

## COMPANY NOTE

Target | Estimate Change

Belgium | Healthcare | Biotechnology

20 November 2017

# Jefferies

## Ablynx (ABLYX BB) Impressive caplacizumab Phase III Sets the Stage for New aTTP Standard-of-Care

### Key Takeaway

**Positive Phase III data further boost our belief caplacizumab for rare blood disorder aTTP is a potential game-changer for Ablynx. Our probability rises to 90%, with price and penetration also raised, as it may become a standard-of-care, hiking the PT to €29/share (\$34/ADS) suggesting substantial potential upside as capla's value seems to remain underappreciated. ALX-0171 for RSV and numerous partnered assets could also drive upside. Reiterate Buy.**

**HERCULES hits the mark:** Caplacizumab met the primary endpoint and two key secondary measures in the Phase III HERCULES study for acquired thrombotic thrombocytopenic purpura (aTTP), demonstrating a highly relevant clinical benefit, in our view. The drug significantly curtails costly plasma exchange, a risky procedure, reduces the risk of exacerbations, and protects organ damage, providing a window for physicians to resolve the underlying disease. These pivotal data confirm the earlier Phase II TITAN publications, with the safety profile also as expected. We view the results to be near "best" case, hence boost our probability to 90% from 60%, underscoring our confidence in future regulatory approvals. We expect EU conditional approval during 1H18E, with filing to FDA anticipated shortly for 1H19E US launch. Commercialising capla itself we envisage highly profitable \$500m (from \$400m) WW peak sales from 70% penetration, assuming it is widely adopted as a standard-of-care, for a €21/share NPV.

**Pipeline has significant optionality:** ALX-0171 Phase IIb RSV results are anticipated 2H18E and as a fully-owned asset could then crystallise significant value for Ablynx if data are positive, in our view. Phase II results for vobarilizumab in systemic lupus erythematosus are expected 1H18E, triggering an opt-in decision by AbbVie, with re-partnering the RA indication on hold until after these data. Focus partnered programmes include two Nanobody drugs from the I-O collaboration with Merck likely to enter the clinic next year.

**Funded to crystallise value:** Our forecasts suggest €281m cash at end-Sep, plus \$230m gross proceeds from the recent US IPO, should be sufficient to reach 2020E breakeven assuming capla success.

### Valuation/Risks

Our €29/\$34 Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for caplacizumab, ALX-0171 and vobarilizumab, plus Net Cash. Risks include: (1) efficacy, safety or regulatory setbacks; (2) need to execute on out-licensing and alliances; and (3) clinical trial failures or delays.

EUR	Prev.	2016A	Prev.	2017E	Prev.	2018E	Prev.	2019E
Rev. (MM)	--	85.2	--	57.5	71.9	67.7	110.6	131.9
EV/Rev		13.0x		19.2x		16.3x		8.4x
EBIT (MM)	--	(28.6)	(62.2)	(63.0)	(77.7)	(81.9)	(52.1)	(35.4)
EV/EBIT		NM		NM		NM		NM
Cash Position	--	233.8	171.4	351.0	84.9	260.4	24.5	217.6
<b>EPS</b>								
FY Dec	--	(0.61)	(1.08)	(1.06)	(1.35)	(1.17)	(0.94)	(0.53)
FY P/E		NM		NM		NM		NM
USD	Prev.	2016A	Prev.	2017E	Prev.	2018E	Prev.	2019E
FY Dec	--	(0.68)	--	(1.20)	--	(1.37)	--	(0.62)
FY P/E		NM		NM		NM		NM

**BUY**

Price target €29.00  
(from €19.00)  
Price €17.60^  
ADR Price target \$34.00  
ADR Price \$21.14^

Bloomberg BRU: ABLX BB  
Bloomberg OTC: ABLX

### Financial Summary

Book Value (MM):	€103.1
Book Value/Share:	€1.38
Net Debt (MM):	(€208.6)
Cash & ST Invest. (MM):	€208.6

### Market Data

52 Week Range:	€18.28 - €8.85
Total Entprs. Value (MM):	NM
Market Cap. (MM):	€1,314.7
Insider Ownership:	3.5%
Shares Out. (MM):	74.7
Float (MM):	68.8
Avg. Daily Vol.:	413,881

**Peter Welford, CFA \***

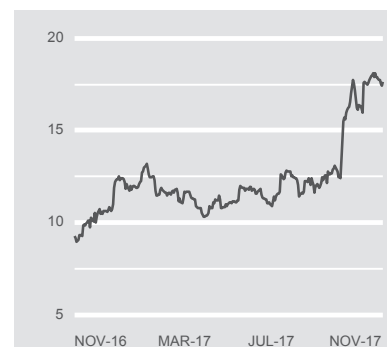
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### Price Performance



^Prior trading day's closing price unless otherwise noted.

## Scenarios

### Base Case

- We are optimistic lead product caplacizumab for rare blood disorder aTTP has the potential to transform Ablynx. The drug represents the most important contributor to our valuation.
- Numerous other pipeline programmes from the proprietary Nanobody platform could also crystallise value, in particular ALX-0171 for RSV infections. Partnered programmes should also generate licensing income.
- Price Target €29 per share (\$34 per ADS) comprises probability-adjusted NPVs for caplacizumab, ALX-0171 and vobarilizumab in SLE, plus Net Cash.

### Upside Scenario

- Caplacizumab European EMA and US FDA approvals for aTTP could add c.€2/share.
- Positive vobarilizumab data in SLE and an opt-in decision by AbbVie could add c.€1/share, with a potential incremental €2/share if a new partner or AbbVie initiates Phase III in the RA indication.
- Positive results from the ALX-0171 Phase IIb trial in RSV infected infants could increase our sum-of-the-parts valuation by at least €2/share.
- Together these potential catalysts could boost our NPV derived Price Target to around €36/share (\$42/ADS).

### Downside Scenario

- Caplacizumab efficacy or safety concerns by regulatory authorities could be detrimental to our valuation, removing at least €16/share.
- If the Phase II vobarilizumab study in SLE fails this could lower NPVs by c.€1/share.
- ALX-0171 efficacy or safety uncertainties in Phase IIb trial could remove around €3/share.
- These setbacks could reduce our NPV derived Price Target to c.€9/share (\$11/ADS).

## Investment Thesis / Where We Differ

- Around €209m Cash at end-September 2017, plus \$230m gross proceeds in a US IPO, should be sufficient to reach 2020E potential breakeven, assuming successful launches of caplacizumab.
- Given management's track record executing Nanobody technology deals we expect our License Revenue estimates to prove conservative.

## Catalysts

- US caplacizumab filing for aTTP around 1H18E and EU conditional approval
- Phase II SLE results for vobarilizumab during 1H18E, triggering AbbVie's opt-in decision
- Phase IIb ALX-0171 results in RSV infected infants in 2H18E
- Partner Merck initiating Phase I trials with two I-O Nanobody drugs during 2018E
- Future potential Nanobody platform licensing deals and achieving milestones in existing alliances

## Long Term Analysis

### Long Term Financial Model Drivers

<b>2016-21E Revenue CAGR</b>	<b>+27%</b>
2016 Net Cash (€m)	129
2017E Net Cash (€m)	247
2018E Net Cash (€m)	156

## Reiterate Buy; Price Target +53% to €29

**Impressive positive Phase III HERCULES data for lead product caplacizumab in rare blood disorder aTTP underscore our confidence in regulatory approvals. We continue to believe caplacizumab is a potential game-changer for Ablynx that remains largely underappreciated by investors, despite the highly profitable commercial opportunity in this orphan disease. Results from the Phase IIb RESPIRE study for wholly-owned inhaled anti-RSV Nanobody ALX-0171 by 2H18E could potentially trigger a lucrative partnership deal. We remain cautious on the commercial prospects for anti-IL-6R vobarilizumab given the highly competitive landscape of biologics targeting IL-6, in addition to the already crowded market of approved drugs and novel small molecules in clinical development. Importantly the numerous other early-stage alliances and the Nanobody discovery platform can all crystallise incremental value, in our view. Notably the broad immuno-oncology collaboration with Merck (MRK, \$55, Hold) could generate substantial future income given potential milestones total over €5.7bn. We reiterate our Buy rating with the Price Target hiked +53% to €29 per share (\$34 per ADS) on boosting our probability of commercial success for caplacizumab to 90% from 60%, in addition to raising the estimated price and peak penetration rates.**

## Caplacizumab opportunity undervalued

- **Peak sales:** \$500m from \$400m in 2024E after launch mid-2018E EU and 1H19E US assuming 70% from 60% peak penetration
- **NPV:** c.€21 per share assuming a 90% from 60% probability of success
- **News flow:** US filing and possible European conditional approval in 1H18E; Potential presentation of detailed Phase III HERCULES data at the ASH conference, 8-12 December

Caplacizumab is Ablynx's most advanced project and promises to be the first therapeutic approved for acquired thrombotic thrombocytopenic purpura (aTTP), potentially transforming the treatment paradigm for this rare disorder. With limited competition on the market or in development pipelines, orphan drug designation by both the FDA and EMA, plus FDA Fast Track, this represents a significant commercial opportunity, in our view. We forecast \$500m global peak sales from 70% penetration of aTTP patients treated with plasma exchange assuming caplacizumab is widely adopted as a standard-of-care. This suggests a c.€21/share NPV at a 90% probability, representing the most important contributor to our sum-of-the-parts and a key share price catalyst.

In Europe Ablynx is pursuing conditional approval of caplacizumab based on the TITAN Phase II results. The marketing authorisation application was submitted to the EMA on 6 February, for potential approval in 1H18E. We envisage US filing soon based on the positive HERCULES Phase III trial. We forecast caplacizumab launch around mid-2018E in Europe and 1H19E in the US.

### Impressive Phase III HERCULES results near "best" case

Caplacizumab met the primary endpoint with a statistically significant reduction in the time to platelet count response (rate ratio 1.55;  $p < 0.01$ ); median 2.69 vs. 2.88 days. Patients receiving the drug were 1.55x more likely to achieve platelet count response at any given time point versus those on placebo. This positive outcome supports the result achieved in the Phase II TITAN trial (RR=2.197;  $p=0.013$ ) and confirms caplacizumab should prevent further microvascular thrombosis.

Importantly the first two key secondary endpoints were also met, demonstrating the drug's highly relevant clinical benefits, in our view, likely facilitating discussions with payers for pricing and reimbursement.

- The composite endpoint was reduced by 74% ( $p < 0.0001$ ), largely driven by substantially fewer recurrences of aTTP with caplacizumab (3 vs. 28 events). The composite was defined as the proportion of subjects with aTTP-related death, a recurrence of aTTP, or at least one treatment-emergent major thromboembolic event during the study drug treatment period. We note there were six patients with at least one treatment-emergent major thromboembolic events in both arms, potentially as on recurrence of aTTP subjects in the placebo cohort could receive open label caplacizumab.
- Recurrences of aTTP in the period until 28 days after the last dose were 67% lower in the caplacizumab arm versus placebo, with 9 vs. 28 subjects. Of note six of the nine recurrences in the caplacizumab cohort were during the follow-up period, all in patients with ADAMTS-13 still below 10%, whereas all occurred during the treatment period on placebo. 4/6 patients on caplacizumab with aTTP recurrence received the drug for the maximum duration per protocol. We believe this demonstrates while on caplacizumab patients are protected from recurrence, enabling the physician to address the underlying disease during this time (e.g. with immunosuppressants).
- There were no cases of refractory aTTP in the caplacizumab cohort compared to three patients treated with placebo ( $p = 0.057$ ), just missing statistical significance given the lower number of events. Refractory disease is defined as the absence of platelet count doubling after 4 days of standard treatment and  $LDH > ULN$ .
- There was a trend to faster normalisation of three organ damage biomarkers ( $LDH \leq 1 \times ULN$ , cardiac Troponin I (cTnI)  $\leq 1 \times ULN$ , and serum creatinine  $\leq 1 \times ULN$ ) in the period until 28 days after the last dose.

The safety profile of caplacizumab was broadly as expected, with serious treatment-emergent adverse events (TEAEs) more common in the placebo cohort given the higher recurrence of aTTP. As expected given its mechanism of action, bleeding-related TEAEs were more frequent with caplacizumab (66.2% vs. 49.3%) but most were mild-moderate in severity, with TESAEs on drug mostly epistaxis (nose bleeds). There were three deaths in the placebo cohort and none in the caplacizumab group during the treatment period, with one death in the drug arm on follow-up due to cerebral ischaemia assessed by the investigator to be not related to therapy. We note across both the TITAN and HERCULES trials' treatment periods there have been five deaths on placebo versus none on caplacizumab, an encouraging sign, albeit based on few events.

The Phase III HERCULES trial for caplacizumab in aTTP began in September 2015. The initial target enrolment of 92 was achieved, and the trial subsequently expanded to include 132 patients, with 145 subjects finally enrolled by May 2017 across over 80 sites worldwide. This double-blind placebo-controlled study randomised patients 1:1 to receive daily plasma exchange (PEX) together with either caplacizumab or placebo. Caplacizumab was dosed as a 10mg i.v. bolus followed by 10mg subcutaneous daily during PEX and for an additional 30 days, similar to the earlier Phase II TITAN trial. Patients who relapse post-treatment or have an exacerbation post-PEX can restart daily PEX and open label caplacizumab, with a 3-year follow-up period planned.

### **Retaining commercial rights in key markets to maximise value**

After reviewing several partnering options for caplacizumab, management decided 2H15 to lead commercialisation in the US and Europe. We believe this is an optimal strategy to maximise value, albeit carrying greater execution risk, given aTTP is a rare orphan indication predominantly treated by only a subset of leading haematologists at select hospitals in each country and relatively few key opinion leaders (KOLs).

In November 2014, Ablynx announced it had successfully demonstrated bioequivalence between liquid and lyophilised formulations of caplacizumab in a Phase I trial. The lyophilised form should be more convenient than the liquid preparation of caplacizumab,

Lyophilised formulation is being used in the Phase III trial

which was used in TITAN, as it can be stored and transported at 5°C. This lyophilised formulation was used in the Phase III trial and will be used for future commercialisation. Importantly, we note the lyophilised version could allow for self-administration by the patient in the home setting.

### Highly profitable opportunity that could transform Ablynx

We forecast 70% caplacizumab penetration of an estimated 1,900 US aTTP patient episodes and nearly 5,000 in other geographies for \$500m WW peak sales, assuming \$128k and €68k average revenue per treatment, respectively. Commercialising caplacizumab itself, the drug could represent a highly profitable opportunity for Ablynx to become a fully integrated biopharmaceutical company.

### Additional indications under investigation

Preclinical data from non-human primate trials of caplacizumab for reperfusion injury after embolic stroke could be presented later this year, potentially demonstrating the drug can reduce reperfusion injury after thrombectomy. If these data are supportive then a Phase II trial may be initiated.

**Table 1: Caplacizumab sales model**

(EUR millions Dec YE)	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
US Population (m)	321.9	324.1	326.4	328.7	331.0	333.3	335.6	338.0	340.3
% Incidence of Acquired TTP Events	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%
US TTP Patient Events	1,931	1,945	1,958	1,972	1,986	2,000	2,014	2,028	2,042
Hospitalisation Rate for PEX Treatment	100%	100%	100%	100%	100%	100%	100%	100%	100%
US TTP Patient Events Treated with PEX	1,931	1,945	1,958	1,972	1,986	2,000	2,014	2,028	2,042
caplacizumab Penetration			18.0%	30.0%	42.8%	53.6%	63.0%	70.0%	70.0%
caplacizumab TTP Patient Events			352	591	851	1,071	1,269	1,419	1,429
Average Revenue per Patient per Treatment			\$127,500	\$131,325	\$135,265	\$139,323	\$143,502	\$147,807	\$152,242
<b>US caplacizumab Sales (\$mn)</b>			<b>44.9</b>	<b>77.7</b>	<b>115.1</b>	<b>149.2</b>	<b>182.0</b>	<b>209.8</b>	<b>217.6</b>
Ex-US Population (m) - Assume EU & Japan	905.4	914.5	923.6	932.9	942.2	951.6	961.1	970.7	980.5
% Incidence of Acquired TTP Events	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%	0.0006%
Ex-US TTP Patient Events	5,433	5,487	5,542	5,597	5,653	5,710	5,767	5,824	5,883
Hospitalisation Rate for PEX Treatment	90%	90%	90%	90%	90%	90%	90%	90%	90%
Ex-US TTP Patient Events Treated with PEX	4,889	4,938	4,988	5,037	5,088	5,139	5,190	5,242	5,294
caplacizumab Penetration	0.0%	6.9%	22.9%	38.2%	50.9%	59.9%	66.5%	70.0%	70.0%
caplacizumab TTP Patient Events		339	1,142	1,922	2,588	3,076	3,451	3,669	3,706
Average Revenue per Patient per Treatment (EUR)		68,000	68,000	68,000	68,000	68,000	68,000	68,000	68,000
<b>Ex-US caplacizumab Sales (EURmn)</b>		<b>23.1</b>	<b>77.6</b>	<b>130.7</b>	<b>176.0</b>	<b>209.1</b>	<b>234.7</b>	<b>249.5</b>	<b>252.0</b>
<b>Ex-US caplacizumab Sales (\$mn)</b>		<b>27.2</b>	<b>91.6</b>	<b>154.2</b>	<b>207.7</b>	<b>246.8</b>	<b>276.9</b>	<b>294.4</b>	<b>297.4</b>
<b>WW caplacizumab Sales (\$mn)</b>		<b>27.2</b>	<b>136.5</b>	<b>231.9</b>	<b>322.8</b>	<b>396.0</b>	<b>459.0</b>	<b>504.2</b>	<b>515.0</b>
% Sales Growth		n/a	401.8%	69.8%	39.2%	22.7%	15.9%	9.9%	2.1%

Source: Jefferies estimates

## RSV therapy could be 1<sup>st</sup> to market

- **Peak sales:** \$800m assuming use in 65% of children under the age of 5 years hospitalised with RSV infection in the US and Europe
- **NPV:** c.€3 per share assuming 30% probability of success and an out-licensing deal after Phase IIb results in 2H18E
- **News flow:** Data from the Phase IIb RESPIRE efficacy study in hospitalised infants in 2H18E which could trigger a partnership deal. Japanese Phase II study in hospitalised infants begins during 1H18E, in addition to a Phase IIa trial in RSV-infected patients undergoing haematopoietic stem cell transplant (HSCT)

Respiratory Syncytial Virus (RSV) is a cause of severe morbidity and mortality, responsible for an estimated three million annual hospitalisations in children under the age of five and the leading viral cause of infant death. It is now also recognised to be a significant cause of respiratory illness among elderly and high-risk adults. Despite this substantial global burden, therapeutic options are limited to select patient populations. We conducted a deep dive into the [RSV development landscape](#). Our research suggests that an approved RSV therapeutic could be a potential blockbuster, even when limited to hospitalised infants under the age of five years, with upside from use in outpatient settings and in elderly patients.

ALX-0171 is an inhaled anti-RSV Nanobody in Phase II development for the treatment of hospitalised infants with RSV infection. The innovative trivalent Nanobody consists of three identical nanobodies linked together by peptides, targeting the F protein. This trivalent format results in increased potency, whilst the robustness of the Nanobody enables maintained efficacy even after nebulisation offering a less invasive mode of administration for infants and elderly patients, potentially a faster onset of action, and reduced chance of side effects versus systemic dosing.

### Phase I/II demonstrates anti-viral effect and signs of clinical efficacy

In April 2016, Ablynx reported positive top-line results of the Phase I/IIa study of ALX-0171 in 53 infants aged 1-24 months hospitalised with RSV infection. After an initial open label lead-in phase with five infants aged 5-24 months, there followed a double-blind placebo-controlled phase with 48 infants, aged 1-24 months, randomised 2:1 to either inhaled ALX-0171 delivered via a vibrating mesh device or placebo for three consecutive days.

ALX-0171 was safe and well tolerated, meeting the primary endpoint. No treatment-related serious adverse events were reported. At follow-up, treatment-emergent anti-drug antibodies were detected in 23% of patients, however there was no apparent effect on pharmacokinetics and no relationship seen with adverse events.

**Table 5: Safety and tolerability in Phase I/IIa study**

	Open-label ALX-0171 n=5	Randomised ALX0171 n=30	Randomised Placebo n=16
Adverse Events (AEs)			
No. with an AE	4 (80%)	9 (30%)	4 (25%)
No. treatment-related	1 (20%)	2 (6.7%)	0 (0%)
Serious Adverse Events (SAEs)			
No. with a SAE	3* (60%)	1** (3.3%)	0 (0%)
No. treatment-related	0 (0%)	0 (0%)	0 (0%)

Source: Jefferies research and Ablynx presentation

Note \* one subject discontinued; \*\* the subject discontinued

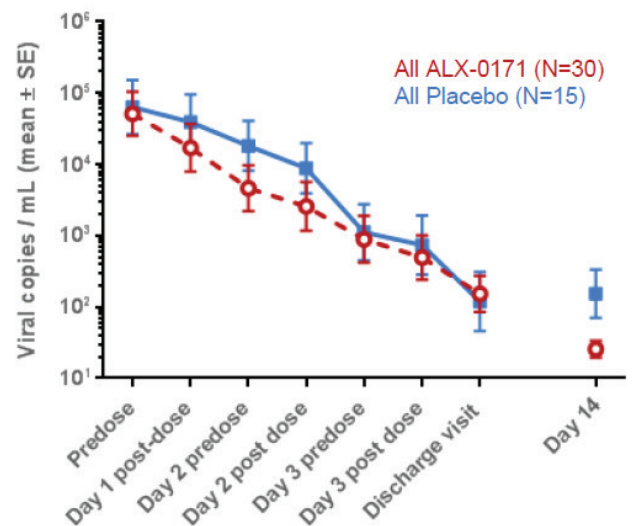
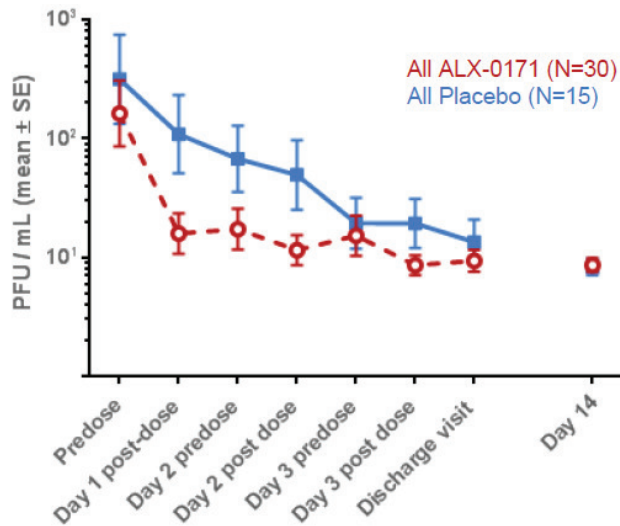
Encouragingly, ALX-0171 showed early signs of anti-viral effect, as measured by RSV viral replication and viral load versus placebo. ALX-0171 showed a rapid and immediate effect on infectious viral load, as measured by plaque assay at six hours post-dose and sustained thereafter versus placebo. A reduction in all viral RNA load, as measured by qRT-PCR, was also shown, though to a lesser magnitude. ALX-0171 was also superior to placebo in time

to undetectable virus, with the majority undetectable by plaque assay at 24 hours post-dose, versus 48 hours in the placebo group. The study was not powered for statistical significance for these measures. We discussed the data with experts who, although not familiar with these headline data, felt that such an immediate impact on viral load is promising and could lead to meaningful impact on length of hospital stay and outcomes.

**Exhibit 4: Viral load measured over time with ALX-0171 and placebo in the Phase I/IIa study**

**Infectious viral load (plaque assay)**

**All viral RNA (qRT-PCR)**



Source: Jefferies research adapted from Ablynx presentation

A post-hoc assessment of clinical benefit was performed based on the Global Severity Score, providing an initial suggestion of therapeutic effect for ALX-0171 versus placebo, with a separation between groups observed as early as day 1 post-dose. The Global Severity Score is a clinical score of up to 20 points that allows categorisation of infants with respiratory infections on seven different parameters: feeding intolerance, medical intervention, respiratory difficulty, respiratory frequency, apnoea, general condition and fever. Our discussions with experts suggest that clinical severity scores are not used in routine practice, since they have proved unreliable in the past. However, a correlation between reduced viral load and clinical improvement was felt to be an encouraging sign. Importantly, these benefits were seen in children treated in the hospital setting with established RSV infection, providing a more realistic reflection of efficacy than human challenge models, in our view.

**Phase IIb study initiated with additional studies planned**

On the basis of these positive findings, Ablynx initiated the Phase IIb RESPIRE dose-ranging efficacy study, with the first patient dose in early January 2017. The study evaluates three different doses of inhaled ALX-0171 (3, 6 and 9mg/kg) in c.180 hospitalised infants aged 1-24 months across the Northern and Southern Hemispheres.

The study consists of a sequential dose escalation phase in c.36 infants, which was completed during 3Q17 with a positive assessment by the Data Monitoring Committee, followed by a parallel phase in which c.144 infants are randomly assigned to one of the three dose groups of inhaled ALX-0171 or placebo. The primary endpoint of the study is to evaluate the anti-viral effect of treatment measured in nasal swabs. Secondary endpoints include safety, pharmacokinetics, clinical activity with assessment of composite clinical scores such as the Global Severity, and time to clinical response. Top-line data are expected in 2H18E and could potentially trigger a lucrative partnership deal.

Plans are also underway to initiate a Phase II trial in Japanese infants during 1H18E, possibly exploring the lower 1.5mg/kg dose in addition to the three investigated in RESPIRE. Clinical development in RSV infected stem cell transplant patients is also being pursued, with a Phase IIa study expected to commence during 1H18E.

**ALX-0171 could be first to market for infants**

Using current RSV infection and hospitalisation rates, we estimate that around 250,000 children under the age of five are hospitalised with severe RSV infection in the US and Europe each year. Since there are currently no approved treatments for RSV infection, we expect that Ablynx could gain a significant share of the market.

Our research suggests the average RSV hospital admission in the US costs around \$20,000. We assume average revenues per patient of \$6,000 in the US and €3,000 in Europe on the assumption that ALX-0171 is able to shorten the length of hospital stay by one day from the average 2.5 days, reducing the cost of hospital admission by c.40%.

Our base case assumes ALX-0171 is used in 65% of children hospitalised with RSV infection, for peak sales of around \$800m, of which \$450m are in the US. This could prove conservative, in our view, since it seems reasonable that the threshold for treatment with an effective therapy would be relatively low in severely ill children. Our sales scenario analysis suggests peak sales of around \$1bn should Ablynx achieve peak penetration of 90%.



## €29/\$34 NPV sum-of-the-parts valuation

Our €29 per share (\$34 per ADS) Price Target is based on a sum-of-the-parts valuation comprising probability-adjusted NPVs for caplacizumab, ALX-0171 and vobarilizumab in SLE, plus Net Cash. We include in Net Cash any milestone income received from partners during the current financial year.

**Table 2: Ablynx sum-of-the-parts valuation**

		Peak Sales (\$mn)	Value (EURmn)	Prob.	Adj. Value (EURmn)	EUR per share
caplacizumab (anti-vWF)	Thrombotic thrombocytopenic purpura (TTP)	500	1,705	90%	1,534	20.5
vobarilizumab (anti-IL-6R)	Rheumatoid arthritis	750	514	0%	0	0.0
	Systemic lupus erythematosus	300	223	20%	45	0.6
ALX-0171 (anti-RSV)	RSV infected infants	800	795	30%	239	3.2
Net Cash/(Debt)			349	100%	349	4.7
<b>Valuation</b>			<b>3,586</b>		<b>2,167</b>	<b>29.0</b>
Potential Dilution for Funding	Min. Yrs of Cash	3.0		0%	0	0.0
<b>Potential Diluted Valuation</b>						<b>29.0</b>

Source: Jefferies estimates

**Table 3: Sources of upside potential and downside risk**

	Upside	EUR per share	Downside	EUR per share
caplacizumab approvals for aTTP	EMA & FDA approvals	2.3	Safety and/or efficacy concerns	(16.0)
vobarilizumab in RA	New partner or AbbVie initiates P3	1.4	No new partner or discontinued	0.0
vobarilizumab Phase II in SLE	Positive and AbbVie opts-in	0.9	Fails and/or AbbVie rejects opt-in	(0.6)
ALX-0171 RSV Phase IIb infected infants	Positive results	2.1	Safety and/or efficacy concerns	(3.2)
<b>Potential Upside/(Downside)</b>		<b>6.7</b>		<b>(19.8)</b>
<b>Potential Valuation</b>		<b>35.7</b>		<b>9.2</b>

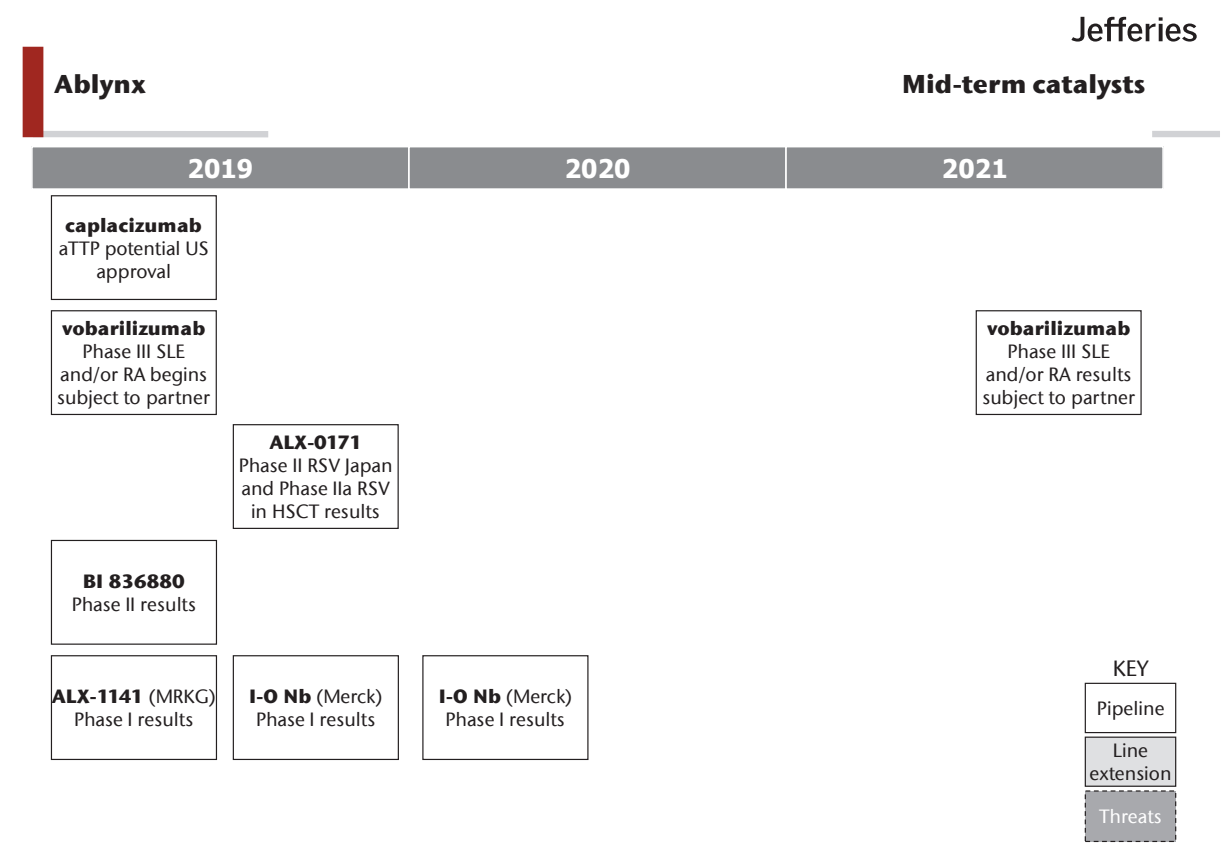
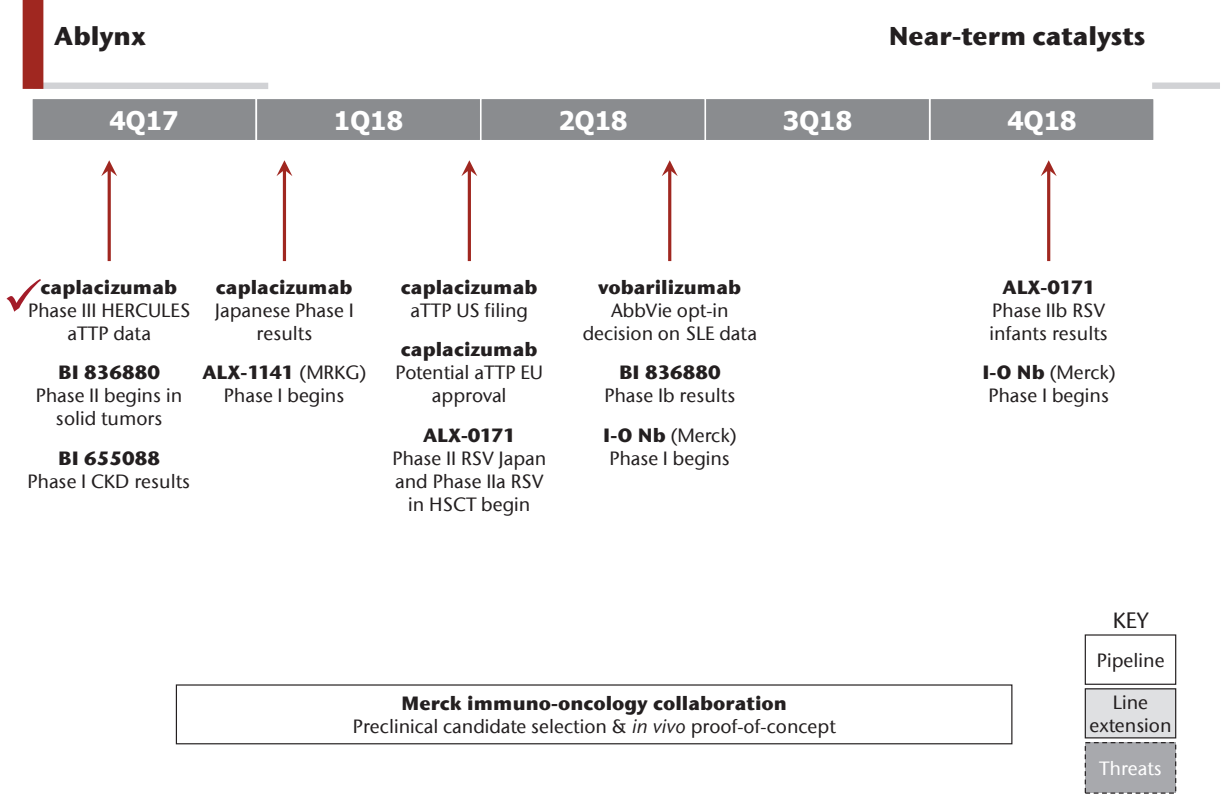
Source: Jefferies estimates

### Sufficient funds to crystallise value

Ablynx raised \$230m gross proceeds in a US IPO in October, which together with €208.6m cash at 30 September 2017 suggests current funds around €390m. We believe if caplacizumab is successfully launched around mid-2018E in Europe then Ablynx has sufficient cash to reach a potential 2020E breakeven, excluding possible upsides from incremental deals or future milestones. Given management's track record executing Nanobody technology deals we expect our License Revenue estimates to be conservative. Furthermore, Ablynx could out-license its anti-human serum albumin half-life extension technology and/or products rights, such as ALX-0171.

Future income benefits from the Belgian patent box legislation exempting 80% of IP related Revenue from taxation. We assume an attractive c.7% tax rate on license income. For caplacizumab, management may utilise transfer pricing to take advantage of the patent box, even if commercial rights are retained by Ablynx, hence we estimate a blended c.20% tax rate on profits.

**Exhibit 1: Ablynx catalysts**



Jefferies

Source: Jefferies

## Financial models

**Table 6: Ablynx Profit and Loss Model**

(EUR millions except EPS Dec YE)	2017E							
	2016A	1H17A	2H17E	2017E	2018E	2019E	2020E	2021E
Research & Development	84.8	34.7	22.4	57.1	44.3	16.0	8.0	2.0
Grants	0.4	0.0	0.3	0.4	0.3	0.2	0.2	0.1
caplacizumab Sales (TTP)	0.0	0.0	0.0	0.0	23.1	115.7	196.5	273.5
Revenue	85.2	34.7	22.8	57.5	67.7	131.9	204.7	275.7
Cost of Sales	0.0	0.0	0.0	0.0	(4.6)	(20.8)	(33.4)	(43.8)
<b>Gross Profit</b>	<b>85.2</b>	<b>34.7</b>	<b>22.8</b>	<b>57.5</b>	<b>63.0</b>	<b>111.1</b>	<b>171.3</b>	<b>231.9</b>
Total Operating Expenses	(113.8)	(59.5)	(61.0)	(120.5)	(145.0)	(146.5)	(147.6)	(155.0)
Sales & Marketing Expenses	0.0	0.0	(5.0)	(5.0)	(37.5)	(40.5)	(42.5)	(44.7)
General & Admin. Expenses	(13.5)	(9.0)	(6.6)	(15.5)	(16.6)	(17.6)	(18.5)	(19.4)
R&D Expenses	(100.3)	(50.5)	(49.5)	(100.0)	(90.9)	(88.5)	(86.7)	(91.0)
o/w Acquisition-related Amortisation/Write-down	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Other Operating Income	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Operating Exceptionals	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Operating Income</b>	<b>(28.6)</b>	<b>(24.8)</b>	<b>(38.3)</b>	<b>(63.0)</b>	<b>(81.9)</b>	<b>(35.4)</b>	<b>23.6</b>	<b>76.9</b>
<b>Adjusted Operating Income</b>	<b>(28.6)</b>	<b>(24.8)</b>	<b>(38.3)</b>	<b>(63.0)</b>	<b>(81.9)</b>	<b>(35.4)</b>	<b>23.6</b>	<b>76.9</b>
Net Financial Income	(6.8)	(0.6)	(3.1)	(3.7)	(5.8)	(4.6)	(2.5)	4.2
Exceptionals	34.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Income from Associates & JVs	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Pretax Profit</b>	<b>(1.1)</b>	<b>(25.3)</b>	<b>(41.4)</b>	<b>(66.7)</b>	<b>(87.7)</b>	<b>(40.0)</b>	<b>21.1</b>	<b>81.1</b>
<b>Adjusted Pretax Profit</b>	<b>(35.4)</b>	<b>(25.3)</b>	<b>(41.4)</b>	<b>(66.7)</b>	<b>(87.7)</b>	<b>(40.0)</b>	<b>21.1</b>	<b>81.1</b>
Taxation	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income from Continuing Operations</b>	<b>(1.1)</b>	<b>(25.3)</b>	<b>(41.4)</b>	<b>(66.7)</b>	<b>(87.7)</b>	<b>(40.0)</b>	<b>21.1</b>	<b>81.1</b>
Net Income from Discontinued Operations	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income</b>	<b>(1.1)</b>	<b>(25.3)</b>	<b>(41.4)</b>	<b>(66.7)</b>	<b>(87.7)</b>	<b>(40.0)</b>	<b>21.1</b>	<b>81.1</b>
<b>Adjusted Net Income</b>	<b>(35.4)</b>	<b>(25.3)</b>	<b>(41.4)</b>	<b>(66.7)</b>	<b>(87.7)</b>	<b>(40.0)</b>	<b>21.1</b>	<b>81.1</b>
WA Basic Shares (mn)	57.9	63.0	65.5	63.0	75.2	75.8	80.3	84.9
WA Shares Diluted (mn)	57.9	63.0	65.5	63.0	75.2	75.8	81.8	86.4
<b>EPS (EUR)</b>	<b>(0.0)</b>	<b>(0.4)</b>	<b>(0.6)</b>	<b>(1.1)</b>	<b>(1.2)</b>	<b>(0.5)</b>	<b>0.3</b>	<b>1.0</b>
<b>Adjusted EPS (EUR)</b>	<b>(0.6)</b>	<b>(0.4)</b>	<b>(0.6)</b>	<b>(1.1)</b>	<b>(1.2)</b>	<b>(0.5)</b>	<b>0.3</b>	<b>1.0</b>
Diluted EPS (EUR)	(0.0)	(0.4)	(0.6)	(1.1)	(1.2)	(0.5)	0.3	0.9
<b>Diluted Adjusted EPS (EUR)</b>	<b>(0.6)</b>	<b>(0.4)</b>	<b>(0.6)</b>	<b>(1.1)</b>	<b>(1.2)</b>	<b>(0.5)</b>	<b>0.3</b>	<b>0.9</b>
<b>% Change Year over Year</b>								
Revenue	9.9%	(35.1%)	(28.2%)	(32.5%)	17.7%	95.0%	55.1%	34.7%
Cost of Sales	n/a	n/a	n/a	n/a	n/a	351.6%	60.4%	31.0%
Gross Profit	9.9%	(35.1%)	(28.2%)	(32.5%)	9.7%	76.2%	54.2%	35.4%
Total Operating Expenses	20.5%	7.1%	4.7%	5.8%	20.3%	1.1%	0.8%	5.0%
Sales & Marketing Expenses	n/a	n/a	n/a	n/a	650.0%	8.0%	5.0%	5.0%
General & Admin. Expenses	18.6%	37.5%	(6.7%)	14.6%	7.0%	6.0%	5.0%	5.0%
R&D Expenses	20.7%	3.1%	(3.5%)	(0.3%)	(9.1%)	(2.7%)	(2.0%)	5.0%
Operating Income	(68.7%)	(1123.2%)	(44.0%)	(120.4%)	(30.0%)	56.7%	166.7%	225.3%
Adjusted Operating Income	(68.7%)	(1123.2%)	(44.0%)	(120.4%)	(30.0%)	56.7%	166.7%	225.3%
Pretax Profit	98.0%	(210.9%)	(73.2%)	(6039.8%)	(31.4%)	54.4%	152.8%	283.6%
Adjusted Pretax Profit	35.1%	(378.4%)	(37.5%)	(88.4%)	(31.4%)	54.4%	152.8%	283.6%
Net Income	98.0%	(210.9%)	(73.2%)	(6039.8%)	(31.4%)	54.4%	152.8%	283.6%
Adjusted Net Income	35.1%	(378.4%)	(37.5%)	(88.4%)	(31.4%)	54.4%	152.8%	283.6%
EPS (EUR)	98.1%	(197.2%)	(53.0%)	(5538.3%)	(10.2%)	54.7%	149.8%	263.1%
Adjusted EPS (EUR)	38.9%	(319.0%)	(21.4%)	(73.0%)	(10.2%)	54.7%	149.8%	263.1%

Source: Jefferies estimates, company data

**Table 7: Ablynx Cash Flow Model**

(EUR millions Dec YE)	2016A	2017E	2018E	2019E	2020E	2021E
Operating Income	(28.6)	(63.0)	(81.9)	(35.4)	23.6	76.9
Depreciation and Amortisation	2.2	2.7	2.7	3.0	3.0	3.4
<b>EBITDA</b>	<b>(26.4)</b>	<b>(60.4)</b>	<b>(79.2)</b>	<b>(32.4)</b>	<b>26.6</b>	<b>80.3</b>
Other Adjustments and Exceptionals	2.6	2.8	2.9	3.1	3.2	3.4
Decrease/(Increase) in Inventories	0.0	0.0	(0.1)	(0.4)	(0.3)	(0.3)
Decrease/(Increase) in Receivables	0.1	1.2	0.5	(1.8)	(2.0)	(1.9)
Increase/(Decrease) in Payables	(43.2)	(0.9)	4.8	2.9	2.3	2.8
Increase/(Decrease) in Deferred Income	0.0	(1.0)	(14.8)	(10.0)	(4.0)	0.0
Change in WC	(43.1)	(0.8)	(9.6)	(9.3)	(4.1)	0.6
Taxation Paid	0.0	0.0	0.0	0.0	0.0	0.0
Interest Paid	(0.0)	(7.2)	(7.0)	(7.0)	(5.5)	(0.8)
<b>Net Cash Flow from Operating Activities</b>	<b>(66.6)</b>	<b>(62.1)</b>	<b>(91.7)</b>	<b>(43.3)</b>	<b>23.3</b>	<b>88.5</b>
Purchase of Tangible Fixed Assets	(2.9)	(3.5)	(2.7)	(4.0)	(6.1)	(8.3)
Proceeds from Sale of PP&E	0.0	0.0	0.0	0.0	0.0	0.0
Purchase of Intangible Assets	(1.7)	(0.2)	0.0	0.0	0.0	0.0
(Purchase)/Sale of Investments	0.1	0.0	0.0	0.0	0.0	0.0
(Acquisitions)/Disposals of Subsidiaries	0.0	0.0	0.0	0.0	0.0	0.0
Dividends Received from Associates	0.0	0.0	0.0	0.0	0.0	0.0
Interest Received	0.3	3.5	1.2	2.4	3.0	5.0
<b>Net Cash Flow from Investing Activities</b>	<b>(4.6)</b>	<b>(3.7)</b>	<b>(2.7)</b>	<b>(4.0)</b>	<b>(6.1)</b>	<b>(8.3)</b>
Management of Available-for-Sale Financial Assets	0.0	(0.0)	0.0	0.0	0.0	0.0
Capital Changes	73.7	183.0	3.8	4.4	5.0	5.8
Debt Changes	(3.3)	0.0	0.0	0.0	0.0	0.0
Equity Dividends Paid	0.0	0.0	0.0	0.0	0.0	0.0
Other Financing Cash Flows	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Cash Flow from Financing Activities</b>	<b>70.4</b>	<b>183.0</b>	<b>3.8</b>	<b>4.4</b>	<b>5.0</b>	<b>5.8</b>
Effect of FX on Cash and Cash Equivalents	0.0	0.0	0.0	0.0	0.0	0.0
<b>Increase in Cash</b>	<b>(0.8)</b>	<b>117.2</b>	<b>(90.6)</b>	<b>(42.9)</b>	<b>22.2</b>	<b>86.0</b>
<b>Change in Net Debt</b>	<b>(2.5)</b>	<b>(117.2)</b>	<b>90.6</b>	<b>42.9</b>	<b>(22.2)</b>	<b>(86.0)</b>
<b>(Cash Burn)</b>	<b>(71.2)</b>	<b>(65.8)</b>	<b>(94.4)</b>	<b>(47.2)</b>	<b>17.1</b>	<b>80.2</b>

Source: Jefferies estimates, company data

**Table 8: Ablynx Balance Sheet Model**

(EUR millions Dec YE)	2016A	2017E	2018E	2019E	2020E	2021E
<b>Non-current Assets</b>	<b>24.6</b>	<b>25.7</b>	<b>25.6</b>	<b>26.6</b>	<b>29.7</b>	<b>34.6</b>
Intangible Assets	1.6	1.2	0.6	0.1	0.0	0.0
Property, Plant and Equipment	3.7	5.3	5.7	7.2	10.5	15.4
Investments	1.6	1.6	1.6	1.6	1.6	1.6
Other Long-term Assets	17.6	17.6	17.6	17.6	17.6	17.6
<b>Current Assets</b>	<b>242.2</b>	<b>358.2</b>	<b>267.3</b>	<b>226.6</b>	<b>251.1</b>	<b>339.3</b>
Inventories	0.0	0.0	0.1	0.6	0.9	1.2
Trade Accounts Receivable	3.5	2.4	1.9	3.6	5.6	7.6
Other Current Assets	4.8	4.8	4.8	4.8	4.8	4.8
Cash and Cash Equivalents	233.8	351.0	260.4	217.6	239.7	325.7
<b>Total Assets</b>	<b>266.8</b>	<b>383.9</b>	<b>292.9</b>	<b>253.2</b>	<b>280.8</b>	<b>373.9</b>
<b>Current Liabilities</b>	<b>59.4</b>	<b>39.6</b>	<b>39.6</b>	<b>36.4</b>	<b>34.7</b>	<b>37.5</b>
Trade Accounts Payable	20.3	19.4	24.1	27.0	29.3	32.1
Other Current Liabilities	5.4	5.4	5.4	5.4	5.4	5.4
Accrued Expenses	0.0	0.0	0.0	0.0	0.0	0.0
Deferred Income	33.6	14.8	10.0	4.0	0.0	0.0
Short-term Debt	0.0	0.0	0.0	0.0	0.0	0.0
Leasing Obligations	0.0	0.0	0.0	0.0	0.0	0.0
Dividends	0.0	0.0	0.0	0.0	0.0	0.0
<b>Non-current Liabilities</b>	<b>104.3</b>	<b>122.2</b>	<b>112.2</b>	<b>108.2</b>	<b>8.2</b>	<b>8.2</b>
Long-term Debt	104.3	104.3	104.3	104.3	4.3	4.3
Leasing Obligations	0.0	0.0	0.0	0.0	0.0	0.0
Deferred Tax Liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Deferred Income	0.0	17.8	7.8	3.8	3.8	3.8
Long-term Provisions	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total Shareholders' Equity</b>	<b>103.1</b>	<b>222.1</b>	<b>141.1</b>	<b>108.5</b>	<b>237.9</b>	<b>328.2</b>
Share Capital	106.1	106.1	106.1	106.1	106.1	106.1
Share Premium Account	252.3	435.3	439.1	443.4	548.5	554.2
Other Reserves and Adjustments	8.1	8.1	8.1	8.1	8.1	8.1
Retained Earnings	(263.4)	(327.3)	(412.1)	(449.1)	(424.7)	(340.2)
Minority Interests	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total Liabilities and Shareholders' Equity</b>	<b>266.8</b>	<b>383.9</b>	<b>292.9</b>	<b>253.2</b>	<b>280.8</b>	<b>373.9</b>

Source: Jefferies estimates, company data

**Key changes to forecasts**
**Table 10: Summary estimates changes for Ablynx**

Forecasts (EURm)	2017E New	2017E Old	% Chg	2018E New	2018E Old	% Chg
<b>Sales</b>	57.5	57.5	+0%	67.7	71.9	-6%
<b>Adj. EBIT</b>	(63.0)	(62.2)	+1%	(81.9)	(77.7)	+5%
<b>Adj. EPS</b>	(1.06)	(1.08)	-2%	(1.17)	(1.35)	-14%
<b>Net Cash/(Debt)</b>	246.6	67.0	+268%	156.1	(19.5)	-902%
<b>Drivers of Change</b>	Minor changes to underlying OpEx, with higher peak penetration for caplacizumab boosting sales from 2018E. Cash is increased following the October US IPO on NASDAQ raising \$230m gross proceeds.					

Source: Jefferies estimates

## Company Description

Ablynx is a Belgian biotech company engaged in the discovery and development of Nanobodies, a novel class of therapeutic proteins based on single-domain antibody fragments. The company has alliances with Merck Serono, Merck, Boehringer Ingelheim and Novartis to use its platform technology to generate Nanobodies against specific disease targets. Lead pipeline product caplacizumab (anti-vWF) treats the rare blood disorder thrombotic thrombocytopenic purpura (TTP). Ablynx has partnered ALX-0061 (anti-IL-6R) with AbbVie for rheumatoid arthritis and systemic lupus erythematosus, and has ALX-0171 (anti-RSV) in early-stage clinical development for respiratory syncytial virus infections.

## Analyst Certification:

I, Peter Welford, CFA, certify that all of the views expressed in this research report accurately reflect my personal views about the subject security(ies) and subject company(ies). I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the specific recommendations or views expressed in this research report.

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## Investment Recommendation Record

### (Article 3(1)e and Article 7 of MAR)

Recommendation Published , 17:52 ET. November 19, 2017  
 Recommendation Distributed , 00:00 ET. November 20, 2017

## Company Specific Disclosures

Steven DeSanctis owns shares of Merck & Co. Inc. common shares.

Jefferies Group LLC makes a market in the securities or ADRs of Ablynx.

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Buy - Describes securities that we expect to provide a total return (price appreciation plus yield) of 15% or more within a 12-month period.

Hold - Describes securities that we expect to provide a total return (price appreciation plus yield) of plus 15% or minus 10% within a 12-month period.

Underperform - Describes securities that we expect to provide a total return (price appreciation plus yield) of minus 10% or less within a 12-month period.

The expected total return (price appreciation plus yield) for Buy rated securities with an average security price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform rated securities with an average security price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% or less within a 12-month period.

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Jefferies' methodology for assigning ratings may include the following: market capitalization, maturity, growth/value, volatility and expected total return over the next 12 months. The price targets are based on several methodologies, which may include, but are not restricted to, analyses of market risk, growth rate, revenue stream, discounted cash flow (DCF), EBITDA, EPS, cash flow (CF), free cash flow (FCF), EV/EBITDA, P/E, PE/growth, P/CF,

P/FCF, premium (discount)/average group EV/EBITDA, premium (discount)/average group P/E, sum of the parts, net asset value, dividend returns, and return on equity (ROE) over the next 12 months.

### Jefferies Franchise Picks

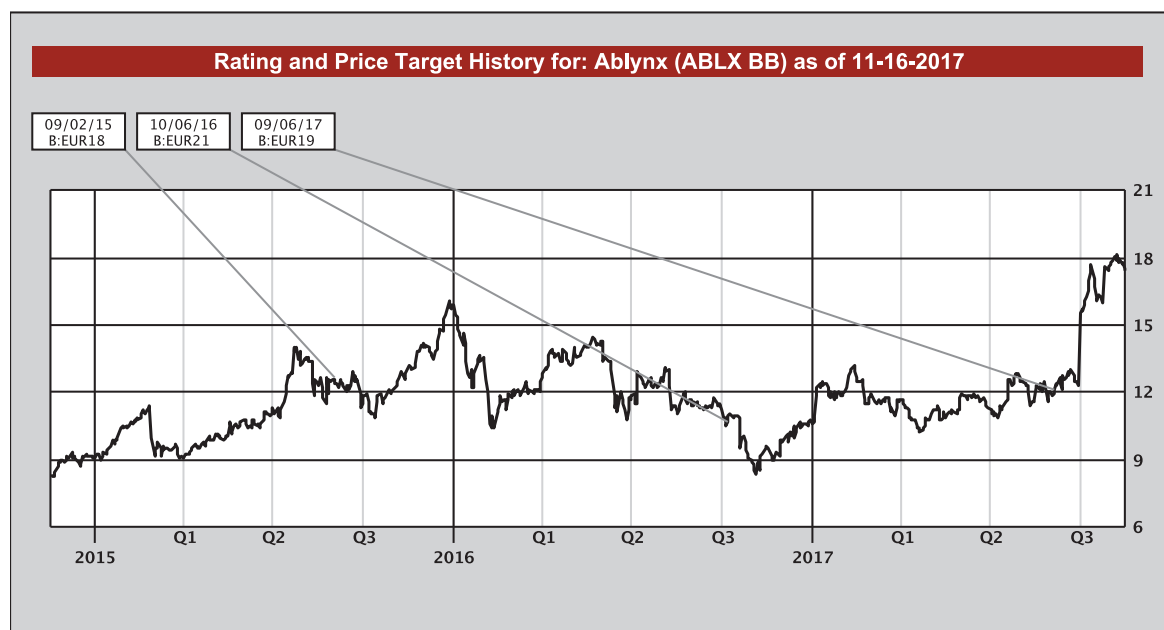
Jefferies Franchise Picks include stock selections from among the best stock ideas from our equity analysts over a 12 month period. Stock selection is based on fundamental analysis and may take into account other factors such as analyst conviction, differentiated analysis, a favorable risk/reward ratio and investment themes that Jefferies analysts are recommending. Jefferies Franchise Picks will include only Buy rated stocks and the number can vary depending on analyst recommendations for inclusion. Stocks will be added as new opportunities arise and removed when the reason for inclusion changes, the stock has met its desired return, if it is no longer rated Buy and/or if it triggers a stop loss. Stocks having 120 day volatility in the bottom quartile of S&P stocks will continue to have a 15% stop loss, and the remainder will have a 20% stop. Franchise Picks are not intended to represent a recommended portfolio of stocks and is not sector based, but we may note where we believe a Pick falls within an investment style such as growth or value.

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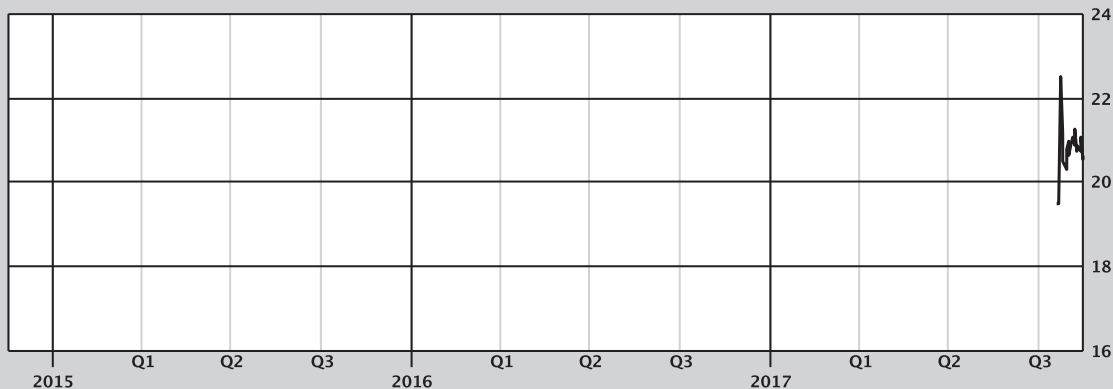
## Other Companies Mentioned in This Report

- AbbVie (ABBV: \$93.61, BUY)
- Ablynx (ABLX: \$21.14, BUY)
- Ablynx (ABLX BB: €17.60, BUY)
- Merck & Co. (MRK: \$55.20, HOLD)





Rating and Price Target History for: Ablynx (ABLX) as of 11-16-2017



**Notes:** Each box in the Rating and Price Target History chart above represents actions over the past three years in which an analyst initiated on a company, made a change to a rating or price target of a company or discontinued coverage of a company.

Legend:

I: Initiating Coverage

D: Dropped Coverage

B: Buy

H: Hold

UP: Underperform

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### Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos.		JIL Mkt Serv./Past 12 Mos.	
			Count	Percent	Count	Percent
BUY	1064	51.98%	332	31.20%	63	5.92%
HOLD	840	41.04%	167	19.88%	20	2.38%
UNDERPERFORM	143	6.99%	16	11.19%	4	2.80%

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