



## **ABLYNX ANNOUNCES 2016 FULL YEAR RESULTS**

***Significant progress in key pre-clinical and clinical development programmes***

**[Conference call and webcast](#) today at 4pm CET/10am ET**

**GHENT, Belgium, 23 February 2017 - Ablynx [Euronext Brussels: ABLX; OTC: ABYLY]** today announced its financial results for the year ended 31<sup>st</sup> December 2016, which have been prepared in accordance with IFRS as adopted by the European Union, business highlights year-to-date and the outlook for the remainder of the year.

- Total revenues of €85.2 million (+10%); cash position of €235.4 million, strengthened by the successful private placement of new shares via an accelerated book building procedure that raised €74.2 million
- Net cash burn<sup>1</sup> of €72.2 million, in line with the previously guided range of €65-75 million
- R&D highlights:
  - strong recruitment of patients with acquired thrombotic thrombocytopenic purpura (aTTP) in the Phase III HERCULES study with caplacizumab
  - successful completion of two Phase IIb studies in rheumatoid arthritis (RA) with vobarilizumab in approximately 600 patients
  - completed recruitment of 312 patients with systemic lupus erythematosus (SLE) in Phase II study of vobarilizumab
  - positive topline results for the anti-respiratory syncytial virus (RSV) Nanobody® (ALX-0171) in 53 hospitalised infants
  - three Phase I trials started in partnered programmes
  - initiated 19 new discovery programmes both proprietary and as part of collaborations
  - extended one pharmaceutical partnership and received four milestone payments from partners
- *Post-period highlights:*
  - initiated the global Phase IIb RESPIRE study of ALX-0171 in 180 infants hospitalised as a result of a RSV infection
  - encouraging Phase Ib data in the Merck KGaA partnered anti-IL-17A/F programme in psoriasis
  - submitted an application in Europe for regulatory approval of caplacizumab for the treatment of aTTP

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<sup>1</sup> Net cash burn is the difference between the cash position of the current and the previous year minus the proceeds (net of issue costs) from the issuance of ordinary shares and/or the issue of convertible bonds

- *Additional significant clinical and regulatory catalysts anticipated in 2017:*
  - topline results from the Phase III HERCULES study of caplacizumab in aTTP patients expected in H2 2017
  - initiation of the first clinical trial of a Nanobody developed as part of the immuno-oncology collaboration with Merck & Co., Inc.
  - dependent on establishing a new pharmaceutical partnership, initiation of a Phase III programme in RA with vobarilizumab
  - at least one additional Phase I start in a partnered programme
  - completion of the ~300 patient systemic lupus erythematosus (SLE) study with vobarilizumab, with topline data expected in early 2018

“We have made significant progress across a number of our key clinical programmes during 2016 and continue to advance our growing pipeline of products which now has more than 45 proprietary and partnered programmes” said Dr Edwin Moses, CEO of Ablynx. “We are approaching a key inflection point with our filing for regulatory approval of caplacizumab in Europe, results from our Phase III trial expected in H2 2017 and commercial preparations well underway for the first launch of the product expected in 2018. We remain focused on delivering sustainable value to all our stakeholders and look forward to an exciting year with multiple catalysts across our extensive pipeline.”

## **Financial highlights**

(€ million)	<b>FY 2016</b>	<b>FY 2015</b>	<b>Variance</b>
Total revenue and grant income	85.2	77.5	10%
R&D income	84.8	76.8	10%
Grants	0.4	0.7	(43%)
Operating expenses	(113.8)	(94.5)	20%
R&D	(100.3)	(83.1)	21%
G&A	(13.5)	(11.4)	18%
Operating result	(28.6)	(17.0)	(68%)
Net financial result	27.5	(37.6)	> 100%
Net result	(1.1)	(54.5)	98%
Net cash flow	(72.2) <sup>(1)</sup>	(67.2) <sup>(3)</sup>	(7%)
Cash* at 31 December	235.4 <sup>(2)</sup>	236.2 <sup>(2)</sup>	-

<sup>(1)</sup> excluding €71.4 million net proceeds from the private placement (which raised €74.2 million, announced on 1 June 2016)

<sup>(2)</sup> including €1.6 million in restricted cash

<sup>(3)</sup> excluding €97.2 million net proceeds from the convertible bonds (which raised €100 million, announced on 20 May 2015)

\* defined as liquidity position in the cash flow statement

## **Operational review**

### **R&D update**

In [January](#), Ablynx’s partner, Boehringer Ingelheim, initiated a Phase Ib study with an anti-VEGF/Ang2 Nanobody in patients with solid tumours, triggering an €8 million milestone payment. Boehringer Ingelheim is expected to recruit 80 patients into this study.

In [February](#), the positive results from the Phase II TITAN study of caplacizumab in 75 patients with aTTP were published in [The New England Journal of Medicine](#).

In [April](#), Ablynx’s partner, Boehringer Ingelheim, initiated a Phase I study of an anti-CX3CR1 Nanobody being explored as a potential therapeutic for chronic kidney disease, triggering an €8 million milestone payment.

Also in [April](#), Novartis received clearance for its Investigational New Drug (IND) application to begin a Phase I study with a Nanobody to a G-protein coupled receptor (GPCR) target, triggering an undisclosed milestone payment.

In [May](#), Ablynx reported positive topline results for its inhaled anti-RSV Nanobody (ALX-0171) in a Phase I/IIa study in 53 infants hospitalised as a result of a RSV infection.

Also in [May](#), Ablynx reported on a post-hoc analysis of the Phase II TITAN study which showed that 73.6% fewer patients experienced one or more major thromboembolic events, or died, when treated with caplacizumab compared to placebo.

In [July](#), Ablynx announced positive topline results from a Phase IIb study of its anti-IL-6R Nanobody, vobarilizumab, as a monotherapy in 251 RA patients.

In [August](#), Ablynx announced topline results from a Phase IIb study of its anti-IL-6R Nanobody, vobarilizumab, in a combination study with methotrexate in 345 RA patients.

In [October](#), Ablynx announced the initiation of a three-year Phase III follow-up study of patients with aTTP who had completed the Phase III HERCULES trial.

In [November](#), Ablynx announced it had achieved an initial discovery milestone with a multi-specific Nanobody as part of its collaboration with Novo Nordisk, triggering a €1 million milestone payment.

In December, Ablynx completed recruitment of 312 patients in a Phase II study with vobarilizumab in patients with SLE. Topline results from this trial are expected in H1 2018.

### **Corporate developments**

In [June](#), Ablynx successfully raised €74.2 million through a private placement of new shares via an accelerated book building procedure. The private placement was oversubscribed and was upsized from the €60 million initially targeted.

In [October](#), Ablynx announced a second extension of its research collaboration with a subsidiary of Merck & Co., Inc. to develop and commercialise Nanobody candidates directed towards an undisclosed voltage gated ion channel. The extension triggered a €1 million payment, and Merck will extend their funding of the research collaboration at Ablynx to September 2018.

Also in [October](#), Ablynx communicated AbbVie's decision not to exercise its opt-in right, at that time, and license vobarilizumab in RA. Ablynx confirmed that it would continue preparations for a Phase III programme with vobarilizumab in RA while in parallel exploring the possibility of a new partnership which would be needed to support further clinical development of vobarilizumab in this indication.

### **Post-period highlights**

In [January 2017](#), Ablynx initiated the Phase IIb RESPIRE study of its wholly-owned, first-in-class, inhaled anti-RSV Nanobody, ALX-0171, for the treatment of RSV infection, in a world-wide trial to include 180 hospitalised infants.

Also in [January 2017](#), Ablynx's partner, Merck KGaA, announced encouraging results from their Phase Ib study of the bi-specific anti-IL-17A/F Nanobody, in patients with moderate to severe psoriasis.

In [February 2017](#), Ablynx submitted a Marketing Authorisation Application to the European Medicines Agency for caplacizumab, its anti-vWF Nanobody for the treatment of aTTP.

### **Outlook for the rest of 2017**

During H1 2017, Ablynx expects to hold scientific advice and “end-of-Phase II” meetings with regulators in Europe and the USA to discuss its Phase IIb results with vobarilizumab in RA and plans for a Phase III programme. In parallel, Ablynx will continue to explore the possibility of a new partnership which would be needed to support further clinical development of this molecule in RA.

In the second half of 2017, Ablynx expects to:

- report topline results from its Phase III HERCULES study of caplacizumab in approximately 132 patients with aTTP
- advance its caplacizumab commercialisation strategy and continue preparations for launch in 2018
- start clinical development for Japan with both caplacizumab and the anti-RSV Nanobody (ALX-0171)
- initiate clinical development of ALX-0171 in patients who have undergone stem cell transplantation and have a RSV infection
- complete the ~300 patient trial of vobarilizumab in SLE, with topline results expected in early 2018

During 2017, the Company expects that at least two new partnered programmes could enter clinical development (including the first Nanobody programme arising from the immune-oncology collaboration with Merck & Co., Inc.) which would trigger milestone payments to Ablynx.

The net cash burn for the full year 2017 is expected to be in the range €75-85 million.

### **Detailed financial review**

#### **Income statement**

Total revenues increased by 10% to €85.2 million (2015: €77.5 million), mainly driven by milestone payments from the collaboration with Boehringer Ingelheim, partially offset by lower recognised income, mainly from the upfront payment by AbbVie made in 2013.

Total research and development costs increased to €100.3 million (2015: €83.1 million) in line with growth in external development costs, largely related to clinical trials expenditure for caplacizumab, vobarilizumab and ALX-0171.

General and administrative costs increased to €13.5 million (2015: €11.4 million), mainly driven by pre-commercialisation expenditure for caplacizumab.

As a result of the foregoing, the operating loss increased to €28.6 million (2015: €17.0 million).

The net financial profit of €27.5 million comprises finance income of €34.7 million resulting from a decrease in the fair value of the derivative associated with the convertible bond (following a decrease in the Ablynx share price at year-end compared to that at the end of 2015), and finance costs of €7.2 million, (mainly related to the amortisation of the debt component of the convertible bond).

As a result of the foregoing, the net loss for 2016 decreased to €1.1 million (2015: €54.5 million).

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

**Balance sheet**

Ablynx's intangible assets include a portfolio of patents which are fully amortised, and technology licenses which are being amortised over 5, 18 and 20 years. The intangible assets also include software licenses. The Company expenses all its research and development activities.

Ablynx's non-current assets include the Company's laboratory and office equipment, the investments in its facilities, €17.6 million in R&D related tax receivables and €1.6 million restricted cash, which is a cash pledge that the Company has provided for the lease of its main office and laboratory building. Ablynx owns one small facility and continues to invest in equipment for its research activities.

Ablynx's current assets of €242.2 million consist mainly of cash and cash equivalents and other short-term financial investments. Cash and cash equivalents consist of cash and deposits held on call with several banks. The Company also places cash in term accounts with maturities limited to a maximum of one year.

Shareholders' equity increased from €27.9 million at the end of 2015 to €103.1 million at the end of 2016, mainly as a result of the €71.4 million net proceeds from the private placement announced 1 June 2016.

Non-current liabilities relate to the senior unsecured bonds due on 27 May 2020 with a principal value of €100 million.

Current liabilities consist mainly of trade payables and deferred income related to the upfront payments received from partners.

**Cash flow statement**

Cash flow from operating activities represented a net outflow of €66.6 million in 2016 compared to a net outflow of €69.0 million in 2015.

Cash flow from investing activities represented a net inflow of €45.9 million compared to a net outflow of €39.7 million in 2015. The net cash inflow mainly results from the sale of short term financial investments.

Cash flow from financing activities represented a net inflow of €70.4 million compared to a net inflow of €100.6 million in 2015. The difference primarily relates to higher net proceeds from the issue of convertible bonds in 2015 compared to the net proceeds raised via an accelerated book building procedure in 2016.

Ablynx ended the period with a total liquidity position of €235.4 million (2015: €236.2 million) which consists of cash and cash equivalents of €53.3 million, other short-term financial investments of €180.5 million and restricted cash of €1.6 million.

**Webcast and presentation**

Ablynx will host a conference call/webcast today at 4 pm CET, 10 am ET. The webcast may be accessed by clicking [here](#). To participate in the Q&A, please dial +32 (0)2 4023092, using confirmation code 8519613. Shortly thereafter, a replay of the webcast will be available on the Company's website: <http://www.ablynx.com/news/events-presentations/>.

**Financial calendar 2017**

31 March – online publication Annual Report 2016  
27 April – Annual General Meeting 2017  
11 May – results Q1 2017  
24 August – half year results 2017  
16 November – results Q3 2017

**2017 shareholders' clubs at Ablynx (Dutch language only)**

8 March at 5.30pm  
24 May at 5.30pm  
13 September at 5.30pm  
6 December at 5.30pm

To attend an event, please register via email: [investors@ablynx.com](mailto:investors@ablynx.com), stating your name and preferred day.

**About Ablynx**

[Ablynx](#) is a biopharmaceutical company engaged in the development of [Nanobodies®](#), proprietary therapeutic proteins based on single-domain antibody fragments, which combine the advantages of conventional antibody drugs with some of the features of small-molecule drugs. Ablynx is dedicated to creating new medicines which will make a real difference to society. Today, the Company has approximately [45 proprietary and partnered programmes](#) in development in various therapeutic areas including inflammation, haematology, immuno-oncology, oncology and respiratory disease. The Company has collaborations with multiple pharmaceutical companies including AbbVie, Boehringer Ingelheim, Eddingpharm, Merck & Co., Inc., Merck KGaA, Novartis, Novo Nordisk and Taisho Pharmaceuticals. The Company is headquartered in Ghent, Belgium. More information can be found on [www.ablynx.com](http://www.ablynx.com).

**For more information, please contact:**

**Ablynx:**

Dr Edwin Moses  
CEO

t: +32 (0)9 262 00 07

m: +32 (0)473 39 50 68

e: [edwin.moses@ablynx.com](mailto:edwin.moses@ablynx.com)


Marieke Vermeersch

Director IR & Corporate Communications

t: +32 (0)9 262 00 82

m: +32 (0)479 49 06 03

e: [marieke.vermeersch@ablynx.com](mailto:marieke.vermeersch@ablynx.com)

 [@AblynxABLX](#)

**Ablynx media/analyst relations:**

**FTI Consulting**

Julia Phillips, Brett Pollard, Mo Noonan, Matthew Moss

t: +44 20 3727 1000

e: [ablynx@fticonsulting.com](mailto:ablynx@fticonsulting.com)

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## **FINANCIAL INFORMATION**

The 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 full IFRS consolidated financial statements which will be published on 31 March 2017.

The statutory auditor, Deloitte Bedrijfsrevisoren/Reviseursd'Entreprises, represented by Gert Vanhees, has substantially completed the audit procedures on the IFRS statements as of and for the year ended 31 December 2016, and has confirmed that the statements of comprehensive income, the balance sheet, the cash flow statement and changes in shareholders' equity, included in this press release, are consistent in all material aspects with the accounts from which they have been derived.



## STATEMENT OF COMPREHENSIVE INCOME

(€ '000)	Year ended 31 December	
	2016	2015
Revenue:		
Research and development	84,773	76,761
Grants	414	779
<b>Total revenue and grant income</b>	<b>85,187</b>	<b>77,540</b>
Research and development expenses	(100,315)	(83,084)
General and administrative expenses	(13,528)	(11,405)
<b>Total operating expenses</b>	<b>(113,843)</b>	<b>(94,489)</b>
Other operating income	68	
Other operating expenses	(12)	(6)
<b>Operating result</b>	<b>(28,600)</b>	<b>(16,955)</b>
<b>Financial result (net)</b>	<b>27,513</b>	<b>(37,592)</b>
Finance income	34,761	1,768
Finance cost	(7,248)	(39,360)
<b>Loss before taxes</b>	<b>(1,087)</b>	<b>(54,547)</b>
<b>Loss for the year</b>	<b>(1,087)</b>	<b>(54,547)</b>
<b>Total comprehensive income for the period</b>	<b>(1,087)</b>	<b>(54,547)</b>
Loss attributable to equity holders	(1,087)	(54,547)
Total comprehensive loss attributable to equity holders	(1,087)	(54,547)
Basic and diluted loss per share	(0.02)	(1.00)

## BALANCE SHEET

(€'000)	As at 31 December	
	2016	2015
Non-current assets	24,573	19,124
Intangible fixed assets	1,585	339
Property, plant and equipment	3,746	2,620
Restricted cash	1,600	1,648
R&D tax credit receivable	17,642	14,517
Current assets	242,191	246,148
Trade receivables	3,512	6,782
Other current assets	899	1,976
Tax receivables	2,299	1,766
Accrued income and deferred charges	1,641	1,030
Other short-term financial investments	180,484	230,992
Cash and cash equivalents	53,356	3,602
<b>Total assets</b>	<b>266,764</b>	<b>265,272</b>
Equity attributable to equity holders	103,055	27,909
Share capital	106,057	96,287
Share premium account	252,297	187,316
Share-based compensation reserve	8,093	6,610
Retained earnings	(263,392)	(262,304)
Non-current liabilities	104,349	134,828
Borrowings	104,349	134,828
Current liabilities	59,360	102,535
Trade payables	20,319	11,656
Other current liabilities	5,419	4,756
Deferred income	33,622	86,123
Total liabilities	163,709	237,363
<b>Total equity and liabilities</b>	<b>266,764</b>	<b>265,272</b>

## CASH FLOW STATEMENT

(€'000)	Year ended 31 December	
	2016	2015
<b>Cash flows from operating activities</b>		
Loss before income tax	(1,087)	(54,547)
Adjustments for:		
Amortisation	485	201
Depreciation	1,761	1,140
Share-based compensation expense	2,572	1,821
Net financial income	(298)	(1,100)
Net loss arising on the convertible bond designated as at fair value through profit and loss	(34,334)	34,646
Finance expense recognized in respect of the convertible bond	7,105	4,623
Net movement in trade and other receivables	85	(11,648)
Net movement in trade and other payables	(43,183)	(45,197)
<b>Cash used in/provided by operations</b>	<b>(66,894)</b>	<b>(70,061)</b>
Interest paid	(1)	(1)
Interest received	298	1,101
<b>Net cash (used in)/provided by operating activities</b>	<b>(66,597)</b>	<b>(68,961)</b>
<b>Cash flows from investing activities</b>		
Purchases of property, plant and equipment	(2,890)	(1,459)
Purchases of intangible assets	(1,730)	(101)
Sale / (Purchase) of short-term financial investments	50,560	(38,118)
<b>Net cash (used in)/provided by investing activities</b>	<b>45,940</b>	<b>(39,678)</b>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of ordinary shares	71,442	
Proceeds from exercise of warrants	2,220	5,160
Proceed from issue of convertible bond (net of issue costs)		97,185
Interest paid convertible bond	(3,250)	(1,625)
Repayments of borrowings		(141)
<b>Net cash generated from financing activities</b>	<b>70,412</b>	<b>100,579</b>
<b>Net (decrease)/increase in cash and cash equivalents</b>	<b>49,755</b>	<b>(8,060)</b>
<i>Cash and cash equivalents at beginning of the period</i>	<i>3,601</i>	<i>11,661</i>
<b>Cash and cash equivalents at end of the period</b>	<b>53,356</b>	<b>3,601</b>

## STATEMENT OF CHANGES IN SHAREHOLDER EQUITY

(€'000)	Share capital	Share premium	Share- based compensation	Retained loss	Total Equity
<b>Balance at 31 December 2014</b>	<b>91,975</b>	<b>183,645</b>	<b>7,615</b>	<b>(207,761)</b>	<b>75,474</b>
<b>Loss of the period</b>				<b>(54,547)</b>	
<b>Warrant plans</b>					
Share-Based Compensation			1,817	4	
<b>Transactions with owners</b>					
Exercise of warrants	4,311	3,671	(2,821)		
<b>Balance at 31 December 2015</b>	<b>96,286</b>	<b>187,316</b>	<b>6,611</b>	<b>(262,304)</b>	<b>27,909</b>
<b>Loss of the period</b>				<b>(1,087)</b>	
<b>Warrant plans</b>					
Share-Based Compensation			2,571		
<b>Transactions with owners</b>					
Capital increase	10,348	63,804			
Issuance costs	(2,710)				
Exercise of warrants	2,133	1,177	(1,090)		
<b>Balance at 31 December 2016</b>	<b>106,057</b>	<b>252,297</b>	<b>8,092</b>	<b>(263,391)</b>	<b>103,055</b>