

Ablynx

Price EUR11.51

A first taste of ALX-0061's best-in class profile

Fair Value EUR18 (+56%)

BUY

Bloomberg	ABLX.BB
Reuters	ABLX.BR
12-month High / Low (EUR)	16.1 / 10.4
Market Cap (EURm)	700
Ev (BG Estimates) (EURm)	852
Avg. 6m daily volume (000)	187.2
3y EPS CAGR	15.0%

	1 M	3 M	6 M	31/12/15
Absolute perf.	-15.1%	-11.6%	-25.1%	-27.7%
Healthcare	1.4%	8.2%	-5.2%	-5.4%
DJ Stoxx 600	-5.0%	-1.2%	-9.7%	-11.4%

YEnd Dec. (EURm)	2015	2016e	2017e	2018e
Sales	77.5	81.6	39.6	54.2
% change		5.2%	-51.4%	36.7%
EBITDA	-15.6	-21.9	-64.3	-44.4
EBIT	-17.0	-23.3	-65.0	-45.4
% change		-37.6%	NS	30.2%
Net income	-54.5	-60.9	-102.6	-83.0
% change		-11.7%	-68.4%	19.1%

	2015	2016e	2017e	2018e
Operating margin	-21.9	-28.6	-164.1	-83.8
Net margin	-70.3	-74.7	-258.9	-153.1
ROE	-195.4	184.5	75.7	38.0
ROCE	NM	NM	NM	NM
Gearing	NM	NM	NM	NM

(EUR)	2015	2016e	2017e	2018e
EPS	-1.01	-1.13	-1.90	-1.53
% change	-	-11.7%	-68.4%	19.1%
P/E	NS	NS	NS	NS
FCF yield (%)	NM	NM	NM	NM
Dividends (EUR)	0.00	0.00	0.00	0.00
Div yield (%)	NM	NM	NM	NM
EV/Sales	8.0x	10.4x	21.3x	15.6x
EV/EBITDA	NS	NS	NS	NS
EV/EBIT	NS	NS	NS	NS

Ablynx released positive phase IIb results for ALX-0061 (vobarilizumab) monotherapy in severe RA patients with ACR20, 50 and 70 scores of up to 81%, 49% and 24% respectively and up to 41% of patients in clinical remission at 12 weeks. Safety profile is clean. Results from the second phase IIb trial (vobarilizumab + MTX) are expected in the upcoming weeks and should be followed by AbbVie's decision whether or not to in-license the product candidate. Vobarilizumab, which is key for AbbVie's post-Humira period in our view, is not taken into account in current share price.

ANALYSIS

- Results from this first phase IIb study are very encouraging with the highest ACR20, ACR50 and ACR70 responder rates of up to 81%, 49% and 24% respectively and up to 41% of patients in clinical remission at 12 weeks. The latter results were reached in the groups benefitting from the Q2W dosing (see detailed results below). It is hard to directly compare vobarilizumab (ALX-0061) to tocilizumab as the trial was not powered for it, however, we would note that 1/ the vobarilizumab Q4W dose group achieved results consistent with tocilizumab with an improved dosing regimen (once monthly vs. one a week) and that 2/ the vobarilizumab Q2W high dose group showed improved efficacy over tocilizumab, especially with 41% of patients in remission at 12 weeks vs 27%.
- Safety wise, vobarilizumab confirms its best-in-class profile, which we already had the opportunity to highlight in our report (please [see here](#)). 2.1% of vobarilizumab's patients discontinued treatment due to AEs vs 6.3% for the tocilizumab group. SAEs occurred in 0.5% of voba patients vs. 3.1% for tocilizumab we would pay attention to neutrophil count (possibility of serious infections) whom led to discontinuations in both groups. Roll over rate in the open-label follow-up is high and stands at 91% of the eligible patients.
- These results from the first trial of vobarilizumab phase IIb program assessed safety and efficacy of SC IL-6R product candidate, vobarilizumab, as a monotherapy in 251 severe RA patients. The compound was tested at three different doses (150mg/Q4W, n=62; 150mg/Q2W, n=62; 225mg/Q2W, n=63) over a 12 week treatment course in either a 1L or 2L setting i.e. patients naïve to MTX or non-responder to MTX respectively. Note that the study was not powered to demonstrate any statistical significance over tocilizumab (Roche, Actemra; n=64) which constituted the fourth group of the trial.

	ALX-0061 150mg/Q4W (n=62)	ALX-0061 150mg/Q2W (n=62)	ALX-0061 225mg/Q2W (n=63)	tocilizumab 162mg/Q1W (n=60) or /Q2W
ACR20	73%	77%	81%	78%
ACR50	44%	37%	49%	45%
ACR70	16%	24%	21%	23%
improvement in HAQ-DI score	65%	68%	71%	72%
DAS28 remission	26%	27%	41%	27%
DAS28 low disease activity + remission	42%	57%	60%	44%

Source : Company Data.

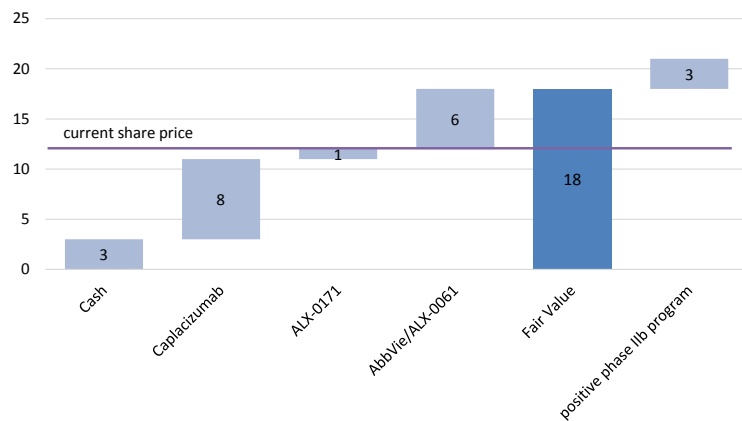
- We have a good taste of Ablynx' IL-6R best-in-class profile, ahead of the readout of the second phase IIb trial which compares vobarilizumab as an add-on to MTX vs. placebo. Results from this study are expected in the coming weeks and should trigger the beginning of AbbVie's opt-in period. Should the big pharma decides to opt-in, Ablynx would be eligible for a USD75m milestone payment.



- While vobarilizumab would not be the first IL-6 to reach the market, we believe that 1/ its best-in class safety profile and 2/ AbbVie's strong commercial capabilities should be decisive in making it a blockbuster. Our non-risk adjusted peak sales stands at EUR1.5bn. We see vobarilizumab as key in the durability of AbbVie's RA franchise, with Humira coming off patent in 2018. As a reminder, Ablynx' partner has no IL-6 developed in-house and our research showed that AbbVie might have already started to work on the autoinjector for vobarilizumab.

VALUATION

- We reiterate our BUY rating and EUR18 fair value.
- ABLYNX is in our Top Pick list for Q3.
- **Vobarilizumab is not taken into account in the current share price!** While we do not move our PoS yet as we prefer to wait for complete results from the phase IIb program expected in the upcoming weeks, note that increasing our PoS from 40% to 60% would add EUR3 to our (which would add EUR3 to our fair value).



NEXT CATALYSTS

- **Today 4:00pm CET/10:00am EDT: Conference call on trial's results (+32 2 402 30 92; access code 6440754).**
- Q3 2016: results of ALX-0061's placebo controlled phase IIb trial.
- August 25th: H1 results

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Distribution of stock ratings

BUY ratings 72%

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