

Visit to Ablynx Knowledge Based Bio-Economy Conference Delegation

Sandra Turconi, Director of Discovery 13 September 2010



Inspired by Nature

Nanobodies[®]: delivering therapeutics beyond antibodies

Forward looking statements



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▼ Introduction

- ➤ Nanobody platform overview
- **▼** Product pipeline
- **Y** Business development
- Y Prospects for 2010 €



Overview

- Drug discovery and development company
- A pioneer in next generation biologics Nanobodies[®]
- Y >25 programmes in the R&D pipeline
- Y 4 Nanobody products in the clinic 2 Phase II and 2 Phase I
- Exclusive rights to >450 patent applications and granted patents
- ▼ 4 partnerships with leading pharmaceutical companies
- Y >250 staff
- ▼ 8,000 m² space in Ghent, Belgium (headquarters)
- ▼ Listed on Euronext Brussels since November 2007
- Y Market capitalization ~€300M



Key highlights in H1 2010



- Y €121.3 million in cash, cash equivalents and short-term investments at 30 June 2010
- Y Successful SPO raising €50 million
- Y Revenues of €10.1 million (2009: €11.9 million)
- Y Received a €2.0 million milestone from BI as part of our Alzheimer's collaboration
- Y Continuing Phase II trials for anti-vWF in ACS and anti-TNF α , with Pfizer, in RA
- Completed the recruitment for the Phase I study for ALX-0141 (anti-RANKL)
- Selected ALX-0651 (anti-CXCR4) and ALX-0171 (anti-RSV) as pre-clinical candidates
- Reported on functional Nanobodies to ion channels and data on alternative delivery



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Conventional antibodies vs Nanobodies





Nanobody discovery process



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Nanobodies – beyond antibodies & small molecules



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- ✓ 4 Nanobodies in clinical trials 3 more expected during 2011
- Clinical testing of Nanobodies on 3 continents
- Regulatory authorities in >10 countries (to date) have approved clinical testing of Nanobodies
- ✓ >300 patients have been treated with Nanobodies via intravenous and/or sub-cutaneous administration in single and multiple doses

Ablynx's internal and funded programmes





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Anti-vWF Nanobody for Acute Coronary Syndrome (ACS)



✓ Pre-clinical and clinical status

- Pre-clinical data in the Folt's model showed increased effectiveness in the prevention of clot formation compared with other anti-thrombotics
- Phase I and Phase Ib trials successfully completed and Phase II trial in progress with primary endpoint (bleeding) data expected in Q2 2011
- Phase II primary goal to show superiority in safety and equivalence in efficacy compared with ReoPro[®]

Phase	Population	# subj.	Regimen/dose	Status
1	Healthy volunteers	40	Single dose 0.5 – 12mg	Final report
lb	ACS patients	47	Single and multiple dose 2mg – 18mg	Final report
II	ACS patients	370	Multiple dose 18mg vs GPIIb/IIIa inhibitor ReoPro®	Ongoing with primary endpoint bleeding data expected Q2 2011

Source: Ablynx

Ablynx

Anti-vWF Nanobody in thrombotic thrombocytopenic purpura (TTP)

▼ Initial target indication and opportunity

- acquired and congenital forms of thrombotic thrombocytopenic purpura (TTP)
- more than 10,000 patients¹ in the Key Geographic Markets* require treatment annually
- plasma transfusion/exchange required, unmet medical need
- orphan designation granted by the FDA and EMEA
- potential to impact quality of life and overall cost
- Phase I trial of ALX-0681 (subcutaneous administration) successfully completed
- Phase II (possibly pivotal) study expected to start in Q3 2010, 110 patients recruited over 2 years treatment with intravenous bolus (ALX-0081) followed by subcutaneous injections (ALX-0681)





Anti-TNF α Nanobody product - initial indication RA

▼ Product description: ATN-103

- bivalent TNF $\!\alpha$ targeting Nanobody with a half-life extended format

Initial target indication and opportunity

- RA, with potential expansion into Crohn's disease, psoriasis, ankylosing spondylitis and psoriatic arthritis
- the TNFα inhibitors achieved sales in all indications in 2008 of \$16.9Bn¹, with Enbrel[®] achieving \$6.4Bn¹ sales in the Key Geographic Markets*
- nearly 30% of RA patients fail to respond to their first TNFα inhibitor and then many patients develop anti-drug antibodies and no longer respond to current treatment
- Ablynx signed a licensing deal with Pfizer in 2006 for Nanobodies to TNFα, potentially worth \$212.5M in milestone payments plus royalties



Source: 1 Thomson Pharma and 2008 filings * United States, Japan, Germany, France, United Kingdom, Italy and Spain

Anti-TNF α Nanobody product - ATN-103

Pre-clinical and clinical status

- pre-clinical data in a mouse RA model showed the anti-TNF α Nanobody product to be more efficacious than Enbrel[®]
- Pfizer successfully completed Phase I studies in the US and Japan in the summer of 2009
- in September 2009, Phase II trials in the US and Japan were initiated in RA patients with the primary endpoint being ACR 20 response at week 16 (dosing is either every four or every eight weeks)

Phase	Region	Indication	# subj.	Treatment	Status
1	US	healthy volunteers	72	SAD	Completed
1	Japan	healthy volunteers	72	SAD	Completed
Ш	US	RA	240	MAD (16w)	Ongoing
II	Japan	RA	60	MAD (16w)	Finished recruitment
II	US / Japan	open label extension of RA Phase II - long term safety	260	MD (48w)	Ongoing





ALX-0141 (anti-RANKL) - cancer related bone loss, Ablynx osteoporosis and RA

- ▼ Product description
 - bivalent RANKL targeting Nanobody with a half-life extended format
- ▼ Clinical development
 - ongoing Phase I study in postmenopausal women
 - treatment phase completed
 - on track to report safety data in September 2010 and final results in H1 2011
 - Phase II development to commence in H2 2011
- ▼ Initial target indication and opportunity
 - patients with cancer related bone loss, with opportunities in osteoporosis and RA
 - first mAb targeting RANKL from Amgen, Prolia[®], with anticipated peak sales of \$4Bn¹
 - ALX-0141 may offer more convenient frequency of administration, reduced side-effect profile and significantly lower cost of goods



extension (HLE)



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Business strategy

- Continue to leverage the advantages of the Nanobody technology broadly across a range of therapeutic areas
- ▼ Rapidly demonstrate proof-of-concept in the clinic
- Y Advance programmes internally to the optimal value creation point
- Partner very selectively while ensuring delivery and possible expansion of some existing relationships where appropriate

Ablynx's key partnerships



Partners

Boehringer

Ingelheim

Boehringer

Ingelheim

Scope

Collaboration focussed on Alzheimer's disease 1st lead Nanobody selected for development

Strategic alliance: up to 10 programmes with a potential value of €1.3Bn, co-promotion options in EU

2 target 50/50 co-discovery/codevelopment collaboration (oncology & immunology)

2 Nanobodies licensed for further development

 $\text{TNF}\alpha$ research and licensing collaboration ATN-103 in Phase II clinical trials

Potential value:

~ €2.2 Bn

+ royalties



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SERONO



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Prospects for the next period



- First clinical centres are expected to open for the TTP Phase II study (ALX-0081/ALX-0681) in September 2010
- Safety data from the anti-RANKL Phase I study (ALX-0141) will be reported in September 2010
- The Phase II trial in RA (ATN-103) with Pfizer is expected to complete recruitment in Q4 2010 and they should have data by Q2 2011
- The Phase II trial in ACS (ALX-0081) will complete recruitment in early 2011 with data available in Q2 2011
- On track to file an IND-equivalent for our anti-IL-6R Nanobody (ALX-0061) in Q4 2010 with Phase I/II trials in RA patients in Q1 2011
- Expect to receive additional milestones from current partnerships
- Y Expect to enter into at least one new commercial agreement
- In October, in Ghent, hosting an R&D day and sponsoring a separate single domain antibody conference



Visit by Flanders Bio to Ablynx

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