26th April 2016

Healthcare

Ipsen

Price EUR52.64

Cabometyx approved by the FDA two months ahead of schedule

Fair Value EUR60 (+14%) **BUY-Top Picks**

Bloomberg	IPN FP
Reuters	IPN.PA
12-month High / Low (EUR)	62.0 / 47.1
Market Cap (EURm)	4,382
Ev (BG Estimates) (EURm)	4,480
Avg. 6m daily volume (000)	80.70
3y EPS CAGR	11.6%

	1 M	3 M	6 M	31/12/15
Absolute perf.	9.3%	-2.0%	-4.7%	-13.7%
Healthcare	6.2%	-2.5%	-7.5%	-7.7%
DJ Stoxx 600	3.5%	3.1%	-8.1%	-5.2%

YEnd Dec. (€m)	2015	2016e	2017e	2018e
Sales	1,444	1,552	1,683	1,823
% change		*7.5%*	*8.4%*	*8.3%*
EBITDA	366	398	438	517
EBIT	322.5	332.1	367.2	441.0
% change		*3.0%*	*10.6%*	*20.1%*
Net income	228.0	230.8	261.1	316.9
% change		*1.2%*	*13.1%*	*21.4%*

	2015	2016e	2017e	2018e
Operating margin	22.3	21.4	21.8	24.2
Net margin	12.5	13.7	13.4	15.3
ROE	15.5	16.4	15.7	17.0
ROCE	22.6	17.1	18.4	21.4
Gearing	NM	NM	NM	NM

(€)	2015	2016e	2017e	2018e
EPS	2.78	2.81	3.18	3.86
% change	-	*1.2%*	*13.1%*	*21.4%*
P/E	18.9x	18.7x	16.5x	13.6x
FCF yield (%)	4.0%	4.4%	5.1%	6.3%
Dividends (€)	0.85	0.85	1.04	1.16
Div yield (%)	1.6%	1.6%	2.0%	2.2%
EV/Sales	3.0x	2.9x	2.6x	2.3x
EV/EBITDA	11.7x	11.3x	10.0x	8.2x
EV/EBIT	13.3x	13.5x	12.0x	9.6x

Ipsen's recently partnered drug cabozantinib was approved yesterday in the US by the FDA in 2nd line RCC, well ahead of schedule. Top-line OS data are included in the press release (HR=0.66)

ANALYSIS

- We had a clear sequence of news for Ipsen over the coming two months that should have started next Thursday with the first-quarter sales release. Then would have come the OS data from the phase III METEOR trial at ASCO early June and lastly the FDA approval of cabozantinib with a PDUFA date set for 22nd June 2016.
- But this calendar has been changed as the US agency yesterday approved the newly named Cabometyx for advanced renal cell carcinoma in second-line of treatment after first antiangiogenic therapy. By approving the drug two months ahead of schedule, the FDA is sending a strong sign of confidence in the clinical data package that Exelixis had submitted at the beginning of the year. As a reminder, the drug received fast-track designation and breathrough therapy designation and was therefore soon been detected as a true innovation in the field of oncology and for the time in RCC.
- In the same press release, Exelixis also disclosed headline clinical data from the METEOR study in terms of overall survival (OS). So far, only median PFS had been presented at the ECC/ESMO meeting in Vienna last September (showing a significant improvement from 3.8 months with everolimus to 7.4 months with cabozantinib). And so median OS with Cabometyx was 21.4 months compared to 16.5 months with everolimus (HR=0.66, p=0.0003). Obviously this data will be compared with that obtained from nivolumab in the CheckMate-025 study i.e. a median OS of 25.0 months vs 19.6 months for the same comparator (p=0.002) i.e. a 27% risk reduction. The complexity relies on the performance of the comparative arm in the two studies which is quite different so that in absolute terms, nivolumab is better but in relative terms, cabozantinib improves survival more significantly.
- In the end, as we said in our note dated 29th March 2016 ("Cabozantinib makes Ipsen a different story"), we do not see Opdivo and Cabometyx fighting head to head for the same patients. Other studies are ongoing in first-line and in combination and we see both products taking the lead at the expense of existing drugs like Afinitor, Sutent or Votrient. Short-term, it is going to be a question of physician's preference and a mix of efficacy perception, patient selection, safety profile and treatment price. We think there is room for two in this segment.
- In the context of a noisy and still highly productive IO segment which particularly includes nivolumab and avelumab in RCC, it is important that Exelixis last week confirmed that OS data for cabozantinib would be presented at an oral session of the ASCO meeting on 5th June 2016. Not only will the METEOR full phase III results be presented but also posters of some of the subgroup analysis like patients with bone mets or patients pre-treated with another TKi and a PD-1 inhibitor. Note that Exelixis has already scheduled a conference call to discuss the data presented at ASCO on 5th June 2016at 7.30pm EDT.
- As for Ipsen, it is good to see that things are developing well in the US but obviously the acquired rights are ex-North America and Japan. In Europe, the filing has been accepted and granted accelerated assessment which suggests a final approval in September whereas the launch is expected to take place in the first markets in early 2017 when the sales force is recruited and trained.

VALUATION

- So far there is nothing to add to our base-scenario that was based on positive OS data and 100% PoS in RCC. New clinical data of interest for Ipsen are in first-line RCC and in HCC but this is expected to be presented late in 2016/early 2017.

NEXT CATALYSTS

- 28th April 2016: First-quarter sales (CS is EUR374m and we do not expect a beat here)

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