Source: *argenx SE*

October 30, 2025 02:00 ET

argenx Reports Third Quarter 2025 Financial Results and Provides Business Update

$1.13 billion in third quarter global product net sales

On track to submit seronegative gMG sBLA by year-end and report ADAPT-OCULUS results in 1H26 – supporting pursuit of broadest MG label of any biologic

Five registrational study readouts expected in 2026 from leading immunology pipeline

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

October 30, 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 third quarter 2025 financial results and provided a business update.

“argenx continues to deliver on our bold innovation agenda, driving transformational impact for patients worldwide,” said Tim Van Hauwermeiren, Chief Executive Officer of argenx. “This year, we expanded our global reach with VYVGART in two blockbuster indications, advanced five registrational programs, and are on track to complete our goal of four Phase 1 molecules by year-end, reflecting our ongoing investment in innovation. VYVGART is redefining expectations for people living with gMG and CIDP, and we see continued growth potential driven by strong patient demand for better outcomes, earlier use in the treatment paradigm, and our commitment to pursuing the broadest possible labels for our medicines. We aim to leverage the successful innovation playbook of MG and CIDP as we prepare for five registrational readouts next year. Building on this momentum, our pipeline is positioned to expand into new indications and reach tens of thousands more patients—bringing us closer to our Vision 2030 goal.”

Vision 2030 Strategic Priorities

argenx is advancing its Vision 2030 strategic priorities, anchored in the ambition to treat 50,000 patients globally with its medicines, secure 10 labeled indications across approved medicines, and progress five pipeline candidates into Phase 3 development by 2030.

Expand global VYVGART opportunity

VYVGART® (IV: efgartigimod alfa-fcab and SC: efgartigimod alfa and hyaluronidase-qvfc) is a first-and-only IgG Fc-antibody fragment that targets the neonatal Fc receptor (FcRn). It is approved in three indications, including generalized myasthenia gravis (gMG) and chronic inflammatory demyelinating polyneuropathy (CIDP) globally, and primary immune thrombocytopenia (ITP) in Japan.

- Delivered $1.13 billion in global product net sales in the third quarter of 2025, an increase of $554 million year-over-year and $178 million quarter-over-quarter, reflecting strong fundamentals and continued confidence from patients and prescribers.

- VYVGART SC prefilled syringe (PFS) for self-injection approved in Japan in September 2025; Canada decision on approval expected by end of 2025
- Supplemental Biologics License Application (sBLA) for VYVGART in three anti-acetylcholine receptor antibody negative (AChR-Ab seronegative) gMG subtypes (MuSK+, LRP4+, triple seronegative) on track for filing with U.S. Food and Drug Administration (FDA) by year-end 2025
- Pursuing label expansion through ongoing registrational studies:
  - Topline results expected in first half of 2026 for ocular MG (ADAPT OCULUS)
  - Topline results expected in the second half of 2026 for primary ITP (ADVANCE-NEXT)
- Expanded partnership with FUJIFILM to include new manufacturing site in North Carolina, strengthening global supply chain and supporting anticipated growth in efgartigimod and pipeline assets

Execute 10 registrational and 10 proof-of-concept studies across efgartigimod, empasiprubart and ARGX-119 to advance 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.

Efgartigimod Development

Efgartigimod is being studied in severe IgG-mediated autoimmune diseases, highlighting the broad potential of FcRn biology across several therapeutic areas including neurology, rheumatology and endocrinology.

- Registrational studies are currently ongoing in two rheumatology indications, including idiopathic inflammatory myopathies (IIM or myositis) 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 UNITY study (Sjögren's disease) expected in 2027
- Registrational study in Graves' disease (GD) to initiate in first half of 2026, expanding development in thyroid-driven autoimmunity, including ongoing registrational studies in thyroid eye disease (TED)
  - Topline results from UplighTED studies expected in second half of 2026
- Proof-of-concept studies ongoing in systemic sclerosis (SSc) and antibody mediated rejection (AMR)
- Topline Phase 2 data from lupus nephritis do not support advancing to registrational study

Empasiprubart Development

Empasiprubart, a first-in-class, monoclonal antibody that specifically binds to C2, is currently being evaluated in three indications, including multifocal motor neuropathy (MMN), CIDP and delayed graft function (DGF).

- Topline results from registrational EMPASSION study (MMN) expected in second half of 2026
- Registrational EMVIGORATE and EMNERGIZE studies ongoing (CIDP)
- Topline data from Phase 2 VARVARA study (DGF) expected around year-end 2025
- Stopped development of empasiprubart in DM due to operational challenges with enrollment of proof-of-concept EMPACIFIC study

ARGX-119 Development

ARGX-119, a first-in-class agonist antibody that targets muscle-specific kinase (MuSK), is now a registrational asset following positive proof-of-concept data in congenital myasthenic syndromes (CMS). ARGX-119 is also being evaluated in amyotrophic lateral sclerosis (ALS) and spinal muscular atrophy (SMA).

- CMS registrational study on track to start in 2026
- 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 by end of 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 study for ARGX-109 expected to complete by end of 2025; Phase 1 studies for ARGX-213 and ARGX-121 expected to complete in first half of 2026

THIRD QUARTER 2025 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 per share data)	**2025**	**2024**	**2025**	**2024**
Product net sales	$ 1,126,961	$ 572,997	$ 2,865,605	$ 1,448,915
Other operating income*	24,377	15,881	60,290	41,904
Total operating income	**$ 1,151,338**	**$ 588,878**	**$ 2,925,895**	**$ 1,490,819**
Cost of sales	$ (109,426)	$ (59,072)	$ (300,978)	$ (154,633)
Research and development expenses	(355,651)	(235,940)	(992,418)	(686,195)
Selling, general and administrative expenses	(336,291)	(277,698)	(937,441)	(769,392)
Loss from investment in a joint venture	(3,776)	(1,981)	(8,863)	(5,294)
Total operating expenses	**$ (805,144)**	**$ (574,691)**	**$ (2,239,700)**	**$ (1,615,514)**
Operating profit/(loss)	**$ 346,194**	**$ 14,187**	**$ 686,195**	**$ (124,695)**
Financial income	$ 42,700	$ 40,586	$ 118,217	$ 118,414
Financial expense	(993)	(676)	(3,254)	(1,760)
Exchange (losses)/gains	(1,848)	33,927	74,155	6,712
Profit/(loss) for the period before taxes	**$ 386,053**	**$ 88,024**	**$ 875,313**	**$ (1,329)**
Income tax (expense)/benefit	$ (41,795)	$ 3,386	$ (116,228)	$ 60,208
Profit for the period	**$ 344,258**	**$ 91,410**	**$ 759,085**	**$ 58,879**
Profit for the period attributable to:				
Owners of the parent	$ 344,258	$ 91,410	$ 759,085	$ 58,879

Weighted average number of shares used for basic profit per share	61,371,508	60,087,498	61,147,873	59,633,179
Basic profit per share (in $)	5.61	1.52	12.41	0.99
Weighted average number of shares used for diluted profit per share	66,441,326	65,636,686	65,944,952	65,024,955
Diluted profit per share (in $)	5.18	1.39	11.51	0.91

*Comparative figures have been presented to be consistent with the one adopted in the current period with respect to the combination of collaboration revenue and other operating income.

DETAILS OF THE FINANCIAL RESULTS

Total operating income for the three and nine months ended September 30, 2025 was $1.2 billion and $2.9 billion, respectively, compared to $0.6 billion and $1.5 billion, respectively, for the same periods in 2024, and mainly consisted of:

- **Product net sales** of VYVGART for the three and nine months ended September 30, 2025, were $1.1 billion and $2.9 billion, respectively, compared to $0.6 billion and $1.4 billion, respectively, for the same periods in 2024.

- **Other operating income** for the three and nine months ended September 30, 2025 was $24 million and $60 million, respectively, compared to $16 million and $42 million, respectively, for the same periods in 2024. The other operating income in these periods primarily related to research and development tax incentives and payroll tax rebates.

Total operating expenses for the three and nine months ended September 30, 2025 were $805 million and $2.2 billion, respectively, compared to $575 million and $1.6 billion, respectively, for the same periods in 2024, and mainly consisted of:

- **Cost of sales** for the three and nine months ended September 30, 2025 was $109 million and $301 million, respectively, compared to $59 million and $155 million, respectively, for the same periods in 2024. The cost of sales related to the sale of VYVGART.

- **Research and development expenses** for the three and nine months ended September 30, 2025 were $356 million and $992 million, respectively, compared to $236 million and $686 million, respectively, for the same periods in 2024. The research and development expenses mainly related to:

    - Advancing efgartigimod across multiple severe autoimmune indications, supporting ongoing registrational and expansion studies;
    - Progressing empasiprubart into multiple indications namely in MMN, DGF and CIDP;
    - Executing studies for ARGX-119 in rare neuromuscular diseases, including a registrational study in CMS and proof-of-concept studies in ALS and SMA; and
    - Early-stage discovery and preclinical programs to sustain long-term pipeline growth.

- **Selling, general and administrative expenses** for the three and nine months ended September 30, 2025 were $336 million and $937 million, respectively, compared to $278 million and $769 million, respectively, for the same periods in 2024. The selling, general and administrative expenses mainly related to professional and marketing fees linked to global commercialization of the VYVGART franchise, and personnel expenses.

Financial income for the three and nine months ended September 30, 2025 was $43 million and $118 million, respectively, compared to $41 million and $118 million, respectively, for the same periods in 2024.

Exchange losses/gains for the three and nine months ended September 30, 2025 were a $2 million loss and a $74 million gain, respectively, compared to $34 million and $7 million gains, respectively, for the same

periods in 2024. Exchange losses/gains were mainly attributable to unrealized exchange rate fluctuations on the cash, cash equivalents and current financial assets denominated in Euros.

Income tax for the three and nine month periods ended September 30, 2025 and 2024 is detailed below:

	Three Months Ended 30 September,		Nine Months Ended 30 September,	
(in millions of $)	**2025**	**2024**	**2025**	**2024**
Current tax expense	$ (52)	$ (13)	$ (122)	$ (29)
Deferred tax benefit	10	17	6	89
Income tax (expense)/benefit	**$ (42)**	**$ 3**	**$ (116)**	**$ 60**

Profit for the three and nine month periods ended September 30, 2025 was $344 million and $759 million, respectively, compared to $91 million and $59 million, respectively, for the same periods in 2024. On a per weighted average share basis, the basic earnings per share was $12.41 for the nine months ended September 30, 2025 compared to $0.99 for the nine months ended September 30, 2024.

Cash, cash equivalents and current financial assets[1] consisted of $2.6 billion in cash and cash equivalents and $1.7 billion in current financial assets which totals $4.3 billion as of September 30, 2025 compared to $1.5 billion in cash and cash equivalents and $1.9 billion in current financial assets which totals $3.4 billion as of December 31, 2024.

FINANCIAL GUIDANCE

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

REMAINING KEY DATES

- February 26, 2026: Full-year 2025 Financial Results and Fourth Quarter 2025 Business Update

CONFERENCE CALL DETAILS

The third quarter 2025 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

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.

For further information, please contact:

Media:

Ben Petok
bpetok@argenx.com

Investors:
Alexandra Roy
aroy@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 "advance," "aim," "ambition," "bring," "committed," "continue," "deliver," "execute," "expand," "expect," "generate," "goal," "improve," "position," "potential," and "pursue" and include, among other things, statements argenx makes concerning its intention to submit seronegative gMG sBLA by year-end and report ADAPT-OCULUS results in 1H26; its advancement of five registrational programs with readouts expected in 2026 from leading immunology pipeline; its goal to complete four Phase 1 molecules by year-end; its continued growth potential driven by strong patient demand for better outcomes, earlier use in the treatment paradigm, and its commitment to pursuing the broadest possible labels for its medicines; its aim to leverage the successful innovation playbook of MG and CIDP as it prepares for five registrational readouts next year; the positioning of its pipeline to expand into new indications and reach tens of thousands more patients; its advancement of its Vision 2030 strategic priorities, anchored in the ambition to treat 50,000 patients globally with its medicines, secure 10 labeled indications across approved medicines, and progress five pipeline candidates into Phase 3 development by 2030; the advancement of anticipated clinical development, data readouts and regulatory milestones and plans, including: (1) the PFS decision on approval expected in Canada by end of 2025, (2) the filing of the sBLA for VYVGART in three AChR-Ab seronegative gMG subtypes by year-end 2025, (3) its pursuit of label expansion through ongoing registrational studies, with topline results expected in first half of 2026 for ocular MG and second half of 2026 for primary ITP; (4) the topline results from ALKIVIA study expected in second half of 2026; (5) the topline results from UNITY study expected in 2027; (6) the registrational study in GD to initiate in first half of 2026, (7) the topline results from UplighTED studies expected in second half of 2026, (8) the topline results from registrational EMPASSION study (MMN) expected in second half of 2026, (9) the topline data from Phase 2 VARVARA study (DGF) expected around year-end 2025, (10) the expected ARGX-119 CMS registrational study start in 2026, (11) the topline results from the ARGX-119 Phase 2a proof-of-concept study expected in first half of 2026, (12) the expected ARGX-119 SMA proof-of-concept study start by end of 2025, (13) the expected completion of the Phase 1 study for ARGX-109 by end of 2025 and (14) the expected completion of the Phase 1 studies for ARGX-213 and ARGX-121 in first half of 2026; its generation of sustainable value through continued investment in Immunology Innovation Program; its commitment to improve the lives of people suffering from severe autoimmune diseases; its goal of translating immunology breakthroughs into a world-class portfolio of novel antibody-based medicines; its commercialization of the first approved neonatal Fc receptor (FcRn) blocker and evaluation of its broad potential in multiple serious autoimmune diseases; and its advancement of several earlier stage experimental medicines within its therapeutic franchises. 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.

Alternative Performance Measures Statement

In this document, argenx's financial results are provided in accordance with IFRS® Accounting Standards (IFRS) and using a non-IFRS financial measure, cash, cash equivalents and current financial assets.

This value should not be viewed as a substitute for the company's IFRS financial information and is provided as a complement to financial information provided in accordance with IFRS and should be read in conjunction with the most directly comparable IFRS financial information as set out below. Management believes this non-IFRS financial measure is useful for securities analysts, investors and other interested parties to gain a more complete understanding of the company's available financial liquidities given that the company's current financial assets are held in term accounts with an initial maturity of more than three months but less than twelve that may be used to meet its financial obligations. Such non-IFRS financial

information, as calculated herein, may not be comparable to similarly named measures used by other companies and should not be considered comparable to IFRS financial measures. Non-IFRS financial measures have limitations as an analytical tool and should not be considered in isolation from, or as a substitute for, an analysis of the company's financial results as reported under IFRS.

A reconciliation of the IFRS financial information to non-IFRS financial information is included below:

Cash, cash equivalents and current financial assets totaled $4.3 billion as of September 30, 2025, compared to $3.4 billion as of December 31, 2024. The balance as of the period ended September 30, 2025 consisted of $2.6 billion in cash and cash equivalents and $1.7 billion in current financial assets and the balance as of the period ended December 31, 2024 consisted of $1.5 billion in cash and cash equivalents and $1.9 billion in current financial assets.

---

[1] A non-IFRS Alternative Performance Measure (APM). Refer to the “Alternative Performance Measures Statement” below for a reconciliation to the IFRS financial information.