Hyloris Pharmaceuticals Reports 2024 Results and Provides Business Outlook

- Total revenue and Other operating income increased to over €10 million (+138%), fueled by an increase in royalties and milestones (+305%), with cost of sales of €0.2 million
- Net losses decreased to a historical post IPO low of €6.3 million (-59%)
- Strong R&D progress, including acceptance of NDA submission for Valacyclovir Oral Suspension and a successful Dofetilide IV pivotal clinical trial
- On track to reach 30 product (candidate)s in 2025[1]
- Up to 9 product submissions expected by or before the end of 2026
- Maxigesic® IV launched in the U.S. and obtained a reimbursement code from CMS
- Analyzing different go-to-market strategies for commercial launch in the U.S. for the cardio portfolio products
- Multiple out licensing deals signed
- Strong Equity at €32.1 million
- Cash position of €23.6 million

Liège, Belgium – 20 March 2024 – 06 PM CET - Regulated information – Inside information - Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces its annual financial results for the period ending 31 December 2024, along with recent achievements and a business outlook.

Stijn Van Rompay and Thomas Jacobsen, Co-Chief Executive Officers of Hyloris, commented:

"We continue to build strong momentum in our product development and commercialization efforts. We have expanded our pipeline with four new product candidates - two in 2024 and two more in early 2025 - reinforcing our commitment to addressing unmet medical needs. Notably, we submitted the NDA for Valacyclovir Oral Suspension in the U.S., a significant milestone in our portfolio's progression.

In parallel, we successfully executed multiple out-licensing agreements, including a key deal with Rosemont Pharmaceuticals for Valacyclovir Oral Suspension in the U.S. These partnerships validate our strategy of developing differentiated medicines and expanding patient access through strategic collaborations.

While sales remain in the early stages, they continue to grow, driven by our first three marketed products. With a robust pipeline, strategic partnerships, and a clear path forward, we remain focused on delivering value through innovation and execution."

[1] Currently the product (candidate) portfolio has 24 products

COMMERCIALIZED PRODUCTS

The Hyloris portfolio includes 24 product (candidate)s of which 3 are commercialized.

Maxigesic® IV

Maxigesic® IV is a novel, unique combination, intravenous formulation for the treatment of mild to moderate acute pain and is currently licensed to partners covering over 100 countries across the globe. Maxigesic® IV has received approval in over 50 countries, with launches completed in more than 30 of those markets. In February, Hikma Pharmaceuticals ("Hikma") launched Maxigesic® IV in the U.S. under the tradename Combogesic® IV. Hikma is a leading supplier of complex, injectable hospital products in the U.S.

Hyloris obtained a milestone payment of approximately USD 2,1 million related to the launch of Combogesic® IV in the U.S. in H1 2024. Royalty payments for the U.S. market will be received when cumulative sales surpass a contractually specified threshold. As this threshold was not yet reached in 2024, no royalties have been recognized in the financial statements. The Company does not anticipate the threshold will be met in the next few quarters.

Hikma announced in July 2024 that the U.S. Centers for Medicare and Medicaid Services (CMS) assigned a unique, permanent Healthcare Common Procedure Coding System (HCPCS) J-code for Combogesic® IV. The new J-code became effective October 1, 2024.

Maxigesic® IV aims to provide an alternative, non-opioid treatment option for mild to moderate acute pain. In the U.S., chronic opioid usage in patients following surgery averages around 9%, ranging from 4% to 24% among various specialties drug overdoses involving opioids resulted in over 80,000 deaths in the U.S. in 2021. Patients who experienced an opioid overdose account nearly USD 2 billion in annual hospital costs[2]. We expect to see steady and continued growth of Maxigesic® IV related royalties over a prolonged period.

Currently the country with the highest sales of Maxigesic® IV is South Korea. In 2024, South Korea experienced a significant strike by medical professionals, which impacted orders and sales. The strike persisted for several months.

Sotalol IV

Sotalol IV is a novel, patented, intravenous formulation of Sotalol for the treatment of atrial fibrillation, and life-threatening ventricular arrhythmias and was developed for the U.S. Sotalol IV reduces hospital stay length and potentially the overall cost of care, potentially improving patient outcomes.

The Company and its commercialization partner AltaThera were involved in arbitration proceedings. On September 13, 2024, the American Arbitration Association provided its final opinion that all AltaThera claims were denied, except for a limited use of confidential information, and imposed no financial liabilities on Hyloris. This decision was an endorsement of Hyloris' position, and a clear rejection of the damages claims.

[2] https://pubmed.ncbi.nlm.nih.gov/27163960/

In addition, Hyloris' ownership of its intellectual property was confirmed. The arbitration panel confirmed termination of the license agreement as requested by AltaThera, confirming a perpetual survival of the Sotalol IV license allowing AltaThera to continue commercialization. Hyloris' claims (including the claim regarding the lack of commercially reasonable efforts) were denied but Hyloris will continue to receive sales-related royalties, as defined in the license agreement in accordance with the royalty structure already applied prior to termination. Hyloris believes the decision is final and that there are no grounds for appeal.

Podofilox Gel

In December 2023, Padagis US LLC, Hyloris' development and commercialization partner, received approval from the United States Food & Drug Administration (FDA) on its Abbreviated New Drug Application (ANDA) for Podofilox Gel, the first drug product generic to Condylox Gel 0.5%® in the U.S. Podofilox was launched shortly after its approval.

Podofilox Gel is an antimycotic drug for the topical treatment of external genital and perianal warts which are caused by certain types of the Human Papilloma Virus (HPV), a common sexually transmitted disease.

COMMERCIAL ROLL-OUT PREPARATION

Significant developments include

- An exclusive licensing agreement for Maxigesic® IV for China with Xizang Weixinkang Pharmaceutical Co., Ltd., a pharmaceutical company specializing in injectable medications.
- An exclusive licensing and distribution agreement for Maxigesic® IV for Brazil with Halex Istar, a Brazilian pharmaceutical company specializing in injectable medications. This agreement will bring Maxigesic® IV to South America's largest pharmaceutical market and a global top 10 market.
- Regulatory approvals for Maxigesic® IV were received in several countries including Canada.
- An exclusive licensing and distribution agreement for Atomoxetine liquid for Australia and New Zealand with AFT Pharmaceuticals. Under the terms of the agreement, there are no upfront or milestone payments, and profits will be shared between Hyloris and its licensee.
- Exclusive commercialization rights were secured for Valaciclovir Oral Suspension in a wide range of new territories including major European markets (such as the Nordics, Germany, France, Italy and the U.K.), Canada, Mexico, Australia, China, South Korea and the GCC countries.
- An exclusive licensing and supply agreement with Rosemont Pharmaceuticals for Valacyclovir Oral Suspension for the U.S.
- An exclusive licensing and distribution agreement with Colonis Pharma Ltd. for XTRAZA™ (tranexamic oral rinse) in the UK.
- An agreement with Avenacy for the exclusive commercialization of Tranexamic Acid Intravenous Ready-to-Use 10 mg/ml 100 ml in the U.S.

With a growing portfolio and multiple product candidates progressing towards commercialization, the Company intends to sign further partnerships with leading companies in their respective territories. The strategic objective is to capture a significant part of the net product margin realized by our commercial partners. The Company aims to achieve this by partnering these assets near the time of regulatory submission, except in countries where additional local clinical trials are required. In general, the Company prioritizes in-market product sales or profit-based participation over (upfront) milestone payments.

Hyloris is exploring several commercial strategies to bring its cardiovascular product candidates to the U.S. healthcare market. One of the key options under consideration is licensing these assets. This approach would enable Hyloris to enter the market without making significant investments in a U.S. product launch. The company expects to select its preferred pathway in 2025. However, even if this licensing strategy is pursued, Hyloris still plans to establish operations in the U.S. with select, later-stage pipeline assets.

Subject to successful R&D activities, the company expects up to 9 product filings in 2025 and 2026 to regulatory agencies including Valacyclovir oral liquid (outside the U.S.), Dofetilide IV (U.S.), Atomoxetine oral liquid, Aspirin IV, XTRAZA, Phosphate oral liquid, Metolazone IV, HY-074 and Ondansetron ER.

In addition, although these generic products are not a strategic focus:

- A regulatory approval for Tranexamic Acid RTU has been obtained in Portugal. Hyloris is not targeting to launch in Portugal, but the registration will facilitate a roll-out in some of the targeted countries.
- An agreement with Avenacy has been signed for the exclusive commercialization of Tranexamic Acid Intravenous Ready-to-Use 10 mg/ml 100 ml in the U.S. An ANDA[3] has already been submitted to the U.S. FDA, with a decision expected in 2025.
- Fusidic acid could be submitted for regulatory approval in Canada before the end of 2026.

PIPELINE EXPANSION

Despite the challenges faced in 2024, which impacted management resources and caused some delays, we remain fully committed to expanding our product portfolio. We are actively engaged in negotiations for new opportunities and anticipate accelerating pipeline growth in the coming months, with a target of reaching 30 assets by the end of 2025. This milestone reflects our ongoing momentum rather than a final objective, as we continue to build a diverse and high-potential portfolio.

In line with our strategic focus, Hyloris added two new assets to its portfolio in 2024, followed by an additional two in early 2025. Each of these assets meets our key selection criteria, including a maximum estimated development timeline of seven years and an average R&D investment by Hyloris of no more than €7 million (excluding inflation adjustments). We believe these additions represent strong global market opportunities, reinforcing our commitment to bringing innovative solutions to patients worldwide.

[3] An Abbreviated New Drug Application (ANDA) is a submission to the FDA for the approval of a generic drug

In January 2024, the pipeline was broadened with a new product candidate (HY-091) for Vulvar Lichen Sclerosus (VLS), a chronic inflammatory skin condition that primarily affects the vulva, the external female genitalia. HY-091, which will be developed as an equal partnership together with AFT Pharmaceuticals, targets to have an extended duration release of a known molecular entity and to offer a convenient application method, ensuring simplicity and improving compliance. VLS is a chronic, distressing, inflammatory disease with an enormous impact on quality of life. There is no curative treatment for VLS, which usually occurs in postmenopausal women, although children and premenopausal women may also be affected.

In August 2024, Hyloris announced the development of HY-095, a long-acting injectable formulation of a well-known Proton Pump Inhibitor (PPI) designed to treat Equine Gastric Ulcer Syndrome (EGUS). EGUS is a condition in horses characterized by the development of ulcers in the lining of the stomach. A gastric ulcer occurs when the lining has been damaged by stomach acid and digestive enzymes. EGUS is a widespread condition affecting millions of horses globally and causes significant discomfort, weight loss, and reduced performance. Ulcers can be found in approximately 30% of adult horses. The condition is particularly prevalent in high-performance horses, with up to 90% of racehorses and up to 60% of sport horses experiencing ulcers[4]. There are currently no injectable EGUS treatments approved by the regulatory agencies. Proton Pump Inhibitors (PPIs) are a class of medications that block the proton pump to reduce the gastric acid secretion. The Hyloris development costs are currently projected to remain well below €7 million.

In addition, 2 product candidates were added to the Hyloris pipeline in 2025.

In February 2025, Hyloris announced an exclusive licensing agreement to develop a ready-to-use intravenous (IV) formulation of pantoprazole, improving upon the current lyophilized (freeze-dried) version that requires reconstitution. This innovation simplifies administration, reduces preparation time, and enhances cost efficiency for healthcare professionals. With over 351 million vials of lyophilized pantoprazole IV sold in 2023, generating USD 454 million in revenue[5], the market is expected to grow at a CAGR of 12.7% through 2031. Hyloris aims to enter its first markets in about three years, with projected development costs under €5 million and the potential to capture a double-digit market share.

In February 2025, Hyloris signed an exclusive licensing agreement with RedHill Biopharma for a once-daily, bimodal extended-release (ER) formulation of ondansetron. The agreement grants Hyloris global rights outside North America, aiming to improve nausea and vomiting management for chemotherapy (CINV), radiotherapy (RINV), and post-operative recovery.

Ondansetron ER combines immediate and sustained release for prolonged symptom relief, enhancing patient compliance. Hyloris will leverage RedHill's clinical data, including available Phase 3 results, and aims for market entry by 2028. The global 5-HT3 antagonist market was valued at USD 1.5 billion in 2024, with steady growth projected.

[4] https://www.merckvetmanual.com/horse-owners/digestive-disorders-of-horses/stomach-gastric-ulcers-in-horses
[5] IQVIA

R&D UPDATE & OUTLOOK

Significant progress was achieved in 2024 and early 2025, advancing product candidates.

Other value-added product candidates

Selected notable points of progress for these product candidates are described below:

- **Alenura®**: The recruitment for a 4-arm factorial design phase 2 trial is ongoing in sites across the U.S. The Independent Data Monitoring Committee, based on an interim analysis, recommended to continue the study and to adjust the sample size. The recruitment is expected to be finalized in 2025. In addition, a multi dose study is ongoing to support an end of phase 2 meeting, currently anticipated in H1 2026.

  Alenura® is being developed as a ready-to-use intravesical administration. The product candidate targets acute pain flares in patients with IC/BPS. IC/BPS is a global issue, impacting millions of individuals worldwide affecting more than 6 million in the U.S. alone.

- **HY-083**: Hyloris is developing a new proprietary formulation using a known chemical entity, a TRPV1 agonist, delivered intranasally as a spray. Simultaneously, Hyloris is exploring several new chemical entities (NCE) through in silico modeling. Multiple NCEs have been synthesized and will undergo evaluation in a specialized lab. While this NCE approach involves a longer development timeline, it provides the potential for additional patent protection and enhanced returns. A decision regarding the preferred approach is expected in 2025.

  HY-083 targets idiopathic rhinitis, a medical disorder characterized by a collection of nasal symptoms that resemble nasal allergies and hay fever (allergic rhinitis) but are not caused by a known cause like allergens or infectious triggers.

- **Tranexamic Acid Oral Mouth Rinse:** A randomized, double-blind, multicenter, placebo-controlled phase 3 trial is currently ongoing to evaluate the efficacy, safety, and tolerability of Tranexamic Acid Oral Solution in preventing oral bleeding in patients taking anticoagulants and undergoing tooth extraction. Approximately 280 patients across Europe and the United States will be enrolled and the results are expected by late 2025. Approximately half of the targeted patient number has been included, with an acceleration over the last months. Pending successful study results, an FDA submission for approval could be initiated shortly thereafter.

  TXA oral mouth rinse aims to reduce oral bleeding in patients undergoing dental procedures.

- **Miconazole Domiphen–Bromide cream**: A full read-out of the phase 2 dose-finding study was completed, demonstrating positive results for the phase 2 trial of Miconazole Domiphen-Bromide (MCZ-DB) in patients with acute vulvovaginal candidiasis. For additional information reference is made to the press release issued 30 January 2024.

Various strategic possibilities are currently being assessed to determine the preferred development pathway, including the exploration of additional indications. If developed, the Company does not anticipate completing this product development within its originally targeted seven-year development timeline.

- **Valaciclovir Oral Suspension** (previously HY-029): Positive results from a pivotal clinical study were obtained, demonstrating comparable relative bioavailability to Valtrex® tablets, as sold in the U.S, under fasted conditions[6]. These results further strengthened the clinical data package and supported the NDA submission to the U.S. Food & Drug Administration (FDA) completed in December 2024. A PDUFA date was set on October 12, 2025.

  An additional clinical study was conducted to support the first regulatory application for European markets, targeted before H2 2025. Most regulatory filings are expected by H2 2025.

  Valaciclovir, currently commercialized as a solid oral in the U.S. and the E.U., is used to treat herpes virus infections, including herpes labialis (also known as cold sores), herpes zoster (also known as shingles), and herpes simplex (also known as genital herpes) in adults. For pediatric patients, the drug was approved for cold sores (herpes labialis) and chickenpox. Valaciclovir is available by prescription only, and the dosage and duration of treatment depend on the specific condition being treated and the individual patient's medical history.

- **Atomoxetine Oral Liquid:** The manufacturing of the registration batches was completed before the summer of 2024 at the selected Contract Manufacturing Organization (CMO) and the data read out for the trial supporting the U.S. submission is expected in Q2 2025. Hyloris is also targeting additional territories, which will require an additional clinical trial (expected in H2-2025).

  Atomoxetine is a medication primarily used to treat Attention-Deficit/Hyperactivity Disorder (ADHD).

- **PTX-252:** The U.S. Food and Drug Administration (FDA) granted Orphan Drug Designation to PTX-252 for the treatment of Acute Myeloid Leukaemia (AML).

  This product candidate, developed in collaboration with Pleco Therapeutics BV, incorporates a novel molecular entity that is a derivative of a known established molecule and is designed to enhance the responsiveness of cancer cells to chemotherapy. A drug product formulation was developed and preparations for a phase 1 clinical trial have been initiated.

[6] The abstinence of food and drinks except water for a period of time prior to dosing

Acute Myeloid Leukemia (AML) is a type of cancer that affects the blood and bone marrow, characterized by the rapid growth of abnormal white blood cells.

- **Phosphate Oral Liquid**: The final CMO has been selected, and registration batches are being prepared to be manufactured in H1 2025 with an anticipated regulatory filing in early 2026.

  This medicinal product is designed to treat hypophosphatemia, which is a condition in which blood has a low level of phosphorous.

- **HY-090:** Various formulations are being explored to develop and finalize a unique formulation eligible for patent protection.

  HY-090 is a locally acting product candidate in Burning Mouth Syndrome (BMS) and is co-developed together with AFT Pharmaceuticals (equal partnership). BMS is characterized by sensations of a burning pain in the oral cavity with normal appearance of the oral mucosa. Painful episodes of BMS usually last from least four to six months. The condition is idiopathic, and the underlying pathophysiology is not well understood. Patients with burning mouth syndrome commonly experience changes in gustatory function.

- **HY-091:** Multiple formulation strategies are being investigated and evaluated, both in-house and with external technology partners, to develop a novel, user-friendly formulation with a convenient application method. HY-091 is designed to offer prolonged release of a known molecular entity. A partnership has been established with a company specializing in topical applications that holds a patented technology.

  HY-091 is a locally acting product candidate to treat Vulvar Lichen Sclerosus (VLS) and is co-developed with AFT Pharmaceuticals.

  VLS is a chronic, distressing, inflammatory disease that primarily affects the vulva (the external part of the female genitalia) and potentially has an enormous impact on quality of life.

- **HY-095**: Various formulations are being explored and compared, with an external partner, to develop and finalize a unique formulation eligible for patent protection. The Company expects the (first) prototype testing in horses to be initiated before or by the summer of 2025.

  HY-095 is a long-acting injectable formulation of a well-known Proton Pump Inhibitor (PPI) designed to treat Equine Gastric Ulcer Syndrome (EGUS).

  PPIs are a class of medications that block the proton pump to reduce gastric acid secretion. EGUS is a condition in horses characterized by the development of ulcers in the lining of the stomach. A gastric ulcer occurs when the lining has been damaged by stomach acid

and digestive enzymes. EGUS is a widespread condition affecting millions of horses globally and causes significant discomfort, weight loss, and reduced performance.

Cardiovascular portfolio

Progress has been made on the cardiovascular assets in 2024 and early 2025, including:

- **Dofetilide IV:** The pivotal clinical trial has been completed successfully and will support the regulatory submission to seek a marketing authorization in the U.S.

  Dofetilide IV aims to reduce hospitalization stays and related risks and costs. Currently, Dofetilide is only available as an oral capsule, and Dofetilide formulated as an IV could be used as an initial loading dose with subsequent oral Dofetilide dosing to reduce the time to reach steady state and hospital discharge. Intravenous formulation will also allow drug administration in patients who are too ill to receive oral medications or who are unconscious.

- **Milrinone ER:** Significant progress has been made with an alcohol dose-dumping-resistant formulation, and a transfer to a GMP-accredited manufacturing site is under preparation. The in vitro-in vivo correlation will be established by assessing 3 different release profiles in healthy subjects. The Company expects to complete its non-clinical program during the summer of 2025 and to conduct a phase 1 study by year-end.

  Milrinone ER is an extended-release oral formulation of milrinone designed for long-term at-home use. It is intended to treat right heart failure in patients with a Left Ventricular Assist Device (LVAD).

- **Metolazone IV**: The manufacturing of the final registration batches for Metolazone IV was delayed due to unforeseen circumstances at the selected contract manufacturing organization (CMO). The delay also impacted the availability of the clinical batch, necessitating a postponement of the clinical trial. The Company believes the issues relating to manufacturing have been resolved and is executing the clinical batch. The pivotal clinical trial is currently in preparation.

  Metolazone tablets are used in patients with congestive heart failure, the most rapidly growing cardiovascular condition globally and the leading cause of hospitalization. The potential benefits of Metolazone IV include accelerating onset of action, allowing simultaneous administration with furosemide IV (the most frequently used intravenous hospital diuretic), and improving drug absorption for patients with concomitant gastrointestinal oedema. Intravenous formulation will also allow drug administration in patients who are too ill to receive oral medications or who are unconscious.

- **Aspirin IV**: Following successful registration batches, which demonstrated sufficient product stability, an additional API source for Aspirin IV will be incorporated to finalize the CMC section for product filing and ensure product supply. Additional registration batches,

which have been executed, are required to qualify this new API source. A new pivotal study to support the U.S. filing will be performed in Q3 2024, with data read out expected in late Q4 2025.

Aspirin IV is an intravenous formulation of acetylsalicylic acid (aspirin) targeting Acute Coronary Syndrome (ACS). Acute Coronary Syndrome refers to a group of conditions caused by a sudden reduction or blockage of blood flow to the heart. When ACS occurs, fast diagnosis and treatment is crucial and potentially lifesaving.

- **HY-074**: Trial batches have been done at the selected CMO. Pending successful analysis and manufacturing of the clinical batch, a pivotal clinical trial will be conducted in H2 2025.

  HY-074 is an IV formulation of a current standard of care treatment significantly reducing risk of death in ACS patients. HY-074 aims to offer faster onset of action, more convenient administration (more notable in patients who are nauseated or unconscious) and dosage control. For HY-074, Hyloris is exploring additional indications outside of the cardiovascular space.

The total headcount of the Company grew to 49 people on December 31, 2024. To enhance the development activities, only limited additional hiring is required.

Assuming continued strategic out-licensing (including some or all of its cardio assets), commercial success for its commercial products, additional non-dilutive funding, expected milestone payments, and successful development activities, the Company believes it is sufficiently capitalized to fund the anticipated R&D expenditures of the current product candidates. However, additional funding would be required to cover the investment required for the commercialization of its nearer-term cardiology products in the U.S. with an internal sales team.

The Company is considering partnering some or all of its cardiology products (reducing the commercial activity investments required), to attract co-investors for specific product developments or to fund commercialization efforts, to raise additional capital (subject to market conditions and share price evolution) or to pursue loan agreements.

GOVERNANCE

On April 30, 2024, Hyloris announced that it had initiated a forensic independent review with respect to the QliniQ transactions, including internal communication and documentation practices. The forensic independent review was completed early June 2024 and its conclusions and the resulting decisions taken by the Board of Directors were announced on 8 July 2024. Based on the decisions of the Board of Directors following this forensic review, the following measures have already been implemented or are being implemented as of today:

- Mr. Thomas Jacobsen (Hyloris' Chief Business Development Officer and co-founder) has been appointed as co-CEO, together with Mr. Stijn Van Rompay.
- Hyloris' CFO and CLO have left their roles within the Company. A new CFO has been appointed and joined in December 2024 and the search for a new CLO is ongoing.
- Actions plans have been initiated to strengthen the Company's governance. The review of the governance and internal control systems by an independent third party is ongoing and will be concluded in the coming weeks.
- Pending the outcome of the independent review, the Company will initiate a transition process to an independent CEO, with a view to the current Co-CEO, Mr. Stijn Van Rompay, assuming a dedicated role focused on driving and implementing the Company's global strategy.
- After completion of the independent review, the Board of Directors, as appointed on September, 30th 2024, will take the necessary actions and decisions.

For more details on the QliniQ transactions, their accounting treatment, the FSMA's concerns and the key findings of the forensic independent review, reference is made to the FSMA communication of 5 July 2024 and the Company's press release of 8 July as well as to the Company's press releases of 20 January 2023, 14 March 2024 and 30 April 2024.

COMMUNICATION POLICY

On August 1, 2024, Hyloris announced a new communication policy.

The Communication Policy applies to communications that include information concerning the business activities of the Company or any subsidiary of the Company, whether its business strategy, financial position (including future profits or losses or valuation), management (including its track record), assets, liabilities, investment strategy, investment and product portfolio, investment and product pipeline, cash flows, expenditures or prospects (including any periodic information or inside information to be disclosed by the Company), taking into account the sensitivity and/or confidentiality of such information.

The Communication Policy must be complied with by all directors, officers and employees of the group.

The Board has also approved limited changes to the Company's communication policy. Henceforth, all communications on behalf of the Company should be made exclusively by or at the written instruction of at least two of the following persons: (i) the Chair of the Board (or, in his absence, the chair of the Audit Committee), (ii) either of the co-CEOs, (iii) the CFO, (iv) the Investor Relations Officer, and (v) any person specifically designated by the Board to make such communication. In case of oral communications about regulated information, at least two of the aforementioned persons must be present when the communication is made.

FINANCIAL HIGHLIGHTS 2024

(in € thousands)	Year ended 31 December 2024	2023	Variance
Total revenue and other income	**10,043**	**4,214**	**138%**
Revenues	8,458	2,087	305%
Other operating income	1,584	2,127	(26%)
Cost of sales	**(227)**	**(93)**	**144%**
Operating expenses	**(16,946)**	**(20,114)**	**(16%)**
Research and development expenses	(10,265)	(14,421)	(29%)
General and administration expenses	(5,627)	(5,546)	1%
Share of result of equity-accounted investees	(81)	(147)	(45%)
Impairment on equity accounted investees	(972)	-	-
Operating result	**(7,130)**	**(15,993)**	**(55%)**
Net financial result	**788**	**613**	**29%**
Net result	**(6,342)**	**(15,380)**	**(59%)**

Net operating cashflow	**(6,703)**	**(12,808)**	**(48%)**
Cash and cash equivalents	**23,594**	**30,406**	**(22%)**

Income statement

In 2024, total revenue and other income surged to €10,043 thousand, more than doubling from €4,214 thousand in 2023.

This strong growth was primarily driven by a significant increase in Revenues, supported by substantial royalties from Maxigesic® IV and Podofilox, as well as a USD 2.1 million milestone payment related to the commercial launch of Maxigesic® IV in the U.S. Additionally, upfront and regulatory milestones payments related to the licensing and supply agreement on Valacyclovir Oral Suspension, signed in December 2024, contributed to the growth.

Other operating income includes the first-time recognition of the fair value (€292 thousand) of AltaThera litigation costs (classified as financial assets under IFRS), which are to be recouped from royalties payable to API once several cardio assets are commercialized, as well as Belgian R&D tax credits, which increased slightly to €499 thousand in 2023. The Belgian R&D tax credits reported in 2024 include a correction of €225 thousand for the 2023 R&D tax credit calculation. This correction already reported in the 2024 interim result report resulted from applying a 13.5% deduction rate instead of the revised 20.5% rate. However, total operating income, amounting to €1,584 thousand, is lower than in 2023 (€2,087 thousand), which included a one-off settlement agreement with Biorasi.

R&D expenditure during 2024 amounted to €10,265 thousand, compared to €14,421 thousand for 2023. This decrease was primarily driven by the timing and phasing of development projects. Additionally, a USD 2 million investment (provided to cover R&D costs) in Vaneltix was booked as R&D expenses in 2023, whereas no additional investment was made in 2024 outside of contractual R&D funding, further contributing to the overall reduction.

General and Administrative expenses remained elevated, totaling €5,627 thousand in 2024, compared to €5,546 thousand in 2023. This was primarily driven by high legal and investigation costs of € 2,172 thousand, including AltaThera arbitration costs, provisions for lawyers' discretionary fees and forensic audit fees. This amount of €5,627 thousand includes the reversal of share-based payments costs for 2019, 2020 and 2022 Warrants Plans (-€584 thousand), which is a non-cash item. Excluding shared-based payments adjustments, General and Administrative expenses would have amounted to €6,211, compared to €5,006 thousand in 2023. With the arbitration now concluded, and all else being equal, General and Administrative expenses are expected to be lower going forward.

An impairment on financial assets (a non-cash item) related to the development collaboration agreement with FHP BV (a joint venture with company, Maatschap Purna and other shareholders) is reported at -€972 thousand, see *Statement of financial position* section for more information.

Financial income in 2024 amounted to €1,165 thousand, an increase from €898 thousand in 2023. This positive evolution was primarily driven by a foreign exchange gain of €268 thousand in 2024, compared to €30 thousand in 2023. Interest income remained stable compared to last year, despite a decrease in cash, benefiting from the increase in short-term interest rates compared to 2023.

Financial expenses in 2024 amounted to €378 thousand, compared to €285 thousand in 2023, primarily due to a decrease of the fair value of a loan to API. This loan to API which will be recouped from royalties payable once several cardio assets (developed with API) are commercialized. This decrease reflects both a revised business case and an adjustment to royalties payable.

As a result, the company's net losses in 2024 were reduced by nearly 59%, reaching a historical low (post IPO) of €6,342 thousand versus €15,380 thousand in 2023.

Statement of financial position

The Group remains free of financial debt[7].

The increase in current Trade and other receivables is in line with revenue growth, reflecting the natural rise in outstanding receivables as sales increase.

The increase in non-current Trade and other receivables is driven by the higher aggregate fair value of both a loan to API (€98 thousand on 31 December 2024) and first-time recognition of a portion of incurred costs related to the AltaThera litigation (€292 thousand on 31 December 2024). Both are financial assets under IFRS and could be recouped from royalties payable to API once several cardio assets (developed with API) are commercialized. Additionally, the increase is also attributed to higher R&D tax credits (€1,774 thousand on 31 December 2024).

Borrowings reflect lease liabilities and rental obligations recognized on the balance sheet under IFRS 16. These include a lease agreement for lab equipment and car leases, along with rental office obligations totaling €1,816 thousand (€1,489 thousand non-current) on 31 December 2024. The total

[7] The group has no long or short term financial debt, but leases for lab equipment and cars, plus the renting of the office must be reported as liability under IFRS16

amount remains consistent with last year. The corresponding assets are recorded under Property, Plant and Equipment and Right-of-Use Assets on the asset side of the balance sheet.

A provision related to the AltaThera arbitration for discretionary fees to a law firm is recognized for €581 thousand (of which €173 thousand is non-current and €408 thousand is current).

In 2024, the company reduced the carrying amount of its investment in FHP BV to €2,748 thousand, a decrease of €1,053 thousand from the €3,801 thousand reported as of December 31, 2023. This reduction (a non-cash item) impacts the Profit and Loss Account for €972 thousand recorded as an impairment on financial assets and €81 thousand recognized under the share of results of equity-accounted investees. Given ongoing discussions regarding the U.S. development for the Miconazole-Domiphen Bromide asset, the updated business cases (risk-weighted and non-risk-weighted), when presented to the Board of directors in March 2025, resulted in a revised NPV (Value in Use) stake which is the new carrying amount reported under Equity accounted investments. The company and FHP BV shareholders are exploring various options to expand the asset beyond its current indication for rVVC, with the aim of increasing its underlying NPV.

Equity remains strong at €32,143 thousand, down from €39,069 thousand as reported on December 31, 2023, a decrease being the result of the comprehensive loss for the period and a non-cash impact related to ESOP warrants plans for €584 thousand.

Cash flow statement

The Company maintains its strong cash position, with cash and cash equivalents totaling €23,594 thousand as of 31 December 2024, compared to €30,406 thousand as of 31 December 2023.

Net cash outflow from operating activities amounted to €6,703 thousand in 2024, a significant improvement from €12,808 thousand outflow in 2023, driven by revenue growth.

Cash flow from investment activities decreased by €9,630 thousand compared to the previous year, primarily due to the expiry of a cash investment at year-end in 2024.

The financing activities resulted in a net cash outflow of €368 thousand, mainly due to leasing repayments.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED DECEMBER 31

in € thousands	31 December 2024	31 December 2023
Revenue	8,458	2,087
Other operating income	1,584	2,127
Operating income	**10,043**	**4,214**
Cost of sales	(227)	(93)
Research and development expenses	(10,265)	(14,421)
General and administrative expenses	(5,627)	(5,546)
Share of result of equity-accounted investees, net of tax	(81)	(147)
Impairment on equity accounted investees	(972)	-
Operating expenses	**(16,946)**	**(20,114)**
Operating profit/(loss) (EBIT)	**(7,130)**	**(15,993)**
Financial income	1,165	898
Financial expenses	(378)	(285)
Profit/(loss) before taxes	**(6,342)**	**(15,380)**
Income taxes	-	-
PROFIT/(LOSS) FOR THE PERIOD	**(6,342)**	**(15,380)**
Other comprehensive income	**-**	**-**
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	**(6,342)**	**(15,380)**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION FOR THE YEAR ENDED DECEMBER 31

ASSETS (in thousands of euros)	31 December 2024	31 December 2023
Non-current assets	***11,628***	***12,373***
Intangible assets	3,838	3,828
Property, plant and equipment	340	429
Right-of-use assets	1,652	1,724
Equity accounted investments	2,748	3,801
Other investments	1,000	1,000
Trade and other receivables	2,050	1,591
Current assets	***29,707***	***35,308***
Trade and other receivables	4,858	3,565
Other investments	556	499
Current tax assets	508	244
Prepayments	191	594
Cash and cash equivalents	23,594	30,406
TOTAL ASSETS	**41,335**	**47,681**

EQUITY AND LIABILITIES (in thousands of euros)	31 December 2024	31 December 2023
Equity attributable to owners of the parent	***32,143***	***39,069***
Share capital	140	140
Share premium	121,513	121,513
Retained earnings	(80,128)	(65,381)
Result of the period	(6,342)	(15,380)
Share based payment	944	2,161
Cost of Capital	(4,460)	(4,460)
Other reserves	476	476
Total equity	***32,143***	***39,069***
Non-current liabilities	***2,030***	***1,853***
Borrowings	1,489	1,510
Other financial liabilities	368	344
Provisions	173	-
Current liabilities	***7,162***	***6,759***
Borrowings	326	241
Other financial liabilities	3,000	3,200
Provisions	408	-
Trade and other liabilities	3,428	3,318
Total liabilities	**9,192**	**8,613**
TOTAL EQUITY AND LIABILITIES	**41,335**	**47,681**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

31 December 2024	Attributable to equity holders of the Company						
			Other reserves			Retained earnings and result of the period	Total Equity
(in thousands of euros)	Share capital	Share premium	Share-based payment reserve	Cost of Capital	Other reserves		
Balance at December 31, 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 December 31, 2024	**140**	**121,513**	**944**	**(4,460)**	**476**	**(86,470)**	**32,143**

CONSOLIDATED STATEMENT OF CASH FLOWS

in € thousands	2024	2023
CASH FLOW FROM OPERATING ACTIVITIES		
Net result	(6,342)	(15,380)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation, amortisation and impairments	648	349
Impairment on equity-accounted investees	972	-
Provisions	581	-
Share-based payment expense	(584)	540
Net finance result	(788)	(613)
Share of profit of equity-accounted investees, net of tax	81	147
Other non-cash adjustments		15
Bank fees paid	(56)	(48)
Changes in working capital:		
Trade and other receivables	(1,681)	29
Prepayments	403	1,155
Trade and Other liabilities	140	1,050
Cash generated from operations	**(6,626)**	**(12,756)**
Interest paid	(77)	(52)
Net cash generated from operating activities	**(6,703)**	**(12,808)**
CASH FLOW FROM INVESTING ACTIVITIES		
Interest received	556	638
Purchases of property, plant and equipment	(29)	(298)
Purchases of Intangible assets	(268)	(452)
Proceeds from other financial assets	-	10,000
Net cash provided by/(used in) investing activities	**259**	**9,889**
CASH FLOW FROM FINANCING ACTIVITIES		
Reimbursements of borrowings and other financial liabilities	(40)	-
Proceeds from borrowings and other financial liabilities	139	51
Reimbursements of lease liabilities	(267)	(170)
Other financial liabilities	(200)	-
Interests paid	-	(12)
Net cash provided by/(used in) financing activities	**(368)**	**(131)**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(6,812)**	**(3,051)**
CASH AND CASH EQUIVALENTS at beginning of year	30,406	33,457
Net e□ffect of currency translation on cash and cash equivalents		
CASH AND CASH EQUIVALENTS at end of year, calculated	23,594	30,406

Audit Report

The statutory auditor, KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises, represented by Tanguy Legein, has informed the Company that the audit procedures to date have not revealed additional qualifications beyond the previously reported qualifications on 1) the income recognition on the contract to provide strategic advice to Pleco Therapeutics BV and 2) the timing of the recognition of recovery of legal costs (overstatement of current period profit/(Loss) for the period for an amount of EUR 0.5 million which should have been recognized at 31 December 2023)

EXPECTED FINANCIAL CALENDAR

30 April 2025	**Annual Report 2024**
10 June 2025	**Annual General Meeting of Shareholders**
25 September 2025	**Half-Year Results 2025**
26 March 2026	**Full-Year Results 2025**

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, patented portfolio of 21 reformulated and 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 mild to moderate acute pain treatment. In addition to its core strategic focus, the Company has 1 approved high barrier generic product launched in the U.S. and 2 high barrier generic products in development.

Hyloris is based in Liège, Belgium. 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, lower risk”, which relates to the 505(b)(2) regulatory pathway for product approval on which the Company focuses, but in no way relates or applies to an investment in the Shares.

Certain statements in this press release are “forward-looking statements.” These forward-looking statements can be identified using forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended 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 to be materially different from those expressed or implied by any forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.

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