

## Ablynx

Price EUR12.25

## Feedback from roadshow with CEO: the tip of the iceberg

Fair Value EUR18 (+47%)

BUY

Bloomberg	ABLX.BB
Reuters	ABLX.BR
12-month High / Low (EUR)	16.1 / 9.1
Market Cap (EURm)	671
Ev (BG Estimates) (EURm)	823
Avg. 6m daily volume (000)	170.0
3y EPS CAGR	15.0%

We hosted ABLYNX' Roadshow in Paris and have returned increasingly confident in the company's upcoming catalysts. CEO, Edwin Moses provided details regarding the filing strategy for Capla and ongoing interactions with ABBV for ALX-0061. Early stage programmes and opportunities confirm that the company's pipeline is significantly undervalued.

## ANALYSIS

- Results from the Caplacizumab HERCULES phase III trial that should support the US filing are well on track and are expected towards H2 2017, with roughly 2/3rds of the 80 centers opened (EU filing for conditional approval in H1 2017). We believe that two recent events should support the company's filing strategy. Firstly, the publication and supportive editorial in the NEJM in Feb. 2016 should help to gain further recognition from KOL and educate both regulators and physicians for which treatment regarding acquired Thrombotic Thrombocytopenic Purpura (aTTP, rare disorder of blood coagulation) are not standardised in each and every treatment center yet. Secondly, and following the nomination of a new CMO (Dr. Robert K. Zeldin, ex-Merck & Co and Novartis) in Nov. 2016, a post-hoc analysis on the TITAN trial which already released positive results in 2014 has been carried out. The endpoint of this post-hoc analysis is a composite endpoint of adverse events observed during the phase II trial (death, TTP recurrence, AMI ect.), which highlights the statistical significance between the active and placebo groups, if it had been used as a prospective one (p=0.006). In the case of an orphan disease with a high unmet medical need, we consider this data should not be overlooked by the regulator and might ease interaction (although not representing the backbone of the filing case). As a reminder, we would expect Ablynx to retain the full value of the product. The stand-alone strategy to be adopted should be based on a hybrid sales organisation (30-40 direct sales reps and 60-70 sales reps via a contract sales organisation).

	1 M	3 M	6 M	31/12/15
Absolute perf.	17.2%	-11.3%	1.9%	-23.0%
Healthcare	6.7%	-4.4%	-7.1%	-9.7%
DJ Stoxx 600	10.3%	-1.4%	-2.5%	-5.8%

YEnd Dec. (EURm)	2015	2016e	2017e	2018e
Sales	77.5	81.6	39.6	54.3
% change		5.2%	-51.4%	37.0%
EBITDA	-15.6	-21.9	-64.3	-44.3
EBIT	-17.0	-23.3	-65.0	-45.3
% change		-37.6%	NS	30.4%
Net income	-54.5	-60.9	-102.6	-82.9
% change		-11.7%	-68.4%	19.2%

	2015	2016e	2017e	2018e
Operating margin	-21.9	-28.6	-164.1	-83.4
Net margin	-70.3	-74.7	-258.9	-152.7
ROE	-195.4	184.5	75.7	37.9
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%	19.2%
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	7.6x	10.1x	20.6x	15.1x
EV/EBITDA	NS	NS	NS	NS
EV/EBIT	NS	NS	NS	NS

Component	Caplacizumab N=35	Placebo N=37
Death	0	2
TTP recurrence	3	11
Acute myocardial infarction	0	2
Cardiac failure	0	1
Deep venous thrombosis	0	2
Ischaemic stroke	0	1
Pulmonary embolism	1	1
<b>TOTAL</b>	<b>4* (11%)</b>	<b>16* (43%)</b>

\* A subject may have experienced more than one event

Had the composite endpoint been prospectively defined, the difference between both groups would have been statistically significant (post-hoc nominal p-value of 0.006).

- ALX-0171 phase IIa trial in RSV-infected infants should read out in Q2. As a reminder, the inclusion age has been lowered to 1 month which enabled Ablynx to recruit an extra cohort of infants aged 1 to 5 months. Edwin Moses seemed excited about the opportunity for Ablynx to penetrate the RSV market which features a high unmet medical need. High differentiation vs. available treatments or those in development (nebulisation) as well as the potential to address three other market subsegments reassured us as to the product's ability to reach peak sales of EUR1.3bn (BGe). Indeed, beyond the hospitalised infants being targeted by the company at the moment (BGe 214k hospitalizations / year, US+Eu+Japan), three other populations might be of interest. Hospitalised elderly people as well as at-home infants and the elderly. Note that although the company could address the first population on a standalone basis, a partner might be needed to reach the "at-home" market. Initiating clinical trials in this setting could maximise the value of a potential commercialisation/development deal. Each other market subsegment could be valued at around EUR1-2bn.
- AbbVie's potential opt-in decision for ALX-0061 in RA is expected to occur in Q4, i.e. after publication of phase IIb results for both the monotherapy and combination with MTX trials expected in the summer. Recently published results which favourably compared Sarilumab (Sanofi/Regeneron IL-6R) to adalimumab highlighted the need for ABBV to have an IL-6 compound to be able to face tough competition in the RA space and Humira going off-patent. We would expect ALX-0061 to differentiate on 1/ efficacy with ACR50 scores showing responder rate of 63% and 75% at the 1mg/kgQ4W and 3mg/kgQ4W doses in phase IIa trial i.e. results +/-25% superior to other IL-6 compounds marketed or in development. 2/ safety, as no LDL increase nor neutropenia



has been observed in phase IIa. Milestone upon in-licensing from ABBV would be USD75m. Will the large biotech be willing to throw some sand into the wheels of its future BD activities with another opt-out, should ALX-0061 results compare well with the competition?

- Partner Merck KGaA should release phase IIa results from anti-IL-17A/F in psoriasis shortly. We would wait for the results before integrating any potential from the product, as psoriasis has become a highly competitive market.
- Early programmes should still be in the spotlight, especially the partnership with Merck & Co in Immuno-oncology. Exclusivity in I-O allows for transparency and rapid interections in between the two companies. Next milestones might well be the announcement of pre-IND studies in late 2016/early2017 (~12 months before the first compound reach the clinic). Recall that Keytruda was brought to the market 4-5 years following initiation of phase I trial and that although being guess/examples at the moment, the robustness of Ablynx' nanobodies could features "exotic" administration pathways in I-O such as nebulization in NSCLC or cream in melanoma.

#### VALUATION

- We reiterate our BUY rating and EUR18 Fair Value.
- Cash burn for the year is expected to be within the EUR65-75m range (cash position by 2015 year end was EUR236.2m)

#### NEXT CATALYSTS

- **Q1/Q2 2016:** phase Ib results from anti-IL17A/F in psoriasis (Merck KGaA) and results from phase IIa for ALX-0171 in RSV-infected infants.
- **Q3 2016:** ALX-0061 phase IIb results (MTX combo and monotherapy trials).
- **H2 2016:** ABBV's opt-in decision for ALX-0061 and initiation of phase IIb for ALX-0171 in RSV

2016	2017
<ul style="list-style-type: none"> <li>• <b>Q1 2016</b> <ul style="list-style-type: none"> <li>- Phase I start with VEGF/Ang2 (BI) - €8M ✓</li> <li>- publication of data from TITAN study in the NEJM ✓</li> </ul> </li> <li>• <b>Q2 2016</b> <ul style="list-style-type: none"> <li>- Phase I/IIa results with ALX-0171 (53 RSV-infected infants)</li> </ul> </li> <li>• <b>Q3 2016</b> <ul style="list-style-type: none"> <li>- ALX-0061 results from Phase IIb monotherapy study</li> <li>- ALX-0061 results from Phase IIb combination study</li> <li>- start follow-up study with HERCULES patients</li> </ul> </li> <li>• <b>Q4 2016</b> <ul style="list-style-type: none"> <li>- opt-in decision by AbbVie for ALX-0061 in RA</li> <li>- start Phase II dose-ranging study of ALX-0171</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• <b>Caplacizumab (aTTP)</b> – wholly-owned <ul style="list-style-type: none"> <li>- filing for conditional approval in Europe (H1)</li> <li>- HERCULES Phase III study results (H2)</li> </ul> </li> <li>• <b>ALX-0061 (RA)</b> – AbbVie have an option <ul style="list-style-type: none"> <li>- potential start of Phase III RA study (H2)</li> </ul> </li> <li>• <b>ALX-0171 (RSV)</b> – wholly-owned <ul style="list-style-type: none"> <li>- complete recruitment of Phase II dose-ranging study (H2)</li> </ul> </li> <li>• <b>Immuno-oncology</b> – with Merck &amp; Co., Inc. <ul style="list-style-type: none"> <li>- start of multiple IND enabling studies</li> <li>- pre-clinical milestones</li> </ul> </li> </ul>
<p><b>PLUS</b></p> <ul style="list-style-type: none"> <li>• Anti-IL-17A/F (psoriasis) – with Merck KGaA <ul style="list-style-type: none"> <li>- results of Phase Ib study (40 patients)</li> </ul> </li> <li>• Start clinical studies with partners <ul style="list-style-type: none"> <li>- up to 3 additional Phase I studies</li> </ul> </li> <li>• Pre-clinical milestones</li> </ul>	<p><b>PLUS</b></p> <ul style="list-style-type: none"> <li>• BI starts Phase II with anti-VEGF/Ang2 (BI)</li> <li>• Merck KGaA starts Phase II in psoriasis with anti-IL-17A/F</li> <li>• up to 6 additional Phase I/II starts (internal + partnered)</li> </ul>

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