

Auris Medical Holding

Q318 results and business updates

Financial update

Pharma & biotech

19 November 2018

Price **US\$0.54**

Market cap **US\$17m**

US\$1.01/CHF

Net cash (\$m) at 30 September 2018 5.9
(proceeds from exercise of warrants and
LPC equity drawdown)

Shares in issue 30.6m

Free float 79.3%

Code EARS

Primary exchange NASDAQ

Secondary exchange N/A

Share price performance



% 1m 3m 12m

Abs (63.3) 126.3 (93.2)

Rel (local) (62.3) 134.9 (93.6)

52-week high/low US\$9.3 US\$0.2

Business description

Auris Medical is a Swiss biopharmaceutical company developing neurology therapeutics. The company is developing intranasal betahistine in a Phase I trial for mental disorder supportive care and is entering Phase II for vertigo; both are designed to demonstrate proof-of-concept.

Next events

Initiate AM-201 PK/PD study Q119

Initiate AM-125 Phase II study Q119

AM-201 PK/PD top-line readout Summer 2019

AM-125 Phase II top-line data Q319
readout

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research client of Edison
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Auris Medical recently reported its Q318 results and provided a brief business update on its active programs. R&D expenditure for the period was down roughly 60% over Q317, which reflects management's swift pivot to focus on Phase I development. Auris plans to initiate two intranasal betahistine trials in Q119: the AM-125 Phase II trial in acute vertigo and AM-201 Phase I trial for olanzapine-induced weight gain.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHF)	DPS (CHF)	P/E (x)	Yield (%)
12/16	0.0	(31.0)	(0.90)	0.0	N/A	N/A
12/17	0.0	(25.9)	(0.54)	0.0	N/A	N/A
12/18e	0.0	(12.7)	(0.42)	0.0	N/A	N/A
12/19e	0.0	(11.8)	(0.31)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Upcoming Phase II AM-125 trial

Auris is developing AM-125, an intranasal formulation of betahistine for the treatment of acute vertigo. As AM-125 bypasses the digestive tract where the oral compound is readily metabolised, the intranasal formulation has demonstrated superior bioavailability over oral betahistine. Auris expects to initiate the Phase II trial in Q119 in 138 patients with surgically induced acute vertigo following vestibular schwannoma excision.

Phase I trial to demonstrate PK/PD of AM-201

Auris is also developing AM-201, an intranasal betahistine formulation, for co-administration with olanzapine to counteract adverse effects such as weight gain and somnolence. Auris plans to initiate the pharmacokinetics/pharmacodynamics (PK/PD) trial in Q119 in 50 healthy volunteers at one site in Europe.

Actively seeking a partner for Sonsuvi (AM-111)

The company recently announced that it has initiated the search to identify a partner for further development of AM-111 for the treatment of acute inner ear hearing loss. Auris has enlisted JSB Partners, a transaction advisory firm, to assist in identifying a partner and to support partnering discussions. AM-111 was also recently commercially branded as Sonsuvi.

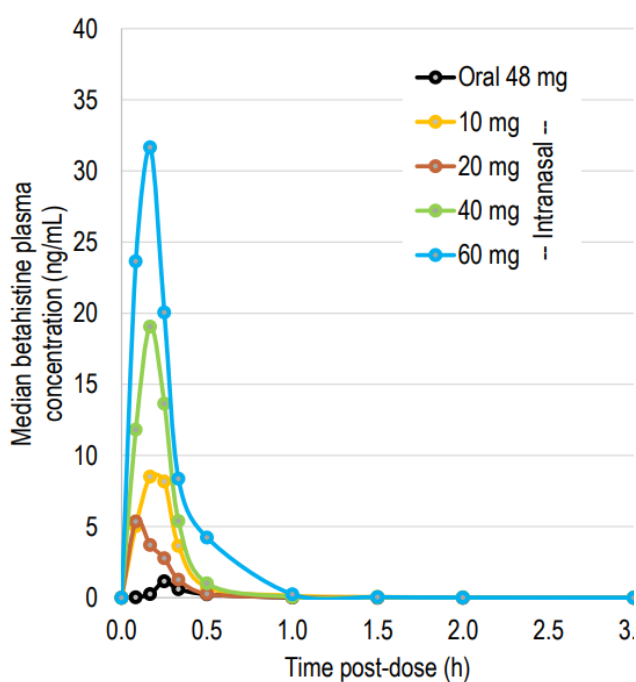
Valuation: \$119.8m or \$3.92 per basic share

We have slightly adjusted our valuation to \$119.8m or \$3.92 per basic share (\$3.19 per diluted share) from \$117.6m or \$4.89 per basic share (\$3.20 per diluted share). The increase in overall valuation was primarily driven by rolling forward our NPVs and an increase in net cash attributed to ~CHF2.7m in proceeds from financial instruments, which concurrently increased the share count and consequently decreased the price per share.

Plans to initiate two trials in Q119

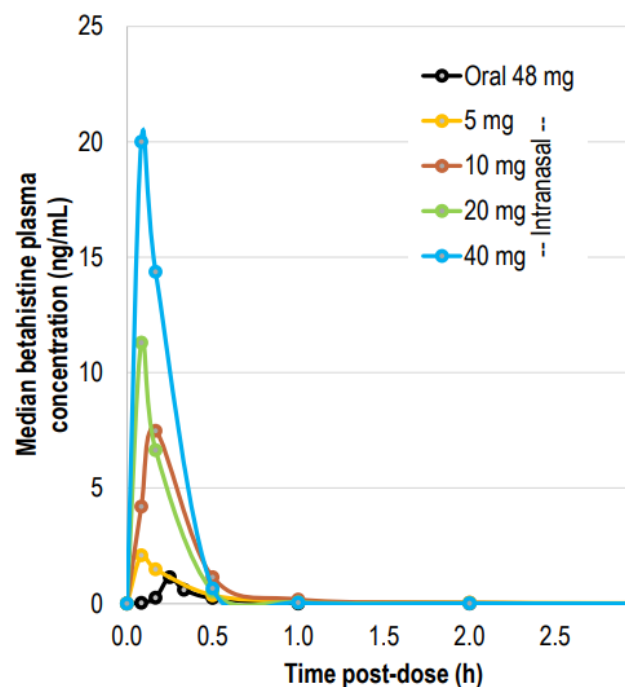
Auris previously demonstrated the superior bioavailability of AM-125, intranasal betahistine, compared to oral betahistine (48mg) in both single and multiple doses (Exhibits 1 and 2). Adverse events (AE) were mild to moderate, described as transient, and included sneezing and nasal congestion, which corresponded to dose. One patient withdrew from the trial due to an AE, but no serious AEs were reported. According to Auris, the maximum tolerated repeated dose based on local tolerability in the nose was identified and set at 40mg; the maximum tolerated single dose was not reached at 60mg.

Exhibit 1: Single-dose AM-125 bioavailability vs oral betahistine



Source: Auris Medical

Exhibit 2: Multi-dose AM-125 bioavailability vs oral betahistine



Source: Auris Medical

Auris plans to initiate its Phase II clinical trial in 138 patients with surgically induced acute vertigo following the removal of vestibular schwannoma (ie a noncancerous tumor located on the main nerve leading from the inner ear to the brain, also known as acoustic neuroma). Vestibular schwannoma surgery triggers acute vertigo, which can leave patients with the loss of peripheral vestibular input on one side.

Auris Medical's randomized, controlled, double-blind Phase II trial, TRAVERS, will be divided into two parts (Exhibit 3). Part A of the trial, which the company plans to initiate in Q119, will include 50 patients who will be administered five steps with AM-125 three times daily and 16 patients who will receive 48mg three times daily. The company anticipates top-line data readout in Q319, and expects to determine a dose-response curve and select a low dose and a high dose of AM-125 for the second part of the trial, which will be measured against placebo. Then, in Part B of the trial, the company plans to enrol 72 patients. Furthermore, Auris received EMA feedback on the TRAVERS trial and expects to initiate the study in Q119. The trial will be conducted in about 12-15 sites in Europe and possibly in Canada. If successful, this could be an important catalyst.

Exhibit 3: TRAVERS Phase II trial outline

	No. patients	Dose (3x daily)	Time frame	Primary endpoints	Secondary endpoints
Part A	50 (experimental) 16 (placebo)	5 doses up to 40 mg with AM-125 48mg oral betahistine	4 weeks	Standing on foam, tandem Romberg test	Tandem gait, subjective visual deviation and subjective questionnaires
Part B	72	High dose and low dose (determined by interim analysis) vs placebo (48mg oral betahistine)	4 weeks	Standing on foam, tandem Romberg test	Tandem gait, subjective visual deviation and subjective questionnaires

Source: Auris Medical

Concurrently, Auris plans to initiate the PK/PD trial in AM-210, intranasal betahistine for olanzapine-induced weight gain, as the company expects to receive pre-IND feedback from the FDA in Q418 and subsequently plans to enrol 50 healthy volunteers at one site in Europe in Q119 (Exhibit 4).

Exhibit 4: AM-201 Phase I PK/PD trial design

Screening	Olanzapine titration	Maintenance
<ul style="list-style-type: none"> Male and female healthy volunteers 18-50 years of age BMI 18-25kg/m² 	<ul style="list-style-type: none"> Titrate up to 10mg (7.5mg) once daily within first week Replace subjects who do not tolerate olanzapine or gain a clinically relevant amount of weight/high glucose level 	<ul style="list-style-type: none"> Maintain olanzapine dose for three weeks

Source: Auris Medical

The primary and secondary endpoints are weight gain and daytime sleepiness, respectively, while PK analysis should demonstrate potential drug-drug interaction. The company expects to read out top-line data in summer 2019.

Valuation: \$119.8m or \$3.92 per basic share

We have slightly adjusted our valuation to \$119.8m or \$3.92 per basic share (\$3.19 per diluted share) from \$117.6m or \$4.89 per basic share (\$3.20 per diluted share). The increase in overall valuation was primarily driven by rolling forward our NPVs and an increase in net cash attributed to ~CHF2.7m in proceeds from the exercise of warrants from the July 2018 offering and drawdown from its equity line established with Lincoln Park Capital Fund (LPC). The decrease in price per share is also attributed to the exercise of warrants from the July 2018 offering and a small drawdown from its LPC equity line.

Exhibit 5: Valuation of Auris Medical

Program	Market	Indication	Clinical stage	Probability of success	Launch year	Peak sales (\$m)	rNPV (\$m)
AM-125	US	Acute vertigo	Phase I	30%	2023	88.73	\$22.3
AM-125	Europe	Acute vertigo	Phase I	45%	2022	113.12	\$56.3
AM-201	US	Mental health supportive care	Phase I	20%	2024	128.72	\$15.0
AM-201	Europe	Mental health supportive care	Phase I	20%	2025	143.85	\$20.3
Total							113.93
Net cash and equivalents (as of 30 September 2018 plus proceeds from warrants from July offering and LPC draw down) (\$m)							5.92
Total firm value (\$m)							119.84
Total basic shares (as of 30 September 2018 plus exercise of warrants from July offering and LPC draw down, m)							30.6
Value per basic share (\$)							3.92
Options and warrants (as of 30 September 2018 plus exercise of warrants from July offering, m)							7.0
Total diluted shares (m)							37.6
Value per diluted share (\$)							3.19

Source: Edison Investment Research

Financials

Auris recently reported its Q318 results. R&D expenditure was CHF1.7m, which is down roughly 60% from Q317 (CHF4.2m), and reflects the company's strategic shift to focus on Phase I development programs. As of 30 September 2018, Auris had CHF5.3m in cash and equivalents and CHF2.1m in debt. Subsequent to the end of the quarter, net proceeds from the exercise of warrants from the July 2018 offering (~CHF2.2m), in addition to a partial drawdown from its equity line established with LPC (\$0.5m), increased shareholders' equity by CHF2.7m.

In our forecasts, we model a total of CHF65m in financing needs through 2023, which we record as illustrative debt, to bring the two intranasal betahistine programs from Phase I to commercialization (Exhibit 6). However, these financing needs may be offset by potential strategic partnering. Auris may also draw down from its LPC equity line (~\$9.5m remaining). We forecast slight increases in R&D expenditure to about CHF7m in 2019 and CHF11m in 2020, primarily associated with the advancement of AM-125 into Phase II and the initiation of the AM-201 Phase I program, which is expected in Q119.

Exhibit 6: Financial summary

	CHF'000s	2016	2017	2018e	2019e
Year end 30 December		IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue		0	0	0	0
Cost of Sales		0	0	0	0
Gross Profit		0	0	0	0
Research and development		(24,777)	(19,211)	(7,128)	(6,732)
Selling, general & administrative		(5,447)	(5,150)	(4,512)	(4,557)
EBITDA		(30,321)	(24,484)	(11,717)	(11,443)
Operating Profit (before amort. and except.)		(30,223)	(24,361)	(11,640)	(11,366)
Intangible Amortisation		0	0	0	0
Exceptionals/Other		0	0	0	0
Operating Profit		(30,223)	(24,361)	(11,640)	(11,366)
Net Interest		(761)	(1,586)	(1,102)	(400)
Other (change in fair value of warrants)		191	1,520	3,432	0
Profit Before Tax (norm)		(30,984)	(25,947)	(12,742)	(11,766)
Profit Before Tax (IFRS)		(30,793)	(24,427)	(9,310)	(11,766)
Tax		131	18	26	0
Deferred tax		(414)	322	1,282	0
Profit After Tax (norm)		(30,853)	(25,929)	(12,716)	(11,766)
Profit After Tax (IFRS)		(31,076)	(24,087)	(8,002)	(11,766)
Average Number of Shares Outstanding (m)		34.3	48.4	30.6	38.2
EPS - normalised (CHF)		(0.90)	(0.54)	(0.42)	(0.31)
EPS - IFRS (CHF)		(0.91)	(0.50)	(0.26)	(0.31)
Dividend per share (CHF)		0.0	0.0	0.0	0.0
Gross Margin (%)		N/A	N/A	N/A	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
BALANCE SHEET					
Fixed Assets		1,967	1,959	1,962	1,885
Intangible Assets		1,483	1,629	1,664	1,664
Tangible Assets		369	253	30	(47)
Other		115	77	268	268
Current Assets		33,691	15,868	7,716	4,470
Stocks		0	0	0	0
Debtors		297	241	92	116
Cash		32,442	14,973	7,117	3,846
Other		953	653	507	507
Current Liabilities		(8,957)	(10,426)	(6,858)	(5,300)
Creditors		(6,745)	(5,884)	(5,358)	(5,300)
Short term borrowings		(2,213)	(4,542)	(1,500)	0
Long Term Liabilities		(12,558)	(9,563)	(2,088)	(12,088)
Long term borrowings		(10,151)	(5,584)	0	(10,000)
Other long term liabilities		(2,406)	(3,979)	(2,088)	(2,088)
Net Assets		14,143	(2,162)	732	(11,034)
CASH FLOW					
Operating Cash Flow		(30,071)	(25,827)	(12,482)	(11,771)
Net Interest		749	1,569	965	0
Tax		(131)	(18)	(26)	0
Capex		(244)	(153)	(20)	0
Acquisitions/disposals		0	0	68	0
Financing		11,439	10,308	12,769	0
Dividends		0	0	0	0
Other		68	(2,034)	0	0
Net Cash Flow		(18,192)	(16,154)	1,275	(11,771)
Opening net debt/(cash)		(38,251)	(20,078)	(4,847)	(5,576)
HP finance leases initiated		0	0	0	0
Exchange rate movements		(397)	1,316	283	0
Other		416	(393)	(829)	0
Closing net debt/(cash)		(20,078)	(4,847)	(5,576)	6,195

Source: Company reports, Edison Investment Research

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