



argenx Reports First Quarter 2025 Financial Results and Provides Business Update

\$790 million in first quarter global product net sales

First patients treated with VYVGART Hytrulo pre-filled syringe for self-injection in US and Germany

CIDP global expansion with positive CHMP opinion for VYVGART-SC (vial and pre-filled syringe) in EU

Management to host conference call today at 2:30 PM CET (8:30 AM ET)

May 8, 2025, 7:00 AM CET

Amsterdam, the Netherlands – argenx SE (Euronext & Nasdaq: ARGX), a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases, today announced its first quarter 2025 financial results and provided a business update.

“We continue to execute on our bold innovation agenda, guided by our ‘Vision 2030’ to reach 50,000 patients across 10 labeled indications,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “We remain committed to delivering meaningful outcomes with VYVGART by setting a new benchmark for sustained efficacy and safety, and generating data that matter most to improving the lives of patients. This strategy has driven strong launch fundamentals to date, and we see consistent patient and prescriber expansion in both gMG and CIDP. Looking forward, we have several reasons to be confident in our growth trajectory. We are thrilled to bring even more optionality to gMG and CIDP patients with the recent approval of our pre-filled syringe for self-injection in the United States, receiving an optimal label that supports our ability to reach patients earlier in the treatment paradigm. In line with our ‘Vision 2030’, we are advancing 10 Phase 2 and 10 Phase 3 studies across efgartigimod, empasiprubart and ARGX-119, creating significant opportunity to expand into new therapeutic areas and reach broader patient populations. By year end, we expect key insights from proof-of-concept and registrational studies across many of these programs, while continuing to progress four IND candidates that reflect the depth and diversity of our pipeline.”

Advancing Vision 2030

argenx has established its strategic priorities to advance “Vision 2030”, aiming to treat 50,000 patients globally with its medicines, secure 10 labeled indications across all approved medicines, and advance five pipeline candidates into Phase 3 development by 2030.

Expand the global VYVGART opportunity and launch VYVGART SC as a pre-filled syringe

VYVGART® (IV: efgartigimod alfa-fcab and SC: efgartigimod alfa and hyaluronidase-qvfc) is a first-and-only targeted IgG Fc-antibody fragment approved in three indications, including generalized myasthenia gravis (gMG) globally, primary immune thrombocytopenia (ITP) in Japan, and chronic inflammatory demyelinating polyneuropathy (CIDP) in the U.S., Japan and China. The VYVGART-SC pre-filled syringe (PFS) is now approved for use in the U.S. and EU. argenx is well-positioned to sustain commercial growth through 2025, driven by global expansion, earlier treatment adoption, and the launch of the PFS to support growth momentum in both gMG and CIDP. In addition to bringing VYVGART to more patients early in the treatment paradigm, argenx is working to reach broader MG populations with ongoing studies in seronegative, ocular, and pediatric MG.

- Generated global product net sales (inclusive of both VYVGART and VYVGART SC) of \$790 million in the first quarter of 2025
 - Strong underlying fundamentals across key patient and prescriber metrics with 99% product net sales growth year-over-year from first quarter 2024, and 7% product net sales growth from fourth quarter 2024
- Multiple regulatory decisions on approval for PFS completed or underway:

- First patients treated with VYVGART-SC PFS for self-injection in the U.S. and Germany following regulatory approval
- Received positive recommendation from Committee for Medicinal Products for Human Use (CHMP) of European Medicines Agency (EMA) for VYVGART-SC (PFS and vial) for CIDP
- PFS decision on approval for gMG and CIDP expected in Japan and Canada by end of year
- Evidence generation through Phase 4 and label-enabling studies in MG, CIDP and ITP:
 - Topline results expected in second half of 2025 for seronegative gMG (ADAPT-SERON) and first half of 2026 for ocular and pediatric MG (ADAPT-OCULUS, JR)
 - Topline results from Phase 4 switch study to inform treatment decisions when switching patients on IVIg to VYVGART SC in CIDP expected in second half of 2025 and to be presented at an upcoming medical meeting
 - ADVANCE-NEXT topline results expected in second half of 2026 to support FDA submission of VYVGART IV for primary ITP

Execute 10 registrational and 10 proof-of-concept studies across efgartigimod, empasiprubart and ARGX-119 to advance the next wave of launches

argenx continues to demonstrate breadth and depth within its immunology pipeline, advancing multiple first-in-class product candidates with potential across high-need indications. argenx is solidifying its leadership in FcRn biology with efgartigimod, complement inhibition with empasiprubart and in the role of MuSK at the neuromuscular junction with ARGX-119.

Efgartigimod Development

Efgartigimod is being evaluated in 15 severe autoimmune diseases (including MG, CIDP, and ITP), exploring the significance of FcRn biology across neurology and rheumatology indications, as well as new therapeutic areas.

- Registrational studies are currently ongoing in three subsets of myositis, thyroid eye disease (TED), and Sjögren's disease.
 - Topline results from ALKIVIA study evaluating three myositis subsets (immune-mediated necrotizing myopathy (IMNM), anti-synthetase syndrome (ASyS), and dermatomyositis (DM)) expected in second half of 2026
 - Topline results from two registrational UplightTED studies (TED) expected in second half of 2026
 - Topline results from registrational UNITY study (Sjögren's disease) expected in 2027
- Proof-of-concept studies ongoing in lupus nephritis (LN), systemic sclerosis (SSc) and antibody mediated rejection (AMR); topline results expected for LN in fourth quarter of 2025, SSc in second half of 2026, and AMR in 2027

Empasiprubart Development

Empasiprubart is currently being evaluated in four indications, including two registrational studies in multifocal motor neuropathy (MMN) and CIDP, and proof-of-concept studies in delayed graft function (DGF) and DM.

- Topline results from registrational EMPASSION study (MMN) evaluating empasiprubart head-to-head versus IVIg expected in second half of 2026
- Registrational EMVIGORATE study in CIDP evaluating empasiprubart head-to-head versus IVIg expected to start in first half of 2025
- Topline results expected for DGF in second half of 2025 and for DM in first half of 2026



ARGX-119 Development

ARGX-119 is being evaluated in congenital myasthenic syndromes (CMS), amyotrophic lateral sclerosis (ALS), and spinal muscular atrophy (SMA).

- Phase 1b proof-of-concept study ongoing in CMS; topline results expected in second half of 2025
- Phase 2a proof-of-concept study ongoing in ALS; topline results expected in first half of 2026
- SMA proof-of-concept study on track to start in 2025

Advance four new pipeline molecules and generate sustainable value through continued investment in Immunology Innovation Program

argenx continues to invest in its Immunology Innovation Program (IIP) to drive long-term sustainable pipeline growth. Through the IIP, four new pipeline candidates have been nominated, including: ARGX-213, targeting FcRn and further solidifying argenx's leadership in this biology; ARGX-121, a first-in-class molecule targeting IgA; ARGX-109, targeting IL-6, which plays an important role in inflammation, and a fourth pipeline candidate, a first-in-class sweeping antibody for which the target has not yet been disclosed. Phase 1 results from ongoing ARGX-109 study expected in second half of 2025, and from ongoing ARGX-213 study and ARGX-121 study expected in first half of 2026.



FIRST QUARTER 2025 FINANCIAL RESULTS

argenx SE

UNAUDITED CONDENSED CONSOLIDATED INTERIM STATEMENTS OF PROFIT OR LOSS

(in thousands of \$ except for shares and EPS)	Three Months Ended March 31,	
	2025	2024
Product net sales	\$ 790,050	\$ 398,283
Collaboration revenue	633	2,718
Other operating income	16,687	11,512
Total operating income	807,370	412,513
Cost of sales	\$ (80,805)	\$ (43,178)
Research and development expenses	(309,070)	(224,969)
Selling, general and administrative expenses	(276,248)	(235,995)
Loss from investment in a joint venture	(2,307)	(1,792)
Total operating expenses	(668,430)	(505,934)
Operating profit/(loss)	\$ 138,940	\$ (93,421)
Financial income	\$ 37,118	\$ 38,895
Financial expense	(1,135)	(512)
Exchange gains/(losses)	27,438	(19,312)
Profit/(loss) for the period before taxes	\$ 202,361	\$ (74,350)
Income tax (expense)/benefit	\$ (32,892)	\$ 12,753
Profit/(loss) for the period	\$ 169,469	\$ (61,597)
Profit/(loss) for the period attributable to:		
Owners of the parent	\$ 169,469	\$ (61,597)
Weighted average number of shares outstanding	60,983,325	59,309,996
Basic profit/(loss) per share (in \$)	\$ 2.78	\$ (1.04)
Weighted average number of shares outstanding for diluted profit/(loss) per share	65,664,300	59,309,996
Diluted profit/(loss) per share (in \$)	\$ 2.58	\$ (1.04)



DETAILS OF THE FINANCIAL RESULTS

Total operating income for the three months ended March 31, 2025, was \$807 million compared to \$413 million for the same period in 2024, and consists of:

- **Product net sales** of VYVGART and VYVGART SC for the three months ended March 31, 2025, were \$790 million compared to \$398 million for the same period in 2024.
- **Other operating income** for the three months ended March 31, 2025, was \$17 million compared to \$12 million for the same period in 2024. The other operating income primarily relates to research and development tax incentives and payroll tax rebates.

Total operating expenses for the three months ended March 31, 2025, were \$668 million compared to \$506 million for the same period in 2024, and mainly consists of:

- **Cost of sales** for the three months ended March 31, 2025, was \$81 million compared to \$43 million for the same period in 2024. The cost of sales was recognized with respect to the sale of VYVGART and VYVGART SC.
- **Research and development expenses** for the three months ended March 31, 2025, were \$309 million compared to \$225 million for the same period in 2024. The expenses mainly relate to:
 - the clinical development and expansion of efgartigimod in 15 severe autoimmune diseases;
 - the ramp-up of studies for our development of empasiprubarb into MMN, DGF, DM and CIDP;
 - the investments for ARGX-119 in proof-of-concept studies ongoing in ALS and CMS; and
 - other discovery and preclinical pipeline candidates.
- **Selling, general and administrative expenses** for the three months ended March 31, 2025, were \$276 million compared to \$236 million for the same period in 2024. The selling, general and administrative expenses mainly relate to professional and marketing fees linked to global commercialization of the VYVGART franchise, and personnel expenses.

Financial income for the three months ended March 31, 2025, was \$37 million compared to \$39 million for the same period in 2024.

Exchange gains for the three months ended March 31, 2025, were \$27 million compared to exchange losses of \$19 million for the same period in 2024. Exchange gains and losses are mainly attributable to unrealized exchange rate gains or losses on the cash, cash equivalents and current financial assets denominated in Euro.

Income tax for the three months ended March 31, 2025, consisted of \$33 million of income tax expense compared to income tax benefit of \$13 million for the same period in 2024. Income tax expense for the three months ended March 31, 2025, consists of \$29 million of current income tax expense and \$4 million of deferred tax expense, compared to \$6 million of current income tax expense and \$19 million of deferred tax benefit for the comparable prior period.

Profit for the period of three months ended March 31, 2025, was \$169 million compared to a loss for the period of \$62 million in 2024. The profit per share was \$2.78 compared to a loss per share of \$1.04 for the three months ended March 31, 2025 and 2024, respectively.

FINANCIAL GUIDANCE

The financial guidance on the combined selling, general and administrative expenses and research and development expenses remains unchanged at approximately \$2.5 billion.



EXPECTED 2025 FINANCIAL CALENDAR

- May 27, 2025: Annual General Meeting of Shareholders in Amsterdam, the Netherlands
- July 31, 2025: Half Year and Second Quarter 2025 Financial Results and Business Update
- October 30, 2025: Q3 2025 Financial Results and Business Update

CONFERENCE CALL DETAILS

The first quarter 2025 financial results and business update will be discussed during a conference call and webcast presentation today at 2:30 pm CET/8:30 am ET. A webcast of the live call may be accessed on the Investors section of the argenx website at argenx.com/investors. A replay of the webcast will be available on the argenx website.

Dial-in numbers:

Please dial in 15 minutes prior to the live call.

Belgium	32 800 50 201
France	33 800 943355
Netherlands	31 20 795 1090
United Kingdom	44 800 358 0970
United States	1 888 415 4250
Japan	81 3 4578 9081
Switzerland	41 43 210 11 32

This press release contains inside information within the meaning of Article 7(1) of the EU Market Abuse Regulation (Regulation 596/2014).

About argenx

argenx is a global immunology company committed to improving the lives of people suffering from severe autoimmune diseases. Partnering with leading academic researchers through its Immunology Innovation Program (IIP), argenx aims to translate immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. argenx developed and is commercializing the first approved neonatal Fc receptor (FcRn) blocker and is evaluating its broad potential in multiple serious autoimmune diseases while advancing several earlier stage experimental medicines within its therapeutic franchises. For more information, visit www.argenx.com and follow us on [LinkedIn](#), [Instagram](#), [Facebook](#), and [YouTube](#).

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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 "aim," "anticipate," "are," "believe," "can," "continue," "expect," "may," "strive," and "will" and include statements argenx makes concerning its innovation agenda and growth strategy, including its Vision 2030 to reach 50,000 patients globally across 10 labeled indications and to advance 10 Phase 2 and 10 Phase 3 studies across efgartigimod, empasiprubart and ARGX-119 to create significant opportunity to expand into new therapeutic areas and reach broader patient populations; its commitment to delivering meaningful outcomes with VYVGART by setting a new benchmark for sustained efficacy and safety, and generating data that matter most to improving the lives of patients; the patient and prescriber expansion in both gMG and CIDP; our confidence in our growth trajectory; its goal to bring even more optionality to gMG and CIDP patients; its ability to reach patients earlier in the treatment paradigm; its expectation regarding the insights from proof-of-concept and



registrational studies across various programs; its belief that argenx is well-positioned to sustain commercial growth through 2025, driven by global expansion, earlier treatment adoption, and the launch of the PFS to support growth momentum in both gMG and CIDP; its goal to reach broader MG populations with ongoing studies in seronegative, ocular and pediatric MG; the advancement of anticipated clinical development, data readouts and regulatory milestones and plans, including: (1) PFS decision on approval for gMG and CIDP expected in Japan and Canada by end of 2025; (2) topline results for seronegative gMG (ADAPT-SERON) expected in second half of 2025 and for ocular and pediatric MG (ADAPT-OCULUS, JR) expected in first half of 2026; (3) topline results from Phase 4 switch study to inform treatment decisions when switching patient on IVIg to VYVGART SC in CIDP expected in the second half of 2025; (4) topline results for ADVANCE-NEXT to support FDA submission of VYVGART IV for primary ITP expected in second half of 2026; (5) its plan to execute 10 registrational and 10 proof-of-concept studies across efgartigimod, empasiprubar and ARGX-119 to advance the next wave of launches by exploring the significance of FcRn biology across neurology and rheumatology indications, as well as new therapeutic areas and ongoing registrational studies in three subsets of myositis, thyroid eye disease (TED), and Sjögren's disease, with topline results from (a) ALKIVIA expected in second half of 2026, (b) two registrational UplightTED studies expected in second half of 2026 and (c) registrational UNITY study expected in 2027, (6) proof-of-studies ongoing in LN, SSc and AMR, with topline results expected in fourth quarter of 2025, second half of 2026 and 2027, respectively; (7) its plans to develop empasiprubar, including (a) registrational EMPASSION study in MMN, with topline results expected in second half of 2026, (b) registrational EMVIGORATE study in CIDP, expected to start in first half of 2025 and (c) topline results for DGM and DM expected in second half of 2025 and first half of 2026, respectively; (8) its plans to develop ARGX-119, including: (a) Phase 1b proof-of-concept study in CMS, with topline results expected in second half of 2025; (b) Phase 2a proof-of-concept study in ALS, with topline results expected in first half of 2026; and (c) SMA proof-of-concept study, on track to start in 2025; and (9) its plans to advance four new pipeline molecules and generate sustainable value through continue investment in its IIP, through (a) ongoing studies for ARGX-213 and ARGX-121, with results expected in first half of 2026, (b) ARGX-109, with Phase 1 results expected in second half of 2025, and (c) a fourth pipeline candidate, a first-in-class sweeping antibody for which the target has not yet been disclosed; its 2025 anticipated research and development, selling, general and administrative expenses; and its goal of translating immunology breakthroughs into a world-class portfolio of novel antibody-based medicines. 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. argenx's actual results may differ materially from those predicted by the forward-looking statements as a result of various important factors, including but not limited to, the results of argenx's clinical trials; expectations regarding the inherent uncertainties associated with the development of novel drug therapies; preclinical and clinical trial and product development activities and regulatory approval requirements; the acceptance of its products and product candidates by its patients as safe, effective and cost-effective; the impact of governmental laws and regulations, including tariffs, export controls, sanctions and other regulations on its business; its reliance on third-party suppliers, service providers and manufacturers; inflation and deflation and the corresponding fluctuations in interest rates; and regional instability and conflicts. A further list and description of these risks, uncertainties and other risks can be found in argenx's U.S. Securities and Exchange Commission (SEC) filings and reports, including in argenx's most recent annual report on Form 20-F filed with the SEC as well as subsequent filings and reports filed by argenx with the SEC. Given these uncertainties, the reader is advised not to place any undue reliance on such forward-looking statements. These forward-looking statements speak only as of the date of publication of this document. argenx undertakes no obligation to publicly update or revise the information in this press release, including any forward-looking statements, except as may be required by law.