

## **ABLYNX ANNOUNCES RESULTS FOR THE FIRST NINE MONTHS OF 2016 AND A YEAR-TO-DATE BUSINESS UPDATE**

### **Strong clinical progress across our product portfolio**

**GHENT, Belgium, 23 November 2016 – Ablynx [Euronext Brussels: ABLX; OTC: ABYLY]** today announced its financial results, summarising the non-audited financial position for the first nine months of 2016, a business update for the year-to-date and the outlook for the next period.

#### **Operational highlights year-to-date**

- Caplacizumab – wholly-owned anti-vWF Nanobody® for the treatment of acquired TTP (aTTP)
  - Publication of the Phase II TITAN study results for caplacizumab in The New England Journal of Medicine (NEJM).
  - Post-hoc analyses of the TITAN study results demonstrated that caplacizumab has a significant effect on clinically relevant endpoints showing a 71% reduction in frequency of major thromboembolic events (e.g. stroke) and a dramatic reduction in refractoriness to treatment; the latter is associated with a very poor prognosis for survival of an acute episode of aTTP.
  - Initial target recruitment of 92 patients in HERCULES Phase III study of caplacizumab already achieved, 6 months ahead of schedule. Target enrolment increased to 132 patients with results still expected in H2 2017.
  - Started 3-year follow-up study with patients who completed the HERCULES study to evaluate the long-term safety and efficacy of caplacizumab, the safety and efficacy of repeated use of caplacizumab and to characterise the severity and long-term impact of aTTP.
  - On track to file for conditional approval of caplacizumab in Europe in early 2017.
- ALX-0171 – wholly-owned inhaled Nanobody for the treatment of RSV infections
  - Once daily inhalation, for 3 consecutive days, of ALX-0171 in infants hospitalised with a RSV infection was safe and well tolerated, had a significant and immediate impact on viral replication and an encouraging initial therapeutic effect.
  - Phase IIb dose-ranging efficacy study in 180 hospitalised infants with a RSV infection on track to start by year-end.
- Vobarilizumab – anti-IL-6R Nanobody for the treatment of RA and SLE
  - Delivered excellent efficacy and safety results from the Phase IIb monotherapy and combination therapy studies of vobarilizumab in RA; AbbVie subsequently decided not to exercise its right to opt-in and license vobarilizumab in this indication. Ablynx has started the process of identifying a new partner for vobarilizumab in RA.
  - Recruitment of 300 patients in SLE Phase II study ahead of schedule; results anticipated in H1 2018.
- Three partnered Nanobody programmes began Phase I clinical development, which triggered >€16 million in success fees to Ablynx.
- Ion channel collaboration with Merck & Co., Inc. extended for the second time, triggering a €1 million milestone payment to Ablynx.
- Initiated >15 new wholly-owned and partnered pre-clinical programmes bringing the total number of active programmes in the R&D pipeline to >45.

#### **Financial highlights – at 30 September 2016**

- Successfully raised €74 million (gross) through an oversubscribed private placement of new shares
- Total revenues were €68.9 million, a 29% increase compared with 2015
- Operating loss of €13.7 million, compared with €13.3 million in 2015

- Net profit of €10.9 million, mainly driven by the accounting treatment of the outstanding convertible bond
- Cash position of €263.6 million compared to €262.2 at 30 September 2015
- Financial guidance for the full year 2016 reiterated

**Commenting on today's update, Dr Edwin Moses, CEO of Ablynx, said:** "Year-to-date, we have made tremendous progress in our R&D portfolio with excellent results from three clinical studies, the expansion of our Nanobody clinical pipeline with three new partnered Phase I programmes starting, and the progression of wholly-owned and partnered early-stage programmes. Our lead programme, caplacizumab, is advancing very well and we are on track to commercialise this product ourselves with the first launch anticipated in Europe in 2018. We were of course disappointed that AbbVie decided not to exercise its right to license vobarilizumab after our Phase IIb results in RA but we remain on track to organise the end-of-Phase II regulatory consultations with the FDA and EMA in H1 2017. We have initiated the process to identify a new partner for vobarilizumab in RA to help take this innovative drug candidate through Phase III and into commercialisation. Recruitment in the Phase II SLE study with vobarilizumab is progressing well. We further strengthened our cash position through an oversubscribed private placement of new shares and agreed a second extension of our ion channel collaboration with Merck & Co."

"We look forward to reporting on important developments throughout 2016 and beyond."

#### **Financial review – 1<sup>st</sup> January 2016 to 30<sup>th</sup> September 2016**

(€ million)	First nine months 2016	First nine months 2015	% change
Total revenue and grant income	68.9	53.6	29%
R&D income	68.5	53.1	29%
Grants	0.4	0.5	(20%)
Operating expenses	(82.6)	(66.9)	23%
R&D	(72.8)	(58.5)	25%
G&A	(9.8)	(8.4)	17%
Operating result	(13.6)	(13.3)	2%
Net financial result	24.5	(8.4)	>100%
Net result	10.9	(21.7)	>100%
Net operational cash flow	(44.1) <sup>(1)</sup>	(41.3) <sup>(2)</sup>	7%
Cash at 30 September	263.6 <sup>(3)</sup>	262.2 <sup>(4)</sup>	0.5%

<sup>(1)</sup> Excluding €71.4 million net proceeds from the private placement of new shares (1 June 2016)

<sup>(2)</sup> Excluding €97.2 million net proceeds from the convertible bond (20 May 2015)

<sup>(3)</sup> Including €1.3 million in restricted cash

<sup>(4)</sup> Including €1.6 million restricted cash

Revenues increased 29% to €68.9 million (2015: €53.6 million) mainly driven by milestone payments received from Boehringer Ingelheim and recognised income from the upfront payments received from Merck & Co., Inc. and Novo Nordisk. As a result of the pipeline maturing with later-stage clinical assets, the operating expenses increased to €82.6 million (2015: €66.9 million), primarily driven by higher R&D expenses attributable to investment in personnel and external development costs. As a result of the above, the operating loss was €13.6 million during the first nine months of 2016 (2015: €13.3 million).

The net financial result of €24.5 million primarily relates to the fair value impact (mainly non-cash) of the convertible bond (driven by the lower share price on 30 September 2016 as compared to 31 December 2015).

As a result of the above, the Company ended the first nine months of 2016 with a profit of €10.9 million (2015: loss of €21.7 million).

Following the successful private placement of new shares, raising €71.4 million in net proceeds, the Company had a positive net cash inflow of €27.4 million for the first nine months of 2016 and ended the period with €263.6 million in cash, cash equivalents, restricted cash and short-term investments.

### **2016 outlook and financial guidance confirmed**

Ablynx will attend the annual American Society of Hematology (ASH) meeting being held on 3-6 December 2016, in San Diego, USA. Prior to the start of the conference, a HERCULES investigator meeting will be hosted by Ablynx and the first global aTTP workshop with key physicians in TTP will be held.

Before year-end, Ablynx expects to start a Phase IIb dose-ranging efficacy study with inhaled ALX-0171 in 180 infants who have been hospitalised as a result of a RSV infection. The results from this study are anticipated in the second half of 2018.

The Company reiterates its net cash burn guidance for the full year 2016 of €65-75 million, not including the net proceeds from the private placement of new shares announced on the 1<sup>st</sup> of June 2016.

### **Financial calendar 2017**

23 February 2017 – full year results 2016

27 April 2017 – Annual General Meeting

11 May 2017 – Q1 results 2017

24 August 2017 – half year results 2017

16 November 2017 – Q3 results 2017

### **Shareholders' clubs @ Ablynx**

7 December 2016 at 5.45pm – in Dutch

8 March 2017 at 5.45pm – in Dutch

If you would like to attend, please contact us via [investors@ablynx.com](mailto:investors@ablynx.com).

### **Glossary**

EMA	European Medicines Agency
FDA	U.S. Food and Drug Administration
IL-6R	receptor of interleukin-6
RA	rheumatoid arthritis
RSV	respiratory syncytial virus
SLE	systemic lupus erythematosus
aTTP	acquired thrombotic thrombocytopenic purpura

### **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 more than [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, Genzyme, 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)

**Disclaimer**

Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company or, as appropriate, the Company 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 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.