argenx Reports Third Quarter 2024 Financial Results and Provides Business Update

$573 million in third quarter global net product sales

CIDP global expansion on track, with decisions on approval under review in Japan, Europe, China, and Canada

Management to host conference call today at 1:30 PM CET (8:30 AM ET)

Regulated information - Inside information

October 31, 2024 7:00AM 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 third quarter 2024 financial results and provided a business update.

“We delivered significant patient impact with VYVGART over the quarter, expanding our gMG footprint and delivering innovation to CIDP patients three months into launch,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “We continued to advance our goal of reaching more gMG patients earlier in their treatment journey, supported by VYVGART’s strong safety and efficacy profile, and real-world data showing the ability to meaningfully reduce steroid use. Expanding upon our leadership in gMG, we are now paving the future in CIDP. The strength of our data, combined with execution across the team to reach key stakeholders, contributed to the initial success of our CIDP launch, with more than 300 patients on therapy at the end of the third quarter. There remains significant opportunity ahead as we work towards achieving our Vision 2030, with innovation implemented across our pipeline to deliver transformative outcomes to more patients.”

Advancing ‘Vision 2030’ in Third Quarter 2024

Vision 2030 is the next phase in argenx’s long-term commitment to transform the treatment of autoimmune diseases by strengthening its leadership in FcRn biology, investing in its continuous pipeline of differentiated antibody candidates, and scaling in a disciplined way to ensure innovation remains core to the argenx mission. As a part of this vision, argenx plans to reach at least 50,000 patients globally, advance the pipeline to achieve 10 labeled indications, and bring five new molecules into Phase 3 by 2030.

Reaching 50,000 Patients Globally by 2030

VYVGART® (efgartigimod alfa-fcab) is a first-in-class antibody fragment targeting FcRn and is now approved for both intravenous use and subcutaneous injection (SC) (efgartigimod alfa and hyaluronidase-qvfc) in three indications, including generalized myasthenia gravis (gMG) globally, primary immune thrombocytopenia (ITP) in Japan (IV only), and chronic inflammatory demyelinating polyneuropathy (CIDP) in the U.S. (SC only).

- Generated global net product revenues (inclusive of both VYVGART and VYVGART SC) of $573 million in the third quarter of 2024
- Multiple VYVGART regulatory submissions completed or underway for gMG, including:
  - Swissmedic approved VYVGART for the treatment of gMG in Switzerland
  - Regulatory decisions on approval expected in Australia and Saudi Arabia in 2024, and South Korea in 2025
- Multiple VYVGART SC regulatory submissions under review or planned for CIDP, including:
  - Regulatory submissions completed in Japan, Europe, and China with decisions on approval expected in 2025
  - Regulatory submission to be completed in Canada by end of 2024
- VYVGART now reimbursed in 11 countries in Europe, with new agreements in place in France, Luxembourg, and Belgium
- FDA review of VYVGART SC pre-filled syringe (PFS) for gMG and CIDP ongoing with Prescription Drug User Fee Act (PDUFA) target action date of April 10, 2025

Advancing Pipeline to Achieve 10 Labeled Indications by 2030

argenx continues to demonstrate breadth and depth within its immunology pipeline, advancing multiple pipeline-in-a-product candidates. argenx is solidifying its leadership in FcRn biology, with efgartigimod currently in development in 15 indications. argenx is also advancing its first-in-class C2 inhibitor, empasiprubart, which is being evaluated in multifocal motor neuropathy (MMN), delayed graft function (DGF), dermatomyositis (DM), and CIDP. In addition, argenx is evaluating ARGX-119, a muscle-specific kinase (MuSK) agonist in both congenital myasthenic syndrome (CMS) and amyotrophic lateral sclerosis (ALS).

- Registrational studies ongoing of efgartigimod in thyroid eye disease (TED)
- Registrational studies ongoing to support label-expansion into broader MG, including ADAPT SERON in seronegative gMG and ADAPT OCULUS in ocular MG
- Registrational study in primary Sjögren’s disease (SjD) on track to start by end of 2024

- Confirmatory study of efgartigimod in primary ITP to start by end of 2024 to enable registration in U.S.
- Topline data from seamless Phase 2/3 ALKIVIA study evaluating efgartigimod across three myositis subsets (immune-mediated necrotizing myopathy (IMNM), anti-synthetase syndrome (ASyS), and DM) expected by end of 2024
- Update on BALLAD study development plan evaluating efgartigimod in bullous pemphigoid (BP) expected by end of 2024
- Decision made to discontinue development of efgartigimod in membranous nephropathy (MN); proof-of concept study ongoing with efgartigimod in lupus nephritis (LN)
- Proof-of-concept study ongoing with efgartigimod in antibody mediated rejection (AMR), with systemic sclerosis (SSc) to start by end of 2024
- Registrational study of empasiprubart in MMN to start by end of 2024
- Additional proof-of-concept studies of empasiprubart ongoing, including VARVARA study in DGF and EMPACIFIC study in DM
- Registrational study of empasiprubart in CIDP to start in 2025
- Ongoing Phase 1b/2a studies of ARGX-119 to assess early signal in patients with CMS and ALS

Investing in Immunology Innovation Program to Support Five New Molecules in Phase 3 by 2030

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 studies of ARGX-213 and ARGX-121 expected to start in second half of 2025
- Investigational new drug (IND) applications for ARGX-220 and ARGX-109 on track to be filed by end of 2025

THIRD QUARTER 2024 FINANCIAL RESULTS

argenx SE

UNAUDITED CONDENSED CONSOLIDATED INTERIM STATEMENTS OF PROFIT OR LOSS

	Three Months Ended September 30		Nine Months Ended September 30	
(in thousands of $ except for shares and EPS)	**2024**	**2023**	**2024**	**2023**
Product net sales	$ 572,997	$ 329,097	$ 1,448,915	$ 816,432
Collaboration revenue	239	692	2,905	3,047
Other operating income	15,642	10,050	38,999	31,275
Total operating income	**$ 588,878**	**$ 339,839**	**$ 1,490,819**	**$ 850,754**
Cost of sales	$ (59,072)	$ (35,999)	$ (154,633)	$ (78,358)
Research and development expenses	(235,940)	(191,755)	(686,195)	(553,119)
Selling, general and administrative expenses	(277,698)	(191,930)	(769,392)	(503,079)
Loss from investment in a joint venture	(1,981)	(743)	(5,294)	(2,623)
Total operating expenses	**$ (574,691)**	**$ (420,427)**	**$ (1,615,514)**	**$ (1,137,179)**
Operating profit/(loss)	**$ 14,187**	**$ (80,588)**	**$ (124,695)**	**$ (286,425)**
Financial income	$ 40,586	$ 30,049	$ 118,414	$ 67,078
Financial expense	(676)	(231)	(1,760)	(626)
Exchange gains/(losses)	33,927	(32,509)	6,712	(23,345)
Profit/(loss) for the period before taxes	**$ 88,024**	**$ (83,279)**	**$ (1,329)**	**$ (243,318)**
Income tax (expense)/benefit	$ 3,386	$ 10,637	$ 60,208	$ 47,437
Profit/(loss) for the period	**$ 91,410**	**$ (72,642)**	**$ 58,879**	**$ (195,881)**
Profit/(loss) for the period attributable to:				
Owners of the parent	$ 91,410	$ (72,642)	$ 58,879	$ (195,881)
Weighted average number of shares outstanding	60,087,498	58,128,233	59,633,179	56,512,254
Basic profit/(loss) per share (in $)	1.52	(1.25)	0.99	(3.47)
Diluted profit/(loss) per share (in $)	1.39	(1.25)	0.91	(3.47)

Net increase in cash, cash equivalents and current financial assets compared to year-end 2023 and 2022	$	194,523	$	993,035
Cash and cash equivalents and current financial assets at the end of the period	$	3,374,367	$	3,185,583

DETAILS OF THE FINANCIAL RESULTS

Total operating income for the third quarter and year-to-date in 2024 was $589 million and $1,491 million, respectively, compared to $340 million and $851 million for the same periods in 2023, and mainly consists of:

- **Product net sales** of VYVGART for the three months ended and nine months ended September 30, 2024, were $573 million and $1,449 million, compared to $329 million and $816 million for the same periods in 2023.
- **Other operating income** for the third quarter and year-to-date in 2024 was $16 million and $39 million, respectively, compared to $10 million, and $31 million for the same periods in 2023. The other operating income for the three and nine months ended September 30, 2024 primarily relates to research and development tax incentives and payroll tax rebates.

Total operating expenses for the third quarter and year-to-date in 2024 were $575 million and $1,616 million, respectively, compared to $420 million and $1,137 million for the same periods in 2023, and mainly consists of:

- **Cost of sales** for the third quarter and year-to-date in 2024 was $59 million and $155 million, respectively, compared to $36 million and $78 million for the same periods in 2023. The cost of sales was recognized with respect to the sale of VYVGART and VYVGART Hytrulo.
- **Research and development expenses** for the third quarter and year-to-date in 2024 were $236 million and $686 million, respectively, compared to $192 million and $553 million for the same periods in 2023. The research and development expenses mainly relate to external research and development expenses and personnel expenses incurred in the clinical development of efgartigimod in various indications and the expansion of other clinical and preclinical pipeline candidates.
- **Selling, general and administrative expenses** for the third quarter and year-to-date in 2024 were $278 million and $769 million, respectively, compared to $192 million and $503 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 VYVGART and VYVGART Hytrulo, and personnel expenses.

Financial income for the third quarter and year-to-date in 2024 was $41 million and $118 million, respectively, compared to $30 million and $67 million for the same periods in 2023. The increase in financial income is mainly due to an increase in interest income on current financial assets and cash and cash equivalents.

Exchange gains for the third quarter and year-to-date in 2024 were $34 million and $7 million respectively, respectively, compared to $(33) million and $(23) million of exchange losses for the same periods in 2023. Exchange gains/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 for the third quarter and year-to-date in 2024 was $3 million and $60 million of tax benefit, respectively, compared to $11 million and $47 million of tax benefit for the same periods in 2023. Tax benefit for the nine months ended September 30, 2024 consists of $29 million of income tax expense and $89 million of deferred tax income, compared to $24 million of income tax expense and $71 million of deferred tax income for the comparable prior period.

Net income for the three and nine month periods ended September 30, 2024, was $91 million and $59 million, respectively, compared to a net loss of $(73) million and $(196) million over the prior year periods. On a per weighted average share basis, the earnings per share was $0.99 for the nine months ended September 30, 2024 and a net loss per share of $(3.47) for the nine months ended September 30, 2023.

Cash, cash equivalents and current financial assets totaled $3.4 billion as of September 30, 2024, compared to $3.2 billion as of December 31, 2023. The increases in cash and cash equivalents and current financial assets over the period was from financing activities due to the exercise of stock options which is offset by net cash flows used in operating and investing activities.

FINANCIAL GUIDANCE

With the increase in cash, cash equivalents and current financial assets in the quarter and year-to-date, the previously issued cash guidance no longer applies. The financial guidance on the combined selling, general and administrative expenses and research and development expenses remains unchanged at approximately $2 billion.

EXPECTED 2024 FINANCIAL CALENDAR

- February 27, 2025: Full-year 2024 financial results and 4Q 2024 business update

CONFERENCE CALL DETAILS

The third quarter 2024 financial results and business update will be discussed during a conference call and webcast presentation today at 1:30 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	1 888 415 4250
Japan	81 3 4578 9081
Switzerland	41 43 210 11 32

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 in the U.S., Japan, Israel, the EU, the UK, China and Canada. The Company is evaluating efgartigimod in multiple serious autoimmune diseases and 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.

For further information, please contact:

Media:

Ben Petok
bpetok@argenx.com

Investors:
Alexandra Roy (US)
aroy@argenx.com

Lynn Elton (EU)
lelton@argenx.com

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," "achieve," "advance," "bring," "complete," "expect," "initiate," "plan," "reach," "start," "support," "to be," or "will," and include statements argenx makes regarding its goal to reach more gMG patients in an early-line setting; its growth opportunity; its Vision 2030 plan, including (1) transforming the treatment of autoimmune diseases by strengthening its leadership in FcRn biology, (2) investing in its continuous pipeline of differentiated antibody candidates, (3) scaling in a disciplined way to ensure innovation, and (4) reaching 50,000 patients globally with an argenx medicine, 10 labeled indications across all approved assets, and five new molecules in Phase 3 development; the advancement of anticipated clinical development, data readouts and regulatory milestones and plans, including (1) the anticipated timing of additional VYVGART regulatory decisions on approval for gMG in Australia, Saudi Arabia, and South Korea, (2) the anticipated timing of VYVGART SC regulatory submissions for CIDP, including decisions on approval in China, Japan, and Europe and an anticipated regulatory submission filing in Canada, (3) the anticipated timing of the initiation of a registrational study for efgartigimod in primary SjD, (4) the anticipated timing of a confirmatory study of efgartigimod in primary ITP, (5) the anticipated timing of topline data from Phase 2/3 ALKIVIA study evaluating efgartigimod across three myositis subsets, (6) the anticipated timing of an update on the BALLAD study development plan evaluating efgartigimod in BP, (7) the anticipated timing of proof-of-concept study data for efgartigimod in LN, (8) the anticipated timing of the initiation of a study on efgartimod in SSc, (9) the anticipated timing of the initiation of a registrational study of empasiprubart for MMN, (9) the anticipated timing of the initiation of a registrational study of empasiprubart in CIDP, (10) the anticipated timing of the initiation of Phase 1 studies of ARGX-213 and ARGX-121, (11) the anticipated timing of the filing of investigational new drug applications for ARGX-220 and ARGX-109; the advancement of empasiprubart; its 2024 selling, general and administrative expenses and research and development expenses; the anticipated timing of releases of future financial results and business updates; 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 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 in products and product candidates; the acceptance of argenx's products and product candidates by patients as safe, effective and cost-effective; the impact of governmental laws and regulations on our business; disruptions caused on our reliance of third parties suppliers, service provides and manufacturing; 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.