Consolidated 2025 Half-Year Results and Outlook:

# Hyloris Achieves Strong Royalty Growth and Portfolio Expansion with Solid Cash Position

- Operating income of €3.8 million, down 18% versus H1 2024, reflecting the very limited (non-recurring) milestone revenue.
- Royalties up nearly 30% year-on-year to €2.9 million across the three commercialized products.
- Portfolio expanded to 26 products and candidates with four new additions; on track to reach 30 diversified assets by year-end.
- Sustained R&D progress with several positive study results and multiple product approval submissions in preparation.
- Multiple new licensing agreements and partnerships signed across international markets.
- Additional strategic partnerships expected in the coming months, with significant out-licensing milestones anticipated; continued progress on defining the U.S. cardiovascular commercialization strategy.
- Solid equity position of €28.9 million with a contained net loss of €3.5 million.
- Cash position of €18.6 million provides solid funding for R&D and strategic growth.

**Liège, Belgium - 25 September 2025 - 07:00 CET - Regulated information - Inside 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 first half of 2025.

Hyloris reported operating income of €3.8 million for the first half of 2025, down 18% compared to the same period in 2024, reflecting the very limited milestone revenue and the weakening of the USD against the EUR in H1 2025. Royalties from its three commercialized products rose nearly 30% to €2.9 million, underscoring the growth of recurring income. The portfolio expanded to 26 products and candidates with four new additions, keeping the Group on track to reach its target of 30 diversified assets by year-end. At the same time, Hyloris sustained strong R&D momentum, reporting several positive study results and regulatory submissions underway. The Company also signed multiple strategic licensing agreements and partnerships across international markets, with additional transactions expected in the coming months, and continued to define its U.S. cardiovascular commercialization strategy. The Group ended the period with a solid equity base of €28.9 million, a contained net loss of €3.5 million, and a cash position of €18.6 million to support ongoing R&D and strategic growth.

*"The first half of 2025 has been rich in promising developments that reconfirm the strength of our pipeline and business model. Our portfolio continues to expand and diversify, and this momentum is not an endpoint but part of a broader growth trajectory. At the same time, we are advancing important clinical and regulatory milestones, including recent FDA approval of our intravenous Tranexamic Acid and encouraging results for intravenous Dofetilide in heart rhythm management and Atomoxetine liquid for attention deficit disorder. Together, these highlight our ability to bring forward treatments that*

*address clear unmet medical needs while building sustainable growth,"* **said Stijn Van Rompay, co-CEO of Hyloris.**

*"Commercialization of our three marketed products is progressing well and in line with expectations. At the same time, we are strengthening our governance and forging new strategic partnerships in key regions, including for late-stage assets such as Valacyclovir oral suspension, for the treatment of herpes virus infections, and XTRAZA®, an oral rinse developed for patients on anticoagulant therapy undergoing dental procedures,"* **adds Thomas Jacobsen, co-CEO of Hyloris**.

## PRODUCT OVERVIEW, DEVELOPMENTS, AND OUTLOOK

The progress achieved in the first six months of 2025 strengthens the foundation for Hyloris' ambition to build a portfolio of 30 diversified assets by year-end and prepare for future growth opportunities.

### THREE COMMERCIALIZED PRODUCTS ACCELERATING GROWTH

Revenue from our first three commercialized products, still in the early stage of their launch, continues to build momentum, generating €2.9 million in royalties in the first half of 2025, which represents a 30% increase versus H1 2024. Growth was driven primarily by Maxigesic® IV and Sotalol IV, which are progressing strongly despite some impact from adverse USD exchange rate movements.

**Maxigesic® IV**

Maxigesic® IV is a novel, non-opioid intravenous formulation that combines paracetamol and ibuprofen to treat mild to moderate acute pain. It has been licensed to partners in over 100 countries, approved in over 50 and launched in over 30 markets.

The opioid crisis in the U.S. is a critical healthcare issue, with chronic opioid use after surgery being one of the most common post-operative complications[1]. In 2024, opioid overdoses claimed roughly 81,700 lives[2] and drove nearly USD 11 billion in hospital costs[3]. By offering effective pain relief without opioids, Maxigesic® IV provides a much-needed alternative in this critical area of care.

Hyloris received milestone payments of approximately USD 2.1 million tied to the U.S. launch of Combogesic® IV[4] in the first half of 2024, while no milestone payments were recorded in the first half of 2025. Sales related milestone payments will only commence once cumulative sales exceed the contractual threshold, which has not yet been reached in 2025. In the U.S., adoption is expected to accelerate following the assignment of a unique and permanent Healthcare Common

[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

Procedure Coding System (HCPCS) J-code by the Centers for Medicare & Medicaid Services (CMS) at the end of 2024.

In China, Maxigesic® IV has not yet been registered or launched, but the current distribution partner has indicated its intention to terminate the licensing agreement. While the termination has yet to be formalized, alternatives are already being assessed in anticipation of appointing a new partner to ensure continued progress in the Chinese market.

**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 from its commercialization partner.

**Podofilox Gel**

Podofilox Gel is indicated for the treatment of external genital and perianal warts caused by certain types of Human Papilloma Virus (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.

## DEVELOPMENT PORTFOLIO: FOUR ADDITIONAL PRODUCT CANDIDATES IN H1 2025

- In February 2025, Hyloris entered into a worldwide exclusive licensing 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 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.
  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.

[5] Lyophilized (freeze-dried) formulations are dehydrated to improve stability and must be reconstituted with a liquid before use, adding preparation time and complexity.
[6] https://www.verifiedmarketreports.com/product/pantoprazole-sodium-for-injection-market/
[7] IQVIA, Q1 2025 data.
[8] IQVIA, Q1 2023-Q1 2025

- In February 2025, Hyloris entered into an exclusive licensing 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. Hyloris will build on available clinical data and targets a commercial launch by 2028.

- In March 2025, Hyloris, in collaboration with AFT Pharmaceuticals (AFT), **licensed 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.

- 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 sleeping sickness. Suramin IV is currently in Phase 3 clinical development and has been granted orphan drug designation by the U.S. FDA. 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]. Under the agreement, Hyloris will provide USD 2 million in R&D funding as milestone-based payments going forward 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 sale of the PRV.

[9] https://www.biospace.com/iron-drugs-market-size-to-worth-around-7-41-billion-by-2033

[10] https://hyloris.com/wp-content/uploads/2025/06/PR-Hyloris_Kuvatris-Therapeutics_Partnership-EN.pdf

## R&D UPDATE & OUTLOOK

### ADVANCES IN THE CARDIOVASCULAR PORTFOLIO

Hyloris' cardiovascular development portfolio currently includes six product candidates at various stages of development. Hyloris is currently evaluating the most effective route to commercialization for its cardiovascular products, which may include self-commercialization, joint ventures, licensing agreements, or other strategic partnerships.

Significant progress was made during the first half of the year, including:

- **Dofetilide IV**: The pivotal clinical trial has been completed successfully and preparations for a regulatory submission in the U.S. are ongoing.

  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 could allow an initial dose to be administered directly into a patient's vein followed by oral treatment, helping them reach therapeutic drug level faster and potentially leave the hospital sooner than the multiple day 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 the development of the product prototypes at a GMP manufacturing site, Hyloris expects to initiate the first Phase 1 study before year-end.

  Milrinone IV is currently used for short-term treatment of severe heart failure or low cardiac output. Milrinone ER, a novel, twice-daily oral extended-release milrinone capsule developed for patients with left ventricular assist devices (LVADs), designed to maintain steady and predictable blood levels, enable long-term use at home, improve convenience and adherence, and avoid complications associated with intravenous administration.

- **Metolazone IV:** Final registration batches have been initiated, and the clinical trial is currently in preparation, with completion anticipated in 2026.

  Metolazone is currently available only as an oral tablet and is 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 oedema. In addition, the IV formulation would enable treatment of patients who are too ill to take oral medication or who are unconscious.

- **Aspirin IV**: A new pivotal study to support the preparation of a U.S. regulatory submission has been conducted, and bioanalysis is currently underway, with topline results expected later in 2025. If the study is successful, Hyloris will proceed with regulatory submission.

  Aspirin IV is an intravenous formulation of acetylsalicylic acid (aspirin) designed for the treatment of 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**: Trial batches have been produced by the selected CMO, with formulation and process optimization now complete. Clinical batches are expected in the fourth quarter of 2025, and, pending positive results, a pivotal clinical trial is planned for 2026.

  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, the product is currently on hold to prioritize partnership discussions before moving to the next development steps.

  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 WITHIN OTHER VALUE-ADDED PRODUCT CANDIDATES

The non-cardiovascular value-added product pipeline currently includes 15 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 four new product candidates added to the pipeline in H1 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), with a PDUFA[11] date in October 2025. In May, Hyloris signed exclusive commercialization agreements with AFT Pharmaceuticals for Canada, Australia, and New Zealand, and with QliniQ for the Netherlands.

  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.

- **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

[11] The target action date set by the U.S. Food and Drug Administration (FDA) under the *Prescription Drug User Fee Act (PDUFA)*, by which the FDA aims to complete its review of a new drug application.

United States will be enrolled, with results expected in 2026. Subject to positive outcomes, an FDA submission could follow shortly thereafter.

Tranexamic Acid, currently available as an oral tablet and as an intravenous formulation, is indicated for the prevention of excessive bleeding. XTRAZA® is an easy-to-use oral rinse in development for administration to patients on anticoagulant therapy undergoing dental procedures. 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, which is also anticipated in 2026. Pending positive results, the program will advance into Phase 3 to support regulatory approval.

  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 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 based on TRPV1[12] agonists, and the program has advanced to focus on 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 additional patent protection and enhanced value creation.

- **Miconazole Domiphen–Bromide cream:** Preparations are underway for an exploratory clinical trial to confirm potential efficacy against bacterial strains such as *Gardnerella*.

  Miconazole DB cream is a dual-action vaginal cream 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, including biofilm-related cases. By delivering medication directly to the vaginal mucosa, the cream aims to improve outcomes in patients with persistent, recurrent, 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 in the summer of 2025, the NDA for the U.S. FDA is expected to be filed shortly, while an additional trial planned for H2 2025 will enable filings in other territories.
  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.

- **PTX-252:** The compound is currently in early clinical development, with formulation completed and Phase 1 trial preparations underway. Developed in collaboration with Pleco Therapeutics BV, HY-086 (PTX-252) 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.

- **HY-088** Registration batches have been successfully completed, and the first European regulatory filings are planned for 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.

- **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 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, leading to the selection of two pre-prototypes now advancing in development to assess tolerability and performance. Development is being conducted through an equal partnership with AFT Pharmaceuticals.
  Vulvar Lichen Sclerosus (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 as an extended-release mucoadhesive film to reduce inflammation, relieve itching, and prevent progression of skin changes, providing long-term symptom control.

- **HY-095**: First prototype testing in horses is planned for Q4 2025.
  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 shortening treatment duration and improving adherence compared with daily oral therapies. EGUS affects a large proportion of horses, including many high-performance race 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.

**Finally**, in addition to its main 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 second half of 2025 under a profit-sharing agreement between Hyloris and Avenacy.
  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.

## POST-CLOSING EVENTS

- **Atomoxetine Oral Solution:** In July, Hyloris reported positive results from a pivotal clinical study of its proprietary, patent-pending liquid formulation of atomoxetine, developed as a precise and titratable alternative to Strattera® capsules for ADHD patients who struggle with swallowing or require flexible dosing. The study showed comparable bioavailability to Strattera® under fasting conditions, with no impact from food intake.

- **XTRAZA™:** in August, an exclusive license and supply agreement for XTRAZA in South Korea was signed with Huons Co., Ltd.

## HUMAN RESOURCES AND GOVERNANCE

Hyloris employs over 50 people from 15 countries, reflecting a diverse and inclusive culture with an almost equal gender balance.

At the June General Assembly meeting, 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 now represent 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, Hyloris welcomed Mrs. Ann De Jaeger as Chief Legal Officer and Secretary General of the Board of Directors.

Moreover, several governance initiatives are already in place and will be further formalized and strengthened going forward.

## FINANCIAL HIGHLIGHTS

| (in € thousands) | 30 June 2025 | 30 June 2024 | Variance in % |
|---|---|---|---|
| Revenue | 3,018 | 4,153 | (27%) |
| Other operating income | 765 | 487 | 57% |
| **Operating income** | **3,784** | **4,640** | **(18%)** |
| Cost of sales | (128) | (108) | 18% |
| Research and development expenses | (4,975) | (5,313) | (6%) |
| General and administrative expenses | (2,203) | (3,150) | (30%) |
| Other operating expenses | (12) | (45) | (74%) |
| **Operating expenses** | **(7,318)** | **(8,616)** | **(15%)** |
| **Operating profit (loss) / EBIT** | **(3,534)** | **(3,976)** | **(11%)** |
| Financial income & expenses | (183) | 491 | (137%) |
| Income taxes | 162 | - | N.A. |
| **Profit (loss) for the period** | **(3,555)** | **(3,486)** | **2%** |
| | | | |
| **Net cash flow from operating activities** | **(3,341)** | **(3,353)** | **(0%)** |
| **Net cash flow from investing activities** | **(1,313)** | **386** | **(440%)** |

| (in € thousands) | 30 June 2025 | 31 December 2024 | Variance in % |
|---|---|---|---|
| **Equity** | **28,889** | **32,143** | **(10%)** |
| **Cash & cash equivalent** | **18,615** | **23,594** | **(21%)** |

### Operating income

In the first half of 2025, total revenue and other operating income declined by 18% to €3,784 thousand compared to the same period in 2024. This decrease is solely attributable to the very limited milestone revenue, as both royalties and other operating income were substantially higher

than in the prior period. Further details on revenue and other operating income can be found in the notes to the half-year report.

## Results

R&D expenses were 6% lower than last year, while R&D activity remained strong and several positive study results were achieved.

General and administrative expenses amounted to €2,203 thousand, down 30% compared to €3,150 thousand in 2024, mainly due to much lower legal and investigation fees partly compensated by higher employee benefits and share based payment expenses.

Further details on the operating expenses can be found in the notes to the half-year report

Net financial income and expenses for the first half of 2025 amounted to €-183 thousand, compared with €491 thousand for the same period of 2024. The decline mainly reflects lower interest income from cash placements due to reduced interest rates in 2025, as well as foreign exchange losses following the weakening of the USD against the EUR in H1 2025. These FX losses - €-469 thousand in 2025, compared with €124 thousand in FX gains in 2024 - arose from the adverse impact of USD depreciation against the EUR on the valuation of USD-denominated assets, as well as on USD royalties collected and recognized during the period.

Net losses remained stable at €3,555 thousand, reflecting continued cost discipline, while R&D activities advanced steadily.

## Equity, cash position and cash flow

Hyloris' Equity remains solid at €28,889 thousand as of June 30, 2025, down from €32,143 thousand as of December 31, 2024, reflecting a well-contained net loss of €3,555 thousand for the period.

Hyloris maintains a sufficient cash position, with cash and cash equivalents totaling €18,615 thousand as of June 30, 2025, compared to €23,594 thousand as of December 31, 2024, providing solid funding for R&D and strategic growth.

Net cash flow from operating activities amounted to -€3,341 thousand in the first half of 2025, stable compared to same period last year (-€3,353 thousand). Net cash flow from investing activities amounted to -€1,313 thousand in the first half of 2025, mainly reflecting the equity investment made in Kuvatris Therapeutics Inc., net of interest income from cash placements. In 2024, cash flow from investing activities mainly consisted of interest income.

It is the Company's preference to out-license its cardiovascular assets for U.S. distribution That said, should additional financing be required - in case of limitations to out-licensing, to advance ongoing or new developments, accelerate onboarding of new assets , or pursue other opportunities - the Company believes it has access to financial and strategic partners willing to provide support.

## AUDIT REPORT

The auditor, BDO Réviseurs d'Entreprises SRL, represented by Christophe Pelzer, has completed their review procedures and has issued a qualified opinion which is fully reproduced in the condensed financial statements i. The qualifications included are a follow-up of the qualifications raised by the predecessor auditor. The Group's half-year financial report can be found at www.hyloris.com in the "Events and Presentations" section within the section dedicated to Investors.

## FINANCIAL CALENDAR

| | |
|---|---|
| March 26, 2026 | **2025 Annual Results** |
| April 30, 2026 | **2025 Annual Report** |
| June 9, 2026 | **Annual General Meeting of Shareholders** |
| September 24, 2026 | **Half-Year Results 2026** |

**About Hyloris Pharmaceuticals SA**

Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimizing existing medications to address important healthcare needs and deliver relevant improvements for patients, healthcare professionals and payors. The Company's development strategy primarily focuses on leveraging established regulatory pathways, such as the FDA's 505(b)2 pathway in the U.S or equivalent regulatory frameworks in other regions which are specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This approach can reduce the clinical burden required for market entry, and significantly shorten the development timelines, leading to reduced costs and risks. Hyloris has built a broad development portfolio of 26 products, including 23 reformulated and/or repurposed value-added medicines that have the potential to offer significant advantages over existing alternatives. Two products are currently in early phases of commercialization in collaboration with commercial partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. In addition to its core strategic focus, the Company has 2 high barrier generic products approved in the U.S. and 1 high barrier generic product in development.

Hyloris is based in Liège, Belgium, and listed on Euronext Brussels (Euronext: HYL). For more information, visit www.hyloris.com and follow us on LinkedIn.

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**Disclaimer and forward-looking statements**

Hyloris means "high yield, low risk," which refers to the 505(b)(2) regulatory pathway for product approval on which the Company is focused, but does not relate to or apply in any way to an investment in the Shares.

Certain statements in this press release are "forward-looking statements." These forward-looking statements can be identified by the use of forward-looking terminology, including the words "believe," "estimate," "anticipate," "expect," "intend," "may," "plan," "continue," "ongoing," "potential," "predict," "project," "target," "seek," or "must," and include statements by the company regarding the expected results of its strategy. These statements relate to future events or the Company's future financial performance and involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Company's control, that may cause the actual results, levels of activity, performance, or achievements of the company or its industry differ materially from those expressed or implied in the forward-looking statements. The Company does not undertake to publicly update or revise any forward-looking statements, except as required by law.