28th July 2016

Healthcare

Roche

Price CHF249.30

Follow-up data confirm the efficacy/safety profile of ACE910

Fair Value CHF293 (+18%) **BUY**

Bloomberg	ROG VX
Reuters	ROG.VX
12-month High / Low (CHF)	281.0 / 233.2
Market Cap (CHFm)	175,149
Ev (BG Estimates) (CHFm)	187,592
Avg. 6m daily volume (000)	1,452
3y EPS CAGR	6.3%

	1 M	3 M	6 M	31/12/15
Absolute perf.	3.5%	0.3%	-7.1%	-9.8%
Healthcare	9.3%	6.0%	2.5%	-3.0%
DJ Stoxx 600	11.0%	-1.6%	0.7%	-6.3%

YEnd Dec. (CHFm)	2015	2016e	2017e	2018e
Sales	48,145	50,762	51,908	53,128
% change		*5.4%*	*2.3%*	*2.4%*
EBITDA	19,430	20,345	21,444	21,699
EBIT	13,821	17,114	18,644	19,499
% change		*23.8%*	*8.9%*	*4.6%*
Net income	11,626	12,677	13,722	13,947
% change		*9.0%*	*8.2%*	*1.6%*

	2015	2016e	2017e	2018e
Operating margin	28.7	33.7	35.9	36.7
Net margin	24.1	25.0	26.4	26.3
ROE	43.7	50.4	45.8	40.7
ROCE	28.1	27.9	28.7	28.6
Gearing	60.4	44.1	27.6	13.8

(CHF)	2015	2016e	2017e	2018e
EPS	13.49	14.71	15.92	16.18
% change	-	*9.0%*	*8.2%*	*1.6%*
P/E	18.5x	17.0x	15.7x	15.4x
FCF yield (%)	5.5%	4.6%	5.5%	6.1%
Dividends (CHF)	8.10	8.83	9.56	9.72
Div yield (%)	3.2%	3.5%	3.8%	3.9%
EV/Sales	3.9x	3.7x	3.6x	3.4x
EV/EBITDA	9.7x	9.2x	8.6x	8.3x
EV/EBIT	13.7x	11.0x	9.9x	9.3x

Updated data from a Phase I study evaluating ACE910/emicizumab hemophilia A (with and without inhibitors) were presented at the World Federation of Haemophilia 2016 Congress. Overall, the efficacy and safety profile of the compound was very consistent with previous data which confirms in our view its attractiveness, especially in patients who developed inhibitors.

ANALYSIS

- Roche presented the long-term follow-up data from its Phase I study evaluating ACE910/Emicizumab in Haemophilia A at the World Federation of Haemophilia 2016 Congress (median follow-up: 32.6, 27.0 and 21.4 months with weekly doses of 0.3, 1.0 and 3.0 mg/kg respectively).
- The efficacy profile of ACE910 is very consistent with previous data. And we even note that patients experienced a continued decrease in the ABR (annualized bleeding rate), irrespective of their inhibitor status and previous treatment regimen (see table below for more details).

Treatment Arm (n=6 per arm)	Bleeding events	Median ABR Baseline (as previously reported)	Median ABR 12 week follow-up (as previously reported)	Median ABR Long-term follow-up
Cohort-1 0.3 mg/kg emicizumab	All bleeds	32.5	4.4	1.4
	Joint bleeds	27.4	4.3	1.1
Cohort-2 1 mg/kg emicizumab	All bleeds	18.3	0	0.2
	Joint bleed	15.2	0	0.2
Cohort-3 3 mg/kg emicizumab	All bleeds	15.2	0	0
	Joint bleeds	9.1	0	0

Source : Company Data; Bryan Garnier & Co. ests.

- The same goes for the safety part, knowing that 1/ most adverse events were of mild or moderate intensity, with nonetheless the exception of 2 severe AE (appendicitis, mesenteric hematoma);2/ no thromboembolic adverse events were observed; 3/ some anti-ACE910 antibodies were developed in 3 patients, but it apparently did not affect its performance.
- What's next? Phase III results in haemophilia A patients who developed inhibitors (20% of the overall population) are still expected by year end, or in H1 17 at the latest... And we understand that Roche is planning to commence a Phase III trials to evaluate the compound 1/ in patients without inhibitors, including paediatric ones, and 2/ different doses/administration schedule (e.g. weekly, every 4 weeks).
- We reiterate our view that ACE910 is a very promising candidate, and especially when it comes to the patients with inhibitors (for whom there is an increased mortality risk). Conversely, we find it hard to predict how ACE910 could address the non-inhibtor market, as Roche's management is struggling with its pricing in two sub-indications with very different prices… The annual cost per patient with inhibitors being in a USD500k-1m range vs USD3-400k for the others. Plus, as stated in our Shire's initiation report (here), we believe it will be extremely difficult to rapidly dislodge recombinant and plasma-derived FVIII (for which we have a pretty good view on their LT efficacy/safety profile), especially when the patient is well-controlled.

VALUATION

- BUY rating with a FV of CHF293.

NEXT CATALYSTS

- 7-11 October : Presentation of data from the GALLIUM study. - *Click here to download document*

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

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