EDISON

Auris Medical Holding

A nasal spray to help protect against COVID-19

Development update

Pharma & biotech

Auris recently announced the development of the AM-301 nasal spray for protection against SARS-COV-2 (COVID-19) infection (though it is also intended to protect against other airborne pathogens and allergens as well). AM-301 is a gel that would form a protective layer in the nasal mucosa, preventing contact between the pathogen and cells. In vitro data so far suggest contact between AM-301 and COVID-19 reduced the viral load by up to 99%. The company is targeting regulatory submission as an over the counter (OTC) product in 2021.

Year end	Revenue (CHFm)	PBT* (CHFm)	EPS* (CHF)	DPS (CHF)	P/E (x)	Yield (%)
12/18	0.0	(12.0)	(15.33)	0.0	N/A	N/A
12/19	0.0	(7.3)	(2.43)	0.0	N/A	N/A
12/20e**	0.0	(5.4)	(0.91)	0.0	N/A	N/A
12/21e**	0.0	(14.0)	(1.95)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortization of acquired intangibles, exceptional items and share-based payments. **Note that the company capitalizes a portion of R&D whereas our forecasts do not capitalize such expenses in FY21 and beyond, and hence reported R&D expenses will likely be lower than our forecasts.

Part A of Phase II TRAVERS trial interim analysis

Part A of the TRAVERS trial of AM-125 in patients with acute vertigo showed a dose dependent improvement in balance in patients (three dose levels were tested, 1mg, 10mg and 20mg three times daily). At the highest dose (20mg), patients receiving AM-125 were able to balance themselves for 6.0 seconds vs 3.1 seconds on placebo 14 days post-surgery. In a separate test where patients were asked to stand on foam, AM-125 patients stood for 10.5 seconds versus 4.3 seconds for those who received placebo. The changes were statistically significant vs baseline.

Part B of TRAVERS trial underway

Following the interim results from part A, the company has selected the two highest doses from part A (10mg and 20mg three times daily) for Part B, which will be testing those doses versus placebo in 72 patients. Improvement in the standing on foam test (2 weeks after surgery) will be the sole primary endpoint while the Tandem Romberg test (6 weeks after surgery) will be the key secondary endpoint.

AM-201 Phase Ib trial data at 30mg dose

At the 30mg dose of AM-201 for anti-psychotic induced weight gain, subjects receiving 30mg three times daily in the Phase Ib study showed a 24% reduction in weight gain following treatment with olanzapine at the 28 day time point (2.8kg gained for those taking AM-201 in addition to olanzapine vs 3.7kg weight gain for those only on olanzapine, p<0.02). The company is preparing for a Phase II trial.

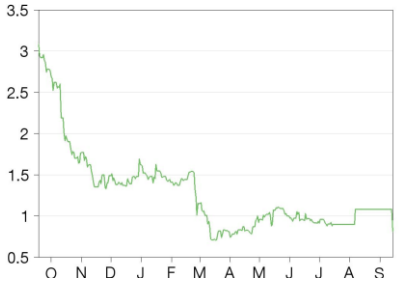
Valuation: $127.1m or $17.93 per basic share

We are adjusting our valuation to $127.1m or $17.93 per basic share, from $121.1m or $27.47 per basic share. The total value increased as we rolled forward our NPV though this was partially offset by lower net cash. The per-share value fell due to a higher number of shares outstanding as the company raised capital.

18 September 2020

Price	**US$0.82**
Market cap	**US$6m**
	US$0.91/CHF
Net debt ($m) as of 30 June 2020	0.01
Shares in issue	7.1m
Free float	59.2%
Code	EARS
Primary exchange	Nasdaq
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	(24.9)	(20.4)	(72.8)
Rel (local)	(24.4)	(26.2)	(75.7)
52-week high/low	US$3.08		US$0.70

Business description

Auris Medical is a Swiss biopharmaceutical company developing neurotology and central nervous system targeting therapeutics. It is developing intranasal betahistine for mental disorder supportive care (recently completed Phase I) and it is in Phase II for vertigo. Additionally, it has begun development on AM-301 for the protection against airborne pathogens and allergens.

Next events

AM-125 Part B completion of enrolment	Q121

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Edison profile page

H120 update highlights progress

Auris on 8 September 2020 announced a new product and therapeutic area. The company has started development of AM-301, a nasal spray for protection against SARS-COV-2 (COVID-19) infection, which is intended to also protect against other airborne pathogens and allergens. AM-301 is a gel that would form a thin protective layer in the nasal mucosa, preventing contact between the pathogen and cells. In addition, the composition is able to trap and bind the pathogens. In vitro data so far suggest contact between AM-301's key component and COVID-19 reduced the viral load by up to 99% (depending on concentration) with testing of additional pathogens and allergens expected to begin in the coming months.

The company is looking to develop AM-301 as an OTC product, hence available to consumers without a prescription as the formulation would be drug-free. The target market will likely be those consumers who will seek short-term protection (likely a few hours per use) from infection while outside their homes at various venues (schools, movie theatres, restaurants, public transportation).

In order to fund this product, the company has set up a new subsidiary, Altamira Medical. So far CHF1.5m in convertible debt has been raised (in Q320) to fund Altamira and AM-301's development. The debt has an 8% annual interest rate, an 18-month term and would be convertible into shares of either Altamira or Auris. Currently Auris owns 100% of Altamira but this is expected to decrease as additional investors come in as further financing for AM-301 is needed.

Auris also recently provided an update on its AM-125 clinical program for the treatment of acute vertigo, announcing interim results from Part A of the Phase II TRAVERS trial. In Part A of the trial, a total of 33 patients (suffering from vertigo following neurosurgery) were administered AM-125 or placebo in three dose cohorts (1mg, 10mg and 20mg) three times daily. At the highest dose (20mg), patients receiving AM-125 were able to balance themselves with eyes closed for 6.0 seconds vs. 3.1 seconds on placebo 14 days post-surgery using the 'Tandem Romberg' test. In a separate test where patients were asked to stand on foam, AM-125 patients stood for 10.5 seconds versus 4.3 seconds for those who received placebo. Improvement from baseline was statistically significant in all dose groups ($p<0.01$ to $p<0.05$), however this initial part of the study was not powered to show statistical significance versus placebo and this data was not provided.

The two highest doses, 10mg and 20mg three times daily, have been selected to move forward into Part B, which will be testing those doses versus placebo in 72 patients. Improvement in the standing on foam test two weeks post-surgery will be the sole primary endpoint, while the Tandem Romberg test six weeks post-surgery will be the key secondary endpoint. Enrolment is expected to begin shortly and to complete in Q121.

With regards to AM-201 for anti-psychotic induced weight gain, in May the company reported data from the 30mg dose (interim data from lower doses was announced in October 2019) of its Phase Ib study. At the 30mg dose, subjects showed a 24% reduction in weight gain following treatment with olanzapine (an anti-psychotic that causes weight gain) at the 28 day time point (2.8kg gained for those taking AM-201 in addition to olanzapine vs 3.7kg weight gain for those only on olanzapine, $p<0.02$, $n=81$). The company is preparing for both an IND filing and a Phase II trial with timing dependent on the completion of preclinical trials involving the combination of olanzapine and AM-201. An IND filing could occur as soon as Q121.

Valuation

We are adjusting our valuation to $127.1m or $17.93 per basic share, from $121.1m or $27.47 per basic share. The total value increased as we rolled forward our NPV though this was partially offset by lower net cash. The per-share value fell due to a higher number of shares outstanding as the company raised capital through both an 'at-the-market' offering and an equity line. We are not currently including AM-301 due to the early nature of its development.

Exhibit 1: Auris valuation table

Program	Market	Indication	Clinical stage	Probability of success	Launch year	Peak sales ($m)	rNPV ($m)
AM-125	US	Acute vertigo	Phase II	30%	2024	88.73	$23.1
AM-125	Europe	Acute vertigo	Phase II	45%	2023	113.12	$60.3
AM-201	US	Mental health supportive care	Phase I	20%	2024	128.72	$18.4
AM-201	Europe	Mental health supportive care	Phase I	20%	2025	143.85	$25.2
Total							127.13
Net cash and equivalents (as of 30 June 2020) ($m)							(0.01)
Total firm value ($m)							127.12
Total basic shares (m)							7.1
Value per basic share ($)							17.93

Source: Edison Investment Research

Financials

Auris recently reported its H120 results. The company reported R&D expenses of CHF0.9m for the period (an additional CHF0.7m in R&D spend was capitalized) compared to CHF1.3m (with an additional CHF1.6m capitalized) in H119. G&A expenditure for H120 was CHF1.5m, down from CHF2.8m the year before. Total net loss was CHF2.7m down from CHF3.6m in the same period the year before. We have lowered our 2020 R&D estimate from CHF7.2m to CHF2m (with an additional CHF2.5m capitalized) due to lower than expected spending. Note that for the year the company has guided for CHF7.0–8.5m in total cash needs with total operating expenses of CHF4.5–5.5m and capitalized R&D of CHF2.5–3.0m. We have also reduced our FY21 R&D estimates from CHF13.2m to CHF10.0m as the company has been lowering their expenses. Note that the company capitalizes R&D expenses, but our forecasts use uncapitalized R&D expenses for FY21 and beyond so we expect reported R&D will likely be lower than our estimates (overall cash flow would be unchanged however, as that would not be affected by capitalization of R&D expenses).

As of 30 June 2020, Auris had CHF0.04m in cash and equivalents, but has raised $2.1m subsequent to the end of the period through its equity line with Lincoln Park Capital and the at-the-market (ATM) offering agreement with Alliance Global Partners (AGP). The Lincoln Park agreement was originally for up to $10m and the company has approximately $8.9m remaining under that facility. The ATM with AGP was for up to $25m and the company has approximately $22.1m remaining.

In our forecasts, we model a total of CHF50m (previously CHF65m) in additional financing needs through 2024 (including CHF22m by the end of 2021, assuming accelerated investment in all of its ongoing R&D programs), which we record as illustrative debt. An important item to note is that Auris has announced that it has initiated a review of strategic options, which may include the partnering of various programs or a sale or merger of the company as a whole.

Exhibit 2: Financial summary

CHF'000s	2018	2019	2020e	2021e
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	(6,690)	(3,325)	(2,000)	(10,000)
Selling, general & administrative	(4,265)	(3,934)	(3,072)	(3,133)
EBITDA	(11,027)	(7,290)	(5,084)	(13,146)
Operating Profit (before amort. and except.)	(10,954)	(7,259)	(5,072)	(13,133)
Intangible Amortisation	0	0	0	0
Exceptionals/Other	0	0	0	0
Operating Profit	(10,954)	(7,259)	(5,072)	(13,133)
Net Interest	(1,070)	(11)	(282)	(882)
Other (change in fair value of warrants)	690	444	(245)	0
Profit Before Tax (norm)	(12,024)	(7,270)	(5,354)	(14,015)
Profit Before Tax (IFRS)	(11,334)	(6,826)	(5,599)	(14,015)
Tax	(162)	194	11	0
Deferred tax	0	0	0	0
Profit After Tax (norm)	(12,186)	(7,076)	(5,343)	(14,015)
Profit After Tax (IFRS)	(11,496)	(6,632)	(5,589)	(14,015)
Average Number of Shares Outstanding (m)	0.8	2.9	5.8	7.2
EPS - normalised (CHF)	(15.33)	(2.43)	(0.91)	(1.95)
EPS - IFRS (CHF)	(14.46)	(2.28)	(0.96)	(1.95)
Dividend per share (CHFc)	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	3,812	6,852	9,340	9,328
Intangible Assets	3,535	6,766	9,266	9,253
Tangible Assets	34	67	54	54
Other	243	20	20	20
Current Assets	6,065	2,374	4,692	6,515
Stocks	0	0	0	0
Debtors	320	335	151	151
Cash	5,393	1,385	4,342	6,165
Other	351	654	199	199
Current Liabilities	(4,563)	(2,278)	(2,422)	(3,324)
Creditors	(3,127)	(2,278)	(2,422)	(3,324)
Short term borrowings	(1,435)	0	0	0
Long Term Liabilities	(1,665)	(912)	(8,063)	(23,063)
Long term borrowings	0	0	(7,050)	(22,050)
Other long term liabilities	(1,665)	(912)	(1,013)	(1,013)
Net Assets	3,649	6,036	3,547	(10,545)
CASH FLOW				
Operating Cash Flow	(14,447)	(8,201)	(4,367)	(13,101)
Net Interest	1,053	1	0	0
Tax	162	(194)	0	0
Capex	(1,891)	(3,019)	(2,570)	(77)
Acquisitions/disposals	68	0	0	0
Financing	15,005	8,841	2,895	0
Dividends	0	0	0	0
Other	0	18	0	0
Net Cash Flow	(50)	(2,553)	(4,042)	(13,178)
Opening net debt/(cash)	(4,847)	(3,958)	(1,385)	2,707
HP finance leases initiated	0	0	0	0
Exchange rate movements	258	(8)	0	0
Other	(1,097)	(12)	(50)	0
Closing net debt/(cash)	(3,958)	(1,385)	2,707	15,885

Source: company reports, Edison Investment Research

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