18th July 2016

Healthcare

Roche

Price CHF255.60

GOYA misses its primary endpoint

Fair Value CHF293 (+15%) **BUY**

Bloomberg	ROG VX
Reuters	ROG.VX
12-month High / Low (CHF)	282.5 / 233.2
Market Cap (CHFm)	179,575
Ev (BG Estimates) (CHFm)	192,018
Avg. 6m daily volume (000)	1 491
3y EPS CAGR	6.3%

	1 M	3 M	6 M	31/12/15
Absolute perf.	6.1%	3.0%	-0.4%	-7.5%
Healthcare	8.6%	4.9%	5.1%	-4.3%
DJ Stoxx 600	4.4%	-1.4%	2.4%	-7.6%

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	19.0x	17.4x	16.1x	15.8x
FCF yield (%)	5.3%	4.5%	5.3%	5.9%
Dividends (CHF)	8.10	8.83	9.56	9.72
Div yield (%)	3.2%	3.5%	3.7%	3.8%
EV/Sales	4.0x	3.8x	3.6x	3.5x
EV/EBITDA	10.0x	9.4x	8.8x	8.5x
EV/EBIT	14.0x	11.2x	10.1x	9.5x

The picture is now almost complete for Gazyva which will undoubtedly be an interesting line of defense for rituximab, although today's piece of news is that the phase III study GOYA missed its primary endpoint of improving PFS with Gazyva+CHOP vs Rituxan+CHOP in DLBCL. Our understanding from discussions with management at our BG Oncology Day in June was that the risk with GOYA was higher than with GALLIUM, as phase II work had been largely skipped with interim data limited to ORR. This is a missed opportunity, but not the end of the world. To defend itself against biosimilars, rituximab will play with the subcutaneous formulation, Gazyva and Venclexta.

ANALYSIS

- In our report dated 13 July 2016 summarizing what we learnt from our Oncology Day, we wrote on page 23: "Although Gazyva proved superior in CLL and in indolent NHL (GALLIUM), Roche considers that the history of the drug in this disease is such that the risk of failure is largely carried from phase I/II into phase III, because only ORR has been clearly assessed so far". As such, the risk of failure was considered to be higher than 50%. Actually GOYA used to be a major triggering event for Gazyva and Roche more generally, but since GALLIUM unveiled positive top-line data, it was more like a free option, although it would have been a clear plus to have it positive too in the race against biosimilars, the first of which should be approved by the end of 2017.
- It is worth keeping in mind that rituximab is Roche's leading product by sales and should reach about CHF7.3bn this year, which is likely to be the year when sales peak. More than half is generated in the US, about a quarter in Europe. This is in Europe where first biosimilars should be approved next year. That said, it is unlikely that all Europe will adopt first biosimilars at the same speed, if only for reimbursement reasons.
- Rituxan's sales are split in four main approved indications (although it is used in many others because of off-label use, for instance in primary progressive multiple sclerosis). It is estimated that about a quarter of sales are generated in rheumatology i.e. in rheumatoid arthritis (RA) and here, there will not be any second-generation compound from Roche, so that biosimilar should fairly easily take a meaningful part of the segment if physicians feel comfortable with it. We assume this slice of the pie should go. The remaining three quarters are made of sales in haematology and here Gazyva proved superior to Rituxan in about two-thirds of the total (GADOLIN, CLL11, GALLIUM).
- So, we expect Gazyva to target a market that currently represents about half of Rituxan's revenues and should take only part of it in volumes, it is worth having in mind that Gazyva's price is much higher than Rituxan's with a premium around 80% in Europe and 25% in the US. So it is fair to expect Gazyva to generate about 40-50% of what Rituxan achieved i.e. CHF3-3.5bn. So far, we have factored in only CHF2bn at peak in 2024, waiting for the full GALLIUM data to be presented at a medical congress. 2018 onwards in Europe, we see Rituxan declining at a rate of 20% p.a., mainly thanks to the subcutaneous formulation of the drug to which about 35-40% of patients have been switched.

VALUATION

- We make no change to our numbers. Roche will release H1 figures on Thursday. Sales are expected to reach CHF24.8bn and core EPS is anticipated at CHF7.47. We are in line with sales and slightly lower on core EPS (CHF7.39).

NEXT CATALYSTS

- 21 July 2016: First-half results

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