

Safe to inhale

The first clinical trial with an inhaled Nanobody has been successfully completed. ALX-0171, developed to treat respiratory syncytial virus (RSV) infections, was well tolerated and no immunogenicity was detected. Additional Phase I studies are planned before the Nanobody enters paediatric Phase II development, and Ablynx aims to partner the product before then. These results further highlight the potential of Nanobodies, as monoclonal antibodies cannot be delivered in a similar way.

Year end	Revenue (€m)	PBT* (€m)	EPS* (c)	DPS (c)	P/E (X)	Yield (%)
12/10	31.4	(24.0)	(56.9)	0.0	N/A	N/A
12/11	21.9	(43.3)	(99.1)	0.0	N/A	N/A
12/12e	27.4	(34.3)	(78.5)	0.0	N/A	N/A
12/13e	36.7	(29.8)	(68.1)	0.0	N/A	N/A
NU ADDT						

Note: *PBT and EPS are normalised, excluding intangible amortisation and exceptional items.

No safety signal detected with inhaled Nanobody

ALX-0171 or placebo were delivered via a nebuliser to the lungs of 60 healthy adults. The Nanobody was well tolerated and did not show any clinically relevant adverse events or have a clinically significant impact on lung function. The maximum dose delivered was 210mg per day for five days and no dose-limiting toxicity was detected. There was a concern that the pulmonary delivery of a Nanobody would induce an immunogenic response, but no immunogenicity was detected locally or systemically.

Additional Phase I studies expected next year

Additional Phase I trials will probably start next year: one could be to determine more accurately the pharmacokinetic profile and another in adults with hypersensitive lungs. If these trials proceed as expected, a Phase II trial in small children with RSV infections could start in 2014, but Ablynx will aim to partner the product beforehand as it has no experience of conducting clinical trials in children. In preclinical studies ALX-0171 has already been shown to reduce RSV particles.

Nanobodies reach parts monoclonal antibodies cannot

These trial results highlight another difference between Nanobodies and monoclonal antibodies – Nanobodies can be nebulised and delivered directly to the lungs. This raises the possibility of more Nanobodies for pulmonary delivery being developed to treat other viral infections (eg influenza) or respiratory indication (eg asthma and COPD), either alone or with a partner.

Valuation: DCF valuation of €501m

We have increased our valuation by €22m to €501m, after increasing the likelihood of ALX-0171 achieving peak sales of \$800m by 5% to 15% and reductions to cash burn following tight cost control in H112. We have reduced forecast cash burn by 5.7% to €22.8m and by 10% to €20.7m in FY12 and FY13 respectively. The next catalyst for the shares is the Phase II data on ALX-0061 in rheumatoid arthritis due next month.

Ablynx is a research client of Edison Investment Research Limited

Pharma & biotech

	20 September 2012			
Price	€4.53			
Market cap	€198m			
Shares in issue	43.7m			
Free float	56%			
Code	ABLX			
Primary exchange	Brussels			
Other exchanges	N/A			

Share price performance



Business description

Ablynx is a drug discovery company with a proprietary technology platform. It is developing a novel class of therapeutic proteins called Nanobodies to treat a range of indications. It has seven products in clinical development.

Next events

ALX-0061 data	October 2012				
Q312 results	14 November 2012				
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Exhibit 1: Financial summary

	€'000s 2009	2010	2011	2012e	2013e	2014e
Year end 31 December	IFRS	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS						
Revenue	29,683	31,432	21,869	27,420	36,729	42,238
Cost of Sales	0	0	0	0	0	C
Gross Profit	29,683	31,432	21,869	27,420	36,729	42,238
EBITDA	(19,556)	(22,988)	(42,751)	(33,670)	(28,606)	(25,682)
Operating Profit (before GW and except.)	(21,962)	(25,378)	(44,920)	(35,601)	(30,470)	(27,576)
Intangible Amortisation	(198)	(487)	(609)	(581)	(529)	(519)
Exceptionals	0	0	0	0	0	C
Other	0	0	0	0	0	C
Operating Profit	(22,160)	(25,865)	(45,529)	(36,181)	(30,999)	(28,095)
Net Interest	2,165	1,395	1,634	1,284	712	113
Profit Before Tax (norm)	(19,797)	(23,983)	(43,286)	(34,316)	(29,758)	(27,463)
Profit Before Tax (FRS 3)	(19,995)	(24,470)	(43,895)	(34,897)	(30,287)	(27,982)
Tax	0	0	0	0	0	0
Profit After Tax (norm)	(19,797)	(23,983)	(43,286)	(34,316)	(29,758)	(27,463)
Profit After Tax (FRS 3)	(19,995)	(24,470)	(43,895)	(34,897)	(30,287)	(27,982)
Average Number of Shares Outstanding (m)	36.9	42.2	43.7	43.7	43.7	43.7
EPS - normalised (c)	(53.7)	(56.9)	(99.1)	(78.5)	(68.1)	(62.9)
EPS - FRS 3 (c)						
Dividend per share (c)	(54.3) 0.0	(58.0) 0.0	(100.5) 0.0	(79.9) 0.0	(69.3) 0.0	(64.0) 0.0
Gross Margin (%)	N/A	N/A	N/A	N/A	N/A	N/A
EBITDA Margin (%)	N/A	N/A	N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)	N/A	N/A	N/A	N/A	N/A	N/A
BALANCE SHEET						
Fixed Assets	4,277	10,319	11,979	11,972	12,016	12,166
ntangible Assets	799	1,416	1,018	917	868	829
Tangible Assets	3,478	4,692	4,984	4,415	4,508	4,697
Other	0	4,211	5,977	6,640	6,640	6,640
Current Assets	97,645	121,070	86,550	63,184	43,016	22,736
Stocks	0	0	0	0	0	0
Debtors	1,697	5,277	2,233	1,502	2,013	2,314
Cash	92,321	112,842	80,822	57,939	37,262	16,680
Other	3,627	2,951	3,495	3,742	3,742	3,742
Current Liabilities	(25,796)	(29,465)	(38,147)	(48,253)	(56,535)	(62,412)
Creditors	(7,200)	(7,582)	(9,867)	(8,540)	(9,175)	(9,542)
Short term borrowings	(3)	(322)	(805)	(815)	(815)	(815)
Other	(18,593)	(21,561)	(27,475)	(38,898)	(46,546)	(52,055)
Long Term Liabilities	0	(1,134)	(1,752)	(1,341)	(1,341)	(1,341)
Long term borrowings	0	(1,134)	(1,752)	(1,341)	(1,341)	(1,341)
Other long term liabilities	0	0	0	0	0	0
Net Assets	76,126	100,790	58,630	25,562	(2,844)	(28,851)
CASH FLOW					()- Y	
	(00.040)	(01.000)	(00,000)	(00,000)	(10.050)	(10, 100)
Operating Cash Flow Net Interest	(22,243) 2,332	(21,962) 1,361	(32,302) 1,689	(22,336) 1,317	(18,952) 712	(18,132) 113
	2,002	0	0	0	0	0
Tax						
Capex Acquisitions (disposals	(1,883)	(3,007)	(2,672)	(1,840)	(2,437)	(2,563)
Acquisitions/disposals	0	0	0 164	0	0	0
Financing	527	47,331		0	0	0
Dividends		0	0			
Net Cash Flow	(21,267)	23,723	(33,121)	(22,823)	(20,677)	(20,582)
Opening net debt/(cash)	(113,474)	(92,318)	(114,386)	(81,265)	(58,443)	(37,766)
HP finance leases initiated	0	0	0	0	0	0
Other	111	(1,655)	0	(0)	(0)	0
Closing net debt/(cash)	(92,318)	(114,386)	(81,265)	(58,442)	(37,766)	(17,184)

Source: Edison Investment Research, company accounts

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