

A photograph of a smiling Black man with a grey beard, wearing a dark wetsuit, holding a surfboard under his arm. The background is a bright, sunny beach scene with the ocean and a distant city skyline.

2022

Annual report

Reinventing existing medications

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This Annual Report 2022 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.

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Hyloris is a specialty biopharma company

committed to bringing innovative treatments that offer added value to underserved patient populations.

We apply our knowhow and technological innovations to existing pharmaceuticals to unlock their hidden potential and address important unmet medical needs. We have built a broad proprietary pipeline of complex value-added products with potential to offer significant advantages over currently available alternatives.

Today, we have two, early stage partnered products, Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a novel, dual mode- of-action non-opioid analgesic for the treatment of post-operative pain.

Our development strategy of reformulating and repurposing approved pharmaceuticals primarily utilises the 505(b)(2) regulatory pathway in the U.S. and similar pathways in other countries, which is specifically designed for pharmaceutical agents for which the safety often times has already been established.

This focused strategy can dramatically reduce the clinical burden required to bring a product to market, and significantly shortens the development timelines while also reducing costs and risks.

Hyloris employs 37 people (15 women and 22 men) of 11 nationalities.



Specialty biopharma

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



Broad pipeline

With 14 innovative product-candidates, 2 marketed products and 3 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 under construction



Listed

Hyloris is listed on the Euronext Brussels Stock Exchange (HYL:BB)
Market cap end of January 2023: Average volume weighted market cap in April 2023 +/- €370 million

Environmental, Social and Governance Roadmap & Objectives

Hyloris is committed to develop, manufacture, and deliver therapies to address major clinical unmet needs across a wide range of therapeutic areas. It also considers the impact of our operations on the planet we share. We are committed to considering every aspect of the consequences of our actions not only in ethical business operations but also in our relationships with a broad community of stakeholders including:

- Patients • Physicians • Payors • Governments
- Investors • Employees • Suppliers • Partners

Hyloris strives to operate in a socially responsible manner combining good business ethics, a key focus on the wellbeing of employees, and a relationship with the environment, whilst working to deliver safe, novel products to patients.

In this annual report, Hyloris presents an assessment of ESG standards Hyloris aims to uphold, and signals specific areas where it aims to measurably improve in the future. By incorporating ESG factors into our decision-making process, we can enhance our reputation, reduce risks, increase efficiency, foster innovation and create long-term value for our shareholders. We will continue to engage with our stakeholders and report on our progress as we strive to make a positive difference in the world.

Highlights

During 2022 and early 2023

In 2022 and early 2023, the Hyloris team nearly doubled in headcount, from 21 at the start of last year, to 37 currently. Talented professionals from around the globe have joined us, boosting the number of different nationalities from 6 to 11.

- Increased experience within our expanded team will enable Hyloris to accelerate efforts into expanding our product portfolio and bringing more product candidates across the finish line so they can serve patients, physicians and payors.
- The Hyloris team is better equipped and more confident than ever before in our capabilities to assess new opportunities, find the best partners, speed up crucial R&D steps in our own lab and navigate the regulatory landscape in countries all over the world.

- At the same time, we are convinced that we must remain a lean and mean biopharmaceutical company and be able to offer a diversified portfolio that partially reduces development risk. We reiterate our ambition to be nimble in the execution of our strategy, and to keep overhead and costs low, compared to global standards in the pharmaceutical industry.

In an effort to reinforce bonds between our colleagues working together across country lines, monthly company updates happen virtually to keep the team engaged and informed. The colleagues based in Europe meet each other frequently at our new Liège headquarters, and are offered overnight stays at a hotel in the heart of Liège to bridge multiple working days at the office.



11 nationalities

The number of different nationalities within the Hyloris team nearly doubled since 2021, from 6 to 11.

Breathing health care at a new life sciences hub

In 2022, Hyloris moved into its new offices on the outskirts of Liège. An old coal mine site is now home to the CHC hospital and, right next door, a new Life Sciences Hub called Légiapark. The new location is expected to benefit employee well-being greatly, and will soon incorporate our new and expanded R&D lab facilities as well.

- Légiapark is dedicated to hosting businesses that operate in the life sciences sector. The site is located no more than ten minutes from the city centre of Liège, the heart of Wallonia's biotech ecosystem. The Liège airport and the main highway E40 leading from Brussels and beyond deep into Germany, add extra accessibility.
- The complex has been developed and managed by Noshag group, the leading funding partner for SME's in the region of Liège, founded in 1985, which also supported Hyloris in different stages of its development, including the IPO and the 2022 capital raise.
- The move brings us right across the road from CHC MontLégia and its thousands of patients. This aligns with our corporate ambition to become a leader in value-added medicines. Taken overall, the CHC group employs no less than 1.000 doctors always looking to bring their patients the best possible care.
- In 2023, Hyloris will inaugurate its improved R&D lab facility, which will allow the company to perform drug formulation and analytical activities for an ever growing pipeline, further streamlining processes and more effectively deploying internal resources.
- The choice for Légiapark was also a choice for sustainability. Solar panels will supply the complex with two thirds of its energy needs at full capacity. Read more about Légiapark's sustainability features in our ESG (environmental, social and governance) roadmap further in this annual report.

key figures 2022



14
product candidates
repurposed or
reformulated 3 high
barrier generics and
2 commercialised
products



2 commercial products

- **Sotalol IV**
- for the treatment
- of atrial fibrillation
- commercialised in the US

.....

Maxigesic® IV
for the treatment of postoperative
pain commercial in 20+ countries
(including imminent launches)
with potential regulatory
approval in the US before
end of 2023



€3
million revenues,
with increasing
contributions from
royalties

€43
million in cash &
cash equivalents

€0
no financial debt



Financial highlights

	Year ended 31 December		
(in € thousand)	2022	2021	Variance
Revenues	2.951	3.096	-4,7%
Cost of sales	(94)	(107)	
Research and development expenses	(10,151)	(5,056)	100,8%
General and administration expenses	(3,517)	(2,900)	21,3%
Shares' issuance related expenses	-	-	
Earnings/losses from Associates and joint ventures	(130)	(191)	-31,9%
Other operating result	303	(5,381)	
Operating result	(10,638)	(10,541)	0,9%
Net financial result	(127)	(741)	-82,9%
Income Taxes	(4)	(297)	-98,7%
Result for the period	(10,770)	(11,579)	-7,0%
Net operating cash flow	(13,154)	(11,250)	16,9%
Cash and cash equivalents	43,457	50,012	-13,1%

Letter to Shareholders



Dear Shareholders,

After stringing together a series of successes in 2022, Hyloris has started 2023 on the right foot. Expansion and progress of our product pipeline has once again proven our business model is as successful as it is unique. The development and delivery of added value reformulated medicines is at the heart of our mission. I'm particularly pleased with the addition of HY-083 to our pipeline, which aims to relieve symptoms for patients suffering from idiopathic rhinitis. With the more recent in-licensing of HY-088, targeting phosphate deficiency in the blood, we are on the right track to reach our goal of 30 portfolio assets before 2025.

In the relentless search for the best product candidates our team evaluated around 200 potential product candidates in 2022 whereby our selection criteria lean towards repurposing of existing molecules, rather than only reformulation. Repurposed molecules, while requiring higher R&D investments, have a higher potential to change therapy outcomes for patients and in general offer enhanced value creation for all our stakeholders. For both our reformulated and repurposed assets, the strict goal remains to bring them to market within 7 years at an average cost of less than € 7 million.

We believe the Company is sufficiently capitalised to execute the development of the current pipeline. A € 15 million equity raise in March 2022 solidified our cash position which was supplemented shortly after by the exercise of warrants resulting in an extra € 2,8 million of net proceeds.

2022 was also the year in which royalty income from our 2 commercialised products – Maxigesic® IV a potent but non-opioid post-operative pain killer and Sotalol IV for the treatment of atrial fibrillation – increased significantly. This trend is set to continue in the years to come.

Another big commercial step forward can be expected later this year, with the potential registration of Maxigesic® IV for the US market. In July 2022, regulatory authorities in the US requested additional data relating to the primary packaging of Maxigesic® IV. The regulator did not raise any questions about the data generated during the clinical development program. Our full response, which addresses all of the regulator's questions was filed on April 17th 2023. We expect the submitted data to satisfy the FDA's requirements with approval before the end of the year, with first sales following shortly after. As of this writing, Maxigesic® IV is commercialised in over 20 countries and approved in 40 countries, with multiple launches lined up in the months ahead.

A notable clinical success in 2022 was the positive phase 1/2 trial data for Tranexamic Acid Oral Mouth Rinse – which aims to reduce oral bleeding during dental procedures. We are anticipating that a phase 3 trial can start in 2023. Additionally, pivotal studies for HY-029 and Dofetilide IV are also in preparation.

Several of the other product candidates in our pipeline are clearing hurdles on their way to patients in need, with potential launches in the coming years. Phase 2 clinical trials for Alenura™ (Acute pain in Interstitial Cystitis / Bladder Pain Syndrome) are in



Stijn Van Rompay
CEO Hyloris

preparation, with at least 6 million patients in the US suffering from acute pain flares disrupting their daily lives.

Top line results for the phase 2 dose-finding study of Miconazole-Domiphen Bromide (targeting recurring Vulvovaginal Candidiasis, a chronic infection) will help define the next clinical study. One in two women live through an episode of VVC sooner or later. 20% of them develop severe or recurrent VVC where reinfection happens at least 4 times a year.

Our strategy is championed by a team that almost doubled its headcount since 2021. 37 bright minds of 11 different nationalities apply their tremendous expertise to move our product candidates and the company forward. We have an impressive team, and I'm proud to work with all of them.

During the second half of last year, our Belgian team moved into our new offices at Légiapark, a new biotech hub right next to the CHC hospital in Liège. A few months from now, we will inaugurate our new R&D lab in that same location.

Stock market indices painted a disappointing picture of financial

market conditions in 2022. The global biotech sector showed double digit declines across the board, and the Hyloris share was not spared. Still, our share price remained comfortably above the IPO price of € 10,75.

Meanwhile, sell side analysts remain unified in their positive opinion of our strategy and hence the valuation of the Company. Since our yearly update, two additional investment banks have published buy ratings for our stock. As we report on our progress, we have also noticed increased interest from international investors, as we interacted with many of them throughout the year. Combined with the trust we have received from you, our loyal shareholders, the progress we are making, our confidence in the future is strengthened.

As we are increasingly aware of the impact of our actions enclosed in this annual report you will find an initial assessment and target action plan covering all three areas of ESG: environment, social and governance.

With our sights set on the year ahead, we would like to thank you for your continued support. We are thrilled about what's coming in 2023 and look forward to providing you with updates on our progress.

Sincerely,
Stijn Van Rompay

Our pipeline continues to be guided by a methodical, unmet medical needs-driven assessment covering approximately

200
opportunities
in 2022.



Business overview

Strong financial position

Solid financials in an exceptionally difficult context for financial markets and the healthcare sector, underpin the continued success of Hyloris. The Company had a cash position of €43 million and was free of financial debt on December 31st 2022. Revenues were close to €3 million, thanks to a significantly higher contribution from royalties from the 2 commercialised products and revenue related to out-licensing.

In March of 2022 Hyloris raised €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 Company's outstanding shares (pre-transaction) at an issue price of EUR 15.50 per share, representing a tight discount of 1.6% to the 30-day VWAP (volume-weighted average price).

Assuming continued strategic out-licensing, commercial success for Maxigesic® IV and Sotalol IV, additional non-dilutive funding and milestone payments, the Company believes it is sufficiently capitalised to execute the full development of the current pipeline assets (14 product candidates, 3 high barrier generics and 2 commercial products).

Plecoid™ agents: small cell lung cancer accounts for approximately 13-15% of

2mio

cases of lung cancer per year

Miconazole-Domiphen Bromide: Hyloris will co-develop a topical synergistic combination treatment for Recurrent Vulvovaginal Candidiasis (rVVC), a condition that affects nearly

10%

of women during their lifetime



Alenura™, the product candidate treats acute pain in interstitial cystitis/bladder pain syndrome (IC/BPS), a condition that affects at least

6mio
people in the US.



Commercial success

Commercial progress of the Company was demonstrated by increased royalty contributions from 2 commercialised products.

Sotalol IV is a patented intravenous (IV) solution for the treatment of atrial fibrillation, which is marketed by our partner AltaThera in the US. The new indication of Sotalol IV allows to significantly reduce the length of hospital stay and potentially significantly reduce the overall cost of care, while improving patient outcomes and safety.

Maxigesic® IV, a new patented treatment that meets the urgent need for non-opioid pain treatments in the post-operative hospital environment, to avoid side effects and risk of addiction associated with opioids. Its dual mode of action is a unique combination of paracetamol and ibuprofen for infusion. 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 2019.¹

→ A Complete Response Letter from the United States Food and Drug Administration (FDA) was received, stating that it was unable to complete its review, requesting additional information relating to potential leachable and extractable compounds expected to be present in the drug product based on the drug product packaging. Importantly, the agency

did not report any issues related to the data generated during the clinical development programme. Hyloris and its partner submitted a formal response to the Complete Response Letter on 17 april 2023, and believe to have addressed all questions and recommendations. This implies potential New Drug Application (NDA) approval by the end of 2023.

- Submissions were made in 15 countries in Asia, Africa and Latin America, including large pharmaceutical markets such as Canada and Mexico.
- Marketing authorizations have been granted in several countries including Italy, Norway, Indonesia, The Netherlands, Finland, Singapore and Hong Kong.
- Launches occurred in 7 countries: Denmark, Sweden, Finland, Norway, The Netherlands and Singapore. Near-term launches are expected in several additional countries, bringing the total number of countries where Maxigesic® IV will be available up to more than 20.
- 4 U.S. patents were granted to Hyloris, ranging in expiry between 2035 and 2039.

Growing pipeline

Promising new product-candidates were announced in 2022 and early 2023, both serving patient populations with few effective treatment options today.

HY-083 was announced in November 2022. This novel, proprietary formulation will be administered intranasally to treat idiopathic rhinitis. Idiopathic rhinitis is a medical disorder characterised by a nasal symptoms that resemble nasal allergies and hay fever (allergic rhinitis) but are not related to a known cause like allergens or infectious triggers. An estimated 7% of the world population is affected by

idiopathic rhinitis, representing an estimated 19 million people in the U.S. alone. 13% of them have moderate to severe idiopathic rhinitis, leading them to actively seek out specialist care. Hyloris seeks to offer a new, unique, safe and approved targeted therapy treatment option.

HY-088 was announced in January 2023. The Company in-licensed the technology to develop an oral liquid targeting

hypophosphatemia, a mineral deficiency in the blood. In severe forms, this condition can be life threatening. The condition can result in muscle and bone weakness, respiratory or heart failure, seizures or coma amongst others. It is estimated hypophosphatemia affects around 5% of hospitalised patients, and a subpopulation needs direct treatment during and/or after their hospital stay.

Post-closing event

A formal response to the FDA's Complete Response Letter regarding Maxigesic® IV received in 2022, was filed in 17 April 2023. All questions were addressed implying a potential market approval before the end of 2023.



- **Increased roll out of commercial products : Maxigesic® IV, a novel, unique combination for the treatment of post-operative pain is currently licensed to partners covering over 100 countries across the globe.**



Our strategy and strengths

COMMITTED TO ADDRESSING UNDERSERVED NEEDS THROUGH INNOVATION

Our core focus and mission is to address underserved medical needs and bring added value to the healthcare system through reformulations and repurposing, with the goal to change therapy outcomes and improve the lives of patients around the globe.

We have built a broad proprietary portfolio of value-added reformulated and repurposed product candidates by applying our knowhow and technological innovations to existing pharmaceuticals.

Since our inception, we have significantly strengthened our capabilities and skills, and expanded our focus from high barrier generics towards complex, reformulated and repurposed patented products, thereby further moving up the value chain.

Our development strategy primarily utilises the 505(b)(2) regulatory pathway in the U.S. and similar pathways in other countries, which are specifically designed for

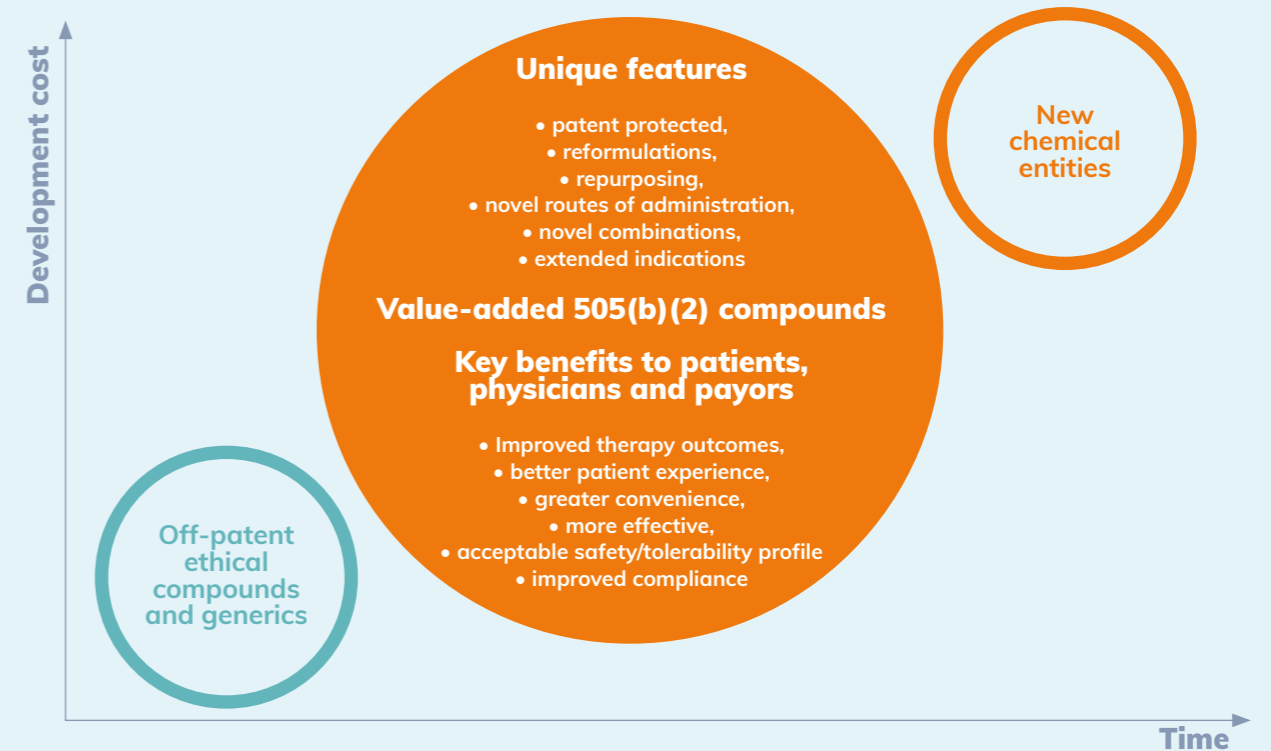
pharmaceutical agents for which the safety and efficacy have already been established. This focused strategy can dramatically reduce the clinical burden required to bring a product to market, and significantly shortens the development timelines while also reducing costs and risks.

To achieve our goal we are in continuous dialogue with healthcare professionals, patient groups, payors and partners as well as leveraging our extensive sourcing network and R&D capabilities.



→ Our core focus and **mission** is to address underserved medical needs and bring added value to the healthcare system

We focus on value-added medicines, pharma's sweet spot



Our ambition is to become a leading 505(b)(2) company

Hyloris aims to become a market leader in the number of value-added products in development eligible for the 505(b)(2) regulatory track.

Acquisition and in-licensing of product candidates based on:

- Clear scientific and medical rationale based on physicians' input
- Approved, well-known molecules
- Clear regulatory pathway
- Landscape review & patent protection
- Addressable market need

7-7 technical feasibility criteria strategy

development in ≤ 7 years for ≤ \$7 million cost on average

Continuously growing diversified product portfolio

characterised by:

- Fast market adoption
- Maximised ROI
- Addressing clear unmet needs
- Large potential



The key elements of our strategy

- **Build a portfolio of patented, complex, proprietary value-added products** that address underserved medical needs by primarily utilising the capital and time efficient 505(b)(2) regulatory pathway in the U.S. (and similar pathways in other countries).

Our mission is to pursue value creation through our product development activities with focus on products that are eligible for the 505(b)(2) in the U.S. and similar regulatory pathways in other countries.

By utilising this pathway, we can accelerate development and lower the clinical and regulatory risk, as compared to products developed under the traditional 505(b)(1) regulatory pathway (i.e. New Chemical Entities, NCEs).

Our 505(b)(2) product development candidates are sourced and selected through multiple channels and are validated based on scientific and medical input from our large network of physicians and KOLs. All our candidates must be able to get protection through patents and trade secrets, and they must have the ability to address unmet medical needs and have large commercial potential.

Furthermore, all our product candidates must meet our predetermined strategic selection criteria, including a total development cost of less than € 7 million on average, a development timeline expected to be less

than 5 years with an additional maximum 2 years for registration, a solid expected return on investment and technically feasible to develop.

- **Build a diversified and growing product pipeline across various stages of development.**

Our ambition is to grow the pipeline with products in various stages of development and commercialisation with the goal to have 30 key assets before 2025 and to become the market leader in number of 505(b)(2) products in the pipeline the next coming years.

- **Build a strong intellectual property portfolio and knowhow.**

For all our 505(b)(2) product candidates, we have a long-term strategy to register and protect our intellectual property to maximise our products' commercial lifespan. Our patent portfolio (as owner, co-owner and/or licensee) provides a wide range of protection, including dosages and formulations, medical indications, methods for preparing a composition and improved methods of production.

- **Flexible go-to-market strategy with the goal to build our own lean commercial organisation in the U.S.**

As the majority of prescribers of our cardiovascular products in the U.S. are employed by hospitals, we believe we will be able to commercialise our cardiovascular portfolio in a cost- efficient manner with our own small sales force in U.S.

More notably, there are currently around 6,000 hospitals and 33,000 cardiologists in the U.S., with more than 70% of cardiologists employed by hospitals. We will commercially target sub-segments for the promotion of our products such as an estimated 3,200 electrophysiologists in the U.S. (with the exception of Sotalol IV, which is partnered with AltaThera and HY-075 which has potential in the larger retail market).

We intend to remain flexible and assess the optimal commercialisation strategy on a case-by-case basis to maximise the return on investment, including potential commercial opportunities outside the U.S. For our existing commercial products, Sotalol IV and Maxigesic® IV, we have agreements with strategic partners for the marketing, sale and distribution, i.e. AltaThera and AFT Pharmaceuticals respectively. The commercial partner for Maxigesic® IV in the U.S. is Hikma Pharmaceuticals, a leading supplier of injectable hospital products in the U.S.

- **Generate diversified revenue streams** with the current commercial portfolio setting the foundation for long-term growth.

We expect that sales from the current commercial products Maxigesic® IV and Sotalol IV will be the primary drivers of short-term revenue growth until additional products are launched.

For the majority of our product candidates which we expect to license out (with the exception of Sotalol IV, Maxigesic® IV and Miconazole-Domiphen Bromide), we expect to retain a large minority or small majority of the net product margin (i.e., the gross profit after deduction of distribution and manufacturing related expenses, insurance, transport etc.) realised by our commercial partners. In general,

we do not target substantial upfront milestone payments from our commercial partners as we prioritise more product sales related income.

The advantages of the 505(b)(2) regulatory pathway

The 505(b)(2) regulatory pathway significantly lowers development risks and costs compared to the traditional 505(b)(1) regulatory pathway. It is intended for molecules that have previously been approved by the FDA or that have a long history of clinical use.

The potential advantages offered by products eligible for the 505(b)(2) pathway compared to the 505(b)(1) pathway include:

- **Lower formulation risk:** developing new formulations of drugs that are extensively described and documented (both clinically and chemically) reduces potential formulation issues.
- **Lower clinical and regulatory risk:** reformulating approved and marketed pharmaceutical agents will usually have higher probability of clinical success and regulatory approval as clinical development can usually be reduced to fewer bridging studies to the reference listed pharmaceutical drug (RLD).
- **Shorter development timelines:** on average 5 years compared to 8 to 15 years for new chemical entities (NCE) that are developed using the 505(b)(1) pathway.
- **Much lower costs:** we expect to spend on average less than €7 million for the entire development through to submission for approval.
- **Lower commercial risk:** as 505(b)(2) products reference

Our goal is to have **30** key assets before 2025

well-established drugs, there is already a high user awareness amongst physicians and payors. We will leverage that user awareness with our products' value dossiers clearly demonstrating the added value and unmet need that is being addressed.

- **Competitive advantage and protection:** although the chemical entity of 505(b)(2) product candidates cannot be patented, we file other types of patents (such as formulation patents, process patents related to the manufacturing or method of use patents) to protect our products from generic competition.



➔ **Our 505(b)(2) product development candidates are sourced and selected through multiple channels and are validated based on scientific and medical input from our large network of physicians and KOLs.**

OUR PORTFOLIO

BUILDING A BROAD, PROPRIETARY INNOVATIVE PRODUCT PORTFOLIO

We are a specialty biopharma company committed to bringing innovative treatments that offer added value to underserved patient populations, physicians, hospitals and payors.

We apply our knowhow and technological innovations to existing pharmaceuticals and have built a broad proprietary product pipeline that has the potential to offer significant advantages over currently available alternatives.

Two products, Sotalol IV and Maxigesic® IV are currently being commercialised by our partners AltaThera and AFT Pharmaceuticals, respectively.

Outside of our core strategic focus, we also have a few high barrier generic products in development and registration phase.



Product	Route of Administration	Indication	Formulation and feasibility	Clinical Development	Regulatory Filing	Target Market
CARDIOVASCULAR (CV) PORTFOLIO			Up to 7 years			
Sotalol IV	IV	Atrial fibrillation	Launched in U.S./partnered with AltaThera			
Aspirin IV U.S.	IV	Acute coronary syndrome				
Milrinone	Extended Release Capsule	Advanced heart failure (LVAD)				
Dofetilide IV	IV	Atrial fibrillation				
Metolazone IV	IV	Congestive heart failure				
HY-074	IV	Acute coronary syndrome				
HY-075	Oral Liquid	Coronary heart disease				
OTHER VALUE-ADDED PORTFOLIO			Up to 7 years			
Maxigesic® IV	IV	Post-operative pain	Licensed in >100 countries /partnered with AFT Pharmaceuticals			
Tranexamic Acid OR	Oral Liquid	Specific dental indication				
Alenura™	PFS	IC / PBS				
Miconazole-DB	Topical	Severe and rVVC				
Plecoid™ Agent	IV	AML/SCLC				
Atomoxetine	Oral Liquid	ADHD				
HY-029	Oral Liquid	Viral infection				
HY-083	Nasal administration	Idiopathic Rhinitis				
HY-088	Oral Liquid	Hypophosphatemia				

* Our high barrier generic products, TXA RTU, HY-038, HY-016 and Fusidic Acid Cream have not been included in the above overview.

Aspirin IV U.S. is formerly known as HY-073;
RTU: ready to use;
LVAD: battery-operated, mechanical surgically implanted pump, which helps the left ventricle of the heart pump blood;
TXA: tranexamic acid;
ADHD: attention deficit hyperactivity disorder;

















Miconazole-DB: miconazole-domiphen bromide;
rVVC: recurring Vulvovaginal Candidiasis;
AML: Acute Myeloid Leukemia;
SCLC: Small cell Lung Cancer

Intended to be commercialised by Hyloris in the U.S.
Intended to be commercialised with partner

Benefits to patients, physicians and payors

Adding value is at the core of everything we do.

Below we present the unique features and benefits of our candidate and commercial products as presented in our pipeline chart:

Product	Route of Administration	IP	Indication	Potential Added Value
CARDIOVASCULAR PORTFOLIO				
Sotalolol IV		'34-'38; granted & pending	AF	Shorter hospital stay; lower overall healthcare cost; facilitate antiarrhythmic therapy for patients unable to swallow tablets
Aspirin IV U.S.		'38; granted & pending	Coronary heart disease	Faster onset of action; lower overall healthcare cost; facilitate antiarrhythmic therapy for patients unable to swallow tablets
Milrinone		Orphan indication	Advanced heart failure (LVAD)	Allow long term use of Milrinone to improve quality of life ; improved drug absorption and concomitant treatment possible
Dofetilide IV		'39; granted & pending	AF	Shorter hospital stay; lower overall healthcare cost; facilitate antiarrhythmic therapy for patients unable to swallow tablets
Metolazone IV		'38; granted & pending	Congestive heart failure	Fast onset of action (essential in critical care) ; improved drug absorption and concomitant treatment possible
HY-074		Confidential	Coronary heart disease	Fast onset of action (essential in critical care) with low drug-drug interaction risk; therapy possible in patients who are nauseous or unconscious
HY-075		Confidential	Coronary heart disease	Possibility for drug titration, ease of administration and indicated dosage control
OTHER VALUE-ADDED PORTFOLIO				
Maxigesic® IV		'30-'39; granted & pending	Pain	Highly effective non-opioid; dual MOA; greater pain relief
HY-004		'39; granted & pending	ND	Address acute issues or possible procedural related complications in dental offices
Miconazole-DB		'38; granted & pending	sVVC/rVVC	Dual MOA; addressing population for whom there is no cure available
Plecoid™		IP; pending	AML/SCLC	A chelator for adjunct therapy to chemotherapy for patients suffering from acute myeloid leukaemia (AML) and small cell lung cancer (SCLC)
Alenura™		IP; '25-'38; granted & pending	IC/PBS	Ready-To-Use solution via a pre-filled syringe for intra-vesicular administration targeting acute pain flar
Atomoxetine		'36-'43; granted & pending	ADHD	Possibility for drug titration, ease of administration and indicated dosage control; improved compliance and convenience
HY-029		Confidential	Viral infections	Ease of administration and dosage control; improved compliance and clinical benefit
HY-083		Confidential	Idiopathic Rhinitis	Restoring normal function of the nasal mucosa, hereby suppressing chronic nasal obstruction, rhinorrhea (a runny nose) and/or sneezing salvos.
HY-088		Confidential	Hypophosphatemia	In many countries, no approved oral treatment exists

ND = non-disclosed

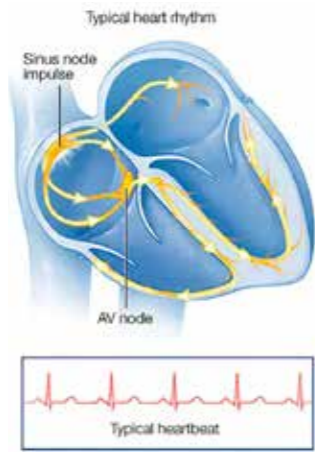
Our commercial portfolio

1. Sotalol IV for the treatment of atrial fibrillation

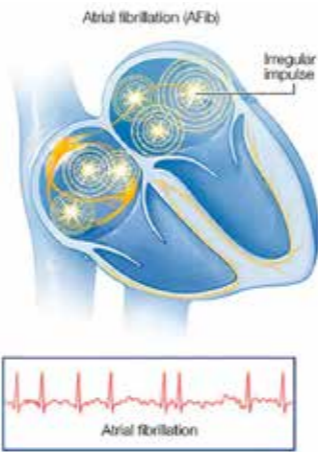
Atrial fibrillation (AF): a life-threatening cardiovascular disease

Atrial fibrillation is a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications.

Normally, the heart contracts and relaxes to a regular beat. In atrial fibrillation, the upper chambers of the heart (the atria) beat irregularly (quiver) instead of beating effectively to move blood into the ventricles.



Source: Mayo Clinic



U.S. prevalence expected to **increase to 12 million** by 2030 in the US¹

454,000 AF-related hospitalisations per year in the U.S. with majority receiving an anti-arrhythmic drug.

AF contributes to about **158,000 deaths** each year in the U.S.

If left untreated, majority of AF patients **will die** within **5 years** following onset of symptoms.

AF is associated with a five-fold increase in the risk of a stroke² and a three-fold increase in the risk of heart failure³

Annual U.S. hospitalisation costs associated with AF amount to **\$6 billion** per year and the total U.S. healthcare costs related to AF are approximately **\$26 billion** per year⁴



Most embolic strokes are due to blood clots that are formed due to AF. They can break off, enter the bloodstream, lodge in an artery leading to the brain, block the blood flow and result in stroke.

Current standard of care and limitations

Treatments for AF may include lifestyle changes, medications and other interventions (e.g. surgery) to try to alter the heart's electrical system. To reduce the risk of blood clot formation, patients also receive blood thinners, including anticoagulants such as warfarin or heparin, antiplatelet drugs such as aspirin, and fibrinolytics such as tissue plasminogen activator.

Most hospitalised patients with AF receive an antiarrhythmic drug, with the oral potassium channel blockers being the principal rhythm control drugs in the U.S. (including amiodarone, dronedarone, Sotalol and Dofetilide).

In 2021, about 810 million tablets and capsules of rhythm control drugs were sold in the U.S. with amiodarone and Sotalol leading the space with 26% and 23% market share, respectively⁵.

Oral Sotalol and oral Dofetilide each are widely used in different patient subgroups. Both carry FDA black box warnings due to their drug induced proarrhythmic (i.e. irregular heartbeats that can lead to cardiac arrest) risk in patients who are initiating or re-initiating on oral Dofetilide or oral Sotalol.

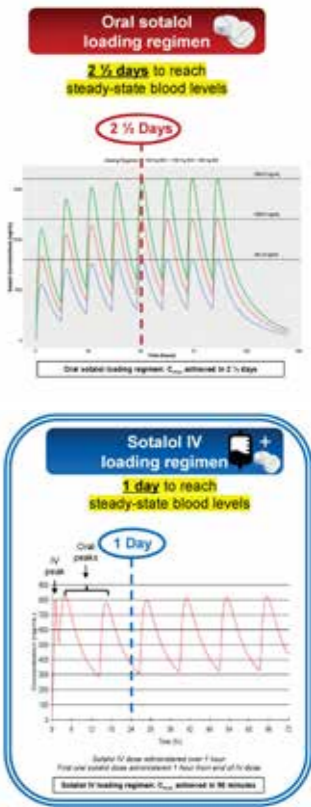
As a result, AF patients from both subgroups who initiate treatment with oral Sotalol or oral Dofetilide, must be continuously monitored in a hospital setting for at least three days or until steady state drug levels (i.e. a constant level of the drug in the blood) are achieved.

Our solution: Sotalol IV: an innovative, patented method of an IV formulation of Sotalol, the 2nd most widely used antiarrhythmic drug in the U.S.

To address the required hospital stay needed to monitor the patient's heart rhythm during oral Sotalol initiation treatment, an IV formulation was developed seeking to reduce the required hospital stay associated with oral Sotalol loading. A safe, effective, and patented method of using Sotalol IV has been developed to replace the current standard loading/drug initiation regimen.

Sotalol IV is administered by an infusion pump over one hour at a constant infusion rate and has a rapid onset of action enabling the transition from acute IV administration to chronic oral therapy. This new procedure of starting with Sotalol IV and then transitioning to oral Sotalol, can reduce hospital stay from 3 days to a 1-day hospital outpatient procedure, thereby potentially significantly decreasing overall cost of care, while potentially improving patient outcomes and safety. Moreover, a fast onset of action is crucial in acute care settings as is the case for patients admitted to the hospital with suspected AF.

Around half of patients currently eligible for oral Sotalol or oral Dofetilide within their respective patient populations, could be switched to intravenous modes of administration when these treatments become available.



Achievements

Prior to March 2020, Sotalol IV was only approved by the FDA for use in patients who are unable to take oral Sotalol, representing a very limited market and was mainly used by paediatric cardiac specialists. 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, thereby significantly expanding its market potential.

Sotalol IV is being commercialised in the U.S. by Hyloris' commercial partner, AltaThera. Revenues from Sotalol IV under the new expanded label, and priced at above \$2,000 per vial, are expected to grow substantially over the next coming years.

1 Centres for Disease Control and Prevention
2 Leila et al, 2011, Stroke Prevention in Nonvalvular Atrial Fibrillation
3 Dipak Kotecha and Jonathan P. Piccini, Eur Heart J. 2015
4 Kim et al, 2011, AHA Journal

2. Maxigesic® IV for the treatment of post-operative pain
\$442M peak sales potential in U.S., Japan and EU5⁶

Post-operative pain and the opioid crisis

Pain is a distressing sensory and emotional feeling which normally occurs due to tissue damage or illness. It is one of the most widespread conditions in the world affecting patient health and quality-of-life.

The duration of pain varies from short term, known as acute pain, to long term referred to as chronic pain. In the hospital setting, acute pain is generally classified as post-operative or non-operative. Post-operative pain is a response to tissue damage during surgery that stimulates peripheral nerves, which signal the brain to produce a sensory and emotional response.

Anaesthetics

There are two major categories of anaesthetics:

- (1) general anaesthetics and
- (2) local anaesthetics.

General anaesthetics are drugs that produce loss of sensation associated with loss of consciousness. Local anaesthetics, in contrast, result in a small region of anaesthesia particularly at the region of the tissue wherein the anaesthetic is injected into.

50.6 million surgical procedures

In 2019, 50.6 million surgical procedures were performed in the U.S.

>80% moderate pain 31-37% severe or extreme pain⁸

Pain remains the leading cause of unanticipated hospital readmission following surgery⁷

Although acute pain is predictable after operations, the management of post-operative pain is a difficult challenge for anaesthesiologists.

In 2019, 50,6 million surgical procedures were performed in the U.S. Pain remains the leading cause of unanticipated hospital readmission following surgery⁷ with > 80% of surgical patients having moderate pain and 31-37% of patients experiencing severe or extreme pain.⁸

The management of pain typically involves treatment using a particular set of drugs and is one of the most frequently dealt with issues by physicians with limited improvements over the last two decades.

Drugs that are used to treat pain can be categorised in two groups: anaesthetics and analgesics:

Analgesics

Analgesics are classified in two groups:

- (1) opioids and
- (2) non-opioids.

Opioids are substances that act on opioid receptors to produce a morphine-like effect and are frequently referred to as narcotics. They can be critical for post-surgical pain management because of their powerful effect. But the misuse of, and addiction to, opioids is a serious public health issue with over 100,000 deaths per year in the U.S. due to opioid-involved overdoses. The Centers for Disease Control and Prevention estimate that the total economic burden of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

Paracetamol and ibuprofen are considered non-opioid analgesics and do not bind to opioid receptors Globally, approximately 1.2 billion vials are sold per year in the non-opioid analgesic space with > 260 million vials of IV paracetamol, representing a market of >\$700 million in 2020. The market for post-operative pain is growing rapidly and is forecasted to reach \$2.6 billion by 2028 (up from \$1.1 billion in 2019)⁹

Our potential solution:
Maxigesic® IV: an innovative, patented, IV formulation of Paracetamol plus Ibuprofen to combat the opioid crisis

Injectable formulations of analgesics are typically used when patients are unable to take oral medications, when faster onset of analgesia is required, or when it is more convenient to administer drugs in the injectable form. Hospitalised patients may be unable to take oral medications for a variety of reasons including post-anesthesia sedation, other forms of sedation, nausea, vomiting, gastrointestinal limitations, or other conditions.

Maxigesic® IV is a novel and unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion for use post-operatively in a hospital setting.

There is an urgent need for safer and more effective non-opioid pain treatments in the post-operative hospital setting, and thanks to its unique, dual mode-of-action, Maxigesic® IV has the potential to become a valuable pain treatment option without the side effects and risk of addiction associated with opioids.

Results from a randomised, double-blind, placebo-controlled Phase 3 trial in 276 patients following bunion surgery demonstrated that Maxigesic® IV was well-tolerated and had a faster onset of action and offered higher pain relief compared to ibuprofen IV or paracetamol IV alone in the same doses. Moreover, the superior analgesic effect of Maxigesic® IV was supported by a range of secondary endpoints, including reduced opioid consumption compared to the paracetamol IV and ibuprofen IV treatment groups (P<0.005)¹⁰.



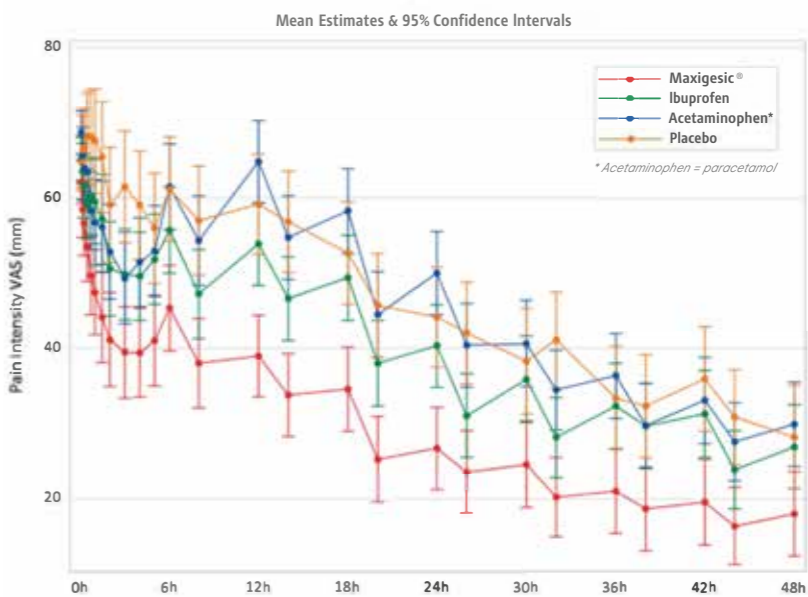
➔ A formal response to the FDA's Complete Response Letter, was filed on 17 April 2023. All questions were addressed implying a potential market approval before the end of 2023.

An additional exposure study has demonstrated Maxigesic® IV's efficacy and safety in an expanded population group over a longer treatment period¹¹.

Recent achievements

In 2022 and early 2023, Maxigesic® IV was launched in 7 countries including Denmark, Sweden, Finland, Norway and The Netherlands. In the near term, additional launches are expected in several countries, bringing the total number of countries where Maxigesic® IV will be available up to more than 20. Meanwhile, out-licensing deals for several additional countries were signed, paving the way for future commercial expansion.

A Complete Response Letter relating to our New Drug Application was received from the United States Food and Drug Administration (FDA) in July 2022. The CRL stated the regulator was unable to complete its review, requesting additional information relating to potential leachable and extractable compounds expected to be present in the drug product based on the drug product packaging. Importantly, the agency did not report any issues related to the data generated during the clinical development programme. Importantly, the FDA did not report any issues related to the data generated during the clinical development programme.



6 DelveInsight market study (EU5: France, Germany, Italy, Spain, UK) (includes Maxigesic® in oral form)
7 Coley K et al. J Clin Anesth. 2002
8 Wonuk Koh et al, Korean J Anesthesiol. 2015
9 IQVIA and DelveInsight Market Research

10 Daniels et al, 2019, Clinical Therapeutics
11 Maxigesic® IV Phase 3 exposure study. Study ID No AFT-MXIV-11. NCT04005755. Submitted for publication

Our cardiovascular product pipeline targeting multi-billion-dollar end-markets

At the date of this annual report, our cardiovascular product pipeline includes six 505(b)(2) reformulated product candidates in various stages of development, and we anticipate that all these products will be in clinical development, or beyond, by early 2024.

As the majority of prescribers of our cardiovascular products in the U.S. are employed by hospitals, we believe we will be able to commercialise our cardiovascular portfolio in a cost- efficient manner with our own small sales force in U.S.



Product	Indication	Unmet Needs	Our Potential Solution
Dofetilide IV	Atrial fibrillation, a life-threatening cardiac condition expected to affect >12 million people in the U.S. by 2030.	On average, the duration of hospital stay required for Dofetilide oral dosing is even longer than that of patients on oral Sotalol.	We have adopted a development strategy for Dofetilide IV aimed at reducing hospitalizations days and hospital related costs. Dofetilide, which is currently only available as an oral capsule, may be introduced first as Dofetilide IV as an initial loading dose with subsequent oral Dofetilide dosing to reduce the time to reach steady state and hospital discharge.
			An IV formulation of Dofetilide can cause side effects similar to those of the tablet but due to the close monitoring during the shortened loading period and the possibility to stop the treatment, the loading related risk is different.
Metolazone IV	Congestive heart failure (CHF) is the most rapidly growing cardiovascular condition globally and the leading cause of hospitalisations, with 30% readmission rate. ~870,000 new cases par year in the U.S. and 8 million people in the U.S. expected to suffer from CHF by 2030. ¹² By 2030, the total cost of heart failure is forecasted to reach \$69.8 billion. ¹³	CHF is progressive and there is currently no cure available. Diuretics and lifestyle changes can reduce symptoms, but patients become resistant to diuretics over time, resulting in insufficient symptom relief, higher risk of in-hospital worsening of heart failure, increased mortality after discharge and 3-fold increase in readmission rates. ¹⁴	We are developing an intravenous formulation of metolazone for the U.S.
		To address this, patients can be administered a combination of a loop diuretic with a thiazine-like diuretic such as metolazone tablets. But tablet formulations have highly variable bioavailability and erratic absorption, particularly in patients with severe gastrointestinal oedema.	The potential benefits of Metolazone IV include accelerating onset of action, allowing simultaneous administrations with furosemide, and improving drug absorption for patients with concomitant gastrointestinal oedema. The intravenous formulation will also allow drug administration in patients who are too ill to receive oral medications or who are unconscious.

12 Benjamin et al, Circulation, 2019
13 AHA association
14 Ellison et al, NEJM 2017

Product	Indication	Unmet Needs	Our Potential Solution
Aspirin IV HY-074 and HY-075	Coronary Heart Disease (CHD) is a serious condition usually caused by atherosclerosis, i.e. plaque (fatty deposits) build-up in the arteries, which may partially or totally block blood flow through large- or medium-sized arteries in the heart, brain, pelvis, legs, arms, or kidneys.	When ACS occurs, fast diagnosis and treatment is crucial and potentially lifesaving. The sooner treatment begins, the better the chances of survival. ¹⁵	Aspirin IV is an intravenous formulation of Aspirin, which offers a faster onset of action and a more predictable response (and thereby potentially significantly reduce the risk of death), more convenient administration (more notably in patients who are nauseated or unconscious), and dosage control. As Aspirin is currently available in oral form, it should allow for an optimal switching strategy from the IV to the oral form.
	Plaque itself can pose a risk. A piece of plaque can break off and be carried by the bloodstream until it gets stuck. And plaque that narrows an artery may lead to a blood clot (thrombus) that sticks to the blood vessel's inner wall, which in return can provoke acute coronary syndrome (ACS). In either case, the artery can be blocked, cutting off blood flow.	If the blood flow is not restored quickly, the damage to the heart muscle can be permanent or the patient may die.	
		Half of all deaths due to a heart attack occur in the first three to four hours after symptoms begin.	
	CHD can result in (i) a stable angina: episodic chest pain occurring on exertion and lasting two to five minutes, (ii) unstable angina: severe chest pain occurring at rest and lasting more than ten minutes, (iii) acute myocardial infarction: heart attack accompanied by a sensation of tightness, pressure or squeezing and (iv) sudden cardiac death: sudden death caused by loss of heart function.	Despite the need for fast onset of action drugs is the majority of current standard of care treatments only available in oral form, resulting on a significant delay in treatment onset. Existing IV formulations are only used during percutaneous coronary intervention and require continuous infusion due to their short drug half-life. Furthermore, the optimal switching strategy from the IV to an oral therapy with another mode-of-action is a concern due to drug-drug interactions and lack of guideline recommendations.	HY-074 is an intravenous formulation of current standard of care treatments to offer faster onset of action (and thereby potentially significantly reduce the risk of death), more convenient administration (more notably in patients who are nauseated or unconscious), and dosage control. It is currently available in oral form, which should allow for an optimal switching strategy from the IV to the oral form.
	The risk of coronary heart disease increases with family history of coronary heart disease before the age of 50, older age, smoking tobacco, high blood pressure, high cholesterol, diabetes, lack of exercise and obesity.		HY-075 is a novel liquid formulation of a commonly used drug for the treatment of specific cardiovascular diseases requiring frequent dosage changes and adjustments. This novel formulation is expected to significantly improve drug administration, ease of use, and dosage control, potentially resulting in potential better compliance and patient outcomes.
	CHD is the leading cause of death in the U.S. with >370,000 deaths every year. ¹⁵ About 18.2 million adults in the U.S., aged >20 years old, had a CHD in 2017 ¹⁶ and the estimated annual incidence of heart attacks in the U.S. amounted to 605,000 new attacks and 200,000 recurrent attacks between 2005 and 2014. ¹⁷		

Product	Indication	Unmet Needs	Our Potential Solution
Milrinone SR	Heart failure (HF) is a severe and chronic condition in which the heart muscle is unable to pump enough blood to meet the body's need for blood and oxygen.	Current standard of care depends on disease severity and treatment of advanced HF is predominantly palliative and includes the use of positive inotropes (such as Milrinone IV), digoxin and opioids, as well as LVADs in some cases, which are used either longer-term or as a bridge to heart transplantation.	Hyloris is developing a novel, patented, extended-release Milrinone formulation for twice a day convenient oral dosing, which provides a steady and predictable exposure of Milrinone. Hyloris will initially pursue a new, longer term use indication in patients with left ventricular assist devices (LVAD) who have developed right heart failure. Orphan drug status has been granted by the FDA in this indication and formulation patent claims have been issued in the U.S., Japan, and China, and are pending in Europe.
	The condition results in a very poor quality of life, that leaves patients breathless even at rest and leads to co-morbidities including ischemia, arrhythmias, and chronic renal failure.		
	HF usually develops because the heart has been damaged by a heart attack, or because of other conditions such as cardiomyopathy, a disease of the heart muscle.	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.	Several smaller trials, have shown that extended-release Milrinone was well tolerated, with no effect on heart rate or blood pressure and was associated with improved functional activity as defined by NYHA Classification. The Milrinone treatment was also associated with significant improvements in both quality of life (Minnesota Living with Heart Failure Score) and functional capacity (6-minute walk distance) with a trend towards improved renal function.
	It is the most rapidly growing cardiovascular disorder in the U.S. with 870,000 new cases every year.		
	HF is the most common cause of hospitalisation in people aged over 65 years of age, with about 1 million hospitalisations in the U.S. per year, and 20% readmissions following discharge.		

The average life expectancy is less than 5 years for 50% of all patients and 90% of patients with advanced HF die within 1 year following diagnosis.

15 American Heart Association, Heart Disease & Stroke Statistics (2016)
16 Centers for Disease Control and Prevention
17 American Heart Association, Heart Disease & Stroke Statistics (2019)
18 The Complete Encyclopaedia of Medicine & Health, Johannes Schade

Other value-added products in the pipeline addressing global healthcare challenges

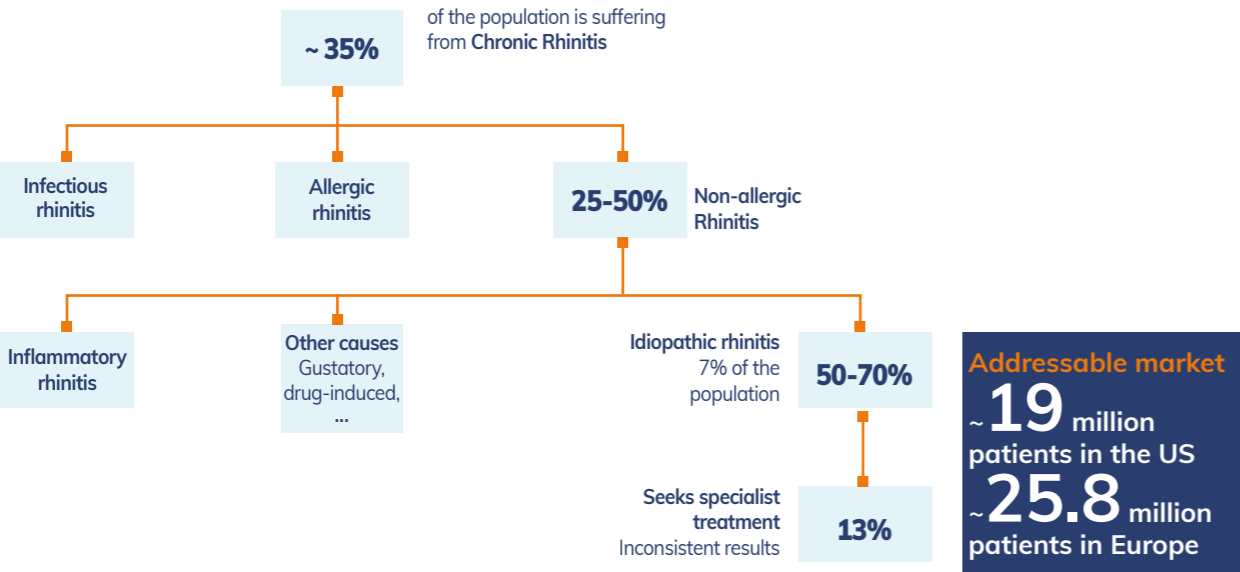
At the date of this annual report, nine repurposed and reformulated products outside our cardiovascular portfolio are in formulation, manufacturing, clinical development or registration phase. As these products represent global opportunities or address a large pool of prescribers in the U.S., we will seek commercial partners and distributors for the commercialisation of these assets.

For competitive reasons, the indications of some of these candidate products have not yet been disclosed and we therefore focus this report on those reformulated and repurposed assets for which the indication has already been publicly announced.

HY-083, a proprietary formulation for the treatment of idiopathic rhinitis

Indication	Current treatments and their limitations
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.	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.
<div><div>Available treatments</div><div>Anti histamines Nasal cortocoids Decongestants (oral/ intranasal)</div><div><div>FIRST LINE CARE</div><div>General practitioner Pharmacy</div><div><div>SPECIALIST CARE</div><div>Rhinologist</div></div></div><div><div>Mild to moderate</div><div>Conservative treatments Saline nasules</div><div><div>Severe</div><div>Turbinate reduction surgery</div></div></div></div>	
Our potential solution: a proprietary formulation of a molecule with a well-known mechanism of action	
Hyloris' treatment approach is to activate and depolarise TRPV1 receptors leading to restoration of a normal function of the nasal mucosa.	

Patient population and addressable market

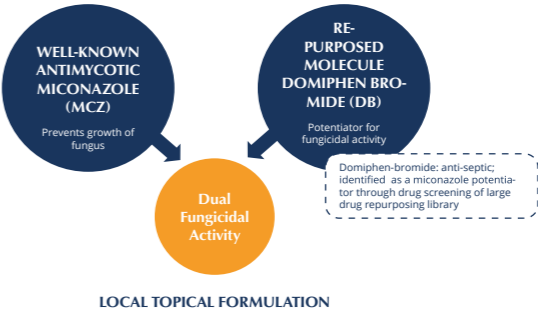


HY-088, an oral liquid targeting phosphate deficiency in the blood

Indication	Current treatments and their limitations
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.
Our potential solution: Treatment protocols for patients deficient in phosphate are well-established and have proven useful in other situations of bone mineral imbalance. Oral administration is the preferred way of treating hypophosphatemia, although in most countries no approved drugs exist. Currently, physicians mostly rely on compounded drugs which have, by definition, not been submitted for regulatory scrutiny regarding safety, efficacy, and quality.	
Hyloris will seek advice and approval from regulators by making use of the rich body of clinical data that has emerged from established clinical practice. With a primary on safety of the product, Hyloris intends to conduct a streamlined development programme to achieve market access in Europe, targeting regulatory approval in European countries as from 2026.	

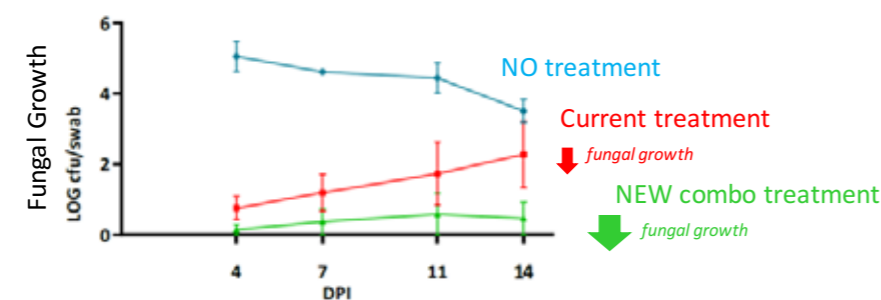
Miconazole-Domiphen Bromide, a novel women's health repurposed product candidate for the treatment of severe and rVVC

Indication	Current treatments and their limitations
Severe and recurrent vulvovaginal candidiasis (VVC) is a chronic and debilitating vaginal infection commonly caused by the yeast <i>Candida albicans</i> .	VVC treatments include topical and systemic anti-fungal treatments with about 175 million drug products sold annually. ¹⁹
As many as 1 in every 2 women will have an acute VVC infection during their life and 20% of these patients develop chronic, severe and recurrent VVC.	However, these are not effective and have severe side effects when used chronically to treat severe and recurrent VVC. With limited innovation over the past decades, there is a high unmet need for effective and safe treatment options for severe and recurrent VVC.
The annual economic burden due to severe and recurrent VVC is estimated at \$14.4 billion and women with severe and rVVC may suffer from pain, depression, shame and loss of control.	
Our potential solution: Miconazole-Domiphen Bromide, a novel, dual-mode-of-action locally administered emulsion	
We have a partnership with Purna Female Healthcare to develop a novel, dual-mode-of-action combination treatment for severe and recurrent VVC based on the current standard antimycotic treatment, Miconazole (MCZ), to which we add Domiphen Bromide (DB), a well-known anti-septic that is currently used in cough medications. Top line results for a phase 2 dose-finding study are expected by the summer of 2023.	



Results from animal studies demonstrate that MCZ, when combined with the potentiator DB, can combat the occurrence and recurrence of mucosal biofilm-related vaginal *Candida* infections²⁰. MCZ and DB work synergistically where DB increases the permeability of the plasma membrane and the vacuolar membrane of *Candida* spp., and MCZ acting fungicidal, thereby effectively destroying fungal activity and preventing further fungal growth.

¹⁹ IQVIA
²⁰ J Tits., J et al., Antimicrob. Agents Chemother (2020); K. De Cremer et al., Antimicrobial agents and chemotherapy (2015)



The synergistic mode-of-action of topical MCZ-DB has the potential to be more effective against azole-resistant infections, addressing the high unmet needs in complicated and recurrent VVC.²¹ The Phase 2 dose-finding study of MCZ-DB has started in 2021.

Atomoxetine, a novel oral liquid formulation of atomoxetine tablets for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)

Indication	Current treatments and their limitations
ADHD is a chronic mental childhood-onset disorder characterised by developmentally inappropriate and impaired inattention, motor hyperactivity, and impulsivity, with difficulties often continuing into adulthood.	Stimulants are the most widely used medications for ADHD. In most cases, non-stimulant medications are considered when stimulants did not work or have caused intolerable side effects. ²³
Children and adolescents suffering from ADHD experience challenging key formative years. Because of impulsive behavior and slower rates of processing information, they perform poorly on standardised tests, score lower grades and are more likely to drop out of school. In addition, ADHD often presents itself with one or more comorbidities such as oppositional defiant disorder, major depressive disorder, and anxiety disorders, thus bestowing additional challenges on these individuals.	Strattera®, also known by its generic name atomoxetine, is a non-stimulant medication approved by the FDA for ADHD treatment and is currently sold under its brand name as well as under generic names sold by several companies.
ADHD is among the most common neurobehavioral problems affecting children between the age of 6 and 17. Its prevalence in the U.S. ranges from 2% to 18% in this age group. About 60% to 80% of the symptoms of ADHD persist into adulthood. Thus, ADHD is not just a childhood disorder that resolves spontaneously after adolescence. It is estimated that about 4.0% to 4.5% of adults in the U.S. have ADHD. ²²	In 2019, atomoxetine had more than 2 million prescriptions ²⁴ in the U.S. and the number of atomoxetine capsules sold over the past few years has grown from 88.5 million in 2016 to 124.1 million in 2021. ²⁵
	Despite its common use, administration of atomoxetine to paediatric patients can be challenging. The drug requires titration from 0.5 mg/kg increasing to 1.2 mg/kg and it is not always commercially available in appropriate dosage formulations and strengths. Furthermore, the capsule is large (16 mm) and can best be avoided in children under the age of 11 years to prevent inadvertent inhalation or choking. ²⁶
Our potential solution	

We are developing an oral solution of atomoxetine for the U.S. market where it is currently not available, which is expected to provide significant clinical benefits to paediatric, adult and elderly patients by:

- Facilitating the use of atomoxetine in patients who do not tolerate or are able to swallow tablets
- Improving compliance and convenience during the therapy
- Facilitating the dose adjustment when the initial dosing is based on body weight, requiring the precise titration of the drug.

Most markets where the liquid formulation has been introduced have seen a significant increase in the market share of the oral liquid, showing that there is a need for this novel formulation of oral forms of current standard of care treatments.²⁷

Following feedback from the FDA, an innovative taste masking strategy was deployed targeting a preferred taste for young patients. A pivotal study is expected to start later in 2023.

Plecoid™ Agent, a novel oral formulation of a chelator for adjunct therapy to chemotherapy for patients suffering from acute myeloid leukaemia (AML) and small cell lung cancer (SCLC)

Indication	Current treatments and their limitations
AML is a type of heterogenous haematological malignancy that originates from immature white blood cells (blasts) in the bone marrow, which may be derived from either a hematopoietic stem cell or a lineage-specific progenitor cell.	Some cancers have shown to be resistant to therapy and many AML patients have significantly elevated levels of toxic metals in their bone marrow and blood, resulting in the poor overall survival.
AML generally spreads quickly to the bloodstream and can then spread to other parts of the body including lymph nodes, spleen, central nervous system, and testicles.	While the current cancer treatments aim to treat the tumour, none of the existing cancer therapies aim to deal with the elevated levels of toxic metals believed to be an important contributor to the therapy resistance.
AML is an orphan disease and is the most common type of acute leukaemia in adults and is primarily a disease of the adulthood; the median age of newly diagnosed AML patients is around 67 years. Additionally, AML is more common in males.	
AML can arise de novo or secondarily either due to the progression of other diseases or due to treatment with cytotoxic agents.	
Datamonitor Healthcare estimates that in 2018, there were 158,400 incident cases of AML worldwide and expects that the number will increase to 169,000 by 2027.	
For AML, the 1-year survival rate is approx. 50% and 5-year survival below 30%.	
SCLC is an aggressive malignancy accounting for 15% of diagnosed lung cancers.	
Rapid deterioration of symptoms and an early development of metastasis results in 95% mortality in five years after diagnosis. Almost all cases are associated with tobacco smoking. Other factors can be arsenic in drinking water, air pollution, etc.,	
It is an potential orphan indication with a significant lack of progress in treatment options in the last three decades.	
In eight major markets, Japan had the highest diagnosed incidence of SCLC in 2019 for men (24.76 cases per 100,000 population) and the US had the lowest diagnosed incidents in 2019 (13.18 cases per 100,000 population).	
Our potential solution	

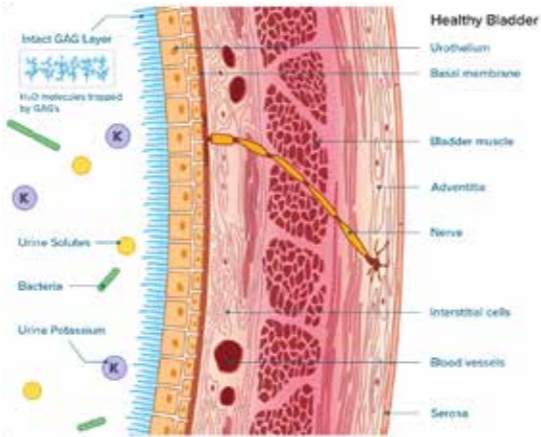
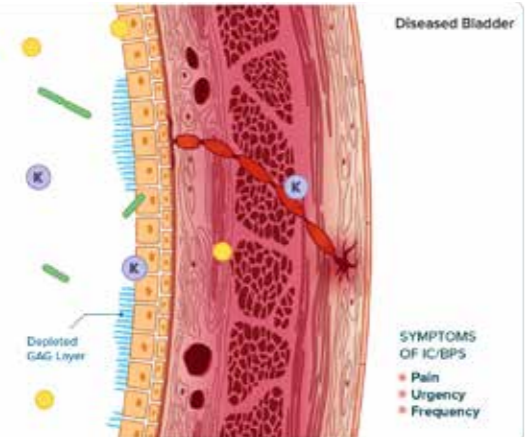
The Plecoid™ Agent is intended for adjunctive treatment to chemotherapy. Plecoid™ is an innovative, clinical-stage product candidate that contains a chelating agent with different characteristics and aims to detoxify the cancer promoting cellular micro-environment and improve the effectiveness of chemotherapy in patients in in turn improve the overall survival rates.

In 2022, the definition of the preferred formulation has progressed significantly in anticipation of clinical trials.

21 Manuscript for scientific paper submitted
22 Sharma and Couture, Ann Pharmacother. 2014
23 <https://www.helpguide.org/articles/add-adhd/medication-for-attention-deficit-disorder-adhd.htm>
24 "The Top 300 of 2019". clincalc.com. Archived from the original on 21 November 2018. Retrieved 22 December 2018
25 IQVIA
26 Van Riet-Nales DA et al. Oral medicines for children in the European paediatric investigation plans. PLoS One 2014; 9(6): e98348.
27 IQVIA

Alenura™, a novel combination of heparin and alkalised lidocaine administered as an instillation to patients suffering from interstitial cystitis/bladder pain syndrome (IC/BPS)

Indication	Current treatments and their limitations
<p>Interstitial Cystitis (IC) is a condition resulting in recurring discomfort and pain in the bladder and the surrounding pelvic region. IC varies in symptoms and severity and is hence often termed Bladder Pain Syndrome (BPS) as pain is the main complaint from patients. The disease is characterised by pelvic pain, urinary urgency, increased urinary frequency, discomfort and pelvic pressure.</p> <p>The cause for the disease is believed to be an anatomical defect in the internal protective bladder lining (the GAG mucous layer), which exposes the nerve ends to toxic components and high levels of potassium of the urine.</p> <p>IC/BPS is more prevalent in women, although men can experience symptoms as well, and although underdiagnosed, it is estimated at least 6 million people in the U.S. suffer from the condition.</p> <p>In the milder end of the disease severity, the acute pain flares are rare and infrequent, but as frequency increases, these flares drive the patients to seek treatment.</p>	<p>Today, there is no standardised treatment protocol and current treatments have clear limitations:</p> <ul style="list-style-type: none">• Oral Elmiron (Pentosan) is the only FDA approved oral treatment, which is both very both expensive, has limited efficacy and takes a 3-6 months for full effect.• In addition, oral tricyclic antidepressants, antihistamines, anti-spasmodic drugs, anticholinergic drugs, or opioids are used.• RIMSO-50 is an FDA approved instillation, which initially is dosed twice a week and less after desired relief is achieved. The product is odorous through breath and skin up to 72 hours after dosing and is toxic.• In addition, compounded cocktails of lidocaine, heparin, steroids, sodium bicarbonate, etc. are used.• More aggressive approaches include Botox and neuromodulation.



Our potential solution
<p>Alenura™ is a unique, Ready-To-Use solution for instillation for intra-vesicular administration and is a combination of alkalised lidocaine and heparin that have a unique collaborative effect on the GAG layer and epithelial cell layer as:</p> <ul style="list-style-type: none">• Lidocaine penetrates the epithelial cell layer, provides immediate pain relief, and downregulates the afferent signal.• Heparin augments the GAG layer and prevents further irritation of the urothelium.• Multiple clinical trials are expected to start throughout 2023, including a four-arm Phase 2, prospective, randomised, double-blind, placebo-controlled, multi-center, single-dose, pharmacodynamic study comparing Alenura™ to its 2 individual components (alkalised lidocaine and heparin) as well as placebo.

High Barrier Generics Portfolio

<p>Outside our core strategic focus, we have three high barrier generic products in late-stage development:</p> <ul style="list-style-type: none">● HY-016, a generic of an off-patent branded reference product sold in the U.S. without generic competition, has been filed with the FDA in the U.S.	<ul style="list-style-type: none">● Fusidic acid cream, a generic of an off-patent reference product currently sold in Canada without generic competition, is in clinical development.● Tranexamic acid RTU, a ready to use Tranexamic acid solution for infusion. The product will be filed as a value-added product outside the US, and has already been partnered in Canada, Australia and New Zealand.	<p>HY-016 is partnered with Padagis. For Fusidic acid cream, we intend to seek a commercial partner closer to approval of the product. In addition, we do not intend to actively pursue new opportunities in the generic space as our core focus is on primarily utilising the 505(b)(2) regulatory pathway and the development of novel, patented, value-added products. This strategy was demonstrated by our divestment of the generic asset HY-038 in early 2023.</p>
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OUTLOOK 2023

MULTIPLE VALUE INFLECTION MILESTONES AHEAD

<p>During 2023, evaluation of new opportunities by our Business Development team will continue, with an end goal of reaching 30 total pipeline assets and marketed products before 2025:</p> <p>Regarding clinical achievements, we anticipate delivering on the several key value inflection milestones, including:</p> <ul style="list-style-type: none">● Alenura™, start of multiple Phase II clinical trials (details mentioned above).● Atomoxetine oral solution, start pivotal study.● Dofetilide IV, open pivotal study.● Tranexamic Oral Mouth Rinse, previously known as HY-004: start of preparations for the pivotal study to support the submission of a marketing application.	<ul style="list-style-type: none">● HY-029 oral liquid (product not disclosed): start of a pivotal study to support the submission of a marketing application.● Miconazole-Domiphen Bromide: anticipated topline results of a Phase 2 dose-finding study.● Maxigesic® IV: A formal response to the FDA's Complete Response Letter regarding Maxigesic® IV received in 2022, was filed on April 17th 2023. All questions were addressed implying a potential market approval before the end of 2023. Further approval and launch of the product happened in 2022, and is expected to continue in 2023.	<p>Commercially, Hyloris' partner AFT Pharmaceuticals will continue the rollout of Maxigesic® IV (with the aim to make it available in more than 100 countries - from twenty today) and AltaThera will continue expanding sales of Sotalol IV to more hospitals, with sales from these products expected to be the primary drivers of short-term revenue for the Company.</p> <p>With cash and cash equivalents of €43 million at year-end , the Company is well-capitalised to advance all current pipeline assets as planned and execute on its ambitious growth strategy with 30 key assets in our portfolio before 2025.</p>
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2030 Environmental, Social and Governance Roadmap

Introduction

The core of our business is unlocking the hidden potential of existing medicines and tackling unmet medical needs through drug repurposing. As an organization we need to act responsibly. Releasing our potential requires embedding sustainability into business practices, processes, product development, operations and strategy.

In publishing this initial report, we want to allow for an assessment of our organization's performance on various sustainability and ethical issues. We believe transparency is linked to better outcomes for stakeholders as it will support informed decision-making.

In this global overview, we consider:

- our potential to contribute positively to the planet we share;
- the human potential and well-being of our colleagues;
- the potential of science to solve some of the greatest health challenges in the world.

We are committed to bringing all of these aspects together, not only in ethical business operations but also in our relationships with a broad community of stakeholders including patients, physicians, payors, governments, investors, employees and suppliers.

In 2022, we shouldered an exercise to identify the practices, initiatives, strategies, and gaps in our approach to Environmental, Social and Governance (ESG) challenges in an effort to more effectively and authentically communicate our positive impact on society. This report is a result of those efforts.

Stijn Van Rompay, CEO of Hyloris

"Our company desires to create value for our stakeholders by developing innovative and affordable medicines that address unmet medical needs, while minimizing our environmental impact, ensuring ethical conduct and promoting social responsibility. In this first report we lay out where we stand at present, and where we want to improve in the future, to make an increasingly positive impact on the world around us."



The United Nations Agenda for Sustainable Development provided the framework for identifying our contributions and for mapping our progress against them. Adopted in 2015 by all United Nations member states, the UN Agenda for Sustainable Development offers 17 goals for global development to be achieved by 2030. These broad goals are further defined by a total of 167 targets, which in turn are measured by 232 indicators of progress. Our first step in assessing Hyloris' contributions to these goals was determining which of them were authentic to our core mission and against which we could measure progress. In all, we mapped our business against four UN SD goals and six corresponding targets.



Selected Goals and Targets



Good health and Well Being

- By 2030, reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being (Target 3.4);
- Strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol (Target 3.5);
- Achieve universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines for all. (Target 3.8);
- Support the research and development of medicines for the communicable and non-communicable diseases that primarily affect developing countries. (Target 3.8B).



Gender Equality

- Ensure women's full and effective participation and equal opportunities for leadership at all levels of decision-making in political, economic and public life (Target 5.5).



Decent Work and Economic Growth

- Protect labour rights and promote safe and secure working environments for all workers, including migrant workers, in particular women migrants, and those in precarious employment. (Target 8.8).

Hyloris ESG Imperatives

Once we identified the UN Agenda for Sustainable Development goals and targets that were authentic to our mission, we organised our commitments under three imperatives.

Imperative I	Imperative II	Imperative III
Commitment to the Good Health and Well-Being of Society	Commitment to Environmental Sustainability	Commitment to Responsible Leadership



Imperative I – Commitment to the Good Health and Well-Being of Society

A. Access to safe, effective, quality and affordable essential (Target 3.8)

We currently have a portfolio of 14 value-added medicines (of which 2 are commercialised) addressing underserved medical needs in areas including cardiovascular diseases, the largest therapeutic area globally. Hyloris aims to develop 30 or more products, targeting a global presence for most of them.

One of our first commercial products, Sotalol IV for the treatment of atrial fibrillation, can significantly reduce the length of hospital stay and hereby reduce the overall cost of care, while improving patient outcomes and safety. Sotalol IV is currently marketed in the US, where overnight hospital stays typically cost thousands of dollars.

Hyloris currently has a portfolio of 3 high barrier generic medicines in development. Once approved, these offer identical, effective, safe and significantly cheaper alternatives to patients and the health care community.

Our development strategy of reformulating and repurposing approved pharmaceuticals, whose safety has often already been established, can dramatically reduce the time and cost it takes to get our medicines approved. A

lower development cost can result in lower costs to patients and health care systems overall

B. Part of the solution to the Opioid Crisis (Target 3.5)

The UN Agenda for Sustainable Development emphasizes a health-oriented approach to the global scourge of drug abuse. According to the World Health Organization (WHO), drug abuse has killed more than 500,000 people with 70 percent of those deaths attributable to opioids. Further, the WHO found that “the number of opioid overdoses has increased in recent years in several countries, in part due to the increased use of opioids in the management of chronic pain and increasing use of highly potent opioids appearing on the illicit drug market.”

(Source: <https://www.who.int/news-room/fact-sheets/detail/opioid-overdose>).

Developing non-addictive alternatives to opioids for pain management is a public health imperative. Our product Maxigesic® IV is a novel, dual mode of action non-opioid analgesic for the treatment of post-operative pain. As of this writing, it is marketed in over 20 countries is and Hyloris is working diligently on market approval for the US, where over 100,000 deaths are reported annually due to opioid-involved overdoses. We are proud to be a part of the solution to this public health crisis and expect that

Maxigesic® IV will be available in the vast majority of all countries, including most developing nations.

C. A portfolio focused on the leading cause of death. (Target 3.4)

Cardiovascular Diseases (CVDs) are the leading cause of death globally. According to WHO, an estimated 17.9 million people died from CVDs, in 2019, representing 32% of all global deaths. Of these deaths, 85 percent were due to heart attack and stroke. At Hyloris, over a third of our current portfolio (7 product candidates) is devoted to addressing cardiovascular disorders.



27%
of people die from
heart attack and
stroke.
Hyloris has
7 product
candidates
addressing
cardiovascular
disorders



Imperative II - Commitment to Sustainable Consumption and Environmental Protection

At Hyloris we have taken specific and proactive initiatives to do our part to address the planetary crises of biodiversity loss, pollution and climate change.

A. Headquarters and Lab Relocation

In 2022, we made a sustainable choice by moving our headquarters to the LégiaPark site in Liege. The complex is a BREEAM-accredited facility with a performance rating of "Excellent". BREEAM (Building Research Establishment Environmental Assessment Method) is the leading international standard for rating green buildings. It validates this office space as an enjoyable and comfortable workplace with respect for the environment.

Solar panels on the roof of the LégiaPark Complex are estimated to cover two thirds (67%) of the energy consumption of the site, at full capacity. Thermal engineering for heat retention, natural light, passive ventilation, rain water recuperation for reduced water consumption and parking capacity for electric vehicles are other key features. In addition, in 2023, we will move our R&D laboratory facility to the complex to further leverage its environmental benefits.

B. Raising the bar for our suppliers

In choosing suitable partners for its drug development & manufacturing, the Company requires certain disclosures in the selection procedure. Hyloris reviews amongst others product quality, supplier capabilities, consistency, and supplier risk but also ESG metrics and policies. Sustainability is expected to become increasingly important, with a strong focus on responsible consumption and production.

C. Leading the push for electric vehicles

Ahead of deadlines incorporated in Belgian law, Hyloris is turning its small fleet of cars green: company cars are chosen by a list of leasing offers pre-approved by Hyloris. From this shortlist, nearly all combustible engine vehicles have been phased out and several types of PHEVs (Plug-in-Hybrid Electric Vehicle) or BEVs (Battery Electric Vehicle) have been added in recent months. In other words: the choice for a car "with a plug" is strongly encouraged.



Imperative III - Commitment to Responsible Leadership

A. A Virtual, Flexible Workplace

Working with dozens of suppliers and partners while relying on an international group of colleagues often based in their native countries, Hyloris sets the example for hybrid working. Virtual meetings are the standard. Over 90% of all recurring (weekly or bi-weekly) meetings were held virtually in 2022.

Colleagues can choose to work at the Liège headquarters 2 to 5 days a week, if it fits their schedule. To further cut down on commuting time, travelling colleagues are offered the option to stay overnight in a company-paid hotel to bridge two in-office workdays.

B. Key Values, Accountability and Leadership Culture

Four key values support the achievement of Hyloris' mission, and will be part of the yearly evaluation procedures as of 2023:

- › Passion and Drive;
- › Entrepreneurship;
- › Professional Excellence;
- › Integrity and Accountability.

Colleagues in leadership position also have their performance review centered around empowerment and coaching. To ensure these values and culture are integrated into every aspect of our operations and after growing its workforce significantly in a short period, Hyloris hired a dedicated human resources director in 2022 who brings decades of experience in "soft HR" into the company, and reports to the executive leadership team with full accountability for employee well-being.

C. Respect for Global Expertise

At Hyloris we abide by the guiding principle to "look for expertise where it is available" Thus, we have recruited colleagues of 11 different nationalities to help fulfill our mission. They are working across three continents (Europe, US and Asia).

Hyloris is proud of the diverse background of its team members, and expects the number of nationalities to grow naturally as the company progresses towards its objectives.

D. Dedication to Workplace Safety (SDG Goal 8.8)

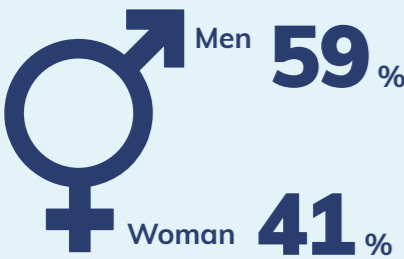
Hyloris is dedicated to upholding the highest standard of workplace safety for our employees. Our newly hired human resources manager has recently obtained the necessary certifications and is outlining a 5-year plan focusing on safety as well as the psychological well-being of our employees.



Peter Mertens, HR Director

"Employee well-being is not just a nice-to-have, it's a must-have for any organization that wants to succeed. We value every team member and want to demonstrate our commitment to a healthy, safe and supportive work environment in every way. Our flexible, location-independent way of working is a testament to that. In the future, we want to offer extra benefits to help everyone working at Hyloris cope with stress, balance work and private life, and achieve professional and personal goals."

Hyloris gender diversity



E. Checks & Balances in place at the highest level



As a quoted company, the Company adheres to all requirements in the Belgian Company Code. As of this annual report, the board consists of 8 members of which 4 are independent directors. The Remuneration Committee consists solely of non-executive directors and is formed in majority by independent directors.

F. Pursuit of Gender Equality (SDG Goal 5)

Hyloris remains committed to further diversifying its leadership, and in particular its board representation. The Company's Board currently counts one female Director. Special efforts are being made to attract additional female Board Members to bring additional experience at the highest decision making level and improve gender diversity.

Hyloris employs 37 people, 15 women and 22 men. While the Company recruited nearly half of the current team in 2022, the gender balance remained stable around 40% (women) to 60% (men). This overall balance is also representative of all the positions in the company, with the exception of the Executive Committee (which does not yet have any women members).

In the future, the goal remains to keep a similar gender balance and pay special attention to bring extra diversity into the team.

G. Ethical Business Practices

Hyloris maintains high ethical standards in all its business practices and relationships with customers, suppliers and its internal workforce. The following ethical guidelines are a cornerstone of day-to-day operations of the company, and apply to all employees:

- 1). Personal conduct;
- 2). Conflict of Interests;
- 3). Confidential Information
- 4). Influence;
- 5). Competition.

Hyloris has also drawn up a set of rules - "Dealing Code" - regarding 'market abuses' such as insider dealing, unlawful disclosure of inside information and market manipulation, and transactions in financial instruments by persons discharging managerial responsibilities and persons closely associated with them.

H. Less Animal Testing

In utilizing the 505(b)(2) development pathway in the US and similar pathways in other countries, the need for additional early stage R&D is reduced compared to New Chemical Entities following the 505(b)(1) regulatory pathway. Hyloris will continue to implement alternatives to animal testing where possible.

Conclusion

As a business of some 40 colleagues, we are cognizant of the limits of our contributions to as ambitious an undertaking as the UN's Agenda for Sustainable Development. Yet, we also are inspired by its call to action "to end poverty, protect the planet and improve the lives and prospects of everyone, everywhere." In particular, the UN Secretary General called for three levels of action to complete this sustainable agenda – global, local and people, defining "people" as inclusive of the private sector.

We believe our core mission of addressing unmet medical needs through reinventing existing medications goes to the heart of improving "the lives and prospects of everyone, everywhere." Further, our first three ESG imperatives will guide us in our efforts to make measurable progress in unlocking the potential of our products, our people and our planet.

Key Performance Indicators

The Company will keep its attention on sustainability on its way to achieving the main commercial goals. Points of attention in the medium term will be:

- increased gender diversity at the board level: by 2026, at least one third of the members of our board must be of another gender than the other members;
- increased focus on sustainability factors in the selection procedure for suppliers;

- maintaining or improving a diverse workforce with different nationalities (currently 11 on a workforce of 37) and cultural backgrounds as the Company hires more team members;
- maintaining or improving gender equality across all levels of the team (currently 40% of the team is female).



The Hyloris share

Hyloris Pharmaceuticals SA (ticker: HYL:BB) is listed on Euronext Brussels since 29 June 2020.

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

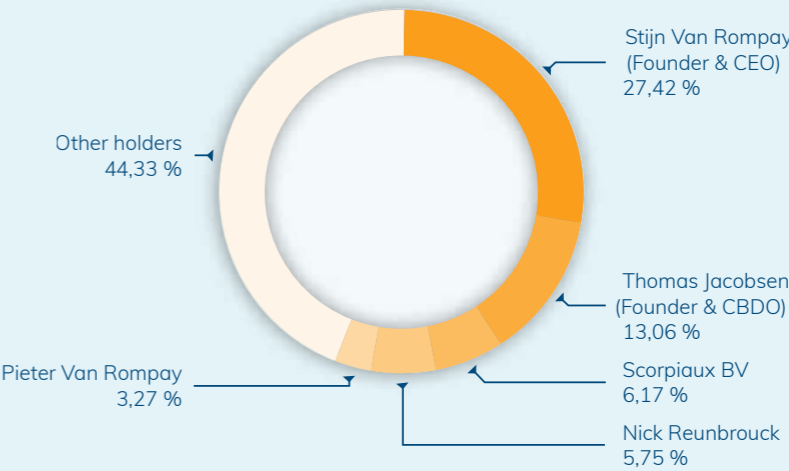
The Hyloris share

Performance versus sector indices since IPO on 29 June 2020.



Breakdown of Share Capital

Major shareholders (status December 31, 2022)



Share capital (excluding share premium)	€140,001.16
Total number of outstanding voting rights (= denominator)	28,000,374
Total number of securities carrying voting rights not yet issued	634,625

Analyst Coverage

Bank	Analyst	Rating
KBC Securities	Jeroen Van den Bossche	Buy
Kempen	Suzanne van Voorthuizen	Buy
Berenberg	Beatrice Allen	Buy
Degroof Petercam	David Seynnaeve	Buy
Kepler Cheuvreux	Arsene Guekam	Buy

Hyloris is followed by the analysts listed above. 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.



Corporate Governance

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

The Company's Executive Committee is an advisory committee to the Board of Directors.

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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

The Company will apply the ten corporate governance principles outlined in the Corporate Governance Code 2020. The Board of Directors is of the opinion that certain deviations from the provisions of the Corporate Governance Code 2020 were justified, in view of our activities, our size and the specific circumstances in which we operate.

The Company intends to comply with the corporate governance provisions set forth in the Corporate Governance Code 2020, except in relation to the following:

● **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.

● **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.

● **Provision 7.12:** the Board believes it is not opportune to take a decision to claim back or withhold payment of the variable part of the remuneration of the members of the Executive Management mainly because the variable part of the remuneration is based on performance during the preceding performance period. No advances on variable remuneration related to future performance are paid by the Company.

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 member of the Executive Committee) and six of whom are Non-Executive Directors, including four Independent Directors.

The Company's Board currently counts one female Director. Special efforts are made 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. the sixth year after Initial Public Offering).

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	Age	Position	Start of term	End of term
Mr. Stefan Yee	61	Non-Executive Director Chairman of the Board of Directors	2020	2024
Mr. Stijn Van Rompay ¹	47	Executive Director	2020	2024
Mr. Thomas Jacobsen ²	48	Executive Director	2020	2024
Mr. Leon Van Rompay ³	73	Non-Executive Director	2020	2024
Mr. Marc Foidart ⁴	47	Independent Director	2020	2024
Mrs. Carolyn Myers	64	Independent Director	2020	2024
Mr. James Gale	74	Independent Director	2020	2024
Mr. Chris Buysse ⁵	59	Independent Director	2021	2025

1 Acting through SVR Management BV
2 Acting through Jacobsen Management BV
3 Acting through Van Rompay Management BV
4 Acting through Noshag Partners SCRL
5 Acting through Pienter Jan BV



Stefan Yee



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 Masters 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



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



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



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, an Euronext listed company.

Marc Foidart



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).

Carolyn Myers



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 Mayne Pharma (ASX:MYX), EyeD Pharma SA and FendX Technologies (CSE:FNDX). 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 Viatris 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.

James Gale



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), Pharma Nobis LLC and RK Pharma. 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).

Chris Buyse



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 EyeD Pharma.

Activity Report

In 2022, 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 Executive and Non-Executive members of the Board of Directors convened eleven times in 2022. All Directors attended all Board Meetings, except for:

- Mr. Leon Van Rompay and Mr. Yee, who were excused once.
- Mr. Foidart, who was excused twice.

In 2022 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.

Committees of the Board of Directors

The Board has established two Board Committees: the Audit Committee and the Remuneration and Nomination Committee. Currently, no Scientific Committee has been formally established within the Company.

The strategic focus is to consult Key Opinion Leaders and specialists in the field to cover the wide range of therapeutic areas in which the Company is active today. Please find more of our reasoning below under "Scientific Committee".

Audit Committee

The Audit Committee comprises the following members:

- Mr. Marc Foidart⁶, Independent Director, Chairperson of the Audit committee
- Mr. Stefan Yee, Non-Executive Director
- Mr. James Gale, Independent Director
- Mr. Chris Buyse⁷, Independent Director

According to the Board of Directors, the members of the Audit Committee satisfy this requirement, as evidenced by the different senior management and director mandates that they have held in the past and currently hold (see also Board of Directors, p. 55 for more information on their curriculum vitae). Both James Gale, Chris Buyse and Stefan Yee have been identified as having the necessary competence in accounting and auditing.

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management and director mandates that they have held in the past and currently hold (see also Board of Directors, p. 55 for more information on their curriculum vitae). Both James Gale, Chris Buyse and Stefan Yee have been identified as having the necessary competence in accounting and auditing.

In accordance with Article 7:99, §4 CCA, the Audit Committee, without prejudice to the legal duties of the Board of Directors, has at least the following tasks:

- inform the Board of Directors of the result of the legal audit of the annual accounts and of the consolidated annual accounts and explain how the legal audit of the annual accounts and of the consolidated annual accounts contributed to the integrity of the financial reporting and what role the Audit Committee has played in this process;
- monitor the financial reporting process and make recommendations or proposals to guarantee the integrity of the process;
- monitor the effectiveness of the Company's internal control and risk management systems and monitor the internal audit and its effectiveness;
- monitor the statutory audit of the annual accounts and the consolidated annual accounts, including follow-up of the questions and recommendations formulated by the statutory auditor;
- assess and monitor the independence of the statutory auditor, in particular as to whether the provision of additional services to the Company is appropriate. In particular, the Audit Committee analyses, together with the

6 Acting through Noshag Partners SCRL competence in accounting and auditing.
7 Acting through Pienter Jan BV

statutory auditor, the threats to the statutory auditor's independence and the security measures taken to mitigate these threats when the total amount of fees exceed the criteria set out in Article 4, §3 of Regulation (EU) no. 537/2014; and

- make reasoned recommendations to the Board of Directors regarding the appointment of the statutory auditor of the Company in accordance with Article 16, §2 of Regulation (EU) No 537/2014.

The Audit Committee meets whenever it deems it necessary for the proper performance of its duties and at least four times a year. The Audit Committee regularly reports to the Board of Directors on the performance of its duties, and in any event when the Board of Directors prepares the annual accounts, the consolidated annual accounts and the condensed financial statements intended for publication.

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.

The Audit Committee convened 3 times in 2022.

Remuneration and Nomination Committee

The Remuneration and Nomination committee consist of the following members:

- **Mr. Stefan Yee,**
Chairperson of the Renumeration and Nomination Committee
- **Mrs. Carolyn Myers,**
Independent Director
- **Mr. Marc Foidart⁸,**
Independent Director

According to Article 7:100, §2 CCA of the Belgian law, all members of the Remuneration Committee must be Non-Executive Directors, and most of its members must be independent directors. 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. 55 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.

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:

Pursuant to its function as Remuneration Committee:

- 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;
- 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;
- 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
- explain the remuneration report at the Annual General Shareholders' Meeting.

Pursuant to its function as Nomination Committee:

- make recommendations to the Board of Directors with regard to the appointment of Board members and members of Executive Committee;
- prepare plans for the orderly succession of Board members;
- lead the re-appointment process of Board members;
- ensure that sufficient and regular attention is paid to the succession of members of Executive Committee; and
- ensure that appropriate talent development programmes and programmes to promote diversity in leadership are in place.

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.

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.

The Remuneration Committee convened three times in 2022.

Scientific Committee

A Scientific Committee has not yet been formally created by the Company. As the Company is progressing with its different product candidates within a wide range of therapeutic areas and health care technologies, the current strategy entails consulting experts and Key Opinion Leaders in their respective domains.

If and when the Scientific Committee is created, it shall consist of not less than three members (who may, but do not have to, be member of the Board of Directors), or more members as determined by the Board of Directors at any time. The Scientific Committee will elect a chairperson amongst its members.

Members of the Executive Management and the Board of Directors can be invited to attend meetings of the Scientific Committee.

The role of the Scientific Committee shall be to assist the Board of Directors with the following matters:

- providing strategic guidance for programme development;
- providing a neutral view on the progress of technology and science;
- providing external validation of intellectual property or new technologies;
- providing ad hoc advice on scientific matters at the request of the Board.

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



8 Acting through Noshag Partners SCRL competence in accounting and auditing.

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.

On 31 December 2022, the Executive Committee consisted of the following members:

- **Mr. Stijn Van Rompay**⁹,
Chief Executive Officer
- **Mr. Thomas Jacobsen**¹⁰,
Chief Business Development Officer
- **Mr. Jean-Luc Vandebroek**¹¹,
Chief Financial Officer
- **Mr. Dietmar Aichhorn**,
Chief Operating Officer
- **Mr. Koenraad Van der Elst**¹²,
Chief Legal Officer

The Executive Committee meets every week. It has also met on an informal basis through conference and video calls every time it was required for its proper functioning.

Stijn Van Rompay



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 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 \$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



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.

Jean-Luc Vandebroek



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 Alcopa 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



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



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 Metris (currently Nikon Metrology) 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.

9 Acting through SVR Management BV.
10 Acting through Jacobsen Management BV.
11 Acting through Finsys Management BV.
12 Acting through Herault BV.

REMUNERATION REPORT

Remuneration Policy

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 retroactively as from 1 January 2021 and was approved by the annual Shareholders' Meeting held on 8 June 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 does not have other persons who hold management positions according to the definition of this term in Article 7:89/1§2,1° of the BCCA.

Executive Committee

The Remuneration Committee meeting of 11 April, 2023 has performed the appraisal of the Board of Directors and of the members of the Executive Committee and has also approved the bonuses of the members the Executive Committee, in line with the principles as outlined in the Remuneration Policy.

Objective of the Hyloris' Remuneration Policy

Hyloris wants to be a competitive market player by benchmarking against appropriate peer groups and by incentivising 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. 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 Remuneration Committee evaluates 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-conform and sufficient manner to motivate and retain its employees.

The Remuneration Policy is reviewed regularly so that its contents are aligned with market practice.

Remuneration Policy for Non-Executive Directors

Remuneration of Non-Executive Directors will be benchmarked regularly with peers to ensure that the remuneration scheme is sufficiently fair, reasonable, and competitive to attract, retain and motivate the Non-Executive Directors.

Remuneration is linked to the amount of time the individual is expected to commit to the Board and its various committees such as the Remuneration Committee and the Audit Committee. The Board submits this proposal for approval to the shareholders at the annual Shareholders' Meeting.

The Remuneration Committee and the Board share the view that all Non-Executive Directors - also 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 and the Audit Committee).

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.

Hyloris does not grant shares to Non-Executive Directors¹³. 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.

The Non-Executive Director mandate can be revoked at any time (at *nutum*) without the Non-Executive Director being entitled to any indemnity payment.

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 considering the interests of all stakeholders.

The remuneration scheme for Executive Committee members consists of short-term and long-term remuneration elements. The short-term remuneration elements have a fixed part (please see Fixed remuneration) (i.e., a base annual remuneration in cash) and a variable part (please see Variable remuneration) (cash bonus). As for the long-term remuneration elements, the Executive Committee members can receive Stock options (please see Stock options, p. 66).

Variable remuneration can be granted if the criteria set out in variable remuneration are met.

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 instalments. Some Executive Committee members receive compensation for costs they incurred in performance of their duties. Executive Committee members do not receive any fringe benefits. Hyloris will conduct external salary-benchmarking exercises regularly to ensure that the remuneration of Executive Directors is in line with market practices and is sufficiently fair, reasonable to attract, retain and motivate individuals with the most appropriate profile.

Variable remuneration

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 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." 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.

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

Granting is driven by the individual's merits and based on the performance-rating system at Hyloris, being the achievement of Hyloris' corporate targets (Corporate Targets) as they are cascaded down as much as possible by translating them and/or reflected into their individual targets (Personal Targets), hence aligning these Personal Targets with the Hyloris corporate targets and the overall Hyloris' strategy. Corporate Targets include factors related to progress in Hyloris' research activities, corporate development and budgetary requirements. The Corporate Targets focus on company growth and value creation for all shareholders. This results in the Personal Targets being aligned optimally to the Corporate Targets of Hyloris, the Shareholders and other stakeholders.

The goal setting and variable remuneration for all members of the Executive Committee (except for the CEO) is based on the following principles:

- 40% of their goals will be based on the Corporate Targets, as these Corporate Targets will also be cascaded down as much as possible into the Personal Targets;
- 60% of their goals will be based on Personal Targets, which will be in line with and/or reflect the Corporate Targets and which will also include objectives with respect to leadership competencies.

For the CEO, the goal setting and variable remuneration is construed along the following principles:

¹³ Only the Chair of the Board, Stefan Yee, holds 100,000 warrants, which were granted prior the date of the IPO – the Company does not consider these warrants to be variable compensation.

- 75% of his goals will be based on the Corporate Targets;
- 25% of his goals will be based on the average of the Personal Targets and performance of the other members of the Executive Committee and which will also include objectives with respect to leadership competencies.

The Targets are set annually. The Board sets the Corporate Targets. The Personal Targets of the Executive Committee (other than the CEO) members are set by the CEO.

The total target variable remuneration amount for an Executive Committee member (i.e., the sum of the first and second components described above) represents maximum 25% of the total fixed annual remuneration of an Executive Committee member.

The variable remuneration is based on a weighted average of the achievement rate of the Personal Targets and the Corporate Targets.

The extent to which the Corporate Targets have been achieved at the end of the year, is evaluated by the Remuneration Committee. The extent to which the Executive Committee members (other than the CEO) have achieved their Personal Targets is evaluated by the CEO at the end of the year. The evaluation is subject to deliberation by the Remuneration Committee and finally decided by the Board.

Variable remuneration, if any, is paid only after approval by the Board of Directors upon proposal of the Remuneration Committee.

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.

Mr. Stijn Van Rompay (CEO)

The current services agreement with Mr. Stijn Van Rompay has been entered into between Mr. Stijn 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, in- solvency, 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, in- solvency, 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, in- solvency, 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. During the first 3 years, it can be terminated by the Company and Mr. Aichhorn 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 Mr. Aichhorn upon 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 Mr. Aichhorn. The non-compete payment will not be due if the Company terminates the services agreement for breach of contract imputable to Mr. Aichhorn.

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.



Stijn Van Rompay (CEO) and Thomas Jacobsen (CBDO)

Stock Options and Other Share- Convertible Securities

The members of the Executive Committee can be granted Stock Options or other instruments that allow the holder to acquire shares through schemes that need to be pre-approved by the annual Shareholder’s Meeting.

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 below 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.

	ESOP Scheme 2019	ESOP Scheme 2020	ESOP Scheme 2022
Conditions for Granting	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
Term	5 years	10 years	7 years
Vesting Period	The 2019 plan is subject to services conditions so that it will vest gradually over the subsequent 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 subsequent 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 subsequent four years (25% after 1 year, and 1/48 for every additional month).
Exercise	Warrants which are definitively acquired (“vested”) may be exercised from the first (1) of January of the fourth (4 th) 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 (4 th) 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 (4 th) 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.

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.

Minimum Shareholding

Considering the shareholders structure and the remuneration package of the members of the Executive Committee, Hyloris already meets the objective of recommendation 7.9 of the Code 2020, which is to promote long-term value creation.

Clawback

No claw-back rights have been provided to the benefit of the Company in respect of variable remuneration granted to the members of the Executive Committee.

Pension Scheme

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

Decision-making and Conflict of Interest

The Remuneration Committee is composed exclusively of Non-Executive Directors, and most of its members are also 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. Regarding the remuneration of Non-Executive Directors, all decisions are approved by the Shareholders’ Meeting.

Deviations from the Remuneration Policy

In exceptional circumstances, the Board may decide to deviate from any rule contained in this Remuneration Policy if it is required for the long-term interests and sustainability of Hyloris. Any such deviation must be discussed within the Remuneration Committee, which will provide a substantiated recommendation to the Board. Any deviation from this Remuneration Policy will be described and explained in any Hyloris remuneration report.

Changes to the Remuneration Policy

Hyloris does not expect any material changes to this Remuneration Policy to be made in the next two years but will review the Remuneration Policy regularly in order to reflect market conditions and optimise and - as the case may be - improve the objective of the Remuneration Policy to attract, motivate and retain diverse, qualified and expert individuals.



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.

Name	Remuneration
Mr. Stefan Yee	22,500
Mr. Leon Van Rompay ¹⁴	12,500
Mr. Marc Foidart ¹⁵	22,500
Mrs Carolyn Myers	17,500
Mr. James Gale	17,500
Mr. Chris Buyse	17,500
TOTAL	110,000

The table below provides an overview of significant positions of warrants held directly or indirectly by the Non-Executive Members

		Warrants ¹⁶
Name	Number	%
Mr. Stefan Yee	100,000	15.76%
Mr. Leon Van Rompay ¹⁴	0	0%
Mr. Marc Foidart ¹⁵	0	0%
Mrs. Carolyn Myers	0	0%
Mr. James Gale	0	0%
Mr. Chris Buyse	0	0%
TOTAL	100,000	15.76%

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

In 2022, the following remuneration and compensation was paid or accrued to the

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 the total remuneration amounted to € 110,000. The table below provides an overview of the remuneration per Non-Executive Director.

of the Board of Directors at December 31, 2022.

CEO (i.e., Mr. Stijn Van Rompay) and the other members of the Executive Committee of Hyloris:

In €	CEO	Other members of the Executive Committee ¹⁶
Annual base salary	185,738	805,050
Annual variable salary	22,323.14	77,997.42
Supplementary pension plan (defined contribution)	n.a.	n.a.
Car lease / transport allowance	n.a.	n.a.
Medical plan	n.a.	n.a.

14 Acting through Van Rompay Management BV.
15 Acting through Noshag Partners SCRL.
16 Calculated as % of all outstanding warrants: 634,625 accepted warrants as of December 31, 2022. 80.000 accepted warrants early 2023 - the remainder has lapsed.

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.

In accordance with the relevant Corporate Governance principles, the Remuneration Committee has assessed the performance and contributions of the CEO and the other members of the Executive Committee on April 11 2023.

The Remuneration Committee determined that the Corporate Targets for 2022, had not always been fully achieved, especially for business development. Not meeting these objectives however has not had a material impact on the operations of the company. The variable remuneration for 2022 has considered the contributions of the members of the Executive Committee made to these achievements.

The 2022 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 5-to-1. Share options (warrants) are excluded from the calculations.

Shares and Share Options - Warrants

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 at 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 11, 2023 under the leadership of the Chairman of the Board of Directors. This evaluation resulted in a positive assessment and also indicating 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.



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.

The Board of Directors has delegated an active role to the Audit Committee to monitor the design, implementation and execution of these internal risk management and control systems. The Audit Committee assists the Board of Directors in respect of control issues in general and acts as the interface between the Board of Directors and the external auditors of the Company.

No internal audit role has currently been assigned due 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.

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. These include but are not limited to:

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 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 and AFT Pharmaceuticals for successful roll-out and commercialisation of its first two commercial products, Sotalol IV and Maxigesic® IV 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 is currently developing its internal sales and marketing functions in order to execute its commercial strategy with respect to its IV Cardiovascular Portfolio in the U. S. and to secure suitable sales and marketing partners for its other products. If Hyloris is unable to do so, it may not successfully commercialise any of its product candidates.

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 knowhow 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 APIs and manufacture its products, and commercialisation 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. And, third parties may claim an ownership interest in Hyloris’ intellectual property.

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 2022, 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 Correctives 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 two 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 Olivier Declercq, réviseur d'entreprises, as permanent representative.

In 2022, a total amount of 115 K€ was paid to the statutory auditor and its network. This amount includes the following elements: 82 K€ for audit fees, 15 K€ for audit related services legally assigned to the statutory auditor and 18 K€ 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 (procurement, payroll, IT, investments, cash management);
- the company has developed procedures in the following cycles: expenditures, payroll, IT, cash management and books closing and reporting;
- Tthe 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 2022, the Company made the following improvements in its internal processes:

- a new enterprise resource ERP was implemented;
- the internal budgeting and forecasting process was further improved;
- improvements were made to the handling of payroll transactions.

MARKET ABUSE REGULATIONS

With a view to preventing market abuse (insider dealing and market manipulation), and pursuant to the Market Abuse Regulation, the Board has established a Dealing Code which is available on the Hyloris website. The Dealing Code describes the declaration and conduct obligations of directors and members of the Executive Management with respect to transactions in shares and other financial instruments of the Company. The Dealing Code sets limits on carrying out transactions in shares and other financial instruments of the Company and

allows dealing by the directors and the members of the Executive Management only during certain windows.

In its Governance Charter, the Company established several rules to prevent illegal use of inside information by Directors, shareholders, management members and employees, or the appearance of such use. An insider can be given access to inside information within the scope of the normal performance of his duties. The insider has the strict obligation to treat this information

confidentially and is not allowed to trade financial instruments of the Company to which this inside information relates.

The Company keeps a list of all persons (employees or persons otherwise working for the Company) having (had) access, on a regular or occasional basis, to inside information. The Company will regularly update this list and transmit it to the FSMA whenever the FSMA requests the Company to do so.

CONFLICTS OF INTEREST AND RELATED PARTIES

Conflicts of Interest

There is a conflict of interest when the administrator has a direct or indirect financial interest adverse to that of the Company. In accordance with Article 7:96 of the Belgian Code on Companies and Associations, a Director of a limited company which "has, directly or indirectly, an interest of an economic nature in a decision or an operation under the Board of Directors" is held to follow a particular procedure. If members of the Board, or of the Executive Committee or their permanent representatives are confronted with possible conflicting interests arising from a decision or transaction of the Company, they must inform the Chairman of the Board thereof as soon as possible.

Conflicting interests include conflicting proprietary interests, functional or political interests or interests involving family members (up to the second degree). If Article 7:96 of the Belgian Code on Companies and Associations is applicable, the Board member involved must abstain from participating in the deliberations

and in the voting regarding the agenda items affected by such conflict of interest.

The Company has adopted additional functional conflict of interest rules in relation to the Directors and members of the Executive Management with respect to matters falling within the competence of the Board or the Executive Management. This procedure is without prejudice to procedures of Articles 7:96 and 7:97 CCA. More specifically, there is a functional conflict of interest on the part of a member of the Board or of the Executive Management when:

- one of the close relatives of the member concerned has a personal financial interest that is in conflict with a decision or transaction that falls within the authority of the Board or the Executive Management; or
- a company that does not belong to the group and in which the member or one of his/her close relatives holds a Board or Executive Management position, has a financial interest that is

in conflict with a decision or a transaction that falls within the authority of the Board or the Executive Management.

When such a functional conflict of interest arises with respect to a member of the Board, the member concerned shall inform his/her fellow Directors of this at the beginning of the meeting of the Board. They will then decide whether the member concerned can vote on the matter to which the conflict of interest relates and whether he/she can participate in the discussion of this matter. The minutes of the Board of Directors shall describe how the procedure was applied. No publicity will be given to the application of the procedure. When such a functional conflict of interest arises with respect to a member of the Executive Management, the matter is submitted to the Board.

Conflicts of Interest of Directors and Members of Executive Management

None of the Directors or the members of the Executive Management have a conflict of

interest within the meaning of Article 7:96 CCA that has not been disclosed to the Board of Directors. Where such a conflict of interest has occurred, Hyloris has applied (or ratified the application of) the statutory conflicts of interest procedure of Article 7:96 CCA.

Below is an overview of the meetings of the Board of Directors in which the conflict of interest procedure has been applied.

Related Party Transactions

The Board of Directors must comply with the procedure set out in Article 7:97, §3-4/1 CCA if it takes a decision or carries out a transaction that relate to a related party within the meaning of the International Accounting Standard 24, as adopted by the European Union (IAS 24), unless the exemptions of Article 7:97, §1, section 4 apply whereby all decisions or transactions to which the procedure applies must first be subject to the assessment of a Committee of three Independent Directors, which, if it so chooses, shall be assisted by one or more independent experts of its choice. The Committee issues a written and reasoned opinion to the Board of Directors on the proposed decision or transaction, in which it addresses at least the elements set out in Article 7:97,§3, section 2 CCA.

After having taken note of the advice of the Committee provided, and applying, where necessary the conflict of interest procedure set forth in Article 7:96 CCA, the Board of Directors shall deliberate on the intended decision or transaction. If a Director is involved in the decision or operation, that director may not participate in the deliberation and voting. If all Directors are involved, the decision or transaction is submitted to the General Shareholders' Meeting; if the General Shareholders' Meeting approves the decision or transaction, the Board of Directors may execute it. The Board of Directors confirms in the minutes of the meeting that the procedure described above has been complied with, and, if necessary, justifies why it deviates from the Committee's opinion.

The statutory auditor assesses whether there are no material inconsistencies in the financial and accounting information included in the minutes of the Board of Director and in the committee's opinion with respect to the information available to it within the scope of

its mission. This opinion shall be attached to the minutes of the Board of Directors.

The Company will publicly announce the decisions or transaction in accordance with Article 7:97,§4/1 CCA.

This procedure does not apply to customary decisions and transactions at market conditions or to decisions and transactions the value of which is less than 1% of the net assets of the Company on a consolidated basis. In addition, decisions, and transactions on the remuneration of the directors or the members of the Executive Committee are exempted as are acquisitions or transfers of own shares, interim dividend payments and capital increases under the authorised capital without limitation or cancellation of the preferential subscription right of the existing shareholders.

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 2022.

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 2022.

SHARE CAPITAL, SHARES AND SHAREHOLDERS

History of Capital – Capital Increase and Issuance of Shares

Securities Issued by the Company

On March 31, 2022, the share capital was increased by a contribution in cash further to the completion of an accelerated bookbuilding, in the amount of €15,000,001 (including issue premium) with issuance of 967,742 new ordinary shares. The new shares were issued at a price of €15.5 per share (including issue premium).

On June 22, 2022, the share capital was increased by contribution in cash further following the exercise of 1,200,000 transaction warrants, in the amount of €2,831,640 (including issue premium) with issuance of 1,200,000 shares. The new shares were issued at a price of €2,3597 per share (including issue premium).

As of December 31, 2022, 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 two 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 (i) 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. The new shares were issued at a price of €15.5 per share (including issue premium).

The ESOP Warrant 2022 plan was approved in June 2022, increasing the authorised capital by an amount of €710 (excluding

any issue premiums) following the issuance of the 142,000 ESOP 2022 warrants.

Consequently, the Board is therefore authorised to increase the share capital of the Company within the framework of the authorised capital for a maximum amount of €110,210.13 (as of 1 April 2023, 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 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, 313,000 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 have lapsed.

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, 142.000 ESOP Warrants are currently granted and outstanding and 71.500 ESOP Warrants have lapsed.

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 all 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 (deter- mined 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 pro- visions 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.

Shares and Share Options - Warrants

The table below provides an overview of the shares and ESOP warrants held by the (former) members of the Executive Committee at the date of December 31, 2022.

		Shares
Name	Number	% ¹⁷
Mr. Stijn Van Rompay ¹⁸	7,676,400	27,42%
Mr. Thomas Jacobsen ¹⁹	3,657,505	13.06%
Mr. Koenraad Van der Elst ²⁰	27,443	0.06%
Mr. Jean-Luc Vandebroek ²¹	3,000	0.01%
Mr. Dietmar Aichhorn	20,000	0.07%

		ESOP warrants
Name	Number	% ²²
Mr. Stijn Van Rompay ¹⁸	68,000	10.71%
Mr. Thomas Jacobsen ¹⁹	0	0%
Mr. Koenraad Van der Elst ²⁰	50,000	7,88%
Mr. Jean-Luc Vandebroek ²¹	40,000	6.3%
Mr. Dietmar Aichhorn	40,000	6.3%

Consequences in Case of a Public Take-Over Bid

The General Meeting of Shareholders of June 8, 2020 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 8, 2020.

Pursuant to the resolution of the General Shareholders' Meeting of June 8, 2020, 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. This authorisation has been granted for a renewable period of five years as from the date of publication of the minutes of the Extraordinary General Shareholders' Meeting of June 8, 2020 in the Annexes to the Belgian Official Gazette. The Company must inform the FSMA of any such contemplated transactions.

17 Calculated as % of total number of voting rights at 31 December 2021 (28,000,374).
18 Acting through SVR Management BV.
19 Acting through Jacobsen Management BV.
20 Acting through Herault BV.
21 Acting through Finsys Management BV.
22 Calculated as % of total number of warrants accepted on December 31st 2022 (634,625). 80.000 warrants were accepted in early 2023 - the remainder has lapsed.

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 own Shares where such acquisition or acceptance in pledge is necessary to prevent imminent serious harm to the Company. This authorisation has been granted for a renewable period of three years as from the date of publication of the minutes of the Extraordinary General Shareholders' Meeting of June 8, 2020 in the Annexes to the Belgian Official Gazette.

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. Pursuant to the resolution of the General Shareholders' Meeting of June 8, 2020, the Board of Directors of the Company is 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

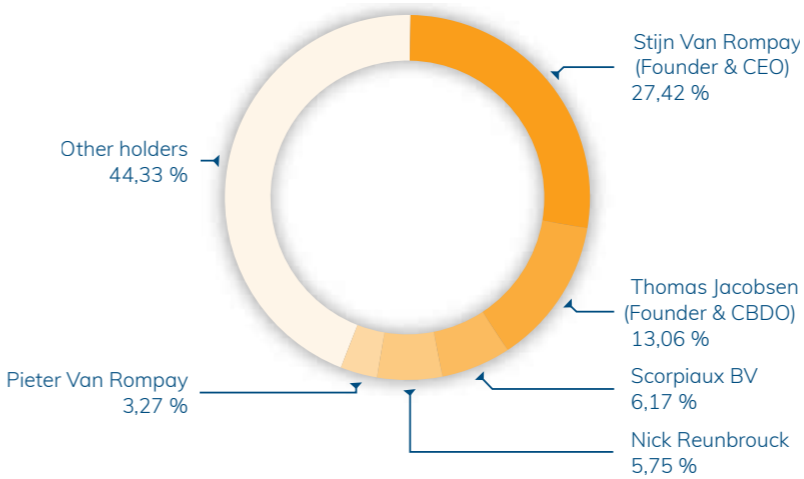
Belgian legislation (the Law of May 2, 2007 on the disclosure of major shareholdings in Companies whose shares are admitted to trading on a regulated market, and the Royal Decree of February 14, 2008 on the disclosure of major shareholdings) imposes disclosure requirements on each natural person or legal 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 below provides an overview of the share- holders 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, 2021).

Major Shareholders



At December 31, 2022, 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), (ii) 400,000 ESOP warrants (November 2020) of which 263,800 warrants have lapsed, all such warrants giving right to subscribe to an equal number of shares, (iii) 142.000 ESOP Warrants (June 2022) of which 71.500 ESOP Warrants have lapsed. All of the afore mentioned warrants give right to subscribe to an equal number of shares.

Dividends and Dividend Policy

Entitlement to Dividends

Pursuant to the Belgian Code of Companies and Associations, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the Annual General Shareholders' Meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Company's Board of Directors. The Company's Articles of Association

also authorise the Board of Directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law based on the Company's stand-alone statutory accounts prepared in accordance with Belgian GAAP.

In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e., summarised, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), and, save in exceptional cases, to be mentioned and justified in the notes to the annual accounts, decreased with the non-amortised costs of incorporation and extension and the non-amortised costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non- distributable reserves (which include, as the case may be, the unamortised part of any revaluation surpluses).

In addition, pursuant to Belgian law and the Company's Articles of Association, the Company must allocate an amount of 5% of its Belgian GAAP annual net profit ("bénéfices nets"/"nettowinst") to a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Company's share capital. The Company's legal reserve currently does not meet this requirement. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, further limiting the Company's ability to pay out dividends to its shareholders.

In accordance with Belgian law, the right to collect dividends declared on ordinary shares expires five years after the date the Board of Directors has declared the dividend payable, whereupon the Company is no longer under an obligation to pay such dividends.

Dividend Policy

The Company has not declared or paid dividends on its shares in the past. Any declaration of dividends will be based upon the Company's earnings, financial condition, capital requirements and other factors considered important by the Board of Directors. Belgian law and the Company's Articles of Association do not require the Company to declare dividends.

Currently, the Board of Directors of the Company expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future.

In the future, the Company's dividend policy will be determined and may change from time to time by determination of the Company's Board of Directors.



Consolidated Financial Statements

STATEMENT OF THE BOARD OF DIRECTORS

On April 26, 2023, 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.

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Today, our solid cash position, lack of financial debt and growing royalty income are already adding crucial ingredients for the future success of Hyloris.

Jean-Luc Vandebroek, CFO



CONSOLIDATED FINANCIAL STATEMENTS
AS AT 31 DECEMBER 2022

Consolidated Statement of Financial Position

ASSETS (in € thousand)	Note	31 December 2022	31 December 2021
Non-current assets		11,063	9,485
Intangible assets	7	3,607	2,944
Property, plant and equipment		176	122
Right-of-use assets	8	885	173
Equity accounted investees	9	3,948	4,079
Other investment, including derivatives	10	1,000	453
Trade and other receivables	11	1,447	1,714
Current assets		50,801	53,959
Trade and other receivables	11	5,127	2,321
Other investment, including derivatives	10	469	528
Prepayments	12	1,748	1,098
Cash and cash equivalents	13	43,457	50,012
TOTAL ASSETS		61,864	63,444
EQUITY AND LIABILITIES (in € thousand)	Note	31 December 2022	31 December 2021
Equity	14	55,045	48,056
Share capital		140	129
Share premium		121,513	103,693
Retained earnings		(53,476)	(43,226)
Result of the period		(10,770)	(11,579)
Share based payment reserve		1,622	2,391
Cost of Capital		(4,460)	(3,827)
Other reserves		476	476
Liabilities		6,819	15,388
Non-current liabilities		1,047	409
Borrowings	15	747	109
Other financial liabilities	15	300	300
Current liabilities		5,772	14,978
Current borrowings	15	138	65
Other current financial liabilities	15	3,212	11,815
Trade and other liabilities	16	2,422	2,749
Current tax liabilities	23.1		349
TOTAL EQUITY AND LIABILITIES		61,864	63,444

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

Consolidated Statement of Profit and Loss and Other Comprehensive Income

(in € thousand)	Note	2022	2021
Revenues	18	2,951	3,096
Cost of sales	19	(94)	(107)
Gross profit		2,857	2,988
Research and development expenses	19	(10,151)	(5,056)
General and administrative expenses	19	(3,517)	(2,900)
Share of result of equity-accounted investees, net of tax	19	(130)	(191)
Other operating income	21	315	389
Other operating expenses	19	(12)	(5,770)
Operating profit/(loss) (EBIT)		(10,638)	(10,541)
Financial income	22	466	32
Financial expenses	22	(594)	(773)
Profit/(loss) before taxes		(10,766)	(11,282)
Income taxes	23	(4)	(297)
PROFIT/(LOSS) FOR THE PERIOD		(10,770)	(11,579)
Other comprehensive income		-	-
TOTAL COMPREHENSIVE INCOME OF THE PERIOD		(10,770)	(11,579)
Profit/(loss) for the period attributable to the owners of the Company		(10,770)	(11,579)
Profit/(loss) for the period attributable to the non-controlling interests			
Total comprehensive income for the period attributable to the owners of the Company		(10,770)	(11,579)
Total comprehensive income for the period attributable to the non-controlling interests			
Basic and diluted earnings/(loss) per share (in €)	24	(0.40)	(0.45)

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

Consolidated Statement of Changes in Equity

Attributable to equity holders of the Company							Total Equity
	Share capital	Share premium		Other reserves		Retained earnings	
(in € thousand)			Share based payment reserve	Cost of Capital	Other reserves		
Balance at 31 December 2020	129	103,693	1,814	(3,827)	476	(43,226)	59,059
Share-based payments	-	-	576	-	-	-	576
Total comprehensive income	-	-		-	-	(11,579)	(11,579)
Balance at 31 December 2021	129	103,693	2,391	(3,827)	476	(54,805)	48,056
Private Placement via an ABB (note 14.2)	5	14,995		(634)	-		14,366
Exercise of warrants (note 14.3)	6	2,826	(1,329)			1,329	2,832
Share-based payments (note 14.3)			560				560
Total comprehensive income						(10,770)	(10,770)
Balance at 31 December 2022	140	121,513	1,622	(4,460)	476	(64,246)	55,045

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

Consolidated Statement of Cash Flows

(in € thousand)	Note	2022	2021
CASH FLOW FROM OPERATING ACTIVITIES			
Profit/(loss) for the period		(10,770)	(11,579)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation, amortisation and impairments	19	196	137
Share-based payment expense	19	560	576
Derivatives financial instruments	22	52	
R&D Tax Credit	11 + 21	(315)	
Interest expenses on shareholders loans	28	164	
Loss on derecognition of shareholder loans	15	486	198
Equity transaction costs		29	
Losses from Associates and joint ventures	9	130	191
Losses on disposal of PPE		16	
Other non-cash adjustments		16	(1)
Changes in working capital:			
Trade and other receivables		(2,261)	(2,068)
Other investment, including derivatives		4	(1,627)
Prepayments	12	(650)	856
Trade and other liabilities		(468)	
Other current and non-current liabilities			2,063
Cash generated from operations		(12,812)	(11,253)
Interest paid		7	3
Taxes paid	22	(349)	
Net cash generated from operating activities		(13,154)	(11,250)
CASH FLOW FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment		(101)	(107)
Purchases of Intangible assets	7	(638)	(954)
Proceeds (from disposal) of intangible assets			219
Investments in equity accounted investees	9		(1,270)
Acquisition in other investments	10	(500)	(21)
Repayment received from other financial assets			216
Payment of other financial assets			(1,157)
Net cash provided by/(used in) investing activities		(1,239)	(3,075)
CASH FLOW FROM FINANCING ACTIVITIES			
Reimbursements of borrowings and other financial liabilities	15	(7,376)	
Reimbursements of lease liabilities		(79)	
Reimbursements of borrowings			(62)
Proceeds from Private Placement via ABB	14	14,337	
Proceeds from Execution Transactions Warrants	14	2,832	
Interests paid	15	(1,877)	
Net cash provided by/(used in) financing activities		7,838	(62)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		(6,555)	(14,387)
CASH AND CASH EQUIVALENTS at beginning of the period		50,012	64,399
CASH AND CASH EQUIVALENTS at end of the period, calculated		43,457	50,012

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 two partnered, commercial-stage products: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid analgesic for the treatment of pain.

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 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 Groups’ operations, the Group finalised prior February 2022 the clinical phase of a clinical study for product candidate HY-004 at a CRO located in Ukraine. The analysis and reporting of this clinical study is organised outside the conflict area. If the CRO experience disruptions to their business due to the military conflict, the Group assesses these disruptions shall not result in delays in the clinical development activities. The impact on ongoing study will remain limited. The Group continues to monitor the situation and is taking measures to mitigate the impact on her ability to conduct clinical development activities.

The consolidated financial statements were authorised for issue by the Board of Directors on April 26, 2023.

Current economic climate
In 2022 the outlook of the worldwide economy has several downside risks including higher general inflation, increasing energy costs, tighter monetary policy, financial stress and rising geopolitical tensions. The company evaluated the impact of the current economic climate and concluded that there is limited impact on the business.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

2.1 BASIS OF PREPARATION

These consolidated financial statements of the Group for the year ended December 31, 2022 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, 2022. No new standards, amendments to standards or interpretations were early adopted.

These 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.

These 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 below).

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 adopted as from 2022

A number of new standards, amendments to standards and interpretations are not yet effective for annual periods ending 31 December 2022, and have not been applied in preparing these consolidated financial statements:

- Amendments to IFRS3 – Business Combinations (effective January 1, 2022, and endorsed in EU): These amendments update a reference in IFRS 3 to the Conceptual Framework for Financial Reporting without changing the accounting requirements for business combinations.
- Amendments to IAS 16 – Property, Plant and Equipment (effective January 1, 2022, and endorsed in EU): These amendments prohibit a company from deducting from the cost of property, plant and equipment amounts received from selling items produced while the company is preparing the asset for its intended use. Instead, a company will recognise such sales proceeds and related cost in profit or loss. The amendments also clarify that testing whether an item of PPE is functioning properly means assessing its technical and physical performance rather than assessing its financial performance.
- Amendments to IAS 37 – Provisions, Contingent Liabilities and Contingent Assets (effective January 1, 2022, and endorsed in EU): These amendments specify which costs a company includes when assessing whether a contract will be loss-making. The amendments clarify that the ‘costs of fulfilling a contract’ comprise both: the incremental costs; and an allocation of other direct costs.
- Annual Improvements to IFRS Standards 2018–2020 make minor amendments to IFRS 1 First-time Adoption of International Financial Reporting Standards, IFRS 9 Financial Instruments, IAS 41 Agriculture and the Illustrative Examples accompanying IFRS 16 Leases.

The above mentioned IFRS pronouncements did not have a significant impact on the consolidated financial statements.

Relevant IFRS accounting pronouncements to be adopted as from 2022 onwards

A number of new standards, amendments to standards and interpretations are not yet effective for annual periods ending 31 December 2022, and have not been applied in preparing these consolidated financial statements:

Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies, issued on 12 February 2021, include narrow-scope amendments to improve accounting policy disclosures so that they provide more useful information to investors and other primary users of the financial statements. The amendments to IAS 1 require companies to disclose their material accounting policy information rather than their significant accounting policies. The amendments to IFRS Practice Statement 2 provide guidance on how to apply the concept of materiality to accounting policy disclosures.

The amendments are effective for annual periods beginning on or after 1 January 2023 with early application permitted. These amendments have been endorsed by the EU.

Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates, issued on 12 February 2021, clarify how companies should distinguish changes in accounting policies from changes in accounting estimates. The distinction is important because changes in accounting estimates are applied prospectively only to future transactions and other future events, but changes in accounting policies are generally also applied retrospectively to past transactions and other past events.

The amendments are effective for annual periods beginning on or after 1 January 2023 with early application permitted. These amendments have been endorsed by the EU.

Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction, issued on 7 May 2021, clarifies how companies should account for deferred tax on transactions such as leases and decommissioning obligations. IAS 12 Income Taxes specifies how a company accounts for income tax, including deferred tax, which represents tax payable or recoverable in the future. In specified circumstances, companies are exempt from recognizing deferred tax when they recognise assets or liabilities for the first time. Previously, there had been some uncertainty about whether the exemption does not apply and that companies are required to recognise deferred tax on such transactions. The aim of the amendments is to reduce diversity in the reporting on deferred tax on leases and decommissioning obligations.

The amendments are effective for annual periods beginning on or after 1 January 2023 with early application permitted. These amendments have been endorsed by the EU.

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.

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 of the amendments are effective for annual reporting periods beginning on or after 1 January 2024, with early adoption permitted. The amendments have not yet 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 recognises 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 to such transactions as of the implementation of IFRS 16 and for annual periods beginning on or after 1 January 2024 with early application permitted. These amendments have not yet been endorsed by the EU.

The amendments are not expected to have a material impact on the Group’s consolidated financial statements.

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

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.

Inter-company transactions, balances and unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated but considered an impairment indicator of the asset transferred.

Business combinations

The acquisition method of accounting is used to account for the acquisition of businesses (meeting the definition of a business in accordance with

IFRS 3 Business Combinations) by the Group. The consideration transferred for the acquisition of a business is the fair values of the assets transferred, the liabilities incurred and the equity interests issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration agreement. Acquisition-related costs are expensed as incurred, except if related to the issue of debt or equity securities. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are generally measured initially at their fair values at acquisition date. On an acquisition-by-acquisition basis, the Group recognises any non-controlling interest in the acquiree at fair value or at the non-controlling interest’s proportionate share of the acquiree’s net assets.

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the net identifiable assets acquired is recorded as goodwill. If this is less than the fair value of the net assets of the subsidiary in the case of a bargain purchase, the difference is recognised directly in the income statement.

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 recognised 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 recognised and measured at the carrying amounts as recognised 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 recognised in retained earnings.

The Group elected the accounting policy choice to re-present 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.

Non-controlling interests

On an acquisition-by-acquisition basis, NCI are measured initially at fair value or at their proportionate share of the acquiree’s identifiable net assets at the date of acquisition.

Changes in the Group’s interest in a subsidiary that do not result in a loss of control are accounted for as equity transactions.

Interests in equity-accounted investees

The Group’s interests in equity-accounted investees comprise interests in associates and joint ventures.

Associates are those entities in which the Group has significant influence, but not control or joint control, over the financial operating policies. A joint venture is an arrangement in which the Group has joint control, whereby the Group has rights to the net assets of the arrangement, rather than right to its assets and obligations for its liabilities.

Interests in associates and the joint ventures are accounted for using the equity method. They are initially recognised at cost, transaction costs included. Subsequent to initial recognition, the consolidated financial statements include the Group’s share of the profit or loss and other comprehensive income of equity-accounted investees, until the date on which significant influence or joint control ceases. The share of profit or loss of associates and joint ventures is presented withing operating profit because the associates and joint ventures are integral vehicle through which the group conducts its operations and its strategy.

2.3 GOODWILL

Goodwill represents the excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the net identifiable net assets acquired

at the date of acquisition. Goodwill is tested annually for impairment and carried at cost less accumulated impairment losses. Impairment losses on goodwill are not reversed. Gains and losses on the disposal of a Cash Generating Unit (CGU) include the carrying amount of goodwill relating to the entity disposed.

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.

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the income statement.

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, 2021	1.1326	1.1196
December 31, 2022	1.0666	1.0530

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 recognised. Expenditure on research is recognised as an expense when it is incurred.

An intangible asset arising from development is recognised 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, a 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 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 recognised 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 recognised 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.

After initial recognition, intangible assets are measured at cost less accumulated amortisation and any accumulated impairment losses. Intangible assets are amortised on a straight-line basis over their estimated useful life. Amortisation begins when the asset is capable of operating in the manner intended by management, i.e. available for commercialisation.

Separately acquired research and development

- Payments for separately acquired research and development are capitalised 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 recognised 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 recognised 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 capitalised 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 capitalised 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 and development 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.

Other intangible assets acquired separately

- An intangible asset is recognised 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.

Intangible assets (research and development costs or other intangible assets as referred above) with finite useful lives that are acquired separately are measured at cost less accumulated amortisation and accumulated impairment losses. 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.

Amortisation

After initial recognition, intangible assets are measured at cost less accumulated amortisation and any accumulated impairment losses. Intangible assets are amortised on a straight-line basis over their estimated useful life. 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. Intangible assets with indefinite useful lives that are acquired separately are carried at cost less accumulated impairment losses.

Intangible assets are amortised on a systematic basis over their useful life, using the straight-line method, and amortisation are presented as Cost of Sale in the

Profit or Loss Statement. 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 derecognised on disposal, 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 recognised in profit or loss when the asset is derecognised.

2.6 PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment ("PPE") are carried at acquisition cost less any accumulated depreciation and less any accumulated impairment loss. Acquisition cost includes any directly attributable cost of bringing the asset to working condition for its intended use. Borrowing costs that are directly attributable to the acquisition, construction and/or production of a qualifying asset are capitalised as part of the cost of the asset.

Expenditures on repair and maintenance which serve only to maintain, but not increase, the value of PPE are charged to the income statement.

The depreciable amount is allocated on a systematic basis over the useful life of the asset, using the straight-line method. The depreciable amount is the acquisition cost, less residual value, if any. The applicable useful lives are:

- Furniture and equipment: 10 years
- IT equipment: 3 years

The useful life of the PPE is reviewed regularly. Each time a significant upgrade is performed, such upgrade extends the useful life of the machine. The cost of the upgrade is added to the carrying amount of the machine (only if it is probable that the future economic benefits associated with the expenditure will flow to the Group) and the new carrying amount is depreciated prospectively over the remaining estimated useful life of the machine.

2.7 LEASES

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

Assets and liabilities arising from a lease are initially measured on a present value basis. 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.

Each lease payment is allocated between the liability and finance charges so as to achieve a constant rate on the remaining balance of the liability. Finance expenses are recognised immediately in profit or loss, unless they are directly attributable to qualifying assets, in which case they are capitalised.

Right-of-use assets are 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.

For short-term leases (lease term of 12 months or less) or leases of low-value items (mainly IT equipment and small office furniture) to which the Group applies the recognition exemptions available in IFRS 16, lease payments are recognised on a straight-line basis as an expense over the lease term.

2.8 JOINT ARRANGEMENTS AND ASSOCIATES

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. 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.

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 associate or 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 associate or joint venture. Unrealised 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.

2.9 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 recognised 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 recognised for the asset in prior years. A reversal of an impairment loss is recognised immediately in profit or loss.

2.10 REVENUE RECOGNITION

Revenue includes royalty revenue, license revenue and revenue from sale of goods, services or out-licensing agreements of product candidates.

In accordance with IFRS 15 – Revenue from Contracts with Customers, revenue from the rendering of services is recognised when the Company transfers control over the product to the customer; control of an asset refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, that asset. For the vast majority of contracts, revenue is recognised when the product is physically

transferred, in accordance with the delivery and acceptance terms agreed with the customer.

In addition, the Group has entered into a number of contracts through which it “out-licenses” to customers the IP it developed related to drugs that have not yet received regulatory approval. Generally, under the terms of the license, the licensee can further develop the IP, and manufacture and/or sell the resulting commercialised product. The Group typically receives an upfront fee, milestone payments for specific clinical or other development-based outcomes, and sales-based milestones or royalties as consideration for the license. Some arrangements also include ongoing involvement by the Group, who may provide R&D and/or manufacturing services relating to the licensed IP.

Licenses coupled with other services, such as R&D, must be assessed to determine if the license is distinct (that is, the customer must be able to benefit from the IP on its own or together with other resources that are readily available to the customer, and the Group’s promise to transfer the IP must be separately identifiable from other promises in the contract). If the license is not distinct, then the license is combined with other goods or services into a single performance obligation. Revenue is then recognised as the Group satisfies the combined performance obligation.

A license will either provide:

- a right to access the entity’s intellectual property throughout the license period, which results in revenue that is recognised over time; or
- a right to use the entity’s intellectual property as it exists at the point in time in which the license is granted, which results in revenue that is recognised at a point in time.

For sales- or usage-based royalties that are attributable to a license of IP, the amount is recognised 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.

2.11 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.

Financial assets are not reclassified subsequent to their initial recognition unless the Group changes its business model for managing financial assets, in which case all affected financial assets are reclassified on the first day of the first reporting period following the change in the business model.

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. On initial recognition, the Group may irrevocably designate a financial asset that otherwise meets the requirement to be measured at amortised cost as FVTPL if doing so eliminates or significantly reduces an accounting mismatch that would otherwise arise.

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 recognised when they are originated. All other financial assets are initially recognised 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 recognised in profit or loss.

Equity investments at FVOCI are subsequently measured at fair value. Dividends are recognised 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 recognised in OCI and are never reclassified to profit or loss.

Financial assets at amortised cost are subsequently measured at amortised cost using the effective interest method, less any impairment if they are held for collection of contractual cash flows where those cash flows represent solely payments of principal and interest.

The effective interest method is a method of calculating the amortised cost of a debt instrument and of allocating interest income over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash receipts (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the debt instrument to the net carrying amount on initial recognition.

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 recognised from initial recognition of the receivables.

The amount of the allowance is deducted from the carrying amount of the asset and is recognised in the income statement within ‘Cost of sales’.

The Group derecognises 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 recognises 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 recognise the financial asset and also recognises a collateralised 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 recognised 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 realise the asset and settle the liability simultaneously.

2.12 CASH AND CASH EQUIVALENTS

Cash and cash equivalents include cash in hand, deposits held at call with banks, other short-term highly liquid investments with original maturities of three months or less. Bank overdrafts are shown within borrowings in current liabilities on the statement of financial position.

2.13 SHARE CAPITAL

Ordinary shares are classified as equity. Where any Group company purchases the company’s equity share capital (treasury shares), the consideration paid is deducted from equity attributable to owners of the company until the shares are cancelled or reissued. Incremental costs directly attributable to the issue of new shares are shown in equity as a deduction, net of tax, from the proceeds.

Incremental costs directly attributable to the issue of ordinary shares are recognised as a deduction from equity. Income tax relating to transaction costs of an equity transaction is accounted for in accordance with IAS12.

2.14 GOVERNMENT GRANTS

Government grants are assistance by government, government agencies and similar bodies, whether local, national or international, in the form of transfers of resources to the Company in return for past or future compliance with certain conditions.

The Company recognises 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 recognised in profit or loss on a systematic basis over the periods in which the Company recognises as expenses the related costs which the grants are intended to compensate. As a result, grants relating to costs that are recognised 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 recognised in the profit or loss statement consistently with the amortisation or depreciation expense of the related assets.

Grants that intend to compensate costs are released as income when the subsidised costs are incurred, which is the case for grants relating to research and development costs. 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 recognised 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 recognised 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 capitalised R&D expenses, or (ii) if no sufficient taxable income is available, apply for the refund of unutilised 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.

R&D tax credit 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 capitalised and subsequently amortised together with the underlying assets.

2.15 EMPLOYEE BENEFITS

Employee benefits are all forms of consideration given in exchange for services provided by employees only. Directors and other management personnel who are under service agreements are presented separately in the Notes.

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.

2.16 SHARE-BASED PAYMENTS

A share-based payment is a transaction in which the Company receives goods or services either as consideration for its equity instruments or by incurring liabilities for amounts based on the price of the Company’s shares or other equity instruments of the Company. The accounting for share-based payment transactions depends on how the transaction will be settled, that is, by the issuance of equity, cash, or either equity or cash.

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 recognised 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 PROVISIONS

Provisions are recognised when (I) the Group has a present legal or constructive obligation as a result of past events; (II) it is probable that an outflow of resources will be required to settle the obligation; (III) and the amount can be reliably estimated. Where there are a number of similar obligations, the likelihood that an outflow will be required in settlement is determined by considering the class of obligations as a whole.

Provisions are measured at the present value of the expenditures expected to be required to settle the obligation using a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the obligation. The increase in the provision due to passage of time is recognised as finance cost.

2.18 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 recognised in profit or loss except to the extent that it relates to a business combination, or items recognised 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 assets and liabilities are measured at the tax rates that are expected to apply to the period when the asset is realised 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.

Deferred tax is recognised 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 recognised 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 recognised 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 recognised for all taxable temporary differences, unless one of the above exemptions would apply.

Deferred tax assets are recognised 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 utilised. Future taxable profits are determined based on the reversal of relevant taxable temporary differences. If the amount of taxable temporary differences is insufficient to recognise 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.

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. Unrecognised deferred tax assets are reassessed at each reporting date and recognised 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. The Group is able to offset deferred tax assets and liabilities only if the deferred tax balances relate to income taxes levied by the same taxation authority and it intends either to settle on a net basis, or to realise the asset and settle the liability simultaneously.

2.19 FINANCIAL LIABILITIES

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

All financial liabilities are initially recognised when the Group becomes a party to the contractual provisions of the instrument. Financial liabilities are recognised 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 recognised 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.

The effective interest method is a method of calculating the amortised cost of a financial liability and of allocating interest expense over the relevant period. The effective interest rate is the rate that exactly discounts estimated future cash payments (including all fees and points paid or received that form an integral part of the effective interest rate, transaction costs and other premiums or discounts) through the expected life of the financial liability to the net carrying amount on initial recognition.

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 derecognises a financial liability when its contractual obligations are discharged or cancelled, or expire. The Group also derecognises 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 recognised at fair value.

When a financial liability measured at amortised cost is modified without this resulting in derecognition, a gain or loss is recognised 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.

Compound financial instruments

Compound financial instruments issued by the Group comprise convertible bonds denominated in euro that can be converted automatically to ordinary shares. The liability component of compound financial instruments is initially recognised at the fair value of a similar liability that does have an equity conversion option. The equity component is initially recognised at the difference between the fair value of the compound financial instruments as a whole and the fair value of the liability component. Any directly attributable transaction costs are allocated to the liability and equity components in proportion to their initial carrying amounts. Subsequent to initial recognition, the liability component is measured at amortised cost using the effective interest method. The change in fair value of the derivative instruments is recognised in profit or loss. Interest related to the financial liability is recognised in profit or loss. On conversion at maturity, the financial liability together with the embedded derivatives are reclassified to equity and no gain or loss is recognised in profit or loss.

2.20 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 organised 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.

2.21 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 recognised 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.

2.22 CONTRACTUAL COMMITMENTS

Hyloris has contractual commitments related to asset purchase, licenses and development agreements. The amounts are due upon reaching certain milestones dependent 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.

2.23 STATEMENT OF CASH FLOWS

The cash flows of the Group are presented using the indirect method. This method reconciles the movement in cash for the reporting period by adjusting profit or loss for the period for any non-cash items and changes in working capital, and identifying investing and financing cash flows for the reporting period.

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 2022 consolidated results of the Group present a negative result, and the consolidated statement of financial position includes a loss carried forward.

Management has prepared detailed budgets and cash flow forecasts for the years 2023 and 2024. These forecasts reflect the strategy of the Group and include significant expenses and cash outflows in relation to the development of the ongoing products candidates, including four new product acquisitions per year. The development of new product candidates does not require a lot of cash in the first year.

With a cash position of the Group at the end of December 2022 (i.e. €43,4 million) and the successfully raised €15 million in gross proceeds end March 2022, the Board of Directors is of the opinion that it has an appropriate basis to conclude on the business continuity over the next 12 months from the 2023 Shareholder’s meeting approving the 2022 statutory accounts. The Board of Directors can decide to postpone development of new product candidates and has different options to manage the cash burn and runaway of the cash including the acceleration of out-license agreements.

3.2 SHARE-BASED PAYMENTS

In accordance with IFRS 2 – Share-based Payment, the fair value of the warrants at grant date is recognised 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 24.

3.3 EFFECTIVE INTEREST RATE OF SHAREHOLDERS’ LOANS

The Group was granted several shareholders’ loans as disclosed in Note 15.2. The shareholders’ loans bear a fixed interest rate of 4%, which is considered to be below market rates if the Group would finance itself on the market in 2020. As such, based on the principles of IFRS 9 Financial Instruments, the Company remeasured the shareholders’ loans at fair value (at the date the loan has been originated or at transition date). Subsequently the loans are measured at amortised cost based on the market-related rate. As such the Group recognises the interest expense it would need to pay if it would finance itself on the market. The differential between the fair value of the loans and the nominal amount is considered as a capital contribution, which is recognised immediately in equity, net of tax.

At 31 December 2022 the shareholder’s loans are reimbursed. Refer to Note 15.2 for further details.

4. FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

4.1 OVERVIEW OF FINANCIAL INSTRUMENTS

The table below summarises all financial instruments by category in accordance with IFRS 9:

Pleco: the valuation is based on last capital increase and decided by Pleco’s general assembly and is considered as market value.

Vaneltix: Discounted cash flows: the valuation model considers the present value of expected payments, discounted using a risk-adjusted rate.

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.

(in € thousand)	IFRS 9 Category	Input level	December 31, 2022	December 31, 2021
Other investment, including derivatives – Vaneltix (Note 10)	FVTPL	2	469	981
Other investment, including derivatives – Pleco (Note 10) (non current)	FVOCI	2	1,000	
Trade receivables (Note 11)	At amortised cost		5,615	3,266
Prepayments (Note 12)	At amortised cost		1,748	
Cash and cash equivalents	At amortised cost		43,457	50,012
Total financial assets *			52,289	54,259

3.4 RECOGNITION OF DEFERRED TAX ASSETS

Deferred tax assets are recognised 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.

Since inception, the Company has reported losses, and as a consequence, the Company has unused tax losses. Management has therefore concluded that deferred tax assets should not be recognised as of 31 December 2022 considering uncertainties regarding future taxable profits relating to the commercialisation of the development projects. 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.

Borrowings (Note 15.1)	At amortised cost	885	174
Other financial liabilities (Note 15.2)	At amortised cost	3,512	12,115
Trade and other liabilities (Note 16)		2,422	2,749
Trade payables	At amortised cost	2,302	2,669
Derivative	FVTPL	152	
Employee benefit liabilities	At amortised cost	68	80
Total financial liabilities		6,699	14,911

* Trade and Other receivables that are not financial assets (VAT / R&D tax credit receivables) are not included.

The Company considers that the carrying amounts of financial assets and financial liabilities measured at amortised 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 and interest rate 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, 2022	December 31, 2021
Assets	4,320	2,264
Liabilities	(1,078)	(3,987)

At December 31, 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 -32 k€ and -17 k€ respectively.

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 is the risk that one party to an agreement will cause a financial loss to another party by failing to discharge its obligation. Credit risk covers trade and other receivables, cash and cash equivalents and short-term deposits.

The Company believes that the credit risk is influenced mainly by the individual characteristics of each counterparty. Based on the ongoing credit evaluation performed, impairment on financial assets is considered as insignificant.

As such, no impairment is recognised for these receivables. Cash and cash equivalent and short-term deposits are invested with highly reputable banks and financial institutions.

The maximum credit risk to which the Company is theoretically exposed as at the balance sheet date is the carrying amount of the financial assets.

4.6 LIQUIDITY RISK

The Company’s main sources of cash inflows are currently obtained through capital increases.

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, after the read-out of the current clinical trial expected in H1 2023.

31/12/2022	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
(In € thousand)					
Borrowings					
Lease liabilities	141	492	426		1,059
Other financial liabilities					
Loans from shareholders	-				-
Other financial liabilities	3,212	300			3,512
Trade and other liabilities	2,422				2,422
Total	5,775	792	426		6,993

31/12/2021	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
(In € thousand)					
Borrowings					
Lease liabilities	67	111			178
Other financial liabilities					
Loans from shareholders	9,126				9,126
Other loans	3,200	300			3,500
Trade and other liabilities	2,749				2,749
Total	15,143	411			15,554

5. OPERATING SEGMENTS

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 Group’s activities are managed and operated in one segment, pharmaceuticals. There is no other significant class of business, either individual or in aggregate. As such, the chief operating decision maker reviews the operating results and operating plans and makes resource allocation decisions on a company wide basis.

Total revenue represents an amount of €2,95 million. The revenue related to products (royalties, milestones, out-license revenues), represents €1,90 million and revenue for services rendered is €1,05 million.

5.1 GEOGRAPHICAL INFORMATION

Revenue reported in the consolidated statement of profit or loss and other comprehensive income and non-current assets recorded in the consolidated statement of financial position are located in Belgium, country of domicile of the Company.

6. LIST OF CONSOLIDATED COMPANIES AS AT DECEMBER 31, 2022

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%
RTU Pharma SA	BE 0669.738.676	Blvd Patience et Beaujonc N°3/1, 4000 Liège	100,00%
Dermox SA	BE 0667.730.677	Blvd Patience et Beaujonc N°3/1, 4000 Liège	100,00%
Purna Female Healthcare BV	BE 0762.693.578	Scheldestraat 31, 2880 Bornem	20,00%*

* equity accounted investee see note 9.

The voting rights equal the percentage of financial interest held.

7. INTANGIBLE ASSETS

(in € thousand)	Development costs	Assets Purchase	In Prepayments Licensing	Total	
Year ended December 31, 2022					
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
At December 31, 2022					
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 € thousand)	Development costs	Assets Purchase	In Licencing	Total
Year ended December 31, 2021				
Opening carrying amount	872	1,008	501	2,381
Additions	249		686	936
R&D Tax Credit	(31)	(17)	(40)	(88)
Disposals		(219)		(219)
Borrowing costs capitalised				0
Amortisation expense		(43)		(43)
Impairment losses			(23)	(23)
Closing carrying amount	1,090	729	1,125	2,944
At December 31, 2021				
Cost	1,570	4,247	1,148	6,965
Accumulated amortisation and impairment	(480)	(3,518)	(23)	(4,022)
Carrying amount	1,090	729	1,125	2,944

In 2022, the Company acquired intangible assets for a total of €779 thousand, of which (i) €284 thousand related to the development costs of product-candidate Maxigesic® IV and (ii) €496 related to the development costs of HY-016.

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 2 years. 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. Once 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.

As long as the assets are not fully amortised, they are tested for impairment losses on an annual basis or more frequently if specific indicators require it. The impairment test conducted is performed by product and consists in measuring 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.

The impairment losses are included in the Research and Development expenses in the consolidated statement of profit or loss and other comprehensive income.

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 probability of success. As defined in Note 2.9, 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 11.26% (was 10.98% in 2021).

The main variables that lead to a discount rate of 11.26% are:

- a risk free rate of 3.18% corresponding to the 10-year OLO rate as of December 31, 2022 (2.98% last year);
- a beta factor of 1.24 (1.02 last year);
- a market risk rate of 2.07% (5.05% last year); decrease compared with 2021 is due to the positive evolution of the company's risk profile following the commercialisation of 2 products, the advancement of the product portfolio and the limitation of the negative impacts related to COVID on our sector;
- 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 2021).

Probability of success (PoS) rate varies from 100% for the commercial products of the Company to 60% for the less developed products of the Company (no change with 2021).

We tested the sensitivity analysis of the impairment tests by increasing the discount rate by 4%, leading the discount rate to 15.26%. We cumulatively decreased the probability of success up to 40%, leading the PoS to 60% and 20% respectively for the commercial products and product in developments. None of these assumptions resulted to 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
Year ended December 31, 2022			
Opening carrying amount	102	71	173
Additions	825	32	857
Depreciation expense	(44)	(27)	(71)
Disposals	(75)	-	(75)
Closing carrying amount	809	76	885
At December 31, 2022			
Cost	825	184	1,251
Accumulated depreciation and impairment	(16)	(109)	(366)
Carrying amount	809	76	885
Year ended December 31, 2021			
Opening carrying amount	145	7	152
Additions		83	83
Depreciation expense	(43)	(19)	(62)
Disposals	-	(29)	(29)
Closing carrying amount	102	71	173
At December 31, 2021			
Cost	242	152	394
Accumulated depreciation and impairment	(140)	(81)	(221)
Carrying amount	102	71	173

The depreciation expenses are all presented as “General and administrative expenses”.

The Group leases its headquarter building and some company cars. The contracts do not include any purchase options. The lease term considered for the building is nine 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.

The amounts recognised in profit or loss can be summarised as follows:

(in € thousand)	2022	2021
Depreciation expense of right-of-use assets	(71)	(62)
Interest expense on lease liabilities	(10)	(5)
Expenses relating to low-value leases	(2)	(2)
Total amount recognised in profit or loss	(83)	(69)
of which as:		
General and administrative expenses (Note 19)	(73)	(64)
Financial expenses (Note 22)	(10)	(5)

9. EQUITY ACCOUNTED INVESTEEES

On 5 February 2021, the Group entered into a partnership with Purna Female Healthcare (“PFH”), a special purpose vehicle founded to develop and commercialise Miconazole-Domiphen Bromide, and which is accounted under the equity method of accounting (Joint Venture). 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. Hyloris committed an investment of €4,270 thousand, of which €1,270 thousand is already paid. The unpaid balance of €3,000 thousand is recognised 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% of the net profits generated by PFH. 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, 2022	December 31, 2021
Opening carrying value	4,078	
Capital Contribution		4,270
Profit/loss of the period	(130)	(191)
Carrying amount at December 31	3,948	4,079

The following table summarises 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 and 2022 are in line with the estimated R&D costs for this specific project.

(in € thousand)	31-Dec-22
FIXED ASSETS	
CURRENT ASSETS	4,495
Amounts receivable within one year	3,026
Cash at bank and in hand	1,469
TOTAL ASSETS	4,495
CAPITAL AND RESERVES	5,146
Capital	6,103
Accumulated profits (losses)	(1,608)
PROVISIONS AND DEFERRED TAXES	
CREDITORS	0,35
Amounts payable within one year	0,35
TOTAL LIABILITIES	4,495

(in € thousand)	2022	2021
Operating income	-	-
Operating charges	(651)	(957)
Services and other goods	(649)	(956)
Other operating charges (-)	(2)	(1)
Operating profit (loss)	(651)	(957)
Profit (Loss) for the period before taxes (-)	(651)	(957)
Profit (loss) for the period available for appropriation	(651)	(957)

10. OTHER INVESTMENT, INCLUDING DERIVATIVES

The other investment, including derivatives can be detailed as follows:

(in € thousand)	December 31, 2022	December 31, 2021
Shares Pleco Therapeutics BV	1,000	
Automatically Convertible loan		500
Optional convertible loan	469	441
Other Financial Assets		40
Other Investment, including derivatives	1,469	981
of which as:		
Non-current	1,000	453
Current	469	528

Automatically converted loan into shares of Pleco

In 2021, the Group entered into a partnership with Pleco Therapeutics to develop a Plecoid™ Agent, a novel combination product of chelating agents for the treatment of Acute Myeloid Leukaemia (AML) and Small Cell Lung Cancer (SCLC). Under the terms of the agreement, Hyloris provided via a €1,000 thousand automatically non-interest bearing convertible loan (whereof as of per 31 December 2021 €500 thousand was paid to Pleco Therapeutics). On 1 June 2022, Pleco Therapeutics issued new shares and conform to the agreement, the loan has been converted into shares. The Group received 7,944 preferred shared at an issuing price of €126 per share (which result in a 4.67% ownership of the company Pleco Therapeutics). See note 4.1 for the valuation.

Subject to feedback from the FDA on the feasibility of the clinical development requirements, the Group may commit to fund (not convertible into equity) up to maximum € 7,700 thousand 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 €7,700 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.

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 Loan will be reimbursed 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 USD \$5 million (the “Capital Increase”). In case 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 28.1).

Management identified Vaneltix Pharma, Inc as a related party of Hyloris (see note 28.1).

11. TRADE RECEIVABLES AND OTHER RECEIVABLES

(in € thousand)	December 31, 2022	December 31, 2021
Trade receivables	4,527	2,621
API	625	-
Alter Pharma	395	645
R&D Tax Credits	811	474
Other amounts receivable	216	295
Total trade and other receivables	6,574	4,035
of which as:		
Current	5,127	2,321
Non Current	1,447	1,714

An impairment analysis of trade receivables is done on an individual level, and there are no individual significant impairments.

The carrying amount of the Group’s trade receivables (gross) is mainly denominated in EUR, primarily resulting from out-licensing revenues and service revenues in EUR.

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 recoverable VAT and interests on deposits.

API

A loan to API of €656 thousand is granted by Hyloris to API, carrying a 0.1% interest per year. This loan is presented as non-current. As soon as 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 initial recognition of a loss of k€ 31 recognised as financial expenses.

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 recognised R&D tax credits for a total of €337 thousand in Other Operating Income (see note 21) and Intangible assets (see note 7).

Receivable from Alter Pharma Group

The balance sheet as at 31 December 2022 held a current receivable from the Alter Pharma Group for € 395 thousand, relating to the termination of the development projects conducted by Alter Pharma and its subsidiaries in 2021.

12. PREPAYMENTS

Pre-paid R&D expenses relate to payments made by the Group for research and development projects conducted by third parties and will be recorded in profit and loss when incurred. Pre-paid R&D expenses of €1,108 thousand in 2022 related to the development agreement with Vaneltix (a related party of Hyloris) to run the clinical development of the Alenura™ product candidate (see note 27) is the main driver of the increase compared to 31 December 2021.

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, 2022	December 31, 2021
Cash at bank	13,457	30,012
Short-term deposit	30,000	20,000
Total cash and cash equivalents	43,457	50,012

The term of two deposits are from 1 September 2020 to 1 September 2023 and the terms of the two other deposits are from 13 December 2022 to 13 June 2023, and from 13 December 2022 to 13 September 23. It is classified as short term deposit as available for use by the group within a 32 days' notice period.

14. EQUITY

14.1 OVERVIEW

(in € thousand)	December 31, 2022	December 31, 2021
Share capital	140	129
Share premium	121,513	103,693
Retained earnings	(64.246)	(54.805)
Other reserves	(2,362)	(960)
Total Equity attributable to owners of the parent	55,045	48,057

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 concerns 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.

Costs associated to equity transactions such as investment bank, legal and audit fees are expensed when incurred and recorded as General and Administrative expenses. Only the one-time costs related to the issuance of new shares are capitalised in the equity as costs of capital.

On 31 March 2022, the Company has successfully raised an amount of €15,000 thousand 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 20 June 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 will use 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
Execution transaction warrants	2,832		(14)	2,818
Total	17,832	(634)	(43)	17,155

14.3 SHARE CAPITAL AND SHARE PREMIUM

Share Capital

As per 31 December 2022, 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 authorised capital of €117,758.84. The Board is allowed to use the authorised capital for a period of 5 years. As per December 31, 2022, the remaining authorised capital amounted to €110,920.13.

The following capital transactions have taken place since January 1, 2017:

Date	Transaction	Increase of share capital (incl. share premium) (€)	Number of Securities issued	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 ¹	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

1 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 31 December 2022, the share premium of the Group amounts to € 121,513 thousand.

Other reserves

(in € thousand)	December 31, 2022	December 31, 2021
Share based payment	1,622	2,391
Cost of Capital	(4,460)	(3,827)
Other	476	476
Total Other reserves	(2,362)	(960)

The movement of the other reserves over the period can be explained by:

- the increase of €560 thousand resulting from the share based payment expenses associated with the ESOP warrants (see note 25);
- the decrease of €1.329 thousand for the transfer to retained earnings of historical share base payment costs linked to the transaction warrants exercised during the year; and
- the decrease of €634 thousand from the Cost of Capital related to the Accelerated Bookbuild (see note 14.2).

15. BORROWINGS AND OTHER FINANCIAL LIABILITIES

15.1 BORROWINGS

(in € thousand)	December 31, 2022	December 31, 2021
Lease liabilities	885	174
Total borrowings	885	174
of which as:		
Non-current borrowings	747	109
Current borrowings	138	65

For more details on the leases, we refer to Note 8 on “Right-of-use assets”.

The weighted average incremental borrowing rate used for the measurement of the lease liabilities is 3.95%. 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, 2022	December 31, 2021
Loans from shareholders	0	8,615
Other financial liabilities	3,512	3,500
Other financial liabilities	3,512	12,115
of which as:		
Non-current other financial liabilities	300	300
Current other financial liabilities	3,212	11,815

Loans from shareholders

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 31 December 2022 or, if and when, the Group will generate a positive EBIT.

At 31 December 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).

Other financial Liabilities

In 2022, the Group has with the Alter Pharma Group related license agreements a non-current other financial liability of €300 thousand and a current financial liability of each €200 thousand.

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:

31/12/2022 (in € thousand)	Opening carrying amount	Cash flows	Non-cash movements					Closing carrying amount
			Acquisition	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	11,815	(9,253)	0	482		-	168	3,212
Total liabilities from financing activities	12,290	(9,332)	848	482	(62)	-	168	4,394
Presented in the statement of cash flows as follows:								
financing activities		(9,253)						
Reimbursement of borrowings		(79)						

31/12/2021 (in € thousand)	Opening carrying amount	Cash flows	Non-cash movements					Closing carrying amount
			Acquisition	Modification	Termination	Re-classes	Accrued interests and exchange differences	
Non-current financial liabilities								
Lease liabilities	106	-	83			(80)	-	109
Other financial liabilities	7,885		300			(7,885)		300
Current financial liabilities								0
Lease liabilities	46	(64)				80	3	65
Other financial liabilities	409	(409)	3,200			7,885	730	11,815
Total liabilities from financing activities	8,447	(473)	3,583	0	-	-	733	12,290
Presented in the statement of cash flows as follows:								
Financing activities		(409)						
Reimbursement of borrowings		(64)						

16. TRADE AND OTHER LIABILITIES

(in € thousand)	December 31, 2022	December 31, 2021
Trade payables	2,302	2,622
Employee benefit liabilities	68	80
Other payables	52	47
Trade and other liabilities - Current	2,422	2,749

The trade payables relate mainly to the R&D activities. Other payables consist of the fair value of a Foreign Exchange spot contract.

17. DEFERRED TAXES

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.

in € thousand	31-Dec-22		31-Dec-21	
	Deferred tax asset	Deferred tax liability	Deferred tax asset	Deferred tax liability
Intangible assets	852		854	
Financial liabilities				(57)
Trade and other liabilities	25			
Associates and joint ventures	81		48	
Tax losses	10,465		7,951	
Total deferred tax assets & liabilities	11,422		8,854	(57)
Net deferred tax assets not recognised	(11,422)		(8,787)	
Offsetting			(57)	57
Total deferred tax assets & liabilities				

The deferred tax liability on the financial liabilities in 2021 relates to the initial recognition of the loans from shareholders at fair value.

Deferred tax assets have not been recognised 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, 2022	December 31, 2021
Deductible temporary differences	3,830	3,002
Tax losses	41,858	31,805
Total	45,688	34,806

In 2022, the Group actively mitigated its foreign exchange risk (USD exposure) utilizing forward foreign exchange contracts for a total nominal value of \$11,270 million, whereof as per end of December \$1 million is still outstanding. As a result and as per 31 December 2022, a derivative with a negative fair value is recognised as a current financial asset for € 52 thousand. (See note 22 for the realised gain of FX forward contracts)

The fair value of trade payables approximates their carrying amount.

Liquidity and currency risk are detailed in Note 4.

The deferred tax assets and liabilities are attributable to the following items:

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 revenues can be detailed as follows:

(in € thousand)	December 31, 2022	December 31, 2021
Sales-based royalties, milestone payments and out-licensing agreement	1,900	2,120
Services rendered	1,052	975
Revenues	2,952	3,095

Currently, the Group generates only limited sales-based royalties as its main projects are in the development pipeline and are not yet commercialised. The continuously increasing sales-based royalties is income mainly from the Group's commercialised products, Sotalol IV and new in 2022: Maxigesic® IV. Revenue from a sales-based royalties is recognised when the subsequent sale occurs. Revenue from sales milestone is recognised when the performance obligation has been met (i.e. sales threshold reached).

Income from Milestone payments in 2022 is driven by the product Tranexamic whereas in 2021 it was coming from out-licensing Maxigesic® IV by the Group's partner AFT Pharmaceuticals, including income from the landmark US Licensing Agreement. Revenue for milestone payment in exchange for a license of intellectual property is only recognised when the performance obligation to which some or all of the milestones payments has been allocated has been satisfied.

Income from out-licensing is mainly related to a transaction with Qliniq.

In order to optimise the product pipeline the Group out-licensed a product candidate HY-038 in line with its long term strategy. Out-licensing agreement qualified for a 'right to use' the license and revenue is recognised at the point in time that the license is granted.

Income from Services rendered in 2022 primary consist of strategic advices incurred by the Group to support a co-developer. Revenue for services rendered are recognised when the services is rendered.

19. EXPENSES BY NATURE

Expenses by nature represent an alternative disclosure 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)	2022	2021
Out-sourced R&D	(7,163)	(3,333)
Employee benefit expenses (Note 20)	(2,576)	(1,659)
Management consultancy fees	(1,091)	(907)
Board related expenses	(178)	(189)
R&D consultancy fees	(420)	
Share based payments	(560)	(576)
Legal & paralegal fees	(645)	(218)
Audit and related consultancy fees	(91)	(172)
Hiring fees	(84)	(103)
Office equipment, rent and utilities	(337)	(292)
Renegotiation and unwinding Alter Pharma	-	(5,770)
Other expenses	(433)	(478)
Amortisation expense of intangible assets (Note 7)	(94)	(43)
Impairment losses on intangible assets (Note 7)		(23)
Depreciation expense on PPE and Right of Use	(102)	(71)
Total operating expenses	(13,774)	(13,833)
of which as:		
Cost of sales	(94)	(107)
Research and development expense	(10,151)	(5,056)
General and administrative expenses	(3,517)	(2,900)
Other operating expenses	(12)	(5,770)

In accordance with IAS 38, we do not capitalise 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.

Total R&D expenditure can be detailed as follows:

(in € thousand)	December 31, 2022	December 31, 2021
Research and Development expenses	(10,151)	(5,033)
Impairment of assets		(23)
Total R&D costs	(10,151)	(5,056)

The Groups' research and development expenses increased by 102%, from €5,033 thousand in 2021 to €10,151 thousand in 2022. The increase was principally driven by the progresses 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 2022, the Group capitalised development costs for a total of € 661 thousand (was €284 thousand in 2021). (See note 7)

Hyloris' General and administrative expenses increased by 21% (or €617 thousand), from €2,900 thousand in 2021 to €3,517 thousand in 2022. The increase was mainly driven by additional communication and legal/HR costs. The company remains focused on strong cost and cash management.

20. EMPLOYEE BENEFIT EXPENSES

In € thousand	December 31, 2022	December 31, 2021
Wages and salaries	(2,142)	(1,494)
Social security costs	(146)	(105)
Defined contribution costs	(20)	(14)
Other employee Benefit expenses	(258)	(45)
Total employee Benefit expense	(2,567)	(1,659)
in full-time equivalents		
Average number of total employees	23.6	13.8

21. OTHER OPERATING INCOME

(in € thousand)	December 31, 2022	December 31, 2021
Grants income related to tax credit	315	387
Other income	0	2
Other Operating Income	315	389

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 Company will comply with the conditions attached to the grant and the grant will be received. The Group recognised R&D tax credits for a total of €337 thousand, of which €315 thousand as other operating income, and €22 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.

22. FINANCIAL RESULT

The various items comprising the net finance cost are as follows:

(in € thousand)	December 31, 2022	December 31, 2021
Realised gain on FX forward contracts	525	-
Interest income on current assets	67	32
Exchange differences	(126)	-
Financial income	466	32
Interest expense on lease liabilities	(11)	(5)
Interest expense on other financial liabilities	(164)	(478)
Other Interest expense	(44)	(73)
Total interest expenses	(219)	(557)
Loss related to substantial modification of the shareholders loan - note 15	(226)	-
FV adjustment on FX forward instruments	(52)	
Bank fees	(38)	(26)
Exchange differences	0	(190)
Other	(59)	-
Total financial expenses	(594)	(773)

23. INCOME TAX EXPENSE

23.1 AMOUNTS RECOGNISED TO PROFIT AND LOSS

The income tax (charged)/credited to the income statement during the year is as follows:

(in € thousand)	December 31, 2022	December 31, 2021
Current Tax (expense)/ income	(4)	(297)
Financial income	(4)	(297)

In 2021, The Group recognised an additional Tax Expenses of €297 thousand related to a request for payment of Taxes related to taxable income realised 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 recognised the Tax Expense in 2021. Payment has been done to the Authorities in 2022.

23.2 RECONCILIATION OF EFFECTIVE TAX

The income tax expense can be reconciled as follows:

(in € thousand)	2022	2021
Loss before income tax	(10,766)	(11,282)
Income tax expense calculated at domestic tax rates (25%)	2,691	2,821
Tax effect of		
Share of Loss of equity-accounted investees reported, net of tax	(33)	(48)
Tax incentives (R&D Tax Credit)	(12)	(97)
Changes in estimates related to prior years	(4)	(297)
Effect of unused tax losses not recognised as deferred tax assets	(2,646)	(2,869)
Total tax Expenses	(4)	(297)

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, 2022	December 31, 2021
Basic earnings		
Profit (Loss) from continuing operations attributable to owners of the parent	(10,770)	(11,579)
Diluted earnings		
Dilution effect of share-based payments		
Profit from continuing operations attributable to owners of the parent, after dilution effect	(10,770)	(11,579)

Earning per share based on the existing number of ordinary shares

Number of shares	December 31, 2022	December 31, 2021
Weighted average number of ordinary shares outstanding during the period	27,198,925	25,832,632
Basic earnings per share	(0.40)	(0.45)
Diluted earnings per share	(0.40)	(0.45)

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.

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.

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

The following share-based payment arrangements were in existence during the current and prior periods:

	Expiry Date	Exercise Price per warrant (€)	Fair value at grant date (€)	Warrants per 31 December 2022	Warrants per 31 December 2021
PLAN 2017					
Warrants	14 June 2022	2.36	1.11	-	1,200,000
PLAN 2019					
Warrants	31 December 2024	5.34	2.47	306,125	313,000
PLAN 2020					
Warrants	27 November 2031	9.88	4.44	69,500	69,500
Warrants	27 November 2031	12.04	5.68	55,000	55,000
Warrants	27 November 2031	13.92	6.20	60,000	60,000
Warrants	27 November 2031	16.64	7.39	2,000	2,000
PLAN 2022					
Warrants	30 June 2029	15.2	6.08	142,000	

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).

remaining warrants of the 2020 plan were cancelled and replaced by a new plan (2022 plan).

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.

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 the date of this annual report 142,000 warrants were accepted by new employees.

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). As at 31 December 2022, 191,500 warrants were offered to new employees of which 186,500 warrants were accepted. The

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 2017	PLAN 2019	PLAN 2020	PLAN 2022
Average Share price (€)	2.36	5.34	11.73	14.84
Average Exercise Price (€)	2.36	5.34	11.89	15.2
Expected volatility of the shares (%)	55%	55%	40%	35%
Expected dividends yield (%)	0%	0%	0%	0%
Risk free interest rate (%)	0.60%	0.10%	0.00%	2.66%

The following reconciles the options outstanding at the beginning and end of the year:

	Average Exercise Price (€)	Numbers of Warrants
Closing balance at 31 December 2018	2.36	1,200,000
Warrants accepted in December 2019	5.34	118
Closing balance at 31 December 2019	2.63	1,318,000
Warrants accepted in 2020	5.34	235,000
Warrants lapsed in 2020	5.34	20,000
Closing balance at 31 December 2020	3.01	1,533,000
Warrants accepted in 2021	11.89	186,500
Warrants lapsed in 2021	5.34	20,000
Closing balance at 31 December 2021	3.68	1,699,500
Warrants accepted in 2022	15.2	142,000
Warrants lapsed in 2022	5.34	6,875
Warrants exercised in 2022	2.36	1,200,000
Closing balance at 31 December 2022	8.74	634,625

26. CONTINGENCIES

At closing 2022, the Group is involved in a litigation with Alta Thera regarding the IP of product Sotalol. With respect to the complaint filed by AltaThera Pharmaceuticals LLC against Academic Pharmaceuticals Inc, Dr. Somberg and Hyloris Pharmaceuticals, for (e.g.) alleged misappropriation

of Alta Thera’s trade secrets and confidential information and breach of contract, Hyloris is fully confident about the outcome of this litigation. Hyloris has filed the necessary counterclaims and also started an arbitration procedure against AltaThera Pharmaceuticals LLC. for breach of contract.

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 dependent 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 31 December 2022, Hyloris has contractual commitments and contingent liabilities for a maximum amount of €33,027 thousand on related to asset purchase, licenses and development agreements recorded under intangible assets.

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 capitalised. 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 (milestone payments only) at 31 December 2022 per product candidates if such products are successfully marketed (in € thousand):

Product Candidate	In \$ thousand	In € thousand	Converted in € (in € thousand)
HY-004 Tranexamic Acid MR	225		211
HY-029		300	300
Atomoxetine oral liquid	150		141
Metolazone IV	1,650		1,547
Dofetilide IV	350		328
HY-073	28,457		26,680
HY-074	175		164
Alenura™ (note 28.1)	3,900		3,656
TOTAL	34,907	300	33,027

As of December 31, 2022, out of the total value of €33,027 thousand, €28,579 thousand should be considered as contingent liabilities as they are not triggered by a performance obligation from the counterparty, but triggered by (future) sales milestones.

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.

28. RELATED PARTY TRANSACTIONS

The reference shareholder is current CEO Stijn Van Rompay.

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:

- Vaneltix Inc and its affiliates, in which non-executive an independent member of the Board of directors, Carolyn Myers her partner, Dr. Dan Vickery is CEO and shareholder;
- the shareholders; Mr Stijn Van Rompay, an executive member of the board of the Company, CEO and reference shareholder of the Company; GRNR Invest BVBA, an entity controlled by Thomas Jacobsen, an Executive member of the board of the Company;
- the Executive Management Team;
- the Board of Directors (Non-Executive Directors).

28.1 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).

Under the terms of the agreement, Vaneltix will be responsible for the further development, manufacturing, regulatory affairs and commercialisation of Alenura™ in collaboration with Hyloris. In return, Hyloris will provide staged investments of in total maximum \$6,700 thousand for Phase 2, manufacturing and regulatory related activities related activities and a 6% interest bearing

(potential convertible) loan of \$500 thousand (see note 10). Hyloris will be eligible to receive a tiered and incremental percentage of the product margin generated by Vaneltix.

The table below provides an overview as per 31 December 2022:

(in € thousand)	Financial Position	Transactions for the period	
		Profit Loss	Commitments
Other investments (see note 10)	494		
Prepayments	1,108		
Research and Development expenses		(1,422)	
Interest income		25	
Commitments and Contingent Liabilities (see note 27)			3,656
Total	1,602	(1,398)	3,656

28.2 TRANSACTIONS WITH THE SHAREHOLDERS

Shareholder loans

On 30 June 2022, the Group successfully renegotiated the Shareholder 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 (see Note 15.2).

The below table provides an overview of the loans outstanding per December 31, 2021 (nominal accounts, excluding accrued interest). No loans were outstanding per December 31, 2022 as these were reimbursed before year-end. The financial interest of the year amounts to € 168 thousand.

(in € thousand)	31-Dec-22	31-Dec-21
Stijn Van Rompay	0	4,428
GRNR Invest BVBA (an entity controlled by Thomas Jacobsen)	0	1,089
Pieter Van Rompay	0	940
Stijn and Ellen Van Rompay-Delimon	0	436
Total	0	6,894

Capital Increase dated 22 June 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. The table below represent the exercised warrants of related parties:

Related Party	Number of Transactions warrants exercised	Exercise Price in €
Stijn Van Rompay	852,096	2.36
Thomas Jacobsen	163,512	2.36
Total	1,015,608	2.36

28.3 TRANSACTIONS WITH THE EXECUTIVE MANAGEMENT TEAM

Executive management team personnel includes those persons having authority and responsibility for planning, directing and controlling the activities of the Group. As of 31 December 2022, members of the Executive Management Team are:

- SVR Management BVBA, 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;
- Herault BV, an entity controlled by Koenraad Vanderelst, Chief Legal Officer.

The table below presents the compensation of all members of Executive Management Team by type of compensation (including members of the EMT that left the Company during 2021, ie Mr Ed Maloney (former CBDO) who left the company in February 2021):

(in € thousand)	December 31, 2022	December 31, 2021
ST compensation (incl. management fees)	1,045	891
Post-employment benefits	-	-
Share-based payments	154	274
Total	1,199	1,165

At 31 December 2022, there were outstanding trade payables related to transactions with the Executive Management Team:

(in € thousand)	December 31, 2022	December 31, 2021
Management fees	160	197
Total	160	197

As of 31 December 2022, 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
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 Vanderelst	27,443	0.10	50,000	6.3
TOTAL	11,374,348	40.66	198,000	31.19

Total outstanding shares and warrants existing as of 31 December 2022 are respectively 28,000,374 and 634,625.

28.4 TRANSACTIONS WITH THE BOARD OF DIRECTORS (NON-EXECUTIVE DIRECTORS)

As of 31 December 2022, non-executive members of the Board of directors are:

- Stefan Yee, Chairman
- Leon Van Rompay
- Marc Foidart
- Carolyn Myers
- James Gale
- Chris Buysse

The table below presents the compensation of all non-executive members of Board of directors by type of compensation:

(in € thousand)	December 31, 2022	December 31, 2021
Board fees	110	110
Share-based payments	30	58
Total	140	168

At 31 December 2021, there were outstanding trade payables related to transactions with the non-executive members of the Board of directors:

(in € thousand)	December 31, 2022	December 31, 2021
Board fees	0	40
Total	0	40

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 unqualified 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, 2022 give a true and fair view of the Company’s equity and financial position as at December 31, 2022 and of its financial performance for the year then ended in accordance with the financial reporting framework applicable in Belgium. The standalone financial statements, together with the

As of 31 December 2022, 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	15.76%
Leon Van Rompay	-	-	-	
Marc Foidart	-	-	-	
Carolyn Myers	-	-	-	
James Gale	-	-	-	
Chris Buysse	-	-	-	
Total	-	-	100,000	15.76%

29. EVENTS AFTER THE END OF THE REPORTING PERIOD

None.

30. AUDIT FEES

During 2022, the statutory auditor provided services for the group Hyloris which fees were as follows:

(in € thousand)	December 31, 2022
Audit services	82
Audit related services – legal engagements	15
Tax Services	18
Total	115

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 €)	2022	2021
ASSETS		
FIXED ASSETS	76,374,779	57,264,376
Intangible fixed assets	112,655	86,861
Tangible fixed assets		
Financial fixed assets	76,262,124	57,177,515
Affiliated companies - Participations	73.161.002	44,944,782
Affiliated companies - Receivables	2,101,122	12,232,733
Investment	1,000,000	-
CURRENT ASSETS	41.456,011	48,534,248
Receivables over one year	656,291	1,681,613
Trade receivables		845,000
Others amounts receivable	656,291	836,613
Amounts receivable within one year	3,893,442	3,378,508
Trade receivables	2,958,075	2,432,586
Others amounts receivables	935,367	945,922
VIII. Cash Investment	30,000,000	20,000,000
IX. Cash at bank and in hand	4,589,023	21,689,562
X. Deferred charges and accrued income	2,317,255	1,784,565
TOTAL ASSETS	117,830,790	105,798,624
CAPITAL AND RESERVES	106,320,976	89,392,780
Capital	140,002	129,163
Share Premium	121,513,447	103,692,645
Reserves	5,000	5,000
Accumulated profits (losses)	(15,337,473)	(14,434,028)
PROVISIONS AND DEFERRED TAXES		
CREDITORS	11,509,814	16,405,844
Amounts payable after more than one year	300,000	300,000
Other financial loans		
Other debts	300,000	300,000
IX. Amounts payable within one year	11,153,196	14,611,123
Current portion of amounts payable after one year	-	7,119,852
Other financial loans	6,633,479	724,821
Suppliers	1,291,575	3,177,696
Taxes, remuneration and social charges	28,142	388,754
Other debts	3,200,000	3,200,000
X. Accrued charges and deferred income	56,618	1,494,721
TOTAL LIABILITIES	117,830,790	105,798,624

Income Statement

(in €)	2022	2021
Operating income	1,249,949	3,151,939
Turnover	1,204,885	2,780,255
Other operating income	45,064	371,684
Operating charges	(3,750,126)	(10,765,549)
Services and other goods	(3,675,309)	(4,990,874)
Other operating charges (-)	(5,219)	(4,670)
Remunerations, social charges and pensions	69.598	-
Non-recurring operating expenses	-	(5,770,005)
Operating profit (loss)	(2,500,177)	(7,613,610)
Financial income	1,928,732	545,677
Income from financial fixed assets	363,784	368,535
Other financial income	1,564,948	177,142
Financial charges (-)	(315,341)	(310,665)
Interest on financial debts	(286,159)	(285,846)
Other financial charges	(29,182)	(24,819)
Profit (Loss) for the period before taxes (-)	(886,786)	(7,378,598)
Income taxes (-)	(16,659)	(306,299)
Profit (loss) for the period available for appropriation	(903,445)	(7,684,897)

Statutory notes

Statement of financial fixed assets

(in €)	2022	2021
Affiliated companies - Participations		
Acquisition value at the end of the preceding period	44,944,782	-
Movements during the period		
Acquisitions, included produced fixed assets	28,216,220	5,770,000
Acquisition value at the end of the period	73,161,002	44,944,782
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		
Net book value at the end of the period	73,161,002	44,944,782
Affiliated companies - Receivables		
Net book value at the end of preceding period	12,232,733	
Movements during the period		
Additions	19,328,396	3,349,045
Reimbursement	(29,460,007)	(12,877,359)
Net book value at the end of the period	2,101,122	12,232,733

Company	Participation held			Data extracted from the last available annual accounts			
	Nature	Direct		By	Annual	Currency	Capital
		Number	%	subsidiaries	Accounts at	Code	Net Profit or Loss
Hyloris Developments SA					12/31/2022	EUR	19,922,424
Boulevard Patience et Beaujonc 3							-9,643,601
4000 Liège							
Belgium							
542,737,368							
	Shares	74,066	99.99%	0%			
RTU Pharma SA					12/31/2022	EUR	(1,569,387)
Boulevard Patience et Beaujonc 3							(148,510)
4000 Liège							
Belgium							
669,738,676							
	Shares	62,000	100 %	0%			
Dermax SA					12/31/2022	EUR	3,048,235
Boulevard Patience et Beaujonc 3							276,823
4000 Liège							
Belgium							
667,730,677							
	Shares	65,875	100%	0%			
Purna Female Healthcare BV					12/31/2022	EUR	4,494,812
Schaldestraat 31							(651,101)
2880 Bornem							
Belgium							
762,693,578							
	Shares	840	20%	0%			

Deferred Charges and accrued income

(in €)	2022
Deferred Charges and accrued income	
Interest earned on receivables from related companies	1,946,679

Income and expenses of exceptional size or impact

(in €)	2022	2021
Non-recurring income		
Non-recurring expenses	-	5,770,005
Other non-recurring expenses (Renegotiation and unwinding Alter Pharma)	-	5,770,005
Other non-recurring expenses (Cost of Capital transactions)		

Statement of Amounts Payable

(in €)	2022
Analysis by current position of amounts initially payable after more than one year, maturing in 1 year	
Other debts (Shareholder loans)	-
Analysis by current position of amounts initially payable after more than one year, maturing in max 5 years	
Other debts	300,000
Tax, wage and social amounts payable	
Taxes payable	8,309
Other salary and social debts	19,833
Accrued charges and deferred income	
Accrued FX forward contracts	51,832
Accrued bonuses	4,390



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 2022

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 2022, as well as other legal and regulatory requirements. Our report is one and indivisible.

We were appointed as statutory auditor by the general meeting of 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 ended 31 December 2024. We have performed the statutory audit of the consolidated financial statements of the Group for 4 consecutive financial years.

Report on the consolidated financial statements

Unqualified opinion

We have audited the consolidated financial statements of the Group as of and for the year ended 31 December 2022, prepared 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. These consolidated financial statements comprise the consolidated statement of financial position as at 31 December 2022, 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 a summary of significant accounting policies and other explanatory information. The total of the consolidated statement of financial position amounts to EUR 61.864.000 and the consolidated statement of profit or loss and other comprehensive income shows a loss for the year of EUR 10.770.000.

In our opinion, the consolidated financial statements give a true and fair view of the Group's equity and financial position as at 31 December 2022 and of its consolidated financial performance and its consolidated cash flows for the year then ended 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.





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 2022

Basis for our unqualified opinion

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.

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 opinion.

Key audit matter

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.

Impairment of intangible assets

We refer to note 7 of the consolidated financial statements.

- Description

The Group has recognized individual intangible assets (EUR 3.607.000) relating to development costs, asset purchases and in-licensing as at 31 December 2022. These intangible assets represent products candidates that are not yet available for use. In accordance with IAS 36 *Impairment of Assets*, an impairment testing is required annually for intangible assets not yet available for use. As a result, the Group assesses whether individual intangible assets shall be impaired or not. Each individual intangible asset generates cash inflows that are largely independent of those from other assets. An impairment loss is recognized to the extent that the carrying amount of an individual intangible asset exceeds its recoverable amount, which is its value-in-use.

We have identified that the impairment of intangible assets was a key audit matter due to the level of judgement required by Management in developing a model to determine the value-in-use of each and every product candidate, as well as for the potential significant impact of impairment losses on the consolidated financial statements.



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 2022

- Our audit procedures

We performed the following procedures:

- We evaluated the process by which management's business plan per product candidate was prepared;
- We inspected relevant internal information such as board of directors' minutes and project status minutes prepared by Management and external parties engaged in the development phases of the product candidates;
- We obtained the annual impairment test and analyzed the consistency of the underlying data used in the impairment test with data from the business plan approved by the board of directors;
- We evaluated the appropriateness of Management's assessment for the determination of the value-in-use per product candidate, including the assumptions used in the discounted cash flow model and the mathematical accuracy of this model;
- We assessed whether any matters arising after the end of the reporting period were relevant to the impairment testing and management's measurement of the value-in-use supporting the carrying value of these intangible assets; and
- We assessed the appropriateness of the disclosures in respect of impairment testing, which are included in note 7 of the consolidated financial statements.

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 2022

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 2022

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 2022

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, 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, 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 which is incompatible with the statutory audit of the consolidated accounts and our audit firm remained independent of the Group during the term of our mandate.

The fees for the additional engagements which are compatible with the statutory audit 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").

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.



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 2022

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, 28 April 2023

KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises
Statutory Auditor
represented by

Olivier Declercq
Bedrijfsrevisor / Réviseur d'Entreprises



Statutory auditor's report to the general meeting of shareholders in accordance with article 4 of the EU Transparency Directive, regarding the compliance of the consolidated financial statements in the form of an electronic file of Hyloris Pharmaceuticals NV as of December 31, 2022 with the ESEF (European Single Electronic Format) requirements as per the Delegated Regulation (EU) 2019/815

Engagement

In accordance with article 4 of the EU Transparency Directive, the statutory auditor is required to report whether the format of and the tagging of information in the consolidated financial statements in the form of an electronic file (hereafter "digital consolidated financial statements") is in compliance with the ESEF requirements and the ESEF technical standards (ESEF Regulatory Technical Standard, "RTS") as laid down in the European Delegated Regulation nr. 2019/815 of 17 December 2018 (hereafter "Delegated Regulation") applicable to the digital consolidated financial statements as per December 31, 2022.

Board of directors' responsibilities

The board of directors is responsible for preparing the digital consolidated financial statements included in the annual financial report in accordance with the ESEF requirements and taxonomy applicable to the digital consolidated financial statements as per December 31, 2022.

This responsibility includes the selection and application of the most appropriate methods to prepare the digital consolidated financial statements. Moreover, the responsibility of the board of directors also includes the design, implementation and maintenance of systems and processes, that are relevant to prepare the digital consolidated financial statements that are free of material misstatement whether due to fraud or error. The board of directors needs to ensure that the digital consolidated financial statements are consistent with the consolidated financial statements presented in human-readable format.

Responsibilities of the statutory auditor

Based on our work performed, it is our responsibility to conclude whether the XBRL tagging of information in the digital consolidated financial statements of Hyloris Pharmaceuticals SA ("the Company") as per December 31, 2022 are, in all material respects, prepared in compliance with the ESEF requirements.

We conducted our procedures in accordance with International Standard on Assurance Engagements (ISAE) 3000 (Revised), "Assurance Engagements Other than Audits or Reviews of Historical Financial Information". This standard prescribes that we comply with the ethical requirements and that we plan and perform our procedures to obtain reasonable assurance that nothing has been brought to our attention that leads us to conclude that the digital consolidated



Statutory auditor's report to the general meeting of shareholders in accordance with article 4 of the EU Transparency Directive, regarding the compliance of the consolidated financial statements in the form of an electronic file of Hyloris Pharmaceuticals SA as of December 31, 2022 with the ESEF (European Single Electronic Format) requirements as per the Delegated Regulation (EU) 2019/815

financial statements have not been prepared in all material respects in accordance with the ESEF requirements applied by the Company.

The procedures selected depend on our judgment, including the assessment of the risks of material misstatements in the digital consolidated financial statements and in the declarations of the board of directors. The set of procedures performed by us included amongst others the following procedures:

- Verifying whether the digital consolidated financial statements in XHTML format were prepared in accordance with article 3 of the Delegated Regulation;
- Obtaining an understanding of the Company's processes for preparing and tagging of its digital consolidated financial statements and of the internal control measures relevant to this engagement, 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 internal control, that are designed to provide reasonable assurance whether the XBRL tagging of the digital consolidated financial statements comply, in all material respects, with the ESEF technical requirements;
- Reconciling the tagged data with the audited consolidated financial statements of the Company as per December 31, 2022;
- Evaluating the completeness and fairness of the Issuer's applied tagging of the digital consolidated financial statements;
- Evaluating the appropriateness of the Company's use of iXBRL elements selected from the ESEF taxonomy and the evaluating the establishment of the extension taxonomy.

Our independence and internal quality control

We have complied with the independence and other ethical requirements of the Belgian legislation and regulations in force in Belgium that are applicable in the context of this engagement. These are based on the fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

Our firm applies International Standard on Quality Control Management (ISQM) 1 which requires the firm to design, implement and operate a and accordingly maintains a comprehensive system of quality control management including documented policies or procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.



Statutory auditor's report to the general meeting of shareholders in accordance with article 4 of the EU Transparency Directive, regarding the compliance of the consolidated financial statements in the form of an electronic file of Hyloris Pharmaceuticals SA as of December 31, 2022 with the ESEF (European Single Electronic Format) requirements as per the Delegated Regulation (EU) 2019/815

Conclusion

In our opinion, based on our work performed, the XBRL tagging of information in the digital consolidated financial statements of the Company as per December 31, 2022 are, in all material respects, prepared in compliance with the ESEF requirements and taxonomy (especially the applicable dispositions as laid down in the ESEF technical standards).

In this report we do not express an audit opinion, review conclusion or any other assurance conclusion on the consolidated financial statements as such. Our audit opinion relating to the consolidated financial statements is set out in our statutory auditor's report dated April 28, 2023.

Other matter

The consolidated financial statements of Hyloris Pharmaceuticals SA and its subsidiaries (together 'the Group') have been prepared by the board of directors of the Issuer on April 26, 2023, and a statutory audit has been performed.

The consolidated financial statements of the Company have been prepared by the Board of Directors of the Company on April 26, 2023 and have been subject to a statutory audit. Our statutory auditor's report (signed on April 28, 2023) includes an unqualified opinion on the true and fair view of the Group's equity and financial position as at December 31, 2022 and of its consolidated financial performance and its consolidated cash flows for the year then ended prepared in accordance with IFRS Standards as issued by the International Accounting Standards Board and adopted by the European Union, and with the legal and regulatory requirements applicable in Belgium.

Liège, May 22, 2023

KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises
Statutory Auditor
represented by

Olivier Declercq
Bedrijfsrevisor / Réviseur d'Entreprises



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GLOSSARY OF TERMS

Active pharmaceutical ingredient (API)	A substance used in a finished pharmaceutical
Atherosclerosis	The build-up of fats, cholesterol and other substances in and on the artery walls. This build-up is called plaque, which can cause the arteries to narrow, blocking blood flow
Atrial Fibrillation (AF)	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
Attention Deficit Hyperactivity Disorder (ADHD)	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
Bioavailability	Assessment of the amount of product candidate that reaches the body’s systemic circulation after administration
Cardiovascular (CV)	A class of diseases that involves the heart or blood vessels
Chemistry, Manufacturing and Controls (CMC)	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. These activities are known as CMC
Dose-range finding study	Phase 2 clinical study exploring the balance between efficacy and safety among various doses of treatment in patients. Results are used to determine doses for later studies
Food and Drug Administration (FDA)	The agency responsible for protecting and promoting public health and in charge of American market approval of new medications
FSMA	The Belgian market authority: Financial Services and Markets Authority, Or Autoriteit voor Financiële Diensten en Markten; Autorité des Services et Marchés Financiers
Full-Time Equivalent (FTE)	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
HY-004	Previously known as HY-REF-004, a liquid formulation of an established product for use following a specific dental procedure, to address a non- disclosed acute issue or possible procedural related complications
HY-016	Previously known as HY-EMP-016, a high barrier generic of an off-patent reference product currently sold in the U.S. without generic competition
HY-029	Previously known as HY-REF-029, a liquid formulation of an existing antiviral drug that is currently only available in oral solid form to treat a non-disclosed viral infection
HY-038	Previously known as HY-REF-038, a prefilled syringe of a commonly used product to treat a specific, non-disclosed deficiency
HY-073 and HY-074	Previously known as HY-CVS-073, HY-CVS-074, IV formulations of oral antiplatelet drugs, offering faster onset of action in patients suffering from coronary heart disease
HY-075	Previously known as HY-CVS-075, a liquid formulation of a commonly used drug for the treatment of coronary heart disease requiring frequent dose adjustments
Initial Public Offering (IPO)	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.

Intellectual Property (IP)	Creations of the mind that have commercial value and are protected or protectable, including by patents, trademarks or copyrights
Intramuscular (IM)	A technique used to deliver a medication deep into the muscles. This allows the medication or vaccine to be absorbed into the bloodstream quickly
Intravenous (IV)	Some medications must be given by an IV injection or infusion, meaning these medications are administered directly into the veins using a needle or tube
Key Opinion Leader (KOL)	An influential physician or researcher who is held in high esteem by their colleagues
Investigational New Drug (IND)	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 Food and Drug Administration (FDA) to begin these trials
In vivo	Animal models of disease
Net Present Value (NPV)	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
New Chemical Entity (NCE)	A compound, without any precedent among the regulated and approved drug products
Pharmacokinetics (PK)	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
Phase 1 studies	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
Phase 2 studies	Second stage of clinical testing of a investigational drug, usually performed in < several hundreds patients in order to determine efficacy, tolerability and drug dose
Phase 3 studies	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
Pivotal studies	Registrational clinical studies
QT interval	A measurement made on an electrocardiogram used to assess some of the electrical properties of the heart. It is calculated as the time from the start of the Q wave to the end of the T wave, and approximates to the time taken from when the cardiac ventricles start to contract to when they finish relaxing. An abnormally long or abnormally short QT interval is associated with an increased risk of developing abnormal heart rhythms and sudden cardiac death
Ready-to use (RTU)	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
Reference listed pharmaceutical drug (RLD)	An approved drug product to which new generic versions are compared to show that they are bioequivalent
Return on Investment (ROI)	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
Torsade de Pointes	An uncommon and distinctive form of polymorphic ventricular tachycardia (VT) characterised by a gradual change in the amplitude and twisting of the QRS complexes around the isoelectric line. Torsade de pointes, often referred to as torsade, is associated with a prolonged QT interval, which may be congenital or acquired. Torsade usually terminates spontaneously but frequently recurs and may degenerate into ventricular fibrillation
Visual Analog Scale Pain (VAS) Score	a validated, subjective measure for acute and chronic pain. Scores are recorded by making a handwritten mark on a 10-cm line that represents a continuum between “no pain” and “worst pain”

FINANCIAL CALENDAR

June 13, 2023

General Assembly

September 7st, 2023

Half-year results 2023

CONTACT

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DISCLAIMER AND 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.

Forward-Looking Statements

Certain statements in this annual report are “for- ward-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.

Note



Hyloris Pharmaceuticals SA

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