

arGEN-X Reports Fourth Quarter Business Update And Full Year 2014 Financial Results

Management to host conference call today at 6 pm CET / 1 pm EDT

18 March 2015

Breda, the Netherlands / Ghent, Belgium - arGEN-X N.V. (Euronext Brussels: ARGX), a clinical-stage biopharmaceutical company focused on creating and developing differentiated therapeutic antibodies for the treatment of cancer and severe autoimmune diseases, today announced its fourth quarter business update and the consolidated full year results for 2014, which have been prepared in accordance with IFRS as adopted by the European Union.

The FY results will be discussed during a conference call and webcast presentation today at 6 pm CET / 1 pm EDT. To participate in the conference call, please select your phone number [here](#), and use the confirmation code 92395735. The webcast may be accessed on the homepage of the arGEN-X website at www.argen-x.com or by [clicking here](#).

OPERATIONAL HIGHLIGHTS

- Advancement of ARGX-110 into expansion cohorts as part of its Phase 1b study in CD70-positive cancer patients with either hematological or solid tumors to further evaluate safety and efficacy and to select indications for study in Phase 2 clinical development.
 - Enrolment completed of first cohort of 15 patients with CD70-positive hematological malignancies and 15 patients with CD70-positive solid tumors into a Phase 1b expansion trial.
 - Initiation of clinical efficacy evaluation of ARGX-110 in dedicated expansion cohort of patients with relapsed/refractory CD70-positive T-cell lymphomas, as part of broader Phase 1b study.
- Acceptance of Investigational New Drug (IND) Application to evaluate ARGX-110 in Waldenström's macroglobulinemia (a rare, incurable B-cell lymphoma).
- Partnership with the Leukemia Lymphoma Society on the development of ARGX-110 for the treatment of Waldenström's macroglobulinemia
- Presentation of positive preclinical data on ARGX-110 in a chronic myelogenous leukemia (CML) model demonstrating potential of ARGX-110 in reversing resistance to tyrosine kinase inhibitors. Data were presented in December 2014 at ASH (American Society of Hematology).
- Positive preclinical data for ARGX-113 supporting its use as a potential breakthrough concept for the treatment of severe autoimmune diseases.
- Collaboration with Bayer, leveraging arGEN-X' SIMPLE Antibody(TM) technology for the discovery and development of first-in-class antibodies addressing complex targets across multiple therapeutic areas.
- Long-term strategic alliance with Shire Pharmaceuticals where arGEN-X focus its suite of human antibody discovery technologies on multiple targets aligned with Shire's therapeutic focus.
- Key patents relating to ARGX-110 and ARGX-111 granted in the US, providing patent protection for both until 2031-2032 and allowing up to five additional years of patent term extension.

FINANCIAL HIGHLIGHTS

- Successful Initial Public Offering ("IPO") on Euronext Brussels raising total gross proceeds of EUR 41.8 million.
- Received two preclinical milestone payments under collaboration with Shire.
- Operating loss totaled EUR 10.7 million in 2014 compared with EUR 6.2 million in 2013.

- Net loss for 2014 increased to EUR 10.3 million compared with EUR 6.1 million in 2013, due to the costs of advancing the Group's clinical pipeline.
- On December 31, 2014 the Group's cash, cash equivalents and financial assets amounted to EUR 56 million compared with EUR 23.2 million on December 31, 2013.

POST-PERIOD HIGHLIGHTS

- Launch of Innovative Access Program ("IAP"), providing SIMPLE Antibody(TM) platform to academic centers of excellence and emerging biotech companies. First collaborations in cancer immunotherapy and dyslipidemia.
- First program in-licensed from IAP for further development: ARGX-115, a first-in-class antibody targeting GARP for cancer immunotherapy.
- Multi-product commercial license agreement with Lonza for the production of arGEN-X' therapeutic antibodies.

Commenting on the 2014 results, Tim Van Hauwermeiren, CEO of arGEN-X, said:

"2014 has been a transformational year for arGEN-X. We made significant progress within our clinical pipeline progressing ARGX-110 towards clinical proof-of-concept in important solid and hematological tumor indications including T-cell lymphoma and Waldenström's macroglobulinemia. We also advanced and expanded our preclinical pipeline adding more depth to our development plan. Our business development activities were further validated the expected utility of our SIMPLE Antibody™ platform with the deepening of partnerships as with Shire and the initiation of new ones as with Bayer and completed a successful IPO on Euronext Brussels," comments Tim Van Hauwermeiren.

"With a well-balanced pipeline of wholly-owned and partnered clinical assets and several innovative early stage programs in oncology and auto-immune diseases, we feel we have positioned the Company for future success. We are entering a period of significant growth during which we intend to remain focused on our initial business strategy, on the execution of our pipeline programs, and on delivering added value to all our stakeholders."

DETAILS OF THE OPERATIONAL RESULTS

PRODUCTS IN CLINICAL PHASE

In 2014, arGEN-X advanced ARGX-110, a novel anti-CD70 therapeutic antibody, into the safety and efficacy expansion part of its open-label Phase 1b study. The objective of the expansion phase is to further investigate the safety of ARGX-110 in CD70-positive cancer patients with either hematological or solid tumors, and to evaluate efficacy in order to select the indications to be studied in Phase 2 clinical development. The study is being supported by a EUR 3.5 million grant from the Flemish Government's Institute for the Promotion of Innovation by Science and Technology (IWT). arGEN-X completed the enrolment of the first cohort of 15 patients with CD70-positive solid tumors and 15 patients with CD70-positive hematological malignancies.

A clinical efficacy evaluation of ARGX-110 was initiated in 30 patients with relapsed/refractory CD70-positive T-cell lymphomas. This evaluation will be conducted as an expansion arm of the ongoing Phase 1b study of ARGX-110. Additionally, the Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) was accepted to initiate a Phase 1b/2 trial of ARGX-110 in patients with relapsed or refractory Waldenström's macroglobulinemia (WM), a rare, incurable B-cell lymphoma. The Phase 1b/2 study, in patients with refractory WM is supported by the Leukemia & Lymphoma Society (LLS) and benefits from clinical expertise at Dana Farber Cancer Institute (Boston), Memorial Sloan Kettering Cancer Center (New York) and the Mayo Clinic (Scottsdale/Phoenix).

For ARGX-110, arGEN-X has also initiated a clinical study with the UZ Gent on nasopharyngeal cancer, which is part of the IWT TGO (*Transformationeel Geneeskundig Onderzoek*) program secured from IWT in 2013.

For ARGX-111, a Phase 1 dose escalation study was executed, testing the biological activity of ARGX-111 in c-MET positive cancer indications.

· PRODUCTS IN PRECLINICAL PHASE

At the American Society of Hematology (ASH) Annual Meeting (December 2014), arGEN-X presented the potential of the CD70 pathway as a targetable mechanism to overcome drug resistance in chronic myelogenous leukemia (CML). These data show that co-treatment of ARGX-110, and imatinib, a first-line BCR/ABL-specific tyrosine kinase inhibitor (TKI), eradicates the disease-initiating CML stem cells, a cell population often resistant to TKI therapy.

ARGX-113, a proprietary antibody fragment that modulates the process of antibody recycling as a novel approach to treating severe autoimmune diseases, completed a preclinical study assessing its pharmacokinetic and pharmacodynamic behaviours. These results proved ARGX-113 to be highly effective in rapidly clearing a tracer antibody from circulation in a dose-dependent manner in non-human primates, thus acting as a surrogate of autoantibody clearance.

Additionally, arGEN-X advanced the preclinical studies on ARGX-112, an antibody targeting IL-22R, which plays a role in skin inflammation. arGEN-X believes that it has the potential to address unmet medical need in inflammatory diseases of the skin, such as atopic dermatitis.

· COLLABORATIONS & STRATEGIC ALLIANCES

arGEN-X entered into a long-term strategic alliance with Shire Pharmaceuticals in June 2014. Under the agreement, arGEN-X will bring its entire suite of human antibody discovery technologies to a partnership focused on multiple targets aligned with Shire's therapeutic focus. The multi-year initiative aimed at helping augment the Shire development pipeline follows an initial R&D collaboration initiated in March 2012. Additionally, Shire has exercised its option to advance into preclinical development one or more product candidates created out of a 2012 therapeutic antibody alliance between the two companies. As a result of the exercise, arGEN-X received a milestone payment from Shire.

arGEN-X also initiated a collaboration with Bayer AG, leveraging arGEN-X' SIMPLE Antibody(TM) technology for the discovery and development of therapeutic antibodies addressing complex targets across multiple therapeutic areas that are often intractable by existing antibody platforms.

arGEN-X has ongoing collaborations with Boehringer Ingelheim Pharmaceuticals, Inc. and RuiYi. Boehringer Ingelheim is evaluating the applicability of the SIMPLE Antibody(TM) Technology for generating and screening antibodies for its drug discovery R&D programs. With RuiYi, arGEN-X is collaborating on the development and potential commercialisation of ARGX-109, a novel anti-IL-6 monoclonal antibody with potential to treat autoimmune diseases and cancer.

For the creation of antibodies across multiple therapeutic areas, the Group started to collaborate with academic centers and emerging biotech companies under its Innovative Access Program.

KEY FIGURES (CONSOLIDATED)

Financial overview

in thousands of euros

Year ended Dec 31, 2014	Year ended Dec 31, 2013	Variance
		Variance

Revenue	3.756	2.677	1.079
Other operating income	1.621	2.577	(956)
Total operating income	5.377	5.254	123
Research and development expenses	(12.641)	(9.352)	(3.289)
General and administrative expenses	(3.479)	(2.132)	(1.347)
Operating profit/(loss)	(10.743)	(6.230)	(4.513)
Financial income	134	182	(48)
Exchange gains/(losses)	295	(83)	378
Result Profit/(loss) before taxes	(10.314)	(6.131)	(4.183)
Net increase in cash and financial assets	32.753	7.790	24.963
Cash and financial assets at the end of the period	55.973	23.220	32.753

DETAILS OF THE FINANCIAL RESULTS

- CONDENSED STATEMENT OF COMPREHENSIVE INCOME

OPERATING INCOME

Operating income totaled EUR 5.4 million in 2014 compared to EUR 5.3 million in 2013. The Group's operating income includes a mix of (i) revenues in the form of research and development funding and technical success milestone payments received from the Group's industrial partnerships and (ii) other operating income corresponding to government grants and tax incentive credits.

In 2014, the revenue increased significantly to reach EUR 3.8 million compared to EUR 2.7 million in 2013. The increase is explained by (i) the payments partially recognized in 2014 following the signature of a new collaboration agreement with Bayer, a new strategic alliance with Shire and a research, development and commercialization agreement with the LLS (Leukemia and Lymphoma Society) in the U.S., and (ii) the milestone received from Shire and immediately recognized in revenue in December 2014 following the exercise of their option to advance one or more product candidates in preclinical development.

The decrease in other operating income from EUR 2.6 million in 2013 to EUR 1.6 million in 2014 is mainly explained by the reduction in 2014 of government grants received from the Flemish government's Institute for the Promotion of Innovation by Science and Technology (IWT).

OPERATING EXPENSES

Research and Development (R&D) expenses were EUR 12.6 million in 2014, compared with EUR 9.4 million in 2013. This significant increase in 2014 is explained primarily by (i) the increased clinical trial and product manufacturing activities incurred with the external clinical research and contract manufacturing organizations working on the most advanced products of the Group, (ii) the recruitment of additional R&D personnel following the signature of a

collaboration agreement with Bayer in May 2014 and a new strategic alliance with Shire in June 2014, and (iii) the share based payment costs recognized in compensation for the grant of stock options to the R&D employees of the Group. In 2014, R&D costs accounted for 78.4% of the total operating expenses compared with 81.4% in 2013. On 31 December 2014, the Group employed the equivalent of 27.5 full time employees in R&D compared to the equivalent of 19.5 full time employees on 31 December 2013.

In 2014, General and Administrative (G&A) expenses amounted to EUR 3.5 million compared with EUR 2.1 million in 2013. The EUR 1.4 million increase in 2014 results from (i) the costs incurred in relation to the preparation of the IPO (ii) the recruitment of new employees to strengthen the G&A department of the Group in the perspective of its IPO, and (iii) the share based payment costs recognized in compensation for the stock options granted to the employees, consultants and board members of the Group. In 2014, G&A costs accounted for 21.6% of the total operating expenses compared with 18.6% in 2013. The Group employed 3 people in its G&A department on 31 December 2014 compared with 2 employees at the same date in 2013.

OPERATING LOSS

The Group's operating loss before net financial income and tax was EUR 10.7 million in 2014 compared with a EUR 6.2 million loss on 31 December 2013. This increase results primarily from the increase in operating expenses as indicated above.

NET FINANCIAL INCOME

In 2014, the Group recorded a net financial income of EUR 0.4 million compared with EUR 0.1 million in 2013. The net financial income generated represents essentially the returns on the financial investments of the Group's cash and cash equivalents and financial instruments, and realized foreign exchange gains and losses. The variance between 2014 and 2013 was mainly due to exchange rate differences.

INCOME TAX

As the Group has incurred losses in all the relevant reporting periods it had no taxable income and therefore no income taxes have been paid.

PROFIT/ (LOSS) FOR THE PERIOD

The Group generated a net loss of EUR 10.3 million on 31 December 2014 compared with a net loss of EUR 6.1 million in 2013. As explained above, this significant increase in the net loss in 2014 results from (i) the strong increase of R&D expenses in relation with the progression of the clinical activities of the Group, (ii) the increase in G&A expenses related to the preparation of the IPO (iii) and the non-cash share based payment accrued on the stock options granted to the employees, consultants and board members of the Group.

• **CONDENSED STATEMENT OF FINANCIAL POSITION**

ASSETS

The Group's main current assets consist of its cash, cash equivalents, current financial assets, prepaid expenses and its trade receivables.

On 31 December 2014 the Group's cash, cash equivalents, financial instruments and current financial assets amounted to EUR 56 million compared with EUR 23.2 million on 31 December 2013. The Group's increase in cash, cash equivalents, financial instruments and current financial assets of EUR 32.8 million in 2014 is due to the EUR 41.8 million (including the exercise of the over-allotment option) in proceeds following the successful completion of the IPO.

LIABILITIES

The Group's current liabilities relate primarily to trade payables and deferred income from its research industrial agreements with pharmaceutical and biotechnology companies.

On 31 December 2014 the trade payables and other payables totalled EUR 5.0 million compared with EUR 2.9 million at the end of 2013. This significant increase results from accruals and invoiced received but not yet paid, mainly regarding manufacturing and clinical development activities incurred by the Group in 2014.

Deferred revenue at the end of December 2014 amounted to EUR 3.5 million compared with EUR 0.5 million on 31 December 2013. The increase in 2014 mainly relates to payments received from industrial partnerships, notably from Shire, Bayer and LLS, which will be recognized as revenue over the course of the agreements.

The Group has no loan outstanding or any long term financial lease commitments at the end of 2014.

- **CONDENSED STATEMENT OF CASH FLOWS**

CASH FLOW from operating activities

Cash flow from operating activities represented a net outflow of EUR 5.2 million in 2014 compared with a net outflow of EUR 6.6 million in 2013. Notwithstanding the significant increase in operating losses in 2014, the small decrease of EUR 1.4 million of net cash outflow from operating activities in 2014 is explained by the significant increase in deferred revenues and trade and other payables over the period as explained above.

CASH FLOW FROM INVESTING ACTIVITIES

Cash flow from investing activities represented a net outflow of EUR 23.3 million in 2014 compared with a net inflow of EUR 0.7 million in 2013. The net cash outflow in 2014 corresponds primarily to the movements in the current financial assets resulting from the transfer of cash from the proceeds of the IPO to money market funds.

CASH FLOW FROM FINANCING ACTIVITIES

Cash flow from financing activities represented a net inflow of EUR 37.7 million in 2014 compared to a net inflow EUR 13.3 million in 2013. The increase in 2014 corresponds to the gross proceeds of EUR 41.8 million from the IPO. In 2013 the Group received EUR 15 million from the second tranche and extension of the Company's B-round financing.

EVENTS AND UPDATES AFTER 31TH DECEMBER 2014

In January 2015, arGEN-X launched its Innovative Access Program (IAP). The IAP leverages the proven power of the SIMPLE Antibody(TM) platform in creating best-in-class antibodies across multiple therapeutic areas complementary to arGEN-X's strategic focus. Through collaboration with academic centers of excellence and emerging biotech companies, arGEN-X provides access to its antibody discovery technologies and offers technical support and proprietary know-how where needed. Deal structures are designed to be flexible with the first collaborations announced with an unnamed US-based biotechnology company active in the field of dyslipidemia research and with the de Duve Institute (Université Catholique de Louvain, Belgium) in the field of cancer immunotherapy.

In February 2015 Lonza and arGEN-X have announced a multi-product license agreement for therapeutic antibodies. The multi-product license agreement secures long-term access for arGEN-X and its strategic partners to Lonza's proprietary GS Xceed(TM) System for creation and development of cell lines to be utilized in the manufacture of biopharmaceuticals. Lonza has manufactured two of arGEN-X' clinical-stage proprietary therapeutic antibodies to date, as well as a third program expected to commence clinical trials in 2015. Under the new

agreement, arGEN-X has access to the GS Xceed(TM) System for the development and manufacture of both current and future therapeutic antibody products.

In March 2015 arGEN-x expanded preclinical pipeline with ARGX-115: a novel SIMPLE Antibody(TM) for cancer immunotherapy. arGEN-X has exercised its option to exclusively license ARGX-115 to target GARP, a novel immune checkpoint with potential in cancer immunotherapy. arGEN-X believes that GARP plays a key role in the ability of tumors to escape the patient's immune system. ARGX-115 was discovered under arGEN-X' Innovative Access Program with Université Catolique de Louvain (UCL)/de Duve Institute (BE).

OUTLOOK 2015

arGEN-X continues to implement its business plan by progressing ARGX-110 towards clinical proof of concept in one or more niche indications including T cell lymphoma and Waldenström Macroglobulinemia, in close collaboration with premier clinical centers in the EU and the US and supported by the Leukemia & Lymphoma Society. Further preclinical work is being undertaken in order to broaden the potential clinical utility of ARGX-110.

Likewise the Phase 1 safety expansion study of ARGX-111 focusing on Met-amplified patients is expected to be completed. A first Phase 1 study for ARGX-113, a potential breakthrough therapy for a number of serious auto-immune diseases, into a first Phase 1 study in healthy volunteers is planned to start. In addition arGEN-X will continue to build and progress its discovery and pre-clinical product pipeline and to deliver highly differentiated antibody programs under its industrial pharma partnerships.

arGEN-X will continue its business development activities, aiming to further leverage its suite of proprietary technologies for the creation of highly differentiated antibody products against novel and complex targets in cancer and autoimmune diseases. For the creation of antibodies across multiple therapeutic areas, arGEN-X will collaborate with academic centers and emerging biotech companies through its Innovative Access Program.

arGEN-X will also aim to transition its shareholders' base from its historic venture capital investors to blue-chip, long-term institutional investors, and to improve liquidity and free float for its stock. In tandem with this process, arGEN-X is aiming to gradually change the composition of its Board to include members with significant industry experience. This experience is anticipated to be crucial in assisting arGEN-X achieve its ambition to become an important player in the fast growing therapeutic antibody market and to generate significant value for its shareholders in a timely and efficient manner.

FINANCIAL CALENDAR

May 13, 2015: Annual General Meeting

May 15, 2015: Q1 2015 Business Update and financial results

August 26, 2015: Half year 2015 Business Update and financial results

November 17, 2015: Q3 2015 Business Update and financial results

About arGEN-X

arGEN-X is a clinical-stage biopharmaceutical company focused on creating and developing differentiated therapeutic antibodies for the treatment of cancer and severe autoimmune diseases. arGEN-X has generated a pipeline of differentiated clinical and preclinical antibody candidates using its SIMPLE Antibody(TM) discovery platform. SIMPLE Antibody(TM) has a particular strength in addressing novel, complex disease targets that are difficult to access using established antibody technology platforms. Proprietary Fc engineering technologies (NHance® and ABDEG(TM)) and POTELLIGENT® technology (licensed from BioWa, Inc.)

further enhance the therapeutic properties of SIMPLE Antibody(TM) leads in terms of tissue penetration/residence time in the body, ability to clear disease targets or pathogenic antibodies and cell-killing potency through Antibody-Dependent Cell-mediated Cytotoxicity (ADCC), respectively. arGEN-X has leveraged its suite of antibody technologies in forging strategic collaborations with pharmaceutical and biotechnology companies to provide new approaches to diseases with unmet medical needs.

arGEN-X is listed on the Euronext Brussels exchange under the symbol ARGX.

www.arGEN-X.com

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Forward-looking Statements

The contents of this announcement include statements that are, or may be deemed to be, "forward-looking statements". These forward-looking statements can be identified by the use of forward-looking terminology, including the terms "believes", "estimates", "anticipates", "expects", "intends", "may", "will", or "should", and include statements arGEN-X makes concerning the intended results of its strategy. By their nature, forward-looking statements involve risks and uncertainties and readers are cautioned that any such forward-looking statements are not guarantees of future performance. arGEN-X' actual results may differ materially from those predicted by the forward-looking statements. arGEN-X undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law. All reported data is unaudited. Financial reporting is in line with the accounting policies as stated in the 2014 consolidated financial statements, unless otherwise stated.