22nd November 2016

Healthcare

Zealand

Price DKK117.00

The approval of Soliqua in the US opens a new phase for Zealand

Fair Value DKK223 vs. DKK172 (+91%) **BUY**

Bloomberg	ZEAL DC
Reuters	22Z.F
12-month High / Low (DKK)	155.0 / 87.0
Market Cap (DKK)	3,050
Ev (BG Estimates) (DKK)	2,862
Avg. 6m daily volume (000)	123.6
3y EPS CAGR	

	1 M	3 M	6 M	31/12/15
Absolute perf.	17.0%	-3.7%	5.4%	-22.8%
Healthcare	-3.5%	-6.8%	-4.7%	-13.9%
DJ Stoxx 600	-1.2%	0.0%	0.7%	-7.0%

YEnd Dec. (DKKm)	2015	2016e	2017e	2018e
Sales	165.4	255.9	320.4	510.4
% change		*54.7%*	*25.2%*	*59.3%*
EBITDA	-75.3	6.4	22.2	168
EBIT	-81.3	0.4	16.2	161.3
% change		*NS*		
Net income	-114.0	-83.9	-42.8	12.0
% change		*26.4%*	*49.0%*	*NS*

	2015	2016e	2017e	2018e
Operating margin	NM	NM	NM	NM
Net margin	NM	NM	NM	NM
ROE	NM	NM	NM	NM
ROCE	NM	NM	NM	NM
Gearing	-50.4	-80.5	-59.1	-44.2

(DKK)	2015	2016e	2017e	2018e
EPS	-4.82	-0.82	-0.22	5.13
% change	-	*83.0%*	*73.4%*	*NS*
P/E	NS	NS	NS	22.8x
FCF yield (%)	NM	NM	NM	NM
Dividends (DKK)	0.00	0.00	0.00	0.00
Div yield (%)	NM	NM	NM	NM
EV/Sales	17.7x	11.2x	9.1x	5.6x
EV/EBITDA	NS	449.9x	131.1x	17.0x
EV/EBIT	NS	7942.7x	179.8x	17.7x

Yesterday the FDA approved both Sanofi's Soliqua and Novo's Xultophy for patients with type II diabetes uncontrolled with either a basal insulin or a GLP1 analogue. Soliqua has been approved with a unique strength and a unique pen which includes 100 units/mL and 33 mcg/mL of glargine and lixi respectively and can deliver 15-60 units of glargine and up to 20 mcg of lixi once-daily. Sanofi plans to launch Soliqua in the US in January 2017 wheras Novo expects to launch Xultophy in H1 2017. The approval triggers a payment of USD25m from Sanofi to Zealand that will reduce the size of the bond.

ANALYSIS

- Soliqua has been approved by the FDA in a unique pen device containing 100 units/mL of glargine and 33 mcg/mL of lixisenatide.
- Of course, not everything is fixed with the approval of the drug and the period of negociations with payers about the right level of discount and rebate to offer to gain access to the reimbursement list in the US is no just beginning. With the simultaneous approval of Novo's Xultophy, it is fair to assume that Sanofi and Novo-Nordisk will together discuss with payers at the same time. And we know that the equation is markedly different for the two players. On one hand, Novo-Nordisk has a strong GLP1 franchise in place that is estimated to generate higher margins than insulins and that Novo has to protect, if only because semaglutide will come next. With a list price of USD16-18 per day in the US for Victoza alone and a list price of USD10-12 for Tresiba, it is difficult to imagine a price for Xultophy that is below USD20 per day. On the other hand, Sanofi has of course a strong Lantus franchise but it is no longer a growth driver since prices have started going down whereas first biosimilar (Lilly's Basaglar) is expected mid-December. Lantus is about USD10 per day but discount rate is probably close to 30%. So a price for Soliqua between USD12 and Victoza's USD16-18 would be beneficial for the mix product and margins at Sanofi while offering an attractive proposition to payers. Because Sanofi is under pressure to save as much as possible from its diabetes franchise and because Xultophy is a better product, price is key to the success of Soliqua in our view. And the objective is to take market share as quickly as possible. It is estimated that about 1 million of basal insulin takers (mainly Lantus ones) are not controlled and candidates for a fixed-dose combination. Using a net daily price of USD12, this would create a market of at least USD4bn.

VALUATION

- With the final approval now, we move our PoS from 90% to 100% (considering also the positive opinion received from the CHMP). To sit on the safe side, we have however decided to fine-tune our estimates for Lyxumia and Soliqua to factor in the tough market conditions for drugs addressing chronic diseases in general and diabetes in particular. We have lowered Soliqua's peak sales to USD1.8bn (vs USD2bn) and have included a softer ramp-up.
- However, our major influencial decision has been to align the WACC used to discount mainstream cash-flows from lixisenatide-derived products at Sanofi with that used to discount royalties (low double-digit) paid by Sanofi to Zealand, which not only makes sense but now that the drug is approved cannot be done in a different way as we are talking about a single and unique product. NPV of Soliqua with 100% PoS would therefore move up from DKK99 (with WACC of 15.6%) to DKK152 (with WACC of 6.88% i.e. Sanofi's WACC).
- All included [PS: -DKK21 – PoS: +DKK10 – WACC: +DKK62], our new FV is DKK223. We reaffirm a strong BUY on Zealand that can now safely think about how to best manage its proprietary pipeline and create value with no need to make overly difficult arbitrages.

NEXT CATALYSTS

- Today 4pm: Conference Call on the US approval of Soliqua
- January 2017: EMA decision and US launch of Soliqua

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