29th September 2016

Healthcare

Actelion

Price CHF169.90

Actelion clarifies its strategy with ponesimod

Fair Value CHF180 (+6%) **NEUTRAL**

Bloomberg	ATLN VX
Reuters	ATLN.VX
12-month High / Low (CHF)	173.8 / 115.9
Market Cap (CHFm)	18,309
Avg. 6m daily volume (000)	344.4

	1 M	3 M	6 M	31/12/15
Absolute perf.	2.8%	10.4%	19.6%	21.7%
Healthcare	0.8%	1.6%	6.4%	-7.5%
DJ Stoxx 600	-0.3%	8.2%	2.2%	-6.4%

	2015	2016e	2017e	2018e
P/E	27.6x	22.2x	25.9x	23.5x
Div yield (%)	0.9%	0.9%	0.9%	0.9%

ANALYSIS

- Despite signs of confidence, Actelion has so far remained fairly secret about the full package of clinical trials it intended to conduct to try to bring ponesimod to the market. However, management clearly stated several times that it did not want to carry on with me-too drugs. That said, and although it may have some differentiating properties compared to Gilenya, ponesimod is an S1P agonist that should come third or fourth to market (considering the recent surprise from BAF312).
- A shorter half-life, a better safety profile, a different selectivity for S1P receptor sub-units can offer differentiation but may not be enough to position ponesimod as a better drug than Gilenya and a differentiated label is uncertain too. So the only way to try making an inroad into this segment of the MS market is through trial design. A head-to-head trial would have been too costly and too risky.
- So, last year, Actelion announced that it was starting the recruitment of a first phase III trial called OPTIMUM that planned to enrol 1,100 patients with RRMS to compare ponesimod to an oral drug and recently-approved drug i.e. Sanofi's Aubagio. Although efficacy is not impressive, the drug is safe and commercially very successful and so is a good comparator for ponesimod in our view. The second study, required by regulators, was more intriguing and was kept secret until today although our understanding was that it could be a first try in combination in order to take advantage from the good safety profile of ponesimod.
- Actelion is today presenting the design of a phase III study agreed under an SPA with the FDA (called POINT). The trial will start recruiting by year-end and targets 600 patients with RMS under Tecfidera, one of the most popular oral drugs, notably in the US. The objective is to test ponesimod as an add-on therapy to Tecifdera and measure efficacy based primarily on ARR (primary endpoint) and then on disability. Of course, as a first study combining two oral drugs, safety will be key too. If successful, it could then open a new paradigm in MS treatment although the cost might limit use of combinations. Hopefully data will be able to offer subgroup analysis.

VALUATION

- Actelion announces POINT will last at least two years and as recruitment starts end of 2016, we see no filing for ponesimod before early 2019. We are therefore delaying launch by one year although this has no impact on our FV (ponesimod accounts for CHF8/share).
- We think Q3 numbers will be strong. However, we are cautious about CS numbers for Opsumit and Uptravi and would like to see our payers react to Tracleer's generics still expected in 2017.

NEXT CATALYSTS

- 20th October 2016: Third-quarter results

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BRYAN, GARNIER & CO

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BUY ratings 72% NEUTRAL ratings 0% SELL ratings 28%

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