Press release
Regulated information

Consolidated Results 2025

Hyloris Achieves Strong Royalty Growth and Portfolio Expansion with Solid Cash Position: a year of bold moves and breakthrough milestones.

- **Royalty income** for the three products currently commercialized on the market increased by 15% year-on-year to €5.6 million, despite temporary Podofilox out-of-stock issues at year-end 2025 and an unfavorable U.S. dollar to euro exchange rate evolution.
- **Royalty growth** was primarily driven by a 98% increase in combined royalties from Maxigesic® IV and Sotalol IV.
- **Combined recurring revenues** (royalties and product sales) increased to €5.9 million compared to €4.9 million in 2024, supported by a first contribution of €0.2 million in product supply revenues from Tranexamic RTU.
- **Milestone income** reached €1.4 million, down 62% year-on-year, as 2024 included a non-recurring milestone related to the U.S. launch of Maxigesic® IV; excluding this one-off, the decline was limited to 14%.
- **Other operating income** remained stable at €1.6 million (+3% vs 2024).
- **Total Operating Income** amounted to €8.8 million, down 12% year-on-year, mainly reflecting lower non-recurring milestone revenue and adverse currency effects.
- **Six new product additions** were announced during 2025; Portfolio expanded to over 30 diversified assets by year-end 2025.
- **Sustained R&D progress** including multiple positive clinical trial results and multiple product approval submissions in preparation.
- **Eight new out-licensing agreements** and partnerships announced across international markets. Additional strategic partnerships discussions are progressing, including with respect to the out-licensing of the Company's cardiovascular portfolio in the U.S.
- **Solid equity position** of €26.5 million thanks to a contained net loss of €6,3 million, in line with the Company's expectations and reflecting disciplined cost management.
- **Cash position** of €13.8 million supporting the continued advancement of the Company's development portfolio and additional strategic growth opportunities.
- No financial debt.

Liège, Belgium – 26 March 2026 - 07:00 AM CET - Regulated information - Hyloris Pharmaceuticals SA ("Hyloris") (Euronext Brussels: HYL), the specialty biopharmaceutical company committed to addressing unmet medical needs through reinventing existing medications, today announces its financial results and operational progress for the year 2025.

"*Full-year 2025 marked one of the most active years in Hyloris' history in terms of portfolio expansion, partnerin' expg activity, and operational execution. In addition to advancing our existing programs, we broadened the scope of our pipeline with six new additions spanning orphan and rare disease opportunities as well as market categories with a larger patient population. We also continued to translate our development efforts into strategic partnerships across key territories, further reinforcing the long-term value potential of our portfolio and the strength of our business model. Overall, we remain confident that Hyloris is progressing well to deliver on its strategic and development objectives*," said Stijn Van Rompay, CEO of Hyloris.

Key Headlines – Revenues – Operating Income

Royalty income increased by 15% year-on-year to €5.6 million, despite temporary out-of-stock of Podofilox Gel at year-end 2025 and the adverse impact of the weaker U.S. dollar against the euro. This performance was notably driven by a 98% increase in combined royalties from the other two commercially available products, Maxigesic® IV and Sotalol IV.

In addition, 2025 marked the first contribution from product sales, amounting to €0.2 million from Tranexamic RTU. This reflects expanded commercialization efforts, with Hyloris supplying the product directly to its partner in addition to its traditional royalty-based model. As a result, combined recurring revenues (royalties and product sales) reached €5.9 million, representing a solid increase compared to 2024 (€4.9 million).

Milestone income totaled €1.4 million, representing a 62% decrease compared to 2024 which included a significant U.S. launch milestone for Maxigesic® IV of USD 2.1 million. Excluding this one-off item, the year-on-year decline would have been limited to 14%.

Other Operating Income, contributing to total Operating Income alongside the revenue streams, remained stable at €1.6 million (+3% compared to 2024).

Overall, despite higher recurring revenues, Operating Income amounted to €8.8 million (down 12% compared to 2024), primarily reflecting the lower contribution from non-recurring milestone revenue, as well as the adverse impact of the weaker U.S. dollar against the euro.

The Group reported a net loss of €6.3 million for the period (2024: €6.3 million), essentially unchanged year-on-year, demonstrating ongoing cost discipline despite continued investment in R&D and portfolio expansion.

Financial Highlights

(in € thousands)	2025	2024	Variance
Royalties	*5,649*	*4,901*	*15%*
Milestones	*1,353*	*3,557*	*(62%)*
Product sales	*205*	*-*	*N.A.*
Revenue	7,207	8,458	(15%)
Other operating income	1,626	1,584	3%
Operating income	**8,832**	**10,043**	**(12%)**
Operating expenses	**(15,641)**	**(17,173)**	**(9%)**
Operating profit (loss) / EBIT	**(6,808)**	**(7,130)**	**(5%)**
Financial income & expenses	101	788	(87%)
Income taxes	374	-	N.A.
Profit (loss) for the period	**(6,334)**	**(6,342)**	**(0%)**
Net cash flow from operating activities	**(6,994)**	**(6,903)**	**1%**
Net cash flow from investing activities	**(2,125)**	**259**	**(920%)**

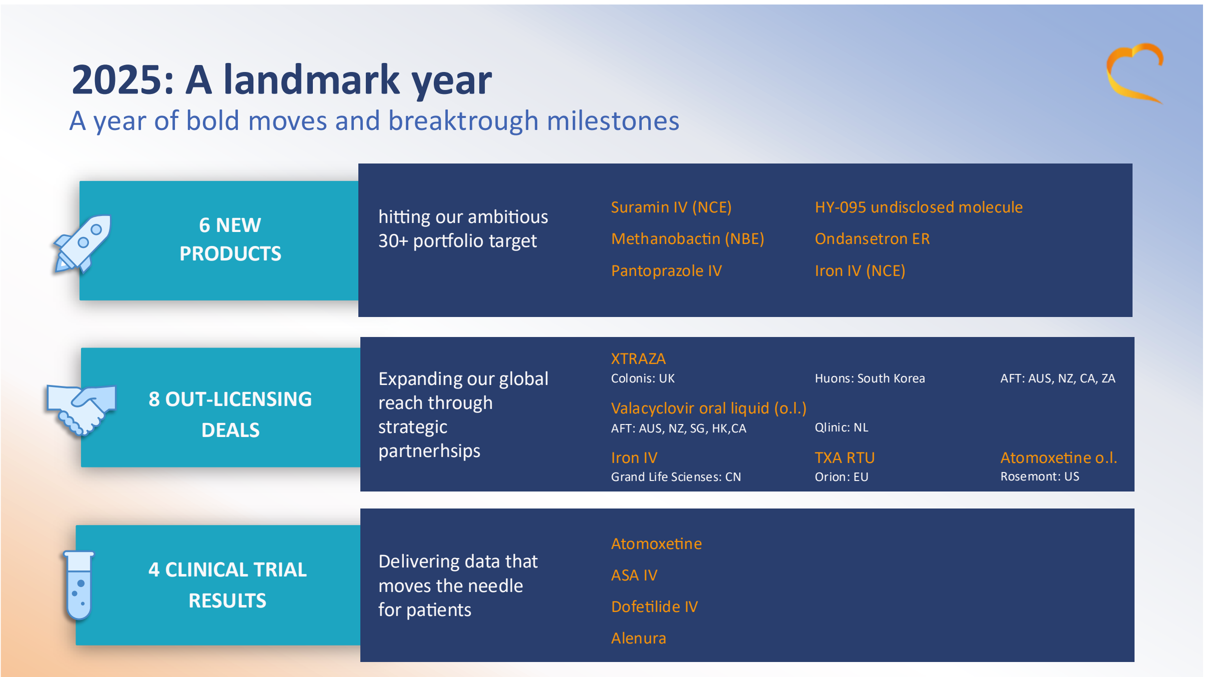
(in € thousands)	31 December 2025	31 December 2024	Variance
Equity	**26,475**	**32,143**	**(18%)**
Cash & cash equivalent	**13,775**	**23,594**	**(42%)**

Key Headlines – Product Portfolio

The portfolio expanded to more than 30 products and product candidates, in line with the Company's strategic objectives, including six newly announced additions. These new additions target both orphan and rare disease indications, as well as broader market opportunities such as iron deficiency and gastric ulcer-related conditions.

In 2025, Hyloris entered eight strategic licensing and partnering agreements across international markets involving later-stage assets. These included agreements related to Valacyclovir Oral Liquid and XTRAZA®, as well as an agreement with Orion for the commercialization of Tranexamic Acid RTU in key European markets, an agreement with Rosemont Pharmaceuticals for Atomoxetine Oral Liquid in the U.S., and an agreement with Grand Life Sciences Group, securing a partner in China for a therapy targeting the treatment of iron deficiency (HY-094).

Hyloris also reported three clinical study results during the year, for Dofetilide IV, Aspirin IV, and Atomoxetine Oral Liquid, as well as interim data for Alenura. The Company advanced multiple regulatory submissions, including the recent U.S. NDA submission for Atomoxetine Oral Liquid. The Group closed the period with an equity base of €26.5 million, a net loss of €6.3 million, and a cash position of €13.8 million to support ongoing R&D activities and continued strategic growth.



Product Overview, R&D Developments and Outlook

The progress achieved in 2025 further validated Hyloris' strategic direction and operational execution. By year-end, the Company reached its target of 30 diversified assets, including 28 publicly announced assets, reinforcing its platform for future growth.

Three commercialized products are accelerating growth

The Company's three commercialized products generated €5.6 million in royalties in 2025, reflecting continued market traction. Growth was led by Maxigesic® IV and Sotalol IV, with combined royalties nearly doubling year-on-year, partly offsetting a temporary Podofilox Gel stock-out and unfavorable currency effects.

The U.S. market continues to evolve amid ongoing policy and reimbursement changes, with several initiatives either implemented or under discussion that could affect the commercial environment for hospital-based and pharmaceutical products. Among these are developments related to the 340B Drug Pricing Program, a U.S. federal initiative requiring manufacturers to offer discounted outpatient drugs to eligible safety net providers, potentially influencing pricing dynamics and product economics. Hyloris and its partners continue to closely monitor these developments and proactively assess any potential implications for market opportunities and future product sales.

Maxigesic® IV

Maxigesic® IV is a novel, non-opioid intravenous formulation that combines paracetamol and ibuprofen for the treatment of mild to moderate acute pain. The product has been licensed to partners in over 100 countries, approved in more than 50, and launched across 30 markets worldwide.

The opioid crisis in the U.S. remains a major public health challenge, with chronic opioid use after surgery representing one of the most common post-operative complications[1]. In 2024, opioid overdoses claimed approximately 81,700 lives[2] and contributed to nearly USD 11 billion in hospital costs[3]. By offering effective, opioid-free pain relief, Maxigesic® IV represents an important alternative in this critical area of care.

Hyloris received milestone payments of approximately USD 2.1 million linked to the U.S. launch of Combogesic® IV[4] (the US brand name for Maxigesic® IV) in 2024, while few milestone payments were recorded in 2025.

In the U.S., market adoption is expected to accelerate following the assignment of a unique and permanent Healthcare Common Procedure Coding System (HCPCS) J-code by the Centers for Medicare & Medicaid Services (CMS) at the end of 2024. Hyloris remains conservative in its outlook, while its U.S. distribution partner plans to intensify commercial promotion from late Q2 2026.

In China, Maxigesic® IV has not yet been submitted for registration. The Chinese partner has issued notice under the current distribution agreement, and discussions with potential alternative partners are ongoing to ensure business continuity and support future development in the territory, should the termination become effective.

Additional patents for Maxigesic® IV were granted in 2025 with further strengthening the product's intellectual property protection in Europe.

[1] https://www.cdc.gov/overdose-prevention/about/index.html

[2] https://www.axios.com/2025/05/20/opioid-use-disorder-costs

[3] https://www.waldenu.edu/online-masters-programs/master-of-healthcare-administration/resource/opioid-crisis-the-strain-it-places-on-the-healthcare-system

[4] U.S. name for Maxigesic IV

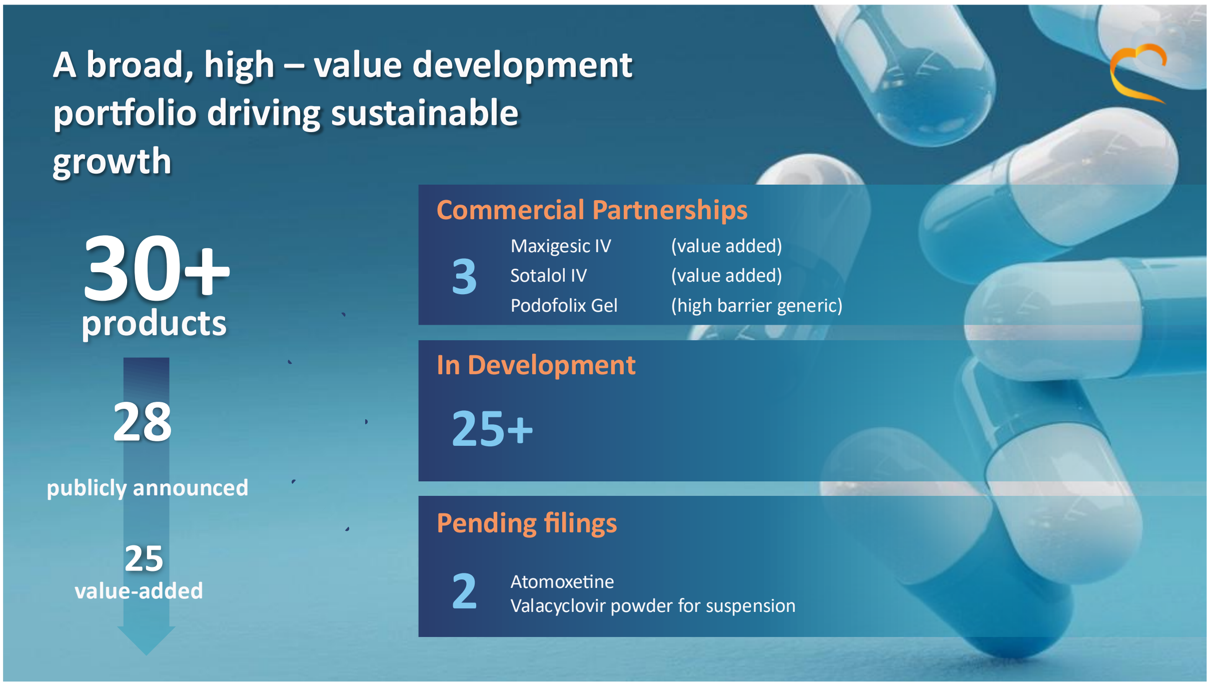
Sotalol IV

Sotalol IV is a patented intravenous formulation of sotalol, developed for the U.S. market to treat atrial fibrillation and life-threatening ventricular arrhythmias. It is designed to reduce the duration of hospital stays, lower overall healthcare costs, and improve outcomes for patients initiating sotalol therapy. Hyloris receives sales-based royalties and milestones from its commercialization partner.

Podofilox Gel

Podofilox Gel is indicated for the treatment of external genital and perianal warts caused by specific types of Human Papillomavirus (HPV), one of the most common sexually transmitted infections. In December 2023, Hyloris' U.S. partner received FDA approval for an abbreviated new drug application (ANDA) for Podofilox Gel, marking the first generic version of Condylox® Gel 0.5% approved in the United States.

Temporary finished product unavailability during the last three months of 2025 resulted in a negative contribution during that period. The product, which is produced in the U.S., is expected to be available by April 2026 enabling the partial recovery of previously missed sales.



Development Portfolio: Six additional Product Candidates in 2025

- In February 2025, Hyloris entered into a worldwide exclusive license agreement to develop a **ready-to-use (RTU) intravenous formulation of Pantoprazole**, designed to improve the current lyophilized (freeze-dried)[5] version that requires reconstitution. This RTU formulation is expected to simplify administration, shorten preparation time, and deliver greater efficiency

[5] Lyophilized (freeze-dried) formulations are dehydrated to improve stability and must be reconstituted with a liquid before use, adding preparation time and complexity.

and cost savings for healthcare professionals. Hyloris is targeting a launch by 2028 with the potential to capture a double-digit market share by volume. U.S. and international patent applications have been filed in 2025.
Pantoprazole is widely used to treat stomach ulcers and acid reflux. The global injectable (IV) Pantoprazole market was valued at USD 450 million in 2024, projected to grow at a 6.5% CAGR and reach USD 750 million by 2033[6]. Pantoprazole IV volumes increased to 395 million units[7], reflecting a compound annual growth rate (CAGR) of approximately 9.2%[8]. This sustained growth highlights the continued expansion of Pantoprazole IV utilization across markets. Since signing, Hyloris has identified a CMO and is preparing pilot and registration batch manufacturing, non-clinical and clinical activities**.** In addition, Hyloris has already signed a license agreement with Orion covering most European markets, supporting the future commercialization of the product.

- In February 2025, Hyloris entered into an exclusive license agreement for a **once-daily, extended-release, bimodal formulation of Ondansetron**, granting Hyloris worldwide rights outside North America. This product is designed to improve the management of nausea and vomiting associated with chemotherapy (CINV), radiation therapy (RINV), and post-operative recovery.

  This oral formulation combines immediate-release and extended-release components, providing prolonged symptom relief and supporting better patient adherence.

- In March 2025, Hyloris, in collaboration with AFT Pharmaceuticals (AFT), entered a co-development and licensing arrangement for a late-stage development program **to advance HY-094, an innovative new chemical entity based injectable therapy for iron deficiency and anemia**, for the global market.

  Iron deficiency remains a prevalent condition, affecting approximately 15% of the global population. The global market for intravenous iron therapies was valued at USD 3 billion in 2024 and is projected to exceed USD 7.41 billion by 2033[9]. While current IV iron therapies are effective, they often present tolerability issues, risk of side effects, and typically require multiple infusions, creating a significant treatment burden. HY-094 has completed Phase 2b trials, is designed to address these limitations and potentially offer a more patient-friendly option. Phase I and Phase II studies have shown that HY-094 is well tolerated, with reduced detection of iron in urine and serum compared to other IV iron therapies, suggesting lower toxicity. Its efficacy appears comparable to existing formulations while potentially requiring only a single injection. One or more Phase 3 clinical trials will be conducted to further evaluate its safety and effectiveness. Since signing, an exclusive license and distribution agreement has been entered into with Grand Life Sciences Group in China. Under this agreement, Grand Life Sciences Group will contribute to the global clinical development program and will commercialize the product in China. Patent applications were filed.

- In June 2025, Hyloris partnered with Kuvatris Therapeutics to **advance the development of Suramin IV for human African trypanosomiasis (HAT), commonly referred to as African**

[6] https://www.verifiedmarketreports.com/product/pantoprazole-sodium-for-injection-market/
[7] IQVIA, Q1 2025 data.
[8] IQVIA, Q1 2023-Q1 2025
[9] https://www.biospace.com/iron-drugs-market-size-to-worth-around-7-41-billion-by-2033

sleeping sickness. Suramin IV has been granted orphan drug designation by the U.S. FDA. The development has incurred delays following issues at the manufacturer impacting the timelines for the clinical Phase 3 study which will be conducted in Africa. If approved, the product would qualify for a Tropical Disease Priority Review Voucher (PRV), an established FDA program that incentivizes innovation in neglected diseases. Since PRVs are transferable and can be sold, this could represent a very meaningful financial opportunity[10] [11]. Under the agreement, Hyloris will provide USD 2 million in R&D funding as milestone-based payments (of which USD 0.8 million has been paid) and has already made a USD 1.6 million equity investment in return for sales-related royalties, just under 20% ownership of Kuvatris, and slightly over 50% of the net proceeds from the sales of the PRV.

- In December 2025, Hyloris announced an exclusive licensing agreement with South Korea–based ArborMed **to obtain the rights in Europe and Turkey for ArborMed's investigational, next-generation injectable Wilson's disease therapy** (ARBM-101), a novel copper chelator designed to address limitations of existing treatments. Wilson's disease is a rare inherited metabolic disorder that causes toxic copper accumulation, with EU prevalence commonly cited up to ~6 per 100,000 (≈31,000 individuals). ArborMed's candidate is positioned as highly copper-selective, with non-clinical data suggesting potential for intermittent dosing (weeks apart) rather than daily treatment. ArborMed plans to begin a first-in-human study in 2026 (healthy volunteers) and study in patients by 2027.

  Under the agreement, Hyloris paid a USD 2 million upfront license fee to support ArborMed's ongoing development and received exclusive commercialization rights (and the right to sub-license) across Europe and Turkey, with no additional upfront payments required. Depending on Hyloris' commercialization route, ArborMed would receive either a substantial share of future profits (if sub-licensed by Hyloris) or royalties plus sales milestones (if Hyloris commercializes directly). ArborMed also retains a contractual option to re-acquire the rights held by Hyloris prior to the initiation of Phase 3 clinical trials, provided that ArborMed secures a broader licensing or partnership transaction covering the U.S. and key European countries. If this option is exercised under the agreed terms, Hyloris will receive reimbursement of its upfront license fee and will remain entitled to ongoing payments, structured either as a significant minority share of profits generated in Europe and Turkey or as a low double digit percentage of global profits, with ArborMed having the ability to recoup certain agreed development and commercialization expenses, provided that a minimum level of profit participation remains payable to Hyloris at all times, including during any recoupment period.

- In December 2025, Hyloris announced an exclusive license option agreement with Wake Forest University School of Medicine for an innovative topical therapy targeting a rare genetic skin disorder. The agreement provides Hyloris with an exclusive option to obtain the license and global commercial rights following an exploratory clinical trial to be conducted by Wake Forest. The program targets a chronic, debilitating condition with significant unmet need and limited treatment options and is aligned with Hyloris' strategy of building a diversified pipeline of

[10] https://hyloris.com/wp-content/uploads/2025/06/PR-Hyloris_Kuvatris-Therapeutics_Partnership-EN.pdf
[11] https://www.biospace.com/business/priority-review-vouchers-by-the-numbers

value-added medicines through disciplined, staged business development. A patent application was filed.

R&D update and Outlook

Broad, innovative cardiovascular portfolio

UP TO 7 YEARS

Product	Route of Administration	Indication	Formulation / Clinical Development / Regulatory Filing and approval	Target Market
Sotalol IV	IV	Atrial Fibrillation	*Partnered in the US with AltaThera*	US
Aspirin IV	IV	Acute Coronary Syndrome		WW
Milrinone	ER oral solid	Heart Failure		WW
Dofetilide IV	IV	Atrial Fibrillation		US
HY-074	IV	Acute Coronary Syndrome		WW
Metolazone IV	IV	Congestive Heart Failure		WW
HY-75	Oral Liquid	Coronary Heart Disease		US

ER: Extended-Release
HF: Heart Failure
LVAD: battery-operated, mechanical surgically implanted pump, which helps the left ventricle of the heart pump blood

Other value-added portfolio

UP TO 7 YEARS

Product	Route of Administration	Indication	Formulation / Clinical Development / Regulatory Filing and approval	Target Market
Maxigesic® IV	IV	Post-operative pain	*Co-development with AFT Pharmaceuticals*	WW
Podofilox Gel	Topical	Ext. genital/perianal warts	*Partnered in the US with Padagis*	US
Tranexamic Acid	Oral Mouth Rinse	Specific dental indication		WW
Alenura™	Instillation	IC / PBS		WW
Miconazole-DB	Topical	rVVC/BV**		WW
Plecoid™ Agent	IV	AML/SCLC		WW
Atomoxetine	Oral Liquid	ADHD		WW
Valacyclovir	Oral Liquid	Viral infection		WW*
HY-083	Nasal spray	Idiopathic Rhinitis		WW
HY-088	Oral Liquid	Hypo Phosphatemia		WW
HY-090	Local-acting dose	Burning Mouth Syndrome		WW
HY-091	Topical	Vulvar Lichen Sclerosus		WW
HY-094	Injection	Iron Deficiency Anemia	*Co-development with AFT Pharmaceuticals*	WW
HY-095	Long-acting Injectable	Equine Gastric Ulcer Syndrome		WW
Pantoprazole	RTU Injection	GERD and EE		WW
Ondansetron	E.R. Tablet	Nausea/vomiting		WW ex. US MX and CA
Suramin IV	Injection	Human African Trypanosomiasis***		WW
HY-098	Topical	Rare, inherited skin disorder		WW
ARBM-0101	Injection	Wilson's disease		Europe and Turkey

Other than Podofilox Gel, our high barrier generic products, TXA RTU and Fusidic Acid Cream have not been included in the above overview.
ADHD: attention deficit hyperactivity disorder; Miconazole-DB: miconazole-domiphen bromide; rVVC: recurring vulvovaginal candidiasis; BV: Bacterial vaginosis
AML: Acute Myeloid Leukemia; SCLC: Small cell Lung Cancer
* US, major European markets, Canada, Mexico, Australia, China, South Korea and the GCC countries
** BV under investigation
*** Phase 2 trial done for another indication, autism spectrum disorder (ASD)

- Optimal commercialization strategy currently under evaluation
- Commercialised with partner
- Intended to be commercialised with partners

Continued progress in the Cardiovascular Portfolio

Hyloris' cardiovascular portfolio currently includes one commercialized product and six product candidates at various stages of development. Hyloris intends to commercialize these assets through partnerships with experienced local partners.

Significant progress was made across the cardiovascular portfolio during 2025, including:

- **Dofetilide IV**: The pivotal clinical trial was completed successfully, and a regulatory submission is expected in Q2 2026 in the U.S. A meeting with the FDA was held in February 2026, confirming the proposed regulatory strategy. Patent applications were filed, and additional U.S. patents have been granted.

  Dofetilide is used to help restore and maintain a normal heart rhythm in patients with certain types of irregular heartbeat including atrial fibrillation and atrial flutter and is currently only available as an oral capsule. Dofetilide IV is designed to shorten hospital stays and lower related risks and costs. The IV formulation may enable an initial dose to be administered directly into a patient's vein followed by oral treatment, thereby helping patients reach therapeutic drug levels faster and potentially reducing the multiple-day hospital stay that is currently required. In addition, the IV option could provide a treatment solution for patients who are too ill to take oral medication or who are unconscious.

- **Milrinone ER**: Following development of the product prototypes at a GMP manufacturing site, Hyloris initiated the first pilot PK study. Multiple dose strengths have been developed with the objective of achieving and maintaining target serum concentrations over a prolonged period, which will be evaluated in the planned study. A patent application was filed.

  Milrinone IV is currently used for short-term treatment of acute decompensated heart failure. Milrinone ER, a novel, twice-daily oral extended-release milrinone capsule is designed to provide long-term support and improve quality of life of patients suffering from chronic heart failure.

- **Metolazone IV:** Delays were incurred in 2025 with respect to the timing of the registration batches due to manufacturing complexities. The registration batches have now been initiated, and the clinical trial is currently being prepared, with completion of preparatory activities anticipated in 2026. An international patent application was filed in selected countries.

  Metolazone is currently available only as an oral tablet and is a diuretic used in patients with congestive heart failure, the fastest-growing cardiovascular condition globally and the leading cause of hospitalization. The IV formulation is expected to provide several benefits, including faster onset of action, the possibility of simultaneous administration with furosemide IV (the most widely used hospital diuretic), and improved drug absorption in patients with gastrointestinal edema. In addition, the IV formulation would enable treatment of patients who are too ill to take oral medication or who are unconscious.

- **Aspirin IV**: The pivotal study has been completed successfully. A meeting with the U.S. FDA is planned to discuss the proposed submission approach and also submissions in the EU are envisaged.

  Aspirin IV is an intravenous formulation of acetylsalicylic acid (aspirin) designed to prevent reinfarction in acute coronary syndrome (ACS), where rapid diagnosis and intervention are critical. IV administration provides faster onset of action and more convenient delivery, particularly for patients who are nauseous or unconscious

- **HY-074**: Registration batches have been produced by the selected CMO. A pivotal clinical trial is planned for 2026. An international patent application was rolled out in selected countries.

  HY-074 is an intravenous formulation of a current standard treatment that significantly reduces the risk of death in patients with acute coronary syndrome. HY-074 is designed to provide faster onset of action, more convenient administration - particularly for patients who are nauseous or unconscious - and improved dosage control. Additional indications outside the cardiovascular field are also being explored.

- **HY-075:** Although formulation work has been successfully completed, further development activities are currently paused pending the outcome of potential partnership discussions. A patent application was filed.

  HY-075 is an oral liquid formulation for the prevention and treatment of specific cardiovascular diseases. It is designed to simplify dosing, improve accuracy, and enhance patient compliance compared to existing oral solid forms, potentially leading to better outcomes.

Advances in other value-added product candidates

The non-cardiovascular value-added product pipeline currently includes 17 product candidates in various stages of development. All are intended to be commercialized through regional or global partners with proven market expertise.

In addition to the six new product candidates added to the pipeline in 2025, the following highlights reflect key progress achieved during the period for the other value-added product candidates:

- **Valacyclovir oral suspension:** Hyloris has submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA). A Complete Response Letter (CRL) was received following issues that got identified during an FDA inspection at the CDMO responsible for manufacturing the product. No issues were raised in relation to the product itself following the FDA's assessment. Hyloris is currently evaluating potential manufacturing solutions with the current CDMO, which is addressing the FDA observations, or alternative CDMOs. Each of these paths may result in a delay extending into 2027. In May, Hyloris signed exclusive commercialization agreements with AFT Pharmaceuticals for Canada, Australia, and New Zealand, and with QliniQ for the Netherlands. A regulatory approval procedure is currently ongoing in multiple European countries.

  Valacyclovir, an established antiviral indicated for the treatment of herpes virus infections, is currently only available in tablet form. Valacyclovir oral suspension is designed to treat infections such as shingles (herpes zoster) and chickenpox, particularly in patients who have difficulty swallowing tablets. With taste-masking technology and room-temperature stability, it offers a convenient, patient-friendly alternative to tablets and compounded suspensions, improving accessibility, dosing accuracy, and treatment adherence. U.S. patents have been granted.

- **Tranexamic Acid Oral Rinse (tradename XTRAZA®)**: A randomized, double-blind, multicentered, placebo-controlled Phase 3 trial is ongoing to evaluate the efficacy, safety, and tolerability of tranexamic acid oral rinse in preventing oral bleeding in anticoagulated patients undergoing tooth extraction. Approximately 280 patients across Europe and the U.S. will be enrolled, with results expected in 2026. Over 200 patients have been enrolled to date. Subject to positive outcomes, an FDA submission could follow shortly thereafter.

XTRAZA® is an easy-to-use oral rinse in development for administration to patients on anticoagulant therapy undergoing dental procedures. The active ingredient, Tranexamic Acid, is currently commercially available as an oral tablet and as an intravenous formulation and is indicated for the prevention of excessive bleeding. Hyloris has signed a series of exclusive licensing agreements for XTRAZA®, including with Colonis Pharma for the United Kingdom (January 2025), AFT Pharmaceuticals for Canada, Australia, New Zealand, South Korea, Singapore, and Hong Kong (May 2025), and Huons for South Korea (August 2025).

- **Alenura™**: is currently in Phase 2 clinical development, including a four-arm trial in the United States and Canada comparing Alenura to its individual components and placebo. Recruitment for this study is underway and expected to be completed in 2026. In parallel, a multi-dose study is ongoing to support an end-of-Phase 2 meeting.

  Alenura™ is a ready-to-use intravesical therapy in development for adults with interstitial cystitis/bladder pain syndrome (IC/BPS), targeting acute pain flares. It combines alkalinized lidocaine for immediate pain relief with heparin to support and potentially aid the regeneration of the bladder's protective mucous layer, providing both rapid and sustained symptom relief.

- **HY-083:** Hyloris is developing a proprietary intranasal spray formulation targeting idiopathic rhinitis, a condition with nasal symptoms similar to allergic rhinitis but without identifiable allergic or infectious triggers. The product is focussed on TRPV1[12] agonist candidates, and the program has advanced to the selection of promising new chemical entity (NCE) candidates. Multiple NCEs have been synthesized, with several showing strong potency in specialized laboratory assays. Pursuing an NCE offers opportunities for improved patent protection and enhanced value creation.
- **Miconazole Domiphen–Bromide cream**: Preparations are underway for an exploratory clinical trial to assess and confirm potential efficacy against bacterial strains such as Gardnerella. The development program between Hyloris and Purna Female Healthcare has been redefined, under which Hyloris has committed to fund the exploratory development of the bacterial diagnosis program. Positive findings could support further development of the product in a second vaginal infection indication beyond VVC.

  Miconazole DB cream is potentially a dual-action vaginal cream being developed to treat difficult-to-eradicate infections caused by *Candida* and bacterial strains such as *Gardnerella*. Initially focused on recurrent vulvovaginal candidiasis (rVVC), the program has been redefined to address both yeast and bacterial infections. By delivering medication directly to the vaginal mucosa, the cream aims to improve outcomes in patients with persistent or co-infections, as well as in those with alternating infections or unclear infection status.

[12] TRPV1 (Transient Receptor Potential Vanilloid 1) is a receptor found on sensory nerves, including those of the nose, that helps regulate pain, irritation, and inflammation. By targeting TRPV1, treatments may reduce these symptoms and improve comfort.

- **Atomoxetine Oral Liquid:** Following successful completion of the clinical trial for the U.S. market in the summer of 2025, the NDA was filed with the U.S. FDA early 2026 by Hyloris' commercial partner Rosemont Pharmaceuticals. In addition, patient participation in an additional clinical trial targeting the EU was completed in Q1 2026, and the study is expected to support future filings in other territories once results become available.

  Atomoxetine is a medication primarily used to treat attention deficit hyperactivity disorder (ADHD). Atomoxetine Oral Liquid is a taste-masked oral solution that enables precise weight-based dosing and easier titration, improving adherence and tolerability in children and adolescents. The first U.S. patent has been granted and others are pending.

- **PTX-252:** The selected compound is currently in early clinical development, with formulation completed and Phase 1 trial preparations underway. Significant delays were incurred in obtaining the required clinical trial authorization to initiate the study.

  Developed in collaboration with Pleco Therapeutics BV, PTX–252 (HY-086) is a new chemical entity (NCE) derived from an established pharmaceutical compound and designed as an adjunctive therapy to standard-of-care chemotherapy for Acute Myeloid Leukemia (AML), with exploratory development in Small Cell Lung Cancer (SCLC). It is believed to act as a chelating agent, potentially detoxifying the cancer-promoting microenvironment in the blood and bone marrow by reducing toxic metal levels, which have been associated with poorer survival in AML. In doing so, PTX-252 has the potential to enhance the effectiveness of chemotherapy and improve patient outcomes. Several patents were obtained in the past years.

- **HY-088** Registration batches have been successfully completed, and the first European regulatory filings are planned for late H1 2026.
  HY-088 is designed to treat hypophosphatemia, a condition caused by low phosphate levels in the blood. This standardized oral liquid enables consistent phosphate dosing and offers a safer, easier-to-administer alternative to compounded or non-standard treatments, improving both efficacy and patient compliance. Patent applications were filed.

  HY-090: Two promising pre-prototypes are advancing in development under an equal partnership with AFT Pharmaceuticals. The goal is to finalize a differentiated formulation that is eligible for patent protection and to move it forward into clinical validation, with global market potential.

  HY-090 is being developed for patients with burning mouth syndrome (BMS), a chronic condition causing persistent burning sensations in the mouth without an apparent cause. This novel, locally acting oral solution is designed to provide targeted, effective symptom relief, addressing a significant gap in care where no approved treatments currently exist.

- **HY-091:** Multiple formulation strategies have been explored and evaluated both in-house and with external technology partners. Development is being conducted through an equal partnership with AFT Pharmaceuticals.

  Vulvar Lichen Sclerosis (VLS) is a chronic inflammatory skin disease that predominantly affects the vulva and perianal regions in postmenopausal women. Hyloris is developing a novel, user-friendly, locally acting product candidate with a convenient application method to treat VLS. The product is designed topical to reduce inflammation, relieve itching and providing long-term symptom control.

- **HY-095**: Initial prototype testing on horses was completed in 2025. Further prototype testing is planned for 2026 to build on these early findings and support continued evaluation and progress of the program.

  HY-095 is a long-acting injectable proton pump inhibitor in development for the treatment of Equine Gastric Ulcer Syndrome (EGUS). This long-acting product can be weight-adjusted and could provide reliable, sustained drug delivery, thereby potentially shorten treatment duration and improve adherence compared with daily oral therapies. EGUS affects a large proportion of horses, including many high-performance races and sport horses, creating strong demand for effective and convenient treatments. With millions of horses in major markets such as the U.S., Europe, and Australia, HY-095 is well positioned to address this significant unmet need.

In addition to its strategic focus, Hyloris has two (high barrier) generic products in development, including Tranexamic Acid RTU:

- **Tranexamic Acid RTU:** In June, Avenacy, Hyloris' exclusive U.S. partner received FDA approval for its Abbreviated New Drug Application (ANDA) for an intravenous, ready-to-use (RTU) formulation of tranexamic acid (10 mg/ml in 100 ml vials). The U.S. launch is planned for the first half of 2026 under a profit-sharing agreement between Hyloris and Avenacy. In the fourth quarter of 2025, Hyloris signed a licensing and commercialization agreement with Orion Corporation covering key European markets, under which Orion will commercialize the product. The license agreement with a South Korean distributor has been terminated.
  Injectable tranexamic acid is currently approved to reduce or prevent bleeding in hemophilia patients undergoing tooth extraction and is also widely used as a versatile hemostatic agent in various clinical settings.

- **Fusidic acid**: Progress has been made on the development of Fusidic acid cream for the Canadian market. We currently anticipate that development activities will be completed by year-end 2026, supporting the next steps toward potential market entry.

Events after balance sheet date

- In January 2026, Hyloris announced an exclusive licensing and commercialization agreement with Orion for its ready-to-use intravenous pantoprazole covering 30 European countries (the EU, Norway, the UK, and Switzerland).
- Hyloris received a Complete Response Letter (CRL) from the U.S. FDA regarding the NDA submitted for its Valacyclovir oral liquid. The CRL relates to observations made during a recent FDA inspection of the Greek-based CDMO responsible for supplying the product, which was found to be in breach of certain U.S. regulatory requirements. No issues were raised concerning the product itself following the FDA's assessment. Hyloris is actively working on a manufacturing solution, which may include transferring production to an alternative supplier.

Human Resources & Governance

Hyloris employs approximately 55 people from 12 countries, reflecting a diverse and inclusive culture with an almost equal gender balance.

At the June 2025 General Assembly, the Board of Directors was partially renewed. Mr. Marc Foidart resigned from his position as independent director, while Mr. Vincent Van Dessel and Ms. Revital Rattenbach are now represented by their respective companies, Sybefica Invest SPRL and IRYL Partners SAS. Biofinance Consulting BV was newly appointed as an independent director for a three-year term, represented by Ms. Mélanie Mestdagt.

In August 2025, Hyloris welcomed Mrs. Ann De Jaeger as Chief Legal Officer and Secretary General of the Board of Directors.

In November 2025, Hyloris announced a governance update under which the Board of Directors appointed Stijn Van Rompay as Chief Executive Officer, following a broader review of the Company's governance and compliance framework. This review, supported by an external expert, confirmed that key governance foundations were already in place, while also leading to the further formalization and implementation of measures to strengthen internal controls, compliance policies, reporting structures, and Board oversight. These enhancements included, among others, reinforced approval flows for regulated communications and the creation of a formal Product Selection Committee.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS (in € thousands)	31 December 2025	31 December 2024
Non-Current assets	**13,398**	**11,628**
Intangible assets	5,689	3,838
Property, plant and equipment	225	340
Right-of-use assets	1,460	1,652
Equity accounted investees	2,543	2,748
Other financial assets	1,000	1,000
Trade and other receivables	2,480	2,050
Current assets	**19,959**	**29,708**
Inventories	52	-
Trade and other receivables	5,154	4,859
Other financial assets	492	556
Current tax assets	362	508
Prepayments	125	191
Cash and cash equivalents	13,775	23,594
TOTAL ASSETS	**33,357**	**41,335**

EQUITY AND LIABILITIES (in € thousands)	31 December 2025	31 December 2024
Equity	**26,475**	**32,143**
Share capital	140	140
Share premium	121,513	121,513
Retained earnings, excluding profit (loss) for the reporting period	(86,470)	(80,128)
Retained earnings, profit (loss) for the reporting period	(6,334)	(6,342)
Share based payment reserve	1,610	944
Cost of capital	(4,460)	(4,460)
Other reserves	476	476
Liabilities	**6,882**	**9,192**
Non-current liabilities	**1,748**	**2,030**
Borrowings	1,246	1,490
Other financial liabilities	87	68
Provisions	416	473
Current liabilities	**5,134**	**7,162**
Borrowings	364	326
Other financial liabilities	-	3,000
Provisions	75	408
Trade and other liabilities	4,695	3,428
TOTAL EQUITY AND LIABILITIES	**33,357**	**41,335**

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

(in € thousands)	2025	2024
Revenues	7,207	8,458
Other operating income	1,626	1,584
Operating income	**8,832**	**10,043**
Cost of sales	(379)	(227)
Research and development expenses	(11,281)	(10,265)
General and administrative expenses	(4,882)	(5,627)
Share of result of equity accounted investees, net of tax	(71)	(81)
Impairment/resersal of impairment on equity accounted investees	972	(972)
Operating expenses	**(15,641)**	**(17,173)**
Operating profit (loss) / EBIT	**(6,808)**	**(7,130)**
Financial income	840	1,165
Financial expenses	(739)	(378)
Profit (loss) before taxes	**(6,707)**	**(6,342)**
Income taxes	374	-
PROFIT (LOSS) FOR THE PERIOD	**(6,334)**	**(6,342)**
Other comprehensive income	-	-
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	**(6,334)**	**(6,342)**
Profit (loss) for the period attributable to owners of the company	(6,334)	(6,342)
Basic and diluted earnings (loss) per share (in €)	(0.23)	(0.23)

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

	Attributable to equity holders of the company						Total equity
	Share capital	Share premium	Other reserves			Retained earnings and result of the period	
(in € thousand))			Share based payment reserve	Cost of capital	Other reserves		
Balance at 31 December 2023	**140**	**121 513**	**2 162**	**(4 460)**	**476**	**(80 762)**	**39 069**
Share based payments			(584)				(584)
Transfer of SBP reserves to retained earnings			(633)			633	-
Total comprehensive income						(6 342)	(6 342)
Balance at 31 December 2024	**140**	**121 513**	**945**	**(4 460)**	**476**	**(86 471)**	**32 143**
Share based payments			666				666
Total comprehensive income						(6 334)	(6 334)
Balance at 31 December 2025	**140**	**121 513**	**1 610**	**(4 460)**	**476**	**(92 805)**	**26 475**

CONSOLIDATED STATEMENT OF CASH FLOWS

(in € thousands)	2025	2024
CASH FLOW FROM OPERATING ACTIVITIES		
Profit (loss) for the period	(6,334)	(6,342)
Adjustments to reconcile net loss to net cash provided by operating activities :		
Depreciation, amortization and impairments	919	648
Impairment/reversal of impairment on equity accounted investees	(972)	972
Provisions	(390)	581
Share based payment expense	665	(584)
Interests received/paid	(306)	(788)
Share of profit of equity accounted investees, net of tax	71	81
Unrealized exchange loss/gain and other non-cash financial result	(211)	
Other non-cash adjustments	255	-
Bank fees paid	-	(56)
Changes in working capital :		
Inventories	(52)	-
Trade and other receivables	(289)	(1,881)
Prepayments	66	403
Trade and other liabilities	(416)	140
Cash generated from operations	**(6,994)**	**(6,826)**
Interest paid	-	(77)
Net cash generated from operating activities	**(6,994)**	**(6,903)**
CASH FLOW FROM INVESTING ACTIVITIES		
Interest received	399	556
Purchases of property, plant and equipment	(4)	(29)
Purchases of intangible assets	(625)	(268)
Investment in Equity accounted investees	(1,895)	-
Net cash provided by (used in) investing activities	**(2,125)**	**259**
CASH FLOW FROM FINANCING ACTIVITIES		
Reimbursements of borrowings and other financial liabilities	-	(40)
Proceeds from borrowings and other financial liabilities	-	139
Reimbursements of lease liabilities	(339)	(267)
Interests paid on lease liabilities	(92)	-
Net cash provided by (used in) financing activities	**(431)**	**(168)**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(9,550)**	**(6,812)**
CASH AND CASH EQUIVALENTS at beginning of the period	**23,594**	**30,406**
Net effect of currency translation on cash and cash equivalents	(270)	
CASH AND CASH EQUIVALENTS at end of the period, calculated	**13,775**	**23,594**

Income statement

Operating income amounted to €8,832 thousand in 2025, compared to €10,043 thousand in 2024, primarily reflecting a lower contribution from non-recurring milestone income, partly offset by robust growth in royalty revenues.

Total revenues decreased to €7,207 thousand (2024: €8,458 thousand), mainly due to lower milestone income, while royalty revenues increased to €5,649 thousand (2024: €4,901 thousand), driven by strong performance of Sotalol IV and Maxigesic® IV. The Company also recognized its first product sales (€205 thousand) from Tranexamic Acid RTU during the period.

Other operating income remained broadly stable at €1,626 thousand (2024: €1,584 thousand), reflecting a combination of grants, tax credits, and other operational items.

Research and development expenses increased to €11,281 thousand (2024: €10,265 thousand), mainly due to higher employee-related costs following headcount expansion and continued investment in the development pipeline. General and administrative expenses decreased to €4,882 thousand (2024: €5,627 thousand), reflecting significantly lower legal and investigation-related costs.

The Group recognized a net reversal of impairment losses on financial assets of €972 thousand (2024: impairment of €972 thousand), related to its investment in FHP. This adjustment resulted from a reassessment of the underlying development strategy, following the amendment of the program from recurrent vulvovaginal candidiasis (rVVC) to a broader indication encompassing bacterial vaginosis (BV) and acute VVC (aVVC), which led to improved expected future economic benefits.

Financial income decreased to €840 thousand (2024: €1,165 thousand), reflecting reduced interest income, while financial expenses increased to €739 thousand (2024: €378 thousand), mainly due to adverse foreign exchange effects linked to the weakening of the U.S. dollar against the euro.

The Group reported a net loss of €6,334 thousand for the period (2024: €6,342 thousand), remaining broadly stable year-on-year and reflecting continued cost discipline despite sustained investment in R&D and portfolio growth.

Statement of financial position

Equity amounted to €26,475 thousand as of December 31, 2025, compared to €32,143 thousand as of December 31, 2024, primarily reflecting the net loss for the period.

The Group maintained a solid financial structure with no financial debt.

Cash and cash equivalents totaled €13,775 thousand as of December 31, 2025 (2024: €23,594 thousand), supporting the continued advancement of the Company's development portfolio and additional strategic growth opportunities.

Cash flow statement

Net cash flow from operating activities amounted to -€6,994 thousand in 2025, remaining broadly stable compared to 2024 (-€6,903 thousand). Net cash flow from investing activities totaled -€2,125 thousand in 2025, mainly reflecting the equity investment in Kuvatris Therapeutics Inc. In 2024, positive cash flow from investing activities primarily reflected interest income.

Comparability of financial statements

The presentation of the comparative figures for financial year 2024 has been adjusted compared to previous publication in order to reclassify an amount of €300 thousand as a 'non-current provision' instead of as a 'non-current other financial liability' as it better corresponds to the underlying characteristics of it. This is then comparable with presentation retained in 2025, knowing that this amount refers to a probable cash outflow which will be triggered by an event expected to occur by the end of 2026 (and likely to be paid the following year).

External Audit

The statutory auditor has confirmed that, to date, no material misstatements have been identified in the financial information included in this press release, with audit procedures for the year ended 31 December 2025 being still ongoing. The audit opinion will include one qualification relating to the comparability of the 'Other operating income' section, which originates from a cut-off error between financial 2023 and 2024 identified by the predecessor auditor.

Financial Calendar

April 30, 2026	**2025 Annual Report**
June 9, 2026	**Annual General Meeting of Shareholders**
September 24, 2026	**Half-Year Results 2026**

For more information, please visit www.hyloris.com and follow us on LinkedIn.

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