



ABLYNX ANNOUNCES 2017 HALF YEAR RESULTS AND YEAR-TO-DATE BUSINESS UPDATE

Important progress in key programmes and a strategic collaboration with Sanofi

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

GHENT, Belgium, 24 August 2017 - Ablynx [Euronext Brussels: ABLX; OTC: ABYLY] today announced its financial results for the six-month period ending 30 June 2017, which have been prepared in accordance with IAS 34 “Interim Financial Reporting” as adopted by the European Union, a business update for the year-to-date and the outlook for the remainder of the year.

Business highlights for the year-to-date

- Caplacizumab – wholly-owned first-in-class anti-vWF Nanobody® for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP)
 - submitted a marketing authorisation application (MAA) to the European Medicines Agency (EMA)
 - completed recruitment of 145 patients in the Phase III HERCULES study, with topline results expected in late Q3 2017
 - received Fast Track designation for aTTP from the U.S. Food and Drug Administration (FDA)
- ALX-0171 – wholly-owned inhaled anti-RSV Nanobody
 - completed the sequential dose escalation part of the Phase IIb RESPIRE study in 36 infants hospitalised as a result of a respiratory syncytial virus (RSV) infection and subsequently initiated the parallel dose part, with topline results expected in H2 2018
- Vobarilizumab – anti-IL-6R Nanobody
 - held “end-of-Phase II” meetings with regulators in Europe and the USA to discuss the Phase IIb data in rheumatoid arthritis (RA) and the design of a potential Phase III programme
 - advanced the Phase II study in patients with systemic lupus erythematosus (SLE), with enrollment completed and topline results expected in H1 2018
 - after discussions with AbbVie and other potential pharmaceutical partners, decided to await the results of the SLE study, and the outcome of AbbVie’s opt-in decision, before deciding on the future strategy for vobarilizumab
- Partnerships
 - entered into a strategic 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
 - reported encouraging results with the bi-specific anti-IL17-A/F Nanobody in a Phase Ib study in plaque psoriasis run by our partner Merck KGaA
 - received a €15 million milestone payment from Merck KGaA for the completion of a pre-clinical package for a novel Nanobody (ALX-1141) targeting ADAMTS-5 in osteoarthritis, with Merck KGaA planning to initiate a Phase I study in H2 2017

- 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 the immunology collaboration

Financial highlights for the first six months of 2017

- Revenues of €34.7 million (2016: €53.1 million)
- R&D expenditure of €50.5 million (2016: €49.0 million)
- Operating loss of €24.8 million (2016: €2.0 million)
- Net cash burn¹ of €30.9 million (2016: €19.0 million)
- Cash position of €204.5 million (2016: €288.7 million)

Dr Edwin Moses, CEO of Ablynx, commented:

“Completing recruitment on time of 145 patients with aTTP in the Phase III HERCULES study was a key achievement and will allow us to communicate topline results in late Q3 2017. In addition, the filing of our first MAA with the EMA for caplacizumab in aTTP was a very important step for Ablynx as was the Fast Track designation received from the FDA. In parallel, we have been further developing our commercial infrastructure in preparation for a potential first launch of caplacizumab in 2018.”

“We have also made good progress with our wholly-owned, inhaled anti-RSV Nanobody (ALX-0171) as we continue the Phase IIb RESPIRE study. The three initial safety cohorts, encompassing 36 RSV-infected infants, have been satisfactorily completed and after a positive recommendation from the Data Monitoring Committee (DMC), we are now proceeding with the parallel dose exploration part of the RESPIRE study with the aim to recruit an additional 144 infants.”

“During the period, we held meetings with regulators in Europe and the USA to discuss the Phase IIb data generated with vobarilizumab, our IL-6R Nanobody, in RA patients and the path to a Phase III programme. We also continued to have discussions with AbbVie and other potential pharmaceutical partners and have now decided to await the outcome of the SLE study with vobarilizumab in H1 2018, and AbbVie’s subsequent decision on whether to opt-in. If AbbVie does opt-in based on the SLE results, they will pay a US\$25 million milestone payment and they will have an obligation to use commercial reasonable efforts to advance the programme in RA. If AbbVie does not opt-in at that point, then all rights to vobarilizumab will revert unencumbered to us and we will decide what next steps we will take with the molecule.”

“As well as achieving important milestones in our collaborations with Merck & Co., Inc. and Merck KGaA, we were also delighted to sign a new strategic collaboration with Sanofi where we will work together on up to eight Nanobody product candidates, initially in the area of immune-mediated inflammatory diseases. In total now we have received payments from our pharmaceutical partners of >€450 million with the potential still to earn >€10 billion in milestone payments plus royalties from the various partnered programmes.”

“Additionally during the period, we were joined by a new Chief Business Officer, Dr Markus Ewert, who will help further strengthen our senior management team.”

“This has been a good period for Ablynx and we look forward to further developments over the next months.”

¹ 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.

Financial review – 1 January 2017 to 30 June 2017

- **Key figures**

(€ millions)	First six months 2017	First six months 2016	% change
Revenue	34.7	53.1	35%
Grant income	-	0.4	100%
Total revenue and grant income	34.7	53.5	35%
Research and development expenses	(50.5)	(49.0)	3%
General and administrative expenses	(8.9)	(6.5)	37%
Operating result	(24.8)	(2.0)	> 100%
Financial income	3.1	28.4	89%
Financial expenses	(3.7)	(3.5)	6%
Profit/(loss) for the period	(25.3)	22.8	> 100%
Net cash flow	(30.9)	(19.0) ⁽¹⁾	62%
Cash at 30 June	204.5 ⁽²⁾	288.7 ⁽³⁾	29%

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

⁽²⁾ including €1.6 million in restricted cash

⁽³⁾ including €1.3 million in restricted cash

- **Income statement**

During the first six months of 2017, total revenue and grant income decreased by 35% to €34.7 million (2016: €53.5 million), mainly driven by lower recognition of upfront payments from the ongoing collaborations with AbbVie and Merck & Co., Inc.

As a consequence of the pipeline maturing with later-stage clinical assets and because we are advancing the commercialisation strategy, operating expenses increased to €59.5 million (2016: €55.5 million). Research and development expenses increased by 3% to €50.5 million (2016: €49.0 million), this was primarily attributable to investment in personnel. General and administrative expenses were up 37% to €8.9 million (2016: €6.5 million), related to expenditure for consultancy, including pre-commercialisation costs for caplacizumab, and staff.

As a result of the above, the operating loss was €24.8 million in the first half of 2017 (2016: €2.0 million).

The net financial loss of €0.6 million primarily relates to the fair value impact and amortisation (mainly non-cash) of the convertible bond (in line with a slightly higher share price on 30 June 2017 as compared to 31 December 2016).

The Company ended the first six months of 2017 with a loss of €25.3 million (2016: profit of €22.8 million).

- **Balance sheet**

The Company's non-current assets of €24.7 million are €0.1 million higher than at 31 December 2016.

The Company's current assets decreased from €242.2 million at 31 December 2016 to €210.5 million at 30 June 2017, mainly as a result of the net cash burn of €30.9 million. The Company's current assets mainly consist of cash and cash equivalents and other financial assets. 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.

The Company's equity decreased from €103.1 million at 31 December 2016 to €80.4 million at 30 June 2017, mainly as a result of the net loss of €25.3 million.

Non-current liabilities of €103.3 million relate to the senior unsecured bonds due on 27 May 2020 with a principal value of €100 million. Current liabilities, which mainly consist of trade payables and deferred income related to the upfront payments received from pharmaceutical partners, decreased from €59.4 million at 31 December 2016 to €51.5 million at 30 June 2017, mainly driven by the revenue recognition of upfront payments received from AbbVie and Merck & Co., Inc.

- **Cash flow statement**

Net cash outflow from operating activities was €29.3 million as compared to a net outflow of €17.2 million during the six months ending 30 June 2016. The difference primarily relates to a lower operating result for the current period.

Cash flow from investing activities resulted in a net inflow of €2.5 million as compared to a net inflow of €31.6 million during the first six months ending 30 June 2016. The net cash inflow primarily relates to the movements in other financial assets from deposits with a term greater than 1 month to deposits with a term of less than 1 month.

Cash flow from financing activities represented a net outflow of €0.2 million compared to a net inflow of €71.9 million during the first six months of 2016. The difference primarily relates to the net proceeds from the private placement of new shares in June 2016.

The Company ended the period with a total liquidity position of €204.5 million (2016: €235.4 million) which consists of cash and cash equivalents of €26.4 million, other financial assets of €176.5 million and restricted cash of €1.6 million.

Corporate update – 1 January 2017 to date

- **Caplacizumab – wholly-owned first-in-class anti-vWF Nanobody**
 - Submitted a MAA to the EMA for approval in aTTP.
 - Awarded Fast Track designation by the FDA for the treatment of aTTP. The FDA's Fast Track programme is designed to facilitate the development and expedite the review of drugs that treat serious conditions and meet an unmet medical need.
 - Completed enrollment of 145 patients with aTTP in the multi-national, double-blind, placebo-controlled Phase III HERCULES study. Topline results are expected in late Q3 2017.
 - Continued the three-year follow-up study for patients who have completed the Phase III HERCULES study, with greater than 80% of eligible HERCULES patients having rolled over into this follow-up study.
 - Initiated a single and multiple dose Phase I study in healthy Japanese subjects. Topline results are expected in Q4 2017.
 - Launched a new website, sponsored by Ablynx, in collaboration with healthcare professionals and patients to increase awareness of TTP (www.understandingTTP.com).
 - Started pre-clinical development of caplacizumab in reperfusion injury (stroke). If these studies are successful, clinical development could be initiated in 2018.

- **ALX-0171 – wholly-owned inhaled anti-RSV Nanobody**
 - Completed the sequential dose escalation part of the Phase IIb RESPIRE study in 36 infants hospitalised as a result of a RSV infection and the DMC recommended that we could proceed to the parallel dose part of the study.
 - Initiated the parallel dose part of the RESPIRE study with the aim of recruiting an additional 144 infants. Topline results from this study are expected in H2 2018.
 - Continued preparations to start a Phase II study in Japanese infants hospitalised as a result of a RSV infection. This trial is expected to commence in H1 2018.
 - Continued preparations to start a global Phase II study in RSV-infected haematopoietic stem cell transplant (HSCT) patients. This trial is also expected to commence in H1 2018.

- **Vobarilizumab – anti-IL-6R Nanobody**
 - Held “end-of-Phase II” meetings with regulators in Europe and the USA to discuss the Phase IIb data in RA and the design of a potential Phase III programme.
 - Following discussions with AbbVie and other potential pharmaceutical partners, we decided to await the results of the SLE study, and the outcome of AbbVie’s decision on whether to opt-in, before deciding on the future strategy for vobarilizumab.
 - Continued the open-label extension study in RA for those patients who completed the Phase IIb studies (94% roll-over rate).
 - Advanced the Phase II study in 312 patients with SLE with enrollment completed, and topline results expected in H1 2018.

- **Partnered programmes**
 - We achieved additional milestones in the immuno-oncology collaboration with **Merck & Co., Inc.** including completion of a second *in-vivo* proof-of-concept study with a mono-specific Nanobody and the start of an IND-enabling toxicology study with a bi-specific Nanobody, the latter triggering a €2.5 million payment to Ablynx. The first Phase I study arising from this collaboration is now expected to start in H1 2018.
 - We received a €15 million milestone payment from **Merck KGaA** following our completion of the pre-clinical package for the anti-ADAMTS-5 Nanobody (ALX-1141) for the treatment of osteoarthritis. Merck KGaA plans to start the single ascending dose part of the Phase I study in healthy volunteers in H2 2017.
 - **Merck KGaA** reported very encouraging efficacy data and a favourable safety and tolerability profile with the bi-specific Nanobody anti-IL-17A/F (ALX-0761) in a Phase Ib study in patients with moderate-to-severe chronic plaque psoriasis. Merck KGaA subsequently partnered with Avillion to advance a potential Phase II study with the bi-specific Nanobody in plaque psoriasis.
 - **Novartis** decided to terminate its anti-CXCR2 Nanobody clinical development programme due to safety concerns which we believe are related to the target.

- **New partnership**
 - In July, we signed a strategic collaboration with **Sanofi** which included a €23 million upfront payment, plus research funding and up to €2.4 billion in future milestone payments plus tiered royalties up to low double digits. This research collaboration is focused on developing and commercialising up to eight Nanobody product candidates with the initial emphasis being on immune-mediated inflammatory diseases.

- **Other disclosures**

- The Executive Committee was strengthened by the appointment of Markus Ewert as Chief Business Officer, effective 20 June 2017.
- On 18 August 2017, a Special General Meeting of shareholders approved the nomination of Mrs. Hilde Windels as a new Independent non-Executive Director on the Ablynx Board.

Outlook for the remainder of 2017

Ablynx is on track to report topline results from the Phase III HERCULES study of caplacizumab in patients with aTTP in late Q3 2017. In parallel, the Company is advancing its commercialisation strategy and preparations for the potential launch of caplacizumab in 2018. In addition, Ablynx expects to report the results of the ongoing single and multiple dose Phase I study of caplacizumab in healthy Japanese subjects before the end of the year.

In Q4 2017, the Company plans to file for regulatory approval to enable a Phase II study in Japan with ALX-0171 in infants hospitalised with a RSV infection. In addition, we will also file for regulatory approvals to enable a global Phase II study with ALX-0171 in adults who have undergone stem cell transplantation and have become infected with RSV.

Following the initiation of the strategic collaboration with Sanofi and a review of the timing of other milestone payments, the Company is lowering its net cash burn guidance for the full year 2017 and it is now expected to be in the range of €65-75 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)2 402 30 92, using confirmation code 7237205. 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

16 November – Q3 results 2017

2017 shareholders' clubs at Ablynx (Dutch language only)

5 October at 5.30pm

6 December at 5.30pm

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

Glossary of terms

aTTP	acquired thrombotic thrombocytopenic purpura
DMC	Data Monitoring Committee
EMA	European Medicines Agency
FDA	Food and Drug Administration
HSCT	haematopoietic stem cell transplant
IND	investigational new drug
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, USA; Merck KGaA; Novartis; Novo Nordisk; Sanofi and Taisho Pharmaceuticals. The Company is headquartered in Ghent, Belgium. More information can be found on www.ablynx.com.

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FINANCIAL INFORMATION

The condensed financial statements for the six month's period ended 30 June 2017 have been prepared in accordance with IAS 34 "Interim Financial Reporting" as adopted by the European Union. They do not include all the information required for the full annual financial statements and should therefore be read in conjunction with the financial statements for the year ended 31 December 2016. The condensed financial statements are presented in thousands of Euros (unless stated otherwise). The condensed financial statements have been approved for issue by the Board of Directors on 23 August 2017.

The statutory auditor, Deloitte Bedrijfsrevisoren/Réviseurs d'Entreprises, represented by Nico Houthaève, has issued a limited review report dated 23 August 2017 on the company's condensed interim financial information as of and for the six month period ended 30 June 2017, and has confirmed that the accounting data reported in the press release is consistent, in all material respects, with the accounts from which it has been derived.

The interim financial report 2017 is available on the Ablynx website:
<http://www.ablynx.com/investors/financial-information/>

CONDENSED STATEMENT OF COMPREHENSIVE INCOME

(€ '000), except for earnings per share	Period ended 30 June,	
	2017	2016
Revenue	34,665	53,116
Grant income	45	391
Total revenue and grant income	34,710	53,507
Research and development expenses	(50,517)	(49,015)
General and administrative expenses	(8,950)	(6,516)
Operating loss	(24,757)	(2,024)
Financial income	3,124	28,387
Financial expenses	(3,691)	(3,535)
Profit/(loss) before taxes	(25,324)	22,828
Profit/(loss) for the period	(25,324)	22,828
Total comprehensive profit/(loss) for the period	(25,324)	22,828
Profit/(loss) attributable to equity holders	(25,324)	22,828
Total comprehensive profit/(loss) attributable to equity holders	(25,324)	22,828
Basic profit/(loss) per share	(0.42)	0.41
Diluted loss per share*	(0.42)	(0.03)

* The diluted loss per share number for the accounting year 2016 has been restated to correct an error with respect to the calculation of the diluted loss per share.

BALANCE SHEET

(€ '000)	As at 30 June 2017	As at 31 December 2016
ASSETS		
Intangible fixed assets	1,411	1,585
Property, plant and equipment	3,912	3,746
Restricted cash	1,600	1,600
Non-current R&D incentives receivable	17,777	17,642
Non-current assets	24,700	24,573
Trade and other receivables	4,132	4,831
Current R&D incentives receivable	2,449	1,879
Other current assets	1,067	1,641
Other financial assets	176,502	180,484
Cash and cash equivalents	26,390	53,356
Current assets	210,540	242,191
Total assets	235,240	266,764
EQUITY AND LIABILITIES		
Share capital	107,244	106,057
Share premium account	253,312	252,297
Reserves	8,592	8,093
Accumulated losses	(288,716)	(263,392)
Equity attributable to equity holders	80,432	103,055
Financial liabilities	103,319	104,349
Non-current liabilities	103,319	104,349
Trade and other payables	27,388	25,738
Deferred income	24,101	33,622
Current liabilities	51,489	59,360
Total equity and liabilities	235,240	266,764

CASH FLOW STATEMENT

(€ '000)	Period ended 30 June,	
	2017	2016
Profit/(loss) before taxes	(25,324)	22,828
Adjustments for:		
Amortisation expense	413	99
Depreciation expense	1,039	786
Share-based compensation expense	1,291	1,308
Net financial income	(29)	(223)
Net (gain)/loss arising on the convertible bond designated as at fair value through profit and loss	(3,044)	(28,122)
Financial expense recognized in respect of the convertible bond	3,639	3,492
Movements in working capital		
(Increase)/Decrease in trade and other receivables	568	3,796
Increase/(Decrease) in trade and other payables	(7,872)	(21,377)
<i>Cash (used in)/from operations</i>	<i>(29,320)</i>	<i>(17,413)</i>
Interest paid	(51)	(43)
Interests received	80	266
Net cash flows (used in) operating activities	(29,291)	(17,190)
Purchases of intangible assets	(239)	(69)
Purchases of property, plant and equipment	(1,204)	(2,112)
Sale of current financial assets*	40,482	78,840
Purchase of current financial assets*	(36,500)	(45,053)
Net cash flows (used in)/from investing activities	2,539	31,606
Proceeds from issuance of ordinary shares (net of share issue costs)		71,442
Proceeds from exercise of warrants	1,411	2,044
Interest paid on convertible bond	(1,625)	(1,625)
Net cash flows from financing activities	(214)	71,861
Net increase (decrease) in cash and cash equivalents	(26,965)	86,277
<i>Cash and cash equivalents at beginning of the period</i>	<i>53,356</i>	<i>3,601</i>
Cash and cash equivalents at end of the period	26,390	89,878

* This statement of cash flows has been restated to present sales and purchases of current financial assets on a gross basis. In previously published financial statements, these items were presented on a net basis in the line item "sale/(purchase) of current financial assets".

REGULATED INFORMATION**STATEMENT OF CHANGES IN SHAREHOLDER EQUITY**

(€ '000)	Share capital	Share premium	Share- based compensation	Retained loss	Total Equity
Balance at 31 December 2015	96,286	187,316	6,611	(262,304)	27,909
Total comprehensive profit for the period				22,828	
Issue of shares	10,348	63,804			
Share issue cost	(2,710)				
Share-based compensation			1,307		
Exercise of warrants	1,959	1,063	(978)		
Balance at 30 June 2016	105,883	252,183	6,940	(239,476)	125,530
Balance at 31 December 2016	106,057	252,297	8,093	(263,392)	103,055
Total comprehensive loss for the period				(25,324)	
Share-based compensation			1,290		
Exercise of warrants	1,187	1,015	(791)		
Balance at 30 June 2017	107,244	253,312	8,592	(288,716)	80,432