland specified by the Company (the "Bank Account"). Upon partial exercise of this Warrant prior to the expiration or earlier termination hereof, the Company shall, upon request, promptly issue an amended Agreement representing the remaining number of shares purchasable hereunder. All other terms and conditions of such amended Agreement shall be identical to those contained herein, including, but not limited to the Effective Date hereof.

(b) Exercise Prior to Expiration and Liquid Sale. (x) To the extent this Warrant is not previously exercised as to all Common Shares subject hereto prior to its expiration, and if the then-current fair market value of one Common Share is greater than the Exercise Price then in effect, this Warrant shall be deemed automatically exercised on a cash basis pursuant to Section 3(a) (even if not surrendered) as of the business day prior to its expiration determined in accordance with Section 2 and (y) to the extent this Warrant is not previously exercised as to all Common Shares subject thereto prior to a Liquid Sale, where the fair market value per Common Share (as determined as of the closing of such Liquid Sale) to be paid to the holders thereof is greater than the Exercise Price then in effect, this Warrant shall be deemed automatically exercised on a cash basis pursuant to Section 3(a) (even if not surrendered) as of the business day prior to the closing of such Liquid Sale. To the extent this Warrant or any portion hereof is deemed automatically exercised pursuant to this Section 3(b), the Company agrees to promptly notify the Warrantholder of the number of Common Shares if any, the Warrantholder is to receive by reason of such automatic exercise. In the case of each such automatic exercise, promptly following the Warrantholder's receipt of such notification from the Company, the Warrantholder shall deliver a Notice of Exercise to the Company and payment of the Purchase Price to the Bank Account. Following receipt of the Purchase Price and the Notice of Exercise, the Company agrees to issue to the Warrantholder the number of Common Shares if any, the Warrantholder is to receive by reason of such automatic exercise by causing its transfer agent to establish book entries evidencing such Common Shares.

For purposes of the automatic exercise referenced above, the current fair market value of Common Shares and Marketable Securities shall mean with respect to each Common Share or Marketable Security:

(i) at all times when the Common Shares or relevant Marketable Security, as applicable, shall be traded on a national securities exchange, inter-dealer quotation system or over-the-counter bulletin board service, the volume-weighted average of the closing prices over a thirty (30) trading day period ending three days before the day the current fair market value of the securities is being determined; or

(ii) if the current fair market value of a Common Shares or relevant Marketable Security, as applicable, cannot be determined as described in the foregoing clause (i), the current fair market value of a Common Shares or relevant Marketable Security, as applicable, shall be determined in good faith by the Company's Board of Directors.

SECTION 4. RESERVATION OF SHARES.

During the term of this Agreement, the Company will at all times have authorized and reserved a sufficient number of its Common Shares as contingent capital (*bedingtes Kapital*) to provide for the exercise of the rights to purchase Common Shares as provided for herein. The Company acknowledges that compensation for damages may not be sufficient remedy for the Warrantholder in case of the Company's failure to comply with its obligation under this Section 4 and therefore expressly confirms that the Warrantholder may in such case request specific performance (*Realerfüllung*) upon due exercise of its purchase rights pursuant to Section 3 hereof from time to time by obligating the Company to deliver such number of shares as would have been issued to the Warrantholder in connection with such exercise of its purchase rights from time to time.

SECTION 5. NO FRACTIONAL SHARES OR SCRIP.

No fractional shares or scrip representing fractional shares shall be issued upon the exercise of this Agreement, but in lieu of any fractional share the Company shall make a cash payment therefor in amount equal to (a) such fraction, multiplied by (b)(i) the then-fair market value of a Common Share as determined in accordance with Section 3(b) above, minus (ii) the then-effective Exercise Price.

SECTION 6. NO RIGHTS AS SHAREHOLDER

Without limitation of any provision hereof, Warrantholder agrees that this Agreement does not entitle the Warrantholder to any voting rights or other rights as a shareholder of the Company prior to the Warrantholder's ownership of the respective Common Shares.

SECTION 7. [RESERVED].

SECTION 8. ADJUSTMENT RIGHTS.

The Exercise Price and the number of Common Shares purchasable hereunder are subject to adjustment from time to time, as follows:

(a) Merger Event. In connection with a Merger Event that is a Liquid Sale, this Warrant shall, on and after the closing thereof, automatically and without further action on the part of any party or other person, represent the right to receive the consideration payable on or in respect of all Common Shares that are issuable hereunder as of immediately prior to the closing of such Liquid Sale less the Purchase Price for all such Common Shares (such consideration to include both the consideration payable at the closing of such Liquid Sale and all deferred consideration payable thereafter, if any, including, but not limited to, payments of amounts deposited at such closing into escrow and payments in the nature of earn-outs, milestone payments or other performance-based payments ("Deferred Payments")), and such Liquid Sale consideration shall be paid to Warrantholder as and when it is paid to the holders of the outstanding Common Shares. To the extent that the maximum aggregate consideration per outstanding Common Share (including, without limitation, all Deferred Payments) in such Liquid Sale (assuming for such determination that all Common Shares for which this Warrant is then exercisable are issued and outstanding) that could, without discount to present value, be paid for, on or in respect of each such outstanding Common Share in accordance with the definitive transaction documents therefor is equal to or

less than the Exercise Price in effect as of immediately prior to the initial closing thereof, then this Warrant shall, effective on and as of such initial closing, terminate and be of no further force or effect.

In connection with a Merger Event that is not a Liquid Sale, the Company shall cause the successor or surviving entity to assume this Warrant and the obligations of the Company hereunder on the closing thereof, and thereafter this Warrant shall be exercisable for the same number and type of securities or other property as the Warrantholder would have received in consideration for the Common Shares issuable hereunder had it exercised this Warrant in full as of immediately prior to such closing, at an aggregate Exercise Price no greater than the aggregate Exercise Price in effect as of immediately prior to such closing, and subject to further adjustment from time to time in accordance with the provisions of this Warrant. The provisions of this Section 8(a) shall similarly apply to successive Merger Events.

(b) Reclassification of Shares. Except for Merger Events subject to Section 8(a), if the Company at any time shall, by combination, reclassification, exchange or subdivision of securities or otherwise, change any of the securities as to which purchase rights under this Agreement exist into the same or a different number of securities of any other class or classes of securities, this Agreement shall thereafter represent the right to acquire such number and kind of securities as would have been issuable as the result of such change with respect to the securities which were subject to the purchase rights under this Agreement immediately prior to such combination, reclassification, exchange, subdivision or other change. The provisions of this Section 8(b) shall similarly apply to successive combination, reclassification, exchange, subdivision or other change.

(c) Subdivision or Combination of Shares. If the Company at any time shall combine or subdivide its Common Shares, (i) in the case of a subdivision, the Exercise Price shall be proportionately decreased and the number of shares for which this Warrant is exercisable shall be proportionately increased, or (ii) in the case of a combination, the Exercise Price shall be proportionately increased and the number of shares for which this Warrant is exercisable shall be proportionately decreased.

(d) Stock Dividends. If the Company at any time while this Agreement is outstanding and unexpired shall:

(i) pay a dividend with respect to the outstanding Common Shares payable in additional Common Shares, then the Exercise Price shall be adjusted, from and after the date of determination of shareholders entitled to receive such dividend or distribution, to that price determined by multiplying the Exercise Price in effect immediately prior to such date of determination by a fraction (A) the numerator of which shall be the total number of Common Shares outstanding immediately prior to such dividend or distribution, and (B) the denominator of which shall be the total number of Common Shares outstanding immediately after such dividend or distribution, and the number of Common Shares for which this Warrant is exercisable shall be proportionately increased; or

(ii) make any other dividend or distribution on or with respect to Common Shares, except any dividend or distribution (A) in cash, or (B) specifically provided for in any other clause of this Section 8, then, in each such case, provision shall be made by the Company such that the Warrantholder shall receive upon exercise or conversion of this Warrant a proportionate share of any such distribution as though it were the holder of the Common Shares as of the record date fixed for the determination of the shareholders of the Company entitled to receive such distribution.

(e) Notice of Certain Events. If: (i) the Company shall declare any dividend or distribution upon its outstanding Common Shares, payable in capital shares or other Company securities, cash, or other property (provided that Warrantholder in its capacity as lender under the Loan Agreement consents to such dividend); (ii) the Company shall offer for subscription pro rata to the holders of its Common Shares any additional shares of stock of any class or other rights; (iii) there shall be any Merger Event; or (iv) there shall be any voluntary dissolution, liquidation or winding up of the Company; then, in connection with each such event, the Company shall give the Warrantholder notice thereof at the same time and in the same manner as it gives notice thereof to the holders of outstanding Common Shares.

SECTION 9. REPRESENTATIONS, WARRANTIES AND COVENANTS OF THE COMPANY.

(a) Reservation of Common Shares. The Company covenants and agrees that all Common Shares, if any, that may be issued upon the exercise of the rights represented by this Warrant will, upon issuance, be validly issued and outstanding, fully paid and non-assessable. The Company further covenants and agrees that the Company will, at all times during the term hereof, have authorized and reserved, free from preemptive rights, a sufficient number of Common Shares to provide for the exercise of the rights represented by this Warrant. If at any time during the term hereof the number of authorized but unissued Common Shares shall not be sufficient to permit exercise of this Warrant in full, the Company will take such corporate action as may, in the opinion of its counsel, be necessary to increase its authorized but unissued Common Shares to such number of shares as shall be sufficient for such purposes.

(b) Due Authority. The execution and delivery by the Company of this Agreement and the performance of all obligations of the Company hereunder, including the issuance to Warrantholder of the right to acquire the Common Shares, have been duly authorized by all necessary corporate action on the part of the Company. This Agreement: (1) does not violate the Company's Charter or current bylaws; (2) except as could not reasonably be expected to have a Material Adverse Effect (as defined in the Loan Agreement), does not contravene any law or governmental rule, regulation or order applicable to it; and (3) except as could not reasonably be expected to have a Material Adverse Effect, does not and will not contravene any provision of, or constitute a default under, any indenture, mortgage, contract or other instrument to which it is a party or by which it is bound. This Agreement constitutes a legal, valid and binding agreement of the Company, enforceable in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or similar laws relating to or affecting creditors' rights generally (including, without limitation, fraudulent conveyance laws) and by general principles of equity, regardless of whether considered in a proceeding in equity or at law.

(c) Consents and Approvals. No consent or approval of, giving of notice to, registration with, or taking of any other action in respect of any state, federal or other governmental authority or agency is required with respect to the execution, delivery and performance by the Company of its obligations under this Agreement, except for any filing of notices pursuant to Regulation D under the Act and any filing required by applicable state securities law, which filings will be effective by the time required thereby.

(d) [Intentionally Omitted].

(e) [Intentionally Omitted].

(f) Exempt Transaction. Subject to the accuracy of the Warrantholder's representations in Section 10, the issuance of the Common Shares upon exercise of this Agreement will constitute a transaction exempt from (i) the registration requirements of Section 5 of the Act, in reliance upon Section 4(2) thereof, (ii) the qualification requirements of applicable US state securities laws, and (iii) the registration and/or qualification requirements of any other securities laws applicable to the Company.

(g) [Intentionally Omitted].

(h) Information Rights. At all times (if any) prior to the earlier to occur of (x) the date on which all Common Shares issued on exercise of this Warrant have been sold, or (y) the expiration or earlier termination of this Warrant, when the Company shall not be required to file reports pursuant to Section 13 or 15(d) of the Exchange Act or comparable applicable law of another jurisdiction or shall not have timely filed all such required reports, Warrantholder shall be entitled to receive the same information as is distributed by the Company to all of its shareholders. All such information shall be held and treated by the Warrantholder in confidence in accordance with the provisions of Section 11.12 of the Loan Agreement (regardless of whether the Loan Agreement is then in effect).

(i) Rule 144 Compliance. The Company shall, at all times prior to the earlier to occur of (x) the date of sale or other disposition by Warrantholder of this Warrant or all Common Shares issued on exercise of this Warrant or (y) the expiration or earlier termination of this Warrant if the Warrant has not been exercised in full or in part on such date, use all commercially reasonable efforts to timely file all reports required under the Exchange Act

and otherwise cooperate with the Warrantholder if the Warrantholder decides to sell or otherwise dispose of this Warrant and the Common Shares issued on exercise hereof pursuant to Rule 144. If the Warrantholder proposes to sell Common Shares issuable upon the exercise of this Agreement in compliance with Rule 144, then, upon Warrantholder's written request to the Company, the Company shall furnish to the Warrantholder, within five (5) business days after receipt of such request, a written statement confirming the Company's compliance with the filing and other requirements of such Rule.

(j)

SECTION 10. REPRESENTATIONS AND COVENANTS OF THE WARRANTHOLDER.

This Agreement has been entered into by the Company in reliance upon the following representations and covenants of the Warrantholder:

(a) Investment Purpose. This Warrant and the shares issued on exercise hereof will be acquired for investment and not with a view to the sale or distribution of any part thereof in violation of applicable US federal and state securities laws, and the Warrantholder has no present intention of selling or engaging in any public distribution of the same except pursuant to a registration or exemption.

(a) Private Issue. The Warrantholder understands (i) that the Common Shares issuable upon exercise of this Agreement are not, as of the Effective Date, registered under the Act or qualified under applicable US state securities laws, and (ii) that the Company's reliance on exemption from such registration is predicated on the representations set forth in this Section 10.

(b) Financial Risk. The Warrantholder has such knowledge and experi-ence in financial and business matters as to be capable of evaluating the merits and risks of its investment, and has the ability to bear the economic risks of its investment.

(c) Accredited Investor. Warrantholder is an "accredited investor" within the meaning of Rule 501 of Regulation D promulgated under the Act, as presently in effect ("*Regulation D*").

(d) No Short Sales. Warrantholder has not at any time on or prior to the Effective Date engaged in any short sales or equivalent transactions in the Common Shares. Warrantholder agrees that at all times from and after the Effective Date and on or before the expiration or earlier termination of this Warrant, it shall not engage in any short sales or equivalent transactions in the Common Shares.

SECTION 11. TRANSFERS.

Subject to compliance with applicable US federal and state securities laws, this Agreement and all rights hereunder are transferable, in whole or in part, without charge to the holder hereof (except for transfer taxes) upon surrender of this Agreement properly endorsed. Each taker and holder of this Agreement, by taking or holding the same, consents and agrees that this Agreement, when endorsed in blank, shall be deemed negotiable, and that the holder hereof, when this Agreement shall have been so endorsed, shall be treated by the Company and all other persons dealing with this Agreement as the absolute owner hereof for any purpose and as the person entitled to exercise the rights represented notified to the Company by a notice of transfer in the form attached hereto as Exhibit III (the "Transfer Notice"), at its principal offices and the payment to the Company of all transfer taxes and other governmental charges imposed on such transfer. Until the Company receives such Transfer Notice, the Company may treat the initial owner hereof as the owner for all purposes. Notwithstanding anything herein or in any legend to the contrary, the Company shall not require an opinion of counsel in connection with any sale, assignment or other transfer by Warrantholder of this Warrant (or any portion hereof or any interest herein) or of any Common Shares issued upon any exercise hereof to an affiliate (as defined in Regulation D) of Warrantholder, provided that the restrictive legend will remain on such transferred Warrant, and provided further that such affiliate shall be, at the time of such sale, assignment or transfer, an "accredited investor" as defined in Regulation D and shall, at the Company's request, represent same to the Company in writing.

SECTION 12. MISCELLANEOUS.

(a) Effective Date. The provisions of this Agreement shall be construed and shall be given effect in all respects as if it had been executed and delivered by the Company on the date hereof. This Agreement shall be binding upon any successors or assigns of the Company.

(b) Remedies. In the event of any default hereunder, the non-defaulting party may proceed to protect and enforce its rights either by suit in equity and/or by action at law, including but not limited to an action for damages as a result of any such default, and/or an action for specific performance for any default where Warrantholder will not have an adequate remedy at law and where damages will not be readily ascertainable.

(c) No Impairment of Rights. The Company will not, by amendment of its Charter or through any other means, avoid or seek to avoid the observance or performance of any of the terms of this Agreement, but will at all times in good faith assist in the carrying out of all such terms and in the taking of all such actions as may be necessary or appropriate in order to protect the rights of the Warrantholder against impairment.

(d) Additional Documents. The Company agrees to supply such other documents as the Warrantholder may from time to time reasonably request.

(e) Attorneys' Fees. In any litigation, arbitration or court proceeding between the Company and the Warrantholder relating hereto, the prevailing party shall be entitled to reasonable attorneys' fees and expenses and all costs of proceedings incurred in enforcing this Agreement. For the purposes of this Section 12(e), reasonable attorneys' fees shall include without limitation fees incurred in connection with the following: (i) contempt proceedings; (ii) discovery; (iii) any motion, proceeding or other activity of any kind in connection with an insolvency proceeding; (iv) garnishment, levy, and debtor and third party examinations; and (v) post-judgment motions and proceedings of any kind, including without limitation any activity taken to collect or enforce any judgment.

(f) Severability. In the event any one or more of the provisions of this Agreement shall for any reason be held invalid, illegal or unenforceable, the remaining provisions of this Agreement shall be unimpaired, and the invalid, illegal or unenforceable provision shall be replaced by a mutually acceptable valid, legal and enforceable provision, which comes closest to the intention of the parties underlying the invalid, illegal or unenforceable provision.

(g) Notices. Except as otherwise provided herein, any notice, demand, request, consent, approval, declaration, service of process or other communication that is required, contemplated, or permitted under this Agreement or with respect to the subject matter hereof shall be in writing, and shall be deemed to have been validly served, given, delivered, and received upon the earlier of: (a) personal delivery to the party to be notified, (b) when sent by confirmed telex, electronic transmission or facsimile if sent during normal business hours of the recipient, if not, then on the next business day, (c) five days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt, and shall be addressed to the party to be notified as follows:

If to Warrantholder:

Hercules CAPITAL, INC.
Legal Department
Attention: Chief Legal Officer and Bryan Jadot
400 Hamilton Avenue, Suite 310
Palo Alto, CA 94301
Facsimile: 650-473-9194
Telephone: 650-289-3060

If to the Company:

Auris Medical Holding AG

Attention: General Counsel
Bahnhofstrasse 21
6300 Zug, Switzerland
Facsimile: +41 61 201 13 51
Telephone: +41 41 729 71 94
Email: rad@aurismedical.com

or to such other address as each party may designate for itself by like notice.

(h) Entire Agreement; Amendments. This Agreement constitutes the entire agreement and understanding of the parties hereto in respect of the subject matter hereof, and supersedes and replaces in their entirety any prior proposals, term sheets, letters, negotiations or other documents or agreements, whether written or oral, with respect to the subject matter hereof. None of the terms of this Agreement may be amended except by an instrument executed by each of the parties hereto.

(i) Headings. The various headings in this Agreement are inserted for convenience only and shall not affect the meaning or interpretation of this Agreement or any provisions hereof.

(j) Advice of Counsel. Each of the parties represents to each other party hereto that it has discussed (or had an opportunity to discuss) with its counsel this Agreement and, specifically, the provisions of Sections 12(n), 12(o) and 12(p).

(k) No Strict Construction. The parties hereto have participated jointly in the negotiation and drafting of this Agreement. In the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of the authorship of any provisions of this Agreement.

(l) No Waiver. No omission or delay by Warrantholder at any time to enforce any right or remedy reserved to it, or to require performance of any of the terms, covenants or provisions hereof by Warrantholder at any time designated, shall be a waiver of any such right or remedy to which Warrantholder is entitled, nor shall it in any way affect the right of Warrantholder to enforce such provisions thereafter during the term of this Agreement.

(m) Survival. All agreements, representations and warranties contained in this Agreement or in any document delivered pursuant hereto shall be for the benefit of Warrantholder and shall survive the execution and delivery of this Agreement and the expiration or other termination of this Agreement.

(n) Governing Law. This Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of New York, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction. For the avoidance of doubt, matters involving the rights of shareholders and the issuance of Common Shares shall be governed by the laws of Switzerland.

(o) Consent to Jurisdiction and Venue. All judicial proceedings arising in or under or related to this Agreement may be brought in any state or federal court of competent jurisdiction located in the State of New York. By execution and delivery of this Agreement, each party hereto generally and unconditionally: (a) consents to personal jurisdiction in New York County, State of New York; (b) waives any objection as to jurisdiction or venue in New York County, State of New York; (c) agrees not to assert any defense based on lack of jurisdiction or venue in the aforesaid courts; and (d) irrevocably agrees to be bound by any judgment rendered thereby in connection with this Agreement. Service of process on any party hereto in any action arising out of or relating to this Agreement shall be effective if given in accordance with the requirements for notice set forth in Section 12(g), and shall be deemed effective and received as set forth in Section 12(g). Nothing herein shall affect the right to serve process in any other manner permitted by law or shall limit the right of either party to bring proceedings in the courts of any other jurisdiction.

(p) Mutual Waiver of Jury Trial. Because disputes arising in connection with complex financial transactions are most quickly and economically resolved by an experienced and expert person and the parties wish applicable state and federal laws to apply (rather than arbitration rules), the parties desire that their disputes arising under or in connection with this Warrant be resolved by a judge applying such applicable laws. EACH OF THE COMPANY AND WARRANTHOLDER SPECIFICALLY WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY OF ANY CAUSE OF ACTION, CLAIM, CROSS-CLAIM, COUNTERCLAIM, THIRD PARTY CLAIM OR ANY OTHER CLAIM (COLLECTIVELY, "CLAIMS") ASSERTED BY THE COMPANY AGAINST WARRANTHOLDER OR ITS ASSIGNEE OR BY WARRANTHOLDER OR ITS ASSIGNEE AGAINST THE COMPANY RELATING TO THIS WARRANT. This waiver extends to all such Claims, including Claims that involve persons or entities other the Company and Warrantholder; Claims that arise out of or are in any way connected to the relationship between the Company and Warrantholder; and any Claims for damages, breach of contract, specific performance, or any equitable or legal relief of any kind, arising out of this Agreement.

(q) Counterparts. This Agreement and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts (including by facsimile or electronic delivery (PDF), and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument.

(r) Specific Performance. The parties hereto hereby declare that it is impossible to measure in money the damages which will accrue to Warrantholder by reason of the Company's failure to perform any of the obligations under this Agreement and agree that the terms of this Agreement shall be specifically enforceable by Warrantholder. If Warrantholder institutes any action or proceeding to specifically enforce the provisions hereof, any person against whom such action or proceeding is brought hereby waives the claim or defense therein that Warrantholder has an adequate remedy at law, and such person shall not offer in any such action or proceeding the claim or defense that such remedy at law exists.

(s) Lost, Stolen, Mutilated or Destroyed Warrant. If this Warrant is lost, stolen, mutilated or destroyed, the Company may, on such terms as to indemnity or otherwise as it may reasonably impose (which shall, in the case of a mutilated Warrant, include the surrender thereof), issue a new Warrant of like denomination and tenor as this Warrant so lost, stolen, mutilated or destroyed. Any such new Warrant shall constitute an original contractual obligation of the Company, whether or not the allegedly lost, stolen, mutilated or destroyed Warrant shall be at any time enforceable by anyone.

(t) Language. The official language of this Warrant and of all notices and other communications between the parties hereunder shall be English.

(u) Legends. To the extent required by applicable laws, this Warrant and the Common Shares issuable hereunder (and the securities issuable, directly or indirectly, upon conversion of such Common Shares, if any) may be imprinted with a restricted securities legend in substantially the following form:

> THIS SECURITY HAS NOT BEEN REGISTERED UNDER THE US SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), ANY US STATE SECURITIES LAWS, OR UNDER THE SECURITIES LAWS OF ANY OTHER JURISDICTION, AND MAY NOT BE SOLD, PLEDGED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION THEREOF UNDER SUCH ACT AND LAWS, OR PURSUANT TO RULE 144 AND/OR OTHER EXEMPTION FROM SUCH REGISTRATION REQUIREMENTS.

(v) Termination of Old Auris Warrant. This Warrant is issued in exchange for and replacement of the Old Auris Warrant. Effective upon the Warrantholder's receipt of this Warrant executed by the Company, the Old Auris Warrant shall automatically terminate and be of no further force or effect. Promptly following such receipt, the Warrantholder shall at its expense return the Old Auris Warrant to the Company for cancellation.

[Remainder of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the parties hereto have caused this Warrant Agreement to be executed by its officers thereunto duly authorized as of the Effective Date.

COMPANY: AURIS MEDICAL HOLDING AG

By:
Name:
Title:

WARRANTHOLDER: HERCULES CAPITAL, INC.

By:
Name:
Title:

EXHIBIT I

NOTICE OF EXERCISE

To: [_____]

(1) The undersigned Warrantholder hereby irrevocably elects to purchase [_____] Common Shares of a par value of CHF 0.02 each of [_____], pursuant to the terms of the Agreement dated the [___] day of [_____, _____] between Auris Medical Holding AG and the Warrantholder (the "Agreement") and by reference to article [_____] of the Charter, and tenders herewith payment of the aggregate Purchase Price of CHF [_____] in full, together with all applicable taxes and charges, if any.

(2) Please issue said Common Shares in the name of the undersigned or in such other name as is specified below and conform in writing to the undersigned such issuance.

(3) Capitalized terms used but not defined herein shall have the meaning ascribed to such term in the Agreement.

_____
(Name)

_____
(Address)

WARRANTHOLDER: HERCULES CAPITAL, INC.

By: _____
Name: _____
Title: _____

EXHIBIT II

1. **ACKNOWLEDGMENT OF EXERCISE**

The undersigned [_____], hereby acknowledge receipt of the "Notice of Exercise" from Hercules Capital, Inc. to purchase [____] Common Shares of [_____], pursuant to the terms of the Agreement, and further acknowledges that [_____] shares remain subject to purchase under the terms of the Agreement.

COMPANY: [_____]

By: _____

Title: _____

Date: _____

EXHIBIT III

TRANSFER NOTICE

(To transfer or assign the foregoing Agreement execute this form and supply required information. Do not use this form to purchase shares.)

FOR VALUE RECEIVED, the foregoing Agreement and all rights evidenced thereby are hereby transferred and assigned to

_____
(Please Print)

whose address is_____

_____

Dated: _____

Holder's Signature: _____

Holder's Address: _____

_____

Signature Guaranteed: _____

NOTE: The signature to this Transfer Notice must correspond with the name as it appears on the face of the Agreement, without alteration or enlargement or any change whatever. Officers of corporations and those acting in a fiduciary or other representative capacity should file proper evidence of authority to assign the foregoing Agreement.

EXECUTION VERSION

CONSENT AND WAIVER

This Consent and Waiver (this "Consent"), dated as of March 8, 2018 (the "Effective Date"), is entered into by and among (a) AURIS MEDICAL HOLDING AG, a company organized under the laws of Switzerland ("Borrower"), (b) the several banks and other financial institutions or entities party hereto as a lender (collectively, referred to as "Lender"), and (c) HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent for itself and Lender (in such capacity, the "Agent"). To the extent not otherwise defined herein, the capitalized terms used herein shall have the meanings assigned to them in the Loan Agreement (as defined below).

WITNESSETH:

WHEREAS, Borrower, Lender and the Agent are parties to a Loan and Security Agreement dated as of July 19, 2016 (the "Loan Agreement");

WHEREAS, Borrower has notified Lender and the Agent that Borrower intends to enter into a merger transaction whereby Borrower will merge with and into AURIS MEDICAL NEWCO HOLDING AG, a company organized under the laws of Switzerland ("NewCo") with NewCo surviving the merger (the "Merger"). The Merger is to be effectuated in accordance with Swiss law pursuant to the terms of a Merger Agreement dated February 9, 2018 by and between Borrower and NewCo in the form attached hereto as Exhibit A (the "Merger Agreement");

WHEREAS, Section 7.9 of the Loan Agreement prohibits the occurrence of the Merger. Borrower has requested that Lender and Agent consent to the occurrence of the Merger;

NOW, THEREFORE, in consideration of the mutual conditions and agreements set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged the parties hereto agree as follows:

1. **Consent**. In reliance upon the representations, warranties and covenants of Borrower herein, in the Loan Agreement and the other Loan Documents, and in the Merger Agreement, Lender and the Agent hereby consent to the consummation of the Merger in accordance with the terms of the Merger Agreement, and (ii) waive compliance by Borrower with the provisions of Section 7.9 of the Loan Agreement which would otherwise prohibit consummation of the Merger (and any Event of Default under Section 9.2 which would arise from such non-compliance). The foregoing consent and waiver is expressly subject to and conditioned on each of the following terms and conditions:

A. The Merger shall be consummated on or before March 31, 2018 (the "Closing") upon substantially the terms contained in the Merger Agreement and without any material amendment or modification thereto (it being agreed that any amendment or modification to the Merger Agreement which may be adverse to the interests of Lender or the Agent shall be deemed to be material) and in accordance with resolutions duly adopted by the Board of Directors of Borrower and NewCo and applicable law.

B. No Event of Default (other than any Event of Default waived herein) shall have occurred on or after the date hereof prior to the Closing of the Merger and no Event of Default (other than any Event of Default waived herein) shall exist immediately prior to, or after giving effect to, the Closing of the Merger.

C. No cash consideration shall be paid by Borrower in connection with the Merger.

D. The assets of NewCo acquired by means of the Merger shall be free and clear of any and all Liens (other than Liens that will be released simultaneously with the Closing of the Merger).

E. Borrower shall deliver to the Agent true and complete copies of the final Merger Agreement and all other documents, instruments and agreements executed in connection with the Merger promptly after the Closing of the Merger.

F. On or before the date that is 5 (five) business days after the consummation of the Merger, (a) NewCo shall execute and deliver to Hercules Capital, Inc., in its capacity as Lender (the "Warrantholder"), a Warrant Agreement (the "NewCo Warrant") substantially the form attached hereto as Exhibit B, in exchange for and replacement of that certain Warrant Agreement dated July 19, 2016, as amended, between the Warrantholder and Borrower (the "Borrower Warrant"), which NewCo Warrant shall be exercisable for such number of NewCo Common Shares as shall equal (i) US$617,500, divided by (ii) the Exercise Price (as defined in the NewCo Warrant and which shall initially equal US$39.40) and (b) Borrower shall deliver to the Agent, (i) evidence of the consummation of the Merger, (ii) such documents and instruments as the Agent deems necessary or advisable for NewCo to become a "Borrower" under the Loan Agreement and to grant to the Agent, for the benefit of Lender, a continuing Lien, pledge and security interest in and to the assets of NewCo, (iii) such other documents and instruments as the Agent deems necessary or advisable to grant to the Agent, for the benefit of Lender, a perfected first priority Lien, pledge and security interest in the Collateral described in the Loan Agreement (substantially as described in Section 3 of the Loan Agreement), (iv) any documents required by the Agent in order for the Agent and Lender to be capable of exercising their rights as a secured lender in respect of the assets of NewCo, (v) evidence that the assets of NewCo are insured in accordance with the requirements of the Loan Agreement, (vi) a secretary's certificate of NewCo, in a form reasonably satisfactory to the Agent, with appropriate insertions and attachments, and (vii) a legal opinion of Swiss counsel to the Agent relating to the matters described above, which opinion shall be in form and substance reasonably satisfactory to the Agent.

2. **Conditions to Effectiveness**. Lender, the Agent and Borrower agree that this Consent shall become effective upon the satisfaction of the following conditions precedent, each in form and substance satisfactory to Lender and the Agent:

(a) The Agent shall have received a fully-executed counterpart of this Consent signed by Borrower;

(b) The accuracy of Borrower's representations and warranties set forth in Section 3 below; and

(c) Lender and the Agent shall have received payment for all reasonable and documented out-of-pocket fees and expenses incurred by Lender and the Agent in connection with this Consent, including, but not limited to, all legal fees and expenses, payable pursuant to Section 11.11 of the Loan Agreement.

3. **Representations and Warranties**. Borrower hereby represents and warrants to Lender and the Agent as follows:

(a) Representations and Warranties in the Loan Agreement. The representations and warranties of Borrower set forth in Section 5 of the Loan Agreement are true and correct in all material respects on and as of the Effective Date with the same effect as though made on and as of such date, except to the extent such representations and warranties expressly relate to an earlier date in which case they shall be true and correct as of such earlier date; provided that for purposes of this Section 3(a), Schedule 5.9, Exhibit D and Exhibit E of the Loan Agreement are revised as set forth in Exhibit C hereto.

(b) Authority, Etc. The execution and delivery by Borrower of this Consent and the performance by Borrower of all of its agreements and obligations hereunder are within the corporate authority of Borrower and have been duly authorized by all necessary corporate action on the part of Borrower. With respect to Borrower, the execution and delivery by Borrower of this Consent does not and will not require any registration with, consent or approval of, or notice to any Person (including any governmental authority).

(c) Enforceability of Obligations. This Consent constitutes the legal, valid and binding obligation of Borrower enforceable against Borrower in accordance with its terms, except as enforceability is limited by bankruptcy, insolvency, reorganization, moratorium, general equitable principles or other laws relating to or affecting generally the enforcement of, creditors' rights and except to the extent that availability of the remedy of specific performance or injunctive relief is subject to the discretion of the court before which any proceeding therefor may be brought.

(d) No Default. Before and after giving effect to this Consent (i) no fact or condition exists that would (or would, with the passage of time, the giving of notice, or both) constitute an Event of Default (other than any Event of Default waived herein), and (ii) no event that has had or could reasonably be expected to have a Material Adverse Effect has occurred and is continuing.

(e) Event of Default. By its signature below, Borrower hereby agrees that it shall constitute an Event of Default if any representation or warranty made herein should be false or misleading in any material respect when made.

4. **Reaffirmations**. Borrower hereby confirms that all of the terms and conditions of the Loan Agreement and the other Loan Documents not waived herein remain in full force and effect. Nothing contained in this Consent shall in any way prejudice, impair or effect any rights or remedies of Lender or the Agent under the Loan Agreement and the other Loan Documents. Borrower hereby ratifies, confirms, and reaffirms all covenants contained in the Loan Agreement and the other Loan Documents.

5. **Miscellaneous.**

(a) This consent has been negotiated and delivered to the Agent and Lender in the State of California, and shall have been accepted by the Agent and Lender in the State of California. This Consent shall be governed by, and construed and enforced in accordance with, the laws of the State of California, excluding conflict of laws principles that would cause the application of laws of any other jurisdiction.

(b) The captions in this Consent are for convenience of reference only and shall not define or limit the provisions hereof.

(c) This Consent expresses the entire understanding of the parties with respect to the transactions contemplated hereby. No prior negotiations or discussions shall limit, modify, or otherwise affect the provisions hereof. This Consent is a Loan Document.

(d) Any determination that any provision of this Consent or any application hereof is invalid, illegal or unenforceable in any respect and in any instance shall not effect the validity, legality, or enforceability of such provision in any other instance, or the validity, legality or enforceability of any other provisions of this Consent.

(e) The parties hereto shall execute and deliver such additional documents to take such additional action as may be reasonably necessary or desirable to effectuate the provisions and purposes of this Consent.

(f) This Consent shall be binding upon and insure to the benefit of the parties hereto and their respective legal representatives, successors or assigns.

(g) The headings listed herein are for convenience only and do not constitute matters to be construed in interpreting this Consent.

(h) This Consent and any amendments, waivers, consents or supplements hereto may be executed in any number of counterparts, and by different parties hereto in separate counterparts, each of which when so delivered shall be deemed an original, but all of which counterparts shall constitute but one and the same instrument. The words “execution,” “signed,” “signature,” and words of like import this Consent or in any amendment or other modification hereof (including waivers and consents) shall be

deemed to include electronic signatures or the keeping of records in electronic form (including PDF), each of which shall be of the same legal effect, validity or enforceability as a manually executed signature or the use of a paper-based recordkeeping system, as the case may be, to the extent and as provided for in any applicable law, including the Federal Electronic Signatures in Global and National Commerce Act or any state laws based on the Uniform Electronic Transactions Act.

(i) No provisions of this Consent are intended, nor will be interpreted, to provide or create any third-party beneficiary rights or any other rights of any kind in any Person other than the Agent, Lender and Borrower and all provisions of this Consent will be personal and solely among the Agent, Lender and Borrower.

(j) The provisions of Section 11.10 of the Loan Agreement (Mutual Waiver of Jury Trial/Judicial Reference) are incorporated by reference into this Consent *mutatis mutandis*.

[Remainder of this page left intentionally blank]

IN WITNESS WHEREOF, Borrower, the Agent and Lender have duly executed and delivered this Consent as of the day and year first above written.

BORROWER:

AURIS MEDICAL HOLDING AG

By: /s/ Thomas Meyer

Name: Thomas Meyer

Its: Chairman & CEO

Accepted in Palo Alto, California:

AGENT:

HERCULES CAPITAL, INC.

By: /s/ Jennifer Choe

Name: Jennifer Choe

Its: Assistant General Counsel

LENDER:
HERCULES CAPITAL, INC.

By: /s/ Jennifer Choe

Name: Jennifer Choe

Its: Assistant General Counsel

JOINDER AGREEMENT

This Joinder Agreement (this "Joinder"), dated as of March 13, 2018 (the "Effective Date"), is entered into by and among (a) AURIS MEDICAL HOLDING AG, a company organized under the laws of Switzerland, as the surviving entity of the Merger defined below and the subsequent name change described below ("Newco"), (b) the several banks and other financial institutions or entities party hereto as a lender (collectively, referred to as "Lender"), and (c) HERCULES CAPITAL, INC., a Maryland corporation, in its capacity as administrative agent for itself and Lender (in such capacity, the "Agent"). To the extent not otherwise defined herein, the capitalized terms used herein shall have the meanings assigned to them in the Loan Agreement (as defined below).

WITNESSETH:

WHEREAS, AURIS MEDICAL HOLDING AG, a company organized under the laws of Switzerland, ("Original Borrower"), Lender and the Agent executed and delivered a Loan and Security Agreement dated as of July 19, 2016 (the "Loan Agreement"), which Loan Agreement remains in full force and effect;

WHEREAS, Newco has notified Lender and the Agent that (i) Original Borrower was a party to a merger transaction whereby Original Borrower merged with and into AURIS MEDICAL NEWCO HOLDING AG, a company organized under the laws of Switzerland ("MergerCo"), with MergerCo surviving the merger (the "Merger"), (ii) pursuant to the terms of the Merger, MergerCo assumed as a matter of law all of the assets and liabilities of Original Borrower, including all of Original Borrower's obligations under the Loan Agreement and the other Loan Documents, and (iii) upon the consummation of the Merger, MergerCo changed its name to "AURIS MEDICAL HOLDING AG". As a result of the foregoing Newco is the successor to all of the assets of Original Borrower and the obligor of all of the liabilities of Original Borrower, including all of Original Borrower's obligations under the Loan Agreement and the other Loan Documents.

AGREEMENT

NOW THEREFORE, parties hereto agree as follows:

1. The recitals set forth above are incorporated into and made part of this Joinder Agreement.

2. By signing this Joinder Agreement, Newco hereby (i) acknowledges and agrees that it is a party to the Loan Agreement and the other Loan Documents as "Borrower" thereunder with the same force and effect as if originally named therein as "Borrower" and, without limiting the generality of the foregoing, hereby expressly assumes all obligations and liabilities of "Borrower" under the Loan Agreement and the other Loan Documents, (ii) acknowledges and agrees that Newco is bound by the terms, conditions and covenants applicable to "Borrower" under the Loan Agreement and the other Loan Documents, (iii) acknowledges and agrees that the Loan Agreement and each of the other Loan Documents remain in full force and effect in accordance with their respective terms and ratifies and reaffirms each and every term, condition and covenant set forth in the Loan Agreement and the other Loan Documents, (iv) ratifies and reaffirms the security interests granted by Original Borrower to Agent pursuant to the Loan Agreement and the other Loan Documents and acknowledges and agrees that the assets of Newco remain subject to such security interests as security for the prompt and complete payment when due (whether on the

payment dates or otherwise) of all the Secured Obligations, and (v) without limiting the security interests described in the foregoing clause (iv), grants to the Agent, as security for the prompt and complete payment when due (whether on the payment dates or otherwise) of all the Secured Obligations, a security interest in all of Newco's Swiss Collateral, in each case whether now owned or hereafter acquired or in which the Newco now has or hereafter acquires an interest and wherever the same may be located.

3. Newco acknowledges that it benefits, both directly and indirectly, from the Loan Agreement and the other Loan Documents, and hereby waives, for itself and on behalf on any and all successors in interest (including without limitation any assignee for the benefit of creditors, receiver, bankruptcy trustee or itself as debtor-in-possession under any bankruptcy proceeding) to the fullest extent provided by law, any and all claims, rights or defenses to the enforcement of this Joinder Agreement on the basis that (a) it failed to receive adequate consideration for the execution and delivery of this Joinder Agreement or (b) its obligations under this Joinder Agreement are avoidable as a fraudulent conveyance.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK]

IN WITNESS WHEREOF, Newco, the Agent and Lender have duly executed and delivered this Joinder Agreement as of the day and year first above written.

NEWCO:

AURIS MEDICAL HOLDING AG

By: /s/ Thomas Meyer

Name: Thomas Meyer

Its: Chairman & CEO

Accepted in Palo Alto, California:

AGENT:

HERCULES CAPITAL, INC.

By: /s/ Jennifer Choe

Name: Jennifer Choe

Its: Assistant General Counsel

LENDER:
HERCULES CAPITAL, INC.

By: /s/ Jennifer Choe
Name: Jennifer Choe
Its: Assistant General Counsel

Share Transfer Agreement

dated as of 9 February 2018

by and between

Thomas Meyer (**TM**)
Birkenweg 6, 4528 Zuchwil, Switzerland

and

Auris Medical Holding AG (the **Company**)
Bahnhofstrasse 21, 6300 Zug, Switzerland

(TM and the Company each a **Party**, and together the **Parties**)

regarding

Merger Share Allocation

Preamble

A. TM is the founder, CEO and Chairman of the board of directors (the **Board**) of the Company.

B. The Company is a stock corporation under Swiss law in accordance with article 620 et seq. of the Swiss Code of Obligations (**CO**), with registered seat in Zug (identification no. CHE-108.297.413). The share capital of the Company amounts to CHF 24,469,555.60, divided into 61,173,889 fully paid-in registered shares with a nominal value of CHF 0.40 each (each an **Auris Share** and together the **Auris Shares**).

C. The Board plans to call a shareholders' meeting of the Company in which the shareholders are requested to approve a merger of the Company into Auris Medical NewCo Holding AG (**NewCo**), a stock corporation under Swiss law in accordance with article 620 et seq. CO, with registered seat in Zug (identification no. CHE-474.294.374), as set forth in a certain merger agreement between the Company and NewCo dated [9 February] 2018 (the **Merger Agreement**). The share capital of the NewCo amounts to CHF 122,347.76, divided into 6,117,388 fully paid-in registered shares with a nominal value of CHF 0.02 each (each a **New Auris Share** and together the **New Auris Shares**).

D. The Auris Shares are listed on the Nasdaq Capital Market (**Nasdaq**) under the ticker symbol "EARS". Immediately following consummation of the Merger Agreement, the New Auris Shares will be listed and traded on Nasdaq in accordance with the listing application and the applicable Nasdaq listing rules.

E. Under the Merger Agreement, each shareholder of the Company shall receive 1 New Auris Share with a nominal value of CHF 0.02 for 10 Auris Shares with a nominal value of CHF 0.40 each, corresponding to an exchange ratio of 10:1 (the **Share Consideration**). The Share Consideration shall not include any fractions of New Auris Shares. If, based on the exchange ratio, shareholders of the Company would be entitled to a fraction of a New Auris Share, they shall receive 1 New Auris Share for such fraction (the **Compensation for Fractions**).

F. For purposes of the Compensation for Fractions, TM considers providing the number of shares required in connection with the exchange to enable the allocation of a full number of New Auris Shares (such shares, the **Rounding Shares**), and to avoid allocation of fractions, as further set forth in this share transfer agreement (the **Agreement**).

Now, therefore, the Parties agree as follows:

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1. Offering and Transfer of Rounding Shares

(a) TM hereby commits towards the Company (and, as a consequence of the Merger, towards NewCo) to transfer, at no consideration, Rounding Shares to any person entitled to a fraction as part of the Merger. TM hereby understands and agrees that such eligibility is not limited to registered shareholders in the Company but also extends to beneficial owners who hold shares in the Company via a broker or other nominee.

(b) The record date to establish the relevant number of Rounding Shares shall be March 9 2018, 6pm ET.

(c) The exact number of Rounding Shares shall be confirmed by the Company and its agents, respectively, and communicated to TM immediately thereafter.

(d) The transfer of Rounding Shares shall be effected no later than the effective date of the Merger, i.e. on or around 12 March 2018.

(e) In view of such transfer of Rounding Shares, TM shall take any necessary actions and execute any documents necessary or advisable to effect such transfers and, for such purposes, hereby authorizes and empowers the Company to arrange for such transfers.

(f) TM acknowledges that that current figures/numbers relating to the share capital, the number of shares issued and the nominal value of the shares in NewCo remain subject to changes/adjustments to reflect possible increases in the Company's share capital as a result of any exercised options/warrants issued by the Company.

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2. Representation by TM

TM represents that he has valid legal title to the Rounding Shares, free from any third party rights. Except as expressly set forth herein, TM does not represent or warrant in any way as to the value of, or any other matter concerning the Rounding Shares transferred hereunder.

3. Condition

The transfer of any Rounding Shares shall be subject to the effectiveness of the Merger. Accordingly, no Rounding Shares shall be transferred to any party without the registration of the Merger in the commercial register, as evidenced in the excerpt of the day register (*Tagebuchauszug*) which shall be issued by the commercial register on or around 12 March 2018.

4. Consideration

TM shall receive no consideration or compensation for any Rounding Shares or any services by TM relating to the offering and transfer of such Rounding Shares.

5. Further Provisions

5.1. No Assignment

Neither Party shall assign or transfer this Agreement or any of its rights or obligations hereunder, in whole or in part, to any third party without the prior written consent of the other Party. Any (attempted) assignment or transfer in violation of this Section 5.1 shall be void.

5.2. Amendments and Waiver

This Agreement may only be modified or amended by a document signed by all Parties. Any waiver by a Party of any provision or of any rights under this

Agreement shall not be valid unless given in a document signed by such Party. Any changes to the provisions of this Section 5.2 shall also not be valid unless documented in writing.

5.3. Costs

The Company shall bear the costs in connection with the drafting, negotiation and the execution of this Agreement and the completion of the transactions contemplated in this Agreement. The Company shall indemnify TM from and against, and shall reimburse TM with respect to any taxes levied from TM, and any losses (other than those explicitly provided for in this Agreement), damages, or other liabilities of any kind incurred by TM, in connection with this Agreement or the transactions contemplated hereunder.

5.4. Severability

If any provision of this Agreement shall be held to be invalid, illegal or unenforceable for any reason, such invalidity, illegality or unenforceability shall not affect any of the other provisions of this Agreement. In such a case, the Parties shall negotiate and agree on a substitute provision that best reflects the intentions of the Parties with respect to the invalid, illegal or unenforceable provision, without being invalid, illegal or unenforceable.

5.5. Termination

This Agreement shall be automatically terminated if the Merger has not been effected by 31 March 2018.

5.6. Applicable Law and Jurisdiction

This Agreement shall be governed by and construed in accordance with the substantive laws of Switzerland (to the exclusion of the Vienna Convention on the International Sale of Goods dated 11 April 1980). Any dispute arising out or in

connection with this Merger Agreement shall be exclusively referred to the courts competent for the City of Zug, Switzerland.

[SIGNATURES ON NEXT PAGE]

Signatures

Auris Medical Holding AG

Zug, 9 February 2018

Ort, Datum /s/Thomas Meyer
Place, Date Chairman & Chief Executive Officer

Zug, 9 February 2018

Ort, Datum /s/Hernan Levett
Place, Date Chief Financial Officer

TM

Zug, 9 February 2018

Place, Date /s/Thomas Meyer

Exhibit 12.1

CERTIFICATION

I, Thomas Meyer, certify that:

1. I have reviewed this annual report on Form 20-F of Auris Medical Holding AG;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 22, 2018

/s/ Thomas Meyer

Thomas Meyer

Chief Executive Officer

Exhibit 12.2

CERTIFICATION

I, Hernan Levett, certify that:

1. I have reviewed this annual report on Form 20-F of Auris Medical Holding AG;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: March 22, 2018

/s/ Hernan Levett

Hernan Levett

Chief Financial Officer

Exhibit 13.1

CERTIFICATION

The certification set forth below is being submitted in connection with Auris Medical Holding AG's annual report on Form 20-F for the year ended December 31, 2017 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Thomas Meyer, the Chief Executive Officer of Auris Medical Holding AG, certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Auris Medical Holding AG.

Date: March 22, 2018

/s/ Thomas Meyer

Name: Thomas Meyer
Chief Executive Officer

Exhibit 13.2

CERTIFICATION

The certification set forth below is being submitted in connection with Auris Medical Holding AG's annual report on Form 20-F for the year ended December 31, 2017 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Hernan Levett, the Chief Financial Officer of Auris Medical Holding AG, certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Auris Medical Holding AG.

Date: March 22, 2018

/s/ Hernan Levett

Name: Hernan Levett

Chief Financial Officer