EDISON

# Auris Medical Holding

Development update

## Interim AM-201 data

Pharma & biotech

**Auris has announced interim data from its 50-subject AM-201 Phase Ib trial for olanzapine-induced weight gain and somnolence. The drug demonstrated safety and tolerability and provided initial signals of efficacy (limitations of the trial in terms of size and duration hamper its ability to provide definitive evidence). In the female study subjects, who showed more pronounced changes than the male study subjects, AM-201 demonstrated a 1.1kg benefit versus placebo over four weeks in those who received the highest dose (20mg three times daily). The company is now proceeding to a final dose level of 30mg in 30 healthy volunteers, with data expected around the end of Q120.**

| Year end | Revenue (CHFm) | PBT* (CHFm) | EPS* (CHF) | DPS (CHF) | P/E (x) | Yield (%) |
|---|---|---|---|---|---|---|
| 12/17 | 0.0 | (25.9) | (10.72) | 0.0 | N/A | N/A |
| 12/18 | 0.0 | (12.0) | (15.33) | 0.0 | N/A | N/A |
| 12/19e | 0.0 | (11.0) | (3.78) | 0.0 | N/A | N/A |
| 12/20e | 0.0 | (18.8) | (4.26) | 0.0 | N/A | N/A |

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

## AM-201 trial continuing to the 30mg dose level

Auris is developing AM-201, intranasal betahistine, for co-administration with olanzapine to counteract adverse effects such as weight gain and sleepiness. There were initial efficacy signals seen and the company is continuing the trial on to 30mg in 30 patients to help confirm the finding.

## TRAVERS trial data in 138 patients coming soon

Auris is developing AM-125, also an intranasal formulation of betahistine, for the treatment of acute vertigo. The Phase II trial, TRAVERS, will include 138 patients with surgically induced acute vertigo following vestibular schwannoma excision. The trial has started enrolling with interim data expected in Q419/Q120.

## Regulatory feedback for the tinnitus program

The company announced in September that it received positive regulatory feedback from the FDA and EMA on the design of a new Phase II/III trial of Keyzilen/AM-101 for acute inner ear tinnitus. The company and agencies are aligned on key aspects of the design (such as using the Tinnitus Functional Index (TFI) questionnaire as the primary outcome measure). Auris is currently exploring non-dilutive funding options to fund development.

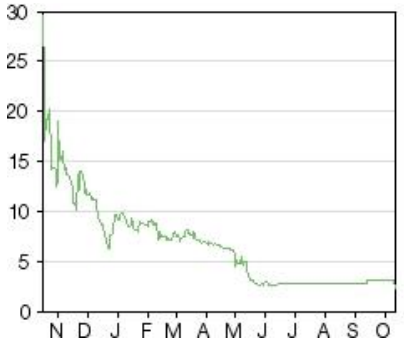
## Valuation: $132.5m or $32.59 per basic share

We are maintaining our valuation of $132.5m or $32.59 per basic share ($20.69 per diluted share). Key upcoming catalysts that may change our valuation for Auris will be the TRAVERS data in Q419/Q120 as well as the 30mg dose level data from the AM-201 proof-of-concept trial. As of the end of H119, Auris had CHF5.8m in cash and equivalents. In our forecasts, we model a total of CHF65m in financing needs through 2023, which we record as illustrative debt.

**15 October 2019**

| | |
|---|---|
| **Price** | **US$2.02** |
| **Market cap** | **US$7m** |
| | US$1/CHF |
| Net cash ($m) at 30 June 2019 | 5.79 |
| Shares in issue | 3.3m |
| Free float | 81.3% |
| Code | EARS |
| Primary exchange | Nasdaq |
| Secondary exchange | N/A |

### Share price performance




| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | (33.1) | (24.9) | (89.7) |
| Rel (local) | (32.2) | (23.7) | (90.4) |
| 52-week high/low | US$29.6 | | US$2.0 |

### Business description

Auris Medical is a Swiss biopharmaceutical company developing neurotology and central nervous system targeting therapeutics. It is developing intranasal betahistine in a Phase I trial for mental disorder supportive care and it is entering Phase II for vertigo; both are designed to demonstrate proof-of-concept.

### Next events

| | |
|---|---|
| AM-125 Phase IIa interim readout | Q419/Q120 |
| AM-201 Phase Ib 30mg dose readout | Q120 |

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## Initial signals of efficacy

Auris announced interim data from its 50-subject AM-201 Phase Ib proof-of-concept trial (across five dose cohorts to date) of intranasal betahistine for olanzapine-induced weight gain and somnolence. According to the company, AM-201 demonstrated safety and tolerability and also showed some initial signs of efficacy. In the female study subjects, who showed more pronounced changes than the male study subjects, AM-201 demonstrated a 1.1kg benefit versus placebo over four weeks at the highest dose (20mg three times daily). There are of course some important caveats with the main one being that this benefit was seen in a subset of only five patients as there were 10 patients in each dose cohort and they were equally split between male and female. The study will now advance to the next higher and final dose level of 30mg three times daily cohort will include 30 patients so that should help provide comfort with the initial signals. Data is expected around the end of Q120 (we hope at that point to also see some data on the impact on somnolence, as the company indicated a benefit but did not release any specific data on it).

There is also the question of whether 1.1kg is a clinically meaningful benefit. It is far too early to tell as we do not have the full data set including baseline weight and how much of the olanzapine weight gain was offset. Also, as AM-201 is not a weight-loss drug but a drug that offsets the weight gain effect of other drugs, there must be weight gain in the control arm in order for it to show a benefit. Based on historical data (see Exhibit 1), it typically takes time for significant weight gain to develop in patients treated with olanzapine and this was only a four-week trial. Hence, there will not be any definitive answer on efficacy prior to longer-term clinical trials.

**Exhibit 1: Schizophrenic patients demonstrating more than 7% body weight gain on SGAs**

| Drug | Percent of patients experiencing weight gain at 12 weeks (%) | Percent of patients experiencing weight gain at 52 weeks (%) |
|---|---|---|
| Olanzapine | 59.8 | 80.0 |
| Risperidone | 32.5 | 57.6 |
| Quetiapine | 29.2 | 50.0 |

Source: Adapted from Patel, J. K., et al. (2009). Metabolic profiles of second-generation antipsychotics in early psychosis: Findings from the CAFE study. *Schizophrenia Research*,111(1-3), 9-16.

## Feedback on the Keyzilen (AM-101) development plan

Auris announced in September that it received positive regulatory feedback from the FDA and EMA on the design of a new Phase II/III trial of Keyzilen/AM-101 for acute inner ear tinnitus. The company and agencies are aligned on key aspects of the design, including the use of the Tinnitus Functional Index (TFI) questionnaire as the primary outcome measure. Another point of agreement includes less frequent collection of patient-reported tinnitus loudness as daily reporting had been an issue in previous trials. The FDA will consider improvement in tinnitus loudness as a co-primary efficacy endpoint, while the EMA will view it as a secondary endpoint. We expect additional details on the design of the new Phase II/III trial in the coming months though that may depend on the source of the funding for the program. The company is currently exploring non-dilutive funding options for the program including partnering, special purpose vehicle financing, grants or a combination of the three. Note that we currently include no value in our model for this potentially late-stage program due to previously missed Phase III trial endpoints, but that may change once a viable path forward is determined.

## Valuation

We are maintaining our valuation of $132.5m or $32.59 per basic share ($20.69 per diluted share). Key upcoming catalysts that may change our valuation for Auris will be the TRAVERS data in Q419/Q120 as well as the 30mg dose level data from the AM-201 proof-of-concept trial around the end of Q120.

**Exhibit 2: Auris Medical valuation table**

| 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 | $25.2 |
| AM-125 | Europe | Acute vertigo | Phase I | 45% | 2022 | 113.12 | $62.8 |
| AM-201 | US | Mental health supportive care | Phase I | 20% | 2024 | 128.72 | $16.4 |
| AM-201 | Europe | Mental health supportive care | Phase I | 20% | 2025 | 143.85 | $22.4 |
| Total | | | | | | | 126.73 |
| Net cash and equivalents (As of 30 June 2019) ($m) | | | | | | | 5.79 |
| Total firm value ($m) | | | | | | | 132.52 |
| Total basic shares (including pre-funded warrants, m) | | | | | | | 4.1 |
| Value per basic share ($) | | | | | | | 32.59 |
| Options and warrants (m) | | | | | | | 2.3 |
| Total diluted shares (m) | | | | | | | 6.4 |
| Value per diluted share ($) | | | | | | | 20.69 |

Source: Auris Medical reports, Edison Investment Research

## Financials

As of the end of H119, Auris had CHF5.8m in cash and equivalents. The company had reiterated at the H119 results prior guidance for operating expenditure in the range of CHF10m to CHF13m for FY19. In our forecasts, we model a total of CHF65m in financing needs through 2023, which we record as illustrative debt.

## Exhibit 3: Financial summary

| CHF000s | 2017 | 2018 | 2019e | 2020e |
|---|---|---|---|---|
| Year end 31 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 | (19,211) | (6,690) | (5,204) | (12,000) |
| Selling, general & administrative | (5,150) | (4,265) | (5,719) | (5,833) |
| EBITDA | (24,484) | (11,027) | (10,951) | (17,889) |
| Operating Profit (before amort. and except.) | (24,361) | (10,954) | (10,923) | (17,861) |
| Intangible Amortisation | 0 | 0 | 0 | 0 |
| Exceptionals/Other | 0 | 0 | 0 | 0 |
| Operating Profit | (24,361) | (10,954) | (10,923) | (17,861) |
| Net Interest | (1,586) | (1,070) | (51) | (900) |
| Other (change in fair value of warrants) | 1,520 | 690 | 267 | 0 |
| Profit Before Tax (norm) | (25,947) | (12,024) | (10,973) | (18,761) |
| Profit Before Tax (IFRS) | (24,427) | (11,334) | (10,706) | (18,761) |
| Tax | 18 | (162) | 261 | 0 |
| Deferred tax | 322 | 1,266 | 261 | 0 |
| Profit After Tax (norm) | (25,929) | (12,186) | (10,712) | (18,761) |
| Profit After Tax (IFRS) | (24,087) | (10,230) | (10,184) | (18,761) |
| Average Number of Shares Outstanding (m) | 2.4 | 0.8 | 2.8 | 4.4 |
| EPS - normalised (CHF) | (10.72) | (15.33) | (3.78) | (4.26) |
| EPS - IFRS (CHF) | (9.96) | (12.87) | (3.59) | (4.26) |
| 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 | 1,959 | 3,812 | 5,416 | 5,388 |
| Intangible Assets | 1,629 | 3,535 | 5,158 | 5,130 |
| Tangible Assets | 253 | 34 | 20 | 20 |
| Other | 77 | 243 | 238 | 238 |
| Current Assets | 15,868 | 6,065 | 4,491 | 5,352 |
| Stocks | 0 | 0 | 0 | 0 |
| Debtors | 241 | 320 | 301 | 301 |
| Cash | 14,973 | 5,393 | 3,965 | 4,826 |
| Other | 653 | 351 | 224 | 224 |
| Current Liabilities | (10,426) | (4,563) | (1,783) | (3,877) |
| Creditors | (5,884) | (3,127) | (1,783) | (3,877) |
| Short term borrowings | (4,542) | (1,435) | 0 | 0 |
| Long Term Liabilities | (9,563) | (1,665) | (5,999) | (23,499) |
| Long term borrowings | (5,584) | 0 | (5,000) | (22,500) |
| Other long term liabilities | (3,979) | (1,665) | (999) | (999) |
| Net Assets | (2,162) | 3,649 | 2,125 | (16,636) |
| **CASH FLOW** | | | | |
| Operating Cash Flow | (25,827) | (14,447) | (12,100) | (16,639) |
| Net Interest | 1,569 | 1,053 | 19 | 0 |
| Tax | (18) | 162 | 0 | 0 |
| Capex | (153) | (1,891) | (1,620) | 0 |
| Acquisitions/disposals | 0 | 68 | 0 | 0 |
| Financing | 10,308 | 15,005 | 8,701 | 0 |
| Dividends | 0 | 0 | 0 | 0 |
| Other | (2,034) | 0 | 0 | 0 |
| Net Cash Flow | (16,154) | (50) | (5,000) | (16,639) |
| Opening net debt/(cash) | (20,078) | (4,847) | (3,958) | 1,079 |
| HP finance leases initiated | 0 | 0 | 0 | 0 |
| Exchange rate movements | 1,316 | 258 | (36) | 0 |
| Other | (393) | (1,097) | 0 | 0 |
| Closing net debt/(cash) | (4,847) | (3,958) | 1,079 | 17,717 |

Source: Auris Medical reports, Edison Investment Research

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