



REGULATED INFORMATION

ABLYNX ANNOUNCES 2011 FULL YEAR RESULTS

Strong year of progress at Ablynx as first Nanobody® reaches clinical proof-of-concept

GHENT, Belgium, 22nd February 2012 – Ablynx (Euronext Brussels: ABLX), the Belgian-based biopharmaceutical company focused on the discovery and development of Nanobodies for the treatment of serious life-threatening diseases, today announced the Company's consolidated results for the year ending 31 December 2011, which have been prepared in accordance with IFRS as adopted by the European Union.

Operating Highlights

- First clinical proof-of-concept for a Nanobody
- Four Phase II and five Phase I trials for Nanobodies advanced or completed
- Third collaborative deal with Merck Serono, including a €20 million up-front payment

Financial Highlights

- Revenues of €21.9 million
- Net loss for the period of €43.9 million, reflecting increased R&D expenditure on higher number of development candidates
- Net cash burn controlled at €32 million
- Strong financial position with €83.8 million in cash at period end including cash, cash equivalents, restricted cash and short-term investments

Commenting on the 2011 results, Dr Edwin Moses, Chairman and CEO of Ablynx, said:

"Our strategy is to create a broad range of Nanobody-based, value-creating opportunities, developed initially both by ourselves and with partners. During 2011, Ablynx made substantial progress on many fronts, with the first clinical proof-of-concept for a Nanobody being achieved in a Phase II trial undertaken with Pfizer, the signing of a major new partnership and the delivery of our first Nanobody to patients using the pulmonary route. All are major achievements and have put our unique Nanobody-based technology platform firmly on the pharmaceutical map."

"We anticipate further strong progress during the coming year. We expect more Nanobodies to enter the clinic for the first time and to add further collaborations with pharmaceutical companies to our partnership list, helping us to widen the number of opportunities to create value for shareholders and at the same time manage our cash and diminish risk. We look forward to reporting news of our progress during 2012."

About Ablynx

[Ablynx](#) is a biopharmaceutical company engaged in the discovery and development of [Nanobodies](#)[®], a novel class of therapeutic proteins based on single-domain antibody fragments, for a range of serious and life-threatening human diseases, including inflammation, haematology, oncology and pulmonary disease. Today, the Company has over [25 programmes in the pipeline](#) and seven Nanobodies at clinical development stage. Ablynx has ongoing research collaborations and significant partnerships with major pharmaceutical companies, including Boehringer Ingelheim, Merck Serono and Novartis. The Company is headquartered in Ghent, Belgium. More information can be found on www.ablynx.com.

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Webcast and presentation

Dr Edwin Moses, CEO and Chairman of Ablynx, will host a conference call webcast during which the full year results for 2011 will be presented, followed by a Q&A session. This event will be held on Thursday, 23 February 2012 at 4.00 p.m. CET.

The conference call will be webcast live and may be accessed on the home page of the Ablynx website at www.ablynx.com. Shortly thereafter, a replay of the webcast will be available on the Company's website.

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company's directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its or their parent or subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.

Results Overview

Revenues were €21.9 million (2010: €31.4 million), comprising up-fronts, milestone payments, payments for full-time equivalents and grants. Cash-in for the period was €28.5 million (2010: €31.1 million) and, including the outstanding €8 million from the new deal signed at the end of 2011 with Merck Serono and received in January 2012, showed a 17% increase compared with 2010. Total research and development costs were €56.3 million (2010: €48.5 million), in line with the increasing number of pre-clinical and clinical development candidates. General and administrative expenses remained well under control at €10.4 million (2010: €8.9 million). The loss from continuing operations, before tax and net finance income, increased to €45.5 million (2010: €25.9 million). The net loss for the period was €43.9 million (2010: €24.5 million). The Company ended the year with €83.8 million in cash, cash equivalents, restricted cash and short-term investments.

Operational Review

Pipeline update

During the last 12 months, the first clinical proof-of-concept for a Nanobody was achieved in the Phase II clinical trials of the anti-TNF α Nanobody (ATN-103) carried out by Pfizer in patients with rheumatoid arthritis (RA). Despite the success of this study with ATN-103, Pfizer decided, as part of an internal R&D prioritisation exercise, not to pursue further development of the anti-TNF α Nanobody programmes and all related rights were returned to Ablynx in November, together with clinical data, clinical trial supplies, assay methods and manufacturing processes. Ablynx believes that the opportunity for a product such as ATN-103 is potentially substantial in a number of indications such as RA, Psoriasis and Crohn's Disease. The Company is now seeking a new partner to advance this asset into the next stages of clinical development.

Elsewhere in our pipeline, we continued to make good progress during 2011 with a strong focus on optimal allocation of resources, product prioritisation and careful management of costs.

After completing a Phase II trial of the anti-vWF Nanobody in Acute Coronary Syndrome (ACS), Ablynx decided to halt further development in this indication because of the highly competitive commercial environment, and instead focus its efforts with this anti-vWF Nanobody on the orphan disease Thrombotic Thrombocytopenic Purpura (TTP), where a Phase II trial continues. The Phase I study for the Nanobody targeting RANKL (ALX-0141), which may be important in osteoporosis and oncology, was completed with promising results.

In addition, three new Phase I trials were initiated with Nanobodies directed at a diverse range of diseases including RA (anti-IL-6R, ALX-0061), cancer (anti-CXCR4, ALX-0651) and viral infections (anti-RSV, ALX-0171). ALX-0061 has already completed this Phase I trial in RA patients and progressed further into a Phase II trial.

Ablynx-led programmes summary

- Reported Phase II data for ALX-0081, an anti-vWF Nanobody, in high risk ACS patients undergoing a PCI procedure. The study showed that ALX-0081 has an acceptable safety profile but is not superior in this respect to ReoPro®.
- Phase II study of the anti-vWF Nanobody in TTP patients continued recruitment, though more slowly than anticipated due primarily to administrative delays in opening new sites.
- Initiated and completed a Phase I study with the anti-IL-6R Nanobody, ALX-0061, in patients with RA. Based on the positive data from this trial, a Phase II study in the same patient population was started.
- Reported promising data from the Phase I study with ALX-0141, a Nanobody targeting RANKL, a key mediator in bone remodelling.
- Initiated a Phase I study with ALX-0171, a Nanobody targeting Respiratory Syncytial Virus (RSV) infections. This is the first Nanobody in clinical development to be delivered by inhalation.
- Initiated a Phase I study with an anti-CXCR4 Nanobody, ALX-0651, for use in stem cell mobilisation. ALX-0651 is the first Nanobody in clinical development targeting a G-protein-coupled receptor (GPCR).

Partnerships update

As reported above, Pfizer demonstrated proof-of-concept for ATN-103, an anti-TNF α Nanobody, in a Phase II study in patients with RA. Ablynx subsequently regained all rights from Pfizer to Nanobodies targeting TNF α , including ATN-103.

Our relationship with Merck Serono goes from strength to strength and during 2011 was expanded with a third co-discovery and co-development deal on two targets for osteoarthritis. This resulted in a €20 million up-front payment to Ablynx. Ablynx and Merck Serono also selected a Nanobody candidate, ALX-0761, for pre-clinical development for the treatment of autoimmune diseases, triggering a €1 million milestone payment to Ablynx.

Our collaborations with Boehringer Ingelheim also made good progress in 2011, with the selection of a second Nanobody for development during the year triggering a €5 million milestone to Ablynx. A third development candidate was announced in early 2012 which also triggered a €5 million payment to Ablynx.

At the end of 2011, there were a total of 18 active partnered Nanobody programmes in various stages of pre-clinical research and development with our partners Merck Serono, Boehringer Ingelheim and Novartis.

Corporate developments

During 2011, it was decided to transfer all activities from the Company's research facility in Portugal to Ghent. Ablynx was also granted a certificate for Good Laboratory Practice (GLP) at its Ghent facility.

Ablynx added a number of granted patents to its expanding patent estate around half-life extension, including a key patent on the half-life extension used in its clinical candidates.

Financial highlights

Key figures

(€ million)	2011	2010
Revenues	21.9	31.4
R&D income	19.9	29.2
Grants	2.0	2.2
Operating expenses	(66.7)	(57.4)
R&D	(56.3)	(48.5)
G&A	(10.4)	(8.9)
Other operating income/(expense)	(0.7)	0.1
Operating result	(45.5)	(25.9)
Finance income (net)	1.6	1.4
Net result	(43.9)	(24.5)
Cash burn	(32.0)	(23.6)
Cash at year end ⁽¹⁾	83.8	115.9

⁽¹⁾ including €3 million restricted cash

Income statement

Total revenues were €21.9 million in 2011 (2010: €31.4 million), comprising up-fronts, milestone payments and payments for full-time equivalents from our partners, together with grants. The decrease relates to lower milestones.

In 2011, research and development expenses increased by €7.8 million to €56.3 million (2010: €48.5 million). This increase was mainly attributable to a €2.5 million increase in personnel costs, as research and development staff increased to 250 by the end of 2011 (2010: 224), and a €5.3 million increase in external development costs largely related to clinical trials.

General and administrative expenses increased by €1.5 million to €10.4 million in 2011 (2010: €8.9 million). This increase was mainly attributable to a €0.9 million increase in personnel costs, as administrative staff increased to 42 by the end of 2011 (2010: 36), and a €0.7 million increase in consultancy costs.

Other operating expenses were €0.7 million (2010: €0.1 million income), mainly because of charges related to the anticipated closing of the Portuguese site in 2012.

As a result of the foregoing, the loss from continuing operations, before tax and net finance income, increased to €45.5 million in 2011 (2010: €25.9 million).

Net finance income primarily comprises interest from deposits and this increased by €0.2 million to €1.6 million in 2011 (2010: €1.4 million). This increase was primarily attributable to higher interest rates.

As a result of the foregoing, the net loss before taxes increased to €43.9 million in 2011 (2010: €24.5 million).

As the Company incurred losses in all of the relevant periods, Ablynx had no taxable income, and therefore paid no taxes.

Balance sheet

The Company's intangible assets include a portfolio of patents which are being amortised over approximately 12 years, and technology licenses that are being amortised over 5 and 18 years. The Company has not capitalised any other patents and it expenses all its research and development activities. The intangible assets also include software licenses.

The Company's non-current tangible assets include the Company's laboratory and office equipment, the investments in its facilities, tax receivables and €3 million restricted cash, which is related to a cash pledge that the Company has provided. The Company does not own any real estate and continues to invest in equipment for its research activities.

Current assets consist mainly of trade receivables, other current assets, other short-term investments, and cash and cash equivalents.

The Company's equity decreased from €100.8 million to €58.6 million mainly as a result of the incorporation of the loss for the year (€43.9 million).

Non-current liabilities relate to the financing of additional investments in the building and the leasing of equipment.

Current liabilities primarily relate to deferred income from collaborative agreements and trade payables.

Cash flow statement

Cash flow from operating activities represented a net outflow of €30.6 million in 2011, as compared to a net outflow of €20.6 million in 2010. The increase is mainly related to the higher loss in 2011.

Cash inflow from investing activities of € 5.3 million comprises primarily expenditure of €2.5 million on property, plant and equipment, and € 8 million movements in short-term investments. Cash flow from financing activities was a net inflow of €1.3 million mainly attributable to increased borrowing (e.g. leasing).

Material events after 31st December 2011

On 1st February 2012, Ablynx reported that Boehringer Ingelheim had selected another candidate for pre-clinical development as part of the companies' Strategic Alliance and that this triggered a €5 million milestone payment to Ablynx.

On 14th February 2012, Ablynx announced the strengthening of its management team with the appointment of Dr Andreas Menrad as Chief Scientific Officer.

Outlook for 2012

Ablynx will continue to exploit the broad applicability of the Nanobody platform and will seek partnerships for target-based, pre-clinical and clinical programmes to maximise potential value creation and manage cash flow by accessing external resources and capabilities. In addition to its own pipeline progression, Ablynx expects to see its 18 partnered pre-clinical programmes make further progress during the year, with the potential for the first Phase I trials from these partnered programmes starting in 2012.

Potential proof-of-concept data are expected from the current Phase II study for ALX-0061 in RA patients in the second half of 2012. Data are also expected from the Phase I study for ALX-0651 (anti-CXCR4) in the first half of 2012 and from the Phase I study for ALX-0171 (anti-RSV) in the second half of 2012. Potential proof-of-concept data for the Phase II study in TTP are expected in H2 2013.

Ablynx believes that further clinical development of its anti-TNF α assets and its anti-RANKL asset will require collaboration with a pharmaceutical partner. In addition, as a consequence of its pipeline prioritisation, the Company does not anticipate taking ALX-0651 beyond Phase I.

During 2012, Ablynx will focus its investments on its more advanced clinical assets, including ALX-0061, ALX-0081/ALX-0681 in TTP, ALX-0171 and the co-discovery and co-development programmes with Merck Serono. In addition, the Company will invest in activities to identify and secure partners to further develop ATN-103 and ALX-0141.

Strong cash management will remain of key importance and the net cash burn target for 2012 is expected to be in the range of €20-25 million.

Financial calendar 2012

31 March – Online publication annual report 2011
26 April – Annual general meeting
16 May – Q1 2012 results
22 August – Half year 2012 results
14 November – Q3 2012 results

Glossary

ACS	Acute coronary syndrome - a set of signs and symptoms that are a result of the narrowing of the vessel in the arteries
GPCRs	G protein-coupled receptors, also known as seven-transmembrane domain receptors
IL-6R	Receptor for interleukin-6 - a cytokine involved in a wide range of biological activities
Nanobody	Protein that is composed of one or more binding domains with the structural and functional characteristics of naturally occurring heavy chain variable domains (VHH's) from Camelidae
Orphan disease	Rare medical condition
PCI	Percutaneous coronary intervention - surgically widening of the arteries using either a balloon or a stainless steel tube (stent)
Proof-of-concept	Proof, demonstrated in a clinical trial, that a product is effective in patients
RA	Rheumatoid arthritis
RANKL	Receptor activator of nuclear factor kappa-B ligand - a key regulator in bone remodelling
RSV	Respiratory syncytial virus
TNF α	Tumour necrosis factor alpha - a cytokine involved in systemic inflammation
TTP	Thrombotic thrombocytopenic purpura - a rare blood disorder
vWF	von-Willebrand factor - a blood glycoprotein involved in haemostasis

FINANCIAL INFORMATION

The consolidated financial statements have been prepared in accordance with IFRS, as adopted by the EU. The financial information included in this press release is an extract from the IFRS consolidated statements that will be published on 31 March 2012.

The statutory auditor, Deloitte Bedrijfsrevisoren/Reviseursd'Entreprises, represented by Gert Vanhees, has issued an unqualified report dated 22 February 2012 on the Company's consolidated accounts as of and for the year ended 31 December 2011, and has confirmed that the consolidated balance sheet, the consolidated statements of comprehensive income, cash flow and changes in shareholders' equity, included in this press release, are consistent in all material aspects with the consolidated accounts from which they have been derived.

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

(€ '000)	Year ended 31 December	
	2011	2010
Revenue:		
Research and development	19,861	29,169
Grants	2,008	2,263
Total revenue	21,869	31,432
Research & development expense	(56,307)	(48,512)
General & administrative expense	(10,423)	(8,882)
Total operating expenses	(66,730)	(57,394)
Other operating income/(expense)	(668)	97
Operating result	(45,529)	(25,865)
Finance income (net)	1,634	1,395
Finance income	1,737	1,607
Finance cost	(103)	(212)
Loss before taxes	(43,895)	(24,470)
Income tax expense	0	0
Loss for the year	(43,895)	(24,470)
Other comprehensive loss :		
Fair value gains/losses on available-for-sale financial assets, net of tax	0	(12)
Total comprehensive income for the period	(43,895)	(24,482)
Loss attributable to equity holders	(43,895)	(24,470)
Total comprehensive loss attributable to equity holders	(43,895)	(24,482)
Basic and diluted loss per share	(1.01)	(0.58)

CONSOLIDATED BALANCE SHEET

(€'000)	As at 31 December	
	2011	2010
Non-current assets	11,979	10,319
Intangible fixed assets	1,018	1,416
Property, plant & equipment	4,984	4,692
Restricted Cash	3,000	3,000
Tax receivables	2,977	1,211
Current assets	86,550	121,070
Trade receivables	2,233	5,277
Other current assets	1,301	1,334
Tax receivables	489	489
Accrued income and deferred charges	1,705	1,128
Other short-term financial investments	77,500	85,500
Cash and cash equivalents	3,322	27,342
Total assets	98,529	131,389
Equity attributable to equity holders	58,630	100,790
Share capital	73,304	73,076
Share premium account	126,457	126,421
Share-based payments	6,648	5,177
Retained earnings	(147,779)	(103,884)
Non-current liabilities	1,752	1,134
Borrowings	1,752	1,134
Current liabilities	38,147	29,465
Borrowings	805	322
Trade payables	9,867	7,582
Other current liabilities	3,868	2,813
Deferred income	23,607	18,748
Total liabilities	39,899	30,599
Total equity and liabilities	98,529	131,389

CONSOLIDATED CASH FLOW STATEMENT

(€'000)	Year ended 31 December	
	2011	2010
Cash flows from operating activities		
Loss before income tax	(43,895)	(24,470)
Adjustments for:		
Amortization	609	487
Depreciation	2,169	2,390
(Profit)/loss on disposal of property, plant and equipment		(49)
Share-based payment expense	1,569	1,814
Finance income – net	(1,689)	(1,359)
Net movement in trade and other receivables	734	(4,124)
Net movement in trade and other payables	8,201	3,349
Cash used in operations	(32,302)	(21,962)
Interest paid	(23)	(13)
Interest received	1,712	1,374
Income tax paid	0	0
Net cash used in operating activities	(30,613)	(20,601)
Cash flows from investing activities		
Purchases of property, plant and equipment	(3,682)	(2,596)
Proceeds from sale of property, plant and equipment	1,221	106
Purchases of intangible assets	(211)	(517)
Purchases of available-for-sale financial assets		0
Purchases of short-term financial investments		(57,500)
Sale of available-for-sale financial assets		20,000
Sale of short-term financial investments	8,000	0
Transfer to non-current asset	0	(3,000)
Net cash used in investing activities	5,328	(43,507)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares		47,181
Proceeds from exercise of warrants	164	150
Proceed of borrowings	1,477	
Repayments of borrowings	(376)	(190)
Net cash generated from financing activities	1,265	47,141
Net (decrease)/increase in cash and cash equivalents	(24,020)	(16,967)
<i>Cash and cash equivalents at beginning of the period</i>	<i>27,342</i>	<i>44,309</i>
Cash and cash equivalents at end of the period	3,322	27,342

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDER EQUITY

(€'000)	Share capital	Share premium	Share based payments	Retained loss	Fair Value Reserve	Total Equity
Balance at 31 December 2009	63,189	88,851	3,489	(79,415)	12	76,126
Loss of the period				(24,470)		
Other comprehensive income						
Available-for-sale financial assets					(12)	
Total Comprehensive Income				(24,470)	(12)	
Warrant plans						
Share Based Payments			1,813			
Transactions with owners						
Capital increase	12,460	37,541				
Issuance costs	(2,819)					
Exercise of warrants	246	29	(125)			
Balance at 31 December 2010	73,076	126,421	5,177	(103,885)	0	100,789
Loss of the period				(43,895)		
Other comprehensive income						
Available-for-sale financial assets						
Total Comprehensive Income						
Warrant plans						
Share Based Payments			1,570			
Transactions with owners						
Capital increase						
Issuance costs						
Exercise of warrants	228	35	(99)			
Balance at 31 December 2011	73,304	126,456	6,648	(147,780)	0	58,628