

## Grifols

Price EUR18.10

Mixed Phase III data for Pulmaquin. We downgrade to SELL

Fair Value EUR19 vs. EUR20 (+5%)

SELL vs. NEUTRAL

Bloomberg	GRF.SM
Reuters	GRF.MC
12-month High / Low (EUR)	22.7 / 17.4
Market Cap (EUR)	11,568
Ev (BG Estimates) (EUR)	15,125
Avg. 6m daily volume (000)	768.1
3y EPS CAGR	8.4%

	1 M	3 M	6 M	31/12/15
Absolute perf.	1.5%	-3.4%	-11.2%	-15.1%
Healthcare	0.9%	-6.3%	-9.7%	-15.3%
DJ Stoxx 600	1.6%	-0.8%	-0.9%	-6.8%

YEnd Dec. (EURm)	2015	2016e	2017e	2018e
Sales	3,935	4,032	4,251	4,434
% change		2.5%	5.4%	4.3%
EBITDA	1,163	1,155	1,258	1,352
EBIT	970.3	953.5	1,042	1,122
% change		-1.7%	9.2%	7.7%
Net income	532.1	563.8	623.4	679.1
% change		6.0%	10.6%	8.9%

	2015	2016e	2017e	2018e
Operating margin	24.7	23.6	24.5	25.3
Net margin	13.5	14.0	14.7	15.3
ROE	16.1	15.4	15.4	15.2
ROCE	6.9	7.2	7.8	8.4
Gearing	112.6	97.4	81.2	66.4

(EUR)	2015	2016e	2017e	2018e
EPS	0.78	0.82	0.91	0.99
% change	-	5.7%	10.6%	8.9%
P/E	23.3x	22.1x	20.0x	18.3x
FCF yield (%)	3.8%	4.9%	4.2%	4.8%
Dividends (EUR)	0.32	0.31	0.33	0.36
Div yield (%)	1.7%	1.7%	1.8%	2.0%
EV/Sales	3.9x	3.8x	3.5x	3.3x
EV/EBITDA	13.1x	13.1x	11.8x	10.8x
EV/EBIT	15.8x	15.9x	14.3x	13.0x

Pulmaquin's Phase III results were very mixed in our view, hence our decision to reduce the PoS we applied on the compound (20% vs 50% previously) and our new FV of EUR19. We also downgraded our recommendation to SELL given the demanding valuation, as well as the negative newsflow we anticipate in the very near term (1/ Phase III results of CSL's Hizentra in CIDP by year end; 2/ BIIB and SOBI initiating a trial to evaluate the potential of Elocate in Haemophilia A with inhibitors... that would ultimately lead to a steep decline in GFS' FVIII sales if positive).

## ANALYSIS

- Aradigm yesterday published top-line results from two Phase III trials, with broadly similar designs, evaluating Pulmaquin (inhaled liposomal ciprofloxacin) in patients non-cystic fibrosis bronchiectasis with chronic Pseudomonas infections.
- **Mixed Phase III results.** We saw the dataset as pretty mixed as the primary endpoint of the ORBIT-4 study (median time to first mild, moderate or severe pulmonary exacerbation vs placebo) was met, though the benefit was far from outstanding ( $p=0.0462$ ). On the other hand, a completely different trend was shown in ORBIT-3, as the improvement was not statistically significant ( $p=0.8488$ )... and even key secondary endpoints such as the reduction in the frequency of pulmonary exacerbation showed no substantial improvement (HR: 0.87,  $p=0.3125$ ).
- **Uncertain prospects.** There is a risk the product is simply not approved with such a clinical package... which would be all the more detrimental that 1/ we saw peak sales of EUR500m by 2026 (on which we applied a 50% PoS); 2/ Pulmaquin was one of the short term assets that we considered attractive. In a less bearish scenario, the different regulators might ask for a third pivotal trial to support a conditional approval... But the commercial ramp-up is likely to be restrained with the current evidence efficacy-wise, especially when compared with those we got from macrolides for example (Wong *et al*, 2012).

## VALUATION

- **Our FV is trimmed from EUR20 to EUR19** after having reduced our PoS from 50% to 20%.
- **We also downgrade the stock to SELL vs NEUTRAL** as 1/ we see A shares' current valuation as highly demanding (20-25% premium vs the European Pharma sector); 2/ we anticipate fairly negative news flow in the next few months (pivotal results for CSL's Hizentra in CIDP that might confirm our scenario for increased competition by 2018, BIIB/SOBI announcing a new trial to evaluate Elocate in Hemophilia A with inhibitors). See our initiation report [here](#) for further details.
- **Where could we be wrong?** Phase III data are expected for Albutein in Alzheimer's disease in the next few months, and it goes without saying that the stock will react very positively should the primary endpoint be achieved. Having said that, 1/ solanezumab's recent failure proved (once again) that targeting  $\beta$ -amyloid might not be the right strategy; 2/ we ask ourselves whether the trial design really is satisfactory (solely 350 patients being enrolled whereas AD affects millions of people worldwide). So we remain cautious about this study's outcome.

## NEXT CATALYSTS

- Q4 2016: Phase III results of CSL's Hizentra (SC IG) in CIDP) + Phase III results of ROG's ACE910 in Hemophilia A with inhibitors.

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