



argenx Reports Full Year 2024 Financial Results and Provides Fourth Quarter Business Update

\$737 million in fourth quarter and \$2.2 billion in full year global product net sales

Received positive CHMP recommendation for VYVGART pre-filled syringe for gMG, enabling launch in the EU; FDA PDUFA (gMG and CIDP) on track for April 10

10 Phase 3 and 10 Phase 2 studies across pipeline ongoing in 2025, positioning for next wave of growth

Recognized one-time tax benefit of \$725 million related to previously unrecognized deferred tax assets

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

February 27, 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 reported financial results for the full year 2024 and provided a fourth quarter business update.

"In 2024, we significantly expanded our global patient reach with VYVGART, surpassing 10,000 patients across three indications," said Tim Van Hauwermeiren, Chief Executive Officer of argenx. "We are extremely proud of the initial launch efforts of VYVGART Hytrulo in CIDP, where the strength of our data has driven early positive feedback from both patients and physicians. This execution has contributed to our position of financial strength as we expect to become a profitable company in 2025. We are now more committed than ever to advancing our mission of transforming the autoimmune treatment landscape by investing in innovation, and leading with our science. Momentum across our business is off to a strong start this year as we continue to execute on our Vision 2030. We are focused on maximizing commercial opportunities in gMG and CIDP, including advancing the pre-filled syringe in multiple regions, expanding our label in MG, and deepening relationships within the CIDP community to explore VYVGART Hytrulo's long-term potential. With an expansive pipeline, we are also excited to drive forward 10 Phase 3 and 10 Phase 2 studies in 2025 across efgartigimod, empasiprubart, and ARGX-119, to unlock significant opportunities in high unmet need areas."

Advancing Vision 2030

argenx has established its commercial and clinical strategic priorities to advance "Vision 2030". Through this vision, argenx aims 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-in-class FcRn blocker 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. argenx plans to drive commercial growth by expanding into new regions; innovating on the patient experience by advancing its pre-filled syringe (PFS) in multiple markets for CIDP and gMG in 2025 and autoinjector in 2027; and reaching 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 \$737 million in fourth quarter and \$2.2 billion in full year of 2024
- Multiple VYVGART regulatory submissions completed for gMG, including:
 - Ministry of Food and Drug Safety approved VYVGART (IV) for gMG in South Korea through Handok Inc.
 - Therapeutic Goods Association (TGA) approved VYVGART (IV and SC) for gMG in Australia
- Four key regulatory decisions on approval for PFS on track for 2025:
 - Received positive CHMP recommendation for approval of PFS for gMG, enabling launch in the EU
 - FDA review ongoing of PFS for gMG and CIDP with Prescription Drug User Fee Act (PDUFA) target action date of April 10, 2025
 - PFS decision on approval for CIDP in the EU expected in first half of 2025
 - PFS decision on approval for gMG and CIDP expected in Japan and Canada in second half of 2025
- 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)
 - Phase 4 switch study ongoing in CIDP to inform treatment decisions when switching patients on IVIg to VYVGART SC
 - 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 ALKIVIA study ongoing evaluating three myositis subsets (immune-mediated necrotizing myopathy (IMNM), anti-synthetase syndrome (ASyS), and dermatomyositis (DM)); topline results expected in second half of 2026



- Two registrational UplighTED studies ongoing in thyroid eye disease (TED); topline results expected in second half of 2026
- Registrational UNITY study ongoing in primary Sjögren's disease; topline results expected in 2027
- Proof-of-concept studies ongoing in lupus nephritis (LN), systemic sclerosis (SSc) and antibody mediated rejection (AMR); topline results expected in LN in fourth quarter of 2025, SSc in second half of 2026, and AMR in 2027
- Next nominated indications include autoimmune encephalitis (AIE) and one that is undisclosed

Empasiprubart Development

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

- Registrational EMPASSION study ongoing in MMN evaluating empasiprubart head-to-head versus IVIg; topline results 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
- Proof-of-concept studies ongoing in DGF and DM; 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 new class of medicine; ARGX-121, a first-in-class molecule targeting IgA; ARGX-109, targeting IL-6, which plays an important role in inflammation, and ARGX-220, a first-in-class sweeping antibody for which the target has not yet been disclosed.

- Phase 1 results expected for ARGX-109 in second half of 2025 and for ARGX-213 and ARGX-121 in first half of 2026

Don deBethizy to retire as non-executive director, Chair of the Remuneration Committee, and Vice Chair of the Company's Board of Directors, effective May 27, 2025.

Mr. deBethizy has served as a non-executive director since 2015. He will be succeeded by Ana Cespedes as Chair of the Remuneration Committee and Tony Rosenberg as Vice Chair of the Board of Directors.



"I would like to express my deep gratitude to Don for his significant contributions during his tenure with argenx. He has been a true champion of our culture, guiding us through several key milestones on our growth journey, while supporting our entrepreneurial spirit and commitment to innovation." commented Mr. Van Hauwermeiren.



FOURTH QUARTER AND FULL YEAR 2024 FINANCIAL RESULTS

argenx SE

UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS

| (in thousands of \$ except for shares and EPS) | Three Months Ended | | Twelve Months Ended | |
|--|--------------------|---------------------|---------------------|---------------------|
| | December 31 | | December 31 | |
| | 2024 | 2023 | 2024 | 2023 |
| Product net sales | \$ 736,968 | \$ 374,351 | \$ 2,185,883 | \$ 1,190,783 |
| Collaboration revenue | 1,443 | 32,486 | 4,348 | 35,533 |
| Other operating income | 22,809 | 11,003 | 61,808 | 42,278 |
| Total operating income | 761,220 | 417,840 | 2,252,039 | 1,268,594 |
| Cost of sales | \$ (72,656) | \$ (39,477) | \$ (227,289) | \$ (117,835) |
| Research and development expenses | (297,228) | (306,373) | (983,423) | (859,492) |
| Selling, general and administrative expenses | (285,945) | (208,826) | (1,055,337) | (711,905) |
| Loss from investment in a joint venture | (2,350) | (1,788) | (7,644) | (4,411) |
| Total operating expenses | (658,179) | (556,464) | (2,273,693) | (1,693,643) |
| Operating profit/(loss) | \$ 103,041 | \$ (138,624) | \$ (21,654) | \$ (425,049) |
| Financial income | \$ 39,095 | \$ 40,308 | \$ 157,509 | \$ 107,386 |
| Financial expense | (704) | (280) | (2,464) | (906) |
| Exchange (losses)/gains | (54,923) | 37,418 | (48,211) | 14,073 |
| Profit/(loss) for the period before taxes | \$ 86,509 | \$ (61,178) | \$ 85,180 | \$ (304,496) |
| Income tax benefit/(expense) | \$ 687,652 | \$ (37,994) | \$ 747,860 | \$ 9,443 |
| Profit/(loss) for the period | \$ 774,161 | \$ (99,172) | \$ 833,040 | \$ (295,053) |
| Profit/(loss) for the period attributable to: | | | | |
| Owners of the parent | \$ 774,161 | \$ (99,172) | \$ 833,040 | \$ (295,053) |
| Weighted average number of shares outstanding used for basic profit/loss per share | 60,517,968 | 59,118,827 | 59,855,585 | 57,169,253 |
| Weighted average number of shares outstanding used for diluted profit/loss per share | 65,661,428 | 59,118,827 | 65,177,815 | 57,169,253 |
| Basic profit/(loss) per share (in \$) | \$ 12.79 | \$ (1.68) | \$ 13.92 | \$ (5.16) |
| Diluted profit/(loss) per share (in \$) | \$ 11.79 | \$ (1.68) | \$ 12.78 | \$ (5.16) |



DETAILS OF THE FINANCIAL RESULTS

Total operating income for the three and twelve months ended December 31, 2024 was \$761 million and \$2,252 million, respectively, compared to \$418 million and \$1,269 million for the same periods in 2023, and mainly consists of:

- **Product net sales** of VYVGART and VYVGART SC for the three and twelve months ended December 31, 2024 were \$737 million and \$2,186 million, respectively, compared to \$374 million and \$1,191 million for the same periods in 2023.
- **Collaboration revenue** for the three and twelve months ended December 31, 2024 was \$1 million and \$4 million, respectively, compared to \$32 million and \$36 million for the same periods in 2023. Collaboration revenue for 2024 mainly relates to our collaboration with Zai Lab in China.
- **Other operating income** for the three and twelve months ended December 31, 2024 was \$23 million and \$62 million, respectively, compared to \$11 million, and \$42 million for the same periods in 2023. The other operating income primarily relates to research and development tax incentives and payroll tax rebates.

Total operating expenses for the three and twelve months ended December 31, 2024 were \$658 million and \$2,274 million, respectively, compared to \$556 million and \$1,694 million for the same periods in 2023, and mainly consists of:

- **Cost of sales** for the three and twelve months ended December 31, 2024 was \$73 million and \$227 million, respectively, compared to \$39 million and \$118 million for the same periods in 2023. The cost of sales was recognized with respect to the sale of VYVGART and VYVGART SC.
- **Research and development expenses** for the three and twelve months ended December 31, 2024 were \$297 million and \$983 million, respectively, compared to \$306 million and \$859 million for the same periods in 2023. The expenses mainly relate to:
 - the clinical development and expansion of efgartigimod in 15 severe autoimmune diseases including MG, CIDP and ITP
 - 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
 - other discovery and preclinical pipeline candidates
- **Selling, general and administrative expenses** for the three and twelve months ended December 31, 2024 were \$286 million and \$1,055 million, respectively, compared to \$209 million and \$712 million for the same periods in 2023. 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 and twelve months ended December 31, 2024 was \$39 million and \$158 million, respectively, compared to \$40 million and \$107 million for the same periods in 2023.

Exchange losses for the three and twelve months ended December 31, 2024 were \$55 million and \$48 million respectively, compared to exchange gains of \$37 million and \$14 million for the same periods in 2023. Exchange



gains or losses are mainly attributable to unrealized exchange rate gains or losses on the cash, cash equivalents and current financial assets position in Euro.

Income tax benefit

The Company recorded a deferred tax benefit of \$802 million for the year ended December 31, 2024 of which \$725 million relates to a one-time non-recurring recognition of previously unrecognized deferred tax assets existing as of December 31, 2023. This recognition results from the Company's determination, in the fourth quarter of 2024, that it was probable that future taxable profits will be available for use of unrecognized deferred tax assets.

| (in millions of \$) | Three Months Ended | | Twelve Months Ended | |
|-------------------------------------|--------------------|-------------|---------------------|----------|
| | December 31 | | December 31 | |
| | 2024 | 2023 | 2024 | 2023 |
| Current tax (expense)/benefit | \$ (25) | 12 | (54) | (12) |
| Deferred tax benefit/(expense) | 713 | (50) | 802 | 21 |
| Income tax benefit/(expense) | \$ 688 | (38) | 748 | 9 |

Profit for the period of the three and twelve months ended December 31, 2024 was \$774 million and \$833 million, respectively, compared to a loss of \$99 million and \$295 million over the prior periods. On a per weighted average share basis, the basic profit per share was \$13.92 for the year ended December 31, 2024, compared to a basic loss per share of \$5.16 for the year ended December 31, 2023.

FINANCIAL GUIDANCE

Based on its current operating plans, argenx expects its combined research and development and selling, general and administrative expenses in 2025 to be approximately \$2.5 billion.

EXPECTED 2025 FINANCIAL CALENDAR

- May 8, 2025: Q1 2025 financial results and business update
- 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 full year 2024 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 and replay may be accessed on the Investors section of the argenx website at argenx.com/investors.

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 | 1 800 715 9871 |
| 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](#), [X/Twitter](#), [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 "advance," "aim," "believe," "continue," "drive," "expand," "expect," "plan," "position," "start," and "strive" and include statements argenx makes regarding its expected profitability in 2025; its mission to transform



the autoimmune treatment landscape by investing in innovation and its goal to lead in science; its focus on maximizing commercial opportunities in gMG and CIDP, including by advancing PFS in multiple regions, expanding its label in gMG and deepening relationships within the CIDP community; its plan to unlock significant opportunities in high unmet need areas; its long-term commitments, including its Vision 2030 goals of treating 50,000 patients globally with its medicines, securing 10 labeled indications across all approved medicines, and advancing five pipeline candidates into Phase 3 development by 2030; its plans to drive commercial growth by expanding VYVGART into new regions, advance its PFS in multiple markets for CIDP and MG in 2025 and autoinjector in 2027, and 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) four key regulatory decisions on approval for PFS expected in 2025; (2) PFS decision on approval for gMG and CIDP expected in Japan and Canada in second half of 2025 and for CIDP expected in the EU in first half of 2025; and (3) ongoing evidence generation through Phase 4 and label-enabling studies in MG, CIDP and ITP, including topline results for seronegative gMG expected in second half of 2025 and those for ocular and pediatric MG expected in first half of 2026, ongoing Phase 4 switch study in CIDP, and ongoing ADVANCE-NEXT confirmatory study of VYVGART IV in primary ITP with topline results expected in second half of 2026; its plans to execute 10 registrational and 10 proof-of-concept studies across efgartigimod, empasiprubart and ARGX-119 in 2025 to advance the next wave of launches; its plans to develop efgartigimod, including: (1) the ongoing registrational ALKIVIA study evaluating IMNM, ASyS, and DM, with topline results expected in second half of 2026; (2) two ongoing registrational UplightTED studies in TED, with topline results expected in second half of 2026; (3) Registrational UNITY study in primary Sjögren's disease, with topline results expected in 2027; (4) ongoing proof-of-concept studies in LN, SSc, and AMR, with topline results expected in fourth quarter of 2025, second half of 2026, and 2027, respectively; and (5) the next nominated indications of AIE and one undisclosed disease to enter clinical studies; its plans to develop empasiprubart, including: (1) registrational EMPASSION study in MMN, with topline results expected in second half of 2026; (2) registrational EMVIGORATE study in CIDP, expected to start in first half of 2025; and (3) proof-of-concept studies in DGF and DM, with topline results expected in second half of 2025 and first half of 2026, respectively; its plans to develop ARGX-119, including: (1) proof-of-concept study in CMS, with topline results expected in second half of 2025; (2) Phase 2a proof-of-concept study in ALS, with topline results expected in first half of 2026; and (3) SMA proof-of-concept study, expected to start in 2025; the expected start and timeline of Phase 1 studies of ARGX-109 in second half of 2025 and ARGX-213 and ARGX-121 in first half of 2026; the expected change from Mr. deBethizy to Ms. Cespedes as the Chair of the Remuneration Committee; the potential of its continued investment in its IIP to drive long-term sustainable pipeline growth; its future financial and operating performance, including its anticipated research and development, selling, general and administrative expenses for 2025; 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 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.