

# 2023

Annual Report



**Reinventing** existing medications



# Contents

<b>Profile</b> .....	<b>4</b>
<b>Key Figures</b> .....	<b>6</b>
<b>Letter to Shareholders</b> .....	<b>8</b>
<b>Business Overview</b> .....	<b>11</b>
<b>Environmental, Social, and Governance</b> .....	<b>31</b>
<b>The Hyloris Share</b> .....	<b>42</b>
<b>Corporate Governance</b> .....	<b>44</b>
<b>Consolidated Financial Statements</b> .....	<b>84</b>
<b>Glossary and Other Info</b> .....	<b>155</b>

This Annual Report 2023 includes the management report in accordance with article 12 of the Royal Decree of 14 November 2007 relating to the obligations of issuers of financial instruments admitted on a regulated market. All information required to be included in such management report pursuant to articles 3:6 and 3:32 of the Belgian Code of Companies and Associations is reported throughout all difference sections of this Annual Report.



# Hyloris: Unlocking Potential for Underserved Patients

**Hyloris is a specialty biopharmaceutical company dedicated to a single purpose: improving the lives of patients facing unmet medical needs.**

We achieve this by focusing on innovative treatments that offer significant added value.

We leverage our expertise and cutting-edge technologies to unlock the hidden potential of existing pharmaceuticals. By reformulating and repurposing these drugs, we aim to address critical gaps in current treatment options. This translates to a robust pipeline of proprietary, complex products with the potential to offer substantial advantages over what's currently available.

Currently, we have three commercially available products in partnership with other companies. Maxigesic® IV, a novel dual-mode-of-action non-opioid analgesic, offers relief for post-operative pain. Podofilox gel - the first generic of Condylox® gel in the U.S. - is an antimycotic drug for the topical treatment of external genital and perianal warts caused by certain types of the Human Papilloma Virus (HPV). Our third commercial product is Sotalol IV for the treatment of atrial fibrillation.

To accelerate development and minimize risks, Hyloris utilizes a focused strategy. We primarily rely on the 505(b)(2) regulatory pathway in the U.S. and similar pathways in other countries. This approach is specifically designed for pharmaceuticals where safety is already established, allowing us to streamline clinical trials and significantly expedite the development process. This translates to lower development costs, faster product launches, and ultimately, quicker access to these innovative treatments for the patients who need them most.

Hyloris employs 41 people  
(20 women and 21 men) of 11 nationalities



### Specialty biopharma

Adding value and innovation to existing drug assets for core unmet medical needs



### Broad Pipeline

With 16 innovative product candidates, 3 marketed products, and 2 high barrier generics



### In Europe (Belgium) and US

Founded in 2012 in the heart of Europe



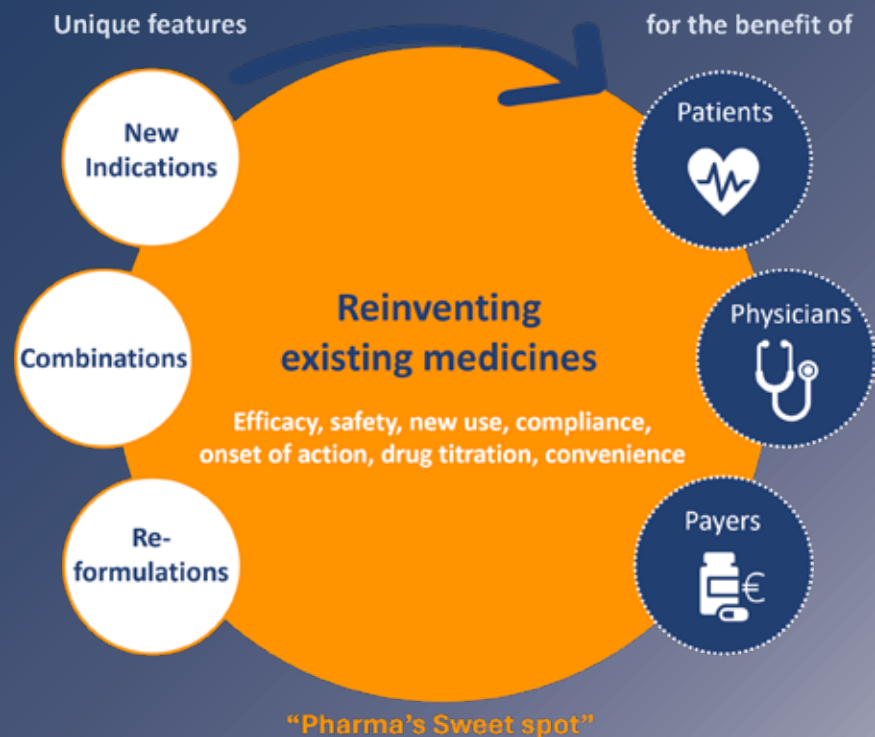
### Strong Network and Knowhow

KOL & partners network, in-house research facility with a new and improved R&D lab



### Listed

Listed on the Euronext Brussels Stock Exchange (HYL:BB)




# Key Figures 2023

**€4,2**  
million revenue  
& other income

**€30,4**  
million cash & cash  
equivalents

**€0**  
no financial  
debt

## Financial Highlights

(In € thousands)	Year ended 31 December	
	2023	2022 <sup>1</sup>
Revenue	2,087	900 <sup>1</sup>
Other operating income	2,127	1,487 <sup>2</sup>
<b>Total Revenue and Other operating income</b>	<b>4,214</b>	<b>2,387</b>
Cost of sales	-93	-94
Research and development expenses	-14,421	-10,272
Selling, general and administrative expenses	-5,546	-3,517
<b>Operating profit/(loss) (EBIT)</b>	<b>-15,993</b>	<b>-11,638<sup>1</sup></b>
Financial result	613	-264
PROFIT/(LOSS) FOR THE PERIOD	-15,380	-11,906 <sup>1</sup>
 <b>Cash and cash equivalents</b>	<b>30,406</b>	<b>33,457<sup>3</sup></b>

<sup>1</sup>See restatement for the year 2022 and press release dated 14 March 2024 relating to the restatement for additional information on HY-038 and HY-088

<sup>2</sup>Reclassification of the withholding tax on R&D salaries (payroll tax rebates)

<sup>3</sup>Excludes €10M short-term deposits

**19**  
**Portfolio  
Products\***



**16**  
**Products in  
Development\***



**3**  
**FDA Approved  
Products**



**3**  
**Commercial  
Products**



**Maxigesic<sup>®</sup>  
IV**  
**(U.S. & ROW)**



for the treatment of  
post-operative pain



**Podofilox  
Gel**  
**(U.S.)**

for the treatment of  
genital & perianal warts



**Sotalol  
IV**  
**(U.S.)**



for the treatment of  
atrial fibrillation



\*Does not include 2 high barrier generics in development

# Letter to Shareholders

Dear Shareholders,

Hyloris has made remarkable advances this past year while navigating the evolving dynamics of the pharmaceutical industry. I am thrilled to share a comprehensive update with you about them, as well as our exciting plans for the future.

We remain committed to repurposing and reformulating existing molecules, primarily utilizing the U.S. FDA's 505(b)(2) pathway and similar pathways globally. This innovative approach allows us to bring critically needed products to market significantly faster and at a fraction of the cost of new chemical entities, all while mitigating risk. Since our initial public offering (IPO) in 2020, we've been intensifying our focus on "repurposing" with reformulated products, solidifying our position as a unique player in the industry.

2023 was a year of marketing approvals for Hyloris' products

- Maxigesic®IV received approval in multiple countries. A significant milestone was achieved in October with the U.S. FDA approval opening up the largest and most attractive market for Maxigesic®IV globally. The U.S. marketing partner, Hikma Pharmaceuticals launched the product under the tradename Combogesic® IV in February (2024).
- The FDA also approved podofilox gel, the first generic ever of Condylox Gel. The approval was obtained in December 2023 by our partner Padagis. This approval is not only a testament to our skill in navigating regulatory pathways, but it also positions us at the forefront of providing patients with cost-effective alternatives.

We also made progress in building our pipeline of innovative products. This year, we added two innovative 505(b)(2) product candidates to our portfolio, solidifying our commitment to innovation and addressing unmet medical needs. Notably, we announced the development of a possibly pioneering treatment for Burning Mouth Syndrome (BMS), a currently underserved area with no approved pharmaceutical treatment. The product candidate is a co-development with our long-standing partner AFT Pharmaceuticals from New Zealand. Additionally, we expanded our portfolio with a product candidate for Hypophosphatemia.

While initially focused solely on the U.S. market, we strategically licensed Atomoxetine oral liquid in Canada. This liquid formulation offers several advantages, including easier administration, individual and precise dosing as well as greater flexibility in tailoring treatment plans, ultimately improving patient adherence and experience. This decision aligns with our commitment to providing innovative solutions for better patient outcomes.

Despite challenging market conditions, Hyloris remains resilient and committed to keeping our shareholders informed. We expect to submit several product candidates to the U.S. FDA within the next 18 months, fueled by the recent positive clinical trial data for our Valacyclovir liquid



formulation. Looking forward, we anticipate a robust year, targeting up to 30 product (candidates) in development, or on the market. This translates to a significant number of announcements, making 2024 one of our busiest years yet in business development.

This ambitious goal is coupled with a commitment to focus on cost-efficiency. We aim to develop all new products for an average cost of less than EUR 7 million (non-inflation adjusted) and within 7 years after announcement. This cost-effective approach, combined with our focus on shareholder value, positions us for sustained growth and profitability. We are confident in our unique position, holding one of the largest dedicated 505(b)(2) value-added development portfolios and maintaining such stringent financial requirement.

In the spirit of full transparency, I acknowledge that the recent suspension of the trading of our company's shares, may have raised questions and created uncertainty for our investors. This temporary measure is related to inquiries regarding the Qliniq product transactions about which we communicated through various press releases. We understand this has caused concerns among many of you and we apologize for any inconvenience. However, it is our expectation that this matter will be resolved upon the publication of this report.

We are committed to upholding the highest standards of corporate governance and are confident in the integrity of our business practice. We ensure you that we will work diligently to implement the measures announced by our Board of Directors to improve our governance practices in the interest of the Company and all its stakeholders.

I'm also pleased to announce the appointment of Thomas Jacobsen as Co-CEO, while we search for a new and independent CEO. Thomas and I co-founded Hyloris and with our company expecting exciting growth, I will be focusing more on strategic implementation to guide us through this expansion. Together with new and expanded leadership, I am confident we will navigate this new chapter with continued success.

Your continued support is crucial as we shape the future of Hyloris. Together, we are driving healthcare advancements through innovation, patient dedication, and a commitment to shareholder value.

Sincerely,

**Stijn Van Rompay**





# Business Overview

## Solid Financial Position

Hyloris' financial performance in 2023 was positive, with total revenue and other income growing to €4.2 million. This trend is expected to continue, with the company forecasting stronger growth in both sales and gross margin for 2024. This optimism is fueled by the recent launch of key products like Maxigesic® IV and Podofilox gel in the U.S. market, along with planned global rollouts and additional commercial deals in the pipeline.

Despite increased investments in research and development (R&D) leading to higher operating expenses, Hyloris managed to maintain stable net operating cash outflow compared to 2022. This demonstrates our commitment to financial discipline while still prioritizing innovation.

Hyloris' financial health remains robust. The Company boasts a solid cash position with **€30.4 million and zero financial debt**. This strong foundation positions Hyloris to capitalize on future growth opportunities.



### 3 commercial products

## COMMERCIAL PROGRESS

Hyloris saw progress across the commercial portfolio in 2023. This is demonstrated by the U.S. FDA approval and subsequent launches of Maxigesic® IV

and Podofilox gel, a rise in royalty contributions from existing commercial partnerships, and strategic out-licensing agreements for additional products in key markets.

Maxigesic® IV is a patented, unique combination of Paracetamol and Ibuprofen for intravenous infusion for the treatment of post-operative pain and is currently licensed to partners covering over 100 countries across the globe. Maxigesic® IV is developed with our partner AFT Pharmaceuticals.

The non-opioid analgesic space and the market for post-operative pain is growing rapidly and is forecasted to reach \$1.7 billion in 2028 in the U.S., up from \$745 million in 2019.

A marketing authorization was granted by the U.S. FDA in October 2023. Hikma Pharmaceuticals (Hikma), a leading supplier of complex injectable hospital products, has launched the product in the U.S. under the tradename Combogesic® IV. An exclusive license and distribution agreement had previously been signed between Hyloris' partner AFT and Hikma.

- Additional submissions for marketing authorization were made in 13 countries in the Middle East, Africa, Latin America, and Asia.
- Additional marketing authorizations have been granted in 8 countries including Poland, South Africa, and Spain. In early 2024, Health Canada granted approval bringing the total number of approvals to 50.
- Launches occurred in 14 countries including Norway, Singapore, Belgium, The Netherlands, the Czech Republic, and Romania. Imminent launches are expected in several additional countries, bringing the total number of countries where Maxigesic® IV will be available up to more than 30.

In December 2023, our partner Padagis US LLC (Padagis) received marketing authorization for Podofilox gel 0.5% (previously referenced as HY-016) from the FDA.

Podofilox gel is an antimycotic drug for the topical treatment of external genital and perianal warts caused by certain types of the Human Papilloma Virus (HPV). Padagis launched the product in December 2023. It is the first generic approved for Condylox® Gel in the U.S.

Sotalol IV is a patented, intravenous formulation of Sotalol for the treatment of atrial fibrillation, and life-threatening ventricular arrhythmias developed for the U.S. Sotalol IV potentially allows to significantly reduce the length of hospital stay and the overall cost of care and potentially improve patient outcomes. Hyloris is taking further steps targeting to increase product related revenues from the sale of Sotalol in the future (see also: [Ongoing Legal Proceedings](#) in the financial notes).

Additional out-licensing agreements for Tranexamic Acid (TXA) RTU – a ready-to-use formulation under development of an established antifibrinolytic used in emergency haemorrhaging situations – were made in 2023. These new agreements cover a large European country and several major Asian countries. In 2023, our licensing partner for Canada submitted an application for approval by Health Canada. Additional regulatory submissions in the partnered territories are in progress, and more out-licensing agreements are expected going forward. An Abbreviated New Drug Application (ANDA) has been submitted to the U.S. FDA.

An out-licensing agreement was signed with Kye Pharmaceuticals (Kye) in October 2023 for Atomoxetine Oral Liquid. Kye will exclusively commercialize the product in Canada where atomoxetine is currently not available as an oral liquid formulation. The introduction of an oral liquid formulation in the ADHD (Attention Deficit Hyperactivity Disorder) medication category has historically led to significant market share gains. This suggests a strong potential for Atomoxetine Oral Liquid in Canada, where an estimated 1.8 million people (or 4-6% of adults and 5-7% of children) are diagnosed with ADHD. ADHD is a chronic condition, with symptoms persisting into adulthood for 60-80% of patients.

Under the terms of the agreement, Hyloris will be eligible to receive attractive sales-related milestone payments (totaling up to USD 7.5 million), and a substantial share of the generated revenue.

**2**  
additional pipeline  
products

## EXPANDED PIPELINE

Hyloris strengthened its product portfolio in 2023.

HY-088 was announced in January 2023. This novel, proprietary oral formulation will be administered to patients with hypophosphatemia – a condition where the blood level of phosphorus is lower than 2.5mg/dL. Patients can develop hypophosphatemia from either a genetic abnormality (such as Cushing Syndrome or osteomalacia) or an acquired condition (like long-term use of diuretics or phosphate binders).

HY-090, a promising new treatment candidate for Burning Mouth Syndrome (BMS) was announced in December 2023. BMS is a chronic condition affecting millions, primarily postmenopausal women, causing a burning, tingling, or scalding sensation in the mouth for months at a time. While the mouth appears healthy, sufferers may also experience dry mouth or taste alterations, the exact cause of BMS remains unknown. Studies suggest that 0.7% to 5% of individuals in the U.S. might be affected.

## POST-CLOSING BUSINESS EVENTS (SEE ADDITIONAL INFORMATION IN NOTES 29)

- HY-091, a novel topical treatment candidate for the management of Vulvar Lichen Sclerosus (VLS), was announced in January 2024. VLS is a chronic inflammatory condition affecting an estimated 3% of women, causing severe pain, itching, and discomfort that significantly impacts their quality of life.
- PTX-252, a novel chelating agent, received Orphan Drug Designation from the FDA in January 2024 for the development of a potential treatment for Acute Myeloid Leukemia (AML).
- Hyloris and Purna Female Healthcare announced positive results from a Phase 2 clinical trial evaluating a treatment for Acute Vulvovaginal Candidiasis (VVC) in January 2024.
- Maxigesic® IV was launched in the U.S. and approved in Canada in February 2024. Hikma Pharmaceuticals will commercialize the product as Combogesic® IV in the U.S.
- The first patient was enrolled in a phase 3 clinical trial for a novel Tranexamic Acid Oral Mouth Rinse (previously HY-004) in early 2024.
- Maxigesic® IV expanded its global reach through licensing agreements in additional markets, including Brazil.

# COMMITTED TO ADDRESSING UNMET NEEDS THROUGH INNOVATION

## Strategy & Strengths

Hyloris is a company driven by a mission to improve lives. We focus on underserved medical needs and aim to bring added value to the healthcare system through innovative reformulations and repurposing of existing pharmaceuticals. Our goal is to change therapy outcomes for the better, ultimately improving the lives of patients worldwide.

We've built a substantial portfolio of proprietary reformulated and repurposed product candidates. This achievement is a result of our expertise and commitment to technological advancements. Since our founding, we've strategically shifted our focus and now concentrate on complex, reformulated, and repurposed products with patents. This strategic shift positions us further up the value chain within the pharmaceutical industry.

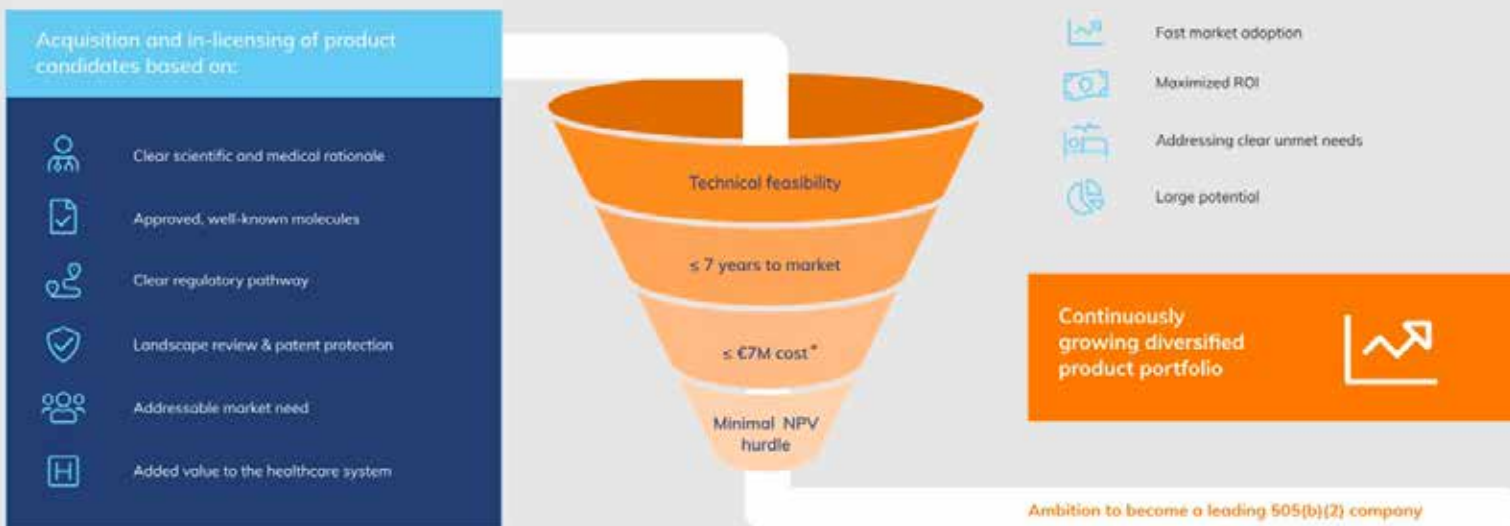
Our development strategy hinges on a streamlined approach. We primarily utilize the 505(b)(2) regulatory pathway in the U.S. and similar pathways in other countries. These pathways are specifically designed for pharmaceuticals where safety and efficacy (in some instances) are already established. This targeted approach significantly reduces the clinical development burden required to bring a product to market. As a result, we can shorten development timelines, minimize costs, and mitigate risks associated with bringing new drugs to market.

To achieve our ambitious goals, we maintain continuous dialogue with key stakeholders. This includes healthcare professionals, patient groups, payers, universities, and potential corporate partners. Additionally, we leverage our extensive sourcing network and robust R&D capabilities to fuel our innovation engine.

We focus on value-added medicines — **pharma's sweet spot**.

### Focus on patented value-added medicines





## FOCUS ON VALUE CREATION THROUGH EFFICIENT DEVELOPMENT

The Company's mission is to generate value through product development. We prioritize products eligible for the **505(b)(2) pathway** due to its numerous advantages. Compared to the traditional 505(b)(1) pathway, this approach allows for faster development, reduced risks, and lower costs.

## BUILDING A PIPELINE OF INNOVATIVE SOLUTIONS

Hyloris is dedicated to creating a robust portfolio of patented, complex, and valuable products that address unmet medical needs. We achieve this by leveraging a time and capital-efficient approach – the 505(b)(2) regulatory pathway in the U.S. and similar pathways in other countries. This streamlined process allows us to focus our resources on developing products with significant market potential.

Hyloris employs a rigorous selection process for our 505(b)(2) product candidates. This process involves:

**Sourcing and Validation:** All candidates are identified through multiple channels and validated based on scientific and medical insights from our extensive network of physicians and key opinion leaders (KOLs).

**Strategic Selection Criteria:** All candidates must meet predefined criteria, including:

- Ability to address significant unmet medical needs
- Technical feasibility for development
- Average development cost €7 million or less\*
- Development timeline under 7 years
- Potential for patent and trade secret protection
- Strong expected return on investment

**Hyloris' goal is to establish a diversified and growing product pipeline with 30 key assets by 2025 which might include early stage product candidates.** This will solidify our position as a leader in the development of 505(b)(2) products.

## ADVANTAGES OF THE 505(B)2 PATHWAY

**Reduced Risks and Costs:** Development risks and costs associated with reformulating existing drugs are substantially lower.

**Lower Formulation Risk:** Developing new formulations of well-documented drugs minimizes potential formulation issues.

**Lower Clinical and Regulatory Risk:** Reformulating approved drugs typically requires fewer studies, leading to a higher probability of success and faster regulatory approval.

**Shorter Timelines:** Development timelines are significantly shorter, averaging five years compared to eight to fifteen years for new chemical entities (NCEs).

**Lower Costs:** Development costs are expected to average €7 million per product\*.

**Lower Commercial Risk:** Since these products reference established drugs, there is greater user awareness among physicians and payers. We will leverage this awareness by demonstrating the added value our products bring to the market.

**Competitive Advantage:** While the chemical entity of 505(b)(2) products typically cannot be patented, we file other patents (formulation, process, method of use) to protect our products from generic competition.

\*Not adjusted for inflation

## **PROTECTING INNOVATION AND BUILDING EXPERTISE**

For all our 505(b)(2) candidates, we have a long-term strategy to file and protect intellectual property (IP) to maximize their commercial lifespan. Our diverse patent portfolio provides broad protection, encompassing dosages, formulations, medical indications, and production methods.

## **TAILORED GO-TO-MARKET STRATEGIES**

Our go-to-market strategy is flexible and adapts to each product's needs. In the U.S., for our cardiovascular portfolio, we currently plan to leverage a lean sales force to target specific sub-segments such as electrophysiologists. This approach is cost-effective given the high number of cardiologists employed by hospitals. We will also consider potential commercialization opportunities outside the U.S.

For existing products like Sotalol IV and Maxigesic® IV, we maintain commercial partnerships with AltaThera and AFT Pharmaceuticals for marketing, sales, and distribution, respectively. Hyloris aims to have most products in the Value Added portfolio commercialized through regional marketing experts.

## **GENERATING REVENUE STREAMS FOR SUSTAINABLE GROWTH**

Sales from our current commercial products, Maxigesic® IV, Podofilox gel, and Sotalol IV, will be the primary drivers of short-term revenue growth. For future products, we expect to out-license the majority at a late stage of development. This strategy prioritizes product sales over upfront milestone payments and allows us to retain a significant share of the net product margin from our commercial partners.





# LOOKING AHEAD

## Expectations for the next 15 months

### Commercial

The Company is actively accelerating the growth of its product pipeline, aiming to reach 30 products by 2025. The Business Development team will continue to actively seek out and evaluate products from multiple sources (including early staged product candidates). They will also continue to find commercial partners for our late-stage portfolio products.

Maxigesic® IV – We expect to see adoption in the U.S. market as Hikma recently started to promote the product. Outside of the U.S. we anticipate additional marketing authorizations in the countries where submissions were made followed by commercial launches.

### R&D

With 16 reformulated and repurposed product candidates, and 2 high-barrier generics, several clinical trials are expected to start and/or finish within 2024, including product candidates.

- HY-074, a PK bridging study is estimated to start at the end of 2024
- Dofetilide, results from pivotal clinical study are expected before end of 2024
- Tranexamic Acid Oral Mouth Rinse, LPLV of the Phase 3 trial started in November 2023 is expected by year-end with study results anticipated in H1 2025
- Alenura™, a pivotal Phase 2 clinical trial comparing the effectiveness of Alenura™ against its individual components and a placebo is expected to be completed (LPLV) in H1 2025

The company is also expecting several regulatory achievements in the next 15 months.

# COMMERCIAL PORTFOLIO

## MAXIGESIC® IV: U.S. FDA APPROVED FOR THE TREATMENT OF POST-OPERATIVE PAIN

**2023 Highlight:** The U.S. FDA approved Maxigesic® IV for commercialization in the U.S. Hikma Pharmaceuticals launched the product in early 2024 under the registered tradename Combogesic® IV.

### POST-OPERATIVE PAIN AND THE OPIOID CRISIS

Pain, a distressing combination of sensory and emotional feelings, is typically caused by tissue damage or illness. As a widespread condition, it significantly impacts patient health and quality of life. The duration of pain can be short-lived (acute pain) or long-lasting (chronic pain). In hospitals, acute pain is often categorized as either post-operative or non-operative. Post-operative pain results from tissue damage during surgery, which stimulates nerves and triggers a sensory and emotional response in the brain.

Despite its predictability after surgery, managing post-operative pain remains a significant challenge for anaesthesiologists. In the United States alone, over 50 million surgeries were performed in 2019. Pain is still the leading cause of unexpected hospital readmissions following surgery. More than 80% of patients experience moderate pain, and a significant portion (31-37%) suffers from severe or extreme pain<sup>1,2</sup>.

Traditionally, pain management is achieved through the use of specific medications. This makes it one of the most frequently addressed issues by physicians. However, significant improvements in pain management strategies have been limited in recent decades. Pain medications can be classified into two main groups:

**Anesthetics** are drugs used to induce a temporary loss of sensation or awareness of feeling (ie pain). Anesthetics are categorized as either general (loss of consciousness) or local (small area such as a surgical site).

**Analgesics**, in contrast, are medications specifically used to relieve pain without causing a loss of consciousness. These are classified as either opioid or non-opioid.

Maxigesic® IV is a powerful analgesic that can help manage post-operative pain in a way that may decrease reliance on opioids.



1 Coley K et al. J Clin Anesth. 2002

2 Wonuk Koh et al, Korean J Anesthesiol. 2015

## OUR POTENTIAL SOLUTION: MAXIGESIC® IV: AN INNOVATIVE, PATENTED, IV FORMULATION OF PARACETAMOL PLUS IBUPROFEN TO COMBAT THE OPIOID CRISIS

Injectable formulations of analgesics are commonly chosen when oral medications cannot be taken by patients. This can occur when a faster onset of pain relief is needed, or when injection is simply the more convenient administration method. In hospital settings, a variety of reasons can prevent patients from taking medications orally. These reasons include post-anesthesia sedation, other forms of sedation, nausea, vomiting, limitations of the gastrointestinal system, or other underlying conditions.

Maxigesic® IV represents a novel and unique combination. This injectable solution, designed for post-operative use in hospitals, combines 1000mg of paracetamol with 300mg of ibuprofen.

There exists a pressing need for safer and more effective pain management options in hospitals that do not rely on opioids. Due to its unique dual mode of action, Maxigesic® IV has the potential to become a valuable tool for treating pain. This potential comes without the side effects and risks of addiction associated with opioids.

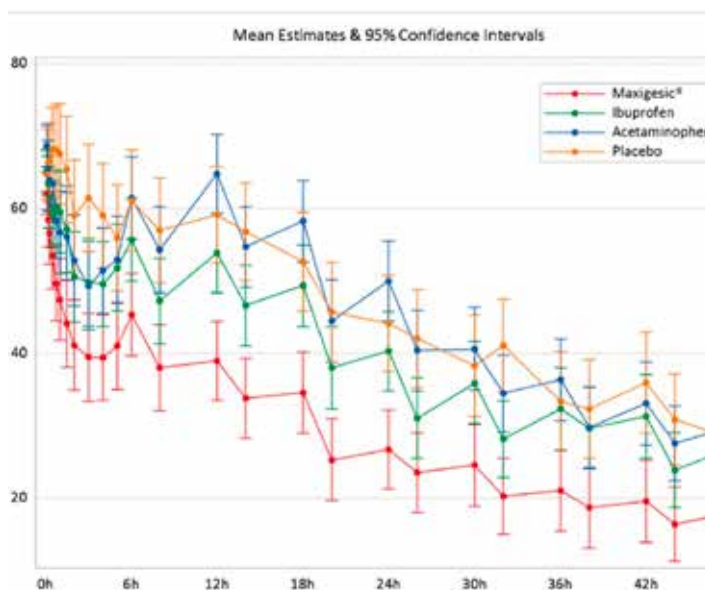
Findings from a randomized, double-blind, placebo-controlled Phase 3 trial involving 276 patients who underwent bunion surgery were positive. The trial demonstrated that Maxigesic® IV was well-tolerated and offered several advantages. Compared to ibuprofen IV or paracetamol IV administered alone at the same doses, Maxigesic® IV provided a faster onset of action and superior pain relief. Additionally, a range of secondary endpoints supported the superior analgesic effect of Maxigesic® IV, including a reduction in opioid consumption compared to the paracetamol IV and ibuprofen IV treatment groups ( $P < 0.005$ )<sup>1</sup>. Furthermore, an additional exposure study has confirmed the efficacy and safety of Maxigesic® IV in a broader patient population over a longer treatment period<sup>2</sup>.

## MAXIGESIC® IV 2023 NUMBERS

**8**  
New  
Marketing  
Authorizations

**13**  
Marketing  
Applications

**14**  
commercial  
launches



<sup>1</sup> Daniels et al, 2019, Clinical Therapeutics

<sup>2</sup> Maxigesic® IV Phase 3 exposure study. Study ID No AFT-MXIV-11. NCT04005755. Submitted for publication

# COMMERCIAL PORTFOLIO

## PODOFILOX GEL

U.S. FDA approved for the treatment of genital & perianal warts caused by certain types of the human papilloma virus (HPV)

Podofilox Gel is an antimycotic drug for the topical treatment of external genital and perianal warts caused by certain types of the Human Papilloma Virus (HPV). Around 1% of the sexually active population in the U.S. presents with genital or perianal warts. To date there is a vaccine for HPV but no cure.

In December 2023, our partner Padagis US LLC (Padagis) received marketing authorization for Podofilox Gel 0.5% from the FDA. Padagis launched the product in December 2023. It is the first generic for Condylox® Gel in the U.S.

For the 12 months period ending December 2022, Condylox® Gel had U.S. sales of approximately \$9 million according to IQVIA Health.

## SOTALOL IV

Atrial fibrillation

Atrial fibrillation (AF) is an irregular heartbeat that starts in the upper chambers of the heart (atria). Normally, these chambers beat regularly and in a coordinated way with the lower chambers (ventricles). With AF, the atria quiver instead of beating effectively, which disrupts the normal flow of blood through the heart. AF can cause symptoms like heart palpitations, fatigue, shortness of breath, and dizziness. It can also increase risk of stroke and heart failure. There are different types of AF, and treatment options

depend on the severity and frequency of the condition.

Antiarrhythmic drugs are frequently given in hospitals to control the heart's rhythm. Oral potassium channel blockers are the leading type, with amiodarone, dronedarone, and sotalol being prominent examples. While commonly used, sotalol carries a strong warning due to the increased risk of irregular heartbeats they can cause. Because of this risk, patients starting treatment with sotalol require close monitoring in a hospital setting for several days until safe drug levels are established in their bloodstream.

Traditionally, patients starting sotalol require a 3-day hospital stay for monitoring. Sotalol IV is infused for over one-hour. It acts quickly, allowing for a smooth transition from initial IV administration to long-term oral treatment. This approach, beginning with Sotalol IV followed by oral sotalol, could potentially significantly shorten hospital stays.

In March 2020, the FDA approved the expanded label of Sotalol IV to using Sotalol IV in adult AF patients until near steady-state exposure to Sotalol is achieved prior to initiating or increasing oral Sotalol dosing.



# DEVELOPMENT PORTFOLIO

## Cardiovascular

Our cardiovascular development portfolio currently contains 6 product candidates at varying stages of development. For the majority of the portfolio, we intend to commercialize the products in the U.S. by ourselves. We plan to build a lean efficient commercial organization that focuses on cardiology specialists in specialty care centers and hospitals.



### ASPIRIN IV

#### Indication

Decrease the risk of morbidity and mortality associated with an emergency cardiac event (such as myocardial infarction (AMI) or stroke).

#### Unmet Need

When AMI or ischemic stroke is suspected, patients are instructed to chew or swallow an aspirin tablet as soon as possible after symptoms arise. However, clinical research has shown that oral aspirin takes between 20 and 40 minutes to take effect and the amount of aspirin absorbed is highly variable; often only half of the administered dose is absorbed.

#### Potential Solution

Intravenous formulation of aspirin for faster onset of action and decrease inter/intra-patient variability of amount of aspirin absorbed.

#### Intellectual Property

'38, granted and pending applications.

### Target Population

Every year about 850,000 in the U.S. experience a heart attack<sup>1</sup>.

### MILRINONE ER

#### Indication

The treatment of right heart failure due to Left Ventricular Device (LVAD).

#### Unmet Need

Milrinone is currently only available as an intravenous solution for continuous infusion. Patients must travel to an infusion clinic where they are monitored closely for any significant adverse reactions. Their dose is adjusted based on hemodynamic responses. IV milrinone is currently limited to a 48-hour time period.

#### Potential Solution

An extended release oral solid formulation of milrinone to allow for long term at-home use.

<sup>1</sup> Tsao et al. Heart Disease and Stroke Statistics—2023 Update: A Report From the American Heart Association. Circulation. 2023;147:e93–e621

**Special Regulatory Designation**

Orphan Drug Designation

**Target Population**

In 2020, there were about 20,000 patients with an LVAD implant in the U.S. and 30% of these patients developed right heart failure. Over the next coming years, the LVAD patient population is expected to grow at an average annual growth rate of 6% in the U.S.

**DOFETILIDE IV****Indication**

Atrial fibrillation.

**Unmet Need**

Patients that are unable to take an oral medication or that require faster onset.

**Potential Solution**

An intravenous product administered in hospital setting providing similar exposure as that of the approved oral product.

**Intellectual Property**

'39, granted and pending applications.

**HY-074 IV****Indication**

Reduce the risk of morbidity and mortality associated with an emergency cardiac event (such as myocardial infarction (AMI) or stroke).

**Unmet Need**

Despite the need for fast onset of action drugs in an acute cardiac event, the majority of current standard of care treatments only available in oral form.

**Potential Solution**

Intravenous formulation of a current standard of care treatment to offer faster onset of action, more convenient administration, and dosage control.

**Intellectual Property**

Application filed.

**Target Population**

Every year about 1.6 million people in the U.S. experience a heart attack or stroke<sup>1</sup>.

**METOLAZONE IV****Indication**

The treatment of salt and water retention including:

- edema accompanying congestive heart failure;
- edema accompanying renal diseases, including the nephrotic syndrome and states of diminished renal function.

**Unmet Need**

CHF is progressive and there is currently no cure available.

Patients can be administered a combination of a loop diuretic with a thiazine-like diuretic such as metolazone tablets. However, tablet formulations have highly variable bioavailability and erratic absorption, particularly in patients with severe gastrointestinal oedema.

**Potential Solution**

Intravenous formulation of metolazone for faster onset of action (essential in critical care); improved drug absorption and concomitant treatment possible.

**Intellectual Property**

Granted & pending applications.

**Target Population**

Around 870,000 new cases per year in the U.S. and 8 million people in the U.S. expected to suffer from CHF by 2030. By 2030, the total cost of heart failure is forecasted to reach \$69.8 billion.

## HY-075 IV

### Indication

Prevention and treatment of specific cardiovascular diseases.

### Unmet Need

The currently approved oral solid requires frequent dosing changes and adjustments. The product is only available in fixed-dose scored tablets that may have to be cut.

### Potential Solution

An oral liquid solution designed to significantly improve drug administration, ease of use, and dosage control, potentially resulting in potential better compliance and patient outcomes.

### Intellectual Property

Confidential.

### Target Population

Cardiovascular disease is the leading cause of death in the U.S. with more than 370,000 deaths every year.























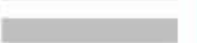












# DEVELOPMENT PORTFOLIO

## Other Value-Added

Our portfolio of other value-added products currently contains 10 product candidates at varying stages of development. All products in the value-added portfolio are intended to be commercialized through region-specific partners who have intimate knowledge of their target markets.

Product	Route of Administration	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Target Market
OTHER VALUE-ADDED (OVA) PORTFOLIO*			Up to 7 years 			
Tranexamic Acid OR	Oral Liquid	Specific dental indication				
Alenura™	PFS	IC / PBS				
Miconazole-DB	Topical	Severe and rVVC				
PTX-252	IV	AML/SCLC				
Atomoxetine	Oral Liquid	ADHD				
HY-029	Oral Liquid	Viral infection				
HY-083	Nasal Administration	Idiopathic Rhinitis				
HY-088	Oral Liquid	Hypo Phosphatemia				
HY-090	Oral Liquid	Burning Mouth Syndrome				
HY-091	Muco Adhesive Patch	Vulvar Lichen Sclerosus				

### TRANEXAMIC ACID ORAL RINSE (PREVIOUSLY HY-004)

#### Indication

To prevent and treat excessive bleeding in patients on blood thinners undergoing dental procedures.

#### Unmet Need

Patients on blood thinners can experience significant bleeding during dental procedures.

#### Potential Solution

A reformulated oral rinse developed for use in minor surgical procedures with complications/bleedings to be used by dental care professionals for patients on anti-coagulant therapies.

#### Intellectual Property

'39; granted and pending.

### ALENURA™

#### Indication

Treatment of pain associated with interstitial cystitis/ bladder pain syndrome (IC/BPS).

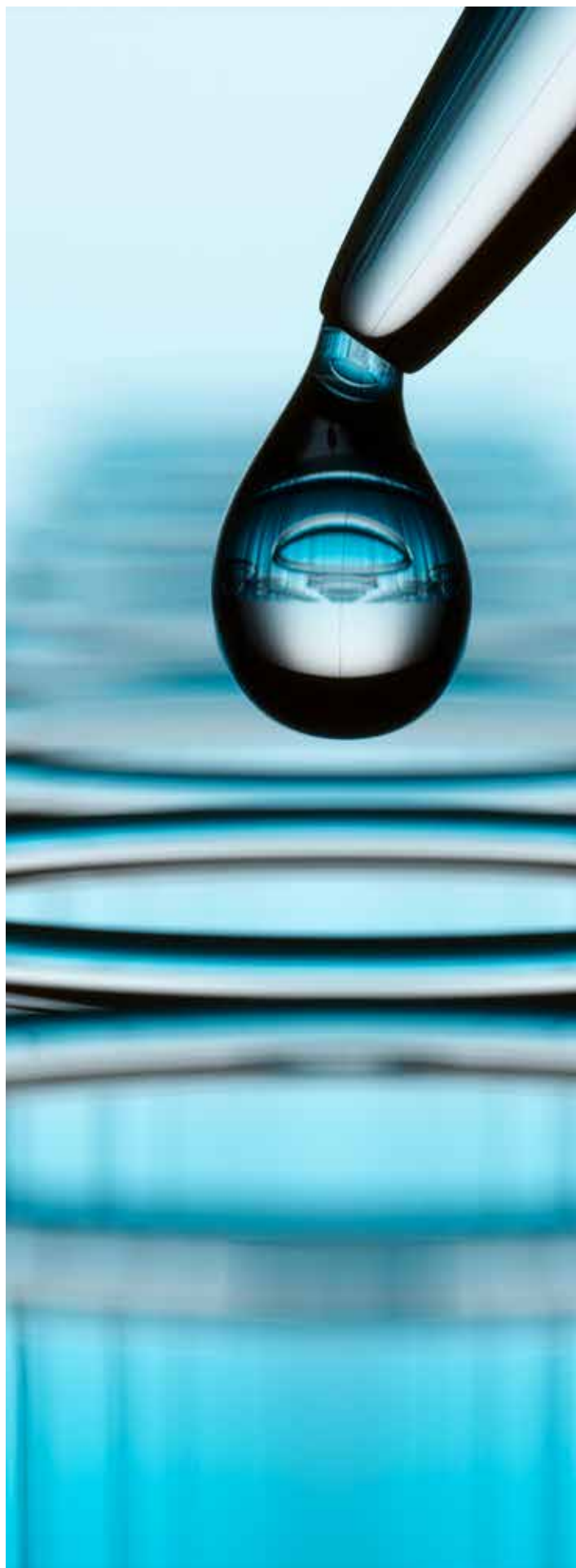
#### Unmet Need

There is currently no standardized treatment protocol. Available treatments have significant limitations such as high cost, delayed onset of effect, and serious side effects.

IC/BPS is more prevalent in women, although men can experience symptoms as well. It is estimated at least 6 million people in the U.S. suffer from the condition.

#### Potential Solution

A ready-to-use solution with an innovative dual mode of action that may provide immediate symptom relieve and potentially aid in the regeneration of the bladder lining. The product is being co-developed with Vaneltix.



### Intellectual Property

'28-'38; granted.

## MICONAZOLE/DOMIPHEN BROMIDE CREAM

### Indication

Treatment of recurrent vulvovaginal candidiasis (rVVC).

### Unmet Need

rVVC is a chronic and debilitating vaginal infection commonly caused by *Candida albicans*. Current treatments include topical and systemic anti-fungals. These products limited efficacy and severe side effects when used chronically.

### Potential Solution

A topical cream combination product containing Miconazole (MCZ), a current standard antimycotic treatment, and Domiphen Bromide (DB), a well-known anti-septic currently used in some cough medicines. We are co-developing the product with Purna Female Healthcare.

### Intellectual Property

'38; granted and pending.

## PTX-252 (PREVIOUSLY PLECOID AGENT)

### Indication

Treatment of Acute Myeloid Leukemia (AML).

### Unmet Need

AML is an aggressive hematological malignancy that originates from immature white blood cells in the bone marrow. AML generally spreads quickly to the bloodstream where it can then spread to other parts of the body including lymph nodes, spleen, and the central nervous system. The 1-year and 5-year survival rates are approximately 50% and below 30%, respectively.

Research has shown that treatment resistant AML have significantly elevated levels of toxic metals in their bone marrow and blood. This contributes to the poor overall survival rate.

### Potential Solution

An intravenous solution containing a chelating agent as an adjunctive therapy aimed at decreasing elevated blood levels of toxic metals. We are co-developing this product with Pleco Therapeutics.

**Intellectual Property**

Pending application.

**ATOMOXETINE ORAL LIQUID****Indication**

Treatment of Attention Deficit Hyperactivity Disorder (ADHD).

**Unmet Need**

ADHD is among the most common neurobehavioral problems affecting children between the age of 6 and 17. It is a chronic disorder characterized by developmentally inappropriate and impaired attention, motor hyperactivity, and impulsivity. These symptoms often continue into adulthood. The prevalence of ADHD in the U.S. ranges from 2% to 18% in this age group.

Treatment options for ADHD are categorized as either a stimulant or a nonstimulant. Straterra® (atomoxetine HCl) is the leading nonstimulant medication for ADHD<sup>1</sup>. However, dosing for children and adolescents less than 70 kg (154) lbs is weight-based and can be difficult to titrate. Too small of a dose and the desired effect may not occur. Too large of a dose and patients can experience side effects ranging from dry mouth to blurred vision. Atomoxetine is also notoriously bitter tasting.

**Potential Solution**

A taste-masked oral solution of atomoxetine for precise dosing and titration as well as palatability.

**Intellectual Property**

'36-'43; granted & pending applications.

**HY-083****Indication**

Treatment of Idiopathic rhinitis.

**Unmet Need**

Idiopathic rhinitis is a medical disorder characterised 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. Idiopathic rhinitis features an overexpression of TRPV1 in the nasal mucosa giving rise to nasal

obstruction, rhinorrhoea (colloquially: a runny nose), and/or sneezing. Approximately 19 million people in the US and 25.8 million in Europe are affected with idiopathic rhinitis and seek treatment.

Current treatment options for idiopathic rhinitis are not consistently successful. This leads to unnecessary and often ineffective surgery for severe cases, such as nasal septal corrections and/or inferior turbinate reductions.

**Potential Solution**

A proprietary formulation of a molecule with a well-known mechanism of action to activate and depolarise TRPV1 receptors leading to restoration of a normal function of the nasal mucosa.

**Intellectual Property**

Confidential.

**HY-088****Indication**

Treatment of hypophosphatemia.

**Unmet Need**

Hypophosphatemia is a deficiency of the vital mineral phosphate in the blood. While mild hypophosphatemia is common and many patients are asymptomatic, severe hypophosphatemia can be life-threatening and requires medical treatment. The condition can result in different health challenges, including muscle and bone weakness, respiratory or heart failure, seizures or coma. Deficiency of this vital mineral is always linked to an underlying condition, such as diabetes, anorexia, use of diuretics or alcohol abuse.

Currently, physicians mostly rely on compounded drugs which have, by definition, not been submitted for regulatory scrutiny regarding safety, efficacy, and quality.

**Potential Solution**

An oral solution to replace compounded drugs which have, by definition, not been submitted for regulatory scrutiny regarding safety, efficacy, and quality.

**Intellectual Property**

Confidential.

**HY-090****Indication**

Treatment of Burning Mouth Syndrome (BMS).

**Unmet Need**

Burning mouth syndrome (BMS) is characterized by burning pain in a normal-appearing oral mucosa lasting at 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. The reported prevalence ranges from 0.7% to 5% of individuals in the U.S. and occurs more frequently in women than men, with a female to male ratio of 7:1. Prevalence increases with age in both men and women, with the highest prevalence reported in postmenopausal women aged 60–69 years.

**Potential Solution**

A novel oral solution that works locally to treat BMS.

**Intellectual Property**

Confidential.

**HY-091****Indication**

Treatment of Vulvar Lichen Sclerosis.

**Unmet Need**

Vulvar Lichen Sclerosus (VLS) is a chronic, distressing, inflammatory disease with an enormous impact on quality of life. Women with VLS can experience severe pain, intense persistent itching, and skin discoloration. There is no curative treatment for VLS, which usually occurs in postmenopausal women, although children and premenopausal women may be affected. Advanced condition severely affects the quality of life and is associated with increases risk of vulvar squamous cell carcinoma. It is a massively underdiagnosed condition, which affects 0.1% to 3% of the general population.

**Potential Solution**

A user-friendly mucoadhesive product with a convenient application method that ensures simplicity and compliance, offering targeted relief for patients experiencing the discomfort, itching, and pain associated with VLS by reducing inflammation and scarring in the affected area of skin and helping in restoring the skin structure.

**Intellectual Property**

Confidential.

**Outside our core strategic focus, we have 2 high barrier generic products in development:**

*Fusidic Acid Cream*, a generic of an off-patent reference product currently sold in Canada without generic competition

*Tranexamic Acid RTU*, a ready to use tranexamic acid solution for infusion. The product has been filed as a generic in the U.S. and as a value-added product outside the U.S., where it has already been partnered in UK, Switerland, one major Asian country, Canada, Australia and New Zealand.





# Environmental, Social, and Governance



# Introduction

ESG (Environmental, Social, and Governance) is becoming increasingly important for the pharmaceutical industry. While developing life-saving drugs is a social good, there's a growing focus on how pharma companies operate sustainably across a range of areas. Environmental considerations include reducing waste and emissions from manufacturing, while socially, fair labor practices, access to medication, and responsible drug pricing are crucial. Strong governance ensures transparency and minimizes risks like fraud or corruption. By prioritizing ESG, Hyloris can build trust with our investors, development partners, and the public, all while ensuring a sustainable and responsible approach to healthcare.

In 2023 Hyloris focused on its commitment towards the sustainability goals it set in 2022. When defining these goals, the Company utilized the United Nations Agenda for Sustainable Development (UNSD). This framework contains 17 global goals for achievement by 2030. Under those goals are 167 different targets each with their own set of metrics. Companies can choose which of these goals and targets most closely align with their priorities.





# Review of Selected UNSD Goals & Targets



Hyloris considered both our core mission and measurable targets when defining the appropriate goals for its ESG strategy in 2022. The goals and targets we chose were organized into 3 separate imperatives.

**Commitment to the Good Health and Well-Being of Society**

**Commitment to Environmental Sustainability**

**Commitment to Responsible Leadership**

## Commitment to the Good Health and Well-Being of Society

### 3 GOOD HEALTH AND WELL-BEING



### Access to safe, effective, quality, and affordable essential medicines

Hyloris focuses on innovation through reformulation and repurposing existing, approved medications. This approach tackles unmet medical needs in areas like cardiovascular disease, the world's largest therapeutic area. We currently have 18 value-added medicines in the portfolio, with two already commercially available.

Outside of our core portfolio, we also have in the portfolio the first commercially available Podofilox Gel in the U.S. ensuring patients suffering from anogenital warts have access to affordable treatment. By leveraging proven safety profiles, our strategy significantly reduces development time and cost, potentially leading to more affordable treatments for patients and healthcare systems. Ultimately, Hyloris aims to develop over 30 products.

### Part of the Solution to the Opioid Crisis

The fight against drug abuse is taking a health-centered approach, as outlined by the UN's Sustainable Development Agenda. This is crucial considering the devastating impact of opioids, highlighted by the World Health Organization (WHO). According to the WHO, drug abuse claims over half a million lives annually, with opioids responsible for a staggering 70% of these deaths. Their report further reveals a concerning rise in opioid overdoses, partly linked to the increased use of these drugs for post-operative pain, chronic pain management, and the emergence of highly potent illicit opioids.

Our commercially available product Maxigesic® IV is a novel non-opioid analgesic for the treatment of post-operative pain. In 2023 Maxigesic® IV was approved in the U.S. which has more than double opioid-related deaths than other countries. The product is now approved in over 50 countries with plans for additional marketing authorization submissions – including most developing nations.

### A Portfolio Focused on the Leading Cause of Death

Cardiovascular diseases (CVDs) are a global health crisis, claiming millions of lives each year. According to the World Health Organization (WHO), CVDs were responsible for a staggering 17.9 million deaths in 2019, representing over a third of all global deaths. Heart attacks and strokes make up a significant portion of these fatalities, accounting for 85 percent. Recognizing this critical public health issue, Hyloris dedicates a third of our product development pipeline to addressing cardiovascular diseases.

Our first commercial product, Sotalol IV for atrial fibrillation, prioritizes both patient safety and cost-effectiveness. By significantly reducing hospital stays, particularly relevant in the US market with its high overnight costs, Sotalol IV can dramatically lower the overall burden of care. This translates to improved patient outcomes while minimizing healthcare system expenses.

## Commitment to Environmental Sustainability

*Hyloris is actively combating the environmental challenges of biodiversity loss, pollution, and climate change through specific initiatives*



### Location of Headquarters and Lab

Our headquarters are located in LégiaPark in Liege. LégiaPark is a top-rated green building – a BREEAM-certified facility with an “Excellent” performance rating. BREEAM (Building Research Establishment Environmental Assessment Method), the world’s leading standard for sustainable buildings, recognizes this space as not only eco-friendly but also designed for employee comfort and well-being. In 2023 we also relocated our R&D laboratory facility to this complex.

### Raising the Bar for Our Suppliers

Hyloris prioritizes responsible sourcing practices when selecting partners for drug development and manufacturing. Our selection process goes beyond traditional metrics like product quality and supplier capabilities. We also evaluate a partner’s environmental, social, and governance (ESG) practices to ensure alignment with our commitment to sustainability.

### Leading the Push for Electric Vehicles

Hyloris is proactively transitioning the company car fleet ahead of Belgian legal deadlines. The Company has significantly reduced combustible engine vehicles from our pre-approved leasing options thereby doing its part to lower emissions. In their place, Hyloris has introduced a wide selection of plug-in hybrid (PHEV) and battery electric vehicles (BEV), actively promoting the switch to electric cars.



## Commitment to Responsible Leadership

**8** DECENT WORK AND  
ECONOMIC GROWTH



### A Virtual, Flexible Workspace

Hyloris fosters a collaborative global environment with a hybrid work model combining in-office and remote-work. Our geographically diverse teams leverage virtual meetings as the standard, with over 90% of recurring meetings held online. This reduces commuting and fosters a flexible work-life balance for our employees with a minimum 2-day on site in the office. To further minimize travel burdens, Hyloris provides hotel accommodations for colleagues needing to bridge in-person workdays.

### Key Values, Accountability, and Leadership Culture

In 2023 Hyloris included four key values into employees' annual review procedure:

- Passion and drive
- Entrepreneurship
- Professional excellence
- Integrity and accountability

The HR team continued to formalize the employee performance review process over 2023. Included in this was incorporating empowerment and coaching to our colleagues in leadership positions.

### Dedication to Workplace Safety

The company is committed to providing a safe and healthy workplace for all employees. Our HR team has enacted a 5-year plan that encompasses several key areas:

- Establishing clear processes, procedures, documentation, and registrations to promote the general welfare of our employees;
- Prioritizing work safety and ergonomics by providing safety trainings (fire response, first aid, etc) and optimizing the physical environment;
- Promote the physical and mental well-being of our employees by offering resources such as regular medical checkups for lab personnel and dedicated maternity policies.

*“At Hyloris, employee well-being isn’t a perk, it’s a priority. We believe a healthy, safe, and supportive work environment fuels success for both individuals and the company. Our flexible, location-independent work model reflects this commitment. Looking ahead, we’re actively developing even more benefits to help our team manage stress, achieve work-life balance, and thrive in their careers and in their personal lives.”*

Peter Mertens, HR Director

## Respect for Global Expertise

At Hyloris we believe in “looking for expertise where it is available”. Our workforce can be found in 11 different countries spanning 3 continents – Europe, North America, and Asia.

## Pursuit of Gender Equality

Hyloris is actively working to enhance diversity at all levels, with a particular focus on increasing female representation on our Board of Directors. Currently, we have one female Director, and ongoing efforts are underway to attract more women with valuable experience to contribute to our highest decision-making body.

While our overall company gender balance is currently at **48% women and 52% men**, we remain committed to achieving greater diversity in leadership positions. This includes the VP, director, and manager levels, which currently reflect the global gender ratio.

Looking ahead, we aim to maintain a balanced workforce while actively seeking opportunities to build a more diverse team across all levels, including leadership.

**Hyloris employs 41 people of 11 different nationalities:**

- American
- Austrian
- Belgian
- Danish
- French
- Greek
- Indian
- Portuguese
- Slovenian
- Spanish
- Swiss



## Ethical Business Practices

Hyloris prioritizes ethical behavior in all interactions, from customer and supplier relationships to internal company culture. This commitment is reflected in our comprehensive ethical guidelines, which all employees are required to follow. These core principles address essential areas like personal conduct, conflict of interest, confidentiality, influence, and competition.

### **Ethical Business Practices Continued...**

Furthermore, Hyloris has established a dedicated “Dealing Code” to ensure compliance with market regulations. This code specifically addresses market abuse practices such as insider trading, information disclosure violations, and market manipulation. It also outlines guidelines for financial transactions by those with managerial responsibilities and their associates.

By implementing these clear standards, Hyloris fosters a culture of integrity and transparency throughout the organization.

### **Checks & Balances in Place at the Highest Level**

Hyloris adheres to the high standards of corporate governance expected of a publicly traded company in Belgium. Our Board of Directors reflects this commitment, with four out of eight members classified as Independent Directors in 2023. Further strengthening transparency and accountability, the Remuneration Committee is comprised solely of Non-Executive Directors, with a majority being independent (See [note 29](#)).



### **Less Animal Testing**

By leveraging the 505(b)(2) development pathway, Hyloris can potentially reduce the need for extensive early-stage research compared to traditional 505(b)(1) approaches for new drugs. This allows us to focus our efforts on developing valuable medicines while potentially minimizing the use of animal testing. We remain committed to exploring alternative testing methods wherever possible.

**In 2022 Hyloris outlined four performance indicators to track its medium-term progress towards sustainability.**

**In 2023 we took action to meet or exceed those targets.**

**Indicator**

At least one third of the members of our Board must be of another gender than the other members by 2026

**2023 Action**

Actively sought women candidates

**Indicator**

Increased focus on sustainability factors in the selection procedure for suppliers

**2023 Action**

Increased focus on sustainability factors in the selection procedure for suppliers

Started a vendor database to track approved vendors

**Indicator**

Maintaining or improving diversity of workforce with different nationalities and cultural backgrounds

**2023 Action**

Maintained the same number of nationalities (11) from 2022 to 2023

**Indicator**

Maintaining or improving gender equality across all levels of the team

**2023 Action**

Increased the percentage of women in the company from 40% in 2022 to 48% in 2023

# Looking Ahead

While we remain committed to the goals we set in 2022, we strive to create as sustainable a business as possible and mitigate risk where we can. To that end, we plan to engage in 2024 a 3rd party consulting firm that specializes in ESG strategy and reporting. We will partner with them on a 3-stage project that critically examines all aspects of Hyloris' business. The project is expected to begin in H1 2024.

## Phase 1 Gap Analysis

Our ESG partner will conduct a review of our current plan to include:

- Defining our specific sustainability goals;
- Evaluating our current performance across the various metrics relevant to our goals;
- Identifying the gaps between our current practices and our desired practices to show where improvement is needed.

This work will produce a non-misleading score of Hyloris' current ESG performance.



## Phase 2 Double Materiality A

A **double materiality** assessment is used by companies to determine which sustainability topics are most important. It takes into account two

**Impact Materiality:** This perspective focuses on environmental and social impacts from the company's operations. Essentially, it asks, "How do our operations affect the world?" This could include emissions, water usage, labor practices, and community relations.

**Financial Materiality:** This perspective focuses on how sustainability issues affect the company's financial performance. It asks, "How do environmental and social issues affect the company's bottom line?" This could include risks associated with climate change, regulatory changes, or changes in consumer preferences.

Our partner will evaluate Hyloris' internal and external perspectives by engaging with key stakeholders inside and outside (wherever possible) to allow them to prioritize ESG issues that matter to the business.





## Assessment

Assessment is a framework to determine which ESG factors are most important to report from two key perspectives:

The first perspective considers the external impacts of a company's activities. It asks: How does the company affect people and the planet? This includes climate change, waste generation, water usage, and community engagement.

The second perspective focuses on internal factors that can affect a company's performance. It asks: How do internal factors affect the company? This could consider risks such as talent shortage, resource scarcity, or operational inefficiencies.

Hyloris will assess its ESG performance from both an internal and external perspective by actively involving all stakeholders both inside and outside the company. This will allow us to identify ESG themes specific to our



### Phase 3 Information Requirements & Reporting

Without the proper data capturing procedures, it would be difficult to track and report our progress towards the identified ESG goals. Our partner will identify which sustainability disclosures Hyloris is required to publish in the future along with which data is needed to be able to do so. They will also provide guidance on how to review our existing data and document processes.

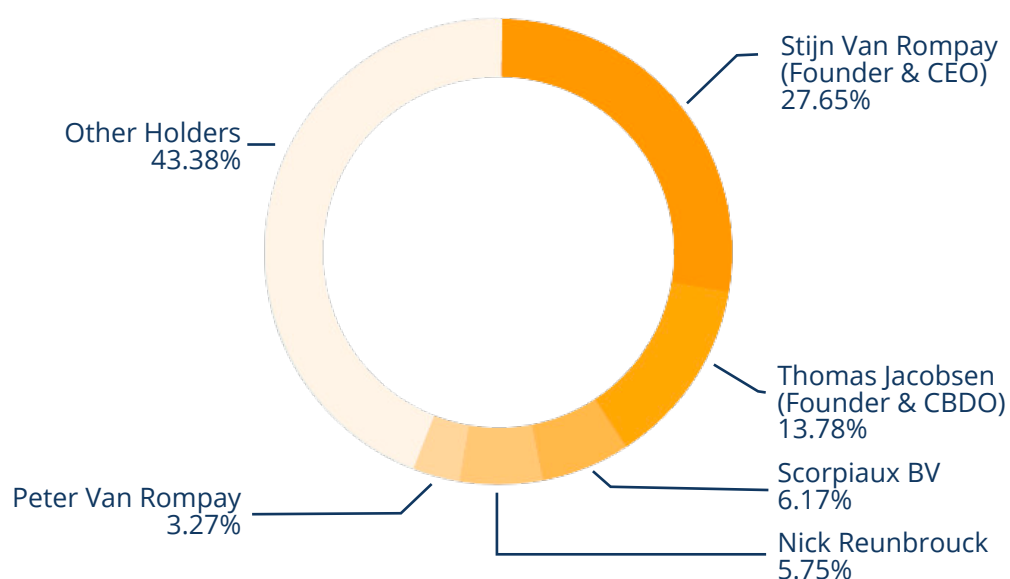


# The Hyloris Share

**Hyloris Pharmaceuticals SA (ticker: HYL:BB)**  
**has been listed on Euronext Brussels since 29 June 2020**

Data and graph can be found at <https://live.euronext.com/en/product/equities/BE0974363955-XBRU>

## BREAKDOWN OF SHARE CAPITAL

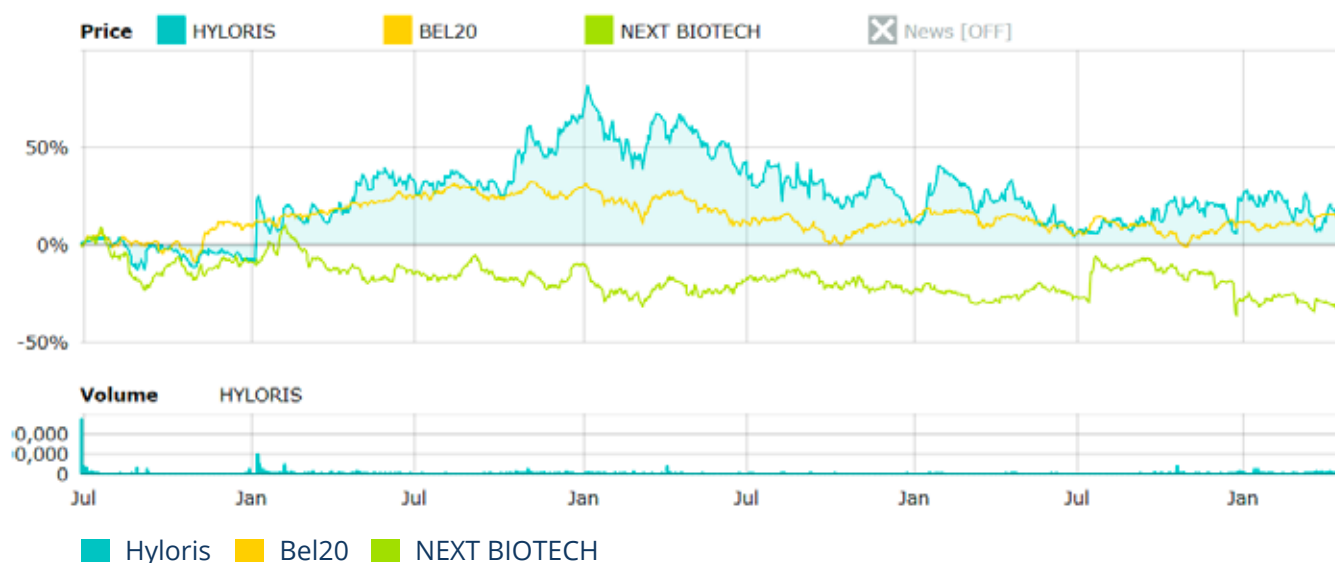


Based on transparency notifications and latest denominator  
 Based on online notification (FSMA website) of managers' transactions

Total number of outstanding voting rights (denominator)	28,000,374
Total number of securities carrying voting rights not yet issued	627,271
Share capital (excluding premium)	€140,001

## PERFORMANCE TO DATE OF HYLORIS VERSUS BEL20 AND NEXT BIOTECH SINCE IPO

Zoom: 1D 5D 1M 3M 1Y 5Y YTD MAX



## ANALYST COVERAGE

Bank	Analyst	Rating
Van Lanschot Kempen	Suzanne van Voorthuizen	Buy
KBC Securities	Jacob Mekhael	Accumulate
Kepler Chevreux	Christophe Dombu	Buy
Degroof Petercam	David Seynnaeve	Buy
Berenberg	Beatrice Allen <sup>1</sup>	Buy

Hyloris is followed by the analysts listed. Please note that any opinions, estimates or forecasts regarding Hyloris' performance made by these analysts are theirs alone and do not represent opinions, forecasts or predictions of Hyloris or its management

<sup>1</sup> Beatrice Allen is no longer with Berenberg but Hyloris is still covered

# Corporate Governance

## Contents

<b>Introduction</b> .....	<b>46</b>
<b>Compliance with the Corporate Governance Code</b> ..	<b>46</b>
<b>Board of Directors</b> .....	<b>48</b>
<b>Executive Committee</b> .....	<b>60</b>
<b>Remuneration Report</b> .....	<b>62</b>
<b>Appraisals</b> .....	<b>72</b>
<b>Internal Control and Risk Management Systems</b> ...	<b>73</b>
<b>Market Abuse Regulations</b> .....	<b>76</b>
<b>Conflicts of Interest and Related Parties</b> .....	<b>76</b>
<b>Share Capital, Shares and Shareholders</b> .....	<b>78</b>



## INTRODUCTION

Hyloris' Corporate Governance Charter is in line with the 2020 Belgian Code on Corporate Governance (the Corporate Governance Code 2020), which the Company needs to apply, in accordance with a '**comply or explain**' approach, pursuant to Article 3:6, §2, 1° CCA and the Royal Decree of May 12, 2019 specifying the corporate governance code to be complied with by listed companies.

The Corporate Governance Charter describes the main aspects of the corporate governance of the Company, including its governance structure, the terms of reference of the Board of Directors and its committees and other important topics. The Corporate Governance Charter must be read together with the Company's Articles of Association, which have been amended by the Extraordinary General Shareholders' Meeting of July 31, 2020.

The Corporate Governance Charter and Articles of Association can be consulted on the website of Hyloris at: <https://hyloris.com/our-governance>

## COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE

As a Belgian listed company, we are subject to the 2020 Belgian Code on Corporate Governance (the Corporate Governance Code 2020). A copy of the Corporate Governance Code 2020 can be found [here](#) or on the Corporate Governance Committee's [website](#).

Companies are required to state the extent to which they comply with the principles and best practice provisions of the Corporate Governance Code 2020 in their annual report and, where they do not comply with them, why and to what extent they deviate from them.

Hyloris will apply the corporate governance principles outlined in the Corporate Governance Code 2020, which is reflected in a charter that complies with the best practice provisions as stated in the Corporate Governance Code 2020 (the Corporate Governance Charter). The Corporate Governance Charter describes

the main aspects of the corporate governance of the Company, including its governance structure, the terms of reference of the Board of Directors and its committees and other important topics.

The Corporate Governance Charter and Articles of Association are available on our website.

Accordingly, this section of the annual report provides more factual information on the Corporate Governance policy pursued in the financial year 2023, with the aim of applying the principles resulting from this Charter as much as possible without affecting the unique character of the Company.

Hyloris acknowledges the importance of good corporate governance, and we fully endorse the underlying principles of the Corporate Governance Code 2020, in accordance with a 'comply or explain' approach, pursuant to Article 3:6, §2, 1° CCA and the Royal Decree of May 12, 2019 that specifies the corporate governance code to be complied with by listed companies.



Hyloris deviates from the best practice provisions in the areas set out below, for the reasons explained in this section. These deviations mostly relate to our remuneration practices, which are in line with our remuneration policy as approved by our annual general meeting of shareholders held in 2022. The Board of Directors is of the opinion that these deviations from the provisions of the Corporate Governance Code 2020 are justified, in view of our activities, our size and the specific circumstances in which we operate.

**Provision 2.19:** the powers of the members of the Executive Management other than the CEO are determined by the CEO rather than by the Board of Directors as the members of the Executive Management perform their functions under the leadership of the CEO, to whom the day-to-day management and additional well-defined powers were delegated by the Board of Directors.

**Provision 4.14:** no independent internal audit function has been established. This deviation is explained by the size of the Company. The Audit Committee will regularly assess the need for the creation of an independent internal audit function.

**Provision 7.6:** except for the Chairman who holds ESOP warrants (allocated prior to the IPO), the Non-Executive members of the Board of Directors do not receive part of their remuneration in the form of shares. This deviation is explained by the fact that the interests of the non-executive members of the Board of Directors are currently considered to be sufficiently oriented to the creation of long-term value for the Company. Since its listing in 2020, Hyloris has always focused on a long-term perspective as reflected in its strategic decision to grow the portfolio of product candidates over the next few years. The Board of Directors has indeed decided not to provide remuneration in the form of shares in the company for Non-Executive Directors and is of the opinion that, considering the limited size of the total remuneration package awarded to Non-Executive Directors, the total or partial remuneration in the form of shares of the company would not have a meaningful impact on the behavior or decisions of the company's Non-Executive Directors. The Board of Directors will in any event continue to safeguard that the contributions of the Non-Executive Directors are made with the company's interest in the long term in mind.

**Provision 7.9:** for the same reasons as mentioned with respect to provision 7.6; no minimum threshold of shares to be held by the members of the Executive Committee has yet been set. The Board has determined that there are sufficient safeguards in place to ensure that the members of the executive management take decisions and perform their tasks in accordance with the interest of the Company in the long term, i.a. through the implementation of a **long-term variable remuneration**. The members of the Executive Committee also hold shares and/or ESOP Warrants which requires them to always take into consideration a long-term perspective of the Company, especially as the ESOP Warrants are only vested after a period of 4 years after granting and cannot be exercised before the 4th year following the year of the offer (see **Warrants Plans**).

**Provision 7.10:** the Board believes that there is no need to formally define a maximum for the variable short-term remuneration for Executive Committee as this remuneration (package) is completely in line with the remuneration (package) of the other members of the Executive committee and also considers the low amounts of this short-term variable remuneration compared to other listed companies. For 2023, the variable remuneration for all members of the Executive Committee is maximum 17% of the amount of the fixed remuneration.

**Provision 7.12:** the Board believes it is not opportune to have specific provisions to claim back or withhold payment of the variable part of the remuneration of the members of the Executive Management mainly because it believes that there are sufficient contractual rights and rights under common law available that allow it to claim back such amounts.

*What constitutes good corporate governance will evolve with the changing circumstances of the company and with the standards of corporate governance globally and must be tailored to meet those changing circumstances. The Board of Directors intends to update the Corporate Governance Charter as required to reflect changes to the Company's corporate governance.*

# BOARD OF DIRECTORS

## COMPOSITION OF THE BOARD OF DIRECTORS

The Board of Directors consists of eight members, two of whom are Executive Directors (as members of the Executive Committee) and six of whom are Non-Executive Directors, including three Independent Directors.

The Company's Board currently counts one female Director. Hyloris is actively looking for new Non-Executive Directors to meet the gender diversity requirements and to attract female Board Members in accordance with Article 3:6 § 2, 6° of the Belgian Companies Code (and with the law of 28 July 2011) to assure that the appropriate quorum and gender diversity will be reached by 2026 (i.e. first day of the sixth year after Initial Public Offering). The intention of the Company is to reduce the number of Board Members to a total of seven, whereby at least 2 Non-Executive Directors would be female directors, meaning that only one additional (new) female Non-Executive Directors should be appointed before 2026. Hyloris is comfortable that this requirement will be met. In the future, the Company will continue taking gender diversity into consideration when renewing the members of its Board of Directors and when filling new positions.

However, Hyloris relies on a relatively small team with a flat structure, so it is appropriate to consider diversity across the entire group where there is a great diversity in terms of gender, nationality, age, seniority, and educational background.

The table below gives an overview of the members of the Company's Board of Directors and their terms as of the date of this annual report:

Name <sup>1</sup>	Age	Position	Start of Term	End of Term
<b>Mr. Stefan Yee</b>	62	Non-Executive Director Chairman of the Board	2020	2024
<b>Mr. Stijn Van Rompay<sup>2</sup></b>	48	Executive Director	2020	2024
<b>Mr. Thomas Jacobsen<sup>3</sup></b>	49	Executive Director	2020	2024
<b>Mr. Leon Van Rompay<sup>4</sup></b>	74	Non-Executive Director	2020	2024
<b>Mr. Marc Foidart<sup>5</sup></b>	48	Independent Director	2020	2024
<b>Dr. Carolyn Myers</b>	65	Non-Executive Director (see <a href="#">note 29</a> )	2020	2024
<b>Mr. James Gale</b>	75	Independent Director	2020	2024
<b>Mr. Chris Buyse<sup>6</sup></b>	60	Independent Director	2021	2025

1 When a director is subsequently mentioned by name it will be assumed they are acting through their associated management company.

2 Acting through SVR Management BV

3 Acting through Jacobsen Management BV

4 Acting through Van Rompay Management BV

5 Acting through Noshaq Partners SCR BV

6 Acting through Pienter Jan BV



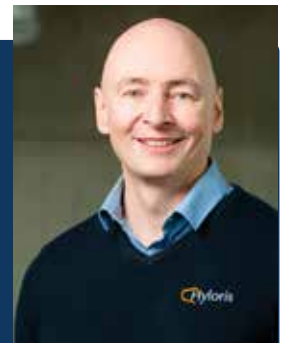


### **Stefan Yee - Chairman of the Board, Non-Executive Director**

Stefan Yee has more than 30 years of experience in audit, corporate law, mergers and acquisitions, corporate finance, investment banking and private equity with companies as KPMG, Linklaters, the Flemish investment bank Lessius, the Belgian Corporation for International Investment (SBI/BMI), Beluga (Euronext Brussels) and as the founder and CEO of the PE Group, a Belgian privately held private equity firm. Stefan is, and has been an investor and/or board member of several listed and private companies such as, amongst others, Beluga, Encare group (Mensura), AXI, The Reference, Alro Holdings, Loomans Group, United Brands, Capco, Faseas International (Spacewell), HD Partners (Dekabo group), AED Rent, UnifiedPost Group, NRG New Generation, Axiles Bionics, including several healthcare companies Docpharma (listed on Euronext Brussels until its acquisition in 2005 by Matrix Laboratories for €218M), Uteron Pharma and Imcyse). Stefan holds a Master's Degrees in Law and Business Management from the Universities of Brussels (VUB and ULB Solvay Business School) and the University of Chicago (as a BAEF Fellow).

### **Stijn Van Rompay - Executive Director**

Stijn Van Rompay has over 20 years of experience in leadership positions in the pharmaceutical industry and is the co-founder and CEO of the Company. Stijn also co-founded, and was CEO of, Alter Pharma, a pharmaceutical company focused on the development of complex generics and pharmacy-related products. He was also co-CEO of Uteron Pharma, a company focused on innovative female healthcare products, which was sold to Watson for up to \$305M in 2013. Prior to these positions, Stijn was CFO and afterwards CEO of Docpharma (listed on Euronext Brussels until its acquisition in 2005 by Matrix Laboratories for €218M) a generics and medical device company. He also holds several Non-Executive Director positions in the biotech sector and acts as an advisor to venture capital investors. Stijn holds a Master in Applied Economics from the University of Antwerp.



### **Thomas Jacobsen - Executive Director**

Thomas Jacobsen has over 20 years of experience in the pharmaceutical industry, with expertise in operational management, business development, licensing, and research and development. He co-founded Alter Pharma and prior to this, he worked with Docpharma, where he focused on out-licensing of Docpharma's products. Thomas started his career in the Scandinavian-based generics company Alternova, where he was responsible for licensing, product registration and launches. Thomas holds a Master's Degree in Pharmacy from the University of Copenhagen and a Business Degree from Copenhagen Business School.



### **Leon Van Rompay - Non- Executive Director**

Leon Van Rompay has more than 40 years of experience in the pharmaceutical industry. During his professional career he held several positions including country & area manager (covering major territories) and Board member of the Zambon Group. He was founder and CEO of Docpharma and served on different Boards including Ecodis and Uteron Pharmaceuticals. He was a founding member of BIGE/IBES (Belgian Institute for Health and Economics), the B.G.A. (Belgian Generic Association), BAPIE (Belgian Association of Parallel Import and Export) and was an executive committee member and Board member of the Belgian Pharmaceutical Industry Association. He also was a member of the pharmaceutical deontological commission and responsible for this commission in the industry association executive committee. He is the former CEO of the Belgian women's health company, Mithra, a Euronext listed company.



### **Marc Froidart - Independent Director**

Marc Foidart is co- founder and Executive Chairman of Eyed Pharma SA, a start-up company developing innovative controlled release micro-implants in ophthalmology and is also co-founder of EKLO ASBL. Marc is also investment manager of Epimede SA, a €50 million Belgian private high-tech growth fund. He has more than 15 years of experience in strategic consulting and investment at all stages of development of small and medium high tech-high growth life sciences enterprises. He played a key role in several financing rounds at critical development stages of various Belgian biotech companies including, Mithra Pharmaceuticals SA, Imcyse SA, Uteron Pharma SA, PDC Line Pharma SA, Diagenode SA. As an entrepreneur, Marc is co-founder and past CEO of Arlenda SA, a spin-off company of the University of Liège providing expert statistical solutions to the pharmaceutical, chemical and environmental industries. Marc is associate professor at the University of Liege since 2011 and obtained a Master in Business Engineering from the University of Liège (1998).of Antwerp.



### **James Gale - Independent Director**

James (Jim) Gale is the founding partner of Signet Healthcare Partners. Jim has over 30 years of healthcare investing and finance experience. Jim is Managing Director of Signet Healthcare Fund and is currently the Chairman of the Board of Bionpharma Inc, is lead director of Knight Therapeutics Inc. (TSX: GUD) and also serves on the Board of Directors of Ascendia Pharmaceuticals, Chr. Olesen Synthesis A/S, Juno Pharmaceutical Corp., Pharmaceutics International (Pii), Lee's Pharmaceutical Holdings (HKX:0950HK), and Pharma Nobis LLC. Prior portfolio company boards include Arbor Pharmaceuticals, Amarin Corporation, eResearch Technologies Inc., and Valera Pharmaceuticals. Prior to founding Signet, Jim was head of principal investment activities and head of investment banking for Gruntal & Co., LLC. While at Gruntal, he made several investments including Andrx Corporation, Royce Laboratories (merged with Watson Pharmaceuticals), Lifecell Corporation, Neurocrine Biosciences, and BML Pharmaceuticals (acquired by Endo Pharmaceuticals).

**Carolyn Myers - Non-Executive Director - see note 29**

Dr. Carolyn Myers is an accomplished senior executive with extensive experience creating, growing, and leading health care businesses. She is currently CEO of FendX Technologies Inc. (CSE:FNDX), a nanotechnology company developing products using a unique pathogen repelling technology to reduce pathogen spread and infection. Carolyn is also a Principal of Bioensemble Ltd, a business strategy consulting firm that provides a comprehensive range of drug development, commercial and business development services to small and mid-size pharma. Carolyn currently serves as a board member of EyeD Pharma SA and FendX Technologies (CSE:FNDX) and is a recently retired board member of Mayne Pharma (ASX:MYX). Prior roles at Allergan (acquired by AbbVie) include Vice President of International Business Development and Alliance Management and Vice President of CNS marketing. Prior to Allergan, she held leadership positions at Mylan (now Viatrix Pharmaceuticals) including President of Dey Laboratories and President of Mylan Technologies. Carolyn earned a PhD in Genetics from the University of British Columbia and an MBA from Rutgers University.

**Chris Buyse - Independent Director**

Chris Buyse is Managing Partner of the Belgian company Fund+ NV which he co-founded in 2015. Fund+ is an open-end fund that invests in innovative life sciences companies primarily active in therapeutics, as well as companies developing diagnostics and medical devices.

He has more than 30 years of experience in international company finance and in running and establishing best financial practice. He was previously CFO of ThromboGenics NV (currently Oxurion), CropDesign and Keyware Technologies and he held several financial positions at Suez Lyonnaise des Eaux and Unilever. He is currently serving as an independent Board Member of a few companies, mostly active in life sciences such as Inventiva Pharma and IPA LTD. He is also member of the board of the Francqui Foundation (Brussels) and trustee of the Louis-Jeantet Foundation (Geneva).

## ACTIVITY REPORT

In 2023, in addition to discussing the financial reporting and the operational development of the Company, the Board of Directors devoted a great deal of attention to product development and business development, considering further expansion of the Company's growth and strategy. The Board of Directors also closely monitored the evolution of cash requirements of the Company and discussed at various occasions the possible remedies to be implemented to meet these requirements.

The Executive and Non-Executive Members of the Board of Directors convened four times in 2023. All Directors attended all Board Meetings, except for Mr. Leon Van Rompay, Mr. Chris Buyse and Mr. Marc Foidart, who were excused once, and Mr. James Gale, who was excused two times.

Name		Attendance Rate
Stefan Yee	Chairman	100%
Stijn Van Rompay	Executive Director	100%
Thomas Jacobsen	Executive Director	100%
Leon Van Rompay		75%
Marc Foidart		75%
Carolyn Myers		100%
James Gale		50%
Chris Buyse		75%

In 2023 the Board of Directors did not convene for specific decision-making as prescribed by article 7:97 of the Belgian Company Code with respect to a decision relating to a related party as defined by EC Directive 1606/2002, nor with respect to any decisions on conflicts of interest.

## THE REAPPOINTMENT OF DIRECTORS

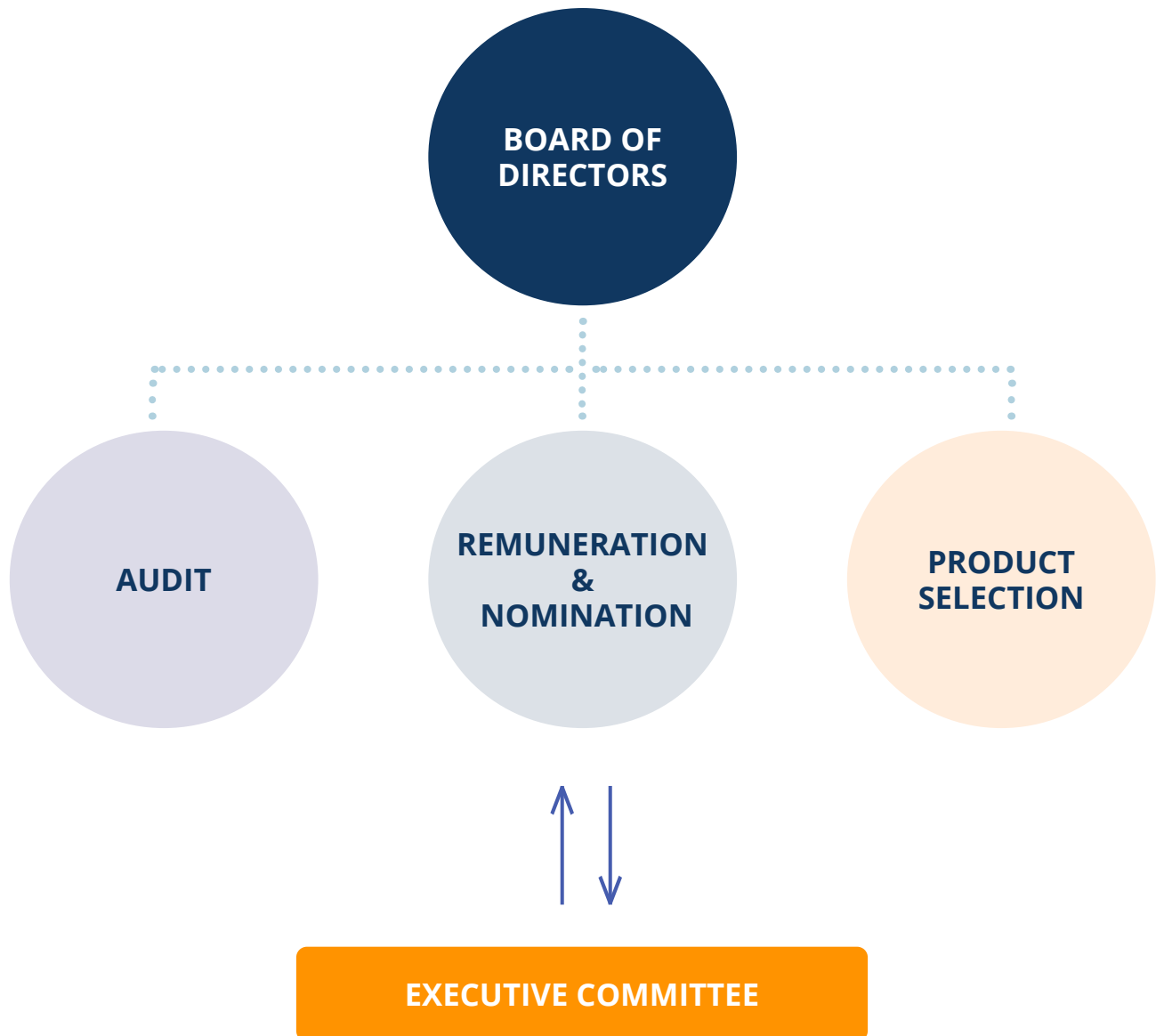
The Board of Directors will propose to the next General Shareholders' Meeting to (re)-appoint new Directors to replace those Directors whose mandates will terminate after the General Shareholders' Meeting approving the 2023 financial statements, in accordance with applicable law and Corporate Governance regulations.

## COMMITTEES OF THE BOARD OF DIRECTORS

The Board had already established two Board Committees: the Audit Committee and the Remuneration and Nomination Committee.

At its meeting of February 28, 2024, the Board of Directors decided to install a new “Product Selection Committee”.

Currently, no Scientific Committee has been formally established within the Company.



## AUDIT COMMITTEE

### Composition

The Audit Committee is a subcommittee of the Board of Directors, composed of Board Members. The Audit Committee's authority is defined by law and the Corporate Governance Code, with the Board of Directors having the power to grant additional responsibilities. It provides comprehensive support to the Board of Directors, enabling them to fulfill their monitoring responsibilities across all areas, including risk management.

The Audit Committee is comprised of the following members:

**Mr. Marc Foidart,**

Independent Director, Chairperson of the Audit committee

**Mr. Stefan Yee,**

Non-Executive Director

**Mr. James Gale,**

Independent Director

**Mr. Chris Buyse,**

Independent Director

The Audit Committee is composed of at least three (3) Non-Executive Directors, and at least one-third of independent directors. Members of the Audit Committee have collective competence in the company's field of activities. At least one member of the Audit Committee has the necessary competence in accounting and auditing. The Chairman of the Board of Directors proposes to the Board of Directors the names of the candidates for membership of the Audit Committee. The Chairman of the Audit Committee is chosen from among its members by the Board of Directors. The Chairman of the Board of Directors cannot chair the Audit Committee.

The members of the Audit Committee have full access to the Executive Committee and to any other employee to whom they may require access to carry out their responsibilities. The statutory auditor of the Company has direct and unrestricted access to the chairperson of the Audit Committee.

### Mission

In accordance with Article 7:99 of the Companies and Associations Code, the Audit Committee fulfills the following missions:

- a) communication to the Board of Directors of the legal control of the statutory and consolidated accounts and explanations on how the legal control on the statutory and consolidated accounts has contributed to the integrity of the financial information and on the role played by the Audit Committee in this process;
- b) monitoring the process of preparing financial information and making recommendations or proposals to ensure its integrity;
- c) monitoring the effectiveness of the company's internal control systems and risk management;
- d) evaluation of the need to establish an internal auditor and its effectiveness;
- e) monitoring the statutory audit of the annual and consolidated accounts, including monitoring the issues and recommendations made by the auditor and, if applicable, by the auditor responsible for the audit of the consolidated accounts;
- f) review and monitoring of the independence of the auditor and, if applicable, of the auditor responsible for the audit of the consolidated accounts, particularly regarding the justification for the provision of additional services to the company. In particular, it analyzes with the auditor the risks to the independence thereof and the safeguard measures applied to mitigate these risks, when the total fees relating to an entity referred to in Article 1:12 of the Companies and Associations Code exceed the criteria set by Article 4, § 3, of Regulation (EU) No. 537/2014;
- g) recommendation to the Board of Directors of the company for the appointment of the auditor and, if applicable, of the auditor responsible for the audit of the consolidated accounts, in accordance with Article 16, § 2, of Regulation (EU) No. 537/2014. The Audit Committee has the power to investigate any matters falling within its remit, subject to compliance

with legal restrictions on access to commercial and other confidential data. For this purpose, it has the necessary resources and access to all information and may request opinions from internal and external experts. The responsibility of the members of the Audit Committee towards the Board of Directors is to assume the mission stipulated in this regulation with the diligence of a good family father and in complete autonomy.

The Audit Committee carries out its mission in the following three areas:

### **Financial information for shareholders and third parties**

The Audit Committee reviews, with the requested assistance of the CFO, the annual and semi-annual social and consolidated financial statements, prospectuses, and other financial information before submitting them to the Board of Directors. Regarding financial data included in interim statements, these are prepared under the responsibility of the CFO who submits them to the Audit Committee for review by the Board of Directors in the context of its general oversight of the financial information preparation process.

In reviewing the financial information preparation process, the Audit Committee examines, in particular, the relevance and consistency of the accounting standards of the Hyloris Group. This includes the criteria for consolidating accounts of companies within the group. This review notably focuses on assessing the completeness and consistency of the financial information. The Audit Committee reviews, with a view to providing an opinion to the Board of Directors, any changes made, if applicable, to accounting principles and valuation rules, particularly considering their impact on financial statements. The CFO informs the Audit Committee of the methods used to account for significant and unusual transactions for which accounting treatment is open to different approaches, as well as the existence and justification of activities carried out through specific structures.

### **Internal control and risk management**

The Audit Committee, at least once a year, reviews the internal control and risk management systems implemented by the CEO to ensure that the main risks (including those related to compliance with existing laws and regulations) are properly identified, managed, and communicated in accordance with the framework approved by the Board of Directors. The Audit Committee reviews information related to internal control and risk management published in the Corporate Governance Statement of the annual report.

### **External audit**

The Audit Committee reviews reports prepared by the auditor(s), including the report describing all relationships between the auditor(s) and the company and its group. The Audit Committee examines the nature, quality, and scope of the auditor(s)' work, the coordination of missions within the Hyloris Group, as well as the conclusions (including management letters) resulting from their work. The Audit Committee assesses to what extent the CEO takes into account the recommendation letter(s) addressed to him by the auditor(s).

The Audit Committee proposes to the Board of Directors the appointment, possible renewal, and remuneration of the auditor(s) for their mission to certify the statutory accounts of Hyloris Pharmaceuticals and the consolidated accounts of the group. It verifies their independence within the meaning of the Companies and Associations Code. Any other mission, falling within Article 3:62 of the Companies and Associations Code, performed by the auditor(s) or by companies or persons related to them, must be previously authorized by the Audit Committee.



Evaluation

The Audit Committee evaluates its internal rules and their effectiveness at least every three years, and, if necessary, recommends adjustments to the Board of Directors.

Meetings

The Audit Committee is called by its Chairman to meet at least four times a year or whenever it deems it necessary for the proper performance of its duties. It is validly constituted when the majority of its members are present or represented. The Audit Committee may meet by telephone conference, video conference, or Internet. Except for decisions for which this regulation would exclude this possibility, decisions of the Audit Committee may be taken by written consent of the directors. The Chairman of the Audit Committee may invite, depending on the items on the agenda:

- the CFO, CEO, or any member of the management and/or any senior executive of the company;
- the auditor(s) who are its natural interlocutors and are received by the Audit Committee at their request and without prior justification. If necessary, these interlocutors may be accompanied by an operational manager. Subjects related to the audit plan and any issues arising from the audit process are regularly included on the agenda of the Audit Committee. Two meetings are mainly dedicated to the annual and semi-annual financial statements. At these meetings, the auditor(s) is (are) invited to report on the result of their work. These meetings also allow for an exchange of views with the auditor(s) on any matter within the competence of the Audit Committee and any other issue highlighted by the audit process, especially significant weaknesses in internal control. The Chairman of the Audit Committee or two of its members may convene a meeting whenever deemed desirable. The Audit Committee may assign the auditor(s) or other experts to specific tasks, and ask them to report to it. The auditor(s) may also address the Board of Directors, through its Chairman, informing the Audit Committee.

In their decision-making process, members of the Audit Committee will seek consensus.

The minutes of the Audit Committee meetings are kept at the Secretariat of Hyloris Pharmaceuticals. The minutes are signed by the Chairman of the Audit

Committee and by the members who wish to do so. The Chairman of the Audit Committee presents activity reports to the Board of Directors. All members of the Board of Directors, as well as the auditor(s), have access to said minutes. Members of the Audit Committee are bound to confidentiality regarding the information received during meetings.

The Audit Committee convened 4 times in 2023.

Name		Attendance Rate
Marc Foidart	Chairman	100%
Stefan Yee		100%
James Gale		100%
Chris Buyse		100%



## REMUNERATION AND NOMINATION COMMITTEE

The Remuneration and Nomination committee consists of the following members:

**Mr. Stefan Yee,**

Chairperson of the Remuneration and Nomination Committee

**Dr. Carolyn Myers,**

Non-Executive Director - see [note 29](#)

**Mr. Marc Foidart,**

Independent Director

The Remuneration and Nomination Committee is composed exclusively of Non-Executive Directors and independent directors within the meaning of Article 7:87 of the Belgian Code of Companies and Associations. This composition helps to avoid conflicts of interest regarding the structure design, adjustment and implementation of the Remuneration Policy towards Executive Committee Members. The CEO and Executive Committee Members are not invited to participate in the Remuneration Committee's deliberations of their own individual compensation. The chair-person of the Board of Directors or another Non- Executive Director is the Chair of the Remuneration and Nomination Committee.

The members of the Remuneration Committee must have the necessary expertise in terms of remuneration policy, which is evidenced by the experience and previous roles of its current members (see also Board of Directors, p. 48 for more information on their curriculum vitae). The CEO may participate in the meetings of the Remuneration Committee in an advisory capacity every time the remuneration of another member of the Executive Committee is discussed.

### Mission

The role of the Remuneration and Nomination Committee consists of making recommendations to the Board of Directors regarding the appointment and remuneration of Directors and members of the Executive Committee and, and has the following tasks:

a) make recommendations to the Board of Directors on the remuneration policy and other remuneration

proposals that the Board of Directors must submit to the General Shareholders' Meeting;

b) make recommendations to the Board of Directors in line with the remuneration policy approved by the General Shareholders' Meeting on the individual remuneration of the Directors and members of the Executive Committee, including variable remuneration and long-term performance bonuses, whether or not linked to shares, in the form of stock options (warrants) or other financial instruments, and severance pay, and, where applicable, the resulting proposals that the Board of Directors must submit to the General Shareholders' Meeting;

c) prepare the remuneration report, in line with the remuneration policy approved by the General Shareholders' Meeting, that the Board of Directors must include in its corporate governance statement, which in turn forms a part of the Company's annual report; and

d) explain the remuneration report at the Annual General Shareholders' Meeting.

e) Pursuant to its function as Nomination Committee:

f) make recommendations to the Board of Directors with regard to the appointment of Board Members and members of Executive Committee;

g) prepare plans for the orderly succession of Board Members;

h) lead the re-appointment process of Board Members;

i) ensure that sufficient and regular attention is paid to the succession of members of Executive Committee; and

j) ensure that appropriate talent development programmes and programmes to promote diversity in leadership are in place.

Evaluation

At the end of each Board Member's term, the Remuneration and Nomination Committee shall evaluate the relevant Board Member's presence at the meetings of the Board of Directors or Committee meetings, their commitment and their constructive involvement in discussions and decision-making and shall also assess whether the contribution of each Board Member is adapted to changing circumstances. The Board of Directors shall act on the results of the performance evaluation, and shall, where appropriate, propose new Board Members for appointment, propose not to re-appoint existing Board Members or take any measure deemed appropriate for the effective operation of the Board of Directors.

Meetings

The Remuneration and Nomination Committee shall meet whenever it deems it necessary for the proper performance of its duties and at least twice a year. The Remuneration and Nomination Committee shall regularly report to the Board of Directors on the performance of its duties.

The Remuneration and Nomination Committee convened only 1 time in 2023 as there were no major changes or decisions that required additional meetings.

Name		Attendance Rate
Stefan Yee	Chairman	100%
Carolyn Myers		100%
Marc Foidart		100%

**PRODUCT SELECTION COMMITTEE**

At its meeting of February 28, 2024, the Board of Directors decided to install a new 'Product Selection Committee'. The Product Selection Committee consists of at least 2 non-executive members of the Board of Directors, the CEO, the COO and the CBDO

The Product Selection Committee shall prepare the dossier for approval of new product candidates by the Board of Directors. It shall discuss the new product candidate(s) to be submitted for approval to the Board of Directors and shall prepare a summary of its findings, covering all aspects going from development stage and regulatory pathway, the cost for further development, registration and commercialization of the product candidate(s), the market potential and positioning, pricing, the financial return, etc. The Product Selection Committee meets whenever it deems it necessary for the proper performance of its duties. The Product Selection Committee regularly reports to the Board of Directors on the performance of its duties, and in any event when a new product candidate is submitted to the Board of Directors for approval.

The members of the Product Selection Committee have full access to the Executive Committee and to any other employee to whom they may require access to carry out their responsibilities.

**SCIENTIFIC COMMITTEE**

A Scientific Committee has not yet been formally created by the Company.



## EXECUTIVE COMMITTEE

The Board of Directors has established an “Executive Committee” and appointed the members of the Executive Committee in consultation with the CEO, based on the recommendations made by the Remuneration and Nomination Committee. The Company’s Executive Committee is an advisory committee to the Board of Directors and does not constitute a “conseil de direction” / “directieraad” per the definition of Article 7:104 CCA. The Board of Directors considers the need for a balanced Executive team.

In proposing candidates for the Executive Committee, particular consideration is given to educational and professional background, complementary skills, knowledge, and experience, as well as to diversity in age, gender, and nationality. All diversity requirements, except for the gender requirement, are fully met. Hyloris’ members of the Executive Committee come from diverse educational and multi-disciplinary professional backgrounds. The 5 members of the Executive Committee represent 3 different nationalities.

On 31 December 2023, the Executive Committee consisted of the following members<sup>1</sup>:

**Mr. Stijn Van Rompay<sup>2</sup>,**

Chief Executive Officer

**Mr. Thomas Jacobsen<sup>3</sup>,**

Chief Business Development Officer

**Mr. Jean-Luc Vandebroek<sup>4</sup>,**

Chief Financial Officer

**Mr. Dietmar Aichhorn,**

Chief Operating Officer

**Mr. Koenraad Van der Elst<sup>5</sup>,**

Chief Legal Officer

The Executive Committee generally meets every week. The members of the Executive Committee also meet on an informal basis through conference and video calls every time it is required for its proper functioning.



**Stijn Van Rompay - CEO**

Stijn Van Rompay has over 20 years of experience in leadership positions in the pharmaceutical industry and is the co-founder and CEO of the Company.

Stijn also co-founded, and was CEO of, Alter Pharma, a pharmaceutical company focused on the development of complex generics and pharmacy-related products. He was also co-CEO of Uteron Pharma, a company focused on innovative female healthcare products, which was sold to Watson for up to \$305M in 2013. Prior to these positions, Stijn was CFO and afterwards CEO of Docpharma (listed on Euronext Brussels until its acquisition in 2005 by Matrix Laboratories for €218M) a generics and medical device company. He also holds several Non-Executive Director positions in the biotech sector and acts as an advisor to venture capital investors. Stijn holds a Master in Applied Economics from the University of Antwerp.



**Thomas Jacobsen - CBDO**

Thomas Jacobsen has over 20 years of experience in the pharmaceutical industry, with expertise in operational management, business development,

licensing, and research and development. He co-founded Alter Pharma and prior to this, he worked with Docpharma, where he focused on out-licensing of Docpharma’s products. Thomas started his career in the Scandinavian-based generics company Alternova, where he was responsible for licensing, product registration and launches. Thomas holds a Master’s Degree in Pharmacy from the University of Copenhagen and a Business Degree from Copenhagen Business School.

<sup>1</sup> When a director is subsequently mentioned by name it will be assumed they are acting through their associated management company.

<sup>2</sup> Acting through SVR Management BV

<sup>3</sup> Acting through Jacobsen Management BV

<sup>4</sup> Acting through Finsys Management BV

<sup>5</sup> Acting through Heralut BV



### **Jean-Luc Vandebroek, CFO**

Jean-Luc Vandebroek is a seasoned executive who joined the Company in 2021 from his role as CFO of Bone Therapeutics, a publicly traded biotech

company based in Gosselies, Belgium. Prior to that, he was CFO and CIO at Alcoba and Fluxys, and before that, he held various senior financial positions at Delhaize Group. Jean-Luc is an experienced Executive Board member and has a track record of developing and implementing financing strategies and transactions and has a large, global network of investors and financial institutions. Jean-Luc holds a Master in Business Administration from the Louvain Management School. He is Board member of BioSenic.



### **Dietmar Aichhorn, COO**

Dietmar Aichhorn has more than 20 years of experience in the pharmaceutical industry leading teams in a broad range of functions, including,

development, regulatory, clinical development, product launch and logistics of small molecules, biologics and Advanced Therapy Medicinal Products. Before joining Hyloris in October 2020, Dietmar worked in clinical development at Polpharma Biologics and Vira Therapeutics, Innovacell Biotechnology as Head of Development. Dietmar's experience also includes Strategic Planning, M&A and post-merger integration at Mylan and Novartis. Dietmar holds a degree in chemistry and a degree in economy from Vienna University of Economy and is a lecturer at the Medical University of Innsbruck and the Austrian Medical Association.



### **Koenraad Van der Elst, CLO**

Koenraad Van der Elst has almost 40 of experience as in-house and external legal and general counsel of various listed companies and was

also involved in numerous capital market and M&A transactions worldwide. Before joining Hyloris in 2020, Koenraad served as General Counsel at Nikon Metrology (previously Metris ) and acted as Secretary General & General Counsel of Punch International and Punch Graphix plc, a company listed on the London Stock Exchange (AIM) and was President of the Supervisory Board ("Raad van Commissarissen") of Punch Technix, a company listed on Euronext Amsterdam. Between 1995 and 2002, Koenraad was Director Legal Documentation at the Investment Banking Department (Corporate Finance and Capital Markets) of Generale Bank/Fortis Bank. Koenraad was also an assistant Professor in Financial Law at the University of Brussels (VUB). Koenraad holds a Master of laws from the University of Brussels (VUB) and holds an MBA from EHSAL Brussels.

# REMUNERATION REPORT

## REMUNERATION POLICY - GENERAL

A revised remuneration policy, as part of the remuneration report, will be submitted for approval to the next 2024 General Meeting of Shareholders.

### INTRODUCTION

The remuneration policy of Hyloris Pharmaceuticals SA (Remuneration Policy) has been established in accordance with the Belgian Code of Companies and Associations (BCCA), and with the recommendations of the Belgian Corporate Governance Code (Code 2020). This Remuneration Policy applies as from 1 January 2021.

The remuneration policy applies to all Non-Executive Directors, Executive Directors of Hyloris and other members of the Executive Committee. The Executive Directors are part of the Executive Committee. At the time of Board approval, Hyloris did not have other persons who hold management positions according to the definition of this term in Article 7:121 of the BCCA.

Our remuneration policy is available on our website.

### OBJECTIVE OF THE HYLORIS' REMUNERATION POLICY

Our remuneration policy rewards contributions to achieving Company objectives and generating stakeholder value. Hyloris wants to be a competitive market player by benchmarking against appropriate peer groups and by incentivizing and rewarding performance at the highest level possible. The objective of the Hyloris Remuneration Policy is to attract, motivate and retain diverse, qualified, and expert individuals whom Hyloris needs to achieve its corporate, strategic and operational objectives. We aim to provide competitive remuneration packages that align with market practices in the key markets where we compete for talent. The Remuneration Policy also aims to ensure consistency between the remuneration of executives and that of all staff members, while soundly and efficiently managing risks and controlling wage-related costs for Hyloris.

The Board requests the Remuneration Committee to evaluate the overall remuneration packages of Executive Directors, Non-Executive Directors, and Hyloris' employees. The Remuneration Committee consults and engages the Board on this subject matter. The Remuneration Committee takes into consideration all the information on its workforce remuneration, its knowledge and research data about the relevant job market to ensure that all Hyloris employees are remunerated in a market-conforming and sufficient manner to motivate and retain its employees.

The Remuneration Policy will evolve and be updated from time to time to align with the development of our company in a competitive environment and is reviewed regularly so that its contents are aligned with market practice. Any proposed amendments will be subject to the approval of our general shareholders meeting.

### REFLECTING OUR MISSION AND VALUES

Our Remuneration Policy is designed to support our mission, our identity, and our core values. We believe in the intrinsic motivation of our entire team to contribute to our mission and we know that maximum alignment between the interests of our senior leadership team and our stakeholders is supportive of our long-term success.

Our mission is to transform patients' lives by providing them with medicines for unmet needs. To achieve our mission, we will need to be successful across a range of challenging activities in an extremely competitive environment. This includes the discovery, research, and development of highly innovative pharmaceutical product candidates, entering into and maintaining successful collaborations with key industry experts across the globe, managing our limited resources in a disciplined manner to enable us to progress our products all the way through to regulatory approval, and finally to successfully commercialize our products by bringing our innovative therapies to patients in need.

We strongly believe that our long-term success depends on our ability to attract and retain exceptionally talented people focused on the execution of our business objectives while promoting and upholding our identity and core values along the way. Our core values and leadership competencies are:

**Core Values:**

- Taking initiative - Problem Solving - Courage - Entrepreneurship - Initiative
- Functional Knowledge and Skills - Communication - Decisiveness - Planning & Organisation
- Teamwork & Orientation - Collaboration - Ambition – Energy
- Service to others - Building trust – Integrity

**Leadership Competences:**

- Coach/Develop others
- Empower/Delegate others
- Lead change
- Strategically focused

This policy should allow us to:

- attract, retain and motivate superior talent by offering market competitive remuneration packages that are strategically aligned in the regions in which we operate;
- promote long-term value creation over short-term success through a combination of co-ownership of our business in the form of ESOP Warrants and both a short-term and long-term variable remuneration scheme;
- offer variable remuneration components to the members of the Executive Committee based on the achievement of challenging short-term goals that are specifically designed to support our long-term business objectives and our core values.

In determining the remuneration packages offered to our team, we strive to ensure that the remuneration offered is competitive and in line with market practice. We are committed to being transparent about our remuneration practices and we strive to have a meaningful dialogue with our stakeholders to help us continually improve the quality of our disclosures.

Any decision that relates to the remuneration level of members of the Executive Committee shall be based on a recommendation from our Remuneration and Nomination committee. The Remuneration and Nomination committee shall justify why its recommendations are competitive, reasonable, and fair, based on the unique talents and expertise of the individual concerned and the value they bring to the Company.

**DEVIATION FROM THE REMUNERATION POLICY**

In exceptional circumstances, the Board may decide to deviate from any rule contained in this Remuneration Policy, if deviation is deemed necessary to serve the long-term interests and sustainability of the company or to safeguard the viability of the company. In case the Board intends to grant any remuneration in deviation from this policy, the following procedural requirements apply:

- (i) the remuneration offered to any individual shall be based on the value that individual brings to the company, shall be competitive in the relevant markets where we compete for talent and shall for executives include a significant variable component linked to specific performance targets aligned with our company strategy;
- (ii) the Remuneration and Nomination Committee will be consulted on the proposed deviation;
- (iii) we will report any deviations from this policy in our annual remuneration report to our shareholders, and such report will include an overview of the key considerations for deviating from the policy and the expected duration of the deviation, and our shareholders will be asked to provide an advisory vote on our remuneration practices for the respective year.

**CHANGES TO THE REMUNERATION POLICY**

This 2024 remuneration policy is based on the principles of the current (2021) policy.

The main difference between the 2021 and 2024 remuneration policy is the implementation of a **long-term variable remuneration** and the proposal for a new remuneration for the Board of Directors and the various committees (**see proposed changes to remuneration policy for non-executive directors**).

Hyloris does not expect any material changes to this Remuneration Policy to be made in the next two years.

## EVOLUTION OF THE EVALUATION & PERFORMANCE OF HYLORIS

		(in € thousand)			
		2020	2021	2022	2023
Remuneration of Excom Members	Fix	199	800	991	1016
	Variable	111	103	100	107
Remuneration of CEO	Fix	162	180	186	191
	Variable	55	30	22	22
Net profit		(7,2)	(11,6)	(11,7)	(15,8)
Average remuneration of employees <sup>1</sup>		84,2	108	127	108

<sup>1</sup> Includes consultants in a service agreement

## REMUNERATION POLICY FOR NON-EXECUTIVE DIRECTORS

Remuneration of Non-Executive Directors will be adjusted as necessary based on regular benchmarking exercises to ensure that we continue to offer fair and competitive remuneration to attract, retain and motivate the Non-Executive Directors. Fees for being on special committees of the Board of Directors serve as compensation for the significant additional time commitment and responsibilities that come with fulfilling these duties in addition to those generally required for serving as Non-Executive Director on our Board of Directors. A Non-Executive Director serving multiple committee positions will receive appropriate additional compensation for each of these committee positions such as the Remuneration Committee and the Audit Committee. The Board submits this proposal for approval to the shareholders at the annual Shareholders' Meeting.

<sup>1</sup> Includes consultants with a service agreement

The Remuneration and Nomination committee and the Board share the view that all Non-Executive Directors - including the independent directors within the meaning of Article 7:87 of the BCCA - should be compensated equally as set out hereafter.

The Non-Executive Directors are paid a fixed remuneration per year plus a fixed remuneration per year as a member of a Board committee (such as the Remuneration Committee or the Audit Committee).

As from 2020, the remuneration for Non-Executive Directors was as follows (in € thousand):

Board of Directors		Audit Committee	Remuneration & Nomination Committee
Chair	Member	Member	Member
12.5	12.5	5	5

The Non-Executive Directors do not receive any fringe benefits and do not receive any variable remuneration i.e., performance-related pay such as bonuses. Reasonable out-of-pocket (travel) costs incurred by Non-Executive Directors in their duties are reimbursed.

Hyloris does not grant shares to Non-Executive Directors. It considers that its general policy and modus operandi already meet the objective of recommendation 7.6 of the Code 2020, which is to promote long-term value creation. Taking into account the current remuneration amounts and the independent nature of the Non-Executive Directors, Hyloris is of the view that providing part of the remuneration in shares would not necessarily contribute to the objective of the 2020 Code to have these Directors act with the perspective of a long-term shareholder. Since its listing in 2020, Hyloris has always focused on a long-term perspective as reflected in its strategic decision to grow the portfolio of product candidates over the next few years.

The Non-Executive Director mandate can be revoked at any time (ad nutum) without the Non-Executive Director being entitled to an indemnity payment. There are no employment or service agreements that provide for notice periods or indemnities between the Company and the members of the Board of Directors, who are not members of the Executive Management Team.



## PROPOSED CHANGES TO REMUNERATION POLICY FOR NON-EXECUTIVE DIRECTORS

(in € thousand)				
Board of Directors		Audit Committee	Remuneration & Nomination Committee	Product Selection Committee
Chair	Member	Member	Member	Member
17.5	17.5	5	5	7.5

The Remuneration & Nomination Committee also proposes to offer a certain number of shares in order to meet the requirement of principle 7.6 of the Belgian Corporate Governance Code. These shares will have to be held at least one year after the Board Member has left the Board of Directors and must be held at least three years after granting.

## REMUNERATION POLICY FOR EXECUTIVE COMMITTEE MEMBERS

### INTRODUCTION

Hyloris wants to offer market-competitive compensation to be able to recruit, retain and motivate expert and qualified professionals, while considering the scope of their responsibilities.

The remuneration scheme that applies to the Chief Executive Officer (CEO) and other Executive Committee Members is designed to balance short-term operational performance with the long-term objective of creating sustainable value, while at the same time also considering the interests of all stakeholders.

The remuneration scheme for Executive Committee Members has a fixed part (i.e., a base annual remuneration in cash) and a variable part that comprises of a short-term variable remuneration (cash bonus) and a long-term variable remuneration that is construed as a retention bonus based on reaching certain EBITDA levels by the Company. As for the long-term remuneration elements, the Executive Committee Members may receive ESOP Warrants (please see [Warrants and Other Share-Convertible Securities](#)).

Article 7:91 of the BCCA reads: "Unless otherwise provided for in the articles of association or expressly approved by the shareholders' meeting, at least one-

quarter of the variable remuneration of an Executive Director in a public-listed company must be based on predetermined and objectively measurable performance criteria over a period of at least two years, and another quarter must be based on predetermined and objectively measurable criteria over a period of at least three years." The Articles of Association of a company can deviate from Article 7:91 of the BCCA, which is what Hyloris has done. Article 7:91 also states that the above principles do not apply if the variable part of the remuneration does not exceed 25% of the total yearly remuneration. Therefore, the rules on variable remuneration laid down in Article 7:91 of the BCCA do not apply.

Furthermore, our Board of Directors may decide to adjust the total amount of variable remuneration payable upward or downward if the remuneration payable would otherwise not be fair or reasonable. This means also that our Board of Directors may decide to award an amount of the variable pay also if the corresponding performance target was not (fully) met, for example if the Board of Directors concludes that unforeseen external circumstances prevented the targets from being (fully) achieved.

In case of significant overachievement, the Board of Directors may decide to award a higher variable remuneration to fairly reflect the individual's value contribution to the Company.

### FIXED REMUNERATION

The fixed annual remuneration consists of a fee paid in cash. The amount of this fee is determined by the Board, upon the recommendation by the Remuneration Committee. The fee is paid in monthly installments. Some Executive Committee Members receive compensation for costs they incurred in the performance of their duties. Hyloris will conduct external salary-benchmarking exercises regularly to ensure that the remuneration of Executive Committee Members are in line with market practices and is sufficiently fair and reasonable to attract, retain and motivate individuals with the most appropriate profile.

## SHORT-TERM VARIABLE REMUNERATION

Short-term variable cash incentives are granted for achieving predetermined specific performance targets. At the start of each financial year, the Board of Directors will determine the company's key priorities and will set specific, challenging performance targets in line with these priorities. The Board of Directors will determine the relative weight of each target and the metrics used for measuring their achievement.

The principles that apply to granting any short-term variable remuneration are the following:

(i) Granting allows for a certain part of the remuneration to be linked to an individual's performance and to the performance of Hyloris over the past calendar year. It also allows for the individual's interest to be aligned optimally to that of Hyloris, the Shareholders and other stakeholders.

(ii) Granting is driven by the individual's merits and based on the performance-rating system at Hyloris, that is the achievement of individual targets (Personal Targets) and the overall performance of Hyloris (Corporate Targets) over the past calendar year.

(iii) Corporate Targets include factors related to progress in Hyloris' research activities (OPS), business development (BD) and finance. The Corporate Targets focus on company growth and value creation for all shareholders.

(iv) For the Executive Committee Members (except for the CEO), the short-term variable remuneration consists of two components:

- the first component represents 60% of the short-term variable remuneration and is determined based on Personal Targets achieved;
- the second component represents 40% of the short-term variable remuneration and is determined based on the Corporate Targets achieved by Hyloris;

(v) For the CEO, the short-term variable remuneration also consists of two components:

- the first component represents 25% of the short-term variable remuneration and is based on the average of the Personal Targets achieved by the other members of the Executive Committee;
- the second component represents 75% of the short-term variable remuneration and is determined based on the Corporate Targets achieved by Hyloris;

(vi) Both the Corporate and Personal Targets are set annually. The Board sets the Corporate Targets for all Executive Committee Members and considers the recommendations made by the Remuneration Committee. The CEO's Personal Targets are set by the Board upon the Remuneration Committee's recommendation, which are made based on the Chairman's proposal. The Personal Targets of other Executive Committee Members are set by the CEO. The total target short-term variable remuneration amount for an Executive Committee Member (i.e., the sum of the first and second components described above) may exceed 25% of the total fixed annual remuneration of an Executive Committee Member. However, the Remuneration and Nomination Committee has currently set the total target short-term variable remuneration amount for the Executive Committee Members at 17% of the total fixed annual remuneration.

(vii) The short-term variable remuneration for Personal and Corporate Targets is paid only when these targets are effectively wholly or partially met. The extent to which the CEO has achieved his Personal Targets is evaluated by the Remuneration Committee when the annual financial results are validated by the Audit Committee. The evaluation is subject to deliberation and a final decision by the Board. The extent to which the other Executive Committee Members have achieved their Personal Targets is evaluated by the CEO at

the same time, which is deliberated by the Remuneration Committee and finally decided by the Board. Appraisal is based on a weighted average of the achievement rate of the Personal Targets.

(viii) Short-term variable remuneration, if any, is paid after approval by the Board of Directors. Usually during the first calendar quarter following the year for which the targets were set, the Board of Directors will determine the extent to which the targets were met. Pay-out of the variable cash incentive will usually occur also in the first calendar quarter following the year for which the targets were set.

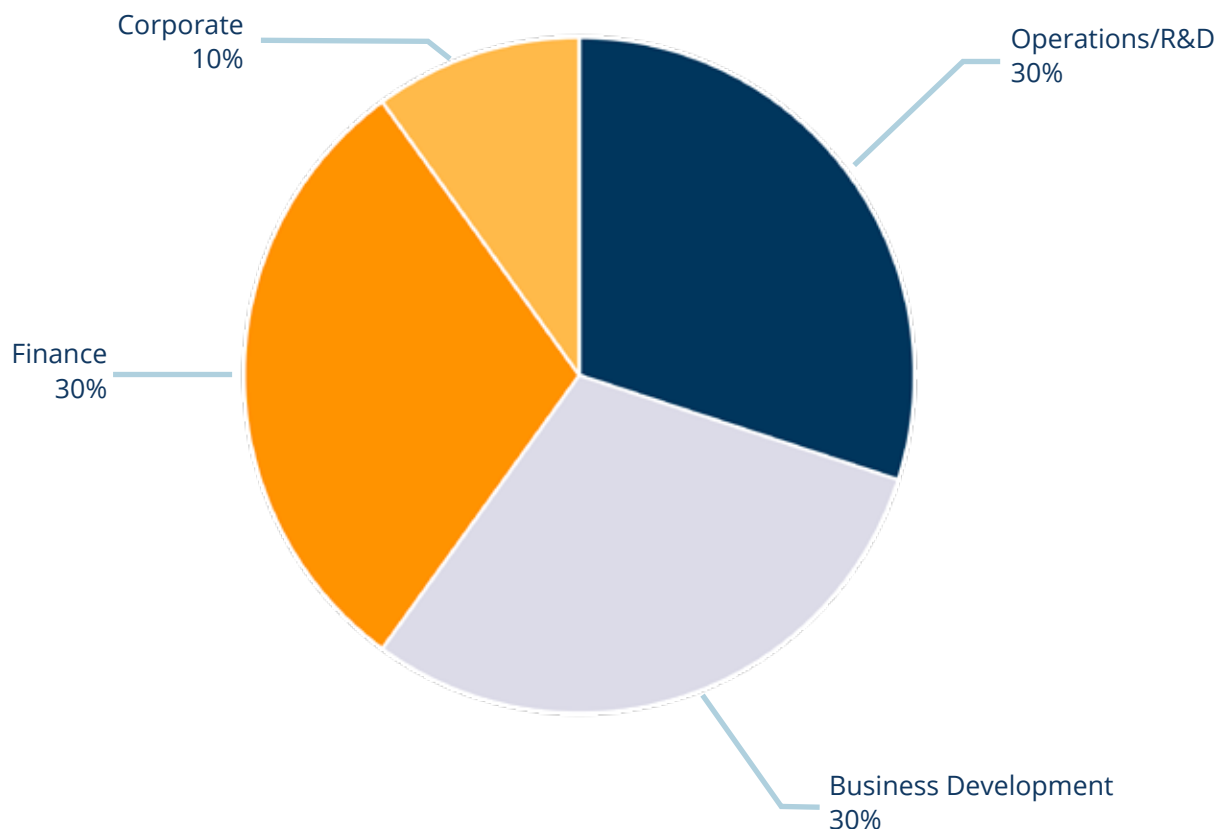
### LONG-TERM VARIABLE REMUNERATION

A long-term variable remuneration is based on the achievement by the Company of certain pre-set cash-based financial results. For each member of the Executive Committee, a fixed amount will be paid the first time a tranche of €20 million EBITDA (calculated on a recurring basis) will be achieved by the Company and this up to €80 million or 4 tranches of €20 million.

The total target short-term variable remuneration amount for an Executive Committee Member (i.e., the sum of the first and second components described above) together with the long-term variable remuneration may exceed 25% of the total fixed annual remuneration of an Executive Committee Member.

## THE 2024 CORPORATE TARGETS

Defined by the Board of Directors and used as a strong guidance for defining the Personal Targets of the entire Hyloris team



## FRINGE BENEFITS

Executive Committee members do not receive any fringe benefits.

## CONTRACT TERM AND SEVERANCE PAYMENT

All Executive Committee members provide their services under a Belgian-law-governed management agreement with Hyloris. The terms, notice periods and severance payments are described hereunder.

We will prevent 'pay for failure' and will therefore not pay a severance arrangement in the event of seriously culpable or negligent behavior on the part of an Executive Committee member being dismissed. We will also not pay severance if the agreement is terminated at the initiative of Executive Committee member, other than due to serious culpable conduct or neglect on the part of the Company.

### Mr. Stijn Van Rompay (CEO)

The current services agreement with Mr. Stijn Van Rompay has been entered into between Mr. Van Rompay's Belgian incorporated management company SVR Management BV and the Company effective as from 1 September 2019, for an indefinite period. It can be terminated by both the Company upon six months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by SVR Management BV upon three months' notice or payment of a compensation equivalent to the fixed remuneration of such three-month period. The agreement also provides for reasons for immediate termination because of a breach by either party (e.g., serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period (subject to certain exceptions) of 18 months after termination, against a payment of 100% of the fixed fee over such 18 months' period. However, SVR Management BV will not be entitled to this payment if it terminates the services agreement at its own initiative or if the Company terminates the services

agreement for breach of contract imputable to SVR Management BV.

### Mr. Thomas Jacobsen (CBDO)

The current services agreement with Mr. Thomas Jacobsen has been entered into between Mr. Thomas Jacobsen's Belgian incorporated management company Jacobsen Management BV and the Company effective as from 1 November 2019, for an indefinite period. It can be terminated by the Company upon six months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by Jacobsen Management BV upon three months' notice or payment of a compensation equivalent to the fixed remuneration of such three-month period. The agreement also provides for reasons for immediate termination because of breach of either party (e.g., serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period of 18 months after termination, against a payment of 100% of the fixed fee over that 18 months' period. However, Jacobsen Management BV will not be entitled to this payment if it terminates the services agreement at its own initiative or if the Company terminates the services agreement for breach of contract imputable to Jacobsen Management BV.

### Mr. Jean-Luc Vandebroek (CFO)

The current services agreement with Mr. Jean-Luc Vandebroek has been entered into between Mr. Vandebroek's Belgian incorporated management company Finsys Management BV and the Company effective as from 23 September 2021, for an indefinite period. It can be terminated by the Company upon three months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by Finsys Management BV upon three months' notice or payment of a compensation equivalent to the fixed remuneration of such three-month period. The

agreement also provides for reasons for immediate termination because of breach of either party (e.g., serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period of 12 months after termination against a payment of 50% of the fixed fee over such 12 months' period. However, Finsys Management BV will not be entitled to this payment if it terminates the services agreement at its own initiative or if the Company terminates the services agreement for breach of contract imputable to Finsys Management BV.

#### **Mr. Dietmar Aichhorn (COO)**

The current services agreement with Mr. Dietmar Aichhorn has been entered into as from 1 October 2020, for an indefinite period. As from December 2023, the services agreement was transferred to Mr. Aichhorn's management company DDA Management GmbH. During the first 3 years, this services agreement can be terminated by the Company and DDA Management GmbH upon three months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. After 3 years, it can be terminated by the Company and DDA Management GmbH six months' notice period or payment of a compensation equivalent to the fixed remuneration of such six-month period. The agreement also provides for reasons for immediate termination because of a breach by either party (e.g. serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period of 12 months after termination against a payment of 50% of the fixed fee over such 12 months' period. However, the Company is entitled to waive this non-compete payment if the services agreement is terminated at the initiative of DDA Management GmbH. The non-compete payment will not be due if the Company

terminates the services agreement for breach of contract imputable to DDA Management GmbH.

#### **Mr. Koenraad Van der Elst (CLO)**

The current services agreement with Mr. Koenraad Van der Elst has been entered into between Mr. Koenraad Van der Elst's Belgian incorporated management company Herault BV and the Company effective as from 1 January 2020, for an indefinite period. It can be terminated by the Company upon six months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by Herault BV upon three months' notice period or payment of a compensation equivalent to the fixed remuneration of such three-month period. The agreement also provides for reasons for immediate termination because of a breach by either party (e.g. serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a non-compete period of 12 months after termination against a payment of 50% of the fixed fee over such 12 months' period. However, Herault BV will not be entitled to this payment if it terminates the services agreement at its own initiative or if the Company terminates the services agreement for breach of contract imputable to Herault BV.

## WARRANTS AND OTHER SHARE-CONVERTIBLE SECURITIES

Upon recruiting new Executive Committee members, the Board of Directors may decide to make an additional one-time sign-on grant of equity incentives if the Board of Directors deems this necessary to attract a specific highly qualified individual.

The Board of Directors may decide to grant the members of the Executive Committee new (annual) grants of equity incentives, consisting of Warrants. Equity incentives will always be subject to a multi-year vesting scheme. As a result, the overall value for the members of the Executive Committee will be directly related to the value created for the Company's shareholders over the course of the vesting period. Vesting is subject to the Executive Committee members' continued involvement with the Company.

The members of the Executive Committee (as well as other colleagues of Hyloris) can be granted Warrants or other instruments that allow the holder to acquire shares through schemes that need to be pre-approved by the annual Shareholder's Meeting.

Article 7:91, first paragraph of the BCCA states that a Director—within three years from the date of the grant—may not definitively acquire shares by way of remuneration or exercise share options or any other right to acquire shares. The company's articles of association may deviate from this rule. Article 3 of the Articles of Association of Hyloris explicitly allows the Board to deviate from this rule when proposing the variable remuneration scheme. In any event, the ESOP warrants can only be exercised the 4th year following the year of the offer. No lock-up period applies to any shares acquired after the exercise of such ESOP warrants.

## MINIMUM SHAREHOLDING

No minimum threshold has been set for shares to be held by the Members of the Executive Committee, as the remuneration package for the Executive Committee is already sufficiently geared towards sustainable long-term value creation and, moreover, because two of the 5 Members of the Executive Committee already hold a significant block of shares in the Company as co-founder of the Company.

## CLAWBACK

No specific claw-back rights have been provided to the benefit of the Company in respect of variable remuneration granted to the members of the Executive Management allowing the Company to partially or fully claim back any variable cash compensation paid to the members of the Executive Management, based on incorrect information about meeting the performance targets on which the variable remuneration is based, or about the circumstances on which the variable remuneration was made dependent, or if such incorrect information was also due to fraud on the part of the beneficiary.

The Company believes that there are sufficient contractual rights and rights under common law available that allow it to claim back such amounts. In any event, over the past 4 years, since its initial listing on Euronext Brussels, there have been no circumstances that would have given rise to a full or partial claw-back of the variable remuneration of any of the members of the Executive Committee, if such claw back provisions would have been provided.

## PENSION SCHEME

Hyloris does not have a complementary pension scheme for any Non-Executive Director or any Executive Committee member.

## REMUNERATION

### REMUNERATION OF NON-EXECUTIVE DIRECTORS

The remuneration package for the Non-Executive Directors was revised and approved by the Shareholders' Meeting of the Company held on June 14, 2021 and consists of a fixed annual fee of €12,500 for the Non-Executive Directors and €5,000 for the members of the various Committees.

Any changes to these fees will be submitted to the Shareholders' Meeting for approval. The Executive Directors will not receive any specific remuneration in consideration for their membership in the Board of Directors.

For the remuneration of the Independent Directors in 2023, the total remuneration amounted to €110 thousand. The table below provides an overview of the remuneration per Non- Executive Director.

Name	Remuneration
Stefan Yee	€22,500
Leon Van Rompay	€12,500
Marc Foidart	€22,500
Carolyn Myers	€17,500
James Gale	€17,500
Chris Buyse	€17,500

The table below provides an overview of significant positions of warrants held directly or indirectly by the Non-Executive Members of the Board of Directors at December 31, 2023.

Name	Warrants	
	Number	%
Stefan Yee	100,000	15.94
Leon Van Rompay	0	0
Marc Foidart	0	0
Carolyn Myers	0	0
James Gale	0	0
Chris Buyse	0	0

The Non-Executive Members of the Board of Directors do not hold any shares of the Company.

## REMUNERATION OF EXECUTIVE DIRECTORS AND MEMBERS OF THE EXECUTIVE COMMITTEE

The remuneration package for the members of the Executive Management consists of a fixed cash compensation and a variable cash incentive. A one-time equity incentive was granted to some of the members of the Executive Management at the time of their hiring and may be granted in the future upon proposal of the remuneration committee and approval of the Board of Directors.

In 2023, the following remuneration and compensation was paid or accrued to the CEO (i.e., Mr. Stijn Van Rompay) and the other members of the Executive Management of Hyloris:

	€ thousand	
	CEO	Other members of Executive Committee
Annual base salary	190,944	824,611
Annual variable salary	21,876	85,328
Supplementary pension plan (defined contribution)	n.a.	n.a.
Car lease / transport allowance	n.a.	n.a.
Medical plan	n.a.	n.a.

The 2023 ratio between the highest remuneration of the members of the Executive Committee and the lowest remuneration (in full-time equivalent) of Hyloris' employees amounted to 6-to-1.

The ratio is calculated based on the lowest FTE pay per 31 December 2023, excluding trainees and internships. The remuneration which has been taken into account in this exercise includes the annual base salary, annual cash bonus and (if any) exceptional bonus; annual cash bonus is included in the year upon which performance is based and not in the year in which it is paid. Share options (warrants) are excluded from the calculations.

The table below provides an overview of the shares and warrants held by the members of the Executive Committee at the date of December 31, 2023.

Name	Shares		ESOP Warrants	
	Number	%	Number	%
Stijn Van Rompay	7,743,067	27.65	68,000	10.84
Thomas Jacobsen	3,857,838	13.78	0	0
Koenraad Van der Elst	17,443	0.06	50,000	7.97
Jean-Luc Vandebroek	9,000	0.03	40,000	6.38
Dietmar Aichhorn	32,500	0.12	40,000	6.38

## APPRAISALS

### BOARD OF DIRECTORS AND COMMITTEES OF THE BOARD OF DIRECTORS

The Board is responsible for a periodic assessment of its own effectiveness to ensure continuous improvement in the governance of the Company. The contribution of each Director is evaluated periodically. The Chairman of the Board and the performance of his role within the Board are also carefully evaluated. Furthermore, the Board will assess the operation of the Committees at least every two to three years. For this assessment, the results of the individual evaluation of the Directors are taken into consideration.

The Non-Executive Directors regularly (and preferably once a year) assess their interaction with the Executive Directors and the Executive Committee and reflect on how to streamline the interactions between both the Non-Executive Directors and Executive.

The Board may request the Remuneration Committee, where appropriate and if necessary, in consultation with external experts, to submit a report commenting on the strengths and weaknesses to the Board and make proposals to appoint new Directors or to not re-elect Directors. A Director who did not attend 50% of the Board meetings will not be considered for re-election on the occasion of the renewal of the mandate.

The evaluation of the operation of the Board of Directors in terms of its scope, composition, operation,



and that of its Committees, as well as of its interaction with the Executive Committee, took place on April 18, 2024 under the leadership of the Chairman of the Board of Directors. This evaluation resulted in a positive assessment and also indicated a few recommendations to improve the performance of the Board of Directors, of the Executive Committee and of its interaction between the Board of Directors and the Executive Committee.

## EXECUTIVE COMMITTEE

The CEO and the Remuneration Committee formally assess the operation as well as the performance of the Executive Committee annually. The evaluation of the Executive Committee occurs in the context of determining the variable remuneration of the Executive Committee members.

The performance-rating system of Hyloris for the achievement of the Personal Targets of each Member of the Executive Committee is based on a formal HR evaluation process with a scoring (from 1 to 6, whereby a rating of 6 reflects a 100 % achievement of the target) given by the CEO. For the CEO, the performance rating for the achievement of his Personal Targets is based on the average of the Personal Targets achieved by the other members of the Executive Committee. The achievement of the Corporate Targets is assessed by the Chairman of the Board. In accordance with the relevant Corporate Governance principles, the Remuneration Committee assesses the performance ratings and contributions of the CEO and the other members of the Executive Management for both the Personal and Corporate Targets. Finally, and after validation by the Remuneration and Nomination Committee, the performance rating is submitted for approval to the Board of Directors. For the performance rating over calendar year 2023, the Remuneration and Nomination Committee made its assessment and recommendation on April 18, 2024.

The Board of Directors has taken note of the positive assessment by the Remuneration and Nomination Committee and determined that the corporate objectives for 2023, which were aimed at supporting the company's long-term performance, had been achieved

at a rate of 65%. The variable remuneration for 2023 has also considered the contributions of the members of the Executive Committee towards these achievements and their individual targets that were assessed between 76,5% and 85%. The Board of Directors approved the recommendations of the Remuneration and Nomination Committee on 26 July, 2024.

## INTERNAL CONTROL AND RISK MANAGEMENT SYSTEMS

### INTERNAL MECHANISM

The Board of Directors, the Audit Committee and the Executive Committee are responsible for measuring business risks and the effectiveness of the internal control and risk management systems.

The Executive Committee has set-up internal risk management and control systems within the Company to assure the realisation of the company objectives, the reliability of financial information and reporting, the adherence to applicable laws and regulations and the monitoring and management of the internal and external impact of the risks identified.

No internal audit role has currently been assigned due to the size of the business. Internal audit activities may be outsourced from time to time whereby the Audit Committee will determine frequency of these audits and select topics to be addressed.

See subsequent event related to Forensic Investigation.

### RISK ANALYSIS

#### KEY RISK FACTORS RELATED TO THE COMPANY'S BUSINESS

A potential investor should carefully consider the following risk factors and all other information contained in the annual report before making an investment decision regarding the Company's shares. If any of these risks would occur, the business, financial condition or results of operations of the Company would likely be materially and/or adversely affected. In such case, the price of the shares could decline, and an investor could lose all or part of the investment.

## RISKS RELATED TO HYLORIS' BUSINESS ACTIVITIES AND INDUSTRY

Hyloris performance depends primarily on the success of its product candidates, a majority of which are in the early reformulation, repurposing and clinical development stage and have not yet received regulatory approval.

Even if Hyloris, or its partners, receive regulatory approval for any of its product candidates, it may be unable to launch the product successfully and the revenue that Hyloris generates from sales of such product, if any, may be limited. Even if Hyloris obtains approval for any of its product candidates, it will be subject to ongoing obligations and continued regulatory review, which may result in significant unforeseen additional expense.

In addition, Hyloris depends on the execution of its partners AltaThera, AFT Pharmaceuticals, and Padagis for successful roll-out and commercialisation of its three commercial products, Sotalol IV, Maxigesic® IV, and Podofilox Gel respectively. Additionally, Hyloris' product candidates could be subject to labelling and other marketing re-strictions and withdrawal from the market and Hyloris may be subject to penalties if it fails to comply with regulatory requirements or if it experiences unanticipated problems with its product candidates.

Hyloris' ability to successfully market its product candidates will depend in part on the level of reimbursement that healthcare organisations, including government health administration authorities, private health coverage insurers and other healthcare payors, provide for the cost of Hyloris' products and related treatments.

Despite receiving regulatory approval for a product candidate, competitors may receive regulatory approval for a product that is identical or substantially the same as one of Hyloris' product candidates, which may prevent Hyloris from commercialising its product candidates in accordance with its business plan or result in significant delays in doing so.

Hyloris' business is dependent on the continuous generation of new ideas and the development of new

product candidates to stay ahead of the competition. Hyloris relies and expects to continue to rely in large part on the know-how of its development partners with respect to the current portfolio. Hyloris expects to be less reliable from external partners in the future for the development and expansion of its portfolio.

The occurrence of a pandemic, epidemic, other health crisis or geo-political imbalance, including the COVID-19 pandemic, could have a negative impact on Hyloris' product development activities, including its access to APIs, the conduct of its clinical trials and its ability to source required funding, which could delay or prevent it from executing its strategy as planned.

The geopolitical situation in Eastern Europe intensified on 24 February 2022, with Russia's invasion of Ukraine. The war between the two countries continues to evolve as military activity proceeds and additional sanctions are imposed. Although the Russia-Ukraine war is not expected to cause disruption in the Hyloris' operations. If an external partner experience disruptions to their business due to the military conflict, this could delay or prevent it from executing its strategy as planned.

Certain of Hyloris' Directors and members of Hyloris' Executive Committee hold directorships or shareholdings in other pharmaceutical companies, which could create potential conflicts of interest.

Hyloris may be unable to successfully manage its growth.

Hyloris is dependent on third parties to supply ingredients and manufacture its products, and commercialization of Hyloris' product candidates could be delayed, halted, or made less profitable if those third parties fail to obtain and maintain the required approvals from the FDA or comparable foreign regulatory authorities, or otherwise fail to provide Hyloris with sufficient quantities of its products.

Any termination or suspension of, or delays in the commencement or completion of, any necessary clinical trials in respect to any of Hyloris' product candidates, including because of Hyloris' reliance on third parties to conduct such clinical trials, could result in increased costs to Hyloris, delay or limit its ability to generate

revenue and adversely affect Hyloris' commercial prospects.

Intellectual property rights are difficult and expensive to obtain, maintain and protect and Hyloris may not be able to fully ensure the protection of its rights, which may adversely impact Hyloris' financial performance and prospects. Third parties may also claim an ownership interest in Hyloris' intellectual property.

## RISKS RELATED TO BUSINESS ENVIRONMENT

Reference made to the US litigation - see [note 26](#).

### FINANCIAL RISKS

Hyloris has a limited operating history and has not yet generated any substantial revenues. Hyloris has incurred operating losses, negative operating cash flows and an accumulated loss since inception and Hyloris may not be able to achieve or subsequently maintain profitability. Hyloris is executing its strategy in accordance with its business model, the viability of which has not been demonstrated.

An inflation spike in the year 2022 reminded investors of the risk of rising interest rates, which made drug development more expensive. For Hyloris, the impact of increased costs in a rising rate environment could partially be offset by a positive effect resulting from the Company's significant cash position which should generate additional deposit income. The company was free of financial debt at the end of 2023 and has limited exposure to exchange rates with non-European countries.

### RISKS RELATED TO THE SHARES

The market price of the shares might be affected by a variety of factors outside management control, such as the global economic situation, the competition, sector M&A and it is difficult to mitigate the risk.

If equity research analysts do not publish research reports on Hyloris, or if they change their recommendations regarding the shares in an adverse way, the market price of the shares may fall, and the trading volume may decline.

Future sell-off of substantial amounts of shares, or the perception that such sell-off may occur, could adversely affect the market value of the shares.

## CONTROLS, SUPERVISION AND CORRECTIVE ACTIONS

### EXTERNAL CONTROL

At the Company's Shareholders' Meeting held on June 14, 2022, KPMG Réviseurs d'Entreprises BV/SRL has been appointed as statutory auditor of the Company for a period of three years. The mandate will expire at the end of the general meeting called to approve the accounts for the 2024 financial year. KPMG Réviseurs d'Entreprises SRL has designated Tanguy Legein, réviseur d'entreprises, as permanent representative.

In 2023, a total amount of €119K was paid to the statutory auditor and its network. This amount includes the following elements: €91K thousand for audit fees, and €28K for tax services.

### INTERNAL CONTROL

Supervision and monitoring of the operations of the Company is done on a permanent basis at all levels within the Company.

The Executive Committee develops a long-term financial plan (5-year business plan) incorporating the Company strategy. This plan is monitored on a regular basis and updated twice a year to keep it in line with the strategy plans. The Executive Committee also develops an annual budget which is approved by the Board and which is closely monitored during the year. Management reporting is prepared monthly, which details the variances between the actuals and the budget.

Internal control activities are performed by the Finance Department related to accounting and financial information and by all persons in charge for all matters related to the operational activities of the company. When deviations are identified, there are reported to the head of department. As of the date of this report there is not yet a dedicated Internal Audit Function, function is supported by the Finance Department.

In order to properly manage identified risks, the Company has set up the following procedures and reporting processes:

- a budgeting process has been installed with a strong involvement of all departments of the Company which provide a more accurate forecast of the spending on a more granular level;
- the company has developed procedures relating to various business processes (expenditures, procurement, payroll, IT, investments, cash management, and books closing and reporting);
- the company has developed a monthly reporting tool which allows a close monitoring of the financial information. The company has a monthly reporting of the actual spending;
- information systems have been developed to assist the company and are constantly being adjusted to meet new needs as they arise;
- external financial reports are produced twice a year (half year reports ended 30 June and full year reports ended 31 December);
- half-year and full-year reporting are discussed by the audit committee and all critical accounting issues and financial uncertainties are reported and discussed.

The Executive Committee supervises the implementation of internal controls and risk management, considering the recommendations of the Audit Committee.

The Executive Committee is also in charge of proposing the Audit Committee corrective actions when identified.

In 2023, the Company made the following improvements in its internal processes:

- a new enterprise resource ERP has been identified and partially implemented mainly for Finance;
- a new reporting tool was developed and implemented;
- the internal budgeting and forecasting process was further improved;
- improvements were made to the handling of payroll transactions;
- A monthly financial reporting reconciliation was developed and implemented.

## MARKET ABUSE REGULATIONS

To prevent insider trading and market manipulation, as required by the Market Abuse Regulation, we have a Dealing Code available on our website. This code outlines the rules for Directors and executives when buying or selling our company's shares and other financial instruments. It restricts their trading activity to specific periods and requires them to declare their transactions.

Our Governance Charter also has safeguards to prevent the misuse of confidential information by anyone with access, including directors, shareholders, managers, and employees. While insiders may receive this information for their work, they are strictly prohibited from trading our company's related financial instruments.

We maintain a comprehensive insider list, which includes all current and past employees or associates who have (or had) access to confidential information. This list is regularly updated and provided to the Financial Services and Markets Authority (FSMA) upon their request.

## CONFLICTS OF INTEREST AND RELATED PARTIES

### CONFLICTS OF INTEREST

In the interest of fair and impartial decision-making, Belgian law (Article 7:96 of the Companies and Associations Code) requires Directors to disclose any potential conflicts of interest arising from their personal financial holdings.

In such cases, Directors must inform the Board Chair immediately. Conflicts can involve personal finances, family ties (up to second-degree relatives), or other outside activities. When a conflict arises, the Director cannot participate in discussions or votes on that specific issue.

Hyloris has additional internal rules to manage potential conflicts beyond the legal requirements. These include situations where a close relative of a Director or Executive has a financial stake that conflicts with the company's decisions, or if the Director/Executive holds a position in another company with conflicting interests.

If a Board Member encounters such a conflict, they must inform the Board at the meeting's start. The Board then decides if the member can participate in the discussion and vote on the matter. The Board meeting minutes will document how the situation was handled, but these details won't be made public.

For Executive Management conflicts, the issue is presented to the Board for a decision.

Currently, no conflicts of interest exist among Directors or Executives that haven't been disclosed to the Board. In any past instances, Hyloris has followed the legal procedures outlined in Article 7:96

## RELATED PARTY TRANSACTIONS

Hyloris adheres to a comprehensive procedure established to safeguard the integrity of decisions involving related parties, as defined by International Accounting Standard 24 (IAS 24) as adopted by the European Union. This procedure, mandated by Article 7:97 of the Belgian Companies and Associations Code (CCA), applies to all material transactions where a potential conflict of interest could arise between the Company and a related party.

To ensure objectivity, an independent committee comprised of three Directors meticulously reviews such transactions. This committee issues a written and reasoned opinion to the Board of Directors, addressing the elements outlined in Article 7:97, Section 3.2 of the CCA. Notably, the Board is precluded from approving a transaction if a Director with a conflict of interest is involved.

In such instances, or if all Directors are conflicted, the proposed transaction is submitted for approval to the General Shareholders' Meeting. Following shareholder approval, the Board may then execute the transaction. The Board is obligated to document its adherence

to this procedure within the meeting minutes, with justifications provided for any deviations from the committee's opinion.

Furthermore, the statutory auditor verifies the financial and accounting information documented within the Board minutes and the committee's opinion for material inconsistencies, based on the information available within the scope of their audit. This auditor's opinion is then attached to the Board minutes.

In accordance with Article 7:97, Section 4.1 of the CCA, the Company publicly discloses all decisions or transactions falling under this procedure.

It's important to note that this procedure is not applicable to routine transactions conducted at market rates, transactions with a value less than 1% of the Company's consolidated net assets, decisions regarding Director or executive committee remuneration, acquisitions or disposals of own shares, interim dividend payments, or capital increases authorized under the existing share capital without limitations or cancellation of existing shareholder preferential subscription rights.

## TRANSACTIONS WITH RELATED PARTIES

The Board of Directors of Hyloris has not applied the procedure set forth in Articles 7:96 and 7:97 CCA, in 2023.

## TRANSACTIONS WITH AFFILIATES

Article 7:97 of the Belgian Code on Companies and Associations provides for a special procedure which must be followed for transactions with the Company's affiliated companies or subsidiaries. Such a procedure does not apply to decisions or transactions that are entered into the ordinary course of business at usual market conditions or for decisions and transactions whose value does not exceed one percent of the Companies' consolidated net assets.

The Board of Directors of Hyloris has not applied the special procedure set forth in Article 7:97 CCA for transactions with the Company's affiliated companies or subsidiaries, in 2023.

# SHARE CAPITAL, SHARES AND SHAREHOLDERS

## HISTORY OF CAPITAL – CAPITAL INCREASE AND ISSUANCE OF SHARES

### SECURITIES ISSUED BY THE COMPANY

As of December 31, 2023, the Company's capital amounted to €140,001.87 (excluding issue premium) represented by 28,000,374 ordinary shares without nominal value.

The Company created four stock option plans under which warrants were granted to employees, Directors, consultants and shareholders of the Company and its subsidiaries: the transaction warrants in May 2017 and three ESOP Warrants plans in December 2019, December 2020, and June 2022.

### HISTORY OF CAPITAL SINCE IPO

#### Authorised Capital

In accordance with the Articles of Association, the Extraordinary General Shareholders' meeting of the Company authorised the Board of Directors to increase the share capital of the Company, in one or several times, and under certain conditions set forth in extenso in the articles of association.

On June 8, 2020, the General Meeting of Shareholders decided, in accordance with articles 604 juncto 607, para. 2, 2° of the Belgian Company Code to give, for a period of five years starting on June 8, 2020, the authorisation to the Board of Directors to increase the capital of the Company with a maximum amount of €117,758.84 (excluding issue premium). The General Meeting of Shareholders also decided to give this authorisation to the Board in case of reception by the Company of a communication by the Financial Services and Markets Authority (FSMA) stating that the FSMA has been informed of a public takeover bid regarding the Company, for all public take-over bids notified to the Company three years after June 8, 2020.

The Board has used its powers to increase the share capital within the framework of the authorised capital

on November 27, 2020 by an amount of €2,000 (excluding any issue premiums) following the issuance of the 400,000 ESOP 2020 Warrants.

On March 31, 2022, the share capital was increased by contribution in cash, as the result of an accelerated bookbuilding, for a total amount of €15 mio (including issue premium) with issuance of 967,742 new shares, also within the framework of the authorized capital. The new shares were issued at a price of €15.5 per share (including issue premium), increasing the capital of the Company for an amount of €4,838.71 (excluding issue premium).

Finally, a third ESOP Warrant 2022 plan was approved in June 2022, using the authorised capital for an amount of €1,067.50 (excluding issue premium) following the issuance of the 213,500 ESOP 2022 warrants and restoring also the amount of the authorized capital corresponding to 213,500 cancelled ESOP 2020 Warrants.

Consequently, the Board is therefore still authorised to increase the share capital of the Company within the framework of the authorised capital for a maximum amount of €110,920.13 (as of 1 April 2024, excluding issue premium).

### CHANGES IN CAPITAL

At any given time, the Shareholders' Meeting can resolve to increase or decrease the share capital of the Company. Such resolution must satisfy the quorum and majority requirements that apply to an amendment of the articles of association.

## WARRANTS PLANS

### WARRANT PLANS ISSUED

The Company created four warrant plans under which warrants were granted to employees, Directors, consultants and shareholders of the Company and its subsidiaries: the transaction warrants in May 2017 and the ESOP Warrants plans in December 2019, November 2020 and June 2022.

## SUMMARY OF THE OUTSTANDING WARRANT PLANS

### Transaction Warrants

On May 12, 2017, the Company issued 300,000 warrants (before stock split - the transaction warrants). All transaction warrants have been subscribed for. The transaction warrants were granted free of charge. Initially all transaction warrants were subscribed by Mr. Stijn Van Rompay. Thereafter they have been transferred at multiple occasions to other persons such as shareholders in the Company.

In June 2022, the afore-mentioned transaction warrants were exercised, resulting in the issuance of 1,200,000 new ordinary shares at a subscription price per share of €2.3597, resulting in a capital increase of €2,831,640.

### ESOP Warrants

On December 31, 2019, the Company approved, in principle, the issue of 90,825 warrants in the context of an employee stock ownership plan, subject to the ESOP Warrants being offered to, and accepted by, the beneficiaries thereof, who must be employees, Directors or consultants of the Company and/or its subsidiaries. As a result of the Share Split, each ESOP Warrant was automatically "divided" into four. Following the Share Split and considering a certain number of warrants that have lapsed or have been cancelled, a total of 306,125 ESOP Warrants are currently granted and outstanding.

On November 27, 2020, the Company approved, in principle, the issue of 400,000 warrants in the context of a second employee stock ownership plan, subject to the ESOP Warrants being offered to, and accepted by, the beneficiaries thereof, who must be employees, Directors or consultants of the Company and/or its subsidiaries. Under this plan, 186,500 ESOP Warrants are currently granted and outstanding and 213,500 ESOP Warrants were cancelled.

On June 22, 2022, the Company approved, in principle, the issue of 213,500 ESOP Warrants in the context of a third employee stock ownership plan. Under this plan, 134,646 ESOP Warrants are currently granted and outstanding and 71,500 ESOP Warrants were cancelled and 7,353 were forfeited.

All ESOP Warrants have been granted free of charge.

Each ESOP Warrant entitles its holder to subscribe for one new Share at an exercise price determined by the Board of Directors in line with a report on the real value of the underlying Share at the date of the offering of the ESOP Warrants in accordance with article 43, §4, 2° of the Belgian Stock Option Act of March 26, 1999.

The exercise price determined for all ESOP Warrants issued in 2019, taking into account the Share Split, is equal to €5.3375 per ESOP Warrant.

The exercise price for the ESOP Warrants issued in 2020 and 2022 is equal (a) to the average closing price of the Company's shares during the thirty (30) days preceding the offer or (b) to the last closing price preceding the day of the offer. It is possible that, when the evolution of the share price is such that such a discount is justified to grant to the beneficiaries of the warrant plan warrants with an exercise price similar to the exercise price of the warrants that others beneficiaries of the warrant plan have acquired and in order to ensure equality between the beneficiaries of the warrant plan as much as possible, that the exercise price of the Stock Option Warrants will be equal to eighty-five percent (85 %) of the average closing price of the Company's shares during the thirty (30) days preceding the offer or (b) at the last closing price preceding the day of the offer (i.e. a maximum discount of fifteen percent (15 %)).

The new Shares (if any) that will be issued pursuant to the exercise of the ESOP Warrants, will be ordinary shares representing the capital, of the same class as the then existing Shares, fully paid, with voting rights and without nominal value. They will have the same rights as the then existing Shares and will be profit sharing as from any distribution in respect of which the relevant ex-dividend date falls after the date of their issuance.

The ESOP Warrants shall only be acquired in a final manner ("vested") in cumulative tranches over a period of four years as of the starting date (determined for each beneficiary separately): i.e., a first tranche of 25% vests on the first anniversary of the starting date and subsequently 1/48th vests each month. ESOP Warrants can only be exercised by the relevant holder of such ESOP Warrants, provided that they have effectively

vested, as of the beginning of the fourth calendar year following the year in which the Company granted the ESOP Warrants to the holders thereof. As of that time, the ESOP Warrants can be exercised during the first fifteen days of each quarter. However, the terms and conditions of the ESOP Warrants provide that the ESOP Warrants can or must also be exercised, regardless of whether they have vested or not, in several specified cases of accelerated vesting set out in the issue and exercise conditions.

The terms and conditions of the ESOP Warrants contain customary good leaver and bad leaver provisions in the event of termination of the professional relationship between the beneficiary and Hyloris. The terms and

conditions of the ESOP Warrants also provide that all ESOP Warrants (whether or not vested) will become exercisable during a special exercise period to be organised by the Board in the event of certain liquidity events. These liquidity events include (i) a transfer of all or substantially all Shares of the Company; (ii) a merger, demerger or other corporate restructuring resulting in the share-holders holding the majority of the voting rights in the Company prior to the transaction not holding the majority of the voting rights in the surviving entity after the transaction; (iii) the launch of a public takeover bid on the Shares; and (iv) any action or transaction with substantially the same economic effect as determined by the Board of Directors.

## HYLORIS ESOP SCHEMES

Hyloris has put in place the following warrant schemes (which are called inschrijvingsrechten/ droits de souscription under the BCCA) of which the details (i.e., conditions for the granting, term, vesting period, exercise) are set out in the following table. The conditions for the granting of these warrants and the vesting period help to align the interests of the Executive Committee members with the long-term interests of Hyloris, its shareholders and other stakeholders.

	2019	2020	2022
<b>Conditions for Granting</b>	Employees, Directors or consultants of Hyloris Pharmaceuticals and/or its subsidiaries	Employees, Directors or consultants of Hyloris Pharmaceuticals and/or its subsidiaries	Employees, Directors or consultants of Hyloris Pharmaceuticals and/or its subsidiaries
<b>Term</b>	5 years	10 years	7 years
<b>Vesting Period</b>	The 2019 plan is subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month).	The 2020 plan is subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month).	The 2022 plan is subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month).
<b>Exercise</b>	Warrants which are definitively acquired ("vested") may be exercised from the first (1) of January of the fourth (4th) calendar year following that of the Date of the Offer and this, only during the first fortnight. (the first fifteen (15) days) of each quarter. The first fortnight (the first fifteen (15) days) of the last quarter of the validity period of the Stock Option Warrants constitutes the last possible exercise period. Each fiscal period will end on the last business day of the relevant fiscal period.	Warrants which are definitively acquired ("vested") may be exercised from the first (1) of January of the fourth (4th) calendar year following that of the Date of the Offer and this, only during the first fortnight. (the first fifteen (15) days) of each quarter. The first fortnight (the first fifteen (15) days) of the last quarter of the validity period of the Stock Option Warrants constitutes the last possible exercise period. Each fiscal period will end on the last business day of the relevant fiscal period.	Warrants which are definitively acquired ("vested") may be exercised from the first (1) of January of the fourth (4th) calendar year following that of the Date of the Offer and this, only during the first fortnight. (the first fifteen (15) days) of each quarter. The first fortnight (the first fifteen (15) days) of the last quarter of the validity period of the Stock Option Warrants constitutes the last possible exercise period. Each fiscal period will end on the last business day of the relevant fiscal period.



## CONSEQUENCES IN CASE OF A PUBLIC TAKE-OVER BID

The Extraordinary Meeting of Shareholders of June 11, 2024 decided to give the authorisation to the Board to increase the capital of the Company in case of reception by the Company of a communication by the Financial Services and Markets Authority (FSMA) stating that the FSMA has been informed of a public takeover bid regarding the Company, for all public take-over bids notified to the Company three years after June 11, 2024. At the Extraordinary General Meeting of 11 June 2024, the Board of Directors approved the renewal of this authorisation for a period of three years from the date of the Extraordinary General Meeting.

Pursuant to the resolution of the Extraordinary Shareholders' Meeting of June 11, 2024, the Board of Directors of the Company is authorised to acquire and accept in pledge its own Shares without the total number of own Shares, held or accepted in pledge by the Company exceeds 20% of the total number of Shares, for a consideration of at least €1 and at most 30% above the arithmetic average of the closing price of the Company's Share during the last thirty days of stock exchange listing prior to the decision of the Board of Directors to acquire or accept in pledge.

The Board of Directors is furthermore authorised, subject to and with effect as from the completion of the Offering, to acquire or accept in pledge its own Shares where such acquisition or acceptance in pledge is necessary to prevent imminent serious harm to the Company.

The Company may transfer its own Shares in accordance with the Belgian Code of Companies and Associations and article 11 of its Articles of Association. And the Board of Directors of the Company is also authorised to transfer its own Shares to one or more specific persons other than employees.

The authorisations referred to above also apply to the Company, the direct subsidiaries of the Company, insofar as necessary, the indirect subsidiaries of the Company, and, insofar as necessary, every third party acting in its own name but on behalf of those companies.

There are no agreements between shareholders which are known by the Company and may result in restrictions on the transfer of securities and/or the exercise of voting rights.

There are no holders of any shares with special voting rights. Each shareholder is entitled to one vote per share. Voting rights may be suspended as provided in the Company's Articles of Association and the applicable laws and articles.

The Company is not a party to agreements which, upon a change of control of the Company or following a takeover bid can enter into force or, subject to certain conditions can be amended, be terminated by the other parties thereto or give the other parties thereto (or beneficial holders with respect to bonds) a right to an accelerated repayment of out-standing debt obligations of the Company under such agreements.

## SHAREHOLDERS

Belgian legislation (the Law of May 2, 2007 on the disclosure of major shareholdings in Companies whose shares are admitted to trading on a regulated market, and the Royal Decree of February 14, 2008 on the disclosure of major shareholdings) imposes disclosure requirements on each natural person or legal entity (including registered business associations without legal personality and trusts) that acquires or transfers, directly or indirectly, (i) securities with voting rights or (the right to exercise) voting rights, (ii) securities granting the right to acquire existing securities with voting rights, or (iii) securities that are referenced to existing securities with voting rights and with economic effect similar to that of the securities referred to in (ii), whether or not they confer a right to a physical settlement, if, as a result of such acquisition or transfer, the total number of voting rights (deemed to be) linked to securities referred to in (i) through (iii) directly or indirectly held by such natural person or legal entity, acting alone or in concert with others, reaches, rises above or falls below a threshold of 5%, or a multiple of 5%, of the total number of voting rights attached to the securities of the Company.

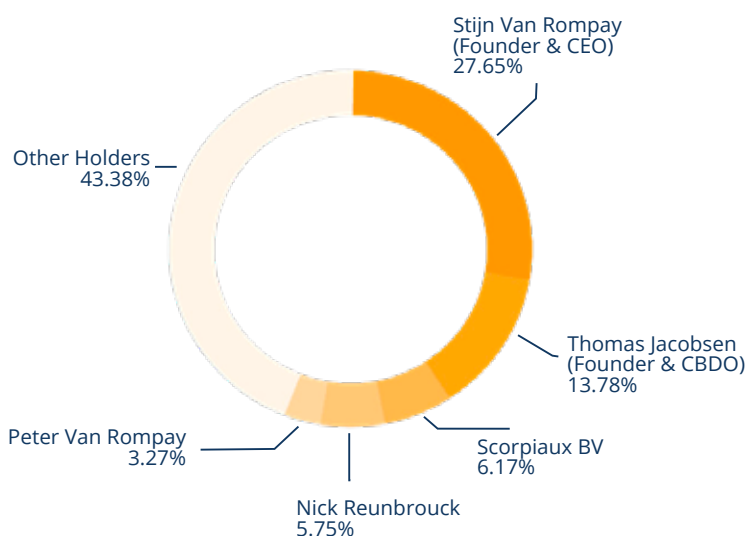
A notification duty applies also if (a) the voting rights (linked to securities) referred to in (i) or (b) the voting

rights deemed to be linked to securities referred to in (ii) and (iii), taken separately, reaches, rises above or falls below the threshold.

The Company has introduced additional disclosure thresholds of 3% and 7.5% in its Articles of Association.

The graph to the right provides an overview of the shareholders of Hyloris Pharmaceuticals SA, taking into account the transparency notifications received pursuant to the Law of May 2, 2007 on the disclosure of large shareholders (situation as per December 31, 2023).

At December 31, 2023, there are 28,000,374 ordinary shares representing a total share capital of the Company of €140,001.87 (excluding issue premium). There are only ordinary shares, and there are no special rights attached to any of the ordinary shares, nor special shareholder rights for any of the shareholders of the Company. The Company has issued a total of (i) 363,300 ESOP warrants (December 2019) of which 57,175 warrants were forfeited, (ii) 400,000 ESOP warrants (November 2020) of which 213,500 warrants were forfeited, (iii) 213,500 ESOP Warrants (June 2022) of which 78,854 ESOP Warrants were forfeited. All the warrants give right to subscribe to an equal number of shares. As per 31 December 2023, a total of 627,271 ESOP warrants were outstanding.



Based on transparency notifications and latest denominator  
Based on online notification (FSMA website) of managers' transactions

## DIVIDENDS AND DIVIDEND POLICY

### ENTITLEMENT TO DIVIDENDS

In accordance with the Belgian Code of Companies and Associations, the distribution of profits to shareholders is determined through a vote at the Annual General Meeting. This vote is based on the most recently audited financial statements prepared in accordance with Belgian Generally Accepted Accounting Principles (Belgian GAAP). A non-binding proposal for dividend distribution is typically presented by the Board of Directors.

The Board of Directors also possesses the authority to declare interim dividends, subject to adherence to relevant legal restrictions.

The Company's capacity to distribute dividends hinges on the presence of sufficient "distributable profits" as defined by Belgian law. This determination is based on the Company's stand-alone statutory accounts prepared in accordance with Belgian GAAP.

Specifically, dividend distribution can only proceed if, following the declaration and issuance of said dividends, the Company's net assets (as reflected in the non-consolidated financial statements at the most recent fiscal year-end) remain above a minimum threshold. This threshold is calculated by subtracting provisions, liabilities, and (in most cases) non-amortized incorporation and research & development costs from the total assets on the balance sheet (all in accordance with Belgian accounting rules). Additionally, the minimum threshold may be further increased by non-distributable reserves, such as any unamortized revaluation surpluses.

It is important to note that Belgian law and the Company's Articles of Association mandate the allocation of 5% of the annual net profit ("bénéfices nets"/"nettowinst") to a legal reserve within the stand-alone statutory accounts. This allocation continues until the legal reserve reaches 10% of the Company's share capital. As the legal reserve currently falls below this requirement, a portion of future annual net profits will

be directed to this reserve, consequently limiting the available pool for dividend distribution.

Belgian law dictates that the right to collect declared dividends on ordinary shares expires five years after the date of declaration by the Board of Directors. Thereafter, the Company is no longer obligated to pay such dividends.

### DIVIDEND POLICY

The Company has not previously distributed dividends on its shares. Any future declaration of dividends will be contingent upon a thorough examination of the Company's financial performance, current financial health, capital needs, and other factors deemed relevant by the Board of Directors.

Neither Belgian law nor the Company's Articles of Association mandate the distribution of dividends.

At present the Board of Directors intends to retain all generated earnings, if any, to fuel the Company's development and growth initiatives. Consequently, dividend payments to shareholders are not anticipated in the near future.

The determination of the Company's dividend policy remains within the purview of the Board of Directors and is subject to potential future adjustments.

# Consolidated Financial Statements

## Contents

<b>Consolidated Financial Statements as at 31 December 2023</b> .....	<b>86</b>
<i>Consolidated Statement of Financial Position</i> .....	86
<i>Consolidated Statement of Profit and Loss and Other Comprehensive Income</i> .....	87
<i>Consolidated Statement of Changes in Equity</i> .....	88
<i>Consolidated Statement of Cash Flows</i> .....	89
<b>Notes to the Consolidated Financial Statements</b> .....	<b>90</b>
<b>Abbreviated Statutory Financial Statements</b> .....	<b>142</b>
<b>Statutory Notes</b> .....	<b>144</b>
<b>Statutory auditor's report</b> .....	<b>146</b>

## STATEMENT OF THE BOARD OF DIRECTORS

On 26 July, 2024, we hereby confirm that, to the best of our knowledge

- the consolidated financial statements, established in accordance with International Financial Reporting Standards (“IFRS”) as adopted by the European Union, give a true and fair view of the equity, financial position and financial performance of Hyloris Pharmaceuticals SA and of the entities included in the consolidation as a whole;
- the annual report on the consolidated financial statements includes a fair overview of the development and the performance of the business and the position of Hyloris Pharmaceuticals SA and of the entities included in the consolidation, together with a description of the principal risks and uncertainties to which they are exposed.

Signed by Stijn Van Rompay (CEO) and Stefan Yee (Chairman) on behalf of the Board of Directors

# Consolidated Financial Statements as at 31 December 2023

## Consolidated Statement of Financial Position

ASSETS (in € thousands)	Note	31 December 2023	31 December 2022 restated <sup>1</sup>
<b>Non-current assets</b>		<b>12,373</b>	<b>10,927</b>
Intangible assets	7	3,828	3,607
Property, plant and equipment		429	176
Right-of-use assets	8	1,724	885
Equity accounted investees	9	3,801	3,948
Other investment, including derivatives	10	1,000	1,000
Trade and other receivables	11	1,591	1,311
<b>Current assets</b>		<b>35,308</b>	<b>49,801</b>
Trade and other receivables	11	3,565	4,127
Other investment, including derivatives	10	499	10,469
Current tax assets	23.3	244	-
Prepayments	12	594	1,748
Cash and cash equivalents	13	30,406	33,457
<b>TOTAL ASSETS</b>		<b>47,681</b>	<b>60,728</b>
<b>EQUITY AND LIABILITIES</b> (in € thousands)			
<b>Equity</b>	14	<b>39,069</b>	<b>53,909</b>
Share capital		140	140
Share premium		121,513	121,513
Retained earnings, excluding profit (loss) for the reporting period		(65,381)	(53,476)
Retained earnings, profit (loss) for the reporting period		(15,380)	(11,905)
Share based payment reserve		2,161	1,621
Cost of Capital		(4,460)	(4,460)
Other reserves		476	476
<b>Liabilities</b>		<b>8,613</b>	<b>6,819</b>
<b>Non-current liabilities</b>		<b>1,853</b>	<b>1,047</b>
Borrowings	15	1,510	747
Other financial liabilities	15	344	300
<b>Current liabilities</b>		<b>6,759</b>	<b>5,772</b>
Borrowings	15	241	138
Other financial liabilities	15	3,200	3,212
Trade and other liabilities	16	3,318	2,422
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>47,681</b>	<b>60,728</b>

<sup>1</sup> See [note 31](#) regarding restated information

The accompanying notes on pages are an integral part of these consolidated financial statements.

## Consolidated Statement of Profit or Loss and Other Comprehensive Income

(in € thousand)	Note	2023	2022 restated <sup>1</sup>
Revenues	18	2,087	900
Other operating income	21	2,127	1,487
<b>Operating income</b>		<b>4,214</b>	<b>2,387</b>
Cost of sales	19	(93)	(94)
Research and development expenses	19	(14,421)	(10,272)
General and administrative expenses	19	(5,546)	(3,517)
Share of result of equity-accounted investees, net of tax	9	(147)	(130)
Other operating expenses	19	-	(12)
<b>Operating expenses</b>		<b>(20,207)</b>	<b>(14,024)</b>
<b>Operating profit/(loss) (EBIT)</b>		<b>(15,993)</b>	<b>(11,638)</b>
Financial income	22	898	466
Financial expenses	22	(285)	(730)
<b>Profit/(loss) before taxes</b>		<b>(15,380)</b>	<b>(11,901)</b>
Income taxes	23	-	(4)
<b>PROFIT/(LOSS) FOR THE PERIOD</b>		<b>(15,380)</b>	<b>(11,906)</b>
Other comprehensive income		-	-
<b>TOTAL COMPREHENSIVE INCOME OF THE PERIOD</b>		<b>(15,380)</b>	<b>(11,906)</b>
Profit/(loss) for the period attributable to the owners of the Company		(15,380)	(11,906)
Profit/(loss) for the period attributable to the non-controlling interests			
Total comprehensive income for the period attributable to the owners of the company			
Basic and diluted earnings/(loss) per share (in €)	24	(0.55)	(0.43)

<sup>1</sup>See [note 31](#) regarding restated information

The accompanying notes are an integral part of these consolidated financial statements

## Consolidated Statement of Changes in Equity

(in € thousand)	Attributable to equity holders of the company						Total Equity
	Share capital	Share premium	Share based payment reserve	Other reserves		Retained earnings and result of the period	
				Cost of Capital	Other reserves		
<b>Balance at 31 December 2021</b>	<b>129</b>	<b>103,693</b>	<b>2,391</b>	<b>(3,827)</b>	<b>476</b>	<b>(54,805)</b>	<b>48,056</b>
Private Placement via an ABB (note 14.2)	5	14,995		(634)	-		14,366
Transfer of SBP reserves to retained earnings (note 25)	6	2,826	(1,329)			1,329	2,832
Share-based payments (note 25)			560				560
Total comprehensive income						(10,770)	(10,770)
<b>Balance at 31 December 2022, as previously reported</b>	<b>140</b>	<b>121,513</b>	<b>1,622</b>	<b>(4,460)</b>	<b>476</b>	<b>(64,246)</b>	<b>55,045</b>
Impact of correction of errors (note 31)						(1,136)	(1,136)
<b>Balance at 31 December, 2022, (restated)</b>	<b>140</b>	<b>121,513</b>	<b>1,622</b>	<b>(4,460)</b>	<b>476</b>	<b>(65,381)</b>	<b>53,909</b>
Share-based payments (note 25)			540				540
Total comprehensive income						(15,380)	(15,380)
<b>Balance at 31 December 2023</b>	<b>140</b>	<b>121,513</b>	<b>2,162</b>	<b>(4,460)</b>	<b>476</b>	<b>(80,761)</b>	<b>39,069</b>

The accompanying notes are an integral part of these consolidated financial statements.



## Consolidated Statement of Cash Flows

(in € thousand)	Note	2023	2022 restated <sup>1</sup>
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Profit/(loss) for the period		(15,380)	(11,906)
<i>Adjustments to reconcile net loss to net cash provided by operating activities:</i>			
Depreciation, amortisation and impairments	19	349	196
Share-based payment expense	25	540	560
Net finance result	22	(613)	264
Equity transaction costs		-	29
Share of profit of equity-accounted investees, net of tax	9	147	130
Losses on disposal of PPE		-	16
Other non-cash adjustments		15	16
Bank fees paid		(48)	-
<i>Changes in working capital:</i>			
Trade and other receivables	11	29	(921)
Other investment, including derivatives		-	56
Prepayments	12	1,155	(650)
Trade and other liabilities	15	1,050	(468)
<b>Cash generated from operations</b>		<b>(12,756)</b>	<b>(12,679)</b>
Interest paid	15/22	(52)	7
Taxes paid	23	-	(349)
<b>Net cash generated from operating activities</b>		<b>(12,808)</b>	<b>(13,020)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Interest received	22	638	
Purchases of property, plant and equipment		(298)	(101)
Purchases of Intangible assets	7	(452)	(638)
Proceeds from settlement of derivatives	22	-	522
Acquisition in other investments	10	(0)	(500)
Loans made to third parties	11	-	(655)
Proceeds of other financial assets	10	10,000	(10,000)
<b>Net cash provided by/(used in) investing activities</b>		<b>9,889</b>	<b>(11,373)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Reimbursements of borrowings and other financial liabilities	15	-	(7,376)
Proceeds from borrowings and other financial liabilities	15	51	-
Reimbursements of lease liabilities	15	(170)	(79)
Reimbursements of borrowings		-	-
Proceeds from Private Placement via ABB	14	-	14,337
Proceeds from Exercise of Warrants	14	-	2,832
Interests paid	15	(12)	(1,877)
<b>Net cash provided by/(used in) financing activities</b>		<b>(131)</b>	<b>7,838</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>		<b>(3,051)</b>	<b>(16,555)</b>
<b>CASH AND CASH EQUIVALENTS at beginning of the period</b>		<b>33,457</b>	<b>50,012</b>
<b>CASH AND CASH EQUIVALENTS at end of the period, calculated</b>		<b>30,406</b>	<b>33,457</b>

<sup>1</sup>See [note 31](#) regarding restated information

The accompanying notes are an integral part of these consolidated financial statements.

# Notes to the Consolidated Financial Statements

## 1. GENERAL INFORMATION

Hyloris Pharmaceuticals SA (the “Company” or “Hyloris”) is a limited liability company governed by Belgian law. The address of its registered office is Boulevard Patience et Beaujonc N°3/1, 4000 Liège, Belgium.

Hyloris is a specialty biopharma company identifying and unlocking hidden potential in existing medications for the benefit of patients and the healthcare system. Hyloris applies its knowhow and technological innovations to existing pharmaceuticals and has built a broad proprietary product pipeline that has the potential to offer significant advantages over currently available alternatives.

Hyloris currently has three partnered, commercial-stage products: Maxigesic® IV, a non-opioid analgesic for the treatment of pain and Podofilox Gel, the first drug product generic to Conylox Gel 0.5%® in the U.S. and Sotalol IV for the treatment of atrial fibrillation.

The Company's development strategy primarily focuses on the FDA's 505(b)2 regulatory pathway, which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule has already been established. This pathway can reduce the clinical burden required to bring a product to market, and significantly shorten the development timelines and reduce costs and risks.

### Armed conflict between Russia and Ukraine

The military action in Ukraine is an element of the current uncertainty in the macroeconomic environment. While we do not have operations in Russia or Ukraine, sanctions and other measures taken in response to the military action have adversely affected – and could further affect – the global economy, financial markets and the supply chain.

### Current economic climate

The macroeconomic situation did not improve, the inflation and interest rates continued to slightly increase

in 2023 impacting for example the internal discount rates (higher risk free rate) used in the financial valuation models. Furthermore, the fear of recession and the geopolitical conflicts remained important and continued to impact the energy prices in 2023. The context of high interest rates combined with high energy prices puts pressure on the costs in general as well as on many APIs (active pharmaceutical ingredient). The crisis in the Middle East, which disrupted supply chains in the Suez Canal, did not impact the company because it has diverse sources of supply. In general, the volatility of interest rates introduces uncertainty into financial markets and can influence investor behavior, company finances, and consumer spending patterns. To mitigate these risks, the company remains very cautious about the level of its expenses and the size of its investments without impacting the ongoing R&D development programs.

The consolidated financial statements were authorized for issue by the Board of Directors on 26 July, 2024.

## 2. SUMMARY OF MATERIAL ACCOUNTING POLICIES

### 2.1 BASIS OF PREPARATION

The consolidated financial statements of the Group for the year ended December 31, 2023 have been prepared in accordance with IFRS (“International Financial Reporting Standards”) as adopted by the European Union. These include all IFRS standards and IFRIC interpretations issued and effective as at December 31, 2023. No new standards, amendments to standards or interpretations were early adopted.

The consolidated financial statements are presented in euro, which is the Company's functional currency. All amounts in this document are represented in thousands of euros (€ thousands), unless noted otherwise. Due to rounding, numbers presented throughout these Consolidated Financial Statements may not add up precisely to the totals provided and percentages may not precisely reflect the absolute figures.

The financial statements are prepared on an accrual basis and on the assumption that the entity is in going concern and will continue in operation in the foreseeable future (see also **Note 3.1**).

The preparation of financial statements in accordance with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise judgment in the process of applying the Group accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in **Note 3**.

*Relevant IFRS accounting pronouncements to be adopted as from 2023 onwards*

In 2021 the IASB issued Disclosure of Accounting Policies (Amendments to IAS 1) and updated IFRS Practice Statement 2 Making Materiality Judgements. IAS 1 Presentation of Financial Statements has been amended to require companies to disclose 'material' rather than 'significant' accounting policies. Although the amendments did not result in any changes to the accounting policies themselves, they impacted the accounting policy information disclosed in the financial statements. Management reviewed the accounting policies and made updates to the information disclosed in certain instances in line with the amendments.

Other pronouncements issued by the IASB have not been disclosed as the Company considers these as not relevant to the business of the Group.

A number of new standards, amendments to standards and interpretations are not yet effective for the year ended 31 December 2023, and have not been applied in preparing these consolidated financial statements:

#### **Amendments to IAS 1 Presentation of Financial Statements:**

- Classification of Liabilities as Current or Non-current Date (issued on 23 January 2020);
- Classification of Liabilities as Current or Non-current - Deferral of Effective Date (issued on 15 July 2020); and
- Non-current Liabilities with Covenants (issued on 31 October 2022)

#### **Amendments to IAS 1 Presentation of Financial**

**statements:** Classification of Liabilities as Current or Non-current, issued on 23 January 2020, clarify a criterion in IAS 1 for classifying a liability as non-current: the requirement for an entity to have the right to defer settlement of the liability for at least 12 months after the reporting period.

The amendments:

- specify that an entity's right to defer settlement must exist at the end of the reporting period;
- clarify that classification is unaffected by management's intentions or expectations about whether the entity will exercise its right to defer settlement;
- clarify how lending conditions affect classification; and
- clarify requirements for classifying liabilities an entity will or may settle by issuing its own equity instruments.

On July 15, 2020, the IASB issued **Classification of Liabilities as Current or Non-current — Deferral of Effective Date (Amendment to IAS 1)** deferring the effective date of the January 2020 amendments with one year.

On October 31, 2022, the IASB issued **Non-current liabilities with Covenants, which amends IAS 1** and specifies that covenants (i.e. conditions specified in a loan arrangement) to be complied with after the reporting date do not affect the classification of debt as current or non-current at the reporting date. Instead, the amendments require a company to disclose information about these covenants in the notes to the financial statements.

All amendments are effective for annual reporting periods beginning on or after 1 January 2024, with early adoption permitted. The amendments have been endorsed by the EU.

**Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback, issued on 22 September 2022, introduce a new accounting model which will impact how a seller-lessee accounts for variable lease payments in a sale-and-leaseback transaction.**

Under this new accounting model for variable payments, a seller-lessee will:

- include estimated variable lease payments when it initially measures a lease liability arising from a sale-and-leaseback transaction; and
- after initial recognition, apply the general requirements for subsequent accounting of the lease liability such that it recognizes no gain or loss relating to the right of use it retains.

These amendments will not change the accounting for leases other than those arising in a sale and leaseback transaction. The amendments apply retrospectively for annual periods beginning on or after 1 January 2024 with early application permitted. These amendments have been endorsed by the EU.

#### **Amendments to IAS 7 Statement of Cash Flows and IFRS 7 Financial Instruments: Disclosures:**

**Supplier Finance Arrangements**, issued on 25 May 2023, introduce additional disclosure requirements for companies that enter into supplier finance arrangements. The amendments are effective for periods beginning on or after 1 January 2024, with early application permitted. However, some relief from providing certain information in the year of initial application is available. These amendments have not yet been endorsed by the EU.

#### **Amendments to IAS 21 The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability,**

issued on 15 August 2023, clarify when a currency is exchangeable into another currency (and when it is not). When a currency is not exchangeable, a company needs to estimate a spot rate. The company's objective when estimating a spot rate is that it reflects the rate at which an orderly exchange transaction would take place at the measurement date between market participants under prevailing economic conditions. The amendments contain no specific requirements for estimating a spot rate. Under the amendments, companies will need to provide new disclosures to help users assess the impact of using an estimated exchange rate on the financial statements. The amendments are effective for annual reporting periods beginning on or after 1 January 2025 with early adoption permitted. These amendments have not yet been endorsed by the EU.

#### **IFRS 18 Presentation and Disclosure in Financial Statements,**

issued on 9 April 2024, will replace IAS 1 Presentation of Financial Statements. The new standard will improve the quality of financial reporting by:

- requiring defined subtotals in the statement of profit or loss;
- requiring disclosure about management-defined performance measures; and adding new principles for aggregation and disaggregation of information.

The standard is effective for annual reporting periods beginning on or after 1 January 2027 with early adoption permitted. The standard has not yet been endorsed by the EU.

#### **IFRS 19 Subsidiaries without Public Accountability:**

**Disclosures**, issued on 9 May 2024, will allow eligible subsidiaries to apply IFRS Accounting Standards with reduced disclosure requirements. A subsidiary will be to apply the new standard in its consolidated, separate or individual financial statements provided that, at the reporting date: it does not have public accountability; and its parent produces consolidated financial statements under IFRS Accounting Standards.

The standard is effective for annual reporting periods beginning on or after 1 January 2027 with early adoption permitted. The standard has not yet been endorsed by the EU.

#### **Amendments to the Classification and Measurement of Financial Instruments—Amendments to IFRS 9 and IFRS 7,**

issued on 30 May 2024, will address diversity in accounting practice by making the requirements more understandable and consistent. The amendments include: Clarifications on the classification of financial assets with environmental, social and corporate governance (ESG) and similar features—ESG-linked features in loans could affect whether the loans are measured at amortized cost or fair value. To resolve any potential diversity in practice, the amendments clarify how the contractual cash flows on such loans should be assessed.

Clarifications on the date on which a financial asset or financial liability is derecognized. The IASB also decided to develop an accounting policy option to allow

a company to derecognize a financial liability before it delivers cash on the settlement date if specified criteria are met.

The IASB has also introduced additional disclosure requirements to enhance transparency for investors regarding investments in equity instruments designated at fair value through other comprehensive income and financial instruments with contingent features, for example features tied to ESG-linked targets.

The amendments are effective for annual reporting periods beginning on or after 1 January 2026 with early adoption permitted. These amendments have not yet been endorsed by the EU.

Except for IFRS 18, for which the analysis is ongoing, these amendments are not expected to have any significant impact on the consolidated financial statements of Hyloris.

## 2.2 CONSOLIDATION

### Subsidiaries

Subsidiaries are all entities over which the Group has control. Control is established when the Group is exposed, or has the rights, to variable returns from its involvement with the subsidiary and has the ability to affect those returns through its power over the subsidiary. Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

Intra-group balances and transactions and any unrealized income and expenses (except for foreign currency transactions gains or losses) arising from intra-group transactions are eliminated. Unrealized gains arising from transactions with equity-accounted investees are also eliminated against the investment to the extent of the Groups interest in the investee. Unrealized losses are eliminated in the same way as unrealized gains, but only to the extent that there is no evidence of impairment.

### Transactions under common control

For business combinations under common control (also "Transactions under common control"), the Group applies predecessor accounting.

The consideration for each acquisition is measured at the aggregate of the fair values (at the date of acquisition) of assets transferred and liabilities incurred or assumed, and equity instruments issued by the Group in exchange for control of the acquiree. Acquisition-related costs are recognized in profit or loss as incurred.

Where applicable, the consideration for the acquisition includes any asset or liability resulting from a contingent consideration arrangement, measured at its acquisition-date fair value.

The acquiree's identifiable assets, liabilities, and contingent liabilities that meet the recognition criteria conditions for recognition under IFRS are recognized and measured at the carrying amounts as recognized in the acquiree's individual financial statements, but adjusted for any deviations with the accounting policies of the Group.

Any difference between the consideration transferred and the net assets at the acquisition date is recognized in retained earnings.

The Group elected the accounting policy choice to represent its comparatives and adjust its current reporting period before the date of the transaction as if the transaction had occurred before the start of the earliest period presented. This restatement should not extend to periods during which the entities were not under common control.

## 2.3 JOINT ARRANGEMENTS

Joint control is the contractually agreed sharing of control of an arrangement, which exists when decisions about relevant activities require the unanimous consent of the parties sharing control.

Joint arrangements are classified as either a joint venture or a joint operation.

A joint venture is a joint arrangement whereby the parties that have joint control of the arrangement have rights to the net assets of the arrangement.

The results, assets and liabilities of joint ventures are incorporated in the consolidated financial statements using the equity method of accounting, except when the

investment is classified as held for sale (in which case it is accounted for in accordance with IFRS 5 Non-current Assets Held for Sale).

Under the equity method, on initial recognition, investments in joint ventures are recognised in the consolidated statement of financial position at cost, and the carrying amount is adjusted for post-acquisition changes in the Group's share of the net assets of the joint venture, less any impairment of the value of individual investments. Losses of a joint venture in excess of the Group's interest in that joint venture (which includes any long-term interests that, in substance, form part of the Group's net investment in the associate or joint venture) are recognised only to the extent that the Group has incurred legal or constructive obligations or made payments on behalf of the joint venture.

Any excess of the cost of acquisition over the Group's share of the net fair value of the identifiable assets and (contingent) liabilities of the joint venture recognised at the date of acquisition is goodwill. The goodwill is included within the carrying amount of the investment and is assessed for impairment as part of that investment.

Where a Group entity transacts with a joint venture of the Group, profits and losses are eliminated to the extent of the Group's interest in the relevant joint venture. Unrealized gains arising from transactions with equity-accounted investees are eliminated against the investment to the extent of the Group's interest in the investee. Unrealised losses are eliminated in the same way as unrealised gains, but only to the extent that there is no evidence of impairment.

A joint operation is a joint arrangement whereby the parties that have joint control of the arrangement have rights to the assets and obligations of the liabilities relating to the arrangement.

A joint operator recognizes its assets, liabilities and transactions, including its share of those incurred jointly. These assets, liabilities and transactions are accounted for in accordance with the relevant accounting standards.

## 2.4 FOREIGN CURRENCIES

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The consolidated financial statements are presented in euro, which is the Group's presentation currency.

Transactions in foreign currencies are translated into the respective rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rate at the reporting date. Non-monetary assets and liabilities that are measured at fair value in foreign currency are translated into the functional currency at the exchange rate when the fair value was determined. Non-monetary items that are measured based on historical cost in a foreign currency are translated at the exchange rate at the date of the transaction. Foreign currency differences are generally recognised in profit or loss and presented within financial result.

The principal exchange rate that has been used is the US dollar. The following table presents the exchange rates used for the USD/EUR

1 EUR =	Closing Rate	Average Rate
December 31, 2022	1.0666	1.0530
December 31, 2023	1.1050	1.0813

## 2.5 INTANGIBLE ASSETS

### Research and development

#### *Internally-generated research and development*

To assess whether an internally generated intangible asset meets the criteria for recognition, the Company classifies the internal generation of assets into a research phase and a development phase.

No intangible asset arising from research is recognized. Expenditure on research is recognized as an expense when it is incurred.

An intangible asset arising from development is recognized if, and only if, the Company can demonstrate all of the following:

- (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- (ii) the intention to complete the intangible asset and use or sell it;
- (iii) the ability to use or sell the intangible asset;
- (iv) how the intangible asset will generate probable future economic benefits;
- (v) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- (vi) the ability to measure reliably the expenditure attributable to the intangible asset during its development.

With respect to the technical feasibility condition, strong evidence is achieved only when Phase III (i.e. final stage before filing for marketing approval) of the related development project is successfully completed, i.e. when filing for marketing approval from the relevant regulatory authorities. Consequently, internally generated development expenses arising before this point, mainly the cost of clinical trials, are expensed as incurred within Research and development expenses.

In some cases (i.e. for high barrier generic products), market approval was obtained previously, but additional costs are incurred in order to improve the process for an active ingredient. To the extent that the above criteria are considered as having been met, such expenses are recognized as an asset in the balance sheet within intangible assets as incurred. Similarly, some clinical trials, for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the above capitalization criteria, in which case the related expenses are recognized as an asset in the balance sheet within intangible assets.

The cost of an internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria. The cost of an internally-generated intangible

asset comprises all directly attributable costs necessary to create, produce and prepare the asset to be capable of operating in the manner intended by management, including any fees to register legal rights (patent costs) and borrowing costs.

#### *Separately acquired research and development*

Payments for separately acquired research and development are capitalized as intangible assets provided that the following conditions are met:

- (i) the asset is identifiable, i.e. either separable (if it can be sold, transferred, licensed) or it results from contractual or legal rights;
- (ii) it is probable that the expected future economic benefits that are attributable to the asset will flow to the Group;
- (iii) the Group can control the resource; and
- (iv) the cost of the asset can be measured reliably.

The second condition for capitalization (the probability that the expected future economic benefits from the asset will flow to the entity) is considered to be satisfied for separately acquired research and development. The management of the company assesses whether and to which amount milestone payments are to be considered as related to the purchase of an asset (capitalization) or related to outsourced research and development. The latter will be recognized as research and development expenses when they occur.

If the separately acquired research and development project meets the conditions for capitalization as mentioned above, related upfront and milestone payments to third parties are recognized as intangible assets, and amortised on a straight-line basis over their useful lives beginning when marketing approval is obtained. However, any subsequent expenditure on the relating projects is added to the carrying amount of the intangible asset only if it meets the recognition criteria for capitalizing development costs (see above section Internally-generated research and development).

Payments under research and development arrangements relating to access to technology or to

databases and payments made to purchase generics dossiers are also capitalized as the conditions mentioned above are met upon acquisition, and amortised on a straight-line basis over the useful life of the intangible asset. Subsequent expenditure incurred are only capitalized if the expenditure meets the conditions mentioned above for capitalizing development costs.

Subcontracting arrangements, payments for research and development services, and continuous payments under research and development collaborations which are unrelated to the outcome of that collaboration, are expensed over the service term except if as part of the development phase of the underlying assets.

Non-refundable advance payments for goods and services that will be used in future research activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Research and development expenses also include upfront and milestone payments, to the amount these payments are assessed to be outsourced research and development and to the amount of the costs effectively occurred.

### **Intangible assets acquired through exchange of assets**

Intangible assets may be acquired in exchange for a non-monetary asset or assets, or a combination of monetary and non-monetary assets.

In the event of such exchange of assets, the cost of the acquired asset is measured at fair value unless (a) the exchange transaction lacks commercial substance or (b) the fair value of neither the asset received, nor the asset given up is reliably measurable. If the acquired asset is not measured at fair value, its cost is measured at the carrying amount of the asset given up.

### **Other intangible assets acquired separately**

An intangible asset is recognized on the statement of financial position when the following conditions are met:

- (i) the asset is identifiable, i.e. either separable (if it can be sold, transferred, licensed) or it results from contractual or legal rights;

- (ii) it is probable that the expected future economic benefits that are attributable to the asset will flow to the Group;

- (iii) the Group can control the resource; and

- (iv) the cost of the asset can be measured reliably.

The cost of a separately acquired intangible asset comprises its purchase price, including import duties and non-refundable purchase taxes, after deducting trade discounts and rebates. Any directly attributable cost of preparing the asset for its intended use is also included in the cost of the intangible asset.

### **Subsequent measurement**

Subsequent to initial recognition, intangible assets are measured at cost less accumulated amortisation and any accumulated impairment losses. Intangible assets are amortised on a systematic basis over their useful life, using the straight-line method. Amortisation begins when the asset is capable of operating in the manner intended by management.

The estimated useful life and amortisation method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis.

The amortisation expense is presented as part of Cost of Sales in the Statement of Profit or Loss. The applicable useful lives are determined based on the period during which the Company expects to receive benefits from the underlying project. Key factors considered to determine the useful life comprises the duration of the patent protection and access of competitors to the market.

### **Derecognition**

An intangible asset is derecognized in case the intangible asset is sold or out-licensed, or when no future economic benefits are expected from use or disposal. Gains or losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds and the carrying amount of the asset, are recognized in profit or loss when the asset is derecognized.



## 2.6 LEASES

Leases are recognized as a right-of-use asset and corresponding liability at the date of which the leased asset is available for use by the Group.

Lease liabilities include the net present value of the following lease payments:

- fixed payments (less any lease incentives receivable),
- variable lease payments that are based on an index or rate,
- the exercise price of a purchase option if the group is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the group exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

The lease payments are discounted using the interest rate implicit in the lease, if that rate can be readily determined, or the Group's incremental borrowing rate, i.e. the rate of interest that a lessee would have to pay to borrow over a similar term, and with a similar security, the funds necessary to obtain an asset of a similar value to the right-of-use asset in a similar economic environment.

The group is exposed to potential future increases in variable lease payments based on an index or rate, which are not included in the lease liability until they take effect. When adjustments to lease payments based on an index or rate take effect, the lease liability is reassessed and adjusted against the right-of-use asset.

The lease liability is subsequently measured at amortised cost under the effective interest method. Finance expenses are recognized immediately in profit or loss, unless they are directly attributable to qualifying assets, in which case they are capitalized.

Right-of-use assets are initially measured at cost comprising the following:

- the amount of the initial measurement of lease liability,

- any lease payments made at or before the commencement date less any lease incentives received,
- any initial direct costs, and
- an estimate of the costs related to the dismantling and removal of the underlying asset.

If it is reasonably certain that the Group will exercise a purchase option, the asset shall be depreciated on a straight-line basis over its useful life. In all other circumstances the asset is depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term.

The Group has elected not to separate non-lease components and account for the lease and non-lease components as a single lease component.

## 2.7 IMPAIRMENT OF NON-FINANCIAL ASSETS

Intangible assets with indefinite useful lives and intangible assets not yet available for use are not subject to amortisation, but are tested annually for impairment, and whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. Other assets which are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

An impairment loss is recognized for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. To determine the value in use, the forecasted future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset.

When an impairment loss subsequently reverses, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset in prior years. A reversal of an impairment loss is recognized immediately in profit or loss.

## 2.8 REVENUE RECOGNITION

Revenue is measured based on the consideration specified in a contract with a customer. The Group recognizes revenue when it transfers control over a good or service to a customer.

In applying IFRS 15 Revenue from contracts with customers the Group determines the separate performance obligations included within the contract with the customer. Currently the Group has contracts in which it grants a license. Some contracts include additional services which are to be provided such as research and development services and/or cost sharing mechanisms. In general, these are all considered separate performance obligations.

The transaction price is allocated to each performance obligation on a stand-alone selling price basis.

The following paragraphs provide information about the nature and timing of the satisfaction of performance obligations in contracts with customers, including significant payment terms, and the related revenue recognition policies:

### Royalties

Royalties received from commercialized products are recorded in accordance with the royalty's exception as foreseen in IFRS 15 Revenue from contracts with customers. Sales- or usage-based royalties that are attributable to a license of intellectual property of commercialized goods, are recognized at the later of:

- when the subsequent sale or usage occurs; and
- the satisfaction or partial satisfaction of the performance obligation to which some or all of the sales- or usage-based royalty has been allocated.

Currently the Group has 3 commercialized products for which royalties are recorded, i.e., Sotalol IV, Maxigesic® IV and Podofilox (in 2022 there were 2 commercialized products, i.e., Sotalol IV and Maxigesic® IV). For each commercialized product specific formulas are stipulated in the contract to determine the royalties attributable to the Group.

Payment terms in general are 30 days after the invoice date.

### Milestone payments

The royalty's exception as applied for the revenue recognition of royalties does not apply to milestone payments which are determined with reference to other events or indicators, i.e., not sales or usage based. The current arrangements which are held with co-development partners can include a license of intellectual property and an obligation to finance research and development costs for which the Group receives a consideration of which a substantial portion of the total consideration is contingent on achieving milestones such as regulatory filling or FDA approval of the product candidate. These milestone payments are generally considered separate performance obligations within the co-development agreement and are recognized in accordance with the variable consideration guidance included within IFRS 15 Revenue from contracts with customers.

The Group only includes estimates of variable consideration in the transaction price to the extent that it is 'highly probable' that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is resolved. In doing so, the Group assess the likelihood of a revenue reversal arising from an uncertain future event and the potential magnitude of the revenue reversal when the uncertainty related to the variable consideration has been resolved. Given the fact that receiving the consideration is highly susceptible to factors outside the entity's influence and the fact that the uncertainty about the consideration is not expected to be resolved for a long period of time the Group only recognizes the milestone payments when the milestone is reached. As such this is not considered a significant estimate with a high level of estimation uncertainty.

Payment terms are 30 days after the invoice date except for AFT where the payment terms are agreed between parties.

### Out-license agreements

When the Group grants a license, that is distinct from other promised goods or services in the contract, then it evaluates the nature of the license to determine if it is:

- a right to access the entity's intellectual property as it exists throughout the license period. If this is the case, then revenue from the license is recognized over time; or
- a right to use the entity's intellectual property as it exists at the point in time at which the license is granted. If this is the case, then revenue from the license is recognized at a point in time.

Up until December 31, 2023, the Group only granted licenses with the right to use.

For licenses which are not distinct from other performance obligations, the Group applies judgment to assess the nature of the combined performance obligations to determine whether the combined performance obligations are satisfied over time or at a point in time. If the performance obligation is satisfied over time, revenue is recognized based on a pattern that best reflects the transfer of control of the service to the customer.

Payment terms are 30 days after the invoice date.

#### Other operating income - Services rendered to co-development partners

Other operating income is measured based on the consideration specified in a contract with a customer. The Group recognizes income when it performs the service to the customer and thus recognizes the income over time.

These services are currently not presented as part of Revenue, as these are not considered output of the company's ordinary activities but it could become core business activities in the future.

## 2.9 COST OF SALES

Cost of sales are related to the sale of products and are recognized when the associated revenue is recognized. Cost of goods sold includes the amortization of intangible assets for the product candidates which are commercialized. Cost of sales does not include any R&D costs due to the lack of internal systems in place which would allow for proper registration and follow-up of costs (incl. personnel cost) and its allocation to cost of sales.

## 2.10 FINANCIAL ASSETS

The Group classifies its financial assets in the following categories: financial assets at fair value through profit and loss (FVTPL) or through other comprehensive income (FVOCI) and financial assets at amortised cost. The classification depends on the entity's business model for managing the financial assets and the contractual terms of the cash flows. Management determines the classification of its financial assets at initial recognition.

A financial asset is measured at amortised cost if it meets both of the following conditions and is not designated as at FVTPL (Fair Value Through Profit and Loss Statement) :

- It is held within a business model whose objective is to hold assets to collect contractual cash flow; and
- Its contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

On initial recognition of an equity investment that is not held for trading, the Group may irrevocably elect to present subsequent changes in the investment's fair value in OCI. This election is made on an investment-by-investment basis.

All financial assets not classified as measured at amortised costs or FVOCI as described above are measured at FVTPL.

In assessing whether the contractual cash flows are solely payments of principal and interest, the Group considers the contractual terms of the instrument. This includes assessing whether the financial asset contains a contractual term that could change the timing or amount of contractual cash flows such that it would not meet this condition. In making this assessment, the Group considers:

- Contingent events that would change the amount or timing of cash flows;
- Terms that may adjust the contractile coupon rate, including variable-rate features,
- Prepayment and extension features; and
- Terms that limit the Group's claim to cash flows from specified assets (e.g. non-recourse features).

Trade receivables are initially recognized when they are originated. All other financial assets are initially recognized when the Group becomes a party to the contractual provisions of the instrument.

At initial recognition, the group measures a financial asset at its fair value plus, in the case of a financial asset not at fair value through profit or loss, transaction costs that are directly attributable to the acquisition of the financial asset. Transaction costs of financial assets carried at fair value through profit or loss are expensed in profit or loss. A trade receivable without a significant financing component is initially measured at the transaction price.

Financial assets at FVTPL are subsequently measured at fair value. Net gains and losses, including any interest or dividend income, are recognized in the financial result in profit or loss.

Equity investments at FVOCI are subsequently measured at fair value. Dividends are recognized as income in profit or loss unless the dividend clearly represents a recovery of part of the cost of investments. Other net gains and losses are recognized in OCI and are never reclassified to profit or loss.

Financial assets at amortized cost are subsequently measured at amortised cost using the effective interest method, less any impairment.

The Group assesses on a forward-looking basis the expected credit losses associated with its financial assets carried at amortised cost. For trade receivables, the group applies the simplified approach permitted by IFRS 9 Financial Instruments, which requires expected lifetime losses to be recognized from initial recognition of the receivables.

The amount of the allowance is deducted from the carrying amount of the asset and is recognized in the income statement within 'Cost of sales'.

The Group derecognizes a financial asset only when the contractual rights to the cash flows from the asset expire, or when it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity. If the Group neither transfers nor retains substantially all the risks and

rewards of ownership and continues to control the transferred asset, the Group recognizes its retained interest in the asset and an associated liability for amounts it may have to pay. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognize the financial asset and also recognizes a collateralized borrowing for the proceeds received.

On de-recognition of a financial asset in its entirety, the difference between the asset's carrying amount and the sum of the consideration received and receivable is recognized in profit or loss.

Financial assets and financial liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Group currently has a legally enforceable right to set off the amounts and it intends either to settle them on a net basis or to realize the asset and settle the liability simultaneously.

## 2.11 FAIR VALUE MEASUREMENT

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date in the principal or, in its absence, the most advantageous market to which the Group has access at that date. The fair value of a liability reflects its non-performance risk.

A number of the Group's accounting policies and disclosure require the measurement of fair values, for both financial and non-financial assets and liabilities.

When one is available, the Group measures the fair value of an instrument using the quoted price in an active market for that instrument. A market is regarded as 'active' if transactions for the asset or liability take place with sufficient frequency and volume to provide pricing information on an ongoing basis.

If there is no quoted price in an active market, then the Group uses valuation techniques that maximise the use of relevant observable inputs and minimize the use of unobservable inputs. The chosen valuation technique incorporates all of the factors that market participants would take into account in pricing a transaction.

If an asset or a liability measured at fair value has a bid price and an ask price, then the Group measures assets and long positions at a bid price and liabilities and short positions at an ask price.

The best evidence of the fair value of a financial instrument on initial recognition is normally the transaction price – i.e. the fair value of the consideration given or received. If the Group determines that the fair value on initial recognition differs from the transaction price and the fair value is evidenced neither by a quoted price in an active market for an identical asset or liability nor based on a valuation technique for which any unobservable inputs are judged to be insignificant in relation to the measurement, then the financial instrument is initially measured at fair value, adjusted to defer the difference between the fair value on initial recognition and the transaction price. Subsequently, that difference is recognized in profit or loss on an appropriate basis over the life of the instrument but no later than when the valuation is wholly supported by observable market data or the transaction is closed out.

## 2.12 CASH AND CASH EQUIVALENTS

Cash and cash equivalents include bank balances and demand deposits meeting the criteria of cash and cash equivalents. Bank overdrafts are shown within borrowings in current liabilities on the statement of financial position.

Deposits with the same level of liquidity as cash, i.e. can be withdrawn at any time without penalty fee are cash. Deposits that don't have the same liquidity level as cash are only considered cash equivalents if the following criteria are met:

- Short term investment, e.g. with a maturity date of three months or less. Three months is a presumption that may be rebutted when the investment is held for the purpose of meeting short-term commitments and when the instrument otherwise meets the definition of a cash equivalent;
- Highly liquid and readily convertible into a known amount of cash, i.e. the amount of cash that would be received is known at the time of the initial investment;

- Subject to an insignificant risk of changes in value;
- Held for the purpose of meeting short-term cash commitments.

Deposits which are excluded from cash and cash equivalents are presented as other investments, including derivatives in the statement of financial position.

## 2.13 SHARE CAPITAL

Ordinary shares are classified as equity. Incremental costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax, from the proceeds.

## 2.14 GOVERNMENT GRANTS

The Company recognizes a government grant only when there is reasonable assurance that the Company will comply with the conditions attached to the grant and the grant will be received.

Government grants are recognized in profit or loss on a systematic basis over the periods in which the Company recognizes as expenses the related costs which the grants are intended to compensate. As a result, grants relating to costs that are recognized as intangible assets or property, plant and equipment (grants related to assets or investment grants) are deducted from the carrying amount of the related assets and recognized in the profit or loss statement consistently with the amortisation or depreciation expense of the related assets.

The portion of grants not yet released as income is presented as deferred income in the statement of financial position, within the Other current liabilities. In the statement of comprehensive income, government grants are presented as other operating income or financial income depending on the nature of the costs that are compensated.

Government grants that become receivable as compensation for expenses or losses already incurred are recognized in profit or loss of the period in which they become receivable.

Recoverable cash advances

With respect to recoverable cash advances (RCA – “avances récupérables”), the RCA gives rise to a financial liability in the scope of IFRS 9 – Financial Instruments. This financial liability is initially measured at fair value and any difference with the cash to be received from the authorities is treated as a government grant in accordance with IAS 20 – Accounting for Government Grants and Disclosure of Government Assistance. Subsequent to the initial recognition, the financial liability is measured at amortised cost using the effective interest method on the basis of the estimated contractual cash flows with changes in value due to a change in estimated cash flows recognized in profit or loss, in accordance with IFRS 9.

R&D Tax Credit

In Belgium, companies that invest in environmental friendly research and developments activities can benefit from increased investment incentives or a tax credit.

Since 2020, the Group applies for the R&D tax credit incentive set-up by the Federal government. When capitalizing its R&D expenses under tax reporting framework, the Group may either (i) get a reduction of its taxable income (if any) corresponding to 13.5% of the capitalized R&D expenses, or (ii) if no sufficient taxable income is available, apply for the refund of unutilized tax credits. The tax credit should be claimed in the year in which the investment takes place. Refund occurs five financial years after the tax credit application filed by the Group and for the part not yet recovered.

R&D tax credits are treated as a government grant under IAS 20 and booked into other operating income if the R&D activities are expensed, or as a reduction to intangible assets if the development activities are capitalized and subsequently amortised together with the underlying assets.

Exemption payroll taxes

The Group applies for the program of partial exemption from payment of withholding tax for organizations employing researchers.

This measure allows companies not to pay the tax authorities up to 80% of the withholding tax on the salaries of staff working on innovative and R&D projects. As of 2023, these payroll tax rebates are recognized in the line Other Operating Income in the financial statements. See [note 31](#).

**2.15 EMPLOYEE BENEFITS**Short-term employee benefits

Short-term employee benefits are recorded as an expense in the income statement in the period in which the services have been rendered. Any unpaid compensation is included in trade and other liabilities in the statement of financial position. A liability is recognized to be paid if the Group has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee and the obligation can be estimated reliably.

**2.16 SHARE-BASED PAYMENTS**

Equity-settled share-based payments to employees and others providing similar services are measured at the fair value of the equity instruments at the grant date. The fair value determined at the grant date of the equity-settled share-based payments is expensed on a straight-line basis over the vesting period, if any, based on the Company's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Company revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equity-settled share-based payment reserve.

**2.17 INCOME TAXES**

Income tax expense represents the sum of the current income tax and deferred tax.

Accounting for the current and deferred tax effects of a transaction or other event is consistent with the accounting for the transaction or event itself. Therefore, income taxes are recognized in profit or loss except to the extent that it relates to items recognized directly in equity or in OCI.

Current tax comprises the expected tax payable or receivable on the taxable income or loss for the year and any adjustment to the tax payable or receivable in respect of previous years. The amount of current tax payable or receivable is the best estimate of the tax amount expected to be paid or received that reflects uncertainty related to income taxes, if any.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the end of the reporting period in the countries where the Group's subsidiaries operate and generate taxable income. In line with paragraph 46 of IAS 12 Income taxes, management periodically evaluates positions taken in tax returns with respect to situations in which applicable tax regulations are subject to interpretation and establishes uncertainty tax provisions within tax payable/receivable where appropriate on the basis of amounts expected to be paid to the tax authorities. This evaluation is made for tax periods open for audit by the competent authorities.

Deferred tax is recognized on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements.

However, the deferred tax is not recognized for:

- the initial recognition of goodwill (in case of taxable temporary differences arising);
- the initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss and
- deferred tax is recognized on temporary differences arising on investments in subsidiaries and associates, except for deferred income tax liabilities where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not reverse in the foreseeable future.

A deferred tax liability is recognized for all taxable temporary differences, unless one of the above exemptions would apply.

Deferred tax assets are recognized for deductible temporary differences and unused tax losses and tax credits to the extent that it is probable that taxable

profits will be available against which they can be utilized. Future taxable profits are determined based on the reversal of relevant taxable temporary differences. If the amount of taxable temporary differences is insufficient to recognize a deferred tax asset in full, then future taxable profits, adjusted for reversals of existing temporary differences, are considered, based on the business plans for individual subsidiaries in the Group.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realized or the liability is settled, based on tax rates (and tax laws) that have been enacted or substantively enacted by the end of the reporting period.

The carrying amount of deferred tax assets is reviewed at the end of each reporting period and reduced to the extent that it is no longer probable that sufficient taxable profits will be available to allow all or part of the asset to be recovered. Unrecognized deferred tax assets are reassessed at each reporting date and recognized to the extent that it has become probable that future taxable profits will be available against which they can be used.

Deferred taxes are calculated at the level of each fiscal entity in the Group. Deferred tax assets and liabilities are offset only if certain criteria are met.

## 2.18 FINANCIAL LIABILITIES

Financial liabilities (including borrowings and trade and other payables) are classified as at amortised cost.

All financial liabilities are initially recognized when the Group becomes a party to the contractual provisions of the instrument. Financial liabilities are recognized initially at fair value, net of transaction costs incurred. Borrowings are subsequently stated at amortised cost; any difference between the proceeds (net of transaction costs) and the redemption value is recognized in the income statement over the period of the borrowings using the effective interest method. Borrowings are classified as current liabilities unless the Group has an unconditional right to defer settlement of the liability for at least 12 months after the end of the reporting period.

Where the loan is from a shareholder acting in the capacity of a shareholder, the difference between cash received and fair value of the loan at initial recognition is reflected in equity because the substance of the favorable terms is typically a contribution by a shareholder.

The Group derecognizes a financial liability when its contractual obligations are discharged or cancelled, or expire. The Group also derecognizes a financial liability when its terms are modified and the cash flows of the modified liability are substantially different, in which case a new financial liability based on the modified terms is recognized at fair value.

When a financial liability measured at amortised cost is modified without this resulting in derecognition, a gain or loss is recognized in profit or loss. The gain or loss is calculated as the difference between the original contractual cash flows and the modified cash flows discounted at the original effective interest rate.

## 2.19 DERIVATIVE FINANCIAL INSTRUMENTS

The Group holds derivative financial instruments to hedge its foreign currency. Derivatives are recognised initially at fair value at the date a derivative contract is entered into and are subsequently remeasured to their fair value at each reporting date and changes therein are generally recognized in the financial result in profit or loss. A derivative with a positive fair value is recognised as a financial asset whereas a derivative with a negative fair value is recognised as a financial liability. Derivatives are not offset in the financial statements unless the Group has both legal right and intention to offset. A derivative is presented as a non-current asset ('Other investments, including derivatives') or a non-current liability ('Other financial liabilities') if the remaining maturity of the instrument is more than 12 months and it is not expected to be realised or settled within 12 months. Other derivatives are presented as current assets or current liabilities.

## 3. CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

In the application of the Group's accounting policies, which are described above, management is required

to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The followings are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

### 3.1 GOING CONCERN

The Company has incurred net losses since its inception and for the 12 months ended December 31, 2023, its audited consolidated statement of profit and loss and other comprehensive income reflects a net loss as well as a loss carried forward. On 26 July 2024, the Board reviewed and approved the audited consolidated financial statements and accounting policies. Taking into account the cash and cash equivalents of €30.4 million on December 31, 2023, the evolution of the expected cash generated by the commercial revenues from the three products, the revenue from the out-license agreements expected in 2024, the expected R&D expenses and the risk assessment related to the US litigation with Alta Thera (see [note 26](#)), the Board is of the opinion that the audited consolidated financial statements are prepared under the assumption of going concern. Whilst the current cash position is sufficient for the Company's to continue the development of the current portfolio of product candidates, the Board pointed out that if the research and development activities related to the new product candidates as from 2024 continue to deliver added value, the Company may seek additional funding to support the continuing development of its portfolio of new product candidates or to be able to execute other business opportunities.

### 3.2 JOINT COLLABORATIONS

The Company has entered into a number of arrangements for the development, co-promotion and/or co-marketing of products. The Company believes that a presentation of the main arrangements is useful to an understanding of the financial statements.



### Arrangement with Purna Female Healthcare

In February 2021, Hyloris and Purna Female Healthcare ('PFH') entered into a partnership to develop and commercialise an innovative combination therapy for the treatment of severe and recurrent vulvovaginal candidiasis (rVVC). PFH is a special purpose vehicle founded to exclusively develop a local topical combination formulation of the well-known antifungal Miconazole with Domiphen Bromide (MCZ-DB).

Under the terms of the arrangement, Hyloris has committed to milestone related investments of up to EUR 4.3 million in PFH (of which EUR 1.3 million is already paid). Hyloris holds 20% of the shares in PFH (Class B) and is eligible to receive up to a maximum of 45% and a minimum of 17.3% of the net profits generated by PFH irrespective of the % of shares held by Hyloris.

Hyloris is represented in the Board of Directors by one member out of a total of four members.

Despite the fact Hyloris holds 20% of the shares in PFH and is represented in the Board of Directors by one member out of a total of 4 members, the Company concluded that it has joint control based on IFRS 11 - Joint Arrangements considering that reserved matters significantly affecting the returns of the joint arrangement require the unanimous consent of all shareholders. The joint arrangement is classified as a joint venture as the arrangement is structured through a separate vehicle and the investors do not have rights to the assets and obligations for the liabilities. Therefore, this arrangement is accounted for via equity accounting.

Purna Female Healthcare is a related party, see **note 28.1**

### Arrangement with Pleco Therapeutics

In November 2021, Hyloris and Pleco Therapeutics signed an agreement to co-develop and register PTX-252, a novel combination product of chelating agents for the treatment of Acute Myeloid Leukaemia (AML) and Small Cell Lung Cancer (SCLC).

Under the arrangement, Hyloris will provide €1 million (automatically convertible into Pleco Therapeutics

equity under certain conditions) in several tranches over time (already converted at 100%) and has obtained global exclusive co-development rights and future joint commercialisation to the Pleco technology in AML and SCLC. Hyloris may commit to fund (not equity) up to an additional €7.7 million in pre-defined R&D activities through to submission for approval in AML, plus initial exploratory development work in SCLC. Pleco will fund all activities that are outside the scope of the maximum €7.7 million funding commitment from Hyloris. In exchange, Hyloris will be eligible to receive up to 65% of the gross product margin generated worldwide in AML and SCLC. Hyloris will be co-owner on all Pleco patents (except for patents held by MD Anderson Cancer Center), inventions, co-development information and market information. The arrangement constitutes a joint operation.

Hyloris agrees to transfer its co-ownership rights on the patent and patent applications to Pleco in order for Pleco to be able to provide a pledge to the innovation credit ("Innovatiekrediet") as a security for the reimbursement of the innovation credit ("Innovatiekrediet"). Upon full reimbursement of the innovation credit, the co-ownership rights of the patent and patent applications under the collaboration agreement will revert back to Hyloris as originally agreed in the collaboration agreement. The innovation credit will be reimbursed to the authorities with the first profit share payments under the collaboration agreement and payment of the profit share will be subordinated until full reimbursement of the innovation credit.

Furthermore, Hyloris entered into a Management Consultancy Agreement in July 2022 for a total amount of €2.5 million. Under this agreement, Hyloris has and will support Pleco Therapeutics with strategic advice. The nature of strategic advice is holistic, and forward-thinking, with a focus on creating value. It covers a wide range of areas including business development, market entry strategies, organisational structure, operational efficiency, investor relations, and risk mitigation. After December 31st 2022, in case the total amount of the invoices exceeds 50% of the amount of innovation credit ("Innovatiekrediet") made available to Pleco, further invoicing will be postponed until additional amounts are made available of the innovation credit

("Innovatiekrediet") and the agreement will be extended accordingly with the same number of months so that the total amount of invoices remains €2.5 million. The services rendered are booked as Other Operating Income over time as discussed in **note 31.2**. In analogy with IFRS15.B16, as a practical expedient, if the entity has the right to invoice a customer in an amount that corresponds directly with its performance to date, then it can recognize income for that amount.

End of December 2023, Hyloris held an ownership interest of 4.50% in Pleco Therapeutics (corresponding to 5.35% of the voting rights). Hyloris is entitled to one observer ('waarnemer') within the Board of Directors of Pleco Therapeutics without voting rights.

Based on the guidance of IAS 28 – Investments in Associates and Joint Ventures, the Company concluded that it does not have a significant influence on Pleco Therapeutics considering the following elements:

- Holding of only 5.35% of the voting rights,
- No voting representation in the Board of Directors,
- No participation in policy-making processes,
- No interchange of key management
- Pleco is developing other products with other 3<sup>rd</sup> parties which are currently in the preclinical development stage, and
- Pleco is not financially dependent of Hyloris.

The arrangement between Hyloris and Pleco Therapeutics is a significant agreement for Pleco Therapeutics, but does not preclude Pleco Therapeutics from making strategic decisions or contracting other parties or other projects.

#### Arrangement with Vaneltix

In December 2021, Hyloris has entered into a strategic collaboration with Vaneltix Pharma, Inc. ('Vaneltix') for the development and commercialisation of Alenura™ as first-line drug treatment for acute pain in interstitial cystitis/bladder pain syndrome (IC/BPS).

Until now, Hyloris has committed to provide a maximum of \$6.7 million for supporting development related activities and a loan of \$0.5 million.

Hyloris will be eligible to receive a tiered percentage of the product margin generated by Vaneltix. The arrangement constitutes a joint operation.

Under this strategic co-development agreement Hyloris provided R&D services in the course of 2023 for a total amount of €145 thousand to Vaneltix. These services were cross-charged by Vaneltix since these are linked to the co-development agreement and are in scope of the Research and Development Expenses to be funded by Hyloris and therefore the income is netted with the cross-charged Research and Development expenses by Vaneltix.

Hyloris will be listed as co-owner on all Vaneltix patents, inventions, co-development information and market information. In addition, Hyloris hereby grants Vaneltix a license on Hyloris' share of the Vaneltix patents and inventions.

End of December 2023 Hyloris:

- Invested \$2.8 million for supporting development related activities;
- Subscribed to series D convertible preferred stock in October 2023 for an amount of \$2.0 million.

Hyloris provided a loan of \$0.5 million to Vaneltix. In relation to the settlement of this loan we refer note 10.

Hyloris holds 4 shares of Vaneltix and is not represented on the Board of Directors of Vaneltix.

Vaneltix is a related party, see **note 28.1**.

Although Hyloris is holding less than 1% of the voting rights, and has no voting representation in the Board of Directors, the Company concluded, based on the guidance of IAS 28 - Investments in Associates and Joint Ventures, that it does have significant influence on Vaneltix considering the following elements: Hyloris is currently one of the main financial contributors for Vaneltix and Vaneltix is financially depending on the funding of Hyloris to be able to develop Alenura™.

The co-development agreement for Alenura™ is a material transaction between Hyloris and Vaneltix as

Vaneltix primarily focused of the development of this product only (other product candidates are in a very early stage of development).

There is interchange of people as Carolyn Myers (non-executive director of Hyloris) has a limited role at Vaneltix as head of commercial affairs. In addition, her partner, Dr. Dan Vickery is CEO of Vaneltix.

As a result, the Group is applying the equity method of accounting. As the percentage of ownership interest is very low (only 0.00053 %) the Group does not take its % share in the loss of Vaneltix in deduction of the equity value.

See [note 9](#) on Equity Accounted Investees.

#### Arrangement with AFT

Hyloris Pharmaceuticals SA and AFT have been collaborating in the development of the Maxigesic IV product. AFT has now licensed the product to a number of partners covering multiple countries. Maxigesic IV is protected by several granted and pending patent applications. Under the terms of the development collaboration agreement between Hyloris and AFT,

Hyloris is eligible to receive a share on any product related revenues, such as license fees, royalties, milestone payments, received by AFT. The arrangement constitutes a joint operation.

### 3.3 LOAN TO ACADEMIC PHARMACEUTICALS

Determining the fair value of the loan to API (see [note 4.1](#)) is assessed to a significant estimate as the fair value is determined on the basis of significant unobservable inputs.

### 3.4 SHARE-BASED PAYMENTS

In accordance with IFRS 2 – Share-based Payment, the fair value of the warrants at grant date is recognized as an expense in the consolidated statement of comprehensive income over the vesting period, the period of service. Subsequently, the fair value is not re-measured.

The fair value of each warrant granted during the year is calculated using the Black-Scholes pricing model. This pricing model requires the input of subjective assumptions, which are detailed in [note 25](#).

## 4. FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

### 4.1 OVERVIEW OF FINANCIAL INSTRUMENTS

(in € thousand)	IFRS 9 Category	Input Level	December 31, 2023	December 31, 2022 Restated*
Investment in Pleco ( <a href="#">note 10</a> ) (non current)	FVOCI	3	1,000	1,000
Loan to Vaneltix ( <a href="#">note 10</a> )	At amortised cost		499	469
Loan to API ( <a href="#">note 11</a> )	FVTPL	3	317	490
Trade receivables ( <a href="#">note 11</a> )	At amortised cost		2,970	3,527
Cash and cash equivalents	At amortised cost		30,406	33,457
Other investment, including derivatives – Deposits ( <a href="#">note 10</a> )	At amortised cost		-	10,000
<b>Total financial assets</b>			<b>35,192</b>	<b>48,943</b>
Borrowings ( <a href="#">note 15.1</a> )	At amortised cost		1,750	885
Other financial liabilities ( <a href="#">note 15.2</a> )	At amortised cost		3,543	3,512
Trade and other liabilities ( <a href="#">note 16</a> )			3,195	2,352
Trade payables	At amortised cost		3,195	2,302
Derivative	FVTPL	2	-	52
<b>Total financial liabilities<sup>1</sup></b>			<b>8,488</b>	<b>6,749</b>

<sup>1</sup>Trade and Other receivables (VAT / R&D tax credit receivables and other receivables), prepayments and trade and other liabilities (deferred income and employee benefit liabilities) that are not financial assets / liabilities are not included

\*See note 31 regarding restated information

The table above summarizes all financial instruments by category in accordance with IFRS 9. The fair value of the financial instruments measured at fair value are determined as follows:

**Investment in Pleco:** The investment is designated at FVOCI because it's not held for trading and it's kept for its expected future return on investment. Considering that Pleco is in the development phase of its product candidates and does not generate revenue yet, the cost of the investment at transaction date has been considered as an appropriate estimate of the fair value as per December 31, 2022 and 2023. In 2023 and 2022 there is no reason to adjust the fair value of this investment as the current development program is in line with the assumptions of the initial plan, and discussions with regulatory authorities do not indicate any significant hurdles at this stage.

**Loan to API: Discounted cash flows:** the valuation model considers the present value of expected payments, discounted using the market rate and a company risk premium at the reporting date. The assumption is that the loan will be offset by royalties on product candidates in 2029. The change compared to last year is mainly due to the assumption that the offset of the loan will happen in 2029 instead of 2024 and that the determination of the fair value was impacted by a change in the risk-adjusted rate from 10.71% to 11.6%.

**FX forward contracts: Forward pricing:** the fair value is determined using the spot FX exchange rates at the reporting date and FX forward price in the contract. There are no outstanding FX forward contracts at December 31, 2023.

The Company considers that the carrying amounts of financial assets and financial liabilities measured at amortized cost in the consolidated financial statements approximate their fair values.

## 4.2 FINANCIAL RISK FACTORS

The Group's activities expose it to a variety of financial risks: market risk (including currency risk, interest rate risk, and price risk), credit risk and liquidity risk. There have been no changes in the risk management since last year-end or in any risk management policies.

## 4.3 FOREIGN EXCHANGE RISK

The Company is currently exposed to foreign currency risk, mainly relating to positions held in USD.

The exposure to exchange differences of the monetary assets and monetary liabilities of the Group at the end of the reporting period are as follows:

(in € thousand)	December 31, 2023	December 31, 2022* restated
Assets	3,466	4,153
Liabilities	(817)	(1,078)

See note 31.3: restatement of the API loan

If the EUR had strengthened/weakened 1% against the USD with all other variables held constant, the impact on the consolidated statement of comprehensive income would have been - €24 thousand and +€24 thousand respectively. Comparative information for 2022: if the EUR had strengthened/weakened 1% against the USD with all other variables held constant, the impact on the consolidated statement of comprehensive income would have been - €29 thousand and + €29 thousand respectively.

By default, the company uses natural hedging by matching the foreign currency-denominated revenues with the foreign currency-denominated expenses. This approach relies on the fact that when the company generates revenues and incurs expenses in the same currency, fluctuations in exchange rates have less impact on the overall financial position.

The Group could as well use derivative financial instruments to manage its exposure to the U.S. Dollar arising from operational activities in the form of cash flow hedges. This exposure is hedged with foreign exchange forward contracts. At the end of 2023 there are no outstanding foreign exchange forward contracts

## 4.4 INTEREST RATE RISK

The Company is currently not exposed to significant interest rate risk as the interest-bearing financial liabilities and assets bear a fixed interest rate, which are not subject to revision.

## 4.5 CREDIT RISK

Credit risk arises from cash and cash equivalents, short-term bank deposits, as well as credit exposure of

collaboration partners. Credit risk refers to the risks that counterparty will default on its contractual obligations resulting in financial loss to the Company.

At the end of 2023, the Company operated with about 10 different customers spread over the world (U.S., Europe and South-Asia). As a result, there is credit risk that is characterized by uncertainty in reimbursement value, delays in payment, and ultimately non-payment. This could potentially impact the Company's revenue recognition and cash collections.

For each customer, annually, the financial department reviews and sets a credit limit based on key financial criteria, geographical area, nature of the business and historical relationship.

We sort our customers into groups which will help to identify patterns and establish a risk profile. Usually, the credit risk related to milestones, royalties and profit share payment fall in one specific group which may lead to offer extended payments terms due to profile of the customers, the nature of the business whereas the credit risk related to other activities like services are classified differently, and are regularly and closely monitored.

Trade accounts receivable amounted to €2,970 million as of December 31, 2023, and no allowance for expected credit loss was recorded in 2023, neither the last years.

Customer's compliance with agreed credit terms is regularly and closely monitored. The payment terms to our partner AFT are extended and exceed 12 months for the specific transactions (see [note 11](#)). The current trade receivables exposure with AFT amounted to €2,124 million at the end of 2023. This amount has been reduced in first quarter 2024 with payments of €495 thousand leading to reduce the AFT's trade receivables to €1,629 thousand. In April 2024 AFT paid the outstanding receivable for an amount of €921 thousand. The remaining unpaid part is paid in the second quarter of 2024.

The average debtor's payment period is 30 days after invoice date. To measure the expected credit losses, trade receivables have been grouped based on credit risk characteristics and the days past due. In assessing

the credit risk characteristics, the Company takes into account any indicators of impairment up until the reporting date, and it applies a pragmatic approach that is consistent with the definition used for internal credit risk management purposes. Given the high quality of our customers the loss allowance provision at year-end is zero. It is the management opinion that at the above reporting date no further provision for doubtful debts was required.

Cash and cash equivalents and current financial assets are invested with several highly reputable banks and financial institutions. The financial institutions have credit ratings varying from A to AA- and are consequently considered as low credit risk.

## 4.6 LIQUIDITY RISK

The Company's main sources of cash inflows are currently obtained through capital increases and revenues. See [Note 14.2 Capital Management](#). The liquidity risk for the Group arises from the financial liabilities but also from commitments and liquidities required to be able to develop product candidates.

The following table details the Company's remaining contractual maturity of its financial liabilities with agreed repayment periods. The tables have been drawn up based on the undiscounted cash flows of financial liabilities based on the earliest date on which the Company can be required to pay. The tables include both interest and principal cash flows. In Other financial liabilities the liability to Purna Female Healthcare of €3M (see [note 9](#)) is payable upon achievement of development milestones, for which €1.5 million is after the completion of the dose finding study which is expected in Q3 2024 and the other €1.5 million is after the process validation report and completion of enrollment of the phase 3 studies.

31/12/2023 (In € thousand)	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
Borrowings					
Lease liabilities	241	871	639		1,751
Other financial liabilities					
Other financial liabilities	3,200	344			3,544
Trade and other liabilities	3,318				3,318
<b>Total</b>	<b>6,759</b>	<b>1,215</b>	<b>639</b>		<b>8,613</b>

31/12/2022 (In € thousand)	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
Borrowings					
Lease liabilities	138	492	255		885
Other financial liabilities					
Loans from shareholders					
Other financial liabilities	3,212	300			3,512
Trade and other liabilities	2,422				2,422
<b>Total</b>	<b>5,772</b>	<b>792</b>	<b>255</b>		<b>6,819</b>

## 4.7 MARKET RISK

Market risk is the risk that changes in equity prices will affect the Group's income or the value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimizing the return. The primary goal of the Group's investment in equity securities is to hold the investments for the long term for strategic purposes.

## 5. OPERATING SEGMENTS

The chief operating decision maker (CODM) of the Company is the Board of Directors. The CODM reviews the operating results and operating plans, and makes resource allocation decisions on a company-wide basis; therefore, the Group operates as one segment.

According to IFRS 8, reportable operating segments are identified based on the "management approach". This approach stipulates external segment reporting based on the Group's internal organizational and management structure and on internal financial reporting to the chief operating decision maker.

The financial information is organized and reported to CODM under one management reporting covering all activities of the Company. There is no specific component in the financial information that would as such represent a specific operating segment.

Information reported to the CODM is aggregated and comprises all activities of the Company. The Group's activities are managed and operated in one segment, pharmaceuticals. Strategic decision and resources allocation are made at the Company level by the CODM.

Total revenue represents an amount of €2,1 million. The revenue relates to royalties for €1,9 million for Sotalol IV, Maxigesic IV and Padagis/Podofilox gel, out-license agreements that provide a right to use for €104 thousand and milestone billings to PFH for €54 thousand. In 2022 the revenue related to royalties is €885 thousand for Sotalol IV and Maxigesic IV, and an out-license agreement that provides a right to use for €15 thousand.

In 2023 there are 3 customers individually exceeding 10% of total revenues: client A for an amount of €804 thousand, client B for an amount of €881 thousand and client C for an amount of €244 thousand.

Those 3 customers are representing 92% of the total recognized revenues.

In 2022 there were 2 customers individually exceeding 10% of total revenues: client A for an amount of €190 thousand and client B for an amount of €695 thousand, representing 98% of the total revenues.

In € thousand	2023	2022
Royalties	1,929	885
Out-license agreements	104	15
Milestones	54	-
<b>Total revenues</b>	<b>2,087</b>	<b>900</b>

In the revenue recognition there are no material contingencies nor amounts which are subject to significant estimation uncertainty. In some cases, the payment terms extended to our partners such as

AFT, which have a low liquidity risk profile, exceed 12 months. See **Note 11** for trade receivables.

## 5.1 GEOGRAPHICAL INFORMATION

Revenues reported in the consolidated statement of profit or loss and other comprehensive income are mainly generated in the United States: €1,125 thousand. Non-current assets recorded in the consolidated statement of financial position are mainly located in Belgium, the country of domicile of the Company.

## 6. LIST OF CONSOLIDATED COMPANIES AS AT DECEMBER 31, 2023

Company name	Company number	Location	% financial interest
Hyloris Pharmaceuticals SA	BE 0674.494.151	Blvd Patience et Beaujonc N°3/1, 4000 Liège	Parent
Hyloris Developments SA	BE 0542.737.368	Blvd Patience et Beaujonc N°3/1, 4000 Liège	99.99%
Hyloris Supply SA	BE 0669.738.676	Blvd Patience et Beaujonc N°3/1, 4000 Liège	100.00%
Dermax SA	BE 0667.730.677	Blvd Patience et Beaujonc N°3/1, 4000 Liège	100.00%

The voting rights equal the percentage of financial interest held.

## 7. INTANGIBLE ASSETS

(in € thousand)	Development costs	Assets Purchase	License fees	Prepayments	Total
<b>Year ended December 31, 2023</b>					
Opening carrying amount	1,678	685	1,125	119	3,607
Additions	325				325
R&D Tax Credit	(11)				(11)
Disposals					
Reclassification	119			(119)	-
Amortisation expense	(50)	(43)			(93)
Impairment losses					
Closing carrying amount	2,061	642	1,125	-	3,828
<b>At December 31, 2023</b>					
Cost	2,640	4,247	1,148		8,036
Accumulated amortisation and impairment	(580)	(3,605)	(23)	-	(4,208)
Carrying amount	2,061	642	1,125	-	3,828

(in € thousand)	Development Costs	Assets Purchase	License fees	Prepayments	Total
<b>Year ended December 31, 2022</b>					
Opening carrying amount	1,090	729	1,125		2,944
Additions	660			119	779
R&D Tax Credit	(22)				(22)
Disposals					-
Amortisation expense	(50)	(44)			(94)
Impairment losses					
Closing carrying amount	1,678	685	1,125	119	3,607
<b>At December 31, 2022</b>					
Cost	2,208	4,247	1,148	119	7,722
Accumulated amortisation and impairment	(530)	(3,561)	(23)		(4,115)
Carrying amount	1,678	685	1,125	119	3,607

In 2023, the Company acquired intangible assets for a total of €325 thousand, of which (i) €74 thousand related to the development costs of product-candidate Maxigesic® IV and (ii) €249 thousand related to the development costs of HY-078.

Grouping of intangible assets of a similar nature and use:

- Capitalized development costs: external incurred development costs. Sotalol IV, Podofilox gel, HY-039 and HY-078.
- Assets purchase: acquisitions of intangibles containing pharmaceutical development data, development analysis for clinical study and intellectual property rights. Used for Maxigesic® IV, Tranexamic Acid Mouth Rinse and HY-075.
- License fees: fees used in in-licensing agreements. For HY-029, Atomoxetine, Metolazone IV, Dofetilide IV, Aspirin IV U.S., HY-074, HY-076 and Milrinone.

The 4 largest product or product candidates in terms of intangible assets are Maxigesic® IV (carrying amount: €1,188 thousand), Podofilox gel (carrying amount: €632 thousand), Aspirine IV U.S. (carrying amount: €623 thousand) and Tranexamic Acid Mouth Rinse (carrying amount: €433 thousand). Only for Maxigesic® IV, the intangible assets are amortised. Since the commercial sales for Podofilox gel is launched in mid December 2023, the amortization will start in 2024.

The intangible assets are not amortised until the moment they are available for use as intended by management, i.e. ready for commercialisation. The company is amortizing since 2014 the development costs of Sotalol IV, an asset for which regulatory approval had been obtained. The development costs of Sotalol IV have a remaining useful life of 1 year. In 2022 the Company has started the amortisation of the development costs of Maxigesic® IV for the 38 countries outside the United States of America where market approval is obtained. In 2024 when the product is available for use in the United States of America the amortisation will start for that market as well.

The amortisation expenses are included in “Cost of sales” in the consolidated statement of profit or loss and other comprehensive income. The applied amortisation rate for all classes of assets is 10%.

As long as the assets are not fully amortised, they are tested for impairment if specific indicators are identified.

Intangible assets under construction are tested for impairment on an annual basis. The impairment test conducted is performed by product by estimating the recoverable amount. The recoverable amount of the product is estimated based on the forecasted future cash flows discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. The time horizon used for the impairment testing is based on the period during which the Company expects to generate cash flows from the project, which period does not exceed 10 years in the management estimates.

Based on the impairment tests conducted at year-end, the recoverable amount of the different products was estimated to be higher than their carrying amount and no impairment was required. The main assumptions used are the discount rate and the success of market penetration. As defined in **Note 2.8**, the discount rate reflecting current market assessments of the time value of money and the risks specific to the asset, and which was used for the impairment test, is estimated at 11.85% (was 11.26% in 2022).

The main input that lead to a discount rate of 11.85% are:

- a risk free rate of 2.58% corresponding to the 10-year OLO rate as of December 31, 2023 (3.18% last year)
- a beta factor of 0.96 (1.24 last year)
- a market risk rate of 2.77% (2.07% last year);
- a Company specific risk premium of 6.60% (no change compared to last year)
- a cost of debt before tax of 6% (no change compared to 2022)

We tested the sensitivity analysis of the impairment tests by increasing the discount rate by 4%, leading the discount rate to 15.85%. We cumulatively decreased the success of market penetration up to 40%, leading the success to 60% and 20% respectively for the commercial products and product in developments. None of these changes to assumptions resulted in an impairment loss.

No intangible assets have been pledged in the context of financial liabilities.



## 8. RIGHT-OF-USE ASSETS

(in € thousand)	Land and buildings	Vehicles and equipment	Total
<b>Year ended December 31, 2023</b>			
Opening carrying amount	809	76	885
Additions	822	211	1,033
Depreciation expense	(145)	(49)	(194)
Closing carrying amount	1,486	238	1,724
<b>At December 31, 2023</b>			
Cost	1,647	395	2,284
Accumulated depreciation and impairment	(161)	(157)	(560)
Carrying amount	1,486	238	1,724
<b>Year ended December 31, 2022</b>			
Opening carrying amount	102	71	173
Additions	825	32	857
Depreciation expense	(44)	(27)	(71)
Disposals	(75)	-	(75)
Closing carrying amount	809	76	885
<b>At December 31, 2022</b>			
Cost	825	184	1,251
Accumulated depreciation and impairment	(16)	(109)	(367)
Carrying amount	809	76	885

The depreciation expenses are all presented as “General and administrative expenses”.

The Group leases its headquarter building and all company cars. In 2023 the Group started with a new lease contract for the labs. The contracts do not include any purchase options. The lease term considered for the building is 9 years, while for the company cars the lease term ranges between 4 and 5 years.

The Group has lease contracts that include termination options. These options are negotiated by management to provide flexibility in managing the leased assets and align with the Group’s business needs. In the lease contracts there are extension options. The lease contracts for the building and the lab will be tacitly renewed, at its end, for periods of one year unless notice given by one of the parties by registered letter sent month 6 before the current contractual expiry or renunciation accepted, expressly and in writing, by the other party.

The Group signed a lease contract for equipment in the lab which commences in February 2024. The total cash flow for the period of 3 years is €153 thousand.

The amounts recognized in profit or loss can be summarized as follows:

(in € thousand)	2023	2022
Depreciation expense of right-of-use assets	(194)	(71)
Interest expense on lease liabilities	(52)	(10)
<b>Total amount recognized in profit or loss</b>	<b>(220)</b>	<b>(83)</b>
of which as:		
General and administrative expenses (note 19)	(168)	(73)
Financial expenses (note 22)	(52)	(10)

## 9. EQUITY ACCOUNTED INVESTEEES

On 5 February 2021, the Group entered into a partnership with Purna Female Healthcare (“PFH”), located in Belgium, a spin-off founded to develop and commercialise Miconazole-Domiphen Bromide, and which is accounted under the equity method of accounting. At the acquisition date, the net assets of PFH were limited to the available cash in the company, hence no fair value adjustment has been identified and as a result a goodwill of 4,3 million is included in the carrying amount which is justified by the potential of the product

candidate. Hyloris committed to an investment of €4,270 thousand, of which €1,270 thousand is already paid at acquisition date. The unpaid balance of €3,000 thousand is recognized against a current financial liability for €3,000 thousand (see [note 15.2](#)).

Hyloris owns 20% of PFH (later payments will not result in a higher percentage of ownership) and is eligible, based on contractual variables driven by the profitability of the company, to receive up to a maximum of 45% and a minimum of 17.3% of the net profits generated by PFH. As long as there is no commercialization of the product candidate, 20% presents the Group's economic interest in PFH's net assets. Hence the future economic interest of Hyloris in PFH will be changed and will be driven by the profitability of the company.

(in € thousand)	December 31, 2023	December 31, 2022
Opening carrying value	3,948	4,078
Profit or loss of the period	(147)	(130)
<b>Carrying amount at December 31</b>	<b>3,801</b>	<b>3,948</b>

The following tables summarize the financial information of PFH as included in its own financial statements, adjusted for fair value and differences in accounting policies, if needed. The negative results of 2021, 2022 and 2023 are in line with the estimated R&D costs for this specific project. No other impairment indicators are identified. The table below is restated for 2022 as the line Uncalled capital contribution was presented in Amounts receivable within one year in prior year figures.

(in € thousand)	31-Dec-23	31-Dec-22 Restated
<b>FIXED ASSETS</b>		
<b>CURRENT ASSETS</b>	<b>834</b>	<b>1,495</b>
Amounts receivable within one year	36	26
Cash at bank and in hand	798	1,469
<b>TOTAL ASSETS</b>	<b>834</b>	<b>1,495</b>
<b>CAPITAL AND RESERVES</b>	<b>758</b>	<b>1,495</b>
Capital	6,103	6,103
Uncalled capital contribution	(3,000)	(3,000)
Accumulated profits (losses)	(2,345)	(1,608)
<b>PROVISIONS AND DEFERRED TAXES</b>		
<b>CREDITORS</b>	<b>76</b>	<b>0,35</b>
Amounts payable within one year	76	0,35
<b>TOTAL LIABILITIES</b>	<b>834</b>	<b>1,495</b>

(in € thousand)	2023	2022
<b>Operating income</b>	-	-
<b>Operating charges</b>	<b>-737</b>	<b>-651</b>
Services and other goods	-736	-649
Other operating charges (-)	-1	-2
<b>Operating profit (loss)</b>	<b>-737</b>	<b>-651</b>
<b>Profit (Loss) for the period before taxes (-)</b>	<b>-737</b>	<b>-651</b>
<b>Profit (loss) for the period available for appropriation</b>	<b>-737</b>	<b>-651</b>
<b>Hyloris' % of interest</b>	<b>20</b>	<b>20</b>
<b>Profit (loss) for the period available for appropriation (20%)</b>	<b>-147</b>	<b>-130</b>

Reconciliation between (a) the 20% of rights to net assets applied to PFH's equity/net assets and (b) the carrying amount of Hyloris' interest in PFH:

(a) 20% of 4,200 shares: 840 shares

The total equity of PFH amounts to €6,103 thousand represented by 4,200 registered shares without nominal value, of which 2,100 A1 shares, 1,260 A2 shares and 840 B shares (held by Hyloris).

Hyloris acquired 840 B shares. In exchange for the 840 B shares, Hyloris Pharmaceuticals ("Hyloris") made a contribution in cash of €4,270 thousand, which was paid-up immediately for an amount of €1,270 thousand. The remaining €3,000 thousand will need to be paid when certain milestones are reached, €1,500 thousand after the completion of the dose finding study required for being able to start a phase 3 study, expected in Q3 2024 and another €1,500 thousand after process the validation report for 6 months stability data on registration batches and completion of enrollment of the phase 3 studies (see [note 4.6](#)).

(b) 3,801 thousand

Committed investment of Hyloris: €4,270 thousand  
 - 20% of Retained earnings of PFH (loss): €469 thousand  
 = Hyloris' carrying amount in PFH: €3,801 thousand

All shares are entitled to profit distribution. However, the interest in the profits is not necessarily equal to the ownership interest and may vary depending on the performance of PFH. Before a commercial launch no

dividends will be distributed. As of the point in time of a commercial launch profits will be distributed to the shareholders according to the distribution mechanism set forth in the shareholder's agreement. When PFH is exactly reaching its net profit target established in the shareholder's agreement class B shares will be entitled to 20% and class A (A1 + A2) shares will be entitled to 80% of the net profits. If PFH does not reach its net profit target, a higher interest in these net profits will be allocated to the Class B shares (preferential class). As such, the interest of the Class B shares in the net profits may increase to 45%. On the other hand, if PFH exceeds its net profit target, Class A shareholders will be entitled to a higher interest in the net profits (and Class B shareholders to a lower interest).

#### Transactions with PFH

In 2023 Hyloris invoiced PFH for a total amount of €55 thousand related to PIND/IND services (€45k) and CRO selection and qualification services (€9k)

#### Vaneltix

On 17 October 2023, the Group has subscribed to a capital increase of Vaneltix for an amount of \$2 million in Vaneltix. The capital increase is against 4 fully paid and non-assessable shares of the Series D Preferred Stock of Vaneltix for \$500 thousand. The 2 mio was provided to cover R&D costs and has been recognized as R&D expenses.

The following tables summarize the financial information of Vaneltix as included in its own financial statements.

(in € thousand)	31-Dec-23
<b>FIXED ASSETS</b>	<b>6</b>
<b>CURRENT ASSETS</b>	<b>800</b>
Amounts receivable within one year	271
Cash at bank and in hand	491
Prepayments	38
<b>NON CURRENT ASSETS</b>	<b>126</b>
Right-of-use assets	108
Other non current assets	18
<b>TOTAL ASSETS</b>	<b>932</b>
<b>CAPITAL AND RESERVES</b>	<b>(3,243)</b>
Capital	30,712
Accumulated profits (losses)	(-33,955)
<b>CURRENT LIABILITIES</b>	<b>3,394</b>
Provisions	1,355
Creditors	2,039
<b>NON CURRENT LIABILITIES</b>	<b>781</b>
Creditors	781
<b>TOTAL EQUITY + LIABILITIES</b>	<b>932</b>

(in € thousand)	2023
<b>OPERATING INCOME</b>	<b>11</b>
Licensing fees	11
<b>OPERATING EXPENSES</b>	<b>1,832</b>
Research and development	1,433
General and administrative	399
<b>Operating profit (loss)</b>	<b>(1,821)</b>
<b>Other income and expenses, net</b>	<b>94</b>
<b>Profit (Loss) for the period before taxes (-)</b>	<b>(1,727)</b>
<b>Profit (loss) for the period available for appropriation</b>	<b>(1,727)</b>

#### Transactions with Vaneltix

In 2023 there were services provided to Vaneltix for a total amount of €145 thousand. Under this strategic co-development agreement Hyloris provided R&D services in the course of 2023 for a total amount of €145 thousand to Vaneltix. These services were cross-charged by Vaneltix since these are linked to the co-development agreement and are in scope of the Research and Development Expenses to be funded by Hyloris and therefore the income is netted with the cross-charged Research and Development expenses by Vaneltix.

The Group applies the Equity method in the consolidated financial statements as the Group has

significant influence over Vaneltix (refer to note 3.2). As the percentage of ownership interest is very low (only 0.00053%) the Group does not take its % share in the loss of Vaneltix in deduction of the equity value. In addition, the investor's share of losses of an equity-accounted investee is recognized only until the carrying amount of the investor's equity interest in the investee is reduced to zero. After the investor's interest is reduced to zero, a liability is recognized only to the extent that the investor has an obligation to fund the investee's operations or has made payments on behalf of the investee. Given the losses of Vaneltix and the fact that Hyloris does not have an obligation to fund the investee (other than funding the product co-developed with Vaneltix), the carrying amount would be zero.

## 10. OTHER INVESTMENT, INCLUDING DERIVATIVES

The other investment, including derivatives can be detailed as follows:

(in € thousand)	December 31, 2023	December 31, 2022 Restated <sup>1</sup>
Term Deposits	-	10,000
Shares Pleco Therapeutics BV	1,000	1,000
Optional convertible loan	499	469
<b>Other Investment, including derivatives</b>	<b>1,499</b>	<b>11,469</b>
<b>of which as:</b>		
Non-current	1,000	1,000
Current	499	10,469

<sup>1</sup>See [note 31](#) regarding restatement information

### Term Deposits

At the end of 2022, two deposits for a total amount of €10 million are reclassified from cash and cash equivalents to other investments as they don't meet the criteria to be presented as cash equivalents. The term of 1 deposit was from December 13 2022 till June 13 2023 and the term of the other deposit is from December 13 2022 till September 13 2023. They could not be withdrawn, in whole or in part, prior to the due date of the term deposit.

### Shares: Pleco Therapeutics BV

In 2021, the Group entered into a partnership with Pleco Therapeutics to develop PTX-252, a novel combination

product of chelating agents for the treatment of Acute Myeloid Leukaemia (AML) and Small Cell Lung Cancer (SCLC). Hyloris provided a non-interest bearing convertible loan of €1,000 thousand which has been converted into 7,944 preferred shares (1 June 2022) at an issuing price of €126 per share (which resulted in a 4.5% ownership of the company Pleco Therapeutics). See [note 4.1](#) for the valuation.

The Group is committed to fund up to an additional €7,700 thousand of which €2,216 million have been already financed.

Pleco will fund all activities that are outside the scope of the maximum €7,700 thousand funding commitment from Hyloris. Hyloris will be eligible to receive up to 65% of the net gross product margin generated worldwide in AML and SCLC. Hyloris will be co-owner on all Pleco patents (except for patents held by MD Anderson Cancer Center), inventions, co-development information and market information. The arrangement constitutes a joint operation.

In 2023 the Group had a few purchase and sale transactions with Pleco Therapeutics. The sales are related to billed strategic advice for an amount of €500 thousand (see [note 3.2](#)) and the purchases are for product development related services regarding pre-clinical, clinical and CMC-related activities for a total amount of €2,216 thousand. At 31 December 2023 the outstanding commitment is €5,484 thousand (€7,700 thousand - €2,216 thousand).

### Optional convertible loan

On 13 December 2021, the Group entered into a collaboration with Vaneltix Pharma, Inc. (a related party of Hyloris) for the development and commercialisation of Alenura™ as first-line drug treatment for acute pain in interstitial cystitis /bladder pain syndrome (IC/BPS). Under the terms of the agreement, the Group granted a 6% interest bearing loan of \$500 thousand.

The initial above agreement included a reimbursement at the earliest of i) 31 December 2023 or ii) sale of equity or other equity-linked instruments by the Borrower to unaffiliated third parties for financing purposes for an amount of at least \$5 million (the "Capital Increase").

A loan amendment dated 17 October 2023 extended the reimbursement date from 31 December 2023 to 31 August 2024. In case of a capital increase on or prior to the reimbursement of the Loan in full, Hyloris shall have the option to convert the entire principal amount of the loan and all interest accrued into shares. Also under the terms of the agreement, the Group will provide staged investments of in total maximum \$ 6,700 thousand for Phase 2, manufacturing and regulatory related activities (see [note 28.2](#)) upon which \$4,700 thousand has already been provided.

In 2023, Hyloris incurred 2,744 thousand of R&D expenses.

Management identified Vaneltix Pharma, Inc as a related party of Hyloris (see [note 28.2](#)).

## 11. TRADE RECEIVABLES AND OTHER RECEIVABLES

(in € thousand)	December 31, 2023	December 31, 2022 <sup>1</sup>
Trade receivables	2,970	3,527
API	317	490
Alter Pharma	-	395
R&D Tax Credits	1,256	811
Tax Credit - Alenura™	368	-
Interests on deposits	-	57
VAT	218	148
Other amounts receivable	26	10
<b>Total trade and other receivables</b>	<b>5,156</b>	<b>5,438</b>
<b>or which as:</b>		
Current	3,565	4,127
Non Current	1,591	1,311

<sup>1</sup>See [note 31](#) regarding restated information

The carrying amount of the Group's trade receivables (gross) is mainly denominated in USD resulting from royalties and milestones.

After the closing period of December 31, 2023 AFT has paid €1,440 thousand.

During the year, the payment terms for the receivables have neither deteriorated nor been renegotiated.

The maximum credit risk exposure at the end of the reporting period is the carrying value of each caption of receivables mentioned above. The Group does not hold any collateral as security.

Other amounts receivable mainly includes guarantees.

### API

A loan to API of of €633 thousand is granted by Hyloris to API, carrying a 0.1% interest per year. This loan is presented as non-current. When the royalties (or other payments) of 3 product candidates, or any other product parties may develop together in the future, exceed \$200 thousand in a calendar year then the amount exceeding \$200 thousand will be used to repay the loan. Hyloris can then withhold this amount from royalty payments. The loan has been measured at FVTPL using an interest market rate and appropriate credit risk resulting in the recognition of a loss of €173 thousand recognized as financial expenses in 2023. For comparative information, the financial expense in 2022 was €167 thousand. The decrease of the fair value in comparison with 2022 is due to the increase of the discount rate and the changed assessment of term of the loan (6 years vs 3 years) and the unrealized FX difference impact (€30 thousand). The reimbursement of the loan is depending on the success of the product candidates being developed by the Group and not depending on any action from the counterparty. The discount rate has been determined by using the market rate and the company risk premium (see [note 4.1](#)). A sensitivity analysis shows that when the year of reimbursement differs 1 year earlier or later than the estimated calendar year of reimbursement, the fair value increases with €37 thousand or decreases with €34 thousand. When the discount rate increases or decreases with 1%, the fair value of the loan decreases with 6% €20 thousand or increases with €21 thousand.

### Alter Pharma

The balance sheet as at 31 December 2022 held a current receivable from the Alter Pharma Group for €395 thousand which has been paid in 2023 in accordance to the settlement agreement signed by Alter Pharma in 2021. The receivable is related to a prepayment of R&D expenses to Alter Pharma Group.

### R&D Tax Credits

The Group applies for R&D tax credit incentives set-up by the Federal government and obtained reasonable assurance in the current reporting period that the Group will comply with the conditions attached to the

grant and that the grant will be received. The Group recognized R&D tax credits for a total of €434 thousand in Other Operating Income (see [note 21](#)) and €11 thousand in Intangible assets (see [note 7](#)). No cash is expected before 2025 based on the tax regulation.

#### Tax Credit - Alenura™

A Tax Credit of €368 thousand was granted from an American state government for the clinical development costs of the Alenura™ product candidate which were incurred in 2022. The Tax Credit is recognized when the approval of the grant request has been confirmed by the authorities. Two other requests for a Tax Credit related to development costs of the Alenura™ product for an amount of approximately €724 thousand are being assessed by the American state authorities and have not been recognized.

## 12. PREPAYMENTS

Pre-paid R&D expenses relate to payments made by the Group for research and development projects conducted by partners (co-development projects) and will be recorded in profit and loss when incurred. Pre-paid R&D expenses of €1,089 thousand were incurred in 2023 and released in the profit and loss and related to the development agreement with Vaneltix (a related party of Hyloris) to run the development of the Alenura™ product candidate (see [note 27](#)) and is the main driver of the decrease compared to December 31, 2022 (€ 1,748 thousand).

Prepayments apply to both research and development activities. Prepayments related to research are expensed when they are incurred.

Development costs are also expensed in the Profit or Loss when they are incurred up until the moment that the recognition criteria under IAS 38 are met, i.e. upon filing for market authorization in the context of 505b2 or when an asset is acquired as an intangible asset, from when any further development costs are capitalized as intangible assets.

Prepayments relating to development costs are presented as intangible assets.

## 13. CASH AND CASH EQUIVALENTS

The net cash position as presented in the consolidated statement of cash flows is as follows:

(in € thousand)	December 31, 2023	December 31, 2022 restated*
Cash at bank	20,196	13,457
Short-term deposit	10,210	20,000
<b>Total cash and cash equivalents</b>	<b>30,406</b>	<b>33,457</b>

\*See [note 31](#) regarding restated information

The term of the only deposit outstanding is from January 3, 2023 to January 3, 2024. It is classified as cash equivalent as the nominal value of €10 million can be withdrawn considering a notice period of 32 days. A penalty is due if the amounts are withdrawn during the entire term. The penalty due depends on when the deposit is withdrawn, during the initial 180 days the penalty amounts to 50% of the already earned interest and after the initial 180 days the penalty amounts to 25% of the already earned interest. The term of the deposit at year-end 2022 is from September 1, 2020 to September 1, 2023. The nominal value of €20 million can be withdrawn considering a notice period of 32 days. There is no additional penalty stipulated in the contract, however, no interest will be earned during the notice period of 32 days.

## 14. EQUITY

### 14.1 OVERVIEW

(in € thousand)	December 31, 2023	December 31, 2022*
Share capital	140	140
Share premium	121,513	121,513
Retained earnings	(80,761)	(65,381)
Other reserves	(1,823)	(2,363)
<b>Total Equity attributable to owners of the parent</b>	<b>39,069</b>	<b>53,909</b>

\*See [note 31](#) regarding restated information

### 14.2 CAPITAL MANAGEMENT

The Group manages its capital to maintain a strong level of capital in order to sustain development of the business and confidence of creditors while optimizing return on capital for shareholders. This ensures that entities

in the Group will be able to continue as going concern while maximizing the return to stakeholders through the optimization of its debt and equity balance. Also refer to [note 3.1](#) for further details on going concern.

The Group is not subject to any externally imposed capital requirements except those provided for by law. The Group's management reviews the capital structure of the Group on a regular basis. As part of this review, management considers the cost of capital and the risks associated with each financing options. The Group's objectives, policies and processes for managing capital have remained unchanged over the past few years.

The transaction costs of an equity transaction are accounted for as a deduction from equity to the extent they are incremental costs directly attributable to the equity transaction that otherwise would have been avoided.

On March 31, 2022, the Company has successfully raised an amount of €15 million in gross proceeds, from new and existing, local and international investors, through an equity offering by means of a private placement via an accelerated bookbuild offering of 967,742 new shares (being approximately 3.7% of the Group's outstanding shares (pre-transaction) at an issue price of EUR 15.50 per share (the "Offering"), representing a discount of 1.6% to the 30-day VWAP.

On June 20, 2022 Hyloris increased Capital and Share Premium with respectively €6 thousand and €2,826 thousand through the issuance of 1.200.000 new shares resulting from outstanding Transaction Warrants exercised.

The Group uses the net proceeds of the Offering primarily to fund the development of new products and accelerate in-house R&D activities.

Equity transactions (In € thousand)	Gross proceeds	Equity transaction costs	Expensed in P&L	Net proceeds
Accelerated Bookbuilding	15,000	(634)	(29)	14,337
Exercise of warrants (see <a href="#">note 25</a> )	2,832		(14)	2,818
<b>Total</b>	<b>17,832</b>	<b>(634)</b>	<b>(43)</b>	<b>17,155</b>

### 14.3 SHARE CAPITAL AND SHARE PREMIUM

#### Share Capital

As per December 31, 2022 and December 31, 2023, the share capital of the Group amounts to € 140,001.87 represented by 28,000,374 shares, without nominal value, each representing 1/28,000,374th of the share capital of the Group. The share capital of the Group is fully and unconditionally subscribed for and is fully paid up. All shares rank equally with regard to the Group's residual assets. Holders of these shares are entitled to dividends as declared from time to time and are entitled to one vote per share at general meetings of the Group.

On June 8, 2020, the General Assembly issued an authorized capital of €117,758.84. The Board is allowed to use the authorized capital for a period of 5 years. As per December 31, 2023, the remaining authorized capital amounted to €110,920.13 (no change with December 31, 2022).

On June 11, 2024, the General Assembly renewed the authorized capital for a period of 5 years (as from the date of the publication of the resolution) amounting to €140,001.9 (excluding emission premium).

The following capital transactions have taken place since January 1, 2017:

Date	Transaction	Increase of share capital (incl. share premium) (€)	Number of securities issues	Issue price / share (rounded, incl. share premium) (€)	Number of shares after the transaction
7 June 2012	Incorporation	50,000	10,000 Shares	5.00	10,000
31 March 2017	Capital increase	11,500	2,300 Shares	5.00	12,300
12 May 2017	Share split	-	-	-	3,075,000
31 May 2018	Capital increase	2,750,000	248,711 Shares	11.06	3,323,711
31 May 2018	Capital increase	3,000,000	271,322 Shares	11.06	3,595,033
31 December 2019	Capital increase	18,259,783 <sup>2</sup>	855,409 Shares	21.35	4,450,442
8 June 2020	Share split	-	Share split (1 to 4)	-	17,801,768
30 June 2020	IPO on Euronext	61,821,500	5,750,000 shares	10.75	23,551,768
30 June 2020	Conversion of convertible bonds	15,358,025	2,040,864 shares	10.75	25,592,632
31 July 31 2020	Over allotment option	2,580,000	240,000 shares	10.75	25,832,632
31 March 2022	Accelerated bookbuild	15,000,000	967,742 shares	15.50	26,800,374
22 June 2022	Transaction warrants exercised	2,832,000	1,200,000 shares	2.36	28,000,374

<sup>2</sup> Accounting wise, the share issue of December 2019 was accounted for as from the date of establishment of common control in Dermax.

### Share premium

As per December 31, 2022 and December 31, 2023, the share premium of the Group amounts to €121,513 thousand.

### Other reserves

(in € thousand)	December 31, 2023	December 31, 2022
Share based payment	2,161	1,622
Cost of Capital	(4,460)	(4,460)
Other	476	476
<b>Total Other reserves</b>	<b>(1,824)</b>	<b>(2,362)</b>

The movement of the other reserves over the period can be explained by the increase of €539 thousand resulting from the share based payment expenses associated with the ESOP warrants (see [note 25](#)).

## 15. BORROWINGS AND OTHER FINANCIAL LIABILITIES

### 15.1 BORROWINGS

(in € thousand)	December 31, 2023	December 31, 2022
Lease liabilities	1,751	885
<b>Total borrowings</b>	<b>1,751</b>	<b>885</b>
of which as:		
Non-current borrowings	1,510	747
Current borrowings	241	138

For more details on the leases, we refer to [note 8](#) on "Right-of-use assets".

The main increase in the lease liabilities is mainly due to the leasing of the new lab which is in use since June 2023.

The weighted average incremental borrowing rate used for the measurement of the lease liabilities is 3.95%. The incremental borrowing costs for the cars is in a range between 1.6% and 3.12%. The Group is not subject to financial covenants. The underlying leased assets act as pledge in the context of the lease liabilities.

### 15.2 OTHER FINANCIAL LIABILITIES

The other financial liabilities can be detailed as follows:

(in € thousand)	December 31, 2023	December 31, 2022
Recoverable cash advance	44	-
Other financial liabilities	3,500	3,512
<b>Other financial liabilities</b>	<b>3,544</b>	<b>3,512</b>
of which as:		
Non-current other financial liabilities	344	300
Current other financial liabilities	3,200	3,212

#### Recoverable cash advance

In June 2023 a recoverable cash advance related to the government grant for HY-083 was received from the Walloon region. A part of this cash advance is a non



refundable grant (€88 thousand) and the other part is refundable to the Walloon region (€169 thousand). In relation to the €169 thousand if the development of the product candidate is successful and will be commercialized the Group has to reimburse the advance. The reimbursement includes a fixed amount and a variable amount depending on the sales of the product. If the product candidate is not successful the Group is not required to refund the advance but only if the Group decides to transfer the IP rights of the product candidate to the Walloon region. In case the Group decides to keep the IP rights, the fix part of the advance has to be reimbursed and the financial liability will be derecognized.

Of the €169 thousand 30% is fixed (€51 thousand) and is, in accordance with the accounting policies, considered a financial liability measured at fair value (with changes in fair value recognised in profit and loss) and 70% (€118 thousand) is variable and accounted for as a government grant and recognised in profit and loss when the related costs are incurred. In 2023 the variable part of the refundable advance has been fully recognized as Other income since sufficient related costs have been incurred during the year. The variable

part of the refundable advance will be reimbursed via royalties to be paid as of commercialization.

#### Other financial Liabilities

With no change with last year, The Group has license agreements with Alter Pharma Group, for which a non-current other financial liability of €300 thousand and a current financial liability of €200 thousand is outstanding. The payments are due when certain milestones are reached: €200 thousand is due upon the first commercial launch of Maxigesic® IV in the United States and €300 thousand is payable upon reaching a worldwide annual sales threshold of €50 million for Maxigesic® IV.

Committed to milestone related investments (contributions to the equity) in Purna Female Healthcare (see [note 9](#)) the Group has a current other financial liability of €3 million.

### 15.3 LIQUIDITY AND CASH FLOW RECONCILIATION

The maturity table of the borrowings and the other financial liabilities is presented in [note 4.6](#) on the liquidity risk.

The following tables reconcile the movements of the financial liabilities to the cash flows arising from financing activities:

31/12/2023 (in € thousand)	Opening carrying amount	Cash flows	Non-cash movements						Closing carrying amount
			Acquisition	Interest expenses leases	Modification	Termination	Re-classes	Accrued interests and exchange differences	
Non-current financial liabilities									
Lease liabilities	747	-	903		(1)		(149)	9	1,509
Other financial liabilities	300	51						(8)	343
Current financial liabilities									
Lease liabilities	134	(223)	130	52			149		241
Other financial liabilities	3,212	(12)	0				0		3,200
<b>Total liabilities from financing activities</b>	<b>4,394</b>	<b>(184)</b>	<b>1 033</b>	<b>52</b>	<b>(1)</b>	<b>0</b>	<b>0</b>	<b>1</b>	<b>5,295</b>
Presented in the statement of cash flows as follows:									
Financing activities - interests paid		(12)							
Financing activities - reimbursement of lease liabilities		(170)							
Financing activities - proceeds from borrowings and other financial liabilities		51							
Operating activities - interest paid		(52)							

31/12/2022 (in € thousand)	Opening carrying amount	Cash flows	Non-cash movements					Closing carrying amount	
			Acquisition	Interest expenses leases	Modification	Termination	Re-classes		Accrued interests and exchange differences
Non-current financial liabilities									
Lease liabilities	109	-	747			(18)	(91)	-	747
Other financial liabilities	300								300
Current financial liabilities									
Lease liabilities	65	(79)	102			(44)	91		134
Other financial liabilities	11,812	(9,253)	0	482			0	168	3,212
<b>Total liabilities from financing activities</b>	<b>12,290</b>	<b>(9,332)</b>	<b>848</b>	<b>482</b>	<b>(62)</b>	<b>0</b>	<b>168</b>		<b>4,394</b>
Presented in the statement of cash flows as follows:									
Reimbursement of borrowings and other financial liabilities and interest paid		(9,253)							
Reimbursement of lease liabilities		(79)							

## 16. TRADE AND OTHER LIABILITIES

(in € thousand)	December 31, 2023	December 31, 2022
Trade payables	3,195	2,302
Employee benefit liabilities	116	68
Other payables	-	52
Deferred income	7	-
<b>Trade and other liabilities - Current</b>	<b>3,318</b>	<b>2,422</b>

The trade payables relate mainly to the R&D activities , payables for lawyers for the litigation case (note 26) and remuneration of different committees and the executive management team, including the accrued bonuses.

The fair value of trade payables approximates their carrying amount.

Liquidity and currency risk are detailed in note 4.

## 17. DEFERRED TAXES

Deferred tax assets are recognized only if management assesses that these tax assets can be offset against taxable income within a foreseeable future.

This judgment is made on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives.

Although, no going concern issues have been identified and significant profits are expected as from the moment more product candidates will be commercialized, the moment of commercialization and the amount

of revenue to be generated from commercialization remain uncertain. Given the history of tax losses and the fact that there are at this moment, no agreements yet for commercialization of additional products that would result in taxable profit in the future against which the tax losses or tax credits can be utilized, no deferred tax asset has been recognized as of 31 December 2023.

Deferred tax assets are reviewed at each reporting date and will be recognised as from and to the extent that it is probable that taxable profit will be available, against which the unused tax losses, unused tax credits and deductible temporary differences can be utilised.

Deferred tax assets and liabilities are offset when there is a legally enforceable right to offset and when the deferred taxes relate to the same fiscal authority. The deferred tax assets and liabilities are attributable to the following items:

(in € thousand)	31-Dec-23		31-Dec-22 restated <sup>1</sup>	
	Deferred tax asset	Deferred tax liability	Deferred tax asset	Deferred tax liability
Intangible assets	17	17	17	17
RoU Asset	-	431		221
Financial liabilities	431		221	
<b>Total deferred tax assets and liabilities</b>	<b>448</b>	<b>448</b>	<b>238</b>	<b>238</b>
Offsetting	(448)	(448)	(238)	(238)
<b>Total deferred tax assets and liabilities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>

<sup>1</sup>Restated to present only recognized deferred tax assets and deferred tax liabilities.

Deferred tax assets have not been recognized in respect of the following items, because it is not probable that future taxable profits are available against which the Group can use the benefits of therefrom:

(in € thousand)	December 31, 2023	December 31, 2022
Deductible temporary differences	16,673	11,344
Deductible temporary differences related to investment in associates	469	-
Tax losses	53,155	37,248
<b>Total</b>	<b>70,297</b>	<b>48,592</b>

The deductible temporary differences disclosed above would reverse over a period ranging between 5 to 10 years. The tax losses carried forward, however, are available indefinitely.

## 18. REVENUE

The revenue can be detailed as follows:

(in € thousand)	December 31, 2023	December 31, 2022 restated <sup>1</sup>
Royalties	1,929	885
Out-license agreements	104	15
Milestones	54	-
<b>Revenue</b>	<b>2,087</b>	<b>900</b>

<sup>1</sup>See [note 31](#) regarding restated information

Currently, the Group generates only limited sales-based royalties as its main projects are in the development pipeline and are not yet commercialized. The continuously increasing sales-based royalties is income mainly from the Group's launched products, Sotalol IV and Maxigesic® IV. In December 2023 a third product was commercialized: Podofilox gel. Royalty revenues

for Podofilox gel are recognized through our partner Padagis US LLC. Revenue from sales-based royalties is recognized when the subsequent sale occurs.

Revenue from sales milestone is recognized when the performance obligation has been met (i.e. sales threshold reached). Income from Milestone payments in 2023 is driven by our joint collaboration with PFH after the positive results from the Phase 2 clinical study.

## 19. EXPENSES BY NATURE

Expenses by nature represent an alternative presentation for amounts included in the consolidated statement of comprehensive income. They are classified under "Cost of sales", "Research and development expenses", "General and administrative expenses" and "Other operating expenses" in respect of the years ended December 31:

(in € thousand)	2023	2022 Restated <sup>1</sup>
Out-sourced R&D	(11,374)	(7,163)
Employee benefit expenses ( <a href="#">note 20</a> )	(3,761)	(3,116)
Management consultancy fees	(1,137)	(1,091)
Board related expenses	(176)	(178)
Share based payments	(539)	(560)
Legal & paralegal fees	(2,205)	(645)
Audit and related consultancy fees	(125)	(91)
Hiring fees	(27)	(84)
Office equipment, rent, and utilities	(290)	(337)
Other expenses	(78)	(433)
Amortisation expense of intangible asset ( <a href="#">Note 7</a> )	(93)	(94)
Depreciation expense on PPE and Right of Use ( <a href="#">Note 8</a> )	(255)	(102)

<b>Total operating expenses<sup>2</sup></b>	<b>(20,060)</b>	<b>(13,894)</b>
<b>of which as</b>		
Cost of sales	(93)	(94)
Research and development expense	(14,421)	(10,271)
General and administrative expenses	(5,546)	(3,517)
Other operating expenses	-	(12)

<sup>1</sup> See [note 31](#) regarding restated information

<sup>2</sup> The loss in PFH is not included in the Operating expenses (€147 K)

In accordance with IAS 38, we do not capitalize our research and development expenses until we file for marketing authorization for the applicable product candidate. Research and development expenditures incurred during the period were accounted for as operating expenses.

The Groups' research and development expenses increased by 40%, from €10,271 thousand in 2022 to €14,421 thousand in 2023. The increase was principally driven by the progress made in the development of our existing product candidates and the related additional out-sourced R&D expenses and the enlargement of the R&D team.

In 2023, the Group capitalized development costs for a total of €325 thousand (was €661 thousand in 2022). (See [note 7](#))

Hyloris' General and administrative expenses increased by 58% (or €2,028 thousand), from €3,517 thousand in 2022 to €5,545 thousand in 2023. The increase was mainly driven by higher legal costs related to the AltaThera's litigation compared to last year (see [note 26](#)).

## 20. EMPLOYEE BENEFIT EXPENSES

(in € thousand)	December 31, 2023	December 31, 2022
Wages and salaries	(3,277)	(2,562)
Social security costs	(247)	(146)
Defined contribution costs	(37)	(20)
Other employee Benefit expenses	(200)	(258)
<b>Total employee Benefit expense</b>	<b>(3,761)</b>	<b>(2,987)</b>
in full-time equivalents		
Average number of total employees	34.7	23.6

## 21. OTHER OPERATING INCOME

(in € thousand)	December 31, 2023	December 31, 2022 restated*
Services rendered related to co-developments	501	1,052
R&D tax credit	434	315
Government grants	578	-
Grants income related to exemption on withholding taxes	159	120
Other income	455	-
<b>Other operating income</b>	<b>2,127</b>	<b>1,487</b>

\*See [note 31](#) regarding restated information

Services rendered in 2023 and 2022 primary consist of strategic advice provided by the Group to Pleco Therapeutics BV to support a co-developer and recharge of services rendered. These strategic advices and services are related to:

- Business Development: advice on strategic partnerships, that could secure additional funding or distributor that could and expand the market reach.
- Market Entry Strategies: assistance in developing effective plans to introduce the therapy to the market and gain traction among healthcare providers and patients.
- Operational Efficiency: guidance on optimizing their internal processes for maximum efficiency, ensuring resources are strategically directed towards achieving their goals.
- Investor Relations: assistance on effectively communicating with potential investors and secure future funding rounds.
- Risk mitigation

The big increase compared to last year is mainly related to:

- a tax credit from an American State government for the clinical development of the Alenura™ product candidate of €369 thousand
- a recoverable cash advance from the Walloon region related to a grant for the research and development of product candidate HY-083 of €207 thousand (see [note 15.2](#)).
- a Settlement agreement with a partner of €394 thousand resulting from long lasting discussion on disputed costs incurred in the past.
- the increase of the R&D tax credit compared with last year. The Group recognised R&D tax credits for a total of €445 thousand, of which €434 thousand as other operating income, and €11 thousand

deduction from the carrying amount of the related assets, which are recognised in the profit or loss statement in line with the amortisation or depreciation expense of the related assets (**note 11**).

## 22. FINANCIAL RESULT

The various items comprising the net finance cost are as follows:

(in € thousand)	December 31, 2023	December 31, 2022 restated*
Realized gain on FX forward contracts	29	525
Interest income on deposits	869	67
Exchange differences	-	(126)
<b>Financial income</b>	<b>898</b>	<b>466</b>
Interest expense on lease liabilities	(52)	(11)
Interest expense on shareholders loans	-	(164)
Other interest expense	-	(44)
<b>Total interest expenses</b>	<b>(52)</b>	<b>(219)</b>
Loss related to substantial modification of the shareholders loans	-	(226)
FV adjustment on FX forward instruments	-	(52)
Fair Value of API loan ( <b>note 11</b> )	(173)	(167)
Bank fees	(48)	(38)
Exchange differences	(12)	-
Other	-	(28)
<b>Total financial expenses</b>	<b>(233)</b>	<b>(511)</b>

\*See **note 31** regarding restated information

### Modification of the shareholders loans

In 2022, the Group successfully renegotiated its Shareholders loans. The changes in the terms of the loan agreements qualified for substantial modifications of the terms resulting in the derecognition of the carrying value of former loans replaced by the carrying value of the loans under the new terms. The loans from shareholders, were unsecured, bear as from 1 January 2022 a fixed nominal interest rate of 0.75% (4% previously) and were payable the earlier of December 31, 2022 or, if and when, the Group will generate a positive EBIT.

At December 31, 2022 all Shareholders loans including the accumulated interests were reimbursed.

Decrease of the Loans from Shareholders can be

explained by (i) the reimbursement of the principal amount of one Shareholder, (ii) payment of incurred interest (€ 1,877 thousand), partly compensated by (iii) the FX impact on the conversion of the loans denominated in USD into EUR (€ 256 thousand), and (iv) the loss resulting from the derecognition of the former carrying value of the loan (€ 226 thousand).

## 23. INCOME TAX EXPENSE

### 23.1 AMOUNTS RECOGNIZED TO PROFIT AND LOSS

The income tax (charged)/credited to the income statement during the year is as follows:

(in € thousand)	December 31, 2023	December 31, 2022
Tax (expense) / income	-	(4)
<b>Income taxes</b>	<b>-</b>	<b>(4)</b>

### 23.2 RECONCILIATION OF EFFECTIVE TAX

The income tax expense can be reconciled as follows:

(in € thousand)	2023	2022* restated
Loss before income tax	(15,380)	(11,901)
Income tax expense calculated at domestic tax rates (25%)	3,845	2,975
Tax effect of		
Share of Loss of equity-accounted investees reported, net of tax	(37)	(33)
Tax incentives (R&D Tax Credit)	108	79
Changes in estimates related to prior years	-	(4)
Effect of unused tax losses not recognized as deferred tax assets	(3,917)	(3,022)
<b>Total tax Expenses</b>	<b>-</b>	<b>(4)</b>

\*See **note 31** regarding restated information

### 23.3 CURRENT TAX ASSETS

The withholding tax on our deposits in Belgium can be fully recovered via the corporate income tax return. The Group will get a refund for the difference between on one hand the recoverable Belgian withholding tax, and on the other hand the corporate income tax due on the minimum taxable basis corresponding to 40% of the benefit in kind for the private use of company cars. The refundable amount for 2023 is €245 thousand and booked on Current tax assets.

## 24. EARNINGS PER SHARE

Basic earnings per share amounts are calculated by dividing net profit for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted earnings per share amounts are calculated by dividing the net profit attributable to ordinary equity holders of the parent (after adjusting for the effects of all dilutive potential ordinary shares) by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares. No effects of dilution affect the net profit attributable to ordinary equity holders of the Group. The table below reflects the income and share data used in the basic and diluted earnings per share computations:

(in € thousand)	December 31, 2023	December 31, 2022 restated*
Basic earnings		
Profit (Loss) from continuing operations attributable to owners of the parent	(15,380)	(11,906)
Diluted earnings		
Dilution effect of share-based payments		
Profit from continuing operations attributable to owners of the parent, after dilution effect	(15,380)	(11,906)

\*See [note 31](#) regarding restated information

Earnings per share based on the existing number of ordinary shares

Number of shares	December 31, 2023	December 31, 2022
Weighted average number of ordinary shares outstanding during the period	28,000,374	27,198,925
Basic earnings per share	(0.55)	(0.43)
Diluted earnings per share	(0.55)	(0.43)

As the Company is suffering operating losses, the stock options have an anti-dilutive effect. As such, there is no difference between basic and diluted earnings per ordinary share. There are no other instruments that could potentially dilute earnings per share in the future.

## 25. SHARE-BASED PAYMENTS

The Company has a stock option scheme for the employees, consultants and directors of the Company and its subsidiaries for rendered services. In accordance with the terms of the plan, as approved by shareholders, employees may be granted options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

Each employee share option converts into one ordinary share of the Company on exercise. No amounts are paid or payable by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights. Options may be exercised at any time from the date of vesting to the date of their expiry.

The following share-based payment arrangements were in existence during the current and prior periods, there is no new plan in 2023:

	Total warrants authorised and granted			Movements per year													Weighted Average Exercise Price per warrant (€)	Fair value at grant date (€)
	Warrants authorised	Warrants cancelled	Warrants granted	Warrants outstanding 31/12/2019	Warrants forfeited	Warrants outstanding 31/12/2020	Warrants granted	Warrants forfeited	Warrants outstanding 31/12/2021	Warrants forfeited	Warrants exercised	Warrants outstanding 31/12/2022	Warrants forfeited	Warrants exercised	Warrants outstanding 31/12/2023	Expiry Date		
<b>PLAN 2017</b>																		
Warrants	1,200,000		1,200,000	1,200,000		1,200,000			1,200,000		(1,200,000)		0			4/05/22	2.36	1.11
<b>PLAN 2019</b>																		
Warrants	363,300	(10,300)	353,000	353,000	(20,000)	333,000		(20,000)	313,000		(6,875)		306,125		306,125	31/12/24	5.34	2.47
<b>PLAN 2020</b>	<b>400,000</b>	<b>(213,500)</b>	<b>186,500</b>				<b>186,500</b>		<b>186,500</b>				<b>186,500</b>		<b>186,500</b>		<b>11.89</b>	<b>5.40</b>
Warrants						-	69,500		69,500				69,500		69,500	27/11/30	9.88	4.44
Warrants						-	55,000		55,000				55,000		55,000	27/11/30	12.04	5.68
Warrants						-	60,000		60,000				60,000		60,000	27/11/30	13.92	6.20
Warrants						-	2,000		2,000				2,000		2,000	27/11/30	16.64	7.39
<b>PLAN 2022</b>	<b>213,500</b>	<b>(71,500)</b>	<b>142,000</b>										<b>142,000</b>	<b>(7,354)</b>	<b>134,646</b>		<b>14.12</b>	<b>5.36</b>
Warrants						-			-				62,000	0	62,000	30/06/29	15.20	6.06
Warrants						-			-				55,000	(7,354)	47,646	30/06/29	12.92	4.76
Warrants						-			-				25,000	0	25,000	1/01/30	13.71	4.76
<b>Total Warrants</b>	<b>2,176,800</b>	<b>(295,300)</b>	<b>1,881,500</b>	<b>1,553,000</b>	<b>(20,000)</b>	<b>1,533,000</b>	<b>186,500</b>	<b>(20,000)</b>	<b>1,699,500</b>	<b>(6,875)</b>	<b>(1,200,000)</b>	<b>634,625</b>	<b>(7,354)</b>	<b>0</b>	<b>627,271</b>		<b>9.17</b>	<b>-</b>

The 2017 plan was fully vested immediately as no vesting conditions were required. The 1,200,000 Transaction warrants were exercised on 22 June 2022 (note 14).

On 31 December 2019, the Company issued a plan of 363,300 warrants in the context of an employee stock ownership plan (ESOP warrants). The 2019 plan is subject to conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month). The Company offered in total 353,000 warrants. For this plan, the expense in the profit or loss is €23 thousand in 2023 and €67 thousand in 2022.

On 27 November 2020, the Company issued a plan of 400,000 warrants. The 2020 plan is subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month). In the 2020 plan, 191,500 warrants were offered to new employees of which 186,500 warrants were accepted. The remaining warrants of the 2020 plan were cancelled. For the 2020 plan, the expense is €161 thousand in 2023 and €382 thousand in 2022.

On 22 June 2022, the Group issued a new plan of 213,500 warrants. The 2022 plan is subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month). As of 31 December 2022, 142,000 warrants were accepted by new employees. In 2023 7,353 warrants additionally have forfeited hence in total 78,854 warrants have forfeited. For the 2022 plan, the expense is €356 thousand in 2023 and €111 thousand in 2022.

The fair value of the warrants has been determined based on the Black Scholes model. For the plans issued in 2017 and 2019, the expected volatility is based on the historical share price volatility over the past 5 years of listed peer companies. For the new plan issued on 27 November 2020, the expected volatility is based on the historical share price volatility since listing of the Company and bench marked with listed peer companies.

Below is an overview of all the parameters used in this model:

	PLAN 2019	PLAN 2020	PLAN 2022
Average share price (€)	5.34	11.73	14.84
Average exercise price (€)	5.34	11.89	15.2
Expected volatility of the shares (%)	55%	40%	35%
Expected dividends yield (%)	0%	0%	0%
Average risk free interest rate (%)	0.10%	0.00%	2.66%

The Risk Free interest rate (%) is based on an OLO with a maturity in relation to the exercise period of each individual plan, which goes within a range between 5 and 10 years.

## 26. CONTINGENCIES

### Ongoing legal proceedings

In August 2022, AltaThera Pharmaceuticals LLC filed a complaint before the District Court for the Northern District of Illinois against Academic Pharmaceuticals Inc, Dr. Somberg and Hyloris Pharmaceuticals, for (a.o.) alleged misappropriation of AltaThera's trade secrets and confidential information, improper inventorship, and breach of contract, which seeks (punitive) damages and termination of the agreement whereby Hyloris licenses Sotalol IV to AltaThera (the "Litigation"). Hyloris moved to dismiss the complaint for improper service of process and lack of jurisdiction.

Further, in November 2022, Hyloris initiated an arbitration against AltaThera for breach of the same licensing agreement between Hyloris and AltaThera in relation to Sotalol IV, including the failure of AltaThera to use commercially reasonable efforts in selling Sotalol IV as required under the licensing agreement, which seeks damages and termination of the licensing agreement (the "Arbitration"). AltaThera responded and counter-demanded, reasserting its claims from the Litigation.

At the end of August 2023, all parties agreed to stipulate to the dismissal of the Litigation and to consolidate the Litigation and the Arbitration before the American Arbitration Association ("AAA") in New York.

Hyloris contests the claims asserted by AltaThera and, based upon Hyloris' assessment of the documents and expert reports put forward to date by AltaThera to support its claims, Hyloris is of the view that there is no convincing evidence supporting AltaThera's claims for

liability or damages. On the other hand, Hyloris believes strongly in the merits of its claims against AltaThera, and that its position is well supported by its expert reports and other documents and evidence submitted to the arbitration panel.

After the arbitration hearings that took place in April 2024, Hyloris remains fully confident about the outcome of this litigation in its favor. A final decision is expected before the end of August 2024. Hyloris however cannot guarantee that the outcome of the litigation, even if in its favor, may not have a negative impact on future sales of Sotalol IV. AltaThera is seeking significant damages, including for lost profits related to future sales of Dofetilide IV and Sotalol IV and for unjust enrichment premised on a perceived value of investment tied to the IPO raise in 2020. While these claims, if fully or partially granted, would potentially jeopardize Hyloris as a going concern, Hyloris believes such an outcome is improbable and that either Hyloris will succeed in its defense or will be subject to damages below an amount that would impact Hyloris' ability to function as a going concern.

Conversely, Hyloris believes it has a strong case against AltaThera for the latter's failure to exert commercially reasonable efforts to sell Sotalol IV and has requested a Panel award of significant damages. However, Hyloris cannot assure that a judgment in this matter will not adversely affect future Sotalol IV sales.

A final decision is expected before the end of August 2024.

The Group is unable to disclose the estimate of the financial effects of the ongoing legal proceedings as under the rules of the International Center for Dispute Resolution and the American Arbitration Association, the Panel in the Consolidated Arbitration has sealed these proceeding with an Agreed Confidentiality Order such that information that is designated "Confidential" or "Highly Confidential—Attorneys' Eyes Only" and cannot be shared with the public.

### Tax expense

In 2021, The Group recognized an additional Tax Expense of €297 thousand related to a request for payment of Taxes related to taxable income realized in 2017, when the Company was still located in Grand



Duchy of Luxembourg. Although the company filed timely her Tax Return related to income year 2016, the company did not receive any Tax Assessments prior to the request for payment. Management protested to the relevant Authorities and decided to adopt a cautious approach and recognized the Tax Expense in 2021. Payment has been done to the Authorities in 2022. The current status is that the first hearing took place. The probability criteria are not met to recognize a receivable given the current status of the procedure.

## 27. COMMITMENTS AND CONTINGENT LIABILITIES

Hyloris has contractual commitments related to asset purchase, licenses and development agreements. The amounts are due upon reaching certain milestones depending on successful completion of development stages of the different product candidates (including FDA approval) or on meeting specified sales targets. The Company disclosed as commitments the maximum that would be paid if all milestones and sales targets are achieved. The amounts are not risk-adjusted or discounted.

As at December 31, 2023, Hyloris has contractual commitments and contingent liabilities for a maximum amount of €41,523 thousand related to asset purchase, licenses and development agreements recorded under intangible assets and R&D expenses.

Commitments are unconditional promises made by the Group to other parties resulting from legal or contractual requirements and related to R&D liabilities (i.e. a commitment to fund R&D activities as part of a (co-)development agreement with a partner). Contingent liabilities are possible obligations of the Group which are dependent on (future) sales milestones that will occur when the product is commercialized (eg. If a certain sales threshold is met). The table includes the contingent liabilities if all sales milestones were reached (maximum exposure).

The accounting treatment of the contractual commitments and contingent liabilities will vary per nature of triggering event. Development milestones up until commercialization will be expensed or capitalized. Sales related commitments such as royalties, profit

sharing and sales milestones will be expensed when incurred.

The following table details the total maximum contractual commitments and contingent liabilities (milestone payments only) at December 31, 2023 per product candidates if such products are successfully marketed (in € thousand):

Product Candidate	Expected timing	Maximum contractual commitments			Contingent liabilities		
		In \$ thousand	In € thousand	Converted in € (in € thousand)	In \$ thousand	In € thousand	Converted in € (in € thousand)
<b>HY-004</b>		225		204			0
	2025	125		113			
	2026	100		90			
<b>HY-029</b>			300	300			0
	2024		100	100			
	2025		100	100			
<b>Atomoxetine oral</b>		75		68			0
	2024	25		23			
	2025	25		23			
<b>Metolazone IV</b>		325		294	1 300		1 176
	2025	75		68			
	2026	100		90			
<b>Atomoxetine oral</b>	2027	150		136			
	2028				100		90
	2030				200		181
	2032				1000		905
<b>Dofetilide IV</b>		300		271			0
	2024	100		90			
	2025	50		45			
<b>HY-073</b>	2026	150		136			
		7 115		6 439	28 000		25 339
	2024	3376		3 055			
	2025	3621		3 277			
	2026	118		107			
	2027				1000		905
<b>HY-074</b>	2029				2000		1 810
	2030				2000		1 810
					23000		20 814
<b>HY-074</b>		150		136			
	2024	50		45			
	2025	25		23			
<b>HY-074</b>	2027	75		68			

<b>Alenura™ (note 29.2)</b>	2 000	1 810
	2024	2000
		1 810
<b>HY-086 (note 10)</b>	5 285	5 285
	2024	2363
	2025	2 422
	2026	500
<b>HY-088</b>	200	200
	2025	200
<b>TOTAL</b>	<b>10 190</b>	<b>5 785 15 007 29 300 0 26 516</b>

For HY-073 the contingent liability is related to future sales milestones for which only the 3 first years can be estimated that the sales threshold will be met.

Contingent liabilities attached to profit split and royalties which percentage varies based on achieved profit and/or sales are not considered in the above table as no maximum amount can be determined. The company believes that the list of these candidate products should, in principle, generate more revenue compared to the total value of €41,523 thousand (maximum commitments).

## 28. RELATED PARTY TRANSACTIONS

As part of the business, the Company has entered into several transactions with related parties. Balances and transactions between the Company and its subsidiaries, which are related parties of the Company, have been eliminated on consolidation and are not disclosed in this note. Details of transactions between the Group and other related parties are disclosed below.

The related parties presented below are identified as:

- Purna Female helthcare, in which the Group has a control of 20% (note 9);
- Vaneltix Inc and its affiliates, in which non-executive independent member of the Board of directors, Carolyn Myers her partner, Dr. Dan Vickery is CEO and over which Hyloris has significant influence (see note 9);
- The shareholders; Mr Stijn Van Rompay, an executive member of the Board of the Company, CEO and reference shareholder of the Company; Mr Thomas Jacobsen, an Executive Member of the Board of the Company;
- The Executive Management Team; and
- The Board of Directors (Non-Executive Directors).

## 28.1 TRANSACTION WITH PURNA FEMALE HEALTHCARE

The table below provides an overview as per December 31, 2023:

In € thousand	Financial Position	Transactions for the period	
		Profit Loss	Commitments
Equity accounted investees	3.801	-	-
Other financial liabilities (note 15.2)	(3.000)	-	-
Milestones revenue	-	54	-
<b>Total</b>	<b>801</b>	<b>54</b>	<b>0</b>

The table below provides an overview as per December 31, 2022:

In € thousand	Financial Position	Transactions for the period	
		Profit Loss	Commitments
Equity accounted investees	3.948	-	-
Other financial liabilities (note 15.2)	(3.000)	-	-
<b>Total</b>	<b>948</b>	<b>54</b>	<b>0</b>

## 28.2 TRANSACTIONS WITH VANELTIX, INC.

In 2021 the Group entered into a strategic collaboration with Vaneltix Pharma Inc. for the development and commercialisation of Alenura™ as first-line drug treatment for acute pain in interstitial cystitis /bladder pain syndrome (IC/BPS).

See note 3.2.

The outstanding commitment to Vaneltix as of December 31, 2023 is \$2 million:

- \$6,7 million commitment
- \$1,6 million payment March 2022
- \$1,2 million payment December 2022
- \$1.9 million equity contribution October 2023  
(excluding 100k for market study)
- = \$2 million commitment at end of 2023

The table below provides an overview as per December 31, 2023:

In € thousand	Financial Position	Transactions for the period	
		Profit Loss	Commitments
Optional convertible loan (note 10)	499		
Shares (Non Current) (note 10)	0.001		
Accounts Receivable	174		
Prepayments	155		
R&D expenses		(2,744)	
Interest income		47	
Commitments and Contingent Liabilities (Note 27)			1,810
<b>Total</b>	<b>654</b>	<b>(2,697)</b>	<b>1,810</b>

The table below provides an overview as per December 31, 2022:

In € thousand	Financial Position	Transactions for the period	
		Profit Loss	Commitments
Optional convertible loan (note 10)	494		
Accounts Receivable	29		
Prepayments	1,108		
R&D expenses		(1,422)	
Interest income		25	
Commitments and Contingent Liabilities (Note 27)			3,656
<b>Total</b>	<b>1,602</b>	<b>(1,398)</b>	<b>3,656</b>

## 28.3 TRANSACTIONS WITH THE SHAREHOLDERS

In 2023 there were no transactions with the shareholders.

### Capital increase dated June 22, 2022

On 22 June 2022 Hyloris increased her Capital and accompanied her Share Premium with respectively €6 thousand and €2,826 thousand via the exercise of

1,200,000 outstanding Transactions Warrants.

In 2022 the following number of warrants from the 2017 ESOP plan were exercised:

Related Party	Number of transactions warrants exercised	Exercise price (in €)
Stijn Van Rompay	852,096	2.36
Thomas Jacobsen	163,512	2.36
<b>Total</b>	<b>1,015,608</b>	<b>2.36</b>

## 28.4 TRANSACTIONS WITH THE EXECUTIVE MANAGEMENT TEAM

Executive management team personnel include those persons having authority and responsibility for planning, directing and controlling the activities of the Group. As of December 31, 2023 and December 31, 2022, members of the Executive Management Team are:

- SVR Management BV, an entity controlled by Stijn Van Rompay, an executive member of the Board of the Company, CEO and reference shareholder of the Company
- Jacobsen Management BV, an entity controlled by Thomas Jacobsen, an executive member of the Board of the Company and CBDO
- Finsys Management BV, an entity controlled by Jean-Luc Vandebroek, Chief Financial Officer
- Dr Dietmar Aichhorn, Chief Operating Officer
- Heralut BV, an entity controlled by Koenraad Van der Elst, Chief Legal Officer

The table below presents the compensation of all members of Executive Management Team by type of compensation:

(In € thousand)	December 31, 2023	December 31, 2022
ST compensation (incl. management fees)	1,137	1,045
Share-based payments	64	154
<b>Total</b>	<b>1,201</b>	<b>1,199</b>

At reporting date, there were outstanding trade payables related to transactions with the Executive Management Team:

(In € thousand)	December 31, 2023	December 31, 2022
Management fees	143	160
<b>Total</b>	<b>143</b>	<b>160</b>

As of December 31, 2023, members of the Executive Management Team owned the following securities of the Company:

	Shares		Warrants	
	Number (#)	Pct (%)	Number (#)	Pct (%)
Mr. Stijn Van Rompay	7,743,067	27.65	68,000	10.84
Mr. Thomas Jacobsen	3,857,838	13.78	-	0.00
Mr. Jean-Luc Vandebroek	9,000	0.03	40,000	6.38
Mr. Dietmar Aichhorn	32,500	0.12	40,000	6.38
Mr. Koenraad Vanderelst	17,443	0.06	50,000	7.97
<b>TOTAL</b>	<b>11,659,848</b>	<b>41.64</b>	<b>198,000</b>	<b>31.57</b>

Compared to 31 December 2022, the members of the Executive Management Team owned the following securities of the Company:

	Shares		Warrants	
	Number (#)	Pct (%)	Number (#)	Pct (%)
Mr. Stijn Van Rompay	7,676,400	27.42	68,000	10.71
Mr. Thomas Jacobsen	3,657,505	13.06	-	0.00
Mr. Jean-Luc Vandebroek	3,000	0.01	40,000	7.88
Mr. Dietmar Aichhorn	20,000	0.07	40,000	6.3
Mr. Koenraad Van der Elst	27,443	0.10	50,000	6.3
<b>TOTAL</b>	<b>11,374,348</b>	<b>40.66</b>	<b>198,000</b>	<b>31.19</b>

Total outstanding shares and warrants existing as of December 31, 2023 are respectively 28,000,374 and 627,271.

## 28.5 TRANSACTIONS WITH THE BOARD OF DIRECTORS (NON-EXECUTIVE DIRECTORS)

As of December 31, 2023, non-executive members of the Board of Directors are:

- Stefan Yee, Chairman
- Leon Van Rompay
- Marc Foidart
- Carolyn Myers
- James Gale
- Chris Buysel

The table below presents the compensation of all non-executive members of Board of directors by type of compensation:

(In € thousand)	December 31, 2023	December 31, 2022
Board fees	110	110
Share-based payments	7	30
<b>Total</b>	<b>117</b>	<b>140</b>

At reporting date, there were outstanding trade payables related to transactions with the non-executive members of the Board of directors:

(In € thousand)	December 31, 2023	December 31, 2022
Board fees	110	0
<b>Total</b>	<b>110</b>	<b>0</b>

As of 31 December 2022 and 31 December 2023, non-executive members of the Board of directors owned the following securities of the Company:

	Shares		Warrants	
	Number (#)	Pct (%)	Number (#)	Pct (%)
Stefan Yee	-	-	100,000	15.94
Leon Van Rompay	-	-	-	-
Mark Foidart	-	-	-	-
Carolyn Myers	-	-	-	-
James Gale	-	-	-	-
Chris Buysel	-	-	-	-
<b>TOTAL</b>	<b>-</b>	<b>-</b>	<b>100,000</b>	<b>15.94%</b>

## 29. SUBSEQUENT EVENT (AFTER THE END OF THE REPORTING PERIOD)

### 16.01.2024: Orphan Drug Designation granted to PTX-252 by U.S. FDA 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.

Obtaining an Orphan Drug Designation provides incentives and benefits to encourage the development of treatments for rare diseases. These include financial incentives, market exclusivity and support in navigating regulatory processes. An estimate of the financial impact for the Group cannot be made.

### 18.01.2024: Hyloris broadens pipeline with new product candidate for Vulvar Lichen Sclerosus (VLS)

The Group has entered into a partnership with AFT to develop a novel mucoadhesive film for the treatment of Vulvar Lichen Sclerosus. Hyloris and AFT will co-develop HY-091 for the purpose of registration and worldwide commercialization. Hyloris is responsible for ensuring the product formulation, manufacturing activities and the coordination of the commercialisation in Europe. AFT is responsible for managing the clinical trials, overseeing all aspects to ensure effective planning, execution and monitoring throughout the trial lifecycle, and the coordination of the commercialisation outside of Europe. Parties are jointly responsible for commercialisation in the United States.

Hyloris and AFT will share the net profit and will split all external costs related to the collaboration. An estimate of the financial impact for the Group cannot be made.

### 30.01.2024: Hyloris and Purna Female Healthcare announce positive results from Phase 2 trial in patients with Acute Vulvovaginal Candidiasis (VVC)

The phase 2 trial of product candidate Miconazole Domiphen-Bromide (MCZ-DB) was a 12-week trial evaluating the safety and efficacy of two doses of

MCZ-DB. The study has been conducted in Belgium with a total of 102 patients enrolled. Topline results are superior efficacy, positive safety and tolerability without significant superiority over the active control.

With these positive results, the Group is prepared to engage in discussions with relevant authorities for further clinical investigations. The financial impact for the Group is that a financial liability of €3 million (see [note 9](#)) €1.5 million is payable after the completion of the dose finding study required for being able to start a phase 3 study and another €1.5 million is due after processing the validation report for 6 months stability data on registration batches and completion of enrollment of phase 3 studies

### 14.02.2024: Hyloris enrolls first patient in Phase 3 Clinical trial for its Proprietary Mouth Rinse to control incidences of bleeding related to dental procedures.

This Phase 3 trial is designed to demonstrate efficacy, safety and acceptability of the oral solution containing tranexamic acid to prevent possible oral hemorrhaging in patients treated with anticoagulants and undergoing extraction of one or more teeth. This study will measure and compare efficacy of the proprietary oral solution containing tranexamic acid against placebo in reducing the number of both clinically relevant and irrelevant bleeds in these patients.

An estimated 280 patients will be recruited at approximately 20 clinical sites across Europe and the United States. Recruitment of eligible patients is expected to be completed around the end of 2024 with final results available in the first half of 2025. An estimate of the financial impact for the Group cannot be made.

### 27.02.2024: Hyloris announces launch of Maxigesic® IV in the U.S. and approval in Canada

- launch in the United States: Hikma has launched Maxigesic® IV in the United States under the tradename Combogesic® IV. Hyloris is entitled to a milestone payment of \$2.1 million.
- approval in Canada: Maxigesic® IV has recently been granted marketing authorization by Health Canada.

#### 18.04.2024: Long-term incentive plan

A long-term incentive plan was approved. The long-term variable remuneration is based on the achievement by the Company of certain pre-set cash-based financial results. For each member of the Executive Committee, a one-time payment will be made for each €20 million EBITDA realized annual basis, capped at €80 million or four tranches of €20 million.

#### 11.6.2024: Decision of the General Assembly regarding the authorized capital.

See [Note 14.3](#)

#### Events after the reporting period with respect to the QliniQ transactions

Hyloris announced on 20 January 2023 that it had successfully concluded agreements regarding (i) the in-licensing by Hyloris from QliniQ BV (“**QliniQ**”) of HY 088 and (ii) the divestment by Hyloris to QliniQ of HY 038. These transactions and their accounting treatment were scrutinized by the Belgian Financial Services and Markets Authority (“**FSMA**”). The inquiries from and exchanges with the FSMA initially led the Company to restate its fiscal year 2022 and fiscal year 2023 results in March 2024.

In the second half of April 2024, a few days before the annual report for the fiscal year 2023 was due to be published, KPMG replaced its permanent representative for the Company and informed the Company's Audit Committee that additional audit work was required. Following further exchanges with the Company's auditor and, subsequently, the FSMA, the Company initiated a forensic independent review on the matter in April 2024. On 29 April 2024 the FSMA suspended trading of the Company's shares.

The forensic independent review was carried out by a reputable international law firm as independent legal expert, appointed by and under the supervision of an ad hoc committee of independent directors of the Company. The work included a forensic data review concerning the QliniQ transactions, interviews with Hyloris' executive management team concerning the QliniQ transactions, as well as obtaining an independent

valuation expert opinion on the purchase price paid for HY-088.

During and after the review process, the Company was formally informed of the executive management team's opinion that the forensic independent review is affected by procedural, methodological and substantive deficiencies. Management disputes the findings and believes inter alia that the independent legal expert lacked impartiality, has not considered their explanations and comments properly, and that the findings give an incomplete and distorted picture. The management team also pointed out that there was regular interaction with the Company's statutory auditor on the accounting treatment of the transactions. Finally, the management team also insisted in particular on the actual substance of the HY-038 and HY-088 transactions and reiterated their firm belief that the HY-088 deal will create value for the Company.

The forensic independent review was completed early June 2024 and established a number of irregularities concerning the transactions with QliniQ and the documentation practices and communication with the FSMA related thereto which are further described in the FSMA communication of 5 July 2024 (see below) and the Company's press release of 8 July 2024 containing its reaction on the FSMA communication.

In the first half of June 2024, the Board has deliberated on multiple occasions on the findings of the forensic independent review, the recommendations of the ad hoc committee (as also described in the FSMA communication of 5 July 2024 – see below), and the comments by the executive management team. Where appropriate, meetings were held in closed session with non-executive directors only. During this time, the Board was also informed that the Company's CEO has offered to step down as CEO and transition into a dedicated strategy-focused role concentrating on long-term company objectives and direction, and that the Company's CFO and CLO have offered to resign and leave their roles within the Company in mutual consent after an appropriate transition period.

As a result, taking into account a.o (i) the findings of the forensic independent review, (ii) the recommendations

of the ad hoc committee (as detailed in the (as detailed in the FSMA's communication of 5 July 2024) FSMA's communication of 5 July 2024), (iii) the views of the executive management team (and the abovementioned proposals by the CEO, CFO and CLO to leave their current roles) and (iv) the Company's corporate interest, the Board has taken the following decisions:

- 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 focussed on driving and implementing the Company's global strategy. During the interim period, Mr. Thomas Jacobsen (Hyloris' Chief Business Development Officer and co-founder) will be appointed as co-CEO alongside the current CEO and all major decisions shall be made jointly by the co-CEOs.
- Subject to a transition period, Hyloris' CFO and CLO will leave their roles within the Company in mutual consent in the interest of the Company (but without acknowledging any of the principal findings of the review). At the request of the Board, the CFO will remain with the Company to finalize the annual accounts for the fiscal year 2023 and (if needed) the half-year results, and hand over to the new CFO.
- The Company's governance will be strengthened by (i) having the internal control systems reviewed by an independent third party, (ii) creating an internal audit function, and (iii) implementing written compliance policies and clear internal reporting lines (including to the Audit Committee).

The Company is evaluating continuously how and when these decisions will be implemented considering the corporate interest and the developments in this matter.

Following the decisions of the Board, the Company has informed the FSMA of the findings of the forensic independent review, the comments of the executive management team, and the Board's decisions. Since then, the Company has had ongoing contacts with the FSMA (including with regard to the content of the press release to be issued concerning the findings of the forensic independent review).

While these contacts were ongoing, on 5 July 2024, the FSMA decided to release a public communication regarding the Company<sup>1</sup>, setting out a.o. the FSMA's

<sup>1</sup> The full text of the FSMA communication is published in French and Dutch on the website of the FSMA.

views of the QliniQ transactions and stating that the FSMA has serious doubts about the reliability of the information that Hyloris has provided to the market. The FSMA expressed the view that this information does not allow investors to assess the risk of an investment in Hyloris shares.

The conclusions of the FSMA's<sup>1</sup> warning are as follows<sup>2</sup> :

“On the basis of its own findings and the independent forensic review, the FSMA has serious doubts as to the economic reality of the transactions with QliniQ. The independent forensic review indeed did not permit to identify any objective element confirming the economic reality of the transactions with QliniQ.

On the contrary, the conclusions of the independent forensic review refer, inter alia, to:

- indications that QliniQ had no interest in HY 038;
- the absence of elements demonstrating that due diligence had been carried out in relation to HY-088 and the lack of substance for the payment of EUR 1 million by Hyloris to QliniQ on 13 February 2023 as compensation for internal research and development costs already incurred by QliniQ in relation to HY 088;
- multiple indications that the two transactions were interrelated, which is an indication of the circular nature of the transactions and the related payments;
- the finding that the agreements with QliniQ were prepared - and further amended after execution - on the basis of accounting and market disclosure objectives.

In addition, the independent forensic review identifies, among other things, the following elements

- strong indications that the documentary practices do not reflect reality but are intended to achieve the desired objectives (i.e. to be able to book revenue in 2022), as well as strong indications of a deliberate attempt to backdate the HY 038 agreement to 31/12/2022;
- evidence of multiple misrepresentations by Hyloris' management to the FSMA
- evidence of management filtering information from the Board of Directors and the Audit Committee.

<sup>2</sup> Free translation of the original French/Dutch text.

The independent forensic review also contains observations regarding the governance and corporate culture of Hyloris<sup>1</sup>

As a result of the findings of the independent forensic review, the independent directors have recommended to the Board of Directors of Hyloris that the internal control systems be reviewed by an independent third party (including with a view to establishing an internal audit function), that the company's compliance policies be reviewed, and that the CEO, CFO and CLO be replaced by strong, independent and qualified candidates.

Hyloris' management has indicated that it strongly opposes the conclusions of the independent forensic review.

Trading in the shares remains suspended pending publication of the 2023 annual financial report and the accompanying report of the statutory auditor."

Further to the FSMA's communication, the Company has issued a press release on 8 July 2024. Therein it has stated that the Company has taken note of the FSMA's communication. The Company is of the view that it has made available (and intended to make available through a press release concerning the forensic independent review drafted in consultation with the FSMA) to the public all information that is relevant for investors. The Company is committed to inform the market correctly and it will continue discussions with the FSMA in a view to agree on a communication policy which meets the concerns of the FSMA.

The Company's 8 July 2024 press release also contains detail on the business rationale and development status of HY-088. In this respect, the Company's executive management team refers to the report of the independent valuation expert which contributed to the forensic independent review and which concludes as follows with regard to the consideration paid for HY 088: "Based on (i) the limited procedures performed, as described above, on the business plan prepared by Management as of the date of the Transaction, (ii) the use of the generally accepted valuation methods under the income approach, and (iii) pursuant to the conditions and limitations contained herein, **it is our preliminary view that nothing leads us to believe that the**

**Transaction Price is not within an acceptable range of preliminary values"**. The Company further notes that the forensic independent review has not conclusively established the absence of substance of the HY-088 and HY-038 transactions and that, even though the forensic independent review concluded that there are strong indications that the two QliniQ transactions were apparently linked, both transactions were aligned with Hyloris' strategic objectives.

The development of HY-088 remains on track for European market access by the second half of 2026, with the total cost of acquisition and development, including licensing fees and external development expenses, staying (well) under €2 million as previously announced. After development completion, Hyloris will not incur any further financial obligations to the original developer. Development began in late 2022 and by early 2023 an external development company identified candidate formulations through product design planning, ingredient selection activities, and testing. Further work throughout 2023 ensured stability, refinement, and successful lab-scale production. GMP batch manufacturing is anticipated for late 2024.

#### **18.7.2024: Expansion of Maxigesic® IV into Brazil**

See the press release.

#### **26.7.2024: Carolyn Myers, a non Executive Director**

Ms. Carolyn Myers is an independent director of the Company since 8 June 2020. She is also a member of the Company's Remuneration and Nomination Committee.

Directors in a listed company are considered independent if they do not maintain a relationship with the company or a major shareholder thereof that compromises their independence. To determine whether a (candidate) director satisfies this condition, at least the criteria set out in the 2020 Belgian Corporate Governance Code are applied.

One of these criteria is that independent directors do not maintain, or have maintained in the past year before their appointment, a significant business relationship with the Company or a related company or person, either directly or as a partner, shareholder, board member, member of the senior management (as



defined in article 19, 2° of the law of 20 September 1948 regarding the organisation of the business industry) of a company or person who maintains such a relationship.

The Company has an ongoing business relationship with Vaneltix Pharma, Inc. ("Vaneltix") for the development and commercialisation of Alenura<sup>TM</sup> as first-line drug treatment for acute pain in interstitial cystitis /bladder pain syndrome (IC/BPS). [The Company also has a shareholding of less than 1% in Vaneltix.]

Ms. Carolyn Myers is associated with Vaneltix due to her relationship with Mr. Dan Vickery, CEO, board member and shareholder of Vaneltix. Based on recent information, Ms. Carolyn Myers also performs an executive function within Vaneltix as Commercial Head.

Because of the business relationship between the Company and Vaneltix on the one hand, and the association of Ms. Carolyn Myers with Vaneltix on the other hand, Ms. Carolyn Myers possibly no longer fulfils the aforementioned criterion of the 2020 Belgian Corporate Governance Code and, consequently, the general condition to be considered an independent director. For this reason, Hyloris' Board of directors has decided on 26 July 2024 that Ms. Carolyn Myers will be considered a non-executive director (but no longer as an independent director) for the remainder of her mandate.

Due to Ms. Carolyn Myers no longer being considered an independent director, the Company's Remuneration and Nomination Committee no longer meets the requirement set out in the Company's corporate governance charter, that a majority of the committee's members must be independent. As previously announced, the Company currently is in a process to strengthen its governance. The Company will address this as part of the ongoing evaluation, at the upcoming annual general meeting. For the avoidance of doubt, this change does not affect the validity of previous meetings and decisions of the Remuneration and Nomination Committee.

## 30. AUDIT FEES

During 2022 and 2023, the statutory auditor provided services for the group Hyloris which fees were as follows:

(In € thousand)	December 31, 2023	December 31, 2022
Audit services	91	82
Audit related services - legal engagements	-	15
Tax services	28	18
<b>Total</b>	<b>119</b>	<b>115</b>

## 31. RESTATEMENT OF 2022 STATEMENTS

### 31.1 QLINIQ TRANSACTION

Following discussions with the Belgian Financial Services and Markets Authority (FSMA) and Hyloris' statutory auditor, the Board of Directors has revised the financial statements due to the correction of a non-cash accounting error regarding the divestment of HY-038 and acquisition of HY-088.

[Clarification on the press release of 20 January 2023 on the transactions with Qliniq](#)

On 20 January 2023 Hyloris announced that the global rights of the ongoing development of HY-088 was licensed-in from a Dutch company, Qliniq, who maintained the rights to commercialize the product candidate in its home country, and a selected number of Middle Eastern and developing countries. In the same press release, Hyloris announced that it had divested HY-038 to the same company, Qliniq, for a price of €1 million.

As detailed in the 2022 Annual Report, HY-038 falls under the category of high-barrier generics and thus lies beyond Hyloris' core portfolio of assets. Limited development activities had occurred for HY038 since the IPO. Hyloris encountered challenges in identifying a suitable Contract Manufacturing Organization (CMO) capable of producing HY-038 at a desired cost.

The transaction price of € 1 million was received on 16 February 2023. HY-088 is a ready-to-administer oral liquid formulation designed for addressing hypophosphatemia. Presently, physicians utilize compounded products for treating this condition, which have not undergone regulatory evaluation regarding their safety, effectiveness, and quality. At the time of the transaction, Qliniq held no exclusive rights to develop the oral liquid formulation.

It is expected that Hyloris will submit HY-088 for registration in the course of 2025. The transaction price of €1.2 million (including €200 thousand designated as prepaid expenses), was paid by Hyloris on 13 February 2023.

Qliniq is a Dutch company which develops and in-licenses drugs and medical supplies in various therapeutic domains and commercializes these in the Netherlands. Qliniq nurtures cooperation and long-lasting business relationships with international companies as part of its successful market approach. At December 31, 2022, Qliniq had a balance sheet total of € 0.8 million, a cash balance of € 0.2 million and 2 FTE's. Qliniq's shareholders have previously successfully build and sold several pharmaceutical companies.

#### Accounting treatment of the transactions with Qliniq

Hyloris 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. Due to the development stage of the products exchanged, the fair value of neither the asset received, nor the asset given up can be reliably determined. As highlighted in 'Note 29 – Forensic investigation outcome', the transfer of control HY-038 occurred in 2023. As a result of this reassessment, the restated financials for 2022 have reversed the €1 million revenue from the divestment of HY-038."

The following tables present the restatements performed on the comparative periods:

#### Consolidated statement of financial position

Per 31 December 2022 (In € thousand)	Impact of correction of error only for Qliniq		
	As previously reported	Adjustment	As restated
<b>Current assets</b>	<b>50,801</b>	<b>(1,000)</b>	<b>49,801</b>
Trade and other receivables	5,127	(1,000)	4,127
<b>Total assets</b>	<b>61,864</b>	<b>(1,000)</b>	<b>60,728<sup>1</sup></b>
<b>Equity</b>	<b>55,045</b>	<b>(1,000)</b>	<b>53,909<sup>1</sup></b>
Result of the period	(10,770)	(1,000)	(11,906) <sup>1</sup>
<b>Total equity and liabilities</b>	<b>61,864</b>	<b>(1,000)</b>	<b>60,728<sup>1</sup></b>

<sup>1</sup>Including restatement of the API loan (refer to note 31.3)

#### Consolidated statement of profit or loss and other comprehensive income

Per 31 December 2022 (In € thousand)	Impact of correction of error only for Qliniq		
	As previously reported	Adjustment	As restated
Revenues	2,951	(1,000)	900 <sup>1</sup>
<b>Gross profit</b>	<b>2,857</b>	<b>(1,000)</b>	<b>805<sup>1</sup></b>
<b>Operating profit/(loss) (EBIT)</b>	<b>(10,638)</b>	<b>(1,000)</b>	<b>(11,638)</b>
<b>Profit (loss) before taxes</b>	<b>(10,766)</b>	<b>(1,000)</b>	<b>(11,901)<sup>2</sup></b>
<b>PROFIT (LOSS) FOR THE PERIOD</b>	<b>(10,770)</b>	<b>(1,000)</b>	<b>(11,906)<sup>2</sup></b>
<b>TOTAL COMPREHENSIVE INCOME FOR THE PERIOD</b>	<b>(10,770)</b>	<b>(1,000)</b>	<b>(11,906)<sup>2</sup></b>

<sup>1</sup> Including reclass from revenue towards other operating income, see note 31.2

<sup>2</sup> Including restatement of the API loan, see note 31.3

#### Consolidated statement of cash flows

Even though there was 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 are presented in the net consolidated cash flow statement for the year ended per December 31, 2023 (i.e., €200 thousand prepaid expenses), as this most faithfully presents the substance of the transactions. The impact on the consolidated statement of cash flows for the year ended on December 31, 2022 is the decrease of the Trade and other receivables.

### 31.2. RECLASSIFICATION OF REVENUE FOR SERVICES RENDERED

Revenues for services rendered in connection with the Management Consultancy Agreement concluded with Pleco Therapeutics (see [note 3.2](#)) has been reclassified from Revenue to Other income as they are not considered as part of the ordinary activities of The Group.

The impact on the consolidated financial statement of profit or loss and other comprehensive income:

Per 31 December 2022 (In € thousand)	Impact of correction of error		
	As previously reported	Adjustment	As restated
Revenue	2,951	(1,052)	900 <sup>1</sup>
Other operating income	315	1,052	1,487 <sup>2</sup>

<sup>1</sup> Including restatement of Qliniq, see note 31.1

<sup>2</sup> Including reclass for grants on payroll withholding taxes, see note 31.4B

### 31.3 RECLASS RELATED TO API LOAN

The loan made to third parties has been reclassified in the statement of cash flow from Trade and other receivables to Investing activities. In accordance with IAS 7, par. 16(e) cash advances and loans made to other parties are part of cash flows from investing activities. Furthermore, in prior year the fair value of the outstanding loan was incorrectly calculated and not in compliance with IFRS 9 as an appropriate risk premium was included. The discount rate was revised impacting the statement of financial position (Trade and other receivables) and statement of profit and loss and other comprehensive income (financial expenses).

The impact on the consolidated financial statement of cash flow:

Per 31 December 2022 (In € thousand)	Impact of correction of error		
	As previously reported	Adjustment	As restated
Trade and other receivables	(2,261)	655	(921) <sup>1</sup>
<b>Cash generated from operations</b>	<b>(12,812)</b>	<b>655</b>	<b>(12,679)<sup>2</sup></b>
<b>Net cash generated from operating activities</b>	<b>(13,154)</b>	<b>655</b>	<b>(13,020)<sup>2</sup></b>
Loans made to third parties	-	(655)	(655)
<b>Net cash provided by investing activities</b>	<b>(1,239)</b>	<b>(655)</b>	<b>(11,373)<sup>3</sup></b>

<sup>1</sup> Including restatement for the R&D Tax Credit, see note 31.4B and restatement for Qliniq transaction, see note 31.1

<sup>2</sup> Including restatement for the R&D Tax Credit, see note 31.4B and restatement for Qliniq transaction, see note 31.1 and restatement for the API loan, see note 31.3 and the netting of the finance result <sup>3</sup> including restatement for cash and cash equivalents, see note 31.4A and the netting of the finance result

The impact on the consolidated financial statement of financial position:

Per 31 December 2022 (In € thousand)	Impact of correction of error		
	As previously reported	Adjustment	As restated
<b>Non Current assets</b>	<b>11,063</b>	<b>(136)</b>	<b>10,927</b>
Trade and other receivables (Non current)	1,447	(136)	1,311
<b>Total assets</b>	<b>61,864</b>	<b>(136)</b>	<b>60,728<sup>1</sup></b>
<b>Equity</b>	<b>55,045</b>	<b>(136)</b>	<b>53,909<sup>1</sup></b>
Result of the period	(10,770)	(136)	(11,906) <sup>1</sup>
<b>Total equity and liabilities</b>	<b>61,864</b>	<b>(136)</b>	<b>60,728<sup>1</sup></b>

<sup>1</sup> Including restatement of Qliniq, see note 31.1

The impact on the consolidated financial statement of profit or loss and other comprehensive income:

Per 31 December 2022 (In € thousand)	Impact of correction of error		
	As previously reported	Adjustment	As restated
Financial expenses	(594)	(136)	(730)
<b>Profit (loss) before taxes</b>	<b>(10,766)</b>	<b>(136)</b>	<b>(11,901)<sup>1</sup></b>
<b>PROFIT (LOSS) FOR THE PERIOD</b>	<b>(10,770)</b>	<b>(136)</b>	<b>(11,906)<sup>1</sup></b>
<b>TOTAL COMPREHENSIVE INCOME FOR THE PERIOD</b>	<b>(10,770)</b>	<b>(136)</b>	<b>(11,906)<sup>1</sup></b>

<sup>1</sup>Including restatement of Qliniq, see note 31.1

### 31.4 OTHER RESTATEMENTS IN THE FINANCIAL STATEMENTS

Next to the above restatement with impact on the income statement and statement of financial position of the comparative period, the Company has also made following reclasses without net impact on the net result.

#### A. Cash and cash equivalents

Two term deposits for a total amount of €10 million have been reclassified from "Cash and cash equivalents" to "Other investment including derivatives" as the term deposit does not meet the definition of cash equivalents in accordance with IFRS. The term of 1 deposit is from December 13, 2022 until June 13, 2023 and the term of the other deposit is from December 13 2022 until September 13, 2023. They cannot be withdrawn, in whole or part, prior to the due date of the term deposit. See [note 13](#).

The impact of the restatement on the consolidated financial statement:

Per 31 December 2022 (In € thousand)	Impact of correction of error		
	As previously reported	Adjustment	As restated
Other investment, including derivatives	469	10,000	10,469
Cash and cash equivalents	43,457	(10,000)	33,457

The impact of the restatement on the consolidated financial statement of cash flow:

Per 31 December 2022 (In € thousand)	Impact of correction of error		
	As previously reported	Adjustment	As restated
Proceeds of other financial assets	-	(10,000)	(10,000)
Cash flow from investing activities	(1,239)	(10,000)	(11,373) <sup>1</sup>
<b>Net (decrease) in cash and cash equivalents</b>	<b>(6,555)</b>	<b>(10,000)</b>	<b>(16,555)</b>
<b>Cash and cash equivalents at end of year</b>	<b>43,457</b>	<b>(10,000)</b>	<b>33,457</b>

<sup>1</sup>Including restatement of the API loan, see note 31.3

#### B. Grants related to payroll withholding taxes and R&D Tax Credit

As from 2023, the grants on payroll withholding taxes for scientific personnel are presented as 'Other operating income' while per December 31, 2022 they were presented as a deduction from the related employee benefit expenses within the 'Research and development expenses'. In order to guarantee comparability, the 2022 statement of profit and loss has been restated to reflect this reclass (impact of €120 thousand). This is now also consistent with the presentation of the Half Year figures.

The grant related to the R&D Tax Credit has been reclassified in the 2022 statement of cash flow from R&D Tax Credit to Trade and other receivables.

The impact on the consolidated statement of profit or loss and other comprehensive income:

Per 31 December 2022 (In € thousand)	Impact of correction of error		
	As previously reported	Adjustment	As restated
Other operating income	315	120	1,487 <sup>1</sup>
<b>Operating income</b>	<b>315</b>	<b>120</b>	<b>2,387<sup>2</sup></b>
Research and development expenses	(10,151)	(120)	(10,272)
<b>Operating expenses</b>	<b>(13,905)</b>	<b>(120)</b>	<b>(14,024)</b>

<sup>1</sup> Including reclass from revenue towards other operating income, see note 31.2

<sup>2</sup> Including reclass from revenue towards other operating income, see note 31.2 and restatement for Qliniq transaction, see note 31.1

The impact on the consolidated financial statement of cash flow:

Per 31 December 2022 (In € thousand)	Impact of correction of error		
	As previously reported	Adjustment	As restated
Trade and other receivables	(2,261)	(315)	(921) <sup>1</sup>
R&D Tax Credit	(315)	315	-

<sup>1</sup> Including restatement of Qliniq, see note 31.1 and restatement of the API loan, see note 31.3

### C. Other reclasses in the statement of cash flow

In the statement of cash flows, fair value gains and losses on derivatives, interest expenses on shareholder's loans and losses on the derecognition of shareholder loans have been reclassified to net financial result.

### D Revised presentation of the consolidated statements of Profit or Loss and Other Comprehensive Income in general

In order to improve the readability of the consolidated financial statement of Profit or Loss and Other Comprehensive income there is a revised presentation of the lines as from 2023 including the comparative of 2022.

In the new presentation, Other operating income is put below Revenue. The sum of both is Operating Income.

Cost of sales is put together with Research and development expenses, General and administrative expenses, share of result of equity-accounted investees and other operating expenses under the new line Operating expenses.

# Abbreviated Statutory Financial Statements of Hyloris Pharmaceuticals SA

The following information is extracted from the separate standalone annual accounts of Hyloris Pharmaceuticals SA ("the Company") and is included as required by article 3:17 of the Belgian Company and Association Code.

The statutory auditor's report is qualified and certifies that the standalone annual accounts of Hyloris Pharmaceuticals SA prepared in accordance with the financial reporting framework applicable in Belgium for the year ended December 31, 2023 give a true and fair view of the Company's equity and financial position as at December 31, 2023 and of its financial performance for the year then ended in accordance with the financial reporting framework applicable in Belgium with the exception of the matter described in the "Basis for

qualified opinion" section of the audit report relating to an agreement with Pleco Therapeutics BV which is also included in the statutory auditor's report on the consolidated financial statements. The standalone financial statements, together with the annual report of the Board of Directors to the general meeting of shareholders as well as the auditors' report, will be filed with the National Bank of Belgium within the legal deadline.

These documents are also available on request, addressed to:

*Hyloris Pharmaceuticals SA  
Boulevard Patience et Beaujonc, N°3/1, 4000 Liège,  
Belgium*

## Statement of Financial Position

(In €)	2023	2022
<b>ASSETS</b>		
<b>FIXED ASSETS</b>	<b>76,097,212</b>	<b>76,374,779</b>
Intangible fixed assets	121,042	112,655
<b>Tangible fixed assets</b>		
<b>Financial fixed assets</b>	<b>75,976,170</b>	<b>76,262,124</b>
Affiliated companies - Participations	73,161,002	73,161,002
Affiliated companies - Receivables	1,815,167	2,101,122
Investment	1,000,001	1,000,000
<b>CURRENT ASSETS</b>	<b>38,607,279</b>	<b>41,456,011</b>
<b>Receivables over one year</b>	<b>634,434</b>	<b>656,291</b>
Trade receivables		-
Others amounts receivable	634,434	656,291
<b>Amounts receivable within one year</b>	<b>7,054,248</b>	<b>3,893,442</b>
Trade receivables	5,695,222	2,958,075
Others amounts receivables	1,359,026	935,367
<b>VIII. Cash Investment</b>	<b>10,000,000</b>	<b>30,000,000</b>
<b>IX. Cash at bank and in hand</b>	<b>18,817,284</b>	<b>4,589,023</b>
<b>X. Deferred charges and accrued income</b>	<b>2,101,313</b>	<b>2,317,255</b>
<b>TOTAL ASSETS</b>	<b>114,704,491</b>	<b>117,830,790</b>
<b>CAPITAL AND RESERVES</b>	<b>102,751,874</b>	<b>106,154,186</b>

(In €)	2023	2022
Capital	140,002	140,002
Share Premium	121,513,447	121,513,447
Reserves	5,000	5,000
Accumulated profits (losses)	(18,906,575)	(15,504,263)
<b>PROVISIONS AND DEFERRED TAXES</b>		
<b>CREDITORS</b>	<b>11,952,617</b>	<b>11,676,604</b>
<b>Amounts payable after more than one year</b>	<b>300,000</b>	<b>300,000</b>
Other financial loans		
Other debts	300,000	300,000
<b>IX. Amounts payable within one year</b>	<b>10,624,769</b>	<b>11,153,196</b>
Current portion of amounts payable after one year	-	-
Other financial loans	3,072,421	6,633,479
Suppliers	3,122,209	1,291,575
Taxes, remuneration and social charges	15,100	28,142
Other debts	4,415,039	3,200,000
X. Accrued charges and deferred income	1,027,848	223,408
<b>TOTAL LIABILITIES</b>	<b>114,704,491</b>	<b>117,830,790</b>

## Income Statement

(In € thousand)	2023	2022
<b>Operating income</b>	<b>(3,639,978)</b>	<b>1,249,949</b>
Turnover	1,120,551	204,885
Other operating income	709,473	1,045,064
Non-recurrent income	1,809,954	-
<b>Operating charges</b>	<b>(5,777,848)</b>	<b>(3,750,126)</b>
Services and other goods	(5,409,842)	(3,675,309)
Other operating charges (-)	(1,859)	(5,219)
Remunerations, social charges and pensions	(346,393)	(69,598)
Depreciations	(19,754)	-
Non-recurring operating expenses	-	-
<b>Operating profit (loss)</b>	<b>(2,137,870)</b>	<b>(2,500,177)</b>
<b>Financial income</b>	<b>1,159,948</b>	<b>1,928,732</b>
Income from financial fixed assets	-	363,784
Income from current assets	1,094,291	-
Other financial income	65,657	1,564,948
<b>Financial charges (-)</b>	<b>(2,446,796)</b>	<b>(482,131)</b>
Interest on financial debts	(360,181)	(286,159)
Other financial charges	-	(195,972)
<b>Profit (Loss) for the period before taxes (-)</b>	<b>(3,424,718)</b>	<b>(886,786)</b>
<b>Income taxes (-)</b>	<b>22,406</b>	<b>(16,659)</b>
<b>Profit (loss) for the period available for appropriation</b>	<b>(3,402,312)</b>	<b>(1,070,235)</b>

# Statutory Notes

## Statement of financial fixed assets

(In €)	2023	2022
<b>Affiliated companies - Participations</b>		
<b>Acquisition value at the end of the preceding period</b>	<b>73,161,002</b>	<b>44,944,782</b>
Movements during the period		
Acquisitions, included produced fixed assets	-	28,216,220
<b>Acquisition value at the end of the period</b>	<b>73,161,002</b>	<b>73,161,002</b>
Depreciation and amounts written down at end of the preceding period		
Movements during the period		
Recorded		
Depreciation and amounts written down at end of the period		
<b>Net book value at the end of the period</b>	<b>73,161,002</b>	<b>73,161,002</b>
<b>Affiliated companies - Receivables</b>		
Net book value at the end of preceding period	2,101,122	12,232,733
Movements during the period		
Additions		19,328,396
Reimbursement	(285,955)	(29,460,007)
<b>Net book value at the end of the period</b>	<b>1,815,167</b>	<b>2,101,122</b>

(In €)	2023	2022
<b>Investment</b>		
<b>Acquisition value at the end of the preceding period</b>	<b>1,000,000</b>	-
Movements during the period		
Acquisitions, included produced fixed assets	1,809,955	1,000,000
<b>Acquisition value at the end of the period</b>	<b>2,809,955</b>	<b>1,000,000</b>
Depreciation and amounts written down at end of the preceding period		
Movements during the period		
Recorded		
Depreciation and amounts written down at end of the period	1,809,954	
<b>Net book value at the end of the period</b>	<b>1,000,001</b>	<b>1,000,000</b>

Company	Nature	Participation held			Data extracted from last available annual accounts			
		Direct		By subsidiaries	Annual accounts at	Currency Code	Capital	Net profit or (loss)
		Number	%	%				
<b>Hyloris Developments SA</b> Boulevard Patience et Beaujonc 3 4000 Liège Belgium  542,737,368	Shares	74,066	99.99%	0%	12/31/2023	EUR	7,853,337	(12,069,087)
<b>Hyloris Supply SA</b> Boulevard Patience et Beaujonc 3 4000 Liège Belgium  669,738,676	Shares	62,000	100 %	0%	12/31/2023	EUR	(1,716,017)	(146,630)



<b>Dermax SA</b> Boulevard Patience et Beujonc 3 4000 Liège Belgium 667,730,677	Shares	65,875	100%	0%	12/31/2022	EUR	3,164,916	1,116,681
<b>Purna Female Healthcare BV</b> Schaldestraat 31 2880 Bornem Belgium 762,693,578	Shares	840	20%	0%	12/31/2023	EUR	758,157	(736,656)
<b>Vaneltix Pharma Inc.</b> 317 George St., Ste. 400 New Brunswick, NJ 08901 United States	Shares	4	<0.1 %	0%	12/31/2023	EUR	30,712	(33,955)

## Deferred Charges and Accrued Income

(In €)	2023	2022
<b>Deferred charges and accrued income</b>		
Interest earned on receivables from related companies	1,725,351	1,946,679

## Statement of Amounts Payable

(In €)	2023	2022
<b>Analysis by current position of amounts initially payable after more than one year, maturing in 1 year</b>		
Other debts (Shareholder loans)		-
<b>Analysis by current position of amounts initially payable after more than one year, maturing in max 5 years</b>		
Other debts	300,000	300,000
<b>Tax, wage and social amounts payable</b>		
Taxes payable	0	8,309
Other salary and social debts	15,100	19,833
<b>Accrued charges and deferred income</b>		
Accrued FX forward contracts	0	51,832
Accrued bonuses	10,379	4,390
AFT - Milestone due at the start of the first commercial manufacturing batch of Maxigesic IV	904,977	-

# Statutory auditor's report



## **Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023**

In the context of the statutory audit of the consolidated financial statements of Hyloris Pharmaceuticals SA ("the Company") and its subsidiaries (jointly "the Group"), we provide you with our statutory auditor's report. This includes our report on the consolidated financial statements for the year ended 31 December 2023, as well as other legal and regulatory requirements. Our report is one and indivisible.

We were appointed as statutory auditor by the general meeting 14 June 2022, in accordance with the proposal of the board of directors issued on the recommendation of the audit committee. Our mandate will expire on the date of the general meeting deliberating on the annual accounts for the year ending 31 December 2024. We have performed the statutory audit of the consolidated financial statements of the Group for 5 consecutive financial years.

### **Report on the consolidated financial statements**

#### ***Qualified opinion***

We have audited the consolidated financial statements of the Group as of and for the year ended 31 December 2023, prepared in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board and as adopted by the European Union, and with the legal and regulatory requirements applicable in Belgium. These consolidated financial statements comprise the consolidated statement of financial position as of 31 December 2023, the consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for the year then ended and notes, comprising material accounting policies and other explanatory information. The total of the consolidated statement of financial position amounts to EUR 47.681.000 and the consolidated statement of profit or loss and other comprehensive income shows a loss for the year of EUR 15.380.000

In our opinion, except for the possible effect of the matter described in the "Basis for qualified opinion" section of our report, the consolidated financial statements give a true and fair view of the Group's equity and financial position as of 31 December 2023 and of its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board and as adopted by the European Union, and with the legal and regulatory requirements applicable in Belgium.



*Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023*

### ***Basis for our qualified opinion***

As described in note 3.2 to the consolidated financial statements, the Group entered into an agreement with Pleco Therapeutics BV ("Pleco") on 8 July 2022. Under the terms of this agreement the Group agreed to provide strategic advice to Pleco from 1 January 2022 to 31 December 2024 for a maximum consideration of EUR 2,5 million. The Group recognized an amount of EUR 1,0 million and EUR 0,5 million as other operating income in the consolidated financial statements for the years ended 31 December 2022 and 2023, respectively.

This agreement is written in a general way ("provision of strategic advice") and does not specify the different performance obligations to be provided by the Group to Pleco. The Group recognized income related to this agreement based on a contractual payment schedule, and not based on an analysis with reference to specific agreed-upon performance obligations, milestones or other objective allocation methods. In the absence of such an analysis, it is impossible for us to assess whether the income of EUR 1,5 million recognized as other operating income in financial years 2022 and 2023 meets the requirements of IFRS Accounting Standards as issued by the International Accounting Standards Board and as adopted by the European Union. There were no alternative procedures we could have performed to assess whether the income related to this agreement was correctly accounted for and disclosed in note 3.2 to the consolidated financial statements in accordance with the applicable accounting standards.

We conducted our audit in accordance with International Standards on Auditing ("ISAs") as adopted in Belgium. In addition, we have applied the ISAs as issued by the IAASB and applicable for the current accounting year while these have not been adopted in Belgium yet. Our responsibilities under those standards are further described in the "Statutory auditors' responsibility for the audit of the consolidated financial statements" section of our report. We have complied with the ethical requirements that are relevant to our audit of the consolidated financial statements in Belgium, including the independence requirements.

Except for the matter described above, we have obtained from the board of directors and the Company's officials the explanations and information necessary for performing our audit.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our qualified opinion.



*Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023*

### **Emphasis of matter – Restatement of the consolidated financial statements for the year ended 31 December 2022**

We refer to note 31 "Restatement of the 2022 statements" to the consolidated financial statements in which the board of directors discloses the correction of material errors identified in the current year with respect to the prior year consolidated financial statements in accordance with IAS 8 *Accounting Policies, Changes in Accounting Estimates and Errors*.

Our audit opinion is not modified in respect of this matter.

#### ***Key audit matters***

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements of the current period. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters. In addition to the matter described in the "Basis for our qualified opinion" section of our report we have determined the matters described below to be key audit matters to be communicated in our report.

#### ***Collaboration agreements between the Group and its partners for product candidates***

- **Description**

We refer to note 3.2 of the consolidated financial statements in which the Group describes that they have entered into several collaboration agreements with partners for the development of product candidates. These agreements can take various forms such as equity investments, loans (convertible or non-convertible), research & development (R&D) funding, strategic advice, etc., and can be subject to contract amendments.

The existence of such collaboration agreements is considered to be a key audit matter due to the complexity in determining the appropriate accounting based on i) their nature including the existence of multiple or mutual obligations with the same party, ii) the existence of contract amendments that could affect their subsequent accounting, iii) the level of judgment required to assess whether the collaboration agreements give rise to significant influence by the Group over the partners and iv) the absence of effective internal controls related to the identification, structuring, modification of and accounting for collaboration agreements, including the monitoring of underlying costs.



*Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023*

- Our audit procedures

We performed the following audit procedures, amongst others:

- We evaluated the substance of the various elements of significant collaboration agreements and discussed the contract terms with management and those charged with governance.
- For a sample of R&D costs recharged by the Group's partners, we traced these costs back to the underlying invoices originating from the partners' subcontractors to verify their existence and accuracy. When deemed necessary, we obtained direct confirmation from the Group's partner as to the existence, completeness and accuracy of R&D costs recharged.
- We evaluated the substance of revenue/other operating income charged by the Group to its partners by obtaining supporting evidence on the performance obligations. In this respect, we also refer to the matter described in the "Basis for our qualified opinion" section of our report.
- We analyzed the level of influence the Group has over its partners by considering amongst others the significance of the Group's relationships to the partners and challenged the judgment made by management. For partners where the Group was determined to have significant influence, we evaluated the appropriateness of the accounting treatment.
- We examined the transactions between the Group and its partners to identify the existence of circular transactions.
- We assessed the adequacy of the disclosures in the consolidated financial statements, particularly under note 3.2 "Joint collaborations" and note 21 "Other operating income" with respect to the collaboration agreements. In this respect, we also refer to the matter described in the "Basis for our qualified opinion" section of our report.

*Impact of the outcome of the independent forensic review on the QliniQ transactions on our audit*

- Description

We refer to note 29 "Subsequent Event (After the End of the Reporting Period)" in which the Group discloses that, starting in April 2024, an independent forensic review was carried out by an international law firm as independent legal expert, appointed by and under the supervision of an ad hoc committee of independent directors of the Company, with respect to two transactions with Qliniq BV ("the Qliniq transactions"). We have considered the observations of the independent forensic review as a key audit matter, as such observations may impact other aspects of our audit.



*Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023*

- Our audit procedures

In accordance with ISAs, we have reevaluated our assessment of the risks of material misstatement due to fraud or error and its resulting impact on the nature, timing and extent of audit procedures to respond to the assessed risks and reconsidered the reliability of evidence previously obtained.

Our incremental procedures as a result of this reevaluation of the risks of material misstatement included amongst others:

- We reevaluated the audit evidence obtained during the audit to assess the reliability of the supporting evidence initially received.
- We evaluated the nature of the other restatements identified and corrected in the current year consolidated financial statements (see note 31 "Restatement of the 2022 statements").
- We inspected the report prepared by and inquired the independent legal expert appointed by the board of directors who carried out the forensic independent review with respect to the QliniQ transactions.
- We obtained specific representations from those charged with governance.
- We assessed the adequacy of the information provided in note 29 "Subsequent Event (After the End of the Reporting Period)".

***Board of directors' responsibilities for the preparation of the consolidated financial statements***

The board of directors is responsible for the preparation of these consolidated financial statements that give a true and fair view in accordance with IFRS Standards as issued by the International Accounting Standards Board and as adopted by the European Union, and with the legal and regulatory requirements applicable in Belgium, and for such internal control as board of directors determines, is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the board of directors is responsible for assessing the Group's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the board of directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.



*Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023*

### ***Statutory auditor's responsibilities for the audit of the consolidated financial statements***

Our objectives are to obtain reasonable assurance as to whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of the users taken on the basis of these consolidated financial statements.

When performing our audit, we comply with the legal, regulatory and professional requirements applicable to audits of the consolidated financial statements in Belgium. The scope of the statutory audit of the consolidated financial statements does not extend to providing assurance on the future viability of the Group nor on the efficiency or effectivity of how the board of directors has conducted or will conduct the business of the Group. Our responsibilities regarding the going concern basis of accounting applied by the board of directors are described below.

As part of an audit in accordance with ISAs, we exercise professional judgement and maintain professional skepticism throughout the audit. We also perform the following procedures:

- Identify and assess the risks of material misstatement of the consolidated financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- Obtain an understanding of internal controls relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Group's internal control;
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by board of directors;
- Conclude on the appropriateness of board of directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern.



*Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023*

If we conclude that a material uncertainty exists, we are required to draw attention in our auditors' report to the related disclosures in the consolidated financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditors' report. However, future events or conditions may cause the Group to cease to continue as a going concern;

- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation;
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the audit committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the audit committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

For the matters communicated with the audit committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter.

## **Other legal and regulatory requirements**

### ***Responsibilities of the Board of directors***

The board of directors is responsible for the preparation and the content of the board of directors' annual report on the consolidated financial statements and the other information included in the annual report.

### ***Statutory auditor's responsibilities***

In the context of our engagement and in accordance with the Belgian standard which is complementary to the International Standards on Auditing as applicable in Belgium, our responsibility is to verify, in all material respects, the board of directors' annual report on the consolidated financial statements and the other information included in the annual report, and to report on these matters.





*Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023*

### **Aspects concerning the board of directors' annual report on the consolidated financial statements and other information included in the annual report**

Based on specific work performed on the board of directors' annual report on the consolidated financial statements and except for the possible effect of the matter described in the "Basis for our qualified opinion" section of our report, we are of the opinion that this report is consistent with the consolidated financial statements for the same period and has been prepared in accordance with article 3:32 of the Companies' and Associations' Code.

In the context of our audit of the consolidated financial statements, we are also responsible for considering, in particular based on the knowledge gained throughout the audit, whether the board of directors' annual report on the consolidated financial statements and other information included in the annual report:

- Business overview;
- Key figures; and
- Corporate Governance.

contain material misstatements, or information that is incorrectly stated or misleading. In the context of the procedures carried out and except for the possible effect of the matter described in the "Basis for our qualified opinion" section of our report, we did not identify any material misstatements that we have to report to you.

### **Information about the independence**

Our audit firm and our network have not performed any engagement that compromises our independence with respect to the statutory audit of the consolidated financial statements and our audit firm remained in substance independent of the Group during the term of our mandate.

The fees for the additional engagements which were assessed not to impair our independence with respect to the statutory audit of the consolidated financial statements referred to in article 3:65 of the Companies' and Associations' Code were correctly stated and disclosed in the notes to the consolidated financial statements.

### **European Single Electronic Format (ESEF)**

In accordance with the draft standard on the audit of compliance of the Financial Statements with the European Single Electronic Format (hereafter "ESEF"), we have audited as well whether the ESEF-format is in accordance with the regulatory technical standards as laid down in the EU Delegated Regulation nr. 2019/815 of 17 December 2018 (hereafter "Delegated Regulation").



*Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2023*

The Board of Directors is responsible for the preparation, in accordance with the ESEF requirements, of the consolidated financial statements in the form of an electronic file in ESEF format (hereafter “digital consolidated financial statements”) included in the annual financial report.

It is our responsibility to obtain sufficient and appropriate information to conclude whether the format and the tagging of the digital consolidated financial statements comply, in all material respects, with the ESEF requirements under the Delegated Regulation.

At the date of this report, we have not yet received the annual financial report and the digital consolidated financial statements prepared by the Board of Directors. We have reminded the Board of Directors of their legal responsibility to provide the documents to the statutory auditor and the shareholders within the deadlines stipulated in the Belgian Companies’ and Associations’ Code. As a result, we were unable to conclude whether the format and the tagging of the digital consolidated financial statements comply, in all material respects, with the ESEF requirements under the Delegated Regulation.

**Other aspect**

This report is consistent with our additional report to the audit committee on the basis of Article 11 of Regulation (EU) No 537/2014.

Zaventem, 29 July 2024

KPMG Bedrijfsrevisoren - Réviseurs d’Entreprises  
Statutory Auditor  
represented by

Tanguy Legein  
Bedrijfsrevisor / Réviseur d’Entreprises



# Glossary and Other Info

# Glossary of Terms

<b>Active pharmaceutical ingredient (API)</b>	The biologically active component in a medication that produces the intended effect on the body
<b>Atrial fibrillation (AF)</b>	An abnormal heart rhythm (arrhythmia) characterised by the rapid and irregular beating of the atrial chambers of the heart. It often begins as short periods of abnormal beating, which become longer or continuous over time
<b>Attention Deficit Hyperactivity Disorder</b>	One of the most common neurodevelopmental disorders of childhood. It is usually first diagnosed in childhood and often lasts into adulthood. Children with ADHD may have trouble paying attention, controlling impulsive behaviours (may act without thinking about what the result will be), or be overly active
<b>Bioavailability</b>	Assessment of the amount of product candidate that reaches the body's systemic circulation after administration
<b>Burning Mouth Syndrome (BMS)</b>	A chronic condition characterized by a burning or scalding sensation in the mouth, often without any visible cause
<b>Cardiovascular (CV)</b>	Refers to the heart, blood vessels, and the circulatory system as a whole
<b>Chemistry, Manufacturing, and Controls (CMC)</b>	To appropriately manufacture a pharmaceutical or biologic, specific manufacturing processes, product characteristics, and product testing must be defined in order to ensure that the product is safe, effective and consistent between batches.
<b>EBITDA</b>	Earnings Before Interest, Taxes, Depreciation, and Amortization is a financial metric used to assess a company's operating profitability
<b>Food and Drug Administration (FDA)</b>	The agency responsible for protecting and promoting public health and in charge of American market approval of new medications
<b>FSMA</b>	The Belgian market authority: Financial Services and Markets Authority, Or Autoriteit voor Financiële Diensten en Markten; Autorité des Services et Marchés Financiers
<b>Full-Time Equivalent</b>	A way to measure an employee's involvement in a project. For example, an FTE of 1.0 means that the equivalent work of one full-time worker was used on the project
<b>HY-029</b>	A liquid formulation of an existing anti-viral drug that is currently only available in oral solid form to treat a non-disclosed viral infection
<b>HY-038</b>	A prefilled syringe of a commonly used product to treat a specific, non-disclosed deficiency
<b>HY-074</b>	IV formulation of oral antiplatelet drug, offering faster onset of action in patients suffering from coronary heart disease
<b>HY-075</b>	a liquid formulation of a commonly used drug for the treatment of coronary heart disease requiring frequent dose adjustments

<b>Initial Public Offering (IPO)</b>	Refers to the process of offering shares of a private corporation to the public in a new stock issuance. A public share issuance allows a company to raise capital from public investors. The transition from a private to a public company can be an important time for private investors to fully realise gains from their investment as it typically includes share premiums for current private investors. Meanwhile, it also allows public investors to participate in the offering.
<b>Intellectual Property (IP)</b>	Creations of the mind that have commercial value and are protected or protectable, including by patents, trademarks or copyrights
<b>Intravenous (IV)</b>	Administration of medications directly into the veins using a needle or tube
<b>Key Opinion Leader (KOL)</b>	An influential physician or researcher who is held in high esteem by their colleagues
<b>Investigational New Drug (IND)</b>	A drug that is ready for clinical trials in humans. When a drug reaches this point, the drug developer submits an application to get the consent of the FDA to begin the trials
<b>Net Present Value (NPV)</b>	A tool of capital budgeting to analyse the profitability of a project or investment. It is calculated by taking the difference between the present value of cash inflows and present value of cash outflows over a certain period
<b>New Chemical Entity (NCE)</b>	A compound, without any precedent among the regulated and approved drug products
<b>Pharmacokinetics (PK)</b>	The study of drug absorption, distribution, metabolism, and excretion. A fundamental concept in pharmacokinetics is drug clearance, i.e., elimination of drugs from the body, analogous to the concept of creatinine clearance
<b>Phase 1 Study</b>	First stage of clinical testing of an investigational drug designed to assess the safety and tolerability, pharmacokinetics of a drug, usually in a small number of healthy human volunteers
<b>Phase 2 Study</b>	Second stage of clinical testing of a investigational drug, usually performed in <several hundreds patients in order to determine efficacy, tolerability and drug dose
<b>Phase 3 Study</b>	Large clinical studies, usually conducted in hundred (and in some indications, thousand) patients to gain a definitive understanding of the efficacy and tolerability of the drug candidate – serves as a basis for approval
<b>Pivotal Study</b>	Registrational clinical study
<b>Ready-to-Use (RTU)</b>	Pre-diluted medicines for intravenous use, known as “ready to use” preparations, help to reduce the amount of errors associated with the preparation and administration of medicines
<b>Return on Investment (ROI)</b>	A performance measure used to evaluate the efficiency or profitability of an investment or compare the efficiency of a number of different investments. ROI tries to directly measure the amount of return on a particular investment, relative to the investment’s cost
<b>Vulvar Lichen Sclerosus (VLS)</b>	A chronic inflammatory skin condition that affects the vulva, the external genitalia in females

# FINANCIAL CALENDAR

**September 30, 2024**

Half year results

## CONTACT

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## DISCLAIMER & OTHER INFORMATION

This report contains all information required by Belgian law. Hyloris Pharmaceuticals SA is a limited liability company organised under the laws of Belgium and has its registered office at

Boulevard Patience et Beaujonc  
N°3/1, 4000 Liège.

Throughout this report, the term “Hyloris Pharmaceuticals” refers solely to the non-consolidated Belgian company and references to “we,” “our,” “the group” or “Hyloris”.

The Company has prepared its Annual Report in English and provided a French translation of the Annual Report, in accordance with Belgian laws. Hyloris is responsible for the translation and conformity between the French and English versions. In case of inconsistency between the French and the English versions, the

English version shall prevail.

This report, including the statutory financial statements of Hyloris Pharmaceuticals SA, is available on the Company's website, [www.hyloris.com](http://www.hyloris.com).

### Forward Looking Statements

Certain statements in this annual report 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. You should not place undue reliance on forward-looking statements. Certain monetary amounts and other figures included in this annual report have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.



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