

arGEN-X – Business Update and First Half 2014 Results

27 August 2014

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 provides a business update and announces its financial results for the first half of 2014 (six-month period ended 30 June 2014).

BUSINESS HIGHLIGHTS

- Completed successful Initial Public Offering (IPO) on Euronext Brussels (pricing on 8 July with overallotment option exercised on 11 August) raising total gross proceeds of EUR 41.8 million
- Advanced ARGX-110 (anti-CD70 SIMPLE Antibody™) into the expansion part of its Phase 1b study. The objective is to further investigate the safety of ARGX-110 in CD70-positive cancer patients with either haematological or solid tumors, and to evaluate its biological activity in order to select the indications to be studied in Phase II clinical development (January)
- Entered partnership with The Leukemia and Lymphoma Society (LLS) to develop ARGX-110 for the treatment of Waldenström's macroglobulinemia, a rare B-cell lymphoma (June)
- Presented clinical data from Phase 1b dose-escalation study with ARGX-110 at the American Society of Clinical Oncology (ASCO; May)
- Announced positive preclinical data for ARGX-113 which supports its use as a potential breakthrough concept for the management of flares in severe autoimmune diseases (August)
- Signed a long-term strategic alliance with Shire (June), which resulted in arGEN-X receiving a EUR 3 million upfront cash payment and a EUR 12 million equity investment. arGEN-X will bring its entire suite of human antibody discovery technologies to the alliance which is focused on multiple targets aligned with Shire's therapeutic focus
- Received two preclinical milestone payments from Shire under initial antibody discovery collaboration (January)
- Initiated collaboration with Bayer to discover and develop therapeutic antibody candidates (May)
- Initiated pilot research agreement with Boehringer Ingelheim (January)
- Elected Werner Lanthaler, CEO of Evotec to the Board of Directors (April)
- Appointed Eric Castaldi, former CFO of Nicox, as CFO (June). Mr Castaldi was elected to the Board of Directors (July)

FINANCIAL HIGHLIGHTS

- Proceeds from IPO totalling EUR 41.8 million, including the overallotment, from high-quality corporate and institutional investors in Europe and the United States and retail investors in Belgium
- Net loss for the period was EUR 4.6 million compared to EUR 4.8 million for the same period in 2013
- Cash position as at 30 June 2014 was EUR 20.6 million. Cash position at the end of July, before the receipt of the proceeds from the exercise of the overallotment option, was EUR 58.1 million



Tim Van Hauwermeiren, Chief Executive Officer of arGEN-X, said: “We have made significant progress in 2014, delivering the key milestones in our strategic plan. Our successful IPO on Euronext Brussels has significantly strengthened our financial position and we are well positioned to generate important data for our lead therapeutic antibody candidates. Our clinical stage programs, ARGX-110 and ARGX-111, are on track and we are pleased with the initial safety and biological activity data observed for ARGX-110 and our recent clinical development partnership with LLS. We were delighted to expand our successful collaboration with Shire for the second time and to have signed new collaborations with Bayer and Boehringer Ingelheim to leverage the power of our SIMPLE Antibody™ platform against multiple, complex targets across a range of indications. We remain focused on executing our well thought out strategy, which we believe will deliver significant value for all of our stakeholders.

BUSINESS UPDATE

Successful Initial Public Offering

arGEN-X launched its Initial Public Offering on Euronext Brussels in June and it was successfully completed in July raising EUR 40 million in gross proceeds from the sale of 4,705,882 new shares at the offer price of EUR 8.50 per share. Additionally, the partial exercise of the over-allotment option raised a further EUR 1.8 million for the Company from the sale of 208,725 shares at the offer price, taking the total gross proceeds to EUR 41.8 million.

The IPO attracted high-quality demand from corporate and institutional investors in Europe and the United States, as well as demand from Belgian retail investors. Among these investors, Shire purchased shares at the offer price for a total of EUR 12 million. In addition, certain existing investors purchased shares for a total of approximately EUR 7.2 million at the offer price.

KBC Securities and Kempen & Co acted as Joint Global Coordinators and Joint Bookrunners, Petercam as Co-Lead Manager, and Wedbush PacGrow Life Sciences as Selling Agent.

The funds raised through the IPO will enable arGEN-X to advance the clinical development of its differentiated therapeutic antibody candidates, ARGX-110, ARGX-111 and ARGX-113 in orphan diseases. This strategy is designed to yield clinical data demonstrating their therapeutic utility for treating cancer and severe autoimmune diseases. Resulting data will be leveraged to partner these therapeutic antibodies for development and commercialization across a number of major indications in these areas.

The funds will also allow arGEN-X to further develop and enhance its SIMPLE Antibody™ platform and suite of complementary antibody technologies on which its pipeline of differentiated therapeutic antibodies has been created. This approach is expected to enable arGEN-X 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.

Pipeline Progress

- **ARGX-110** – arGEN-X started two Phase 1b expansion cohorts with ARGX-110, a novel anti-CD70 antibody, in cancer patients in January 2014. The objective is to further investigate the safety of ARGX-110 in CD70-positive cancer patients with either advanced lymphomas, leukemias or solid tumors (end-stage disease), and to evaluate potential efficacy in order to select one or more



orphan lymphoma indication(s) for Phase 2 trials from which positive data may be used to support accelerated regulatory approval. Once efficacy data from the Phase 2 trials becomes available, arGEN-X intends to seek a partner to undertake clinical development in larger hematological and solid tumors indications.

The study is currently recruiting 60 patients in two 30 patient safety cohorts (one for hematological malignancies and one for solid tumors). The study is being conducted by a consortium of leading academic institutions in Belgium and France, and is supported by a EUR 3.5 million grant from the Flemish government's Institute for the Promotion of Innovation by Science and Technology in Flanders (IWT). This study is expected to read out in 2H 2015.

Based on a Phase 1b dose-escalation study, the main safety observation was infusion-related reactions, which were effectively managed using standard pre-medication. Out of 26 patients treated in this part of the study, no dose-limiting toxicity was identified. One hematological complete response (CR) was documented in a patient with Sézary syndrome, a form of cutaneous T-cell lymphoma. In a second T-cell lymphoma patient, similar biological activity was also observed.

As of June 2014, prolonged stabilization of disease (progression-free survival of 6 months or longer), a validated clinical benefit endpoint in several solid tumors, was observed in five individual patients with renal cell carcinoma, platinum-refractory ovarian cancer, head and neck cancer, myoepithelial carcinoma and mesothelioma.

In June, arGEN-X entered a collaboration with the Leukemia & Lymphoma Society (LLS) to evaluate ARGX-110 in a Phase 2 trial in Waldenström's macroglobulinemia (WM) patients. WM is rare type of B-cell lymphoma in which overactive CD70 signaling has been shown to contribute to tumor growth.

Under the agreement, LLS will contribute funding, of up to USD 2.2 million out of a total of USD 4.5million. arGEN-X plans to submit an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in 2H 2014 with the study commencing shortly thereafter, pending IND acceptance. The study will be led by Dr. Steven P. Treon, MD, PhD, Director of the Bing Center for Waldenström's macroglobulinemia at Harvard Medical School (Cambridge, MA, USA) and be conducted at the Dana-Farber Cancer Institute (US). Recruitment of 30 WM patients is expected to be completed by 1H 2016 with efficacy results expected in 2H 2017.

- **ARGX-111** – The clinical development for ARGX-111, a novel antibody targeting c-Met, a receptor involved in cancer spread (metastasis) in both solid and hematological tumors, has begun with a Phase 1b trial in 34 patients. The study aims to characterize the safety profile and biological activity of ARGX 111 with preliminary results expected in 2H 2015. If this study is positive, arGEN-X intends to seek a partner for the further development of ARGX-111 in a major cancer indication.

The trial is intended to identify the recommended dosing schedule to be used in future efficacy trials. arGEN-X is on track to complete the dose escalation part of the trial and select a safe dose during 2H 2014. The safety expansion part of the trial is envisioned to start in 1H 2015. The Phase 1b is recruiting patients with advanced solid tumors or hematological malignancies over-expressing c-Met. To date, arGEN-X has observed an early sign of biological activity in one gastric



cancer patient with bone metastases who showed a mixed response vs base line after receiving two doses of the study drug at the lowest dose.

The study is being conducted by a consortium of leading academic institutions in Belgium.

- **ARGX-113** – arGEN-X is developing ARGX-113 as a novel approach to treating severe autoimmune diseases. ARGX-113 is a proprietary antibody fragment based on ABDEG™ technology that targets the neonatal Fc receptor (FcRn), which is involved in antibody recycling. ARGX-113 works by preventing pathogenic autoantibodies from being recycled, promoting their degradation and thereby removing, or clearing, them from the circulation.

arGEN-X believes that ARGX-113 has the potential to treat virtually any IgG antibody-mediated pathology, in particular those associated with severe autoimmune diseases (e.g. rheumatoid arthritis, multiple sclerosis, systemic lupus erythematosus), as well as unmet rare diseases (e.g. myasthenia gravis, blistering skin diseases, immune thrombocytopenic purpura, etc).

ARGX-113 is in preclinical development and recent studies have validated this concept. Initially single escalating doses were studied to assess the effects of ARGX-113 on tracer antibody and total IgG levels. A subsequent phase was completed with optimized, repeat dosing of ARGX-113 to understand the drug's effect on total IgG clearance. Single cycle intravenous immunoglobulin (IVIg) was used as the comparator in the study. IVIg is the current standard of care in treating life-threatening flares in autoimmune diseases. In addition to ARGX-113 proving highly effective in rapidly clearing the tracer antibody from circulation in a dose-dependent manner, the following results were seen:

- Repeat administration of ARGX-113 showed a rapid, transient depletion of total IgG levels, reaching the desired target range and exceeding the effect observed at a single dose.
- Both single and repeat dose administrations of ARGX-113 showed faster and more extensive tracer IgG clearance compared to IVIg.
- Total IgA, IgM and serum albumin levels remained unaffected by ARGX-113 treatment.

arGEN-X expects to submit a Clinical Trial Application (CTA) for ARGX-113 to the applicable regulatory body in the second half of 2015, proposing the initiation of a Phase 1 study in healthy volunteers to establish safety and tolerability of the drug.

Partnerships

A key element of arGEN-X' strategy is to leverage its suite of antibody technologies in forging strategic collaborations with pharmaceutical and biotechnology companies to provide new approaches to diseases with unmet medical needs in return for non-dilutive cash and potential future revenues. During 1H 2014, arGEN-X made significant progress in this area, establishing a global strategic alliance with Shire Pharmaceuticals, as well as partnerships with Bayer Pharma AG and Boehringer Ingelheim.

In June 2014, arGEN-X entered into a long-term strategic alliance with Shire Pharmaceuticals. Under this agreement arGEN-X will bring its entire suite of human antibody discovery technologies to a partnership focused on multiple targets aligned with Shire's rare disease focus.



Shire made a total upfront investment of EUR 15 million (USD 20.4 million) in arGEN-X, consisting of EUR 3 million in cash and EUR 12 million in equity. In addition, Shire will fund the collaborative research programs at arGEN-X and pay fees, clinical, regulatory and sales milestones, as well as single digit royalties on therapeutic product sales. Shire will be responsible for clinical development and commercialization of products, with arGEN-X having the right to license any programs not pursued by Shire into its own development pipeline.

The multi-year initiative follows an initial research and development collaboration that began between the companies in March 2012. arGEN-X received two preclinical milestone payments from Shire in January 2014 relating to demonstration of *in vivo* proof of concept for one of the ongoing SIMPLE Antibody™ discovery programs.

During the period arGEN-X also announced it entered a collaboration with Bayer to discover and develop therapeutic antibody candidates. The collaboration aims to leverage the power of the SIMPLE Antibody™ platform to address complex targets across multiple therapeutic areas that are often intractable by existing antibody platforms.

In January, arGEN-X signed a pilot research agreement with Boehringer Ingelheim.

Board of Directors and Management

In April, arGEN-X elected Werner Lanthaler to its Board of Directors. Dr. Lanthaler has an outstanding track record of building and growing life sciences companies. He is currently CEO of Evotec (Frankfurt Stock Exchange: EVT), a role he took in March 2009. Under his leadership Evotec has become one of the leading drug discovery research organisations globally. Before that, he spent nine years as CFO at Intercell AG (2000-2009).

In June, Eric Castaldi, was appointed as CFO. Mr. Castaldi has gained a wealth of finance experience in a career spanning more than 25 years. Prior to joining arGEN-X, Mr. Castaldi was CFO at Nicox S.A. (Euronext: COX) for which he raised over EUR 400 million through various private and public offerings and was responsible for all financial, accounting, legal, fiscal and IT operations of the Group. In July, Mr Castaldi was elected to arGEN-X' Board of Directors

FINANCIAL REVIEW

CONDENSED INTERIM STATEMENT OF COMPREHENSIVE INCOME

Operating income

Operating income was EUR 1.6 million for the six months period ended 30 June 2014 compared to EUR 1.5 million for the same period in 2013. The Group's operating income includes a mix of research and development funding, technical success milestones received from the Group's industrial partnerships and government grants. In the first half of 2014, the Group received payments from Shire following the attainment of two milestones under its SIMPLE Antibody™ collaboration and option agreement.

The higher operating income in 2014 is due to an increase of EUR 0.4 million in other operating income corresponding to the recognition of a new grant received from IWT in July 2013 for its ARGX-110 program. This was partially offset by a EUR 0.3 million decline in industrial partnership revenue

resulting from the reduction in research and development funding following the attainment of two milestones under the SIMPLE Antibody™ agreement with Shire, outlined above.

Research and development expenses

Research and development expenses were EUR 4.9 million for the first six months period of 2014, compared to EUR 5.5 million in the same period in 2013. The EUR 0.6 million decrease is explained by non-recurrent expenses incurred in the first semester of 2013 in connection with the setup of clinical trials and product manufacturing.

General and administrative expenses

General and administrative expenses were EUR 1.4 million and EUR 1 million for the six months period ended 30 June 2014 and 2013 respectively. The EUR 0.4 million increase in 2014 is primarily explained by consulting fees related to the transition of the Group's financial statements into IFRS principles and other costs, including US IR activities, associated with the preparation of the IPO.

Operating profit/(loss)

The Group's loss from continuing operations before net finance income and tax was EUR 4.7 million for the first half of 2014 compared to a EUR 4.9 million loss for the same period in 2013.

Finance income (expense), net

Net finance income amounted to EUR 0.08 million in first half of 2014 compared to EUR 0.09 million for the same period in 2013. Other income (expense), net represents principally interest income on the financial investments of the Group's cash and cash equivalents and short term deposits, and 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

In the six month period ended 30 June 2014, the Group generated a loss of EUR 4.6 million compared to EUR 4.8 million during the first half of 2013.

CONDENSED INTERIM STATEMENT OF FINANCIAL POSITION

Assets

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

Cash and cash equivalents include cash in hand, deposits held at call with banks and other short term highly liquid investments with original maturities of three months or less. On 30 June 2014 the Group's cash and cash equivalents amounted to EUR 20.6 million compared to EUR 22.7 million on 31 December 2013. The Group uses its liquid assets principally to cover its research and development expenditures and its general and administrative expenses.

On 30 June 2014 the prepaid expenses amounted to EUR 3.7 million compared to EUR 0.1 million on 31 December 2013. This significant increase in prepaid expenses results from fees and other expenses related to the Initial Public Offering ('IPO') of the Company which will be deducted from equity following the receipt of the proceeds of the Offering post the period end.

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 30 June 2014 the trade payables and other payables amounted to EUR 6.4 million compared to EUR 2.9 million on 31 December 2013. This significant increase results from the fees and other expenses accrued in relation with the IPO process of the Company and not yet paid at the end of the first half of 2014.

Deferred revenue at the end of June 2014 totalled EUR 3.9 million compared to EUR 0.5 million at the end of 2013. This mainly relates to cash received from research collaboration agreements which will be recognized as revenue over the course of the agreements. The total amount includes an initial payment received from Shire (EUR 3.0 million) and a payment from LLS (EUR 0.7 million).

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

FINANCIAL STATEMENTS
CONDENSED INTERIM STATEMENT OF COMPREHENSIVE INCOME

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (in thousands of euros)	Six months ended June 30, 2014	Six months ended June 30, 2013
Revenue	570	838
Other operating income	1,075	701
Total operating income	1,645	1,539
Research and development expenses	(4,880)	(5,463)
General and administrative expenses	(1,415)	(991)
Operating profit/(loss)	(4,650)	(4,916)
Financial income	65	84
Exchange gains/(losses)	15	5
Result Profit/(loss) before taxes	(4,570)	(4,826)
Income tax (income/expense)	0	0
PROFIT/LOSS FOR THE PERIOD	(4,570)	(4,826)
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	(4,570)	(4,826)
Weighted average number of shares outstanding	18,000	18,000
Basic and diluted loss per share (in €)	(254)	(268)

CONDENSED INTERIM STATEMENT OF FINANCIAL POSITION

ASSETS (in thousands of euros)	Six months ended June 30, 2014	Year ended December 31, 2013
Non-current assets	781	586
Intangible assets	9	0
Property, plant and equipment	99	120
Financial assets	1	1
Tax receivables	671	466
Current assets	27,075	24,427
Trade and other receivables	2,210	1,100
Other financial assets	500	500
Prepaid expenses	3,726	106
Cash and cash equivalents	20,639	22,720
TOTAL ASSETS	27,856	25,013

EQUITY AND LIABILITIES (in thousands of euros)	Six months ended June 30, 2014	Year ended December 31, 2013
Equity		
Equity attributable to owners of the parent		
<i>Share capital</i>	466	466
<i>Share premium</i>	45,304	45,304
<i>Retained earnings</i>	(30,061)	(25,491)
<i>Other reserves</i>	1,796	1,426
Total equity	17,505	21,704
Non-current liabilities	0	0
Current liabilities	10,351	3,309
Trade and other payables	6,424	2,853
Deferred revenue	3,927	456
Total liabilities	10,351	3,309
TOTAL EQUITY AND LIABILITIES	27,856	25,013

The full financial report for 1H 2014 can be found in the Investor section of the arGEN-X website:

www.argen-x.com

**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™ discovery platform. SIMPLE Antibody™ 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™) and POTELLIGENT® technology (licensed from BioWa, inc.) further enhance the therapeutic properties of SIMPLE Antibody™ 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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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



REGULATED INFORMATION

statements. arGEN-X undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.