

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

**FORM 6-K**

**REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16  
OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934**

For the month of November, 2018

**Commission File Number: 001-36582**

**Auris Medical Holding AG**

(Exact name of registrant as specified in its charter)

**Bahnhofstrasse 21  
6300 Zug, Switzerland  
(Address of principal executive office)**

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F  Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Yes  No

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Yes  No

## **INCORPORATION BY REFERENCE**

Exhibits 99.1 and 99.2 to this Report on Form 6-K shall be deemed to be incorporated by reference into the registration statement on Form F-3 (Registration Number 333-228121) and the registration statement on Form S-8 (Registration Number 333-223855) of Auris Medical Holding AG and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

Exhibit 99.3 to this Report on Form 6-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act.

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**SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Auris Medical Holding AG**

By: /s/ Hernan Levett

Name: Hernan Levett

Title: Chief Financial Officer

Date: November 15, 2018

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## EXHIBIT INDEX

<b>Exhibit Number</b>	<b>Description</b>
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99.1	Unaudited Condensed Consolidated Interim Financial Statements
99.2	Management's Discussion and Analysis of Financial Condition and Results of Operations
99.3	Press Release dated November 15, 2018

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Unaudited Condensed Consolidated Interim Financial Statements as of September 30, 2018 and December 31, 2017 and for the Three and Nine Months Ended September 30, 2018 and 2017

Condensed Consolidated Interim Statement of Profit or Loss and Other Comprehensive Income or Loss  
Condensed Consolidated Interim Statement of Financial Position  
Condensed Consolidated Interim Statement of Changes in Equity  
Condensed Consolidated Interim Statement of Cash Flows  
Notes to the Condensed Consolidated Interim Financial Statements

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

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

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

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

**Condensed Consolidated Interim Statement of Financial Position (unaudited)**

As of September 30, 2018 and December 31, 2017 (in CHF)

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

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

**Condensed Consolidated Interim Statement of Changes in Equity (unaudited)**

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

**ATTRIBUTABLE TO OWNERS OF THE COMPANY**

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

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



**Condensed Consolidated Interim Statement of Cash Flows (unaudited)**  
For the Nine Months Ended September 30, 2018 and 2017 (in CHF)

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

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

## AURIS MEDICAL HOLDING AG

### Notes to the Condensed Consolidated Interim Financial Statements

As of September 30, 2018 and December 31, 2017 and for the Three and Nine Months Ended September 30, 2018 and 2017 (in CHF)

#### 1. Reporting entity

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

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

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

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

#### 2. Basis of preparation

##### *Statement of compliance*

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

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

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

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

##### *Functional and reporting currency*

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

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### Considering reorganization / Merger

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

### Related Party Transaction

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

### Significant accounting policies

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

### New standards, amendments and interpretations adopted by the Group

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

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

### Asset Purchase

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

## 3. Taxation

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

	NINE MONTHS ENDED	
	SEPTEMBER 30, 2018	SEPTEMBER 30, 2017
Deferred income tax expense	—	—
Deferred income tax gain	26,179	24,573
<b>Total income tax gain</b>	<b>26,179</b>	<b>24,573</b>

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

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

#### 4. Loan and Warrant

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

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

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

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

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

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

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

#### 5. Capital and reserves

##### *Share capital*

The issued share capital of the Company consisted of:

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

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

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

#### *Equity Offerings*

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

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

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

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

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

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

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

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

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

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

#### *Issue of common shares upon exercise of options*

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

#### *Controlled Equity Offering*

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

## 6. Employee benefits

	<b>NINE MONTHS ENDED</b>	
	<b>SEPTEMBER 30,</b>	<b>SEPTEMBER 30,</b>
	<b>2018</b>	<b>2017</b>
Salaries	2,119,880	2,971,707
Pension costs	302,748	277,554
Share based compensation expense	108,399	259,561
Other employee costs and social benefits	91,225	251,000
<b>Total employee benefits</b>	<b>2,622,252</b>	<b>3,759,822</b>

## 7. Share based payments

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

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

## 8. Loss per share

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

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

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

## 9. Events after the Reporting Period

Subsequent to September 30, 2018, certain holders of Series A warrant issued in the July 2018 Registered Offering exercised their warrant shares to purchase 2,904,518 common shares of the Company for a total amount of CHF 1,132,762 and certain holders of Series B warrant issued in the July 2018 Registered Offering exercised warrant shares to purchase 2,864,422 common shares for a total amount of CHF 1,117,125.

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

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

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

This management's discussion and analysis is designed to provide you with a narrative explanation of our financial condition and results of operations. We recommend that you read this in conjunction with our unaudited condensed consolidated interim financial statements as of and for the three and nine months ended September 30, 2018 and 2017 included as Exhibit 99.1 to this Report on Form 6-K, which have been prepared in accordance with International Accounting Standard ("IAS") 34, *Interim Financial Reporting*. We also recommend that you read our management's discussion and analysis and our audited consolidated financial statements and the notes thereto, which appear in our Annual Report on Form 20-F for the year ended December 31, 2017 (the "Annual Report") filed with the U.S. Securities and Exchange Commission (the "SEC") pursuant to the U.S. Securities and Exchange Act of 1934, as amended.

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 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."

Unless otherwise indicated or the context otherwise requires, all references to "Auris Medical Holding AG" or "Auris," the "Company," "we," "our," "ours," "us" or similar terms refer to Auris Medical Holding 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 discussion and analysis are property of their respective owners.

Unless indicated or the context otherwise requires, all references in this Report on Form 6-K 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.

We prepare and report our consolidated financial statements and financial information in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board (the "IASB"). None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"). We maintain our books and records in Swiss Francs. We have made rounding adjustments to some of the figures included in this management's discussion and analysis. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that precede them. Unless otherwise indicated, all references to currency amounts in this discussion and analysis are in Swiss Francs.

This discussion and analysis is dated as of November 15, 2018.

### Overview

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

### Recent Developments

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

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



The randomized double blind placebo controlled Phase 1 trial with dose escalation enrolled a total of 72 healthy volunteers. One group of study participants received a single dose of intranasal betahistine or placebo and, following a wash-out period, three doses daily for three days. Single doses were escalated up to 60 mg, and repeated doses up to 40 mg. For the latter, the maximum tolerated dose based on local tolerability was determined at 40 mg. The other group of study participants received oral betahistine or placebo for reference. Pharmacokinetic parameters in blood plasma were determined for betahistine and its metabolites, and relative bioavailability for intranasal betahistine was calculated compared to oral betahistine 48 mg, which is the maximum approved daily dose as marketed world-wide (ex US). The Company plans to initiate two randomized double blind placebo controlled proof-of-concept studies with intranasal betahistine (AM-125 and AM-201) in the first quarter of 2019. In the planned Phase 2 clinical trial with AM-125 (“TRIVERS”), the Company will enroll patients suffering from acute vertigo following vestibular schwannoma resection. In the next step for the AM-201 program, the Company will conduct a Phase 1 pharmacokinetic/pharmacodynamic study in healthy volunteers to evaluate intranasal betahistine in the prevention of olanzapine-induced weight gain.

#### *Launch of Project AM-201*

On May 15, 2018, we announced the expansion of our intranasal betahistine development program beyond the treatment of vertigo into mental health supportive care indications. Under project code AM-201 we intend to develop intranasal betahistine for the treatment of weight gain and drowsiness (somnia), which are major side effects of many antipsychotic drugs. As we focus on advancing our AM-125 and AM-201 programs with intranasal betahistine, we announced at the same time that we plan to move forward with our late-stage programs AM-111 for the treatment of acute inner ear hearing loss and AM-101 for the treatment of acute inner ear tinnitus through strategic partnering and with non-dilutive funding.

#### *Scientific Advice from EMA on Development Plan and Regulatory Pathway for AM-111*

On May 7, 2018, we announced that we had received positive Scientific Advice from the Committee for Medicinal Products for Human Use (“CHMP”) of the European Medicines Agency (“EMA”) related to the development plan and regulatory pathway for AM-111. The Scientific Advice (Protocol Assistance) had been requested by us following the results of the HEALOS phase 3 trial. The EMA reviewed our proposed concept for a single pivotal trial with AM-111 0.4 mg/mL in patients suffering from acute profound hearing loss, which builds to a large extent on the design and outcomes from HEALOS. The EMA endorsed the proposed trial design, choice of efficacy and safety endpoints, as well as the statistical methodology. In addition, the EMA provided important guidance on the regulatory path forward and the maintenance of AM-111’s orphan drug designation.

On August 30, 2018, we announced that we received feedback from a Type C meeting with the U.S. Food and Drug Administration (“FDA”) related to the development plan and regulatory pathway for AM-111. The FDA reviewed the Company’s proposed concept for a placebo-controlled pivotal trial with AM-111 0.4 mg/mL in patients suffering from acute profound hearing loss. The trial protocol builds to a large extent on the design and outcomes from HEALOS and also incorporates specific feedback provided by the EMA. In a written response the FDA endorsed the proposed choice of primary and secondary efficacy endpoints, the safety endpoints, as well as the planned sample size and statistical methodology. In addition, the FDA provided important guidance on the regulatory path forward.

#### *Partnering of AM-111*

In early November 2018 we engaged JSB Partners LP, with offices in Boston, Munich and Zug, to identify potential partners for our AM-111 program and to support us in negotiating potential partnering agreements.

#### *Nasdaq Listing Requirements*

On July 31, 2018, we received a letter from the Listings Qualifications Department of The Nasdaq Capital Market (“Nasdaq”) notifying us that our minimum bid price per share of our common shares was below \$1.00 for a period of 30 consecutive business days as required by Nasdaq’s continued listing requirements. We have a compliance period of 180 calendar days, or until January 28, 2019 (the “Compliance Period”), to regain compliance with Nasdaq’s minimum bid price requirement. In the event we do not regain compliance by January 28, 2019, we may be eligible for an additional 180 calendar day grace period. We intend to actively monitor our closing bid price for our common shares between now and January 28, 2019 and intend to take any reasonable actions to resolve our noncompliance with the minimum bid price requirement as may be necessary.

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.

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### *LPC Purchase Agreement*

On May 2, 2018 we entered into a purchase agreement (the “2018 Commitment Purchase Agreement”) and a Registration Rights Agreement (the “2018 Registration Rights Agreement”) with Lincoln Park Capital Fund, LLC (“LPC”). Pursuant to the Commitment Purchase Agreement, LPC agreed to purchase common shares for up to \$10,000,000 over the 30-month term of the 2018 Commitment Purchase Agreement. The 2018 Commitment Purchase Agreement replaces a purchase agreement we entered into with LPC on October 10, 2017 (the “2017 Commitment Purchase Agreement”) which was terminated as a result of the Merger.

As of November 15, 2018, we have issued an aggregate of 750,000 common shares for aggregate proceeds of \$488,075 to LPC under the 2018 Commitment Purchase Agreement.

### *Offering of Common Shares and Warrants*

On January 26, 2018, we issued and sold 12,499,999 of our common shares. The common shares were offered pursuant to our effective shelf registration statement on Form F-3, which was initially filed with the Securities and Exchange Commission on September 1, 2015 and declared effective on September 10, 2015 (File No. 333-206710). We refer to such offering of common shares as the “January 2018 Registered Offering.”

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

### *Amendment of Hercules Loan and Security Agreement*

On April 5, 2018, we entered into an agreement with Hercules Capital, Inc. (“Hercules”) whereby the terms of our Loan and Security Agreement (the “Loan and Security Agreement”) with Hercules were amended to eliminate the \$5 million liquidity covenant in exchange for a repayment of \$5 million principal amount outstanding under the Loan and Security Agreement. As of September 30, 2018, the amount outstanding under the Loan and Security Agreement was CHF 2,144,235.

### *Capital Increase*

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

Since the July 2018 Registered Offering, certain Series A warrant holders exercised their warrant shares to purchase 2,904,518 common shares of the Company and certain Series B warrant holders exercised warrant shares to purchase 2,864,422 common shares. As of November 15, 2018, our issued fully paid-in share capital consists of CHF 611,700.90, divided into 30,585,045 common shares with a nominal value of CHF 0.02 each and no preferred shares.

### **Collaboration and License Agreements**

There have been no material changes to our collaboration and license agreements from those reported in “Item 5—Operating and Financial Review and Prospects—Operating results—Collaboration and License Agreements” in the Annual Report.

### **Research and Development Expense**

Our research and development expense is highly dependent on the development phases of our research projects and therefore may fluctuate substantially from period to period. Our research and development expense mainly relates to the following key programs:

- *Keyzilen*<sup>®</sup> (AM-101). We conducted a Phase 3 clinical development program with *Keyzilen*<sup>®</sup> comprising two
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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 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. We anticipate that our research and development expenses in connection with the Keyzilen<sup>®</sup> trials will be lower in 2018 than in 2017, reflecting the completion of these 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 meaningful and nominally significant improvement in the AM-111 0.4 mg/mL treatment group. We terminated the ASSENT trial as it was very similar in design to the HEALOS trial and, based on the new findings, was no longer adequate for testing AM-111. We received feedback from the EMA regarding the design of a future Phase 3 trial and on the regulatory path forward and have requested regulatory feedback also from the FDA. We expect that our research and development expenses in connection with the AM-111 trials will be lower in 2018 than in 2017, reflecting the completion of these trials.
- *AM-125*. In the first quarter of 2018, we initiated a second Phase 1 trial in healthy volunteers to further test the safety and tolerability and the pharmacokinetics of AM-125. On October 17, 2018 we announced positive results from the second Phase 1 trial evaluating intranasal betahistine in healthy volunteers, please see “Recent Developments— Positive Results From Second Phase 1 Clinical Trial With Intranasal Betahistine (AM-125)” in this discussion and analysis for details. We plan to conduct a Phase 2 clinical study with AM-125 in the first quarter of 2019, which will result in higher research and development expense. The “TRAVERS” Phase 2 trial will enroll 138 patients suffering from acute vertigo following surgical removal of a vestibular schwannoma, a tumor growing behind the inner ear. It will be conducted in several European countries and potentially, Canada. The TRAVERS trial is expected to start recruitment during the first quarter of 2019 and will have two parts. In Part A, five ascending doses of AM-125 or placebo, administered three times daily over a total of four weeks, will be tested in a total of 50 patients. In addition, oral betahistine 48 mg will be tested in 16 patients under open-label conditions for reference. Based on an interim analysis, two doses will be selected and tested in an estimated 72 patients in Part B.
- *AM-201*. We plan to conduct a Phase I clinical study with AM-201 in the first quarter of 2019, which will result in higher research and development expense. The trial will be conducted in a European country and enroll 50 healthy volunteers who will receive either AM-201 or placebo concomitantly with olanzapine over four weeks. Doses will be escalated in five steps, as in the TRAVERS trial. The trial is expected to start recruitment during the first quarter of 2019.

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 synthesis of the pre-clinical compounds and costs paid to academic and other research institutions in conjunction with pre-clinical testing.

For a discussion of our other key financial statement line items, please see “Item 5—Operating and Financial Review and Prospects—Operating results—Financial Operations Overview” in the Annual Report.

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## Results of Operations

The numbers below have been derived from our unaudited condensed consolidated interim financial statements as of and for the three and nine months ended September 30, 2018 and 2017. The discussion below should be read along with this financial information, and it is qualified in its entirety by reference to them.

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

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

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

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

Research and development expense

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

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

- *Clinical projects.* In the three months ended September, 2018 clinical expenses were lower than in the three months ended September 30, 2017 by CHF 1.9 million due to lower service and milestone costs for our Keyzilen<sup>®</sup> and AM-111 studies, mainly reflecting the completion of our late-stage clinical trials.
- *Pre-clinical projects.* In the three months ended September, 2018, pre-clinical expenses increased by CHF 0.2 million compared to the three months ended September, 2017, primarily due to higher expenses in our AM-125 program.
- *Drug manufacture and substance.* In the three months ended September 30, 2018, drug manufacture and substance related costs decreased by CHF 0.7 million compared to the three months ended September 30, 2017, due to lower AM-111 project activities.

- *Employee benefits.* Employee expenses decreased by CHF 0.4 million in the three months ended September 30, 2018 compared to the same period in 2017 primarily due to a reduction in headcount.
- *Other research and development expenses.* Other research and development expenses increased by CHF 0.2 million in the three months ended September 30, 2018 compared to the same period in 2017 primarily due to intellectual property related activities.

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

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

- *Clinical projects.* In the nine months ended September, 2018 clinical expenses were lower than in the nine months ended September 30, 2017 by CHF 7.1 million due to lower service and milestone costs for our Keyzilen<sup>®</sup> and AM-111 studies, mainly reflecting the completion of our late-stage clinical trials.
- *Pre-clinical projects.* In the nine months ended September 30, 2018, pre-clinical expenses increased by CHF 0.3 million compared to the nine months ended September 30, 2017, primarily due to activities related to our AM-125 and AM-201 program.
- *Drug manufacture and substance.* In the nine months ended September 30, 2018, drug manufacture and substance related costs decreased by CHF 0.6 million compared to the nine months ended September 30, 2017, due to lower activities related to our AM-101 and AM-111 project activities.
- *Employee benefits.* Employee expenses decreased by CHF 0.8 million in the nine months ended September 30, 2018 compared to the same period in 2017 primarily due to a reduction in headcount.
- *Other research and development expenses.* Other research and development expenses decreased by 54 thousand in the nine months ended September 30, 2018 compared to the same period in 2017 primarily due to a reduction in regulatory related activities.

## General and administrative expense

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

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

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

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

### *Interest income*

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

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

### *Interest expense*

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

Interest expense decreased in the nine months ended September 30, 2018 compared to the same prior year period by CHF 0.3 million. The decrease relates to a reduction in the outstanding balance of the loan under the Loan and Security Agreement, as we commenced repayment of the loan facility in July 2017. Following the modification of the loan to repay \$5 million, a loss of CHF 334,747 was recognized in connection with the modification of the loan and transaction costs. This loss is presented in the line interest expense in the condensed consolidated interim statement of profit or loss and other comprehensive income or loss.

#### *Foreign currency exchange gain / (loss), net*

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

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

#### *Revaluation gain / (loss) from derivative financial instruments*

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

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

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

On July 17, 2018 we issued 6,282,050 Series A warrants and 4,487,179 Series B warrants in connection with the July 2018 Registered Offering of 17,948,717 common shares, each warrant entitling its holder to purchase one common share at an exercise price of CHF0.39 per common share. As of September 30, 2018 the fair value of the warrants amounted CHF 872,217. Since its initial recognition, the fair value of the warrants has decreased by CHF 24,224, resulting in a gain in the corresponding amount (fair value as of July 17, 2018: CHF 896,441).

#### *Transaction costs*

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

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

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## Cash flows

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

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

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

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

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

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

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

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

## Cash and funding sources

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

On May 2, 2018 we entered into the 2018 Commitment Purchase Agreement and the 2018 Registration Rights Agreement with Lincoln Park Capital Fund, LLC ("LPC"). Pursuant to the 2018 Commitment Purchase Agreement, LPC agreed to purchase common shares for up to \$10,000,000 over the 30-month term of the 2018 Commitment Purchase Agreement. As of November 15, 2018, we have issued an aggregate of 750,000 common shares for aggregate proceeds of \$488,075 to LPC under the 2018 Commitment Purchase Agreement. The 2018 Commitment Purchase Agreement

replaced a prior Commitment Purchase Agreement with LPC (the “2017 Commitment Purchase Agreement”), which was terminated as a result of the Merger. Under the 2017 Commitment Purchase Agreement, LPC agreed to subscribe for up to \$13,500,000 of our common shares and prior to its termination, we had issued an aggregate of 2,600,000 common shares for aggregate proceeds of \$1.8 million to LPC under the 2017 Commitment Purchase Agreement.

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

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

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

On July 19, 2016 the Company entered into a Loan and Security Agreement with Hercules for a secured term loan facility of up to \$20.0 million. An initial tranche of \$12.5 million was drawn on July 19, 2016, concurrently with the execution of the loan agreement. The loan matures on January 2, 2020 and bears interest at a minimum rate of 9.55% per annum, and is subject to the variability of the prime interest rate. The loan is secured by a pledge of the shares of Auris Medical AG owned by 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 \$39.40 per common share. On April 5, 2018 we entered into an agreement with Hercules whereby the terms of the Loan and Security Agreement were amended to eliminate the \$5 million liquidity covenant in exchange for a repayment of \$5 million principal amount outstanding under the Loan and Security Agreement.

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

#### **Funding requirements**

We expect that our operating expenses for 2018 will be in the range of CHF 10.0 to CHF 12.9 million and that the existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the second quarter of 2019. In addition, we anticipate that the issuance of our common shares under the LPC Purchase Agreement will enable the Company to further fund its operations and capital requirements. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including but not limited to:

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

We expect that we will require additional funding to continue our ongoing clinical development activities and seek to obtain regulatory approval for, and commercialize, our product candidates. If we receive regulatory approval for any of our product candidates, and if we choose not to grant any licenses to partners, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. If we are not

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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—Risk factors” in the Annual Report.

### Contractual Obligations and Commitments

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

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

- (1) Operating lease obligations consist of payments pursuant to operating lease agreements relating to leases of our office space and are not accounted for on the balance sheet. The lease term is indefinite and can be terminated with a six month notice period.
- (2) Long-term debt obligations consist of amortization payments and the end of term fee due under the Loan and Security Agreement converted to CHF at an exchange rate of CHF 0.9847 to US\$1.00. The secured term loan under the Loan and Security Agreement has a maturity date of January 2, 2020, with an interest-only period through July 1, 2017, and amortized payments of principal and interest thereafter in equal monthly instalments until the maturity date. The loan bears interest at a minimum rate of 9.55% per annum, and is subject to the variability of the prime interest rate. Interest payments are not included in the table presented above.
- (3) Derivative Financial instruments relate to the warrants issued in connection with the Loan and Security Agreement and the warrants issued in the public offering in February 2017, direct placement in January 2018 and the July 2018 Registered Offering

Under the terms of our collaboration and license agreement with Xigen, we are obliged to make development milestone payments on an indication-by-indication basis of up to CHF 1.5 million upon the successful completion of a Phase 2 clinical trial and regulatory milestone payments on a product-by-product basis of up to CHF 2.5 million, subject to a mid-twenties percentage reduction for smaller indications, e.g., those qualifying for orphan drug status, upon receiving marketing approval for a product. The milestones are not included in the table above as they have not met the recognition criteria for provisions and the timing of these is not yet determinable as it is dependent upon the achievement of earlier mentioned milestones.

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

### Off-Balance Sheet Arrangements

As of the date of this discussion and analysis, we do not have any, and during the periods presented we did not have any, off-balance sheet arrangements except for the Operating Lease mentioned in “Item 5—Operating and Financial Review and Prospects—Tabular disclosure of contractual obligations” in the Annual Report.

### Significant Accounting Policies and Use of Estimates and Judgment

There have been no material changes to the significant accounting policies and estimates described in “Item 5—Operating and Financial Review and Prospects—Operating results—Significant accounting policies and use of estimates and judgment” in the Annual Report.

## Recent Accounting Pronouncements

There are no IFRS standards as issued by the IASB or interpretations issued by the IFRS interpretations committee that are effective for the first time for the financial year beginning on or after January 1, 2018 that had a material impact on our financial position and performance.

## JOBS Act Exemption

On April 5, 2012, the JOBS Act was signed into law. The JOBS Act contains provisions that, among other things, reduce certain reporting requirements for an “emerging growth company”. As an emerging growth company, we are not required to provide an auditor attestation report on our system of internal controls over financial reporting. This exemption will apply for a period of five years following the completion of our initial public offering (2019) or until we no longer meet the requirements of being an “emerging growth company,” whichever is earlier. We would cease to be an emerging growth company if we have more than US\$1.07 billion in annual revenue, have more than US\$700 million in market value of our common shares held by non-affiliates or issue more than US\$1.0 billion of non-convertible debt over a three-year period.

## Cautionary Statement Regarding Forward Looking Statements

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

- our operation as a development-stage company with limited operating history and a history of operating losses;
  - our need for substantial additional funding to continue the development of our product candidates before we can expect to become profitable from sales of our products and the possibility that we may be unable to raise additional capital when needed;
  - the outcome of our review of strategic options and of any action that we may pursue as a result of such review;
  - our dependence on the success of AM-125, AM-201, Keyzilen® (AM-101) and AM-111, which are still in clinical development and may eventually prove to be unsuccessful;
  - the chance that we may become exposed to costly and damaging liability claims resulting from the testing of our product candidates in the clinic or in the commercial stage;
  - the chance our clinical trials may not be completed on schedule, or at all, as a result of factors such as delayed enrollment or the identification of adverse effects;
  - uncertainty surrounding whether any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized;
  - if our product candidates obtain regulatory approval, our product candidates being subject to expensive, ongoing obligations and continued regulatory oversight;
  - 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;
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- 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 set forth in our most recent Annual Report on Form 20-F.

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.

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## Auris Medical Reports Third Quarter 2018 Financial Results and Provides Business Update

- Positive outcomes from second Phase 1 trial with intranasal betahistine
- Further evidence for betahistine's preventive effects in antipsychotic-induced weight gain
- Progressing intranasal betahistine program towards proof-of-concept studies
- Partnering process initiated for AM-111 program
- Sonsuvi® accepted as brand name for AM-111

Zug, Switzerland, November 15, 2018 – Auris Medical Holding AG (NASDAQ: EARS), a clinical-stage company dedicated to developing therapeutics that address important unmet medical needs in neurotology, today announced financial results for the third quarter ended September 30, 2018 and provided a business update.

“We have continued to make great progress with our intranasal betahistine program and recently reached a major milestone as the second Phase 1 clinical trial showed exciting results“, stated Thomas Meyer, Auris Medical's founder, Chairman and CEO. “These positive outcomes include the confirmation of superior bioavailability provided by the intranasal delivery route over the currently used oral administration route, which is the cornerstone of the program. In addition, the trial confirmed that intranasal betahistine is safe and well tolerated even when taken in multiple doses. We look forward to taking our next key development steps with this program, that is the start of our planned proof-of-concept studies in acute vertigo and olanzapine-induced weight gain.”

### Development Program Updates

#### *Intranasal betahistine program*

- Announced results from second Phase 1 clinical trial in healthy volunteers. The randomized double blind placebo controlled trial with dose escalation enrolled a total of 72 subjects. One group of study participants received a single dose of intranasal betahistine or placebo and, following a wash-out period, three doses daily for three days. Single doses were escalated up to 60 mg, and repeated doses up to 40 mg. The study demonstrated superior bioavailability over a range of four intranasal betahistine doses compared to the approved total daily dose for oral betahistine (48 mg); plasma exposure was 6 to 29 times higher (p-value between 0.056 and  $p < 0.0001$ ). Further, it confirmed the good safety profile of intranasal betahistine and showed that the treatment was well tolerated when administered three times daily for three days. The maximum tolerated dose for multiple dosing was determined at 40 mg.

#### *AM-125 for Vertigo*

- Progressed with preparations for Phase 2 trial with AM-125 in acute vertigo. The “TRAVERS” Phase 2 trial will enroll 138 patients suffering from acute vertigo following surgical removal of a vestibular schwannoma, a tumor growing behind the inner ear. It will be conducted in several European countries and potentially, Canada. The TRAVERS trial is expected to start recruitment during the first quarter of 2019 and will have two parts. In Part A, five ascending doses of AM-125 or placebo, administered three times daily over a total of four weeks, will be tested in a total of 50 patients. In addition, oral betahistine 48 mg will be tested in 16 patients under open-label conditions for reference. Based on an interim analysis, two doses will be selected and tested in an estimated 72 patients in Part B.
- Obtained scientific advice from the European Medicines Agency (EMA). The Company received feedback from the EMA on the development plan for AM-125 and in particular the planned Phase 2 clinical trial in acute vertigo. The Agency endorsed the use of the vestibular schwannoma resection model for demonstrating proof of concept with intranasal betahistine in the treatment of acute vertigo.

#### *AM-201 for Antipsychotic-Induced Weight Gain*

- Progressed with preparations for a pharmacokinetic/pharmacodynamic trial with AM-201 in antipsychotic-induced weight gain. The trial will be conducted in a European country and enroll 50 healthy volunteers who will receive either AM-201 or placebo concomitantly with olanzapine over four weeks. Doses will be escalated in five steps, as in the TRAVERS trial. The trial is expected to start recruitment during the first quarter of 2019.

- Further evidence for betahistine’s preventive effects in antipsychotic-induced weight gain. The body of clinical data demonstrating betahistine’s capacity to counteract weight gain induced by antipsychotic drugs was recently further expanded through a publication by Smith and colleagues.<sup>1</sup> The authors conducted a study with oral betahistine 36-48 mg/day or placebo administered over 12 weeks to adolescents and adults who received at the same time various antipsychotic drugs. They found that in the sub-group of patients being treated with olanzapine or clozapine (n=26), betahistine was significantly better than placebo in preventing increases in weight (3.1 kg less weight gain than placebo), body mass index, and waist circumference.

#### *AM-111 for Acute Inner Ear Hearing Loss*

- Obtained FDA guidance on AM-111 development program. The Company was granted a type C meeting with the FDA to discuss the development and regulatory path forward with AM-111. In a written response the FDA endorsed the proposed choice of primary and secondary efficacy endpoints, the safety endpoints, as well as the planned sample size and statistical methodology. In addition, the FDA provided important guidance on the regulatory path forward. The Company had previously obtained scientific advice (protocol assistance) from the EMA, which included endorsement of the proposed design for a single pivotal trial with AM-111 0.4 mg/mL in patients suffering from acute profound hearing loss.
- Sonsuvi<sup>®</sup> accepted as brand name for AM-111. Sonsuvi<sup>®</sup>, the proposed proprietary name for AM-111, has been conditionally approved by the FDA as well as the EMA, subject to final review at the time of marketing approval. The brand name is pronounced as “son-SUE-vee” and has been registered as trademark in various countries.
- Initiated partnering process for AM-111. As previously announced, the Company decided to refocus its development activities on the intranasal betahistine program and to seek partners or other sources of non-dilutive funding for its late-stage development programs. In this context, the Company has mandated JSB Partners, an international transaction advisory firm, to identify potential partners for the AM-111 development program and provide support for partnering discussions and negotiations.

#### **Third Quarter 2018 Financial Results**

- Cash and cash equivalents at September 30, 2018 totaled CHF 5.3 million.
- Total operating expenses for the third quarter of 2018 were CHF 2.9 million compared to CHF 6.0 million for the third quarter of 2017.
- Research and development expenses for the third quarter of 2018 were CHF 1.7 million compared to CHF 4.2 million for the third quarter of 2017.
- General and administrative expenses for the third quarter of 2018 were CHF 1.2 million compared to CHF 1.3 million for the third quarter of 2017.
- Net loss for the third quarter of 2018 was CHF 3.0 million, or CHF 0.14 per share, compared to CHF 6.0 million, or CHF 1.36 per share, for the third quarter of 2017.
- The Company continues to expect that its operating expenses in 2018 will be in the range of CHF 10 to 12.9 million.
- Since the closing of the third quarter, exercises of warrants from the July 2018 offering as well as the sale of shares under the equity line with LPC have increased shareholders’ equity by approximately CHF 2.7 million.

#### **Conference Call & Webcast Information**

Auris Medical will host a conference call and webcast to present the third quarter 2018 financial results and to provide a business update today, November 15, 2018, at 8:00 am Eastern Time (2:00 pm Central European Time). To participate in this conference call, dial 1-877-407-0312 (toll free) or +1 201-389-0899 (International), and enter passcode 13685071. A live webcast of the conference call will

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<sup>1</sup> Smith RC et al. (2018). Betahistine effects on weight-related measures in patients treated with antipsychotic medications: a double-blind placebo-controlled study. *Psychopharmacology (Berl)*, in press.

be available in the Investor Relations section of the Auris Medical website at [www.aurismedical.com](http://www.aurismedical.com) and a replay of the conference call will be available approximately two hours following the live call.

## **About Auris Medical**

Auris Medical is a Swiss biopharmaceutical company dedicated to developing therapeutics that address important unmet medical needs in neurotology and mental health supportive care. The company is focused on the development of intranasal betahistine for the treatment of vertigo (AM-125) and for the treatment of antipsychotic-induced weight gain and somnolence (AM-201). These projects have gone through two Phase 1 trials and will move into proof-of-concept studies in 2019. In addition Auris Medical has two Phase 3 programs under development: Sonsuvi® (AM-111) for acute inner ear hearing loss and Keyzilen® (AM-101) for acute inner ear tinnitus. The Company was founded in 2003 and is headquartered in Zug, Switzerland. The shares of Auris Medical Holding AG trade on the NASDAQ Capital Market under the symbol "EARS."

## **Forward-looking Statements**

*This press release may contain statements that constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Forward-looking statements are statements other than historical fact and may include statements that address future operating, financial or business performance or Auris Medical's strategies or expectations. In some cases, you can identify these statements by forward-looking words such as "may," "might," "will," "should," "expects," "plans," "anticipates," "believes," "estimates," "predicts," "projects," "potential," "outlook" or "continue," and other comparable terminology. Forward-looking statements are based on management's current expectations and beliefs and involve significant risks and uncertainties that could cause actual results, developments and business decisions to differ materially from those contemplated by these statements. These risks and uncertainties include, but are not limited to, Auris Medical's need for and ability to raise substantial additional funding to continue the development of its product candidates, the timing and conduct of clinical trials of Auris Medical's product candidates will not meet its endpoints, the clinical utility of Auris Medical's product candidates, the timing or likelihood of regulatory filings and approvals, Auris Medical's intellectual property position and Auris Medical's financial position, including the impact of any future acquisitions, dispositions, partnerships, license transactions or changes to Auris Medical's capital structure, including future securities offerings. These risks and uncertainties also include, but are not limited to, those described under the caption "Risk Factors" in Auris Medical's Annual Report on Form 20-F and future filings with the Securities and Exchange Commission. Forward-looking statements speak only as of the date they are made, and Auris Medical does not undertake any obligation to update them in light of new information, future developments or otherwise, except as may be required under applicable law. All forward-looking statements are qualified in their entirety by this cautionary statement.*

## **Investor contact:**

Joseph Green / Andrew Gibson

Edison Advisors for Auris Medical

646-653-7030 / 7719

[jgreen@edisongroup.com](mailto:jgreen@edisongroup.com) / [agibson@edisongroup.com](mailto:agibson@edisongroup.com)

Or

[investors@aurismedical.com](mailto:investors@aurismedical.com)

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**AURIS MEDICAL HOLDING AG**  
**Condensed Consolidated Statement of Profit or Loss and Other Comprehensive Loss**  
For the Three Months Ended September 30, 2018 and 2017 (in CHF)

	<b>THREE MONTHS</b>	
	<b>ENDED SEPTEMBER 30</b>	
	<b>2018</b>	<b>2017</b>
Research and development	(1,697,045)	(4,221,324)
General and administrative	(1,170,244)	(1,336,217)
<b>Operating loss</b>	<b>(2,867,289)</b>	<b>(5,557,541)</b>
Interest income	-	7,788
Interest expense	(123,038)	(416,956)
Foreign currency exchange (loss)/gain, net	(114,011)	1,650
Revaluation gain/(loss) from derivative financial instruments	223,904	(55,613)
Transaction costs	(108,809)	-
<b>Loss before tax</b>	<b>(2,989,243)</b>	<b>(6,020,672)</b>
Income tax gain	8,726	8,191
<b>Net loss attributable to owners of the Company</b>	<b>(2,980,517)</b>	<b>(6,012,481)</b>
<b>Other comprehensive loss:</b>		
<b>Items that will never be reclassified to profit or loss</b>		
Remeasurement of defined benefit liability, net of taxes of CHF 0.00	209,760	94,463
<b>Items that are or may be reclassified to profit or loss</b>		
Foreign currency translation differences, net of taxes of CHF 0.00	5,913	(4,594)
<b>Other comprehensive income, net of taxes of CHF 0</b>	<b>215,673</b>	<b>89,869</b>
<b>Total comprehensive loss attributable to owners of the Company</b>	<b>(2,764,844)</b>	<b>(5,922,612)</b>
Basic and diluted loss per share	(0.14)	(1.36)
Average weighted number of shares outstanding, adjusted for effect of reverse stock split	20,944,590	4,432,970

**AURIS MEDICAL HOLDING AG**  
**Condensed Consolidated Statement of Financial Position**  
(in CHF)

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