

10th October 2016

Healthcare

## Novo Nordisk

Price DKK270.30

### Unexpected delay for ultra-fast acting insulin in the US

Fair Value DKK355 vs. DKK360 (+31%)

NEUTRAL

Bloomberg	NOVOB DC
Reuters	NOVOB.CO
12-month High / Low (DKK)	404.2 / 270.3
Market Cap (DKK)	543,996
Avg. 6m daily volume (000)	2,990

	1 M	3 M	6 M	31/12/15
Absolute perf.	-11.0%	-26.1%	-26.9%	-32.4%
Healthcare	-2.8%	-5.0%	0.1%	-10.0%
DJ Stoxx 600	-3.1%	5.4%	3.5%	-7.2%

	2015	2016e	2017e	2018e
P/E	19.9x	17.4x	16.4x	15.7x
Div yield (%)	2.4%	2.6%	2.7%	2.9%

#### ANALYSIS

- Very unexpectedly, Novo-Nordisk announced on Friday after market close that it had received a complete response letter (CRL) from the FDA for its BLA for the ultra-fast acting insulin known as Fiasp. The group mentions that the FDA is asking for more information about the assay for immunogenicity and clinical pharmacology data used in the trials before completing the review. It looks like it might require some new work, if not new trials.
- This was not at all anticipated and is likely to come as an unwelcome surprise for the market at a time when there were already a lot of questions about other parts of the portfolio, including basal insulins and basal/GLP1 combination after recent payer decisions and regulatory delays in the US respectively.
- Fiasp was leading the pack in the field of ultra-fast acting insulins by about two years when compared to Lilly's BC lispro (due to enter phase III in early 2017). Obviously, this is good news for Lilly (and its partner Adocia), which – if everything has been carried out seriously – might close the gap with Novo-Nordisk by several months.

#### VALUATION

- We had expected Fiasp to come to market by the end of 2016 and this is going to be significantly delayed at least in the US (but which is the main market). That said, we cautiously took a 70% PoS and only USD80m for 2017 so the adjusted sequence of sales has a limited impact on our FV.
- Beyond numbers, sentiment is worsening about Novo-Nordisk that proves difficult to translate still very good science in growing numbers as it was used to doing in the past. We maintain our Neutral recommendation.

#### NEXT CATALYSTS

- 28th October 2016: Third-quarter results

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## Distribution of stock ratings

BUY ratings 56.5%

NEUTRAL ratings 31.8%

SELL ratings 11.7%

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