Hyloris Pharmaceuticals Reports Preliminary 2024 Half-Year Results and provides Business Outlook

- Revenues (Royalties and Milestones) Increased to €4,2 Million (+576[1]%)
- R&D Progress Across the Board, including Positive Results on Valacyclovir Oral Suspension
- Maxigesic® IV Launched in the U.S.
- Evaluating External Product Candidates & Advancing Internal Projects to Reach 30 Key Assets in 2025
- Analyzing Different Go-to-market Strategies for Commercial Launch in the U.S.
- Final Opinion Received in Arbitration Case against AltaThera Pharmaceuticals
- Auditor's Limited Review Substantially Completed; Qualified Report Anticipated Mainly Relating to the Potential Recovery of up to 50% of Arbitration Expenses Incurred
- Net Cash Position of €27,4 Million

Liège, Belgium – 4 October 2024 – 11PM 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 preliminary financial results for the six-month period ending 30 June 2024, along with recent achievements and a business outlook.

The preliminary results that Hyloris announces in this press release are still being reviewed by its statutory auditor. Presently the review is substantially complete and the company anticipates a qualification, primarily relating to the absence of a potential receivable relating to the partial of up to 50% of U.S. litigation costs from the arbitration case against AltaThera Pharmaceuticals. For additional information reference is made to page 10 in this press release.

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

*"*We've made significant strides in our product development efforts exemplified by the introduction of 2 new product candidates to the pipeline in the first half of 2024, completion of the clinical work on Valacyclovir Oral Suspension for the U.S. market and the initiation and execution of multiple clinical trials. In addition, our partner launched Maxigesic® IV in the U.S. These achievements demonstrate our unwavering commitment to innovation and our ability to overcome challenges.

While the recent stock suspension temporarily impacted our ability to trade publicly, it is important to note that the suspension does not fundamentally affect the underlying value of our portfolio or the progress we have made on our strategic initiatives. We recognize this situation has created uncertainty and temporarily impacted management and organizational focus, but we remain confident in our ability to navigate this situation and continue to execute the development plan of our current product portfolio.

[1] Versus restated H1 2023

Although sales are currently limited to our first three products and are still in the early stages, this positive development is a promising indicator of future growth potential."

COMMERCIAL VALUE DRIVERS

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. 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 the first half of 2024, no royalties have been recognized in the financial statements. We expect this threshold to be reached for the first time in 2025 and at least annually thereafter.

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 will be 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 $2 billion in annual hospital costs[2]. We expect to see steady and continued growth of Maxigesic® IV related royalties over a prolonged period.

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 until recently involved in arbitration proceedings. The final opinion in these proceedings was received in September 2024 (see concerned section 'AltaThera Arbitration' in this press release).

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.

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

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

Other value-added product candidates

Significant developments in our non-cardiology pipeline include

- An exclusive licensing and distribution agreement for Maxigesic® IV for Brazil was signed 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.
- An exclusive licensing agreement for Maxigesic® IV for China with Xizang Weixinkang Pharmaceutical Co., Ltd., a pharmaceutical company specializing in injectable medications, was signed in September 2024.
- Regulatory approvals for Maxigesic® IV were received in several countries including Canada.
- Hyloris has entered into an exclusive licensing and distribution agreement for Atomoxetine liquid for Australia and New Zealand. 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. Previously only the U.S. was targeted.

With a growing portfolio and multiple product candidates progressing towards commercialization, the Company intends to sign partnerships with leading companies in their respective territories. The Company expects to submit the regulatory filing for Valaciclovir Oral Suspension in the U.S. by late 2024, followed by Atomoxetine Liquid and Tranexamic Acid Mouth Rinse in 2025, in collaboration with a commercial partner.

For product candidates which Hyloris intends to out-license, 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 will prioritize in-market product sales or profit-based participation over (upfront) milestone payments.

Cardiovascular portfolio

Hyloris is currently exploring several strategies to bring its cardiovascular product candidates to the U.S. healthcare market. One of the key options under consideration is licensing these assets to other companies. Although these product candidates would primarily target electrophysiologists and a subset of cardiologists in hospitals, this approach would enable Hyloris to enter the market without making significant upfront investments in a U.S. product launch. However, even if this licensing strategy is pursued, Hyloris still plans to establish operations in the U.S. with select, later-stage pipeline assets.

Dofetilide IV is anticipated to be submitted for regulatory approval subject to the successful completion of its clinical trial, which is expected in the fourth quarter of 2024. Aspirin IV is anticipated to be submitted for regulatory approval in 2025 and it is intended to submit Metolazone IV for regulatory approval shortly after the submission of Aspirin IV.

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.
- In addition, the U.S. FDA requested additional information about the Tranexamic Acid RTU filing. The Company is currently preparing a response and anticipates an approval after further review by the FDA.

PIPELINE EXPANSION

Despite the challenges encountered in 2024, which affected amongst other management time, and caused some delay we remain committed to expanding the product portfolio. We are actively negotiating new opportunities and expect to accelerate the expansion of our pipeline in the coming months and expect to reach 30 assets by or before the end of 2025. This is not a final target, but rather a key milestone in our anticipated growth.

In 2024, Hyloris expanded its portfolio with two new assets, both of which align with our overall criteria, including an average R&D spend for Hyloris of no more than €7 million (non-inflation adjusted) and a maximum development timeline of 7 years. We believe both assets present a worldwide market opportunity.

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[3]. There are currently no injectable EGUS treatments approved

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

by the regulatory agencies. Proton Pump Inhibitors (PPIs) are a class of medications that block the proton pump to reduce the gastric acid secretion.

R&D UPDATE & OUTLOOK

Significant and steady progress was achieved in the first half of 2024, 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, targeting to enroll 120 patients across multiple sites in the U.S., is ongoing. In addition, a PK trial and an exploratory multi dose study will be conducted to support an end of phase 2 meeting, currently anticipated in late 2025.

  Alenura™ is being developed as a ready-to-use intravesical administration. The product candidate targets acute pain flares in patients with IC/BPS, which affects more than 6 million people 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) using in silico modeling. While this NCE approach involves a longer development timeline, it provides the potential for additional patent protection and improved returns. A decision on the preferred approach is expected by 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 mid 2025. 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.

Various strategic possibilities are currently being assessed to determine the preferred development pathway.

- **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[4]. These results further strengthen the clinical data package and support the ongoing preparation of an NDA for submission to the U.S. Food & Drug Administration (FDA) targeted before the end of 2024.

  An additional clinical study is set to commence before the end of 2024, with the aim of submitting the first regulatory application for markets outside of the U.S. in 2025.

  Valaciclovir, currently commercialized as a solid oral in the U.S., 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 at the selected Contract Manufacturing Organization (CMO), and a pivotal clinical trial is expected to be completed around year end, with data read out expected in Q1 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. Hyloris was notified that a drug product formulation was developed and that preparations for a phase 1 clinical trial have been initiated. 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 for H1 2025 with an anticipated regulatory filing in late 2025.

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

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

- **HY-090:** Various formulations are being explored and compared, both in-house and with external technology partners, 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). Burning mouth syndrome (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.

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

  Vulvar Lichen Sclerosus (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.

Cardiovascular portfolio

Progress has been made on the cardiovascular assets in the first half of 2024, including:

Dofetilide IV: The pivotal clinical trial is currently ongoing and the last patient will finish the study early October. The study report is expected by the end of calendar year 2024 and allow subsequent 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 technical production batches are currently being scaled up to support a clinical trial batch.

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 has been 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 until early 2025. 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 stability for product filing, an additional API source for Aspirin IV will be incorporated to finalize the CMC section and ensure product supply. Additional registration batches are required to qualify this new API source.

  Aspirin IV is an intravenous formulation of acetylsalicylic acid (aspirin) targeting Acute Coronary Syndrome (ACS). 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 batches a subsequent pivotal clinical trial should be completed by the summer of 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 41 people on June 30, 2024. To enhance the development activities, only limited additional hiring is required.

Assuming continued strategic out-licensing, commercial success for Maxigesic® IV, Sotalol IV and Podofilox Gel, additional non-dilutive funding and milestone payments, 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 may consider partnering some or all of its cardiology products (reducing the commercial activity investments required), or to raise additional capital through the market, subject to market conditions and share price evolution or to pursue loan agreements. The Company does not expect that the current product portfolio development activities will be impacted.

ALTATHERA ARBITRATION

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. 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 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. Hyloris believes the decision to be final with no grounds for appeal.

FORENSIC INDEPENDENT REVIEW

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. Based on the recommendations 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.
- The Company will initiate a transition process to an independent CEO, with a view to the current CEO, Mr. Stijn Van Rompay, assuming a dedicated role focused on driving and implementing the Company's global strategy.
- Hyloris' CFO and CLO will leave their roles within the Company before the end of 2024. The process for recruiting is ongoing.
- Actions plans have been initiated to strengthen the Company's governance, with respect to e.g. (i) the review of our internal control systems by an independent third party, (ii) the setting up of an internal audit function, and (iii) the implementation of written compliance policies and clear internal reporting lines (including to the Audit Committee).
- The new Board of Directors, as appointed on September, 30th 2024, will take the necessary actions and decisions to follow up on the Board recommendations.

For more detail 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.

REMARK ON THE ONGOING LIMITED REVIEW AND EXPECTED QUALIFIED REPORT

The preliminary results that Hyloris announces in this press release are still being reviewed by its statutory auditor. As in the past, Hyloris has subjected its interim financial results to a limited review by its statutory auditor, KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises, represented by Tanguy Legein. Presently the review is substantially complete and the company anticipates a qualified report, including a qualification relating to the recovery of litigation costs from the arbitration case against AltaThera.

As announced on September 30, 2024, the company, in consultation with the auditor, is still assessing the potential impact on its financial statements of the recovery of 50% of the AltaThera litigation costs from its development partner, following the recent decision by the American Arbitration Association on September 13th, 2024. Hyloris is eligible to recover up to 50% of these expenses through a deduction on royalties payable to API, its partner for Dofetilide IV, Metolazone IV, and HY-074. Hyloris did not record an accrual for these potential receivables, believing at the time that full recovery from API was uncertain, given the various potential scenarios influencing the final outcome. Following the receipt of the final arbitration opinion on September 13, an accrual will be considered in H2 2024. The auditor's report with respect to Hyloris' H1 2024 results a qualification stating that a receivable should have been recorded previously.

In addition, a qualification due to a scope limitation relating to a transaction with Pleco Therapeutics is anticipated. In H1 2024 an amount of 62K was invoiced (Other Income) for services rendered to Pleco Therapeutics.

Hyloris is in continuous dialogue with its statutory auditor with a view to completing the limited review as soon as possible. Hyloris will make public its interim financial report, including the reviewed results and the statutory auditor's report, as soon as the latter becomes available.

UNAUDITED PRELIMINARY FINANCIAL HIGHLIGHTS AND RESULTS OF OPERATIONS (SUBJECT TO COMPLETION OF LIMITED REVIEW)[5]

	Period ended 30 June		
(in € thousands)	**2024**	**2023**	**Variance**
Total revenue and other income	**4,640**	**2,309**	**101%**
Revenues	4,153	614	**576%**
Other income	487	1,695	**(71%)**
Cost of sales	**(108)**	**(46)**	**(135%)**
Operating expenses	**(8,463)**	**(8,278)**	**2%**
Research and development expenses	(5,313)	(5,788)	**8%**
General and administration expenses	(3,150)	(2,490)	**26%**
Operating result	**(3,976)**	**(6,015)**	**34%**
Net financial result	**491**	**478**	**3%**
Net result	**(3,485)**	**(5,622)**	**38%**
Net operating cashflow	**(3,353)**	**(4,146)**	**19%**
Cash and cash equivalents	**27,430**	**30,406**	**(10%)**

Total Revenue and Other Income

In the first six months of 2024, total revenue and other income grew to €4,640 thousand, more than doubling compared to €2,309 thousand in the same period of 2023. This strong growth was primarily driven by increased royalties from the three commercialized products, including Podofilox, which was launched in December 2023, and a milestone payment of USD 2,1 million relating to the commercial launch of Maxigesic® IV in the U.S.

Results

The Company realized a net loss of €3,485 thousand for the six-month period ending 30 June 2024, compared to a net loss of €5,622 thousand for the first half year of 2023.

R&D expenditure during the first six months of 2024 amounted to €5,313 thousand, compared to €5,788 thousand for the same period of 2023. This decrease was primarily due to the timing and phasing of development projects.

General and administrative expenses increased significantly to €3,150 thousand in the first half-year of 2024 versus €2,490 thousand in 2023, primarily driven by higher legal costs and investigation fees and the reversal of share-based costs for 2020 and 2022 Warrants Plan of €716 thousand. Without that adjustment, the General and administrative expenses would have been at €3,866 versus €2,490 in H1 2023.

[5] See above ("Remark on Ongoing Limited Review and Possible Qualified Report").

The net financial income in the first six months of 2024 was €491 thousand compared to €478 thousand in the same period of 2023. The positive evolution of the financial result is mainly due to the impact of an active cash management strategy.

As a result, net losses in the first-half year of 2024 decreased by nearly 38% to €3,485 thousand versus €5,622 thousand in the same period of 2023.

Balance Sheet

The Group remains free of financial debt. The increase in trade receivables reflects the increase in revenue, while the higher borrowings are attributed to the commencement of a lease agreement for new lab equipment. Additionally, the increase in trade payables is due to higher general expenses.

Cash Position and cash flow

The Company maintains its strong cash position, with current cash and cash equivalents totaling €27,430 thousand on 30 June 2024, compared to €30,406 thousand on 31 December 2023.

Net cash outflow generated from operating activities was €3,353 thousand during the first six months of 2024, compared to a net operating cash outflow of €4,146 thousand in the same period of 2023. The decrease of 19% in the operating cash outflow is the result of revenue growth.

QLINIQ TRANSACTIONS

During H1 2024, Hyloris announced a restatement and reclassification regarding its H1 2023 financial statements.

Hyloris had initially recognized (a) €1 million in revenue in 2022 from the divestment of HY-038, and (b) € 1 million in R&D expenses and € 0,2 million in intangible assets in H1 2023 for the purchase of HY-088. A reassessment determined that both transactions qualify as a non-monetary exchange because negotiations and valuations occurred simultaneously.

As a result of this reassessment, the restated financials for 2022 have reversed the €1 million revenue from the divestment of HY-038. This adjustment has also affected the half-year 2023 financial statements, resulting in a reversal of €1 million in R&D expenses for HY-088. These expenses are offset against the €1 million received by Hyloris for HY-038.

Even though there had been an actual cash inflow of € 1 million from the divestment of HY-038 and a cash outflow of € 1.2 million resulting from the in-licensing of HY-088, the transactions were presented in the net consolidated cash flow statement for the year ended per December 31, 2023 (i.e., € 200k prepaid expenses), as this most faithfully presented the substance of the transactions. There was no impact on the consolidated statement of cash flows for the year ended on December 31, 2022, as there is no cash impact.

Per 30 June 2023 (in € thousands)	As previously reported	Adjustment	As restated
Total revenue and income	**2,391**	**(83)**	**2,309**
Revenues	1,160	(547)	614
Other income	1,231	464	1,695
Cost of sales	(46)	-	(46)
Operating expenses	(9,361)	1,083	(8,278)
Research and development expenses	(6,871)	1,083	(5,788)
General and administration expenses	(2,490)	-	(2,490)
Operating result	**(7,100)**	**1,000**	**(6,100)**
Net financial result	466	12	478
Net result	(6,634)	1,012	(5,622)
Net operating cashflow	**(4,129)**	**(18)**	**(4,146)**
Cash and cash equivalents	**39,159**	**(5,000)**	**34,159**
Other investment	**489**	**5,000**	**5,489**

Reference is made to note 31 in the 2023 Annual Report for full explanation on the restatement and reclassification.

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE FIRST HALF-YEAR OF 2024

in € thousands	Note	30 June 2024	30 June 2023(1)
Revenue	15	4,153	614
Other operating income	17	487	1,695
Operating income		**4,640**	**2,309**
Cost of sales		(108)	(46)
Research and development expenses	16	(5,313)	(5,788)
General and administrative expenses	16	(3,150)	(2,490)
Share of result of equity-accounted investees, net of tax	16	(45)	(85)
Operating expenses		(8,616)	(8,409)
Operating profit/(loss) (EBIT)		**(3,976)**	**(6,100)**
Financial income		576	518
Financial expenses		(85)	(40)
Profit/(loss) before taxes		**(3,485)**	**(5,622)**
Income taxes		-	-
PROFIT/(LOSS) FOR THE PERIOD		**(3,485)**	**(5,622)**
Other comprehensive income		**-**	**-**
TOTAL COMPREHENSIVE INCOME OF THE PERIOD		**(3,485)**	**(5,622)**

(1) Restated H1 2023

UNAUDITED CONDENSED CONSOLIDATED INTERIM FINANCIAL POSITION FOR THE FIRST HALF-YEAR OF 2024

ASSETS (in thousands of euros)	**Note**	**30 June 2024**	**31 December 2023**
Non-current assets		***12,671***	***12,373***
Intangible assets	7	3,818	3,828
Property, plant and equipment		399	429
Right-of-use assets		1,722	1,724
Equity accounted investments	8	3,756	3,801
Other investments	9	1,000	1,000
Trade and other receivables	10	1,975	1,591
Current assets		***32,766***	***35,308***
Trade and other receivables	10	4,027	3,565
Other investments	9	527	499
Current tax assets		328	244
Prepayments	11	453	594
Cash and cash equivalents	12	27,430	30,406
TOTAL ASSETS		**45,437**	**47,681**

EQUITY AND LIABILITIES (in thousands of euros)		**30 June 2024**	**31 December 2023**
Equity attributable to owners of the parent		***34,661***	***39,069***
Share capital		140	140
Share premium		121,513	121,513
Retained earnings		(80,761)	(65,381)
Result of the period		(3,485)	(15,380)
Share based payment		1,239	2,161
Cost of Capital		(4,460)	(4,460)
Other reserves		476	476
Total equity		***34,661***	***39,069***
Non-current liabilities		***1,947***	***1,853***
Borrowings	13.1	1,568	1,510
Other financial liabilities	13.2	344	344
Other non-current liabilities		35	-
Current liabilities		***8,829***	***6,759***
Borrowings	13.1	318	241
Other financial liabilities	13.2	3,200	3,200
Trade and other liabilities	14	5,310	3,318
Total liabilities		**10,776**	**8,613**
TOTAL EQUITY AND LIABILITIES		**45,437**	**47,681**

UNAUDITED CONDENSED CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY FOR THE FIRST HALF-YEAR OF 2024

30 June 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			(922)				(922)
Total comprehensive income						(3,485)	(3,485)
Balance at June 30, 2024	**140**	**121,513**	**1,955**	**(4,460)**	**476**	**(84,247)**	**34,661**

UNAUDITED CONDENSED CONSOLIDATED INTERIM STATEMENT OF CASH FLOWS FOR THE FIRST HALF-YEAR OF 2024

in € thousands	Note	30 June 2024	30 June 2023
CASH FLOW FROM OPERATING ACTIVITIES			
Profit/loss for the period		(3,485)	(5,622)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation, amortisation and impairments	16	304	163
Share-based payment expense		(922)	313
Net finance result		(491)	(478)
Other current and non-current liabilities		35	-
Share of profit of equity-accounted investees, net of tax	8	45	85
Other non-cash adjustments		-	(12)
Bank fees paid		(27)	-
Changes in working capital:			
Trade and other receivables	10	(848)	(291)
Other investments		-	(72)
Current tax assets		-	-
Prepayments		140	923

Trade and Other liabilities	14	1,930	849
Cash generated from operations		**(3,320)**	**(4,142)**
Interest paid		(34)	(17)
Interest received		-	12
Net cash generated from operating activities		**(3,353)**	**(4,146)**
CASH FLOW FROM INVESTING ACTIVITIES			
Interest received		452	148
Purchases of property, plant and equipment		(22)	-
Purchases of Intangible assets		(44)	(236)
Proceeds of other financial assets		-	5,000
Net cash provided by/(used in) investing activities		**386**	**4,912**
CASH FLOW FROM FINANCING ACTIVITIES			
Proceeds from borrowings and other financial liabilities		139	44
Reimbursements of lease liabilities		(126)	(95)
Reimbursements of borrowings		(18)	-
Interests paid		(4)	(12)
Net cash provided by/(used in) financing activities		**(9)**	**(63)**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		**(2,976)**	**702**
CASH AND CASH EQUIVALENTS at beginning of period		30,406	33,457
CASH AND CASH EQUIVALENTS at end of period, calculated		27,430	34,159

WEBCAST DETAILS

The Company will host a webcast conducted in English to present its 2024 Half-Year results and Business Outlook, followed by a live Q&A session in function of completion of the statutory auditor's ongoing limited review and the publication of the interim 2024 report.

EXPECTED FINANCIAL CALENDAR

20 March 2025	**Annual Results 2024**
30 April 2025	**Annual Report 2024**
10 June 2025	**Annual General Meeting of Shareholders**

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 19 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.