



**ABLYNX ANNOUNCES RESULTS FOR THE FIRST NINE MONTHS OF 2017  
AND A YEAR-TO-DATE BUSINESS UPDATE**

***Positive Phase III results with caplacizumab and a successful U.S. IPO***

**GHENT, Belgium, 16 November 2017** – Ablynx NV [Euronext Brussels and Nasdaq: ABLX] today announced its non-audited financial results for the first nine months of 2017, a business update for the year-to-date and the outlook for the next period.

**Business highlights for the year-to-date**

- Corporate
  - In October, successfully raised \$230 million (approximately €195 million) as part of an initial U.S. public offering on Nasdaq
  - In October, established a U.S. subsidiary, Ablynx Inc., and appointed a General Manager based in the U.S.A. to lead the commercialisation of caplacizumab
- Caplacizumab – wholly-owned anti-vWF Nanobody® for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP)
  - In February, submitted a marketing authorisation application (MAA) to the European Medicines Agency (EMA)
  - In July, received Fast Track designation from the U.S. Food and Drug Administration (FDA)
  - In October, reported positive topline results from the Phase III HERCULES study, meeting primary and key secondary endpoints
  - In October, completed recruitment of eligible HERCULES patients into the three-year follow-up study (85% roll-over rate)
- ALX-0171 – wholly-owned inhaled anti-RSV Nanobody for the treatment of RSV infections
  - In August, completed the sequential dose escalation part of the Phase IIb RESPIRE study in 36 infants and, after receiving approval from the Data Monitoring Committee, subsequently initiated the parallel dose part in 144 infants, with topline results expected in H2 2018
- Vobarilizumab – anti-IL-6R Nanobody for the treatment of rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE)
  - Advanced the Phase II STEADY study in 312 patients recruited with SLE, with topline results expected in H1 2018
  - Continued the open-label extension study in RA for those patients who had completed the Phase IIb studies (94% roll-over rate), with topline results expected in H2 2018
- Partnered programmes
  - In May, received a €15 million milestone payment from Merck KGaA for the completion of a pre-clinical package for ALX-1141 targeting ADAMTS-5 in osteoarthritis, with Merck KGaA subsequently starting a Phase I study
  - In June, received a €2.5 million milestone payment from Merck & Co., Inc. as a result of their initiation of a toxicology study with a bi-specific Nanobody as part of our immuno-oncology collaboration
  - In July, entered into a new research collaboration with Sanofi on up to eight new programmes, focused initially on immune-mediated inflammatory diseases, with €23 million in upfront payments and up to €2.4 billion in potential milestones plus tiered royalties

**Financial highlights for the first nine months of 2017**

- Revenues of €44.7 million (2016: €68.9 million)
- R&D expenditure of €73.1 million (2016: €72.8 million)
- Operating loss of €42.1 million (2016: €13.6 million)
- Net cash burn<sup>1</sup> of €26.9 million (2016: €44.1 million)
- Cash position of €208.6 million (2016: €263.6 million)

**Commenting on today's update, Dr Edwin Moses, CEO of Ablynx, said:**

"We are very excited about the progress we have made over the period. We successfully completed the Phase III HERCULES study of our lead, wholly-owned product candidate, showing the great potential that caplacizumab has to change the lives of patients with aTTP, for which there is currently no approved therapeutic drug available. We are now finalising the remaining analyses and are working to complete the regulatory filings. Meanwhile, we have strengthened our medical and commercial teams and have established a U.S. subsidiary, underlining our commitment to rapidly bring this treatment to patients."

"Beyond caplacizumab, we have progressed vobarilizumab in SLE according to plan, and are moving forward with ALX-0171 in RSV-infected hospitalised infants and in RSV-infected stem cell transplant patients. Like caplacizumab in aTTP, these three programmes are focussed on patients with a high unmet medical need and with no or limited treatment options."

"Our recent, very successful listing on Nasdaq was the biggest biotech IPO of the year in the U.S.A. and has resulted in a significant increase in the quality and breadth of our investor base. At the end of September, including the net IPO proceeds, we have approximately €390 million to drive our proprietary programmes forward while continuing to expand and develop our pipeline."

**Financial review – 1 January 2017 to 30 September 2017**

(€ millions)	First nine months 2017	First nine months 2016
Revenue	44.7	68.5
Grant income		0.4
<b>Total revenue and grant income</b>	<b>44.7</b>	<b>68.9</b>
Research and development expenses	(73.1)	(72.8)
General and administrative expenses	(13.7)	(9.8)
<b>Operating result</b>	<b>(42.1)</b>	<b>(13.6)</b>
Financial income	2.0	29.8
Financial expenses	(5.6)	(5.3)
<b>Profit/(loss) for the period</b>	<b>(45.8)</b>	<b>10.9</b>
Net cash flow	(26.9)	(44.1) <sup>(1)</sup>
Cash at 30 September	208.6 <sup>(2)</sup>	263.6 <sup>(3)</sup>

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

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

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

<sup>1</sup> Net cash burn is the difference between the liquidity position of the current and the previous year minus the proceeds (net of issue costs), if any, from the issuance of ordinary shares.

Total revenue and grant income was €44.7 million (2016: €68.9 million) and the difference was driven by comparatively lower recognition of upfront payments from the ongoing collaboration with AbbVie and comparatively lower milestone payments received in 2017. Operating expenses increased to €86.8 million (2016: €82.6 million) primarily due to higher general and administrative expenses, including pre-commercialisation costs for caplacizumab, and expenses related to the preparations for a U.S. IPO. The net financial loss of €3.6 million and the variance versus 2016 primarily relate to the fair value impact and amortisation (mainly non-cash) of the convertible bond. As a result of the above, the Company ended the period with a net loss of €45.8 million (2016: net profit of €10.9 million).

The Company ended the period with a total liquidity position of €208.6 million (2016: €263.6 million) which consists of cash and cash equivalents of €20.4 million, other financial assets of €186.5 million and restricted cash of €1.6 million. This does not include proceeds from the \$230 million U.S. public offering on Nasdaq which closed post period end.

**Outlook for the remainder of 2017 – progressing according to plan**

- Report on the results of the ongoing single and multiple dose ethno-bridging Phase I study of caplacizumab in healthy Japanese subjects
- Aim to present the HERCULES data at a key scientific conference and submit them to a peer-reviewed journal
- Continue the regulatory and commercial preparations for the potential approval and launch of caplacizumab in Europe in 2018 and the U.S.A. in 2019
- Seek regulatory approval to enable a Phase II study in Japan with ALX-0171 in infants hospitalised with a RSV infection
- Seek regulatory approval to enable a global Phase II study with ALX-0171 in adults who have undergone stem cell transplantation and have become infected with RSV

**Next shareholders' club at Ablynx (Dutch language only):** 6 December 2017 at 5.30pm

To attend an event, please register via email: [investors@ablynx.com](mailto:investors@ablynx.com)

**Full year results 2017:** 22 February 2018

**Glossary of terms**

aTTP	acquired thrombotic thrombocytopenic purpura
EMA	European Medicines Agency
FDA	Food and Drug Administration
IPO	initial public offering
MAA	marketing authorisation application
RA	rheumatoid arthritis
RSV	respiratory syncytial virus
SLE	systemic lupus erythematosus

## **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; Merck & Co., Inc., Kenilworth, New Jersey, U.S.; Merck KGaA; Novartis; Novo Nordisk; Sanofi and Taisho Pharmaceuticals. The Company is headquartered in Ghent, Belgium and listed on Euronext Brussels and NASDAQ. More information can be found on [www.ablynx.com](http://www.ablynx.com).

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