

5th September 2016

Healthcare

## Novo Nordisk

Price DKK304.80

Xultophy's PDUFA date also delayed by three months

Fair Value DKK360 vs. DKK385 (+18%)

NEUTRAL

Bloomberg	NOVOB DC
Reuters	NOVOB.CO
12-month High / Low (DKK)	404.2 / 304.8
Market Cap (DKKm)	613,430
Avg. 6m daily volume (000)	2 796

	1 M	3 M	6 M	31/12/15
Absolute perf.	-17.7%	-18.0%	-16.7%	-23.8%
Healthcare	-3.8%	-1.7%	1.6%	-7.6%
DJ Stoxx 600	4.5%	1.8%	2.8%	-4.2%

  

	2015	2016e	2017e	2018e
P/E	22.5x	19.6x	18.1x	17.3x
Div yield (%)	2.1%	2.3%	2.5%	2.6%

### ANALYSIS

- Novo-Nordisk issued a very short press release during the week-end to report that the US FDA was requiring a three-month delay in the regulatory review of Xultophy, without further details.
- It looks like the decision is very similar to the one that impacted iGlarLixi a few days ago and that referred to the pen device. At the time, it was uncertain whether both drugs would be questioned or if Sanofi would be hit alone, in particular because of a potential confusion related to the existence of two pens, a specific issue raised at the Advisory Committee meeting.
- At the ADA congress, CSO Mads Krogsgaard Thomsen stated that a requirement by the FDA to change the pen used was unlikely, but said a short delay was possible, especially to address as well as possible the situation when T2D patients switch from basal insulin to the combination, which often translates into small glucose excursions while requiring dose adjustments.
- So, with iDegLira and iGlarLixi now aligned, the FDA's decision looks like an "administrative" one that is not product-specific but relates to the pen devices used for a combination.

### VALUATION

- An approval of both drugs by the FDA in November (iGlarLixi) and December (iDegLira) looks likely. This delay is not good news for Novo-Nordisk which is having a tough time these days, but it should give Sanofi the privilege of being first to launch. This is not necessarily a gift because it will have to price the combination first instead of simply adjusting to Novo.
- In light of the recent developments within the field of diabetes and at Novo-Nordisk, the medium-term looks a touch more uncertain and therefore we are reducing growth rate to infinity from 3% (so far the highest in our sample) to 2.5%, which impacts our FV by DKK25. NEUTRAL rating reiterated.

### NEXT CATALYSTS

- 12-16th September 2016: EASD congress in Munich – SUSTAIN 6 phase III data presentation

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## Distribution of stock ratings

BUY ratings 55,3%

NEUTRAL ratings 33,3%

SELL ratings 11,3%

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