

Roche

Price CHF245.80

APHINITY – it is worth taking the residual risk

Fair Value CHF293 (+19%)

BUY

Bloomberg	ROG VX
Reuters	ROG.VX
12-month High / Low (CHF)	282.5 / 233.2
Market Cap (CHF)	172,690
Ev (BG Estimates) (CHF)	185,271
Avg. 6m daily volume (000)	1,491
3y EPS CAGR	5.7%

Ahead of our Oncology Day, Roche's management was available for meetings and at the heart of them was the APHINITY phase III trial that the company itself describes as game-changing. Whether it delivers positive results or not, the profile of Roche will be significantly and profoundly modified at the turn of the decade. The difference can be as high as CHF5-6bn in revenues and 80%-90% of that is profit. This would also be a major defense against biosimilars trastuzumab, on top of the sc form. Beyond oncology, Roche mainly focused its presentation on ocrelizumab and ACE910. Although the stock is unlikely to perform prior to APHINITY results, we see the benefit-risk profile as favourable.

ANALYSIS

- When Roche has to deal with an audience of generalists asking about future prospects, it refers to its historical sales growth in the mid-single digits and suggests that it should move on at the same pace should the APHINITY phase III study be positive. Otherwise, it is reasonable to expect top-line to be flat by the end of the decade as biosimilars offset innovative compounds coming out of the pipeline. This illustrates how meaningful APHINITY is to the investment case.
- As a reminder, APHINITY is the phase III study investigating Perjeta in combination with Herceptin and chemotherapy in adjuvant HER2+ breast cancer. Because a vast majority of breast cancers are diagnosed in the early stages, adjuvant represents the lion's share of the target market and of current Herceptin prescriptions. So far, Perjeta has demonstrated benefit in combination with Herceptin in metastatic and neo-adjuvant HER2+ BC and for Roche, this is illustrative of a clear synergistic effect between the two drugs. Roche believes that it has done everything well to show benefit across all indications and although each is different with adjuvant working on minimal residual disease, "a failure would be a surprise".
- Of course, positive APHINITY data would give Roche more power to play with Perjeta and Herceptin prices more aggressively in opposite directions. This would leave the HER2+ franchise in good shape to enter the biosimilar trastuzumab period, on top of the subcutaneous formulation that has a market share of approx. 45% currently in Europe. This would give Roche roughly similar weapons to defend Herceptin to the ones it has now for Rituxan, since GALLIUM phase III trial unveiled positive data (HR at least 0.73). Note that Roche is currently working on a subcutaneous formulation of rituximab for the US too, where it is worth investing considering the gain in infusion time. It has also been noted that sc was cheaper than iv in overweight patients. Roche considers the risk of failure with GOYA to be higher than 50%, as earlier studies only looked at ORR so survival benefit has not been clearly assessed.
- Before moving to ex-oncology assets, a word about Avastin. Roche expects to get interim data on its CrossMab project soon that will tell more about its ability to be a new-generation Angio2/VEGF bispecific antibody both in cancer (RG7221 in phase II in CRC, head-to-head vs Avastin) and in ophthalmology (RG7716 in phase II in wet AMD and DME, head-to-head vs Lucentis).
- Outside Oncology, Roche spontaneously pointed to two projects of meaningful impact on its top and bottom line: first is ocrelizumab in MS, for which it expects a PDUFA date very soon and potential priority review and confirms high confidence based on strong MRI data, together with clean safety profile (no concern about cancer). Management also pointed to a lack of ambition in ofatumumab's trial design, low likelihood of disability data and price issue with ofa available in hematology; second is ACE910 with Roche currently investigating how to price the drug in two indications where SoC prices are so different. By chance, haemophilia A with inhibitors will come first (data by year-end) with an annual price that can be as high as USD1m per patient.

VALUATION

- We believe we have room for upside with Perjeta at CHF3.7bn at peak, Gazyva at CHF1.6bn (not impacted by GALLIUM), Tecentriq at CHF3.1bn or ACE910 at CHF800m (40% PoS).
- A P/E 2017 of 15x is attractive in our view, as momentum is expected to improve gradually.

NEXT CATALYSTS

- Coming days: FDA's answer to ocrelizumab filing - [Click here to download document](#)



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NEUTRAL ratings 34%

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