14th November 2016

Healthcare

Zealand

Price DKK98.50

Suliqua recommended for approval by the CHMP

Fair Value DKK172 (+75%) **BUY**

Bloomberg	ZEAL DC
Reuters	22Z.F
12-month High / Low (DKK)	155.0 / 87.0
Market Cap (DKK)	2,567
Avg. 6m daily volume (000)	119.3

	1 M	3 M	6 M	31/12/15
Absolute perf.	-4.4%	-20.2%	-16.2%	-35.0%
Healthcare	-3.5%	-8.5%	-2.6%	-13.3%
DJ Stoxx 600	-0.8%	-2.6%	0.8%	-7.7%

	2015	2016e	2017e	2018e
P/E	NS	NS	NS	8.7x
Div yield (%)	NM	NM	NM	NM

ANALYSIS

- Last week the CHMP had its monthly meeting for November and issued on Friday the list of its decisions, including the recommendations for approval to the EMA. This included a series of products to treat diabetes (second biosimilar glargine, first ultra-fast-acting insulin), among which was Suliqua, the brand name for Europe of the fixed-ratio combination of insulin glargine and lixisenatide. The sponsor responsible for the filing is Sanofi, which will market the drug in Europe, but we include this piece of news in a Zealand short note because the Danish company will receive milestone and royalty payments on sales from Sanofi and this represents a much bigger opportunity relative to its size than for Sanofi.
- Obviously Europe should not be a major opportunity market-wise because if we refer to the GLP1 market, about 60% of the market is in the US, where prices are much higher for the class. Some GLP1s have even found it tough to get good market access in some European countries and adoption is low. Could a combination with insulin change the paradigm? We doubt but maybe for intensification of treatment (the indication is limited to patients that have failed on metformin, any oral combination and basal insulin). That said, Xultophy from Novo-Nordisk is already approved in Europe and it does not seem to be a major success.
- What is more important than anything else for Zealand is to be one step closer to the market with the combination that represents the vast majority of the valuation of the whole company.

VALUATION

- Suliqua/Soliqua represents two-thirds of our FV. However Europe is only 14% of 2024 estimated sales for the drug. Now, with this CHMP recommendation, the door is more widely open for an approval in January 2017 and a launch in the first European markets shortly thereafter.
- Of course, it says little about the decision in the US because the FDA is not bound to European advice. It simply provides some confidence for the market by then.

NEXT CATALYSTS

- Around 21st November 2016: PDUFA date for Soliqua in the US - Click here to download document

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BRYAN, GARNIER & CO

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BUY ratings 56.7% NEUTRAL ratings 31.8% SELL ratings 11.5%

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