



Please find our Research on Bloomberg BRYG <GO>)

23rd May 2016

	Last close	Daily chg (%)	Chg YTD (%)
Indices			
Dow Jones	17500.94	+0.38%	+0.44%
S&P 500	2052.32	+0.60%	+0.41%
Nasdaq	4769.56	+1.21%	-4.75%
Nikkei	16736.35	+0.54%	-12.07%
Stoxx 600	338.007	+1.23%	-7.60%
CAC 40	4353.9	+1.67%	-6.11%
Oil /Gold			
Crude WTI	47.78	-0.67%	+28.44%
Gold (once)	1252.68	+0.26%	+17.91%
Currencies/Rates			
EUR/USD	1.1213	+0.07%	+3.22%
EUR/CHF	1.11265	+0.31%	+2.32%
German 10 years	0.172	-1.05%	-72.96%
French 10 years	0.511	-0.09%	-47.92%
Euribor	-0.258	0.00	+96.95%
Economic releases :			

Date 23rd-May

EUZ - Markit PMI May (51.9E) EUZ- Markit composite (53.2E) US - Manuf. PMI (51 E.)

EUZ - Consumer Confidene (-9E)

Upcoming BG events :					
Date					
24th-May	Petit Déjeuner Thématique avec J. Zelmanovitch, WIMPELCOM				
25th-May	Luxottica (BG Paris Roadshow whit IR)				
7th-Jun	Cahiers Verts de l'Economie (BG Paris Lunch)				
8th-Jun	Cahiers Verts de l'Economie (BG Paris Lunch)				
15th-Jun	GENMAB (BG Paris roadshow)				
27th-Jun	IMERYS (BG Luxembourg with CFO)				

Recent reports :

Date	
19th-May	BURBERRY Too early to sing in the rain!
13th-May	ROYAL UNIBREW Camp Blue Lake
10th-May	SOFTWARE AG French Flair at work
3rd-May	Rémy cointreau The glass is filling up
2nd-May	Moncler Good protection from chilly conditions
11th-Apr	ALTICE NUMERICABLE SFR : The time of Marketing

List of our Reco & Fair Value : Please click here to download



BG's Wake Up Call

BAYER

NEUTRAL, Fair Value UNDER REVIEW

Bayer bids for Monsanto for USD62bn in an all-cash transaction

Bayer has announced this morning that it is offering USD122 per share to acquire Monsanto in an all-cash offer that values the target at USD62bn. Bayer is expecting to generate USD1.5bn in synergies which will make the acquisition accretive by a mid-single digit percentage in year 1 and double-digit percentage in the subsequent years. The offer is not subject to a financing condition. Bayer intends to finance the acquisition by a rights issue representing about 25% of the total amount and 75% in debt. Due to strong cash-flow generation, Bayer anticipates a long-term A credit rating by agencies. 50% of Bayer's revenues would then be generated in Crop Science. We put our FV under review.

RICHEMONT

NEUTRAL vs. BUY, Fair Value CHF63 vs. CHF81 (+7%)

Visibility on short term excessively low!

While Richemont's FY 2015/16 (end-March 2016) results were slightly below expectations, what we would highlight from Friday's release is the 15% sales decline in April and consequently, the poor revenue momentum expected in the short term (at least during H1 2016/17) and the likely deleverage impact that could lead to a 19% FY 2016/17 EBIT decline, implying a 300bp narrowing in EBIT margin. This leads us to lower our estimates by 15%, hence our new FV of CHF63 vs CHF81 and our recommendation downgrade from Buy to Neutral.

SHIRE PLC

BUY Coverage initiated, Fair Value 5900p (+38%)

A rare opportunity!

We are initiating coverage of Shire with a BUY recommendation and a FV of GBp5,900 with the dawn of a transformative merger with Baxalta. Beyond the fact that we see significant upside (+45%), in our view the pressure on the share price caused by the current arbitrage strategies, along with doubts regarding the potential value creation, have created an opportunity as 1/ Shire ex-Baxalta is a strong growth story associated with an attractive valuation (P/E 2017e: 12x); 2/ we believe the merger should accretive on earnings by 2017e.

In brief...

NOVO NORDISK, How much semantic is the discussion recommended on Xultophy? GAMELOFT, The game is over as Amber Capital plans to tender its Gameloft stake to Vivendi ILIAD, Said to consider Italian mobile tie-up with Sky.

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Bayer Price EUR89.54

Healthcare

Bloomberg Reuters 12-month High / L Market Cap (EURn Ev (BG Estimates) Avg. 6m daily volu 3y EPS CAGR	n) (EURm)		137.	BAY GY BAYG.F 8 / 88.5 74,045 91,221 2 696 6.4%
	1 M	3 M	6M 31	/12/15
Absolute perf.	-18.4%	-8.7%	-29.0%	-22.7%
Healthcare	-2.0%	2.7%	-11.3%	-9.6%
DJ Stoxx 600	-3.6%	3.6%	-11.5%	-7.6%
YEnd Dec. (EURm)	2015	2016e	2017e	2018e
Sales	46,325	45,860	47,452	49,008
% change		-1.0%	3.5%	3.3%
EBITDA	10,275	10,653	11,169	11,755
EBIT	8,851	9,274	9,752	10,291
% change		4.8%	5.1%	5.5%
Net income	5,687	5,827	6,399	6,852
% change		2.5%	9.8%	7.1%
	2015	2016e	2017e	2018e
Operating margin	19.1	20.2	20.6	21.0
Net margin	12.3	12.7	13.5	14.0
ROE	25.6	22.9	22.7	21.8
ROCE	11.6	12.4	13.1	13.9
Gearing	71.0	51.8	35.6	20.9
(EUR)	2015	2016e	2017e	2018e
EPS	6.88	7.05	7.74	8.29
% change	-	2.5%	9.8%	7.1%
P/E	13.0x	12.7x	11.6x	10.8x
FCF yield (%)	5.8%	8.1%	8.7%	9.3%
Dividends (EUR)	2.50	2.60	2.70	2.80
Div yield (%)	2.8%	2.9%	3.0%	3.1%
EV/Sales	2.0x	2.0x	1.9x	1.7x
EV/EBITDA	9.2x	8.6x	7.9x	7.1x
EV/EBIT	10.7x	9.8x	9.0x	8.2x

Bayer bids for Monsanto for USD62bn in an all-cash transaction

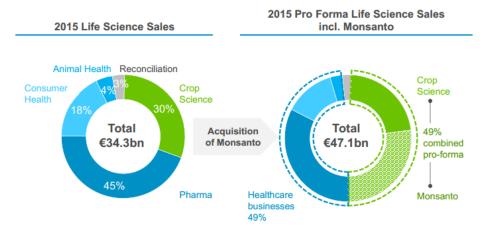
Fair Value UNDER REVIEW

NEUTRAL

Bayer has announced this morning that it is offering USD122 per share to acquire Monsanto in an all-cash offer that values the target at USD62bn. Bayer is expecting to generate USD1.5bn in synergies which will make the acquisition accretive by a mid-single digit percentage in year 1 and double-digit percentage in the subsequent years. The offer is not subject to a financing condition. Bayer intends to finance the acquisition by a rights issue representing about 25% of the total amount and 75% in debt. Due to strong cash-flow generation, Bayer anticipates a long-term A credit rating by agencies. 50% of Bayer's revenues would then be generated in Crop Science. We put our FV under review.

ANALYSIS

- Bayer is today initiating an offer to acquire Monsanto in an all-cash transaction valuing the target at USD62bn (USD122 per share), which represents a premium of about 33-38% over stock prices before rumours arose and an EBITDA multiple of 15.8x, considering also that Monsanto has net debt of between USD5bn and USD6bn in its balance sheet.
- Bayer is convinced it can offer "significant value creation" with this transaction. This factors in USD1.5bn in synergies expected in year 3. The split is not yet provided but total operating expenses at Monsanto in FY 2015 were USD4.7bn, excluding COGS and about USD12.3bn including COGS. This is a meaningful level of synergies that could nevertheless include the already presented cost savings from Monsanto's restructuring initiative that aimed to achieve USD500m in cost cutting through the creation of commercial hubs, optimising IT and supply chain and prioritising overall efforts.
- If the offer is successful, as illustrated below, and very much as expected, Bayer will generate half of its revenues in Crop Sciences.





VALUATION

- The offer is not subject to any financing condition as Bayer is confident in its ability to finance the transaction through a combination of debt (75% or about EUR41.5bn) and equity (25% or about EUR13.8bn) which is expected to be raised primarily via a rights offering. We would therefore anticipate the creation of a conditional new number of shares representing about 16% of the current number (157million).
- Two conference calls are scheduled today that should give more details on synergies and financing. Until then, we put our FV under review.

NEXT CATALYSTS

Today: Conference calls at 9am and 2pm

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Sector Team : Mickael Chane Du Hugo Solvet

Luxury & Consumer Goods

Richemont Price CHF58.95

Bloomberg Reuters 12-month High / L Market Cap (CHFn Ev (BG Estimates) Avg. 6m daily volu 3y EPS CAGR		86	CFR VX CFR.VX 9 / 59.0 33,012 24,864 1 807 2.9%	
	1 M	3 M	6 M 3	1/12/15
Absolute perf.	-11.6%	-9.3%	-24.3%	-18.2%
Pers & H/H Gds	-1.9%	2.5%	-5.0%	-0.3%
DJ Stoxx 600	-3.6%	3.6%	-11.5%	-7.6%
YEnd Mar. (EURm)	03 /15	03/16e	03 /17e	03/18e
Sales	10,410	11,076	10,540	11,250
% change		6.4%	-4.8%	6.7%
EBITDA	3,060	2,471	2,110	2,435
EBIT	2,436	2,158	1,705	2,050
% change		-11.4%	-21.0%	20.2%
Net income	1,336	1,688	1,160	1,455
% change		26.3%	-31.3%	25.4%
	03 /15	03/16e	03/17e	03/18e
Operating margin	23.4	19.5	16.2	18.2
Net margin	12.8	15.2	11.0	12.9
ROE	9.3	9.8	5.8	6.4
ROCE	23.3	18.6	11.3	12.9
Gearing	-39.6	-42.6	-45.8	-48.6
(EUR)	03 /15	03/16e	03/17e	03/18e
EPS	2.39	3.01	2.07	2.60
% change	-	26.3%	-31.3%	25.4%
P/E	22.2x	17.6x	25.6x	20.4x
FCF yield (%)	5.0%	8.3%	9.2%	10.4%
Dividends (EUR)	1.60	1.85	2.10	2.20
Div yield (%)	3.0%	3.5%	4.0%	4.2%
EV/Sales	2.3x	2.0x	1.9x	1.6x
EV/EBITDA	7.8x	9.0x	9.7x	7.6x
EV/EBIT	9.8x	10.4x	12.0x	9.0x



Visibility on short term excessively low!

Fair Value CHF63 vs. CHF81 (+7%)

NEUTRAL vs. BUY

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While Richemont's FY 2015/16 (end-March 2016) results were slightly below expectations, what we would highlight from Friday's release is the 15% sales decline in April and consequently, the poor revenue momentum expected in the short term (at least during H1 2016/17) and the likely deleverage impact that could lead to a 19% FY 2016/17 EBIT decline, implying a 300bp narrowing in EBIT margin. This leads us to lower our estimates by 15%, hence our new FV of CHF63 vs CHF81 and our recommendation downgrade from Buy to Neutral.

ANALYSIS

To briefly review FY 2015/16 sales, we would highlight that jewellery sales (35% of group sales) achieved a strong performance as expected, with an 8% sales increase, following +16% in H1, driven by the three brands (Cartier, Van Cleef & Arpels and Piaget). Watches revenues (46% of group sales) were down 8% over the FY implying a 12% decline in H2. Watches (and particularly Cartier) were clearly affected by significant negative momentum in wholesale in Asia-Pacific (and above all in Hong Kong which accounts for 13% of sales) and in the Americas. By geographical area, note the 10% revenue increase in Mainland China (9% of sales).

Sales by business					
EURm	Sales	org change (%)	as % of sales		
Watches	5,098	-8	46		
Jewellery	3,881	8	35		
Leather goods	698	9	6		
Clothing	442	5	4		
Writing instruments	382	1	4		
Group	11,076	-1	100		

Source: Company Data; Bryan Garnier & Co. ests.

- Current group 2015/16 EBIT was down 11% to EUR2.15bn, implying a margin at 19.5% (-390bp). This excluded a negative EUR97m one-off (o/w EUR67m at COGS level) in 2015/16 and a EUR234m capital gain in 2014/15. The decline in 2015/16 recurring profitability was mainly due to watchmakers (-650bp to 16.9%) and Jewellery Maisons (-320bp to 31.7%). 2015/16 gross margin was down 180bp including -110 from FX.
- For 2016/17, given the very poor start to the year (April sales down 15% same forex) and as we expect no improvement in the short term, we expect FY sales to decline 4% organically (+3% previously expected). H2 will benefit from more favourable comps (H2: -5% after +3% in H1) and should be less affected by the buy-back of Cartier watch inventories (hence +2% expected in H2 after -10% in H1). The sales decline is set to stem from Europe (-7%) while Asia-Pacific sales should be down 3%, an improvement vs 2015/16 (-13%).
- Following our sales adjustments, we have lowered our EBIT estimate by 15% to expect EUR1.7bn (-20%) and now forecast EBIT margin to narrow a further 330bp to 16.2%. While gross margin should remain virtually unchanged at 65% thanks to optimisation of production capacity (positive impact of 2015/16 retructuring costs), selling & distribution should increase mid single digit, following store openings (22 in 2015/16 and almost 10 in 2016/17) and higher rents.

VALUATION

The CFR share price has fallen 18% YTD and 11% over the past month and is trading on 2016 EV/EBIT with a 5% discount vs the peer average. Following 2016/17 adjustments, we lower our FV from CHF80 to CHF63 and have consequently downgraded our recommendation to Neutral versus Buy due to weak visibility on the short term and the lack of momentum.

NEXT CATALYSTS

5m trading statement due out on 14th September.

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Analyst : Loïc Morvan 33(0) 1 70 36 57 24 Imorvan@bryangarnier.com Sector Team : Nikolaas Faes Antoine Parison Cédric Rossi Virginie Roumage

EV/EBIT

BG's Wake Up Call

Shire PLC Price 4,281p

23rd May 2016

Bloomberg				SHP LN
Reuters			SHP.L	
12-month High / Lo			5,73	0/3,480
Market Cap (GBPm				25,397
Ev (BG Estimates) (• •			29,228
Avg. 6m daily volu	me (000)			2,018 12.3%
3y EPS CAGR				12.3%
	1 M	3 M	6 M 3	1/12/15
Absolute perf.	2.2%	12.1%	-9.1%	-8.9%
Healthcare	-2.0%	2.7%	-11.3%	-9.6%
DJ Stoxx 600	-3.6%	3.6%	-11.5%	-7.6%
YEnd Dec. (USDm)	2015	2016e	2017e	2018e
Sales	6,100	6,796	7,604	8,362
% change		11.4%	11.9%	10.0%
EBITDA	2,924	3,248	3,736	4,223
EBIT	2,785	3,078	3,538	3,989
% change		10.5%	14.9%	12.8%
Net income	2,310	2,508	2,839	3,270
% change		8.6%	13.2%	15.2%
	2015	2016e	2017e	2018e
Operating margin	45.7	45.3	46.5	47.7
Net margin	37.9	36.9	37.3	39.1
ROE	23.5	22.7	22.5	22.3
ROCE	16.3	12.8	15.0	17.9
Gearing	13.8	50.4	26.6	3.8
(USD)	2015	2016e	2017e	2018e
EPS	3.89	4.23	4.79	5.51
% change	-	8.5%	13.2%	15.2%
P/E	16.0x	14.7x	13.0x	11.3x
FCF yield (%)	6.0%	4.8%	6.4%	8.1%
Dividends (USD)	0.23	0.26	0.28	0.32
Div yield (%)	0.4%	0.4%	0.5%	0.5%
EV/Sales	6.3x	6.2x	5.3x	4.5x
EV/EBITDA	13.1x	13.1x	10.8x	8.9x

A rare opportunity!

Fair Value 5900p (+38%)

We are initiating coverage of Shire with a BUY recommendation and a FV of GBp5,900 with the dawn of a transformative merger with Baxalta. Beyond the fact that we see significant upside (+45%), in our view the pressure on the share price caused by the current arbitrage strategies, along with doubts regarding the potential value creation, have created an opportunity as 1/ Shire ex-Baxalta is a strong growth story associated with an attractive valuation (P/E 2017e: 12x); 2/ we believe the merger should accretive on earnings by 2017e.

ANALYSIS

- So rare, my precious. On a stand-alone basis, Shire is a growth story which is unparalleled in Europe. Firstly, from a quantitive perspective, EPS growth is expected to average nearly 11% in the 2015-2020e period (vs +8% for the big/specialty pharmas in Europe); but also at the qualitative level since this growth should be underpinned, in particular, by the company's growing exposure to rare diseases (well known for the pricing power it offers, in addition to strong resilience and a degree of immunity given the debate surrounding drug prices).
- The merger with Baxalta will enhance an already-exceptional growth/risk profile; our initial estimates of the EPS impact associated with the integration of this Baxter spin-off suggest that the transaction should be earnings accretive as of 2017e (+1%e then +4-5%e in the following years). In addition to the fact that the Hemophilia franchise should continue to grow despite competition from novel new therapies, in our view a portion of the consensus is underestimating the potential for the ImmunoGlobulin activites (and notably that of Hygvia).
- Initiation of coverage with a BUY recommendation and an ex-Baxalta FV of GBp5,900. The earnings dynamic in our forecasts is more than positive...and yet 1/ the share price has fallen by more than 25% over 12m (vs -13% for the STOXX Europe 600 Healthcare); and 2/ the 2017e PER currently stands at a c.30% discount relative to the rest of the sector. Note also that the stock currently trade at our worst-case valuation (GBp4,200).

VALUATION

We are initiating coverage of Shire with BUY recommendation and a FV of GBp5,900.

NEXT CATALYSTS

9.4x

11.4x

May, 27 2016: approval of the merger by both Shire and Baxalta's shareholders.

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SHIRE

13.7x

13.8x



Sector Team : Eric Le Berrigaud Hugo Solvet

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BUY

Coverage initiated

Novo Nordisk

12-month High / Low (DKK)

Avg. 6m daily volume (000)

1 M

-3.6%

-2.0%

-3.6%

2015

26.5x

1.8%

3 M

5.6%

2.7%

3.6%

2016e

23.9x

1.9%

Price DKK359.10

Market Cap (DKKm)

Healthcare

Bloomberg

Absolute perf.

Healthcare

DJ Stoxx 600

Div yield (%)

P/E

Reuters

How much semantic is the discussion recommended on Xultophy? Fair Value DKK400 (+11%)

NEUTRAL

ANALYSIS

NOVOB DC

NOVOB.CO

722,712

2 581

-10.2%

-9.6%

-7.6%

2018e

20.5x

2.2%

410 7 / 306 4

6 M 31/12/15

-6.3%

-11.3%

-11.5%

2017e

21.7x

2.1%

- 48 hours ahead of any FDA AdCom, briefing documents are posted on the FDA's website and this was the case for Xultophy last Friday as experts are due to meet tomorrow to discuss Novo's application for the fixed-dose combination of liraglutide and degludec.
- At first glance, and as is often the case, the documents posted point our weaknesses in the clinical data package submitted to the regulator. In particular, they point out what they call bias in clinical studies aimed at comparing IdegLira to the single component basal insulin degludec (Tresiba). Novo Nordisk disagrees with the statement and states that it demonstrated superiority against each of the two components of the combination. The FDA actually notes that the 26-week comparator HbA1c does not reflect a period of preceding glycemic stability and so concludes that "due to trial design concerns, [it is] not able to conclude that IdegLira is superior to IDeg".
- It is true that Novo Nordisk spent more time comparing the combination to standard basal insulin Lantus than to its own basal insulin Tresiba, because this makes more sense from a marketing standpoint. What the agency looks uncomfortable with is the concept of combining fixed doses of the two drugs whereas basal insulin usually requires careful up-titration. One of the questions to the panellists is precisely this one.
- But the central question in our view, as anticipated, is very much the one of the positioning of the drug as the first two questions relate to who should receive such a treatment i.e. naïve patients or patients having previously failed on any of the two components.

VALUATION

- We do not expect the experts to fully follow the FDA in its cautious approach to the concept of basal/GLP1 FDC. Approval should not be an issue in our view and we do not expect any need for an extra clinical trial before getting the green light.
- That said, we expect the label could restrict use to resistant patients but this is very much how both Novo-Nordisk and Sanofi presented the opportunity of their respective drugs i.e. as an "efficacious alternative to insulin intensification" as stated by Novo at its CMD 2015.

NEXT CATALYSTS

Today PM: briefing documents for Lyxumia and LixiLan - Click here to download

Eric Le Berrigaud, eleberrigaud@bryangarnier.com

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Gameloft Price EUR7.99

TMT

Bloomberg Reuters 12-month High /		GFT FP GLFT.PA 8.0 / 3.2		
Market Cap (EUR)				696
Avg. 6m daily volu	ume (000)			304.0
	1 M	3 M	6M 3	31/12/15
Absolute perf. Softw.& Comp.	7.2%	24.8%	42.4%	31.8%
SVS	-1.5%	3.2%	-3.9%	-3.9%
DJ Stoxx 600	-3.6%	3.6%	-11.5%	-7.6%
	2015	2016e	2017e	2018e
P/E	NS	36.8x	26.6x	18.5x
Div yield (%)	NM	NM	NM	NM

The game is over as Amber Capital plans to tender its Gameloft stake to Vivendi Fair Value EUR7.2 (-10%) TENDER TO THE OFFER

ANALYSIS

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- Amber Capital (a US-based hedge fund) plans to tender its entire stake in Gameloft (on 21st April, it owned 14.62% of the capital and 13.17% of voting rights) to Vivendi (which owned 29.37% of the capital and 26.47% of voting rights on 19th May). Amber's decision was made public in a statement issued on the website of French market regulator AMF last Friday.
- Gameloft should hold a board meeting in the coming days to evaluate the Vivendi offer. Note that on 1st April, the Guillemot family owned 21.63% of the capital and 29.02% of voting rights.
- With the support of Amber Capital, Vivendi would have ~44% of Gameloft's capital. It only needs a minimum of 6% for its public offer to be successful. So, the situation is now clear... The game is over.

VALUATION

We advise investors to tender their shares to Vivendi. In our view, the offer at EUR8.00 per share is very fair and stands in the middle of our estimated range of EUR7.6-8.6.

NEXT CATALYSTS

Unless the AMF decides to make a change to the calendar, the offer will expire on 27th May.

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Richard-Maxime Beaudoux, rmbeaudoux@bryangarnier.com

TMT Iliad

Said to consider Italian mobile tie-up with Sky. Fair Value EUR212 (+8%)

ANALYSIS

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- According to the Financial Times, Hutchison (3) and VimpelCom (Wind) are in talks with Iliad and Sky to address **regulatory concerns** over the merger between their local businesses. The two groups need to address worries over competition since their merger would create the largest mobile operator in Italy. Iliad and Sky have spoken to Hutchison and VimpelCom about **creating a fourth operator**, according to people with knowledge of the situation.
- We believe the merger is more likely to go through than in the UK since the two companies are in a difficult financial situation and cannot invest aggressively: 3 Italy is hardly making money, with 2015 EBITDA – CAPEX of -EUR170m, and Wind is heavily indebted with Net Debt/EBITDA of 6x.
- A tie-up between Iliad and Sky could make sense in a media/telco convergence move. Iliad could afford debt of EUR5bn to EUR6bn and an equity fuelled investment, and bring innovative pricing in a market where subscription offers, unlimited calls and 3P services are not much developed. But Iliad will need to address the question of fixed infrastructure, possibly relying on Sky's existing partnership with Fastweb, and Xavier Niel's 15% option in Telecom Italia's capital.

VALUATION

We stick to our Fair Value of EUR212 with a Neutral recommendation.

NEXT CATALYSTS

Decision from the EC on the Wind/Three merger expected by 18th August.

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Thomas Coudry, tcoudry@bryangarnier.com

7

NEUTRAL

Price EUR195.80 Bloomberg ILD FP Reuters ILD.PA 12-month High / Low (EUR) 236 3 / 175 5 Market Cap (EURm) 11,495 Avg. 6m daily volume (000) 110.6 1 M 6 M 31/12/15 3 M Absolute perf. 3.9% -12.6% -6.2% -11.0% Telecom -2.0% 1.8% -12.5% -6.9% DJ Stoxx 600 -3.6% 3.6% -11.5% -7.6% 2015 2016e 2017e 2018e P/E 35.1x 33.0x 25.6x 19.8x Div yield (%) 0.2% 0.2% 0.2% 0.2%

Healthcare

Novo Nordisk Price DKK359.10

Dissue			NC	
Bloomberg			OVOB DC	
Reuters			NO	VOB.CO
12-month High /	Low (DKK)		410.7	7 / 306.4
Market Cap (DKK	m)			722,712
Avg. 6m daily volu	ume (000)			2 581
	1 M	3 M	6 M 3	1/12/15
Absolute perf.	-3.6%	5.6%	-6.3%	-10.2%
Healthcare	-2.0%	2.7%	-11.3%	-9.6%
DJ Stoxx 600	-3.6%	3.6%	-11.5%	-7.6%
	2015	2016e	2017e	2018e
P/E	26.5x	23.9x	21.7x	20.5x
Div yield (%)	1.8%	1.9%	2.1%	2.2%

How much semantic is the discussion recommended on Xultophy? Fair Value DKK400 (+11%)

NEUTRAL

ANALYSIS

- 48 hours ahead of any FDA AdCom, briefing documents are posted on the FDA's website and this was the case for Xultophy last Friday as experts are due to meet tomorrow to discuss Novo's application for the fixed-dose combination of liraglutide and degludec.
- At first glance, and as is often the case, the documents posted point our weaknesses in the clinical data package submitted to the regulator. In particular, they point out what they call bias in clinical studies aimed at comparing ldegLira to the single component basal insulin degludec (Tresiba). Novo Nordisk disagrees with the statement and states that it demonstrated superiority against each of the two components of the combination. The FDA actually notes that the 26-week comparator HbA1c does not reflect a period of preceding glycemic stability and so concludes that "due to trial design concerns, [it is] not able to conclude that IdegLira is superior to IDeg".
- It is true that Novo Nordisk spent more time comparing the combination to standard basal insulin Lantus than to its own basal insulin Tresiba, because this makes more sense from a marketing standpoint. What the agency looks uncomfortable with is the concept of combining fixed doses of the two drugs whereas basal insulin usually requires careful up-titration. One of the questions to the panellists is precisely this one. It is not ideal and Sanofi tried and failed to make a fix-flex pen device but after all pre-mixed insulins already use fixed doses of insulins!
- But the central question in our view, as anticipated, is very much the one of the positioning of the drug as the first two questions relate to who should receive such a treatment i.e. naïve patients or patients having previously failed on any of the two components.

VALUATION

- We do not expect the experts to fully follow the FDA in its cautious approach to the concept of basal/GLP1 FDC. Approval should not be an issue in our view and we do not expect any need for an extra clinical trial before getting the green light.
- That said, we expect the label could restrict use to resistant patients but this is very much how both Novo-Nordisk and Sanofi presented the opportunity of their respective drugs i.e. as an "efficacious alternative to insulin intensification" as stated by Novo at its CMD 2015.

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Eric Le Berrigaud, eleberrigaud@bryangarnier.com

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Bryan Garnier Research Team

	Diyun	Guiller 1005		ann
Healthcare Team	Pharmaceuticals	Eric Le Berrigaud <i>(Head of Equities)</i>	33 (0) 1 56 68 75 33	eleberrigaud@bryangarnier.com
	Biotech/Medtech	Mickael Chane-Du	33 (0) 1 70 36 57 45	mchanedu@bryangarnier.com
	Medtech/Biotech	Hugo Solvet	33 (0) 1 56 68 75 57	hsolvet@bryangarnier.com
Consumer Team	Luxury/Consumer Goods	Loïc Morvan	33 (0) 1 70 36 57 24	lmorvan@bryangarnier.com
	Beverages	Nikolaas Faes	33 (0) 1 56 68 75 72	nfaes@bryangarnier.com
	Retailing	Antoine Parison	33 (0) 1 70 36 57 03	aparison@bryangarnier.com
	Luxury /Consumer Goods	Cedric Rossi	33 (0) 1 70 36 57 25	crossi@bryangarnier.com
	Food & Beverages	Virginie Roumage	33 (0) 1 56 68 75 22	vroumage@bryangarnier.com
ТМТ	Video Games / Payments	Richard-Maxime Beaudoux	33 (0) 1 56 68 75 61	rmbeaudoux@bryangarnier.com
	Telecom	Thomas Coudry	33(0) 1 70 36 57 04	tcoudry@bryangarnier.com
	Software & IT Services	Gregory Ramirez	33 (0) 1 56 68 75 91	gramirez@bryangarnier.com
	Semiconductor	Dorian Terral	33 (0) 1 56 68 75 92	dterral@bryangarnier.com
Utilities		Xavier Caroen	33 (0) 1 56 68 75 18	xcaroen@bryangarnier.com
Insurance		Olivier Pauchaut <i>(Head of Research)</i>	33 (0) 1 56 68 75 49	opauchaut@bryangarnier.com
Hotels/Business Services		Bruno de La Rochebrochard	33 (0) 1 56 68 75 88	bdelarochebrochard@bryangarnier.com
Construction/ Infrastructures Building Materials		Eric Lemarié	33 (0) 1 70 36 57 17	elemarie@bryangarnier.com
Marketing		Sophie Braincourt	33(0) 1 56 68 75 36	sbraincourt@bryangarnier.com
Market Data & Information	n Systems Manager	Eric Monnier	33(0) 1 56 68 75 63	emonnier@bryangarnier.com

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London	Paris	New York	Munich	New Delhi
Beaufort House	26 Avenue des Champs Elysées	750 Lexington Avenue	Widenmayerstrasse 29	The Imperial Hotel Janpath
15 St. Botolph Street	75008 Paris	New York, NY 10022	80538 Munich	New Delhi 110 001 Tel +91 11 4132 6062
London EC3A 7BB	Tel: +33 (0) 1 56 68 75 00	Tel: +1 (0) 212 337 7000	Germany	+91 98 1111 5119
Tel: +44 (0) 207 332 2500	Fax: +33 (0) 1 56 68 75 01	Fax: +1 (0) 212 337 7002	+49 89 2422 62 11	Fax +91 11 2621 9062
Fax: +44 (0) 207 332 2559	Regulated by the	FINRA and SIPC member		Geneva
Authorised and regulated by the	Financial Conduct Authority (FCA) and			rue de Grenus 7
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	de resolution (ACPR)			Tel +4122 731 3263
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