

#### **REINVENTING EXISTING MEDICATIONS**

# Annual report

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This Annual Report 2021 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 different sections of this Annual Report.

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Consolidated Financial Statements

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Business Overview р. З

# **10 1**

#### 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<sup>®</sup> 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 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.

Hyloris employs 21 people (9 women and 12 men) of 6 nationalities.



#### Specialty biopharma



**Broad pipeline** With 16 innovative products of which 2 approved products



In Europe (Belgium) and US Founded in 2012 at the heart of Europe.



Strong IP and knowhow Own lab and extensive KOL & partners network



Listed

Hyloris is listed on the Euronext Brussels Stock Exchange (HYL:BB) Market cap year-end 2021: about € 450 mio

#### **Corporate Social** Responsibility

Hyloris is committed to develop, manufacture, and deliver therapies to address major clinical unmet needs across a wide range of therapeutic areas, in addition to ensuring socially responsible behaviour benefiting the community in a broader context and aligning with the high expectations of our stakeholders. Stakeholders include employees, patients, regulators, suppliers, shareholders, the community and the environment. 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. Hyloris' priority CSR focus areas over the short term have been identified as delivery of safe products to patient, and fostering of a positive employee environment and culture.

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



# Commercial launch of **2 products**

#### The commercialization of two partnered products was our main business success in 2021.

- Sotalol IV is a new patented intravenous (IV) solution for the treatment of atrial fibrillation, which is marketed by our partner AltaThera in the US. Compared to the original drug, the new indication of Sotalol IV can significantly reduce the length of hospital stay and potentially significantly reduce the overall cost of care, while improving patient outcomes and safety.
- Maxigesic<sup>®</sup> IV, a new patented treatment that meets the urgent need for nonopioid pain treatments in the post-operative hospital environment. Without the 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<sup>®</sup> IV is developed with our partner AFT Pharmaceuticals.

# 4 new product candidates

Four new product candidates (women's health, cardiovascular, oncology and acute pain in interstitial cystitis/bladder pain syndrome) were added.

#### February

Miconazole + Domiphen Bromide (MCZ/DB): Through a development and commercialization deal with Purna Female Healthcare, 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.

#### October

Hyloris acquires the global rights from the Baker Heart and Diabetes Institute (Melbourne, Australia) to **CRD-102** (and related intellectual property), a novel, clinical-stage, extended-release Milrinone capsule in **late-stage heart failure** (HF) patients with an implanted left ventricular assist device (LVAD) who have developed right HF.

#### November

Plecoid agents. Through its global exclusive co-development rights and future joint commercialization rights with Pleco Therapeutics, Hyloris will co-develop a chelating agent or agents - chemical compounds that capture metal ions - to detoxify the cancer promoting cellular micro-environment and improve the effectiveness of chemotherapy in patients with acute myeloid leukemia (AML) and small cell lung cancer (SCLC).

#### December

Hyloris enters into strategic partnership with Vaneltix Pharma, Inc. for the development and commercialisation of **Alenura**<sup>™</sup> as first-line drug treatment for **acute pain in interstitial cystitis / bladder pain syndrome** (IC/BPS).

#### **New talents**

Hyloris has strengthened:

- its R&D team with new talents,
- its top senior management team with the appointment of Thomas Jacobsen as Chief Business Development Officer and Jean-Luc Vandebroek as Chief Financial Officer, and
- its Board with the appointment of Chris Buyse, as an independent member of the Board of Directors. Chris is an experienced investor, currently Managing Director of Fund+, the largest Belgian life science venture capital fund.

#### Post-closing event

#### April

Hyloris successfully raises **EUR 15 million** in an equity offering by means of a private placement via an accelerated bookbuild offering.

#### Dear Shareholders.

Hyloris enters 2022 emboldened by a remarkable year in which we were laserfocused on executing on our strategy of developing innovative drug assets for core unmet medical needs in cardiovascular medicine and other segments. The past year validated our business model of delivering pragmatic and commercially attractive medical advances via the 505(b)(2) pathway while consistently growing shareholder value, and facilitated Hyloris' recent successful capital raise during a challenging period for the biotech and life science sector.

We achieved our key objective for 2021 with the addition of **four new products** to the Hyloris portfolio in women's health,

cardiovascular, oncology and acute pain in interstitial cystitis/bladder pain syndrome. These exciting and innovative products stem from Hyloris' highly effective opportunity assessment process and exemplify our route to value through pragmatic and cost-efficient development. Each program addresses a clear unmet need and brings value to patients, physicians and payers. These four new product candidates also signal a refocused strategy: while retaining a cost-efficient product development **approach**, we have increased the emphasis on drug repurposing, in which we find a **new** therapeutic use for an already known drug. We believe this strategy will bring Hyloris greater value both clinically and commercially.

> Our pipeline continues to be guided by a methodical, unmet medical needs-driven assessment typically covering in excess of

opportunities per year.

> **Stijn Van Rompay CEO** Hyloris

#### **Commercialisation of** 2 partnered products

Our main business success in 2021 was the commercialization of our two partnered products -Sotalol IV for the treatment of atrial fibrillation and Maxigesic<sup>®</sup> IV for the treatment of postoperative pain. We saw the retier smooth rollout of Sotalol IV in the U.S., with our partner AltaThera significantly expanding its sales force, while Maxigesic® IV achieved a series of licensing deals, filings, approvals and launches throughout 2021. It is now licensed in over 100 countries across the world, with marketing authorization in 33 countries and has been launched in seven markets.

Our pipeline continues to be guided by a methodical, unmet medical needs-driven assessment typically covering in excess of 100 opportunities per year. In 2021, we secured laboratory space to further streamline our development processes and more effectively capitalize on internal resources, placing greater emphasis on our own Research and Development capabilities. The implementation of mitigating measures across the portfolio has largely ensured that Hyloris' clinical programs have not been materially impacted by Covid-19. The company's commercial objectives remain firmly on track.

At the End of March 2022, the Company successfully raised €15.0 million gross from new and existing local and international investors through a private placement at a tight discount to Hyloris' prevailing market price. We will use the net proceeds primarily to fund the development of new products and accelerate in-house R&D activities.

We have strengthened Hyloris' senior management team in the past year with the appointments of Thomas Jacobsen as Chief Business Development Officer in February 2021, and of Jean-Luc Vandebroek as Chief Financial Officer in September 2021. Our corporate governance structure has been augmented with the addition of Chris Buyse, an experienced investor and currently Managing Director of Fund+, to the Board of Directors.

#### Outlook 2022

We expect to carry the momentum of 2021 into 2022, adding at least a further **four product candidates** that meet our stringent 7-7 criteria - development in less than 7 years for less than €7 million on average. We will continue building our commercial network through product out-licensing across our growing portfolio. The key commercial milestone for Hyloris for 2022 is the registration and rollout of Maxigesic® IV in the U.S., where

we see significant potential due to the opioid epidemic. The U.S. Food and Drug Administration is expected to make its decision on our New Drug Application on 30 June 2022, and we are looking forward to working with regulators during the review process and to further executing on our global commercial rollout together with our partners.

We would like to take this opportunity to thank our shareholders, partners and our employees for their continued support. We can look back on 2021 with pride at our achievements given challenging circumstances. We will continue our efforts to attain further important clinical and commercial milestones, boosting the commercial value of existing assets and acquiring new, promising product candidates. We look forward to updating you on the exciting developments ahead.



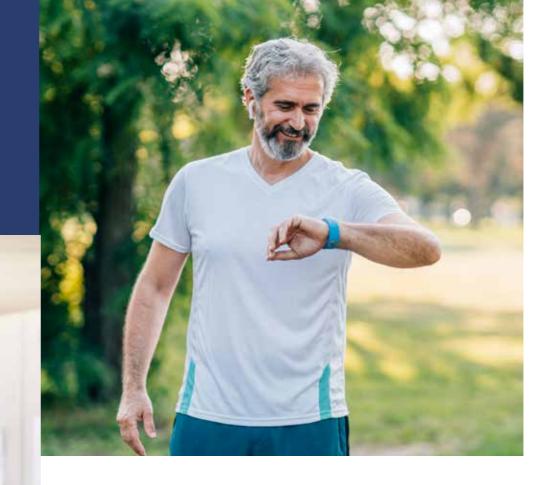
**Stefan Yee** Chairman Hyloris



# key figures 2021

Hyloris portfolio: each program addresses a clear unmet need and brings value to patients, physicians and payers.

products 505(b)(2)



laboratory facilities in Liège, Belgium, bringing drug formulation and analytical activities in-house to further streamline processes and accelerating the R&D activities.

#### **Financial highlights**

		Year ended
(in € thousand)	2021	2020
Revenues	3,096	175
Research and development expenses	(5,056)	(3,413
General and administration expenses	(2,900)	(2,194
Shares' issuance related expenses	-	(1,468
Other operating result	(5,381)	2
Operating result	(10,541)	(7,025
Net financial result	(741)	(120)
Income Taxes	(297)	
Result for the period	(11,579)	(7,145
Net operating cash flow	(11,250)	(4,570
Cash and cash equivalents	50,012	64,399





products commercialized: Sotalol IV for the treatment of atrial fibrillation and Maxigesic<sup>®</sup> IV for the treatment of postoperative pain.

#### Hyloris \_ Annual Report 2021





million raised since foundation Not including the €15 million raised in April 2022.



ed 31 December 20 Variance 75 1,669% 13) 48% 13) 32% 14) 32% 15) -25,724% 15) 50% 10) 518% 15) 62% 10) 146% 16) 99 -22% p. 11

## Business overview

#### **2021 MAJOR ACHIEVEMENTS**

#### STRONG FOUNDATION SET FOR FUTURE GROWTH

#### 4 new innovative product candidates

Underlining the incremental lean and mean value-creation of Hyloris, the company announced the successful addition of four new innovative product candidates to its portfolio during 2021. Each of the product candidates addresses a clear unmet need and has the potential to bring substantial value to patients, physicians and payors.

 February 2021: Miconazole + Domiphen Bromide (MCZ/DB): Through a development and commercialization deal with Purna Female Healthcare, 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. MCZ/DB has a strong scientific and business rationale. A Phase 2 clinical trial is ongoing with results expected in H2 2022.

• October 2021: CRD-102 (modified release Milrinone capsule): a novel, clinical-stage, extended-release long term use Milrinone capsule in late-stage heart failure (HF) patients with an implanted left ventricular assist device (LVAD). Heart failure 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. Earlier studies have demonstrated that treatment with CRD-102 resulted in improved quality of life and functional status of latestage HF patients and it has the potential to address the current unmet needs of latestage LVAD patients with right HF. Orphan drug designation has been granted in the



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



- **O**mio
- November 2021: Plecoid agents: Through its global exclusive co-development rights and future joint commercialization rights with Pleco Therapeutics, Hyloris will co-develop a chelating agent or agents chemical compounds that capture metal ions - to detoxify the cancer promoting cellular micro-environment and improve the effectiveness of chemotherapy in patients with acute myeloid leukemia (AML: 160,000 patients<sup>1</sup> globally) and small cell lung cancer (SCLC: which accounts for approximately 13-15%<sup>2</sup> of 2 million cases of lung cancer per year). Previous studies demonstrate that elevated levels of toxic metals are associated with inferior survival in patients with AML. Exploratory clinical studies are currently ongoing in AML patients to evaluate the metal rebalancing effect of chelating agents administered concomitantly with chemotherapy.
- December 2021: Alenura™: Hyloris' strategic collaboration with Vaneltix Pharma aims to develop and commercialize Alenura<sup>™</sup>, a patented, innovative, clinical-stage bladder instillation product candidate that combines lidocaine<sup>3</sup> in a new alkalinized form with heparin. Thanks to the novel dual mode-of-action, Alenura<sup>™</sup> has the unique potential to i) immediately



relieve pain, and ii) augment the mucous layer of the bladder. The product candidate treats acute pain in interstitial cystitis/ bladder pain syndrome (IC/BPS), a condition that affects at least 6 million<sup>4</sup> people in the U.S.

Currently, there are 3 million instillation procedures per year in the US. A Phase 2 clinical trial is expected to start by mid-2022 with results potentially available by late 2023.

#### Strengthened our internal capabilities and management team

The Company appointed Thomas Jacobsen as as Chief Business Development Officer and Jean-Luc Vandebroek as Chief Financial Officer.

#### Further expanded our Board of Directors

Chris Buyse has been appointed as independent director and member of the Audit Committee.

Increased roll out of

commercial products

During the year 2021 and in the first

distribution agreement was signed

The PDUFA date has been set on

with Hikma (LSE: HIK.L) for the

commercialization in the U.S.

• The marketing authorizations

countries including: Israel,

Greece and Norway.

have been granted in additional

Panama, Albania, South Korea,

UK, Cyprus, France, Luxembourg,

Denmark, Iceland, Ireland, Italy,

• The submission has been done

in further countries including :

Thailand, Hong-Kong, Malaysia,

Pakistan, Oman, Bahrain,

• An exclusive license and

June 30, 2022.

quarter 2022:

#### US, Spain, Netherlands, Canada and Mexico.

- Maxigesic<sup>®</sup> IV, a novel, unique combination for the treatment of post-operative pain is currently licensed to partners covering over 100 countries across the globe. the near future.
  - granted.

Sotalol IV, a novel, patented, IV formulation of oral Sotalol for the treatment of atrial fibrillation. and life-threatening ventricular arrhythmias developed for the U.S.:

- The significant expansion of AltaThera's sales force mid 2021 has been setup in order to accelerate the commercial rolldrug formularies.
- The post expansion sales of access to hospitals but mitigating measures have been implemented.





- Datamonitor Healthcare April 2021; Leukemia & Lymphoma Society, 2019; WHO classification of AML, 2016
- Medscape Abid Irshad, MD Associate Professor, Department of Radiology, Medical University of South Carolina College of Medicine
- 3 Lidocaine is a local anesthetic that works by causing temporary numbness/loss of feeling in the skin and mucous membranes; Heparin is a component of the mucous layer of the bladder wall and is an anticoagulant (blood thinner) that prevents the formation of blood clots
- 4 Data on the female population is from the RAND Study: J Urol. 2011 August, 186(2): 540–544. doi:10.1016/j. juro.2011.03.132

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

• The product has been launched in 4 additional markets : Germany, Austria. South Korea and Panama. More launches are expected in

The additional patents have been

out and the inclusion in hospital

performance has been impacted by COVID 19-related restrictions

• Currently Sotalol IV is investigated in two clinical studies. The first study is investigating a shorter loading regimen and is expected to be completed in 2022. The second study is a patient registry capturing real-world experience on loading and is expected to be completed in 2023.

#### **Repurposing and** reformulation

The new innovative product candidates added in 2021 reflect a continued shift in emphasis for Hyloris on repurposing of existing drugs reaching beyond reformulation. Repurposing is the development of a pharmaceutical product, based on a well know molecule, but in a completely new indication. Repurposing can have important business advantages, it represents a more robust business strategy which is anchored in the demands of the healthcare system that are reflected in the unmet medical needs of patients, physicians and payors.

Data on the male population is from the RICE Study: J Urol. 2013 January, 189(1): 141–145. doi:10.1016/j.juro.2012.08.0



# strategy and strengths

Our core focus and mission

are to address underserved medical needs and bring added value to the healthcare system

#### COMMITTED TO ADDRESSING UNDERSERVED NEEDS THROUGH INNOVATION

Our core focus and mission are 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 and reformulated to repurposed patented products, thereby further moving up the value chain.

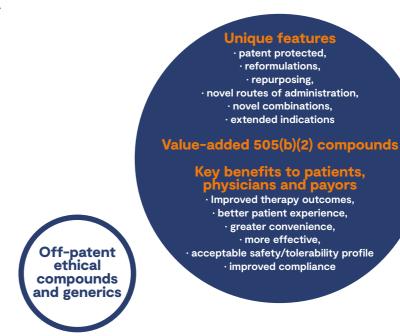
Our development strategy primarily utilizes the 505(b)(2) regulatory pathway in the U.S. and similar pathways in other countries, which are specifically designed for pharmaceutical agents for which the safety and efficacy

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.



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



Development cost

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

New chemical patent protected, entities novel routes of administration,

#### ans and payors

Improved therapy outcomes, · better patient experience, · greater convenience, · more effective, improved compliance

Time

**Continuously growing** diversified product portfolio

#### characterized by:

Fast market adoption · Maximized ROI Addressing clear unmet needs Large potential

#### 7-7 technical feasibility criteria strategy

development in  $\leq$  7 years for ≤ €7 million on average

marketed products - via partners in the U.S. and RoW

#### Network

In-depth discussions with physicians and partners to uncover underserved needs Acquisitions and in-licensing Scouting for strategic fits on an opportunistic basis

#### Real-world data and surveys Polling KOLs and payors to find solvable problems and assess appetite for potential solutions needs

#### FDA-approvable off-label utilisation

Uncovering usage opportunities for indications that are not included in the current package insert

#### Desk research

Conducting extensive market studies and comparing utilisation patterns and labels for pharmaceuticals p. 19



#### 505(b)(2)

differentiating product in the pipeline and growing exponentially across various stages of development and indications

 Repurposing and reformulating approved pharmaceuticals to develop innovative drug assets for core unmet medical needs



#### The key elements of our strategy

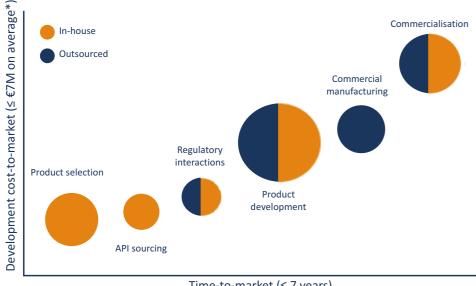
 Build a portfolio of patented, complex, proprietary value-added products that address underserved medical needs by primarily utilising the capital and time efficient 505(b)(2) regulatory pathway in the U.S. (and similar pathways in other countries).

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



#### Time-to-market ( $\leq$ 7 years)

Note: bubble size indicates relative amount of Hyloris time and capital required to complete \* Hyloris' budget API: active pharmaceutical ingredient

#### · Build a diversified and growing product pipeline across various stages of development.

Our ambition is to fuel the pipeline with the addition of four new product candidates on average per year, resulting in a steadily growing pipeline across various stages of development and commercialisation with the goal to have 30 key assets by 2024 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 longterm 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 cardio- vascular products in the U.S. are employed by hospitals, we believe we will be able to commercialise our cardiovascular portfolio in a costefficient manner with our own small sales force in U.S.

More notably, there are currently 6,146 hospitals and less than 33,000 cardiologists in the U.S., with more than 70% of cardiologists employed by target sub- segments for the promotion of our products such as an estimated 3,200 electrophysiologists in Sotalol IV, which is partnered non-partnered cardiovascular product candidate, Dofetilide IV (for the treatment of atrial fibrillation).

For our other product the return on investment, Sotalol IV and Maxigesic<sup>®</sup> IV, we already have agreements with strategic partners for the and AFT Pharmaceuticals respectively.

hospitals. We will commercially the U.S. (with the exception of with AltaThera and HY-075 which has potential in the larger retail market). We expect to have our U.S. specialist sales force on the ground when we are closer to the anticipated approval of our first,

candidates, we intend to remain flexible and assess the optimal commercialisation strategy on a case-by-case basis to maximise including potential commercial opportunities outside the U.S. For our existing commercial products, marketing, sale and distribution of these products, i.e. AltaThera

#### 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<sup>®</sup> IV and Sotalol IV will be the primary drivers of short-term revenue growth until additional products are launched.

For the majority of our partnered products (with the exception of Sotalol IV, Maxigesic<sup>®</sup> 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 prefer to retain more product sales related income.

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

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:

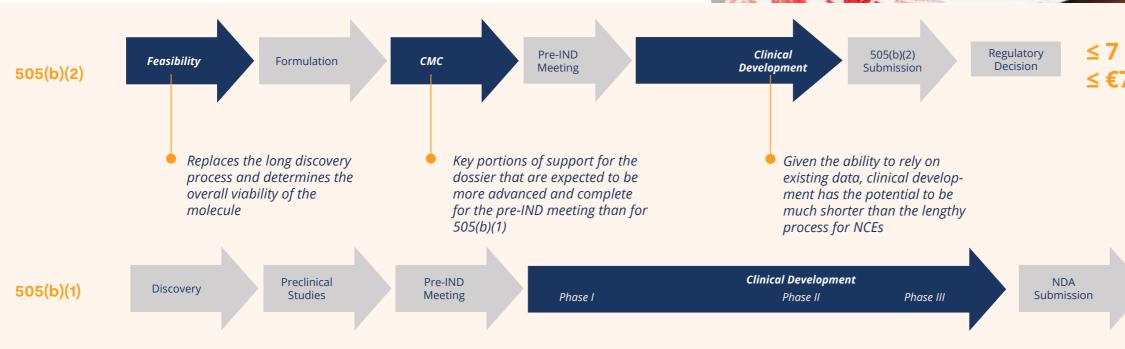
- Lower formulation risk: developing new formulations of drugs that are extensively described and documented (both clinically and chemically) reduces potential formulation issues
- · Lower clinical and regulatory risk: reformulating approved and marketed pharmaceutical agents will usually have higher probability of clinical success and regulatory approval as clinical development can usually be reduced to a single bridging study to the reference listed pharmaceutical drug (RLD)

 Shorter development timelines: on average 3 to 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 (including manufacturing) through to submission for approval
- Lower commercial risk: as 505(b)(2) products reference 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







#### ≤ 7 years ≤ €7 million on average





Source: Wouters et al, Journal of the American Medical Association, 2020

#### **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<sup>®</sup> 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.

the coming years.

Product	Route of Administration	Indication	Formulation and Manufacturing	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		<u> </u>
Aspirin IV U.S.	IV	Acute coronary syndrome				
Milrinone	Extended Release Capsule	Advanced heart failure (LVAD)				6
Dofetilide IV	IV	Atrial fibrillation				
Metolazone IV	IV	Congestive heart failure				<u> </u>
HY-074	IV	Acute coronary syndrome				6
HY-075	Oral Liquid	Coronary heart disease				
OTHER VALUE-ADDE	ED PORTFOLIO			Up to 7 years		
Maxigesic <sup>®</sup> IV	IV	Post-operativepain	Licensed in >10	00 countries /partnered with AFT Pharm	naceuticals	6
HY-004	Oral Liquid	Specific dental indication				
Miconazole-DB	Topical	Severe and rVVC				
Plecoid™ Agent	IV	AML/SCLC				
Alenura™	PFS	IC / PBS				
Atomoxetine	Oral Liquid	ADHD				<b>₩</b>
HY-029	Oral Liquid	Viral infection				

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

Aspirine IV U.S. is formerly known as HY-073; RTU: ready to use; IM: intra-muscular 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

→ Our goal is to fuel the pipeline with at least 4 new product candidates in 2022 with the ambition to have 30 key assets by 2024.

We want to become the market leader in number of 505(b)(2) value-added products over



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

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#### 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 CARDIOVASCULAR PORTE Sotalol	Route of Administration	IP	Indication	Potential Added V
	Â	'34-'38; granted	AF	Shorter hospital s
		54- 56, granieu	AF	facilitate antiarrhy
Aspirin IV U.S.		'38; granted	Coronary heart disease	Shorter hospital s antiarrhythmic the
Milrinone	â	Orphan indication	Advanced heart failure (LVAD)	Fast onset of action and concomitant
Dofetilide IV		'39; pending	AF	Fast onset of action interaction risk; th unconscious
Metolazone IV		'38; pending	Congestive heart failure	Fast onset of action and concomitant
HY-074		Confidential	Coronary heart disease	Fast onset of action interaction risk; th unconscious
HY-075	â	Confidential	Coronary heart disease	Possibility for drug control
OTHER VALUE-ADDED PO	RTFOLIO			
Maxigesic <sup>®</sup> IV		'30-'38; granted & pending	Pain	Highly effective no relief
HY-004	â	'39; granted & pending	ND	Address acute iss dental offices
Miconazole-DB	Ø	'38; granted & pending	sVVC/rVVC	Dual MOA; addres
PlecoidTM		IP; pending	AML/SCLC	A novel oral formu chemotherapy for and small cell lung
AlenuraTM	PFS	IP; '25-'38; granted & pending	IC/PBS	Ready-To-Use sol vesicular administ
Atomoxetine	â	'36; granted & pending	ADHD	Possibility for drug control; improved
HY-029	â	Confidential	Viral infections	Ease of administra

ND = non-disclosed

#### d Value

Il stay; fast onset of action; lower overall healthcare cost; rhythmic therapy for patients unable to swallow tablets

Il stay; lower overall healthcare cost; facilitate therapy for patients unable to swallow tablets

ction (essential in critical care) ; improved drug absorption nt treatment possible

ction (essential in critical care) with low drug-drug therapy possible in patients who are nauseous or

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ction (essential in critical care) with low drug-drug therapy possible in patients who are nauseous or

rug titration, ease of administration and indicated dosage

e non-opioid; tolerable profile; dual MOA; greater pain

issues or possible procedural related complications in

ressing population for whom there is no cure available

mulation of a chelator for adjunct therapy to for patients suffering from acute myeloid leukaemia (AML) ung cancer (SCLC)

solution for instillation via a pre-filled syringe for intraistration

rug titration, ease of administration and indicated dosage ed compliance and convenience

stration and dosage control; improved compliance and

#### **Our commercial portfolio**

1. Sotalol IV for the treatment of atrial fibrillation

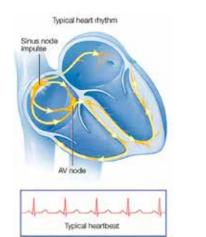
Atrial fibrilla tion (AF): a life-threatening cardiovascular disease

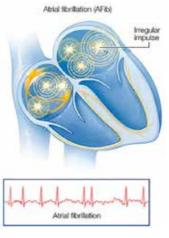
Atrial fibrillation is a quivering or irregular heartbeat (arrhythmia) that can lead to blood clots, stroke, heart failure and other heart-related complications.

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. 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.





If left untreated, majority of AF patients

will die within 5 years

AF is associated with a

five-fold increase in the risk of a stroke<sup>2</sup> and a

three-fold increase in the risk of heart failure<sup>3</sup>

following onset of symptoms.

U.S. prevalence expected to **double** to 12 million by 2030<sup>1</sup>

Source: Mayo Cli nic

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

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

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 year<sup>4</sup>

Leila et al, 2011, Stroke Prevention in Nonvalvular Atrial Fibrillation

Kim et al, 2011, AHA Journal

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 like warfarin or heparin, antiplatelet drugs like aspirin, and fibrinolytics like 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 2019, about 730 million tablets and capsules of rhythm control drugs were sold in the U.S. with amiodarone and sotalol leading the space with 30% and 29% market share, respectively<sup>5</sup>.

Despite their common use, both oral sotalol and oral dofetilide 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 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 potential solution: Sotalol** IV: an innovative, patented, IV formulation of oral 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, a novel IV formulation was developed that has potential to replace the current Inisian IV leading regimair, C ..., antineved to M

of Sotalol IV.

Oral sotalo

ding reg 2 % days to reach

dy-state blood lew

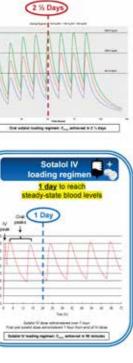
standard loading /drug initiation regimen. Sotalol IV is administered by an infusion pump over one hour at a constant infusion rate and has a rapid onset of action enabling the transition from acute IV administration to chronic oral therapy. This new procedure of starting with Sotalol IV and then transitioning 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.

#### A survey with U.S. electrophysiologists and cardiologists conducted in 2018. indicated that Sotalol IV has potential to capture about 18% of new patients who are administered an arrhythmic drug, thereby confirming the substantial potential

#### **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 new 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.



Centres for Disease Control and Prevention

Dipak Kotecha and Jonathan P. Piccini, Eur Heart J. 2015

#### 2. Maxigesic<sup>®</sup> IV for the treatment of post-operative pain \$442M peak sales potential in U.S., Japan and EU5<sup>6</sup>

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 postoperative 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.

Although acute pain is predictable after operations, the management of postoperative 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:

#### 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



#### 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 nearly 50,000 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<sup>®</sup> IV: an innovative, patented. IV formulation of Paracetamol plus Ibuprofen to combat the opioid crisis

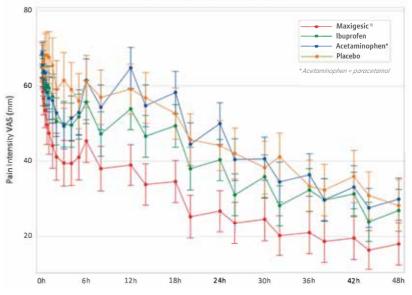


Injectable formulations of analgesics are typically used when patients are unable to take oral medications, when faster onset of analgesia is required, or when it is more convenient to administer drugs in the injectable form. Hospitalised patients may be unable to take oral medications for a variety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

Maxigesic<sup>®</sup> IV is a novel and unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion for use postoperatively 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<sup>®</sup> 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, doubleblind, placebo-controlled Phase 3 trial in 276 patients following bunion surgery demonstrated that Maxigesic<sup>®</sup> 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.



p. 31

#### → Maxigesic<sup>®</sup> IV has the potential to become a valuable pain treatment option without the side effects and risk of addiction associated with opioids.

Moreover, the superior analgesic effect of Maxigesic<sup>®</sup> 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)<sup>10</sup>. An additional exposure study has demonstrated Maxigesic<sup>®</sup> IV's efficacy and safety in an expanded population group over a longer treatment period<sup>11</sup>.

2021 achievements

Hyloris' partner AFT Pharmaceuticals launched Maxigesic<sup>®</sup> IV in New Zealand, Australia and the United Arab Emirates. Maxigesic<sup>®</sup> IV was launched in Germany, Austria, South Korea and Panama by licensing partners. To date, the product has obtained approval in 33 countries, several launches are pending and it is licensed in more than 100 countries. A new drug application has been submitted to the FDA with a PDUFA date of June 30<sup>th</sup> 2022.

Mean Estimates & 95% Confidence Intervals

Delvelnsight market study (EU5: France, Germany, Italy, Spain, UK) (includes Maxigesic® in oral form)

Colev K et al. J Clin Anesth, 2002

Wonuk Koh et al, Korean J Anesthesiol. 2015

IQVIA and Delvelnsight Market Research

<sup>10</sup> Daniels et al, 2019, Clinical Therapeutics

Maxigesic® IV Phase 3 exposure study. Study ID No AFT-MXIV-11. NCT04005755. Submitted for publication

**>** 

Our cardiovascular product pipeline includes six 505(b) (2) reformulated product candidates in various stages of development.



#### Our cardiovascular product pipeline targeting multi-billiondollar 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 2023.

We intend to build out our own commercial organisation in the U.S. focused on specialist cardiac electrophysiologists in specialty care centers and hospitals, and it is estimated that with a small sales force, it will be feasible to address the prescribers of our cardiovascular products.

Product	Indication	Unmet N
Dofetilide IV	Atrial fibrillation, a life-threatening cardiac condition expected to affect >12 million people in the U.S. by 2030.	On avera hospital dofetilide longer th on oral s
	See also section on Sotalol IV.	

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 relief, h U.S. expected to suffer from CHF by 2030.12

> By 2030, the total cost of heart failure is forecasted to reach \$69.8 rates.<sup>14</sup> billion.13

> > To add can be combir diuretic like diu metola tablet highly and err particu severe oedema.

12 Benjamin et al, Circulation, 2019

AHA association
 Ellison et al, NEJM 2017

Unmet Needs	Our Potential Solution
On average, the duration of hospital stay required for dofetilide oral dosing is even longer than that of patients on oral sotalol.	Based on the similarities between sotalol and dofetilide, we have adopted a very similar development strategy for Dofetilide IV, which is currently only available as an oral capsule. We will therefore develop Dofetilide IV and propose a new loading dose strategy based on the same scientific rationale with a faster loading followed by oral therapy. As a result, patients should reach steady state of dofetilide faster, reducing hospitalisation duration. An IV formulation of dofetilide can create 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 <i>Torsades de Pointes</i> happen gradually. In other words, the loading related risk is different.
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. <sup>14</sup> 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	We are developing an intravenous formulation of metolazone for the U.S. 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.

	Product
se e ., n	

American Heart Association, Heart Disease & Stroke Statistics (2016)
 Centers for Disease Control and Prevention

			С	C
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andard of care n disease severity ent of advanced ominantly palliative es the use of otropes (such as V), digoxin and well as LVADs ses, which are r longer-term lge to heart tion.

ere were about ients with an ant in the U.S. f these patients right heart failure. ext coming years, patient population d to grow at an J.S.

#### **Our Potential Solution**

Hyloris is developing a novel, patented, extended-release Milrinone formulationfor 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.

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 nual growth rate of 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.



<sup>16</sup> 17

American Heart Association, Heart Disease & Stroke Statistics (2019)

<sup>18</sup> 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, seven 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.

#### 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. <sup>19</sup>
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
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.	VVC.
Our potential solution: Miconazole-Domip	hen Bromide, a novel, dual-mode-of-action

locally administered emulsion

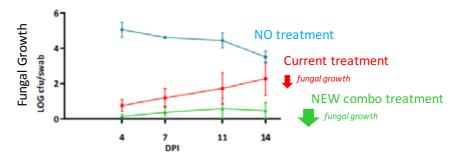
We have a partnership with Purna Female Healthcare to develop a novel, dual-modeof-action combination treatment for severe and recurrent VVC based on the current standard antimycotic treatment, Miconazole (MCZ), to which we add Domiphen Bromide (DB), a well-known anti-septic that is currently used in cough medications.



LOCAL TOPICAL FORMULATION

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 infections<sup>20</sup>. 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 IOVIA 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 effective against azole-resistant infections, addressing the high unmet needs in complicated and recurrent VVC.<sup>21</sup> 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

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.

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 disorders, thus bestowing additional challenges on these individuals.

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

#### 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

The start and results from the pivotal study of Atomoxetine Oral Liquid are anticipated later in 2022.

Current treatments and their limitations

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.<sup>23</sup>

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.

In 2019, atomoxetine had more than 2 million prescriptions<sup>24</sup> in the U.S. and the number of defiant disorder, major depressive disorder, and anxiety atomoxetine capsules sold over the past few years has grown from 88.5 million in 2016 to 99.3 million in 2019.25 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

<sup>21</sup> Manuscript for scientific paper submitted

<sup>22</sup> Sharma and Couture. Ann Pharmacother. 2014

<sup>23</sup> https://www.helpguide.org/articles/add-adhd/medication-for-attention-deficit-disorder-adhd.htm

<sup>24 &</sup>quot;The Top 300 of 2019". clincalc.com. Archived from the original on 21 November 2018. Retrieved 22 December 2018 25 IOVIA

<sup>26</sup> Van Riet-Nales DA et al. Oral medicines for children in the European paediatric investigation plans. PLoS One 2014; 9(6): e98348. 27 IOVIA

#### 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
<b>AML</b> 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 remain 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 the cause of 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 s 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 orphan indication due to lack of progress in treatment	
options in the last three decades.	
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	
•	l is an. innovative, clinical-stage product candidate that contains

The Plecoid Agent is intended for adjunctive treatment. 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.

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

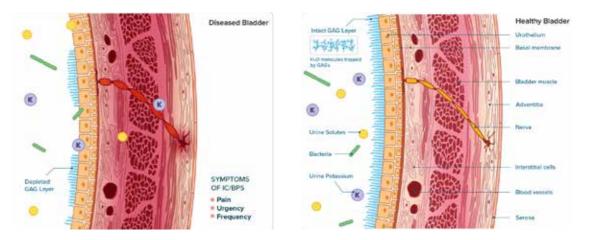
#### Indication

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 characterized by pelvic pain, urinary urgency, increased urinary frequency, discomfort and pelvic pressure.

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.

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.

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.



#### Our potential solution

Alenura<sup>™</sup> is a unique, Ready-To-Use solution for instillation via a pre-filled syringe for intra-vesicular administration and is a combination of alkalized lidocaine and heparin that have a unique collaborative effect on the GAG layer and epithelial cell layer as:

- 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 urotheliu.

- Current treatments and their limitations
- Today, there is no standardized treatment protocol and current treatmentshave clear limitations:
- Oral Elmiron (Pentosan) is the only FDA approved oral treatment, which is both very 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.



#### **High Barrier Generics Portfolio**

Outside our core strategic focus, we have four high barrier generic products in latestage development:

- 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. The Company is doing extra work for answering to FDA's questions.
- Fusidic acid cream, a generic of an offpatent reference product currently sold in Canada without generic competition, is in clinical development.
- Tranexamic acid, a ready to use Tranexamic acid solution for infusion. The product will be filed as a generic in the US and as a value-added product outside the US, where it has already been partnered in Canada, Australia and New Zealand.
- HY-038, a ready to use prefilled-syringe of a product for a specific deficiency.

HY-016 is partnered with Perrigo. 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.

#### **OUTLOOK 2022**

#### MULTIPLE VALUE INFLECTION MILESTONES AHEAD

application

- During 2022, we anticipate delivering on key value inflection milestones within our strategic focus areas:
- **Pipeline expansion**, the business development team is constantly reviewing new opportunities and expect to add at least 4 new product candidates to the pipeline, during the year of 2022
- Alenura™, start of Phase II clinical trial
- Aspirin IV, results from pivotal study
- Atomoxetine oral solution, a novel patented reformulation of Atomoxetine to allow titrated oral liquid doses of Atomoxetine for the treatment of Attention Deficit Hyperactivity Disorder (ADHD): start pivotal study
- **Dofetilide IV**, a novel, patented IV formulation of Dofetilide to allow a faster loading regimen in patients with atrial fibrillation: open pivotal study
- HY-004 oral solution (product not disclosed): results from Phase 1 PK / safety study and start of preparations for the pivotal study to support the submission of a marketing application

U.S. Submission, approval and launch of the product in a range of other markets. 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 seven 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.

With cash and cash equivalents of €50 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 by 2024. p. 41

• **HY-027 oral liquid** (product not disclosed): start and results from pivotal study to support the submission of a marketing

**Miconazole-Domiphen Bromide**: end Phase 2 dose-finding study

 Maxigesic® IV: approval of the New Drug Application by the FDA and launch of the product in the U.S. Submission, approval and launch of the product in a range of



#### CORPORATE SOCIAL RESPONSIBILITY ('CSR') – GUIDELINES

#### Introduction

Hyloris is committed to develop, manufacture and deliver innovative pharmaceutical products to address unmet medical needs in cardiovascular health, oncology, women's health and other major therapeutic areas.

The company operates to ensure socially responsible business practices combining good business ethics, a key focus on employee wellbeing and a relationship with the environment, whilst working to deliver safe, novel products to patients.

Hyloris develops innovative products to address unmet medical needs which provides additional tangible benefits to the community in a broader context. In utilizing the 505(b)(2) development pathway, this leads to shorter development timelines, costs, and risk, in addition to minimizing the need for additional early-stage R&D, and by association lower impact on the environment, including use of raw materials, energy and human effort.

Hyloris recognizes that we must integrate our business values and operations in a way so that we act responsibly in a broader social context and meet key expectations of our stakeholders. These stakeholders include employees, patients, regulators, suppliers, shareholders, the community and the environment.

We have identified the following CSR focus areas;

- a) Patient safety and wellbeing
- b) Employee culture
- c) Supply Chain Management
- d) Human rights
- e) Environmental impact
- f) Anti-Corruption
- g) Open, transparent and clear communication

#### **Ethical Guidelines**

Hyloris maintains high ethical standards in all its business practices and relationships with customers, suppliers and employees.

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

The roles and responsibilities of the Chair of the Board, the Committees of the Board, CEO, Executive Management are set out at length in Hyloris' Corporate Governance Charter, which has an expanded provision on Conflicts of Interest.

Hyloris has 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.

#### Responsibility and Review

Hyloris' Executive Team is responsible for the implementation of the CSR policy and continue to make the necessary resources available to meet our corporate responsibilities. All employees are responsible for adopting and implementing the Company's policy on CSR. The CSR Policy continues to be regularly reviewed and any amendment shall be approved by the Board of Directors.



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#### THE HYLORIS SHARE

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

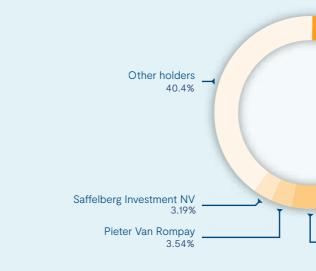
#### The Hyloris share

Performance versus sector indices since IPO on 29 June 2020



#### **Breakdown of Share Capital**

Major shareholders (status December 31, 2021)



Share capital (excluding share premium)

Total number of outstanding voting rights (= denominator)

Total number of securities carrying voting rights not yet issued

#### Analyst Coverage

Bank	Analyst	Rating
KBC Securities	Jeroen Van den Bossche	Buy
Kempen	Christophe Beghin	Buy
Berenberg	Beatrice Allen	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.

#### Hyloris \_ Annual Report 2021

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Stijn Van Rompay (Founder & CEO) 26.42%

Thomas Jacobsen (Founder & CBDO) 13.53%

Scorpiaux BV 6.69%

Nick Reunbrouck 6.23%

€129,163.16
25,832,632
1,699,500

# Corporate Governance

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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.

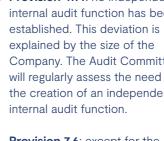
The Corporate Governance Charter describes the main aspects of the corporate governance of the Company, including its governance structure, the terms of reference of the Board of Directors and its committees and other important topics. The Corporate Governance Charter must be read together with the Company's 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 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 4.14: no independent internal audit function has been Company. The Audit Committee will regularly assess the need for the creation of an independent

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	60	Non-Executive Director Chairman of the Board of Directors	2020	2024
Mr. Stijn Van Rompay <sup>1</sup>	46	Executive Director	2020	2024
Mr. Thomas Jacobsen <sup>2</sup>	47	Executive Director	2020	2024
Mr. Leon Van Rompay <sup>3</sup>	72	Non-Executive Director	2020	2024
Mr. Marc Foidart⁴	46	Independent Director	2020	2024
Mrs. Carolyn Myers	63	Independent Director	2020	2024
Mr. James Gale	73	Independent Director	2020	2024
Mr. Chris Buyse⁵	58	Independent Director	2021	2025

- Acting through SVR Management BV
- Acting through Jacobsen Management BV
- Acting through Van Rompay Management BV Acting through Noshaq Partners SCRL
- 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 Imcvse). 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



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**



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



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

Thomas Jacobsen has over 20 years of experience in the pharmaceutical industry, with

Leon Van Rompay has

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 currently 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., a privately held 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, EyeD Pharma SA and FendX Technologies. 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 Dev 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., Leon-Nanodrugs GmbH, 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

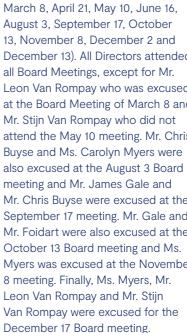
that invests in innovative life sciences companies primarily active in therapeutics. as well as companies developing diagnostics and medical devices.

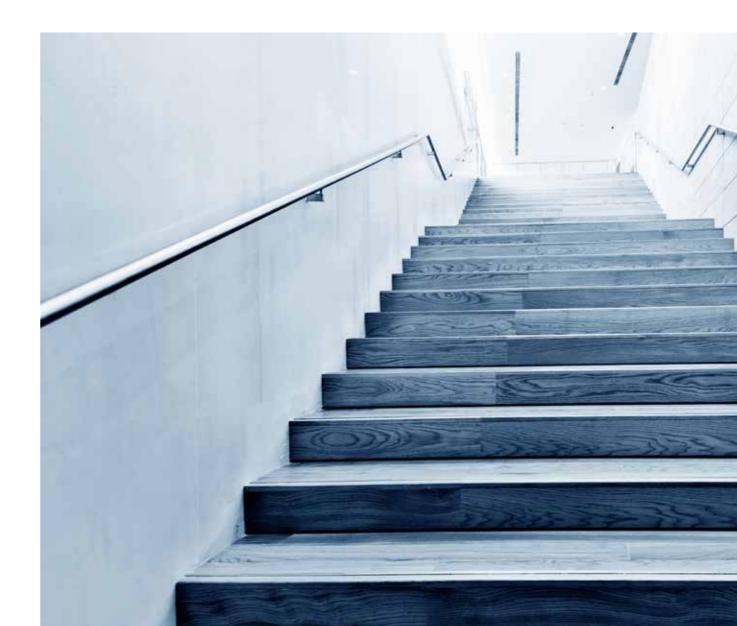
He has more than 30 years of experience in international company finance and in running and establishing best financial practice. He was previously CFO of ThromboGenics NV (currently Oxurion), CropDesign and Keyware Technologies and he held several financial positions at Suez Lyonnaise des Eaux and Unilever. He is currently serving as an independent Board Member of a few companies, mostly active in life sciences such as Celvad, Inventiva Pharma and EyeD Pharma.

#### **Activity Report**

In 2021, in addition to discussing the financial reporting and the operational development of the Company, the Board of Directors devoted a deal of attention to product development and business development, considering further expansion of the Company's growth and strategy. Moreover in 2021, The Board of Directors was convened 2 times 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.

The Executive and Non-Executive members of the Board of Directors convened twelve times in 2021 (January 27, February 17,





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December 13). All Directors attended Leon Van Rompay who was excused at the Board Meeting of March 8 and attend the May 10 meeting. Mr. Chris Mr. Chris Buyse were excused at the September 17 meeting. Mr. Gale and Mr. Foidart were also excused at the Myers was excused at the November

#### **Committees of** the Board of Directors

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

#### Audit Committee

The Audit Committee comprises the following members:

#### > Mr. Marc Foidart<sup>6</sup>.

Independent Director, Chairperson of the Audit committee

Mr. Stefan Yee, Non-Executive Director

#### > Mr. James Gale, Independent Director

> Mr. Chris Buyse<sup>7</sup>, Independent Director

According to Article 7:99, §2 CCA of the Belgian law, all members of the Audit Committee must be Non-Executive Directors, and at least one member must be an Independent Director. The members of the Audit Committee must have a collective competence in the business activities of the Company, and at least one member of the Audit Committee must have the necessary competence in accounting and auditing.

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.

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 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 2021: on March 05, August 02 and December 16.

#### 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 Foidart<sup>8</sup>, 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 longterm 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 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 of members of Executive Committee; and

the Annual General Shareholders'

attention is paid to the succession

• ensure that appropriate talent development programs and programs 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 four times in 2021: on February 23, March 18, August 6 and October 19.

#### **Scientific Committee**

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

Acting through Noshaq Partners SCRL competence in accounting and auditing. Acting through Pienter Jan BV

#### **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 2021, the Executive Committee consisted of the following members:

> Mr. Stijn Van Rompay<sup>9</sup>, Chief Executive Officer

- > Mr. Thomas Jacobsen<sup>10</sup>. Chief Business Development Officer
- > Mr. Jean-Luc Vandebroek<sup>11</sup>, Chief Financial Officer
- Mr. Dietmar Aichhorn, Chief Operating Officer
- > Mr. Koenraad Van der Elst<sup>12</sup>, Chief Legal Officer

#### Stijn Van Rompay



Stiin 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 \$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 ioined the Company in

September 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 Bone Therapeutics and observer in the Board of Auxin Surgery.

#### **Dietmar Aichhorn**



has more than 20 years of experience in the pharmaceutical

Dietmar Aichhorn

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 more than 35 years 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 January 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.

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



Acting through SVR Management BV

<sup>10</sup> Acting through Jacobsen Management BV; Responsible for IP, regulatory and commercial partnerships. As from March 1, 2021, Mr. Jacobsen acts as Chief Business Development Officer

<sup>11</sup> Acting through Finsys Manager ment BV

<sup>12</sup> 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 22 April, 2022 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 Board requests the Remuneration Committee to evaluate the overall remuneration packages of Executive Directors, Non-Executive Directors, and Hyloris' employees. The Remuneration Committee consults and engages the Board on this subject matter. The Remuneration Committee takes into consideration all the information on its workforce remuneration, its knowledge and research data about the relevant job market to ensure that all Hyloris employees are remunerated in a marketconform 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., performancerelated pay such as bonuses.

Hyloris does not grant shares to Non-Executive Directors11<sup>13</sup>. 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 marketcompetitive 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 longterm remuneration elements. The short-term remuneration elements have a fixed part (please see Fixed remuneration, p. 66) (i.e., a base annual remuneration in cash) and a variable part (please see Variable remuneration, p. 66) (cash bonus). As for the long-term remuneration elements, the Executive Committee members can receive Stock options (please see Stock options, p. 69).

Variable remuneration can be granted if the criteria set out in Variable remuneration, p. 66 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 principles that apply to granting any variable remuneration are the following:

- 1. Granting allows for a certain part to an individual's performance and to the performance of Hyloris. It also allows for the optimally to that of Hyloris, the Shareholders and other stakeholders.
- 2. Granting is driven by the individual's merits and based on the performance-rating system at Hyloris, that is, the (Personal Targets) and the overall performance of Hyloris (Corporate Targets).
- related to progress in Hyloris' research activities, corporate development and budgetary requirements. The Corporate Targets focus on company

of the remuneration to be linked individual's interest to be aligned

achievement of individual targets

3. Corporate Targets include factors

growth and value creation for all shareholders.

- 4. For the Executive Committee members (but not the CEO), the variable remuneration consists of two components:
- the first component represents 60% of the variable remuneration and is determined based on Personal Targets achieved;
- the second component represents 40% of the variable remuneration and is determined based on the Corporate Targets achieved by Hyloris.
- 5. For the CEO, the variable remuneration also consists of two components:
- the first component represents 25% of the variable remuneration and is determined based on the average of the Personal Targets achieved by the other members of the Executive Committee.
- the second component represents 75% of the variable remuneration and is determined based on the Corporate Targets achieved by Hyloris.
- 6. The Targets are set annually. The Board sets the Corporate Targets for all Executive Committee members and considers the recommendations made by the Remuneration Committee. The CEO's Personal Targets are set by the Board upon the Remuneration Committee's recommendation. which are made based on the Chairman's proposal. The Personal Targets of other Executive Committee members are set by the CEO.
- 7. The total target variable remuneration amount for an **Executive Committee member** (i.e., the sum of the first and second components described

these warrants to be variable compensatior

above) represents maximum 25% of the total fixed annual remuneration of an Executive Committee member.

- 8. The variable remuneration is paid only if the Personal and Corporate Targets are effectively met. The extent to which the CEO has achieved his Personal Targets is evaluated by the Remuneration Committee at the end of the year. The evaluation is subject to deliberation and final decision by the Board. The extent to which the other Executive Committee members have achieved their Personal Targets is evaluated by the CEO at the end of the year, which is de-liberated by the Remuneration Committee and finally decided by the Board. Appraisal is based on a weighted average of the achievement rate of the Personal Targets.
- 9. Variable remuneration, if any, is paid after approval by the Board of Directors. Recuperation mechanisms of the variable remuneration are set forth in Remuneration of Non- Executive Directors, p. 70.

Article 7:91 of the BCCA reads: "Unless otherwise provided for in the articles of association or expressly approved by the shareholders' meeting, at least one-quarter of the variable remuneration of an executive director in a public-listed company must be based on predetermined and objectively measurable performance criteria over a period of at least two years, and another quarter must be based on predetermined and objectively measurable criteria over a period of at least three years."

The Articles of Association of a company can deviate from Article 7:91 of the BCCA, which is what Hyloris has done. Article 7:91 also states that the above principles do not apply if the variable part of the remuneration does not exceed 25% of the total yearly remuneration. Therefore, the rules on variable remuneration laid down in Article 7:91 of the BCCA do not apply. 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. Stiin 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 threemonth 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 threemonth 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 threemonth 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, nonperformance of the consultancy services for 25 consecutive days, etc.).

In the event of termination of the services agreement, the agreement provides for a noncompete 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 sixmonth period. The agreement also provides for reasons for immediate termination because of a breach by either party (e.g. serious contractual breach, bankruptcy, insolvency, nonperformance 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 threemonth 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 threemonth 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.

#### **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
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
Term	5 years	10 years
Vesting Period	The 2019 plan is subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month).	The 2020 plan is subject to services conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month).
Exercise	Warrants which are definitively acquired ("vested") may be exercised from the first (1) of January of the fourth (4 <sup>th</sup> ) 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 <sup>th</sup> ) 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 longterm value creation.

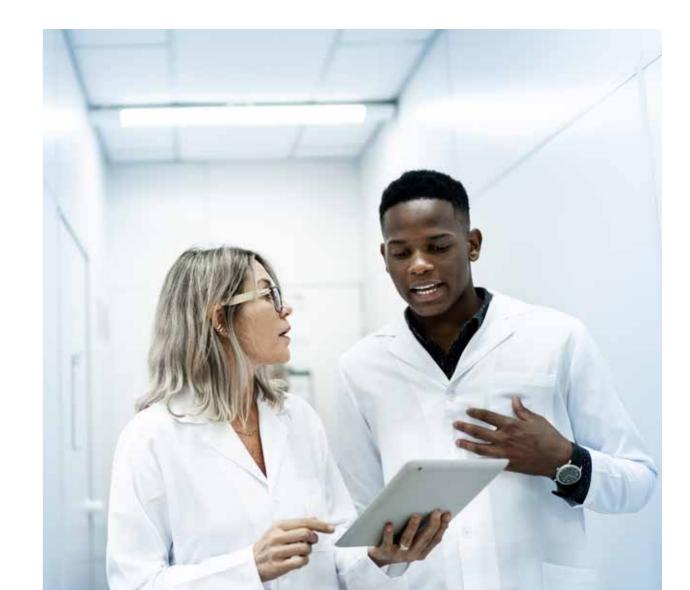
#### Clawback

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 The CEO and Executive Committee Regarding the remuneration of Non-

#### **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.

#### Remuneration

#### **Remuneration of Non-Executive** Directors

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

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

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

Name	Remuneration
Mr. Stefan Yee	22,500
Mr. Leon Van Rompay <sup>14</sup>	12,500
Mr. Marc Foidart <sup>15</sup>	22,500
Mrs Carolyn Myers	17,500
Mr. James Gale	17,500
Mr. Chris Buysse	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 of the Board of Directors at December 31, 2021.

		Warrants <sup>16</sup>
Name	Number	%
Mr. Stefan Yee	100,000	5.88%
Mr. Leon Van Rompay <sup>14</sup>	0	0%
Mr. Marc Foidart <sup>15</sup>	0	0%
Mrs. Carolyn Myers	0	0%
Mr. James Gale	0	0%
Mr. Chris Buysse	0	0%
TOTAL	100,000	5.88%

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 2021, the following remuneration and compensation was paid or accrued to the		CEO (i.e., Mr. Stijn Van Rompay) and the other nembers of the Executive Committee of Hyloris:	
In €	CEO	Autres membres du Comité exécutif <sup>16</sup>	
Annual base salary	180,000	620,340	
Annual variable salary	30,000	77,067	
Supplementary pension plan (defined contribution	n.a.	n.a.	
Car lease / transport allowance	n.a.	n.a.	
Medical plan	n.a.	n.a.	

The 2021 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 7-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 22<sup>nd</sup>, 2022 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.

#### **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 22<sup>nd</sup>, 2021. Including the achievement of the goals with respect to product development and business development. These objectives were indeed the main objectives for the CEO and the other members of the executive management for 2021.

The Remuneration Committee determined that the corporate objectives for 2021, had not always been fully achieved, especially for product development. Not meeting these objectives however has not had a material impact on the operations of the company. The variable remuneration for 2021 has considered the contributions of the members of the Executive Committee made to these achievements.

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<sup>14</sup> Acting through Van Rompay Management BV 15 Acting through Noshaq Partners SCRL

<sup>16</sup> Calculated as % of all outstanding warrants (1,699,500 warrants outstanding as at December 31, 2021)

#### 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.

#### **Risks related to Hyloris' business** activities and industry

Hyloris' 2021 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<sup>®</sup> IV respectively. Additionally, Hyloris' product candidates could be subject to labelling and other marketing restrictions 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 geopolitical 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.

#### **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 December 31, 2019, KPMG Réviseurs d'Entreprises BV/ SRL has been appointed as statutory auditor of the Company for a period of three years. The mandate will expire at the end of the general meeting called to approve the accounts for the 2021 financial year. KPMG Réviseurs d'Entreprises SRL has designated Olivier Declercq, réviseur d'entreprises, as permanent representative. A new mandate for the next 3 years will be submitted to general meeting for approval.

In 2021, a total amount of 172 K€ was paid to the statutory auditor. This amount includes the following elements: 62 K€ for audit fees, and 7 k€ for audit related services legally assigned to the statutory auditor and € 103 thousand 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 vet 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.

- The company has developed a monthly reporting tool which allows a close monitoring of the financial information. The company has a monthly reporting of the actual spending.
- Information systems have been developed to assist the company and are constantly being adjusted to meet new needs as they arise.
- External financial reports are produced twice a year (half year reports ended 30 June and full year reports ended 31 December).
- Half-year and full-year reporting are discussed by the audit committee and all critical accounting issues and financial uncertainties are reported and discussed.

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

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

In 2021, the Company made the following improvements in its internal processes:

- additional development in the budgeting and forecasting process
- additional functionalities in the approval system for expenses
- additional functionalities in the payroll system.

#### 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 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 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.

is in conflict with a decision or transaction that falls within the

Executive Management position,

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

#### **Board of Directors of May** 10.2021

Before the start of the deliberation, SVR Management BV and its permanent representative Mr. Stijn Van Rompay and Jacobsen Management BV, represented by its permanent representative Mr. Thomas Jacobsen, declared having a potential conflict of interest, as defined in Article 7:96 of the Belgian Code on Companies and Associations.

This conflict of interest had arisen from the fact that SVR Management BV and its permanent representative Mr. Stijn Van Rompay and Jacobsen Management BV, represented by its permanent representative Mr. Thomas Jacobsen both had a direct or indirect financial interest with the decision to be taken by the Board of Directors for the modification of the contractual and business arrangements between Hyloris (or one of its affiliates) and Alter Pharma Group NV, a public limited liability company ("naamloze vennootschap") under Belgian law, with registered offices at Marie Curiesquare 50, 1070 Anderlecht, Belgium (or one of its affiliates) (referred to as 'APG'). Because of the relationship between on the one hand SVR Management BV and its permanent representative Mr. Stijn Van Rompay and Jacobsen Management BV, represented by its permanent representative Mr. Thomas Jacobsen and, on the other hand Alter Pharma Group, Alter Pharma Group was also considered a related party within the meaning of Article 7:97 of the Code of Companies and Associations.

More specifically, the Board of Directors had to decide on the following:

- The modification of the Patent and Know-How Licence Agreement dated 22 May 2012, with respect to Maxigesic<sup>®</sup> IV as follows: the obligation of Hyloris to pay to APG a 15% royalty on net revenues received by Hyloris under the present agreement shall be cancelled and replaced by a payment by Hyloris to APG of up to €5.5 million, thereby also waiving al past obligations towards the Alter Pharma Group and its affiliates.
- The modification of the various existing agreements with respect to HY-028 (no longer in development), HY-075, and HY-038 as follows: Hyloris shall continue to bear all development costs but will be released from any fees, expenses or other payments to APG (and hence will no longer have to split the future profit with APG on these products), while APG shall be released from any past and future obligations to develop these products. APG owes Hyloris a net product refund balance of €645,150.
- The modification of the License Agreement and Special Agreement dated 28 June 2019, with respect to Fusidic Acid cream in Canada whereby APG transfers to Hyloris the right to receive a 50% net profit share from Basic Pharma, its current co-development partner, with respect to sales in the Canadian market, against a one-time lump sum of €250,000 paid by Hyloris to APG.

The Board was of the view that the decisions were taken and fit within the context of the Company's corporate interest. The Executive Directors did not participate in the deliberations or the vote on these items on the agenda. In compliance with the Article 7:96 of the Belgian Code of Companies and Associations, the Company's statutory auditor was informed of these conflicts of interest.

#### Board of Directors of December 13, 2021

Before the start of the deliberation, Ms. Carolyn Myers declared having a potential conflict of interest, as defined in Article 7:96 of the Belgian Code on Companies and Associations. Because of the relationship between Ms. Carolyn Myers, Independent Director of the Company, and Mr. Dan Vickery, CEO and shareholder of Vaneltix. Vaneltix Pharma Inc and its affiliates were also considered a related party within the meaning of Article 7:97 of the Code of Companies and Associations.

This conflict of interest had arisen from the fact that Ms. Myers had a direct or indirect financial interest with the decision to be taken by the Board of Directors to approve the transaction between the Company and its affiliates and Vaneltix Pharma Inc. and its affiliates ("Vaneltix") with respect to (i) the co-development for a combination product containing Lidocaine and Heparin, with the aim to develop one or more pharmaceutical product(s) approvable by the regulatory agencies around the world for treatment of all patients suffering from interstitial cystitis/bladder pain syndrome, and (ii) a loan granted by Hyloris to Vaneltix for an amount of 500,000 USD at an interest rate of 6% (and in any case no less than the interest rate paid by Vaneltix to any unaffiliated third party for a (convertible) loan) in exchange for which Vaneltix granted to Hyloris an exclusive right to enter into a final collaboration and co-development agreement between Parties with respect to VNX002 (a glucagon like peptide 2 treatment of IC Bladder Lesions). Vaneltix Pharma Inc. is a corporation incorporated under the laws of the State of Delaware (United States of America) having its registered office at 305 East High Street. Suite 7. Bound Brook, NJ 08805 (United States of America).

The Board was of the view that the decisions were taken and fit within the context of the Company's corporate interest. Ms. Carolyn Myers did not participate in the deliberations or the vote on these items on the agenda. In compliance with the Article 7:96 of the Belgian Code of Companies and Associations, the Company's statutory auditor was informed of these conflicts of interest.

#### 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 authorized capital without limitation or cancellation of the preferential subscription right of the existing shareholders.

#### Transactions with Related Parties

At two occasions, the Board of Directors of Hyloris has applied the procedure set forth in Articles 7:96 and 7:97 CCA, a first time on May 10, 2021 with respect to a certain number of arrangements between Hyloris and Alter Pharma, and a second time on December 13, 2021 with respect to a transaction between Hyloris and Vaneltix. All these transactions with related parties are described in more detail in Chapter Market Abuse Regulations.

#### **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.

## SHARE CAPITAL, SHARES AND SHAREHOLDERS

#### History of Capital – Capital Increase and Issuance of Shares

# Securities Issued by the Company

On June 30, 2020, the share capital was increased by a contribution in cash further to the completion of the initial public offering of the Company, in the amount of  $\leq$ 61,812,500 (including issue premium) with issuance of 5,750,000 new ordinary shares. The new shares were issued at a price of  $\leq$ 10.75 per share (including issue premium). Following this capital increase, the capital of the Company amounted to  $\leq$ 117,758.84 (excluding issue premium) and was represented by 23,551,768 ordinary shares.

On the same day, the share capital was increased further to the conversion of the "cross-over" convertible bonds, in the amount of €15,358,025 (including issue premium) with issuance of 2,040,864 shares. The new shares were issued at a price of €7.525 per share (including issue premium). Following this capital increase, the capital of the Company amounted to €127,963.16 (excluding issue premium) and was represented by 25,592,632 ordinary shares.

On July 31, 2020, the share capital was increased by contribution in cash further to the exercise of the over-allotment subscription right, in the amount of €2,580,000 (including issue premium) with issuance of 240,000 shares. The new shares were issued at a price of €10.75 per share (including issue premium).

At December 31, 2021, the Company's capital amounted to €129,163.16 (excluding issue premium) represented by 25,832,632 ordinary shares without nominal value.

The Company created three 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 and December 2020.

- ESOP Warrants: the Company has issued a total of (i) 363,300 ESOP warrants (under the 2019 ESOP plan of December 2019), (ii) and 400,000 ESOP warrants (under the ESOP plan of November 2020):
- Under the 2019 ESOP plan, a total of 353,000 warrants were granted and accepted (with a total of 40,000 warrants being lapsed).
- Under the 2020 ESOP plan, a total of 186.500 ESOP warrants were granted and accepted (with a total of 213.500 warrants being lapsed).
- Transaction warrants: the Company has issued 300,000 transaction warrants which give right to subscribe to four new shares at a subscription price per share of €2.3597 per share. The transaction warrants have a term of five years and are freely transferable. All 1,200,000 transaction warrants were attributed and can be exercised.

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).

#### **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).

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 €110,920.13 (as of 1 April 2022, 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 three 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 and November 2020.

#### 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.

Each transaction warrant entitles its holder to subscribe for four new shares at a subscription price per share of €2.3597 per share. The transaction warrants have a term of five years and are freely transferable. They are not subject to a vesting mechanism (i.e., the transaction Warrants are immediately acquired in a final manner). The new shares (if any) that will be issued pursuant to the exercise of the transaction warrants will be ordinary shares representing the capital, of the same class as the existing shares, fully paid up, with voting rights and without nominal value. They will have the same rights as the existing shares and will entitle their holder to the dividend distributed in the financial year during which the relevant transaction warrants are exercised, even if the dividend was declared or has been paid prior to the issuance of such new shares, including, in particular in respect of any new shares that would be issued upon exercise of transaction warrants in 2020 (if any), any distributions in relation to the financial year that started on January 1, 2020, as the case may be.

#### **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.

The 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 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 1/48<sup>th</sup> 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 ESPOP warrants held by the (former) members of the Executive Committee at the date of December 31. 2021

		Shares
Name	Number	%17
Mr. Stijn Van Rompay <sup>18</sup>	6,824,304	26.42%
Mr. Thomas Jacobsen <sup>19</sup>	3,493,993	13.53%
Mr. Koenraad Van der Elst <sup>20</sup>	27,443	0.11%
Mr. Jean-Luc Vandebroek <sup>21</sup>	0	0%
Mr. Dietmar Aichhorn	0	0%
		ESOP warrants
Name	Number	%22
Mr. Stijn Van Rompay <sup>18</sup>	68,000	13.61%
Mr. Thomas Jacobsen <sup>19</sup>	0	0%
Mr. Koenraad Van der Elst <sup>20</sup>	50,000	10.01%
Mr. Jean-Luc Vandebroek <sup>21</sup>	40.000	8.08%
Mr. Dietmar Aichhorn	40,000	8.08%

**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 takeover 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.

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

<sup>17</sup> Calculated as % of total number of voting rights at 31 December 2021 (25,832,632)

<sup>18</sup> Acting through SVR Management BV19 Acting through Jacobsen Management BV

<sup>20</sup> Acting through Herault BV

<sup>21</sup> Acting through Finsys Management BV

<sup>22</sup> Calculated as % of total number of warrants accepted at the date of this annual report (499,500)

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

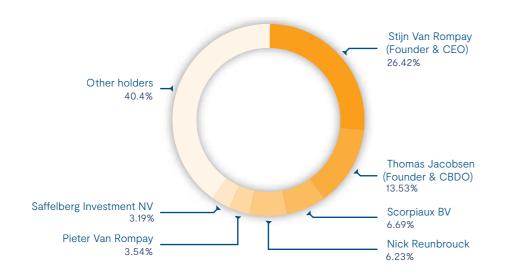
#### **Major Shareholders**

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):



At December 31, 2021, there are 25,832,632 ordinary shares representing a total share capital of the Company of €129.163.16 (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. There are also 300.000 transaction warrants granted, entitling its holders to a total of 1,200,000 ordinary shares. 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.

#### **Dividends and Dividend** Policv

#### **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 In accordance with Belgian law, the dividends is subject to availability right to collect dividends declared of sufficient distributable profits as on ordinary shares expires five defined under Belgian law based vears after the date the Board of Directors has declared the dividend on the Company's stand-alone payable, whereupon the Company statutory accounts prepared in accordance with Belgian GAAP. is no longer under an obligation to In particular, dividends can only pay such dividends. be distributed if following the **Dividend Policy** declaration and issuance of the dividends the amount of the Company's net assets on the date The Company has not declared or of the closing of the last financial paid dividends on its shares in the year as follows from the statutory past. Any declaration of dividends non-consolidated financial will be based upon the Company's statements (i.e., summarized, the earnings, financial condition, capital amount of the assets as shown requirements and other factors in the balance sheet, decreased considered important by the Board with provisions and liabilities, all in of Directors. Belgian law and the accordance with Belgian accounting Company's Articles of Association do not require the Company to rules), and, save in exceptional cases, to be mentioned and declare dividends. justified in the notes to the annual accounts, decreased with the non-Currently, the Board of Directors amortized costs of incorporation of the Company expects to retain and extension and the nonall earnings, if any, generated by amortized costs for research the Company's operations for the and development, does not fall development and growth of its business and does not anticipate below the amount of the paid-up capital (or, if higher, the issued paying any dividends to the capital), increased with the amount shareholders in the foreseeable of non- distributable reserves future. (which include, as the case may In the future, the Company's be, the unamortized part of any revaluation surpluses). In addition, dividend policy will be determined and may change from time to time pursuant to Belgian law and the Company's Articles of Association, by determination of the Company's the Company must allocate an Board of Directors. 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.

# Consolidated Financial Statements

## STATEMENT OF THE BOARD OF DIRECTORS

On April 27, 2022, 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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# CONSOLIDATED FINANCIAL STATEMENTS AS AT 31 DECEMBER 2021

## **Consolidated Statement of Financial Position**

ASSETS (in € thousand)	Note	31 December 2021	31 December 2020
Non-current assets		9,485	2,569
Intangible assets	7	2,944	2,381
Property, plant and equipment		122	24
Right-of-use assets	8	173	152
Investments in associates and joint ventures	9	4,079	-
Financial assets	10	453	12
Other non-current assets	12	1,714	-
Current assets		53,959	66,613
Trade and other receivables	11	2,321	253
Other financial assets	10	528	7
Other current assets	12	1,098	1,954
Cash and cash equivalents	13	50,012	64,399
TOTAL ASSETS		63,444	69,182

EQUITY AND LIABILITIES (in € thousand)	Note	31 December 2021	31 December 2020
Equity	14	48,056	59,059
Share capital		129	129
Share premium		103,693	103,693
Retained earnings		(54,805)	(43,226)
Other reserves		(960)	(1,537)
Liabilities		15,388	10,123
Non-current liabilities		409	7,991
Borrowings	15	109	106
Other financial liabilities	15	300	7,885
Current liabilities		14,978	2,132
Current borrowings	15	65	46
Other current financial liabilities	15	11,815	409
Trade and other liabilities	16	2,749	1,629
Current tax liabilities	23	349	47
TOTAL EQUITY AND LIABILITIES		63,444	69,182

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	2021	2020
Revenues	18	3,096	175
Cost of sales		(107)	(145)
Gross profit		2,988	30
Research and development expenses	19	(5,056)	(3,413)
General and administrative expenses	19	(2,900)	(2,194)
Shares issuance related expenses	19	0	(1,468)
Earnings/losses from Associates and joint ventures	9	(191)	
Other operating income	21	389	21
Other operating expenses	19	(5,770)	-
Operating profit/(loss) (EBIT)		(10,541)	(7,025)
Financial income	22	32	901
Financial expenses	22	(773)	(1,021)
Profit/(loss) before taxes		(11,282)	(7,145)
Income taxes	23	(297)	(1)
PROFIT/(LOSS) FOR THE PERIOD		(11,579)	(7,145)
Other comprehensive income		-	-
TOTAL COMPREHENSIVE INCOME OF THE PERIOD		(11,579)	(7,145)
Profit/(loss) for the period attributable to the owners of the Company		(11,579)	(7,145)
Profit/(loss) for the period attributable to the non-controlling interests			-
Total comprehensive income for the period attributable to the owners of the Company		(11,579)	(7,145)
Total comprehensive income for the period attributable to the non- controlling interests			-
Basic and diluted earnings/(loss) per share (in €)		(0.45)	(0.33)
Number of share		25,832,632	21,818,814

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

	Attributable to equity holders of the Company				Attributable to equity holders of the Company			olders of the Company Total Equity		
	Share capital	Share premium		Other reserves						
(in € thousand)			Share based	Cost	Other					
			payment reserve	of Capital	reserves					
Balance at 31 December 2019	89	23,982	1,329	-	493	(36,081)	(10,188)			
Initial public offering	30	64,363		(3,725)	-	-	60,668			
Issuance of convertible bonds				-	4,531		4,531			
Conversion of convertible bonds	10	15,347		(102)	(4,585)	-	10,671			
Amortised costs on shareholders loans	-	-		-	37	-	37			
Share-based payments	-	-	485	-	-	-	485			
Total comprehensive income	-	-			-	(7,145)	(7,145)			
Balance at 31 December 2020	129	103,693	1,814	(3,827)	476	(43,226)	59,059			
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			

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

## **Consolidated Statement of Cash Flows**

(in € thousand)	Note	2021	2020
CASH FLOW FROM OPERATING ACTIVITIES			
Profit/(loss) for the period		(11,579)	(7,145)
Adjustments to reconcile net loss to net cash provided by operating activ	ities:		
Depreciation, amortisation and impairments	19	137	581
Equity settled share-based payment expense	19	576	485
Cost of equity transactions	19		1,468
Interest expenses on convertible bonds			208
Amortized costs on shareholders loans		198	(139)
Borrowing costs on IPRD			(43)
Losses from Associates and joint ventures		191	
Other non-cash adjustments		(1)	(17)
Changes in working capital:			
Trade and other receivables		(2,068)	81
Other current and non-current assets		(771)	1,246
Trade and other liabilities		1,138	(1,398)
Other current and non-current financial liabilities		623	103
Other current and non-current liabilities		301	(1)
Cash generated from operations		(11,253)	(4,571
Taxes paid		3	·
Net cash generated from operating activities		(11,250)	(4,570)
CASH FLOW FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment		(107)	-
Purchases of Intangible assets	7	(954)	(623)
Proceeds (from disposal) of intangible assets		219	
Investments in associates and joint ventures	9	(1,270)	-
Acquisition of other financial assets		(21)	(10)
Repayment received from other financial assets		216	
Payment of other financial assets		(1,157)	
Other			-
Net cash provided by/(used in) investing activities		(3,075)	(633)
CASH FLOW FROM FINANCING ACTIVITIES			
Reimbursements of borrowings and other financial liabilities			(8,050)
Proceeds from borrowings and other financial liabilities			3,250
Reimbursements of borrowings		(62)	(51)
Net proceeds from Initial Public Offering			59,254
Net proceeds from convertible bonds			14,994
Net cash provided by/(used in) financing activities		(62)	69,397
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		(14,387)	64,194
CASH AND CASH EQUIVALENTS at beginning of the period		64,399	205
CASH AND CASH EQUIVALENTS at end of the period, calculated		50,012	64,399

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

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#### 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 Gustave Kleyer 17, 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, commercialstage products: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic<sup>®®</sup> 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.

The consolidated financial statements were authorized for issue by the Board of Directors on April 27, 2022.

## 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### 2.1 BASIS OF PREPARATION

These consolidated financial statements of the Group for the year ended December 31, 2021 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, 2021. 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 2021

The following new IFRS standards, interpretations and amendments have been applied to the IFRS financial statements closed on 31 December 2021:

 Amendments to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16 - Interest Rate Benchmark Reform
 Phase 2 (effective January 1, 2021): the Amendments aim to assist companies in providing useful information to investors about the effects of interest rate benchmark reform on financial statements.

 Amendment to IFRS 16 Leases: COVID-19-Related Rent Concessions beyond 30 June 2021 (applicable for annual periods beginning on or after 1 April 2021 endorsed in the EU).

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

The following IFRS standards, interpretations and amendments that have been issued but that are not yet effective, have not been applied to the IFRS financial statements closed on 31 December 2021:

- 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 recognize 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

- Amendments to IAS 1 Presentation of Financial statements: Classification of Liabilities as Current or Non-current (effective January 1, 2023, but not yet endorsed in EU): These amendments 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.
- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies (effective January 1, 2023, and endorsed in EU). These amendments aim 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.
- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (effective January 1, 2023, and endorsed in EU). These amendments 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.
- Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction (effective January 1, 2023, but not yet endorsed in EU). These Amendments clarify 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 recognize assets or liabilities for the first time. Previously, there had been some uncertainty about whether the exemption applied to transactions such as leases and decommissioning obligations—transactions for which companies recognize both an asset and a liability. The amendments clarify that the exemption does not apply and that companies are required to recognize deferred tax on such transactions. The aim of the amendments is to reduce diversity in the reporting of deferred tax on leases and decommissioning obligations.

The Company does not expect that the above mentioned IFRS pronouncements will have a significant impact on the 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 unrealized gains on transactions between group companies are eliminated. Unrealized 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 recognizes 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 recognized 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 recognized in profit or loss as incurred.

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

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

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

The Group elected the accounting policy choice to 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 recognized 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 noncontrolling 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.

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#### **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 recognized 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 31,2020	1.2271	1.1142
December 31,2021	1.1326	1.1196

#### **2.5 INTANGIBLE ASSETS**

#### **Research and development**

#### Internally-generated research and development

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

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

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

- (i) the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- (ii) the intention to complete the intangible asset and use or sell it;
- (iii) the ability to use or sell the intangible asset;

- (iv) how the intangible asset will generate probable future economic benefits;
- (v) the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- (vi) the ability to measure reliably the expenditure attributable to the intangible asset during its development.

With respect to the technical feasibility condition, 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 recognized as an asset in the balance sheet within intangible assets as incurred. Similarly, some clinical trials, for example those undertaken to obtain a geographical extension for a molecule that has already obtained marketing approval in a major market, may in certain circumstances meet the above capitalization criteria, in which case the related expenses are recognized as an asset in the balance sheet within intangible assets.

The cost of an internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria. The cost of an internallygenerated 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 capitalized as intangible assets provided that the following conditions are met:

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

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

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

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

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

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

Non-refundable advance payments for goods and services that will be used in future research 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 recognized on the statement of financial position when the following conditions are met:

- 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 nonrefundable 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 derecognized 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 recognized in profit or loss when the asset is derecognized.

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

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 recognized immediately in profit or loss, unless they are directly attributable to qualifying assets, in which case they are capitalized.

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

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

#### 2.10 REVENUE RECOGNITION

Revenue includes royalty revenue, license revenue and revenue from sale of goods or services.

In accordance with IFRS 15 – Revenue from Contracts with Customers, revenue from the rendering of services is recognized 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 recognized 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 commercialized 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 recognized 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 recognized 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 recognized at a point in time.

For sales- or usage-based royalties that are attributable to a license of IP, the amount is recognized at the later of:

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

#### 2.11 FINANCIAL ASSETS

The Group classifies its financial assets in the following categories: financial assets at fair value 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 Trough 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.

All financial assets not classified as measured at amortised costs 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 is would not meet this condition. In making this assessment, the Group considers:

- Contingent events that would change the amount or timing of cash flows;
- Terms that may adjust the contractile coupon rate, including variable-rate features,

- Prepayment and extension features; and
- Terms that limit the Group's claim to cash flows from specified assets (e.g. non-recourse features).

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

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

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

Financial assets at amortized 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 recognized from initial recognition of the receivables.

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

The Group derecognizes a financial asset only when the contractual rights to the cash flows from the asset expire, or when it transfers the financial asset and substantially all the risks and rewards of ownership of the asset to another entity. If the Group neither transfers nor retains substantially all the risks and rewards of ownership and continues to control the transferred asset, the Group recognizes its retained interest in the asset and an associated liability for amounts it may have to pay. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognize the financial asset and also recognizes a collateralized borrowing for the proceeds received.

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

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

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

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

Grants that intend to compensate costs are released as income when the subsidized 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 recognized in profit or loss of the period in which they become receivable.

#### Recoverable cash advances

With respect to recoverable cash advances (RCA – "avances récupérables"), the RCA gives rise to a financial liability in the scope of IFRS 9 – Financial Instruments. This financial liability is initially measured at fair value and any difference with the

cash to be received from the authorities is treated as a government grant in accordance with IAS 20 – Accounting for Government Grants and Disclosure of Government Assistance. Subsequent to the initial recognition, the financial liability is measured at amortised cost using the effective interest method on the basis of the estimated contractual cash flows with changes in value due to a change in estimated cash flows recognized in profit or loss, in accordance with IFRS 9.

#### R&D Tax Credit

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

Since 2020, the Group applies for the R&D tax credit incentive set-up by the Federal government. When capitalizing its R&D expenses under tax reporting framework, the Group may either (i) get a reduction of its taxable income (if any) corresponding to 13.5% of the capitalized R&D expenses, or (ii) if no sufficient taxable income is available, apply for the refund of unutilized tax credits. The tax credit should be claimed in the year in which the investment takes place. Refund occurs five financial years after the tax credit application filed by the Group.

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 capitalized 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 straightline basis over the vesting period, if any, based on the Company's estimate of equity instruments that will eventually vest, with a corresponding increase in equity. At the end of each reporting period, the Company revises its estimate of the number of equity instruments expected to vest. The impact of the revision of the original estimates, if any, is recognized in profit or loss such that the cumulative expense reflects the revised estimate, with a corresponding adjustment to the equitysettled share-based payment reserve.

## 2.17 PROVISIONS

Provisions are recognized 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 recognized 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 recognized in profit or loss except to the extent that it relates to a business combination, or items recognized directly in equity or in OCI.

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

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

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

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

However, the deferred tax is not recognized for:

- the initial recognition of goodwill (in case of taxable temporary differences arising);
- the initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss and

 deferred tax is recognized on temporary differences arising on investments in subsidiaries and associates, except for deferred income tax liabilities where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not reverse in the foreseeable future.

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

Deferred tax assets are recognized for deductible temporary differences and unused tax losses and tax credits to the extent that it is probable that taxable profits will be available against which they can be utilized. Future taxable profits are determined based on the reversal of relevant taxable temporary differences. If the amount of taxable temporary differences is insufficient to recognize a deferred tax asset in full, then future taxable profits, adjusted for reversals of existing temporary differences, are considered, based on the business plans for individual subsidiaries in the Group.

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

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

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

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

#### 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 recognized at the fair value of a similar liability that does have an equity conversion option. The equity component is initially recognized 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 recognized in profit or loss. Interest related to the financial liability is recognized 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 recognized 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 make resource allocation decisions on a company-wide basis; therefore, the Group operates as one segment.

According to IFRS 8, reportable operating segments are identified based on the "management approach". This approach stipulates external segment reporting based on the Group's internal organizational and management structure and on internal financial reporting to the chief operating decision maker.

The financial information is organized and reported to CODM under one management reporting covering all activities of the Company. There is no specific component in the financial information that would as such represent a specific operating segment. Information reported to the CODM is aggregated and comprises all activities of the Company.

The Group's activities are managed and operated in one segment, pharmaceuticals. Strategic decision and resources allocation are made at the Company level by the CODM.

#### 2.21 CONCTRACTUAL 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

#### 2.22 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 noncash 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 2021 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 2022 and 2023. 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. Management acknowledges that uncertainty remains in these cash flow forecasts (such as delays in clinical development, regulatory approval, commercialisation).

With a cash position of the Group at year end 2021 (i.e.  $\leq 50$  million) and the successfully raised  $\leq 15$  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 balance sheet date.

#### 3.2 SHARE-BASED PAYMENTS

In accordance with IFRS 2 – Share-based Payment, the fair value of the warrants at grant date is recognized as an expense in the consolidated statement of comprehensive income over the vesting period, the period of service. Subsequently, the fair value is not re-measured. The fair value of each warrant granted during the year is calculated using the Black-Scholes pricing model. This pricing model requires the input of subjective assumptions, which are detailed in Note 25.

#### **3.3 AUTOMATICALLY CONVERTIBLE BONDS**

In 2021 the Company did not issue any automatically or other convertible bonds.

The Company issued automatically convertible bonds for an amount of  $\notin$  10,800 thousand in March 2020. In April 30, 2020, the Company issued additional convertible bonds of an amount of  $\notin$  4,350 thousand, bringing the total subscription to  $\notin$  15,150 thousand. The bonds bear interest at a rate of 6% per annum. The bonds were converted on June 30, 2020 using a conversion price corresponding to 70% of the IPO price, i.e.  $\notin$ 7.53 per share.

Management concluded that the automatically convertible bonds are hybrid financial instruments containing a host debt instrument and an embedded derivative instrument to be separated as not closely related to the host contract. Whereas the debt instrument was subsequently measured at amortised cost using the effective interest rate method, the derivative was measured at fair value with changes in fair value recognized in profit or loss. Management also concluded that the difference between the initial value of the two instruments (the debt instrument and the derivative) and the proceeds from the bonds was a transaction between the shareholders and the bondholders in their capacity as future shareholders of the Company. As a result, this difference has been recognized in equity (€4,531 thousands in total).

The transaction costs amounting to  $\leq 156$  thousand, that have been incurred on the issuance of the bonds, have been allocated to the debt component and the equity component on the basis of their relative initial values. At conversion the costs directly attributable to the issuance of new shares were recognized in equity, as cost of capital ( $\leq 102$  thousand). The remaining part of the transaction costs were expensed.

An embedded derivative was recognized in the statement of financial position at the respective

issuance dates, and was remeasured end of June, ahead of the conversion in equity, resulting into a financial income of &81 thousand. At conversion, embedded derivatives were offset against equity (other reserves) and the difference between interest accrued and interest paid in shares were recognized as 'other reserves' in equity (&37thousand).

#### **3.4 EQUITY RELATED TRANSACTIONS**

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 capitalized in the equity as costs of capital. When transactions costs are related to both new and existing shares, then such costs are recognized in both equity and profit and loss account using the new shares/exiting shares ratio.

In 2021, the Company did not execute any equity related transaction.

In 2020, the Company incurred the following transactions costs associated to the Convertible bonds and the Initial Public Offering.

Equity transactions (in € thousand)	Gross proceeds	Capitalized costs related to issuance of new shares	Expensed in P&L	Net proceeds
Initial Public Offering	64,392	(3,725)	(1,413)	59,254
Convertible bonds	15,150	(102)	(55)	14,994
Total	79,542	(3,827)	(1,468)	74,248

#### **3.5 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 recognizes 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 recognized immediately in equity, net of tax.

#### **3.6 RECOGNITION OF DEFERRED TAX ASSETS**

Deferred tax assets are recognized only if management assesses that these tax assets can be offset against taxable income within a foreseeable future.

This judgment is made on an ongoing basis and is based on budgets and business plans for the coming years, including planned commercial initiatives.

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 recognized as of 31 December 2021 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.

#### 3.7 COVID-19

Beginning 2020 the World Health Organization declared the novel strain of coronavirus (COVID-19) a global pandemic and recommended containment and mitigation measures worldwide. To date, the Group has experienced limited impact on its operational and financial performance, financial position, cash flows and significant judgements and estimates, although the Group continue to face additional risks and challenges associated with the outbreak.

## 4. FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

#### **4.1 OVERVIEW OF FINANCIAL INSTRUMENTS**

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

(in € thousand)	IFRS 9 Category	December 31, 2021	December 31, 2020
Non-current financial assets	FVTPL	453	12
Trade receivables	At amortised cost	2,026	48
Other financial assets	FVTPL	528	7
Other (non-) current assets *	At amortised cost	1,490	0
Cash and cash equivalents	At amortised cost	50,012	64,399
Total financial assets		54,509	64,466
Non-current financial liabilities			
Lease liabilities	At amortised cost	109	106
Other financial liabilities	At amortised cost	300	7,885
Current financial liabilities			
Lease liabilities	At amortised cost	65	46
Other financial liabilities	At amortised cost	11,815	409
Trade and other liabilities			
Trade payables	At amortised cost	2,622	1,595
Total financial liabilities		14,911	10,041

\* Other (non-) current assets that are not financial assets (pre-paid expenses / R&D tax credit receivables) are not included

The Company considers that the carrying amounts of financial assets and financial liabilities measured at amortized cost in the consolidated financial statements approximate their fair values.

#### **4.2 FINANCIAL RISK FACTORS**

The Group's activities expose it to a variety of financial risks: market risk (including currency risk 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, 2021	December 31, 2020
Assets	2,264	2,469
Liabilities	(3,987)	(3,487)

At December 31, 2021, 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 +/- EUR 17 thousand 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 recognized 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.

31/12/2021 (In € thousand)	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
Borrowings					
Lease liabilities	67	111			178
Other financial liabilities					
Loans from shareholders	9,126				9,126
Other financial liabilities	3,200	300			3,500
Total	12,394	411	-	-	12,805
31/12/2020 (In € thousand)	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
				>10 years	Total
(In € thousand)				>10 years	Total
(In € thousand) Borrowings	year	years		>10 years	
(In € thousand) Borrowings Lease liabilities	year	years		>10 years	
<pre>(In € thousand) Borrowings Lease liabilities Other financial liabilities</pre>	year	years 112		>10 years	160

## **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.

The revenue generated currently relates to royalties generated from one third party customer, Alta Thera (€ 0.3 million) and from out-licensing Maxigesic<sup>®</sup> IV by our partner AFT Pharmaceuticals and revenue for service rendered (€ 2,780 million).

#### **GEOGRAPHICAL INFORMATION** 1.

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, 2021

Company name	Company number	Location	% financial interest
Hyloris Pharmaceuticals SA	BE 0674.494.151	Blvd Gustave Kleyer 17, 4000 Liège	Parent
Hyloris Developments SA	BE 0542.737.368	Blvd Gustave Kleyer 17, 4000 Liège	99.99%
RTU Pharma SA	BE 0669.738.676	Blvd Gustave Kleyer 17, 4000 Liège	100.00%
Dermax SA	BE 0667.730.677	Blvd Gustave Kleyer 17, 4000 Liège	100.00%
Purna Female Healthcare BV	BE 0762.693.578	Scheldestraat 31, 2880 Bornem	20.00%
The voting rights equal the p	ercentage of financ	ial interest held.	

The voting rights equal the percentage of financial interest held.

## 7. INTANGIBLE ASSETS

(in € thousand)	Development costs	Assets Purchase	In Licensing	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)
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 € thousand)	Development	Assets Purchase	In Licencing	Total
. ,	Development costs	Assets Purchase	In Licencing	Total
Year ended December 31, 2020	costs			
Year ended December 31, 2020 Opening carrying amount	<b>costs</b> 712	Assets Purchase	401	2,138
Year ended December 31, 2020 Opening carrying amount Additions	<b>costs</b> 712 622	1,026		2,138 722
Year ended December 31, 2020       Opening carrying amount       Additions       Borrowing costs capitalized	costs 712 622 18	1,026 - 25	401 100 -	2,138 722 43
Year ended December 31, 2020         Opening carrying amount         Additions         Borrowing costs capitalized         Amortisation expense	costs 712 622 18	1,026	401 100 - -	2,138 722 43 (43)
Year ended December 31, 2020         Opening carrying amount         Additions         Borrowing costs capitalized         Amortisation expense         Impairment losses	costs 712 622 18 - (480)	1,026 - 25 (43) -	401 100 - - -	2,138 722 43 (43) (480)
Year ended December 31, 2020         Opening carrying amount         Additions         Borrowing costs capitalized         Amortisation expense         Impairment losses         Closing carrying amount	costs 712 622 18	1,026 - 25	401 100 - -	2,138 722 43 (43)
Year ended December 31, 2020Opening carrying amountAdditionsBorrowing costs capitalizedAmortisation expenseImpairment lossesClosing carrying amountAt December 31, 2020	costs 712 622 18 (480) 872	1,026 - 25 (43) - <b>1,008</b>	401 100 - - 501	2,138 722 43 (43) (480) <b>2,381</b>
Year ended December 31, 2020         Opening carrying amount         Additions         Borrowing costs capitalized         Amortisation expense         Impairment losses         Closing carrying amount         At December 31, 2020         Cost	costs 712 622 18 (480) 872 1,352	1,026 - 25 (43) - <b>1,008</b> 4,483	401 100 - - 501	2,138 722 43 (43) (480) <b>2,381</b> 6,336
Year ended December 31, 2020Opening carrying amountAdditionsBorrowing costs capitalizedAmortisation expenseImpairment lossesClosing carrying amountAt December 31, 2020	costs 712 622 18 (480) 872	1,026 - 25 (43) - <b>1,008</b>	401 100 - - 501	2,138 722 43 (43) (480) <b>2,381</b>

In 2021, the Company acquired intangible assets for a total of  $\notin$  936 thousand, of which (i)  $\notin$  249thousand related to the development costs of product-candidates (mainly Maxigesic<sup>®®</sup> and HY-16), (ii)  $\notin$  686 thousand of in-licensing related to intravenous acetylsalicylic acid (previously known as Hyloris' HY-073).

The latter (in-licensing of product candidate intravenous acetylsalicylic acid), triggered in the second half of 2021 the impairment of the previously capitalized in-licensing fee of product candidate HY-073: an impairment cost of € 23 thousand was recognized.

The disposal is related to the successful renegotiated and unwound license agreements with the Alter Pharma (see note 28.1).

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 3 years. The Company expects to start the amortisation of the development costs of Maxigesic<sup>®</sup> IV in 2022, once the product is available for use in the United States of America.

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 pretax 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 yearend, except for the impairment loss recorded on product-candidate HY-073, 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 10.98% (was 12.43% in 2020).

The main variables that lead to a discount rate of 10.98% are:

- a risk free rate of 0.20% corresponding to the 10-year OLO rate as of December 31, 2021(-0.34% last year)
- a beta factor of 1.02 (1.31 last year)
- a market risk rate of 5.05% (5.96% last year).
- a Company specific risk premium of 6.60% (7% last year)
- a cost of debt before tax of 6% (no change compared to 2020)

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 2020).

We tested the sensitivity analysis of the impairment tests by increasing the discount rate by 4%, leading the discount rate to 14.98%. 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)

Year e	nded December 31, 2021
Openi	ng carrying amount
Additi	ons
Depre	ciation expense
Dispos	als
Closin	g carrying amount
At Dec	cember 31, 2021
Cost	
Accum	nulated depreciation and impairment
Carryi	ng amount
Year e	nded December 31, 2020
Openi	ng carrying amount
Additi	ons
Depre	ciation expense

Disposals

Closing carrying amount

At December 31, 2020

Cost

Accumulated depreciation and impairment

Carrying amount

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 three years, while for the company cars the lease term ranges between 4 and 5 years.

Land and buildings	Vehicles and equipment	Total
145	7	152
	83	83
(43)	(19)	(62)
-	-	-
102	71	173
242	152	394
(140)	(81)	(221)
102	71	173

5:	1 15	66
134	4 32	166
(40	) (11)	(51)
	- (29)	(29)
14	5 7	152
242	2 69	311
(97	) (62)	(159)
14	5 7	152

The amounts recognized in profit or loss can be summarized as follows:

(in € thousand)	2021	2020
Depreciation expense of right-of- use assets	(62)	(51)
Interest expense on lease liabilities	(5)	(3)
Expenses relating to low-value leases	(2)	(2)
Total amount recognized in profit or loss	(69)	(56)
• •	(69)	(56)
or loss	<b>(69)</b> (64)	<b>(56)</b> (53)

The depreciation expenses are all presented as "General and administrative expenses".

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.

# 9. INVESTMENTS IN ASSOCIATES AND JOINT VENTURES

On 5 February 2021, the Group entered into a partnership with Purna Female Healthcare, 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 Purna Female Healthcare were limited to the available cash in the company, hence no fair value adjustment has been identified. Hyloris committed an investment of  $\xi$ 4,270 thousand, of which  $\xi$ 1,270 thousand is already paid. The unpaid balance of  $\xi$ 3,000 thousand is recognized against a current financial liability (see note 15.2).

Hyloris owns 20% of Purna Female Healthcare (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 Purna Female Healthcare will be changed and will be driven by the profitability of the company.

(in € thousand)	December 31, 2021	December 31, 2020
Opening carrying value		
Capital Contribution	4,270	
Profit/loss of the period	(191)	
Carrying amount at December 31	4,078	

The following table summarizes the financial information of Purna Female Healthcare as included in its own financial statements, adjusted for fair value adjusted for fair value adjustments and differences and differences in accounting policies, if needed.

(in € thousand)	31-Dec-21
FIXED ASSETS	
CURRENT ASSETS	5,168
Amounts receivable within one year	3,044
Cash at bank and in hand	2,124
TOTAL ASSETS	5,168
CAPITAL AND RESERVES	5,146
Capital	6,103
Accumulated profits (losses)	(957)
PROVISIONS AND DEFERRED TAXES	
CREDITORS	22
Amounts payable within one year	22
TOTAL LIABILITIES	5,168

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

## 10. (OTHER) FINANCIAL ASSETS

The (other) financial assets can be detailed as follows:

(in € thousand)	December 31, 2021	December 31, 2020
Automatically Convertible loan	500	
Optional convertible loan	441	
Other Financial Assets	40	19
Other Financial Assets	981	19
of which as:		
Non-current financial assets	453	12
Current other financial assets	528	7

# Automatically convertible loan (under certain conditions)

On 10 November 2021, the Group entered into a partnership with Pleco Therapeutics to develop a Plecoid<sup>™</sup> 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 will provide via a €1,000 thousand automatically noninterest bearing convertible loan (convertible into Pleco Therapeutics equity under certain conditions) in several tranches over time, whereof as per 31 December 2021 €500 thousand was paid to Pleco Therapeutics. As the transaction occurred (1) between non-related parties and (2) close to yearend, management asses the transaction price (being €500 thousand at year-end) is considered as the Fair Value. In case the Loan has not been converted, the amount of the Loan that has been made available to lender, will be repaid at the latest on 31 December 2022.

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 an additional  $\notin$ 7,700 thousand predefined 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  $\notin$ 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. As the transaction occurred close to year-end, management asses the transaction price (being € 441 thousand at year-end) is considered as the Fair Value. 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 27).

Management identified Vaneltix Pharma, Inc as a related party of Hyloris – The transaction has been subject to the conflictof interest procedure in accordance to the Belgian Laws (see note 28.2).

## 11. TRADE RECEIVABLES AND OTHER RECEIVABLES

(in € thousand)	December 31, 2021	December 31, 2020
Trade receivables	2,026	48
Less: allowance for impairment of trade receivables	-	-
Trade receivables - net	2,026	48
Prepayments	-	-
Other amounts receivable	295	205
Prepaid expenses and other receivables	295	205
Trade and other receivables - Current	2,321	253

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 denominated in USD, primarily resulting from out-licensing revenue from Maxigesic<sup>®</sup> IV.

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.

## **12. OTHER NON-CURRENT AND CURRENT ASSETS**

(in € thousand)	December 31, 2021	December 31, 2020
Pre-paid R&D expenses	756	1,882
Other pre-paid expenses	92	72
R&D Tax Credits	474	-
Receivable from Alter Pharma Group	645	
Other Assets	845	
Other assets	2,812	1,954
of which as:		
Other non-current assets	1,714	-
Other current assets	1,098	1,954

#### Pre-paid R&D Expenses

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 €756 thousand in 2021 related to the development agreement with Stasisport Pharma (a subsidiary of the Alter Pharma group, a related party of Hyloris prior to 24 June 2021) to run the clinical development of the Fusidic Acid cream product candidate (see note 28.1).

The decrease of €1,126 thousand compared to 31 December 2020, is mainly related to the termination of the development projects conducted by Alter Pharma and its subsidiaries for €894 thousand (see note 28.1).

#### **R&D** Tax Credits

The Group applies for R&D tax credit incentives setup 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 the grant will be received. The Group recognized R&D tax credits for a total of €474 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 2021 held a receivable from the Alter Pharma Group for a total of € 645 thousand, whereof a non-current receivable of € 395 thousand and a current receivable of € 250 thousand, relating to the termination of the development projects conducted by Alter Pharma and its subsidiaries (see note 28.1).

#### Other Assets

Other Assets amounts € 845 thousand and relates to fees, payable in 2023, for services rendered (see note 18).

#### CASH AND CASH EQUIVALENTS **13**.

The net cash position as presented in the consolidated statement of cash flows is as follows:

(in € thousand)	December 31, 2021	December 31, 2020
Cash at bank	30,012	44,399
Short-term deposit	20,000	20,000
Total cash and cash equivalents	50,012	64,399

The term of the deposit is September 2023. It is classified as short term deposit as available for use by the group within a 32 days' notice period.

## 14. EOUITY

#### 14.1 OVERVIEW

(in € thousand)	December 31, 2021	December 31, 2020
Share capital	129	129
Share premium	103,693	103,693
Retained earnings	(54,805)	(43,226)
Other reserves	(960)	(1,537)
Total Equity attributable to owners of the parent	48,057	59,059

#### 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

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

processes for managing capital have remained unchanged over the past few years.

## 14.3 SHARE CAPITAL AND SHARE PREMIUM Share Capital

As per 31 December 2021, the share capital of the Group amounts to €129,163.16 represented by 25.832.632 shares, without nominal value, each representing 1/25.832.632<sup>th</sup> of the share capital of the Group. The share capital of the Group is fully and unconditionally subscribed for and is fully paid up. All shares rank equally with regard to the Group's residual assets. Holders of these shares are entitled to dividends as declared from time to time and are entitled to one vote per share at general meetings of the Group.

On June 8, 2020, the General Assembly issued an authorized capital of €117,758.84. The Board is allowed to use the authorized capital for a period of 5 years. As per December 31, 2021, the remaining authorized capital amounted to €115,758.84.

31 May 2018	Capital increase	3,000,000	271,322 Shares	11.06	3,595,033
31 December 2019	Capital increase	18,259,783 <sup>1</sup>	855,409 Shares	21.35	4,450,442
8 June 2020	Share split	-	Share split (1 to 4)	-	17,801,768
30 June 2020	IPO on Euronext	61,821,500	5,750,000 shares	10.75	23,551,768
30 June 2020	Conversion of convertible bonds	15,358,025	2,040,864 shares	10.75	25,592,632
31 July 31 2020	Over allotment option	2,580,000	240,000 shares	10.75	25,832,632

The company refers to Note 29.2 for information on the successful equity transactions that occurred on 31 March 2022.

#### Share premium

As per 31 December 2021, the share premium of the Group amounts to € 103,693 thousand.

#### Other reserves

(in € thousand)	December 31, 2021	December 31, 2020
Share based payment	2,391	1,814
Cost of Capital	(3,827)	(3,827)
Other	476	476
Total Other reserves	(960)	(1,537)

The movement of the other reserves over the period can be explained by the increase of  $\in$  577 thousand resulting from the share based payment expenses associated with the ESOP warrants (see note 25).

## 15. BORROWINGS AND OTHER FINANCIAL LIABILITIES

#### 15.1 BORROWINGS

(in € thousand)	December 31, 2021	December 31, 2020
Bank borrowings		
Lease liabilities	174	152
Total borrowings	174	152
of which as:		
Non-current borrowings	109	106
Current borrowings	65	46

For more details on the leases, we refer to Note 9 on "Right-of-use assets".

The weighted average incremental borrowing rate used for the measurement of the lease liabilities is 1.60%. 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, 2021	December 31, 2020
Loans from shareholders	8,615	7,885
Recoverable cash advance		409
Other financial liabilities	3,500	
Other financial liabilities	12,115	8,294
of which as:		
Non-current other financial liabilities	300	7,885
Current other financial liabilities	11,815	409

#### 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:

#### Loans from shareholders

The loans from shareholders are unsecured and bear a fixed nominal interest rate of 4% which are payable when the principal is due at the end of 2022, unless agreed otherwise between the parties. The Group reassessed the interest rate under the shareholders loan agreements and considered that a 6% interest rate represented a fair estimate at which it could obtain similar loans based on benchmarking obtained from peer companies with a similar profile and the rate applied in its pre-IPO convertible bonds.

The increase compared to last year is only the result of the accrued interest of the year and changes unrealized foreign exchange difference.

A variance of 1% of the interest rate will have a  $\in$ 80 thousand impact on the statement of profit or loss of the Company (on an annual basis).

#### Recoverable cash advance

In 2021, the Group settled the recoverable cash advance ('RCA') received from the Walloon Region by paying back the unutilized cash for an amount of €409 thousand.

#### Other financial Liabilities

In the 2021, the Group :

- <u>Successfully renegotiated the license</u> <u>agreements</u> for multiple lead products with the Alter Pharma Group. This resulted in a noncurrent 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). As of 31 December 2021, this resulted a current other financial liability of €3,000 thousand.

<sup>&</sup>lt;sup>1</sup> Accounting wise, the share issue of December 2019 was accounted for as from the date of establishment of common control in Dermax

					Non-cas	sh moven	nents			
31/12/2021 (in € thousand)	Opening carrying amount	Cash flows	Acquisition	Modification	Termination		Reclasses	and exchange differences	Accrued interests	Closing carrying amount
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	0	0		733	12,290
Presented in the statement of cash flows as follows:										
Operating activities		(409)								
Reimbursement of borrowings		(64)								
31/12/2020 (in € thousand) Non-current financial liabilities										
Lease liabilities	22			32	134	(29)	(53)			106
Other financial liabilities				-	134	(23)	7,540		345	7,885
Current financial liabilities							7,510		010	,,
Lease liabilities	44	(51)					53		1	46
Other financial liabilities	13,130	(4,800)			(532)	151	(7,540)			409
Total liabilities from financing activities	13,196	(4,851)		32	(398)	122			246	8,447
Presented in the statement of cash flows (financing activities) as follows: Proceeds from borrowings and										
other financial liabilities		3,250								
Repayment of borrowings and other financial liabilities		(8,101)								

## **16.** TRADE AND OTHER LIABILITIES

(in € thousand)	December 31, 2021	December 31, 2020
Trade payables	2,622	1,595
Employee benefit liabilities	80	25
Other payables	47	9
Trade and other liabilities - Current	2,749	1,629

The trade payables relate mainly to the R&D activities. Other payables primary consist of payables related to transactions with Non-Executive member of the Board of Directors (see note 28.5).

The fair value of trade payables approximates their carrying amount.

Liquidity and currency risk are detailed in Note 4.

(in € thousand)
Intangible assets
Financial liabilities
Associates and joint ventures
Tax losses
Total deferred tax assets & liabilities
Net deferred tax assets not recognized
Offsetting
Total deferred tax assets & liabilities

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

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

Decembe Deferred tax asset	r 31, 2021 Deferred tax liability	Decembe Deferred tax asset	er 31, 2020 Deferred tax liability
854		827	
	(57)		(173)
48			
7,951		6,007	
8,854	(57)	6,834	(173)
(8,797)		(6,661)	
(57)	57	(173)	173

Deferred tax assets have not been recognized in respect of the following items, because it is not probable that future taxable profits are available against which the Group can use the benefits of therefrom:

(in € thousand)	December 31, 2021	December 31, 2020
Deductible temporary differences	3,002	2,616
Tax losses	31,805	24,026
Total	34,806	26,462

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, 2021	December 31, 2020
Sales-based royalties	315	175
Milestone payments	1,805	
Services rendered	975	
Revenues	3,095	175

Currently, the Group generates only limited salesbased royalties as its main projects are in the development pipeline and are not yet commercialized. The continuously increasing sales-based royalties is income from the Group's commercialized product, Sotalol IV. Revenue for a sales-based royalty promised in exchange for a licence of intellectual property is only recognized when the subsequent sale occurs.

Income from Milestone payments in 2021 is driven by the strong growth from out-licensing Maxigesic<sup>®</sup> IV by the Group's partner AFT Pharmaceuticals, including income from the landmark US Licensing Agreement. Revenue for milestone payment in exchange for a licence of intellectual property is only recognized when the performance obligation to which some or all of the milestones payments has been allocated has been satisfied.

Income from Services rendered in 2021 primary consist of compensation for additional cost incurred by the Group to support a Contract Manufacturer, including support relating manufacturing capacity and the US GMP approval. Revenue for services rendered are recognized 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)	2021	2020
Out-sourced R&D	(3,333)	(2,128)
Employee benefit expenses (Note 20)	(1,659)	(771)
Management consultancy fees	(907)	(996)
Board related expenses	(189)	(116)
Share based payments	(576)	(485)
IPO related fees	-	(1,413)
Convertible bonds related fees	-	(55)
Legal & paralegal fees	(218)	(143)
Audit and related consultancy fees	(172)	(102)
Hiring fees	(103)	(73)
Office equipment, rent and utilities	(292)	(235)
Renegotiation and unwinding Alter Pharma	(5,770)	-
Other expenses	(478)	(123)
Amortisation expense of intangible assets (Note 7)	(43)	(43)
Impairment losses on intangible assets (Note 7)	(23)	(480)
Depreciation expense on PPE and Right-of Use	(71)	(58)
Total operating expenses	(13,833)	(7,220)
of which as:		
Cost of sales	(107)	(145)
Research and development expense	(5,056)	(3,413)
General and administrative expenses	(2,900)	(2,194)
Share issuance related expenses	-	(1,468)
Other operating expenses	(5,770)	

In accordance with IAS 38, we do not capitalize our research and development expenses until we file for marketing authorization for the applicable product candidate. Research and development expenditures incurred during the period were accounted for as operating expenses.

Total R&D expenditure can be detailed as follows:

(in € thousand)	December 31, 2021	December 31, 2020
Research and Development expenses	(5,033)	(2,933)
Impairment of assets	(23)	(480)
Total R&D costs	(5,056)	(3,413)

The Groups' research and development expenses increased by 72%, from  $\notin$  2,933 thousand in 2020 to  $\notin$  5,033 thousand in 2021. 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 2021, the Group capitalized development costs for a total of  $\notin$  284 thousand (was  $\notin$ 622 thousand in 2020). (See note 7)

In September 2021, the Group and her initial development partner for the product candidate HY-073 Aspirin IV terminated their in-licensing and collaboration. This termination resulted in a write-off of the initially paid upfront fee, an impairment cost of € 23 thousand was recognized.

Hyloris' General and administrative expenses increased by 32% (or  $\notin$ 706 thousand), from  $\notin$  2,194 thousand in 2020 to  $\notin$  2,900 thousand in 2021. The increase was principally driven the enlargement of the management and governance structure of the Company.

Other operating expenses amounted to €5,770 thousand and were driven by the <u>successful</u> renegotiation and unwinding of the license agreements for multiple lead products with the Alter Pharma Group (see note 28.1).

## 20. EMPLOYEE BENEFIT EXPENSES

In € thousand	December 31, 2021	December 31, 2020
Wages and salaries	(1,494)	(682)
Social security costs	(105)	(64)
Defined contribution costs	(14)	(9)
Other employee Benefit expenses	(45)	(16)
Total employee Benefit expense	(1,659)	(771)
in full-time equivalents		
Average number of total employees	13.8	8.1

## 21. OTHER OPERATING INCOME

(in € thousand)	December 31, 2021	December 31, 2020
Grants income related to tax credit	387	-
Other income	2	21
Other Operating Income	389	21

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  $\notin$ 474thousand, of which  $\notin$ 387thousand as other operating income, and  $\notin$ 87 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.

In 2020, the Group realized a capital gain of  $\notin$ 21 thousand on the sale of the HU-REF-038 asset (vial form).

## 22. FINANCIAL RESULT

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

(in € thousand)	December 31, 2021	December 31, 2020
Gain related to the extension of the maturity of the shareholder loans	-	532
Change in fair value of the embedded derivatives	-	81
Interest income on current assets	32	11
Exchange differences	-	277
Financial income	32	901
Interest expense on lease liabilities	(5)	(3)
Interest expense on other financial liabilities	(478)	(567)
Other Interest expense	(73)	(271)
Total interest expenses	(557)	(841)

Fair value adjustment on the shareholder loans	-	(151)
Bank fees	(26)	(21)
Exchange differences	(190)	-
Other	-	(8)
Total financial expenses	(773)	(1,021)

## 23. INCOME TAX EXPENSE

#### 23.1 AMOUNTS RECOGNIZED TO PROFIT AND LOSS

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

(in € thousand)	December 31, 2021	December 31, 2020
Tax (expense)/income	(297)	(1)
Financial income	(297)	(1)

In 2021, The Group recognized an additional Tax Expenses of €297 thousand related to a request for payment of Taxes related to taxable income realized in 2016, 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 Tas Assessments prior to the request for payment. Management protested to the relevant Authorities and decided to adopt a cautious approach and recognized the Tax Expense in 2021.

#### 23.2 RECONCILIATION OF EFFECTIVE TAX

The income tax expense can be reconciled as follows:

(in € thousand)	2021	2020
Loss before income tax	(11,282)	(7,145)
Income tax expense calculated at domestic tax rates (25%)	2,821	1,626
Tax effect of		
Share of Loss of equity- accounted investeess reported, net of tax	(48)	
Tax incentives (R&D Tax Credit)	97	
Changes in estimates related to prior years	(297)	
Effect of unused tax losses not recognized as deferred tax assets	(2,869)	(1,627)
Total tax Expenses	(297)	(1)

## 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, 2021	December 31, 2020
Basic earnings		
Profit (Loss) from continuing operations attributable to owners of the parent	(11,579)	(7,145)
Diluted earnings		
Dilution effect of		
share-based payments		
Profit from continuing operations attributable to owners of the parent, after dilution effect	(11,579)	(7,145)

Earning per share based on the existing number of ordinary shares

Number of shares	December 31, 2021	December 31, 2020
Weighted average number of ordinary shares outstanding during the period	25,832,632	21,818,814
Basic earnings per share	(0.45)	(0.33)
Diluted earnings per share	(0.45)	(0.33)

As the Company is suffering operating losses, the stock options have an anti-dilutive effect. As such, there is no difference between basic and diluted earnings per ordinary share. There are no other instruments that could potentially dilute earnings per share in the future.

## 25. SHARE-BASED PAYMENTS

The Company has a stock option scheme for the employees, consultants and directors of the Company and its subsidiaries for rendered services. In accordance with the terms of the plan, as approved by shareholders, employees may be granted options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

Each employee share option converts into one ordinary share of the Company on exercise. No amounts are paid or payable by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights. Options may be exercised at any time from the date of vesting to the date of their expiry.

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

	Expiry Date	Exercise Price per warrant (€)	Fair value at grant date (€)	Warrants per 31 December 2021	Warrants per 31 December 2020
PLAN 2017					
Warrants	14 June 2022	2.36	1.11	1,200,000	1,200,000
PLAN 2019					
Warrants	31 December 2024	5.34	2.47	313,000	333,000
PLAN 2020					
Warrants	27 November 2031	9.88	4.44	69,500	-
Warrants	27 November 2031	12.04	5.68	55,000	-
Warrants	27 November 2031	13.92	6.20	60,000	-
Warrants	27 November 2031	16.64	7.39	2,000	-

The 2017 plan is fully vested immediately as no vesting conditions were required.

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. As of 31 December 2021, all offered warrants were accepted and 40,000 warrants lapsed. The remaining warrants of the 2019 plan already lapsed as at 31 December 2020.

On November 27 2020, the Company issued a new 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 2021, 191,500 warrants were offered to new employees of which 186,500 warrants were accepted. The remaining warrants of the 2020 plan already lapsed as at 31 December 2021.

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
Average Share price (€)	2.36	5.34	11.73
Average Exercise Price (€)	2.36	5.34	11.89
Expected volatility of the shares (%)	55%	55%	40%
Expected dividends yield (%)	0%	0%	0%
Risk free interest rate (%)	0.60%	0.10%	0.00%

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	118,000
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

The 1,200,000 Transaction warrants are exercisable during the periods set out in the terms and conditions thereof, including notably an annual window during the 60 calendar days preceding the Annual General Shareholders' Meeting.

## 26. CONTINGENCIES

At closing 2021, the Group was not involved in any claim or dispute incidental to the activities of the Group.

## 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 2021, Hyloris has contractual commitments and contingent liabilities for a maximum amount of  $\notin$ 43,254 thousand on related to asset purchase, licenses and development agreements recorded under intangible assets.

	<u>Maximum c</u>	ontractual co	<u>ommitments</u>		Contingent Lia	abilities
Product Candidate	In \$ thousand	In € thousand	Converted in € (in € thousand)	In \$ thousand	In € thousand	Converted in € (in € thousand)
HY-004	225		199	225		199
HY-029		300		0		0
Atomoxetine oral liquid	150		132	150		132
Metolazone IV	1,650		1,457	1,300		1,148
Dofetilide IV	350		309	0		0
HY-073	39,151		34,567	30,500		26,929
HY-074	225		199			
Alenura (note 29.2)	6,700		5,916			
TOTAL	48,451	300	42,778	32,175		28,408

The accounting treatment of the contractual commitments and contingent liabilities will vary per nature of triggering event. Development milestones up until commercialization will be expensed or capitalized. Sales related commitments such as royalties, profit sharing and sales milestones will be expensed when incurred.

The following table details the total maximum contractual commitments (milestone payments only) at 31 December 2021 per product candidates if such products are successfully marketed (in € thousand):

As of December 31, 2021, out of the total value of  $\notin$ 42,954 thousand million,  $\notin$ 28,408 million 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:

- The Alter Pharma group and its subsidiaries, in which Hyloris' CEO, Mr. Stijn Van Rompay, and CBDO, Mr. Thomas Jacobsen, had material ownership interests until 24 June 2021. Both resigned from the Board of Directors of Alter Pharma on 23 June 2021, 2021. As from 24 June 2021, the Alter Pharma Group is no longer considered a related party.
- Vaneltix Inc and its affiliates, in which nonexecutive 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; Pieter Van Rompay (Sibling of Mr Stijn Van Rompay.);
- The Executive Management Team; and
- The Board of Directors (Non-Executive Directors)

#### 28.1 TRANSACTIONS WITH ALTER PHARMA GROUP

Alter Pharma Group was a related party of Hyloris prior to 24 June 2021.

- The transactions made with the Alter Pharma Group in first six-month period of 2021 were the following:
- The successful renegotiation and unwinding of the license agreements with the Alter Pharma Group for the lead products Maxigesic<sup>®</sup> IV, HY-075 and HY-038, and high-barrier generic Fusidic Acid Cream in Canada.

 Development expenses related to the patent and knowhow license agreement of Maxigesic<sup>®</sup> IV with Alter Pharma and clinical developments expenses related to the product candidate Fusidic Acid Cream prior the unwinding of the of agreement (completed on 24 June 2021). The development expenses amounted to €160 thousand.

The renegotiation and unwinding of the licenses agreements with the Alter Pharma Group for multiple lead products resulted as per 30 June 2021 in:

- a one-time other expense of €5,770 thousand, whereof € 5,250 thousand was paid, €500 thousand potential earn-out (classified as other non-current financial liability and representing the fair value of the contingent consideration) and €20 thousand as a non-cash expense as a result of the development agreement in relation to HY-038, a prefilled syringe of a commonly used product to treat a specific deficiency;
- (ii) a cash settlement, whereby the Group will receive a total of €645 thousand (€250 thousand before 1 July 2022 and €395 thousand in the beginning of 2023), for the refund of prepaid R&D expenses, a refund of a paid in-license fee and a settlement of an outstanding trade liability.

The above-described renegotiation and unwinding of the license agreements with the Alter Pharma Group are presented in the Consolidated Statement of Financial Position and Profit and loss as follows:

	Transactions for the period		
(in € thousand)	Financial	Profit	
(in o mousting)	Position	and Loss	
Intangible assets	(219)	-	
Other non-current assets	395	-	
Other current assets	(644)	-	
Cash and cash equivalents	(5,250)	-	
Trade and other liabilities	(447)	-	
Other non-current	500	-	
financial liabilities			
Other operating expenses	-	5,770	

Subsequent to this transaction, the Group still has a development Agreement with Statisport (a subsidiary of the Alter Pharma Group) to run the clinical development for the Fusidic Acid Cream product candidate. The development agreements consist of a pre-paid R&D expenses (see note 12).

At December 31, 2021, there were prepaid expenses related to transactions with Alter Pharma and its subsidiaries:

(in € thousand)	December 31, 2021	December 31, 2020
Fusidic Acid Cream	756	800
HY-038	-	2,000
Unallocated	-	350
Prepaid R&D Expenses related to transactions with APG	756	3150

#### Trade and other payables

At 31 December 2021, there were outstanding payables related to renegotiation and unwinding with Alter Pharma and its subsidiaries, as described above:

(in € thousand)	December 31, 2021	December 31, 2020
Development Agreement		432
Potential earn-out (see note 15.2)	500	
Total	500	1875

The potential earn-out is recognized as a non-current other financial liability of  $\notin$  300 thousand and a current financial liability of each  $\notin$  200 thousand in the financial statements.

At 31 December 2021, there were no outstanding trade payables related to transactions with Alter Pharma and its subsidiaries.

#### Trade and other receivables

At December 31 2021, there were no outstanding trade receivables related to transactions with Alter Pharma and its subsidiaries.

The cash settlement (as described above) resulted in a current asset of €250 thousand and a non-current assets of €395 thousand (see note 12)

## 28.2 TRANSACTIONS WITH VANELTIX, INC.

On 13 December 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 above-described transaction with Vaneltix, Inc and her affiliates has been subject to the application of the <u>Article 7:97, §4/1 of the Belgian Code of Companies</u> <u>and Associations</u> and is presented in the Consolidated Statement of Financial Position and Profit and loss as follows as follows:

	Transactions for the period		
(in € thousand)	Financial Position	Profit Loss	Commitments
Non-current other financial assets (see note 10)	441		
Commitments and Contingent Liabilities (see note 27)			5,916
Total	441	-	5,916

#### 28.3 TRANSACTIONS WITH THE SHAREHOLDERS

The following loans contracted with shareholders were outstanding at the end of year (nominal amounts, excluding accrued interest):

(in € thousand)	December 31, 2021	December 31, 2020
Stijn Van Rompay	4,428	4,092
GRNR Invest BVBA (an entity controlled by Thomas Jacobsen)	1,089	1,039
Pieter Van Rompay	940	828
Stijn and Ellen Van Rompay-Delimon	436	416
Total	6,894	6,375

The amounts outstanding are unsecured and will be settled in cash. No guarantees have been given or received.

The above loans bear fixed interest rates (nominal rate of 4% and effective interest rate of 6%). The amount of accrued interest at year-end amounted to  $\leq 1,722$  thousand for 2021 (2020:  $\leq 1,410$  thousand).

The outstanding loans (including interests) will be repaid the earlier of year end 2022 or when the Company will generate an operating profit (see note 15.2).

#### Interest income and expenses

(in € thousand)	December 31, 2021	December 31, 2020
Gain related to the extension of the maturity of the shareholder loans	-	532
Exchange differences	-	96
Financial income	-	628
Interest expense on shareholder loans	(478)	(567)
Fair value adjustment on the shareholder loans		(151)
Exchange differences	(252)	
Total financial expenses	(730)	(718)

In 2020, agreements with Shareholders were modified: parts of the loans were reimbursed, the remaining part of the loans underwent a change in maturity. This resulted in a gain and a fair value adjustment in 2020 (see table above).

#### 28.4 TRANSACTIONS WITH THE EXECUTIVE MANAGEMENT TEAM

Executive management team personnel include those persons having authority and responsibility for planning, directing and controlling the activities of the Group. As of 31 December 2021, 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 BA, an entity controlled by Jean-Luc Vandebroek, Chief Financial Officer
- Dr Dietmar Aichhorn, Chief Operating Officer
- Herault BVBA, 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, 2021	December 31, 2020
ST compensation (incl management fees)	891	909
Post-employment benefits	-	1
Share-based payments	274	201
Total	1,165	1,111

As of 31 December 2021, members of the Executive Management Team owned the following securities of the Company:

	Shares		Warrants		
	Number (#)	Pct. (%)	Number (#)	Pct. (%)	
Mr. Stijn Van Rompay	6,824,304	26.42	920,096	54.14	
Mr. Thomas Jacobsen	3,493,993	13.53	163,512	9.62	
Mr. Jean-Luc Vandebroek	-	-	40,000	2.35	
Mr. Dietmar Aichhorn	-	-	40,000	2.35	
Mr. Koenraad Vander Elst	27,443	0.11	50,000	2.94	
TOTAL	10,345,740	40.05	1,213,608	71.41	

Total outstanding shares and warrants existing as of 31 December 2021 are respectively 25,832,632 and 1,699,500.

#### 28.5 TRANSACTIONS WITH THE BOARD OF DIRECTORS (NON-EXECUTIVE DIRECTORS)

As of 31 December 2021, non-executive members of the Board of directors are:

At 31 December 2021, there were outstanding trade payables related to transactions with the Executive Management Team:

(in € thousand)	December 31, 2021	December 31, 2020
Management fees	197	320
Total	197	320

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

The table below presents the compensation of all nonexecutive members of Board of directors by type of compensation:

(in € thousand)	December 31, 2021	December 31, 2020
Board fees	110	55
Share-based payments	58	146
Total	168	201

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

(in € thousand)	December 31, 2021	December 31, 2020
Board fees	40	7
Total	40	7

As of 31 December 2021, non-executive members of the Board of directors owned the following securities of the Company:

	Shares		Warrar	nts
	Number (#)	Pct. (%)	Number (#)	Pct. (%)
Stefan Yee	-	-	100,000	5.88%
Leon Van Rompay	-	-	-	
Marc Foidart	-	-	-	
Carolyn Myers	-	-	-	
James Gale	-	-	-	
Chris Buysse	-	-	-	
TOTAL	-	-	100,000	5.88%

There were 1,699,500 warrants outstanding as of 31 December 2021.

## 29. EVENTS AFTER THE END OF THE REPORTING PERIOD

# 29.1 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 finalized 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 organized outside the conflict area. If the CRO experience disruptions to their business due to the military conflict, the Group asses these disruptions shall not result in delays in the clinical development activities. The impact on ongoing study will remain limited. The Group continue to monitor the situation and is taking measures to mitigate the impact on her ability to conduct clinical development activities.

#### 29.2 EQUITY TRANSACTION

On 31 March 2022, the Group successfully 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 at an issue price of EUR 15.50 per share.

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.

#### **30.** AUDIT FEES

During 2021, the statutory auditor provided services for the group Hyloris which fees were as follows:

(in € thousand)	December 31, 2021
Audit services	62
Audit related services – legal engagements	7
Tax Services	103
Total	172

## 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, 2021 give a true and fair view of the Company's equity and financial position as at December 31, 2021 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 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 Blvd Gustave Kleyer 17 4000 Liège, Belgium

## **Statement of Financial Position**

(in €)	2021	2020
ASSETS		
FIXED ASSETS	57,264,376	60,935,829
Intangible fixed assets	86,861	0
Tangible fixed assets		0
Financial fixed assets	57,177,515	60,935,829
Affiliated companies - Participations	44,944,782	39,174,782
Affiliated companies - Receivables	12,232,733	21,761,047
CURRENT ASSETS	48,534,248	44,591,693
Receivables over one year	1,681,613	
Trade receivables	845,000	
Others amounts receivable	836,613	
Amounts receivable within one year	3,378,508	150,603
Trade receivables	2,432,586	69,519
Others amounts receivables	945,922	81,084
VIII. Cash Investment	20,000,000	20,000,000
IX. Cash at bank and in hand	21,689,562	22,976,295
X. Deferred charges and accrued income	1,784,565	1,464,795
TOTAL ASSETS	105,798,624	105,527,522
CAPITAL AND RESERVES	89,392,780	97,077,677
Capital	129,163	129,163
Share Premium	103,692,645	103,692,645
Reserves	5,000	5,000
Accumulated profits (losses)	(14,434,028)	(6,749,161)
PROVISIONS AND DEFERRED TAXES		
CREDITORS	16,405,844	8,449,845
Amounts payable after more than one year	300,000	6,902,269
Other financial loans		6,902,269
Other debts	300,000	
IX. Amounts payable within one year	14,611,123	432,593
Current portion of amounts payable after one year	7,119,852	0
Other financial loans	724,821	0
Suppliers	3,177,696	378,247
Taxes, remuneration and social charges	388,754	54,346
Other debts	3,200,000	
X. Accrued charges and deferred income	1,494,721	1,114,983
TOTAL LIABILITIES	105,798,624	105,527,522

## **Income Statement**

Op	erating income
-	Furnover
(	Other operating income
Op	perating charges
	Services and other goods
	Other operating charges (-)
	Non-recurring operating expenses
Op	erating profit (loss)
Fin	ancial income
	Income from financial fixed assets
	Other financial income
Fin	ancial charges (-)
	Interest on financial debts
	Other financial charges
F	Profit (Loss) for the period before taxes (-)
Inc	ome taxes (-)

## **STATUTORY NOTES**

## Statement of financial fixed assets

(in €)	2021	2020
Affiliated companies - Participations		
Acquisition value at the end of the preceding period		39,174,782
Movements during the period		
Acquisitions, included produced fixed assets	5,770,000	
Acquisition value at the end of the period	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	44,944,782	
Affiliated companies - Receivables		
Net book value at the end of preceding period		21,761,047
Movements during the period		
Additions	3,349,045	
Reimbursement	(12,877,359)	
Net book value at the end of the period	12,232,733	

2021	2020
3,151,939	80,611
2,780,255	0
371,684	80,611
(10,765,549)	(6,811,486)
(4,990,874)	(1,514,597)
(4,670)	(2,702)
(5,770,005)	(5,294,127)
(7,613,610)	(6,730,875)
545,677	701,916
368,535	684,608
177,142	17,308
(310,665)	(591,184)
(285,846)	(576,587)
(24,819)	(14,597)
(7,378,598)	(6,620,143)
(306,299)	(3,236)
 (7,684,897)	(6,623,379)

	Participation held				Data extracted from the last available annual accounts			
Company	Nature	Direct		By subsidiaries	Annual Accounts at	Currency Code	Capital	Net Profit or Loss
		Number	%	%				
Hyloris Developments SA					12/31/2021	EUR	1,372,337	(2,562,333)
Blvd Gustave Kleyer 17								
4000 Liège								
Belgium								
542,737,368								
	Shares	74,066	99.99%	0%				
RTU Pharma SA					12/31/2021	EUR	(1,420,877)	(235,781)
Blvd Gustave Kleyer 17								
4000 Liège								
Belgium								
669,738,676								
	Shares	62,000	100 %	0%				
Dermax SA					12/31/2021	EUR	2,771,412	(194,917)
Blvd Gustave Kleyer 17								
4000 Liège								
Belgium								
667,730,677								
	Shares	65,875	100%	0%				
Purna Female Healthcare BV					12/31/2021	EUR	5,145,913	(957,087)
Schaldestraat 31								
2880 Bornem								
Belgium								
762,693,578								
	Shares	65,875	100%	0%				

## Deferred Charges and accrued income

(in €)	2021
Deferred Charges and accrued income	
Interest earned on receivables from related companies	1,708,923

## Income and expenses of exceptional size or impact

(in €)	2021	2020
Non-recurring income		
Non-recurring expenses	5,770,005	5,294,127
Other non-recurring expenses (Renegotiation and unwinding Alter Pharma)	5,770,005	
Other non-recurring expenses (Cost of Capital transactions)		5,294,127

## Statement of Amounts Payable

(in €)	2021
Analysis by current position of amounts initially payable after more than one year, maturing in 1 year	
Other debts (Shareholder loans)	7,119,852
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	348,754
Other salary and social debts	40,000
Accrued charges and deferred income	
Accrued Interests on other financial loans	1,372,989
Accrued Management fees	121,732

# Auditor's Report



and for the year ended 31 December 2021

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 2021, 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 31 December 2019, in accordance with the proposal of the board of directors. Our mandate will expire on the date of the general meeting deliberating on the annual accounts for the year ended 31 December 2021. We have performed the statutory audit of the consolidated financial statements of the Group for 3 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 2021, prepared in accordance with International Financial Reporting Standards 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 2021, 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 63.444.000 and the consolidated statement of profit or loss and other comprehensive income shows a loss for the year of EUR 11.579.000.

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 2021 and of its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union, and with the legal and regulatory requirements applicable in Belgium.

firm of the KPMG global organiz KPMG International Limited, a private English company limited b

## Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of



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 2021

#### 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 2.944.000) relating to development costs, asset purchases and in-licensing as at 31 December 2021. 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 2021

Our audit procedures

We performed the following procedures:

- product candidate was prepared;
- candidates:
- business plan approved by the board of directors;
- mathematical accuracy of this model;
- intangible assets; and
- 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 International Financial Reporting Standards 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.

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- We evaluated the process by which management's business plan per

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

We obtained the annual impairment test and analyzed the consistency of the underlying data used in the impairment test with data from the

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

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

We assessed the appropriateness of the disclosures in respect of impairment testing, which are included in note 7 of the consolidated



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 2021

#### 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 2021

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;

- manner that achieves fair presentation;
- 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.

- 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

- 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



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 2021

#### 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 2021 major achievements;
- 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 2021

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.

In our opinion, based on our work performed, the format of and the tagging of information in the official French version of the digital consolidated financial statements as per 31 December 2021, included in the annual financial report of Hyloris Pharmaceuticals SA, are, in all material respects, prepared in compliance with the ESEF requirements under the Delegated Regulation.

#### Other aspect

This report is consistent with our additional report to the audit committee on the basis of Article 11 of Regulation (EU) No 537/2014.

Zaventem, 29 April 2022

KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises Statutory Auditor represented by

Olivier Declerca Bedrijfsrevisor / Réviseur d'Entreprises

# Glossary and other info

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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 Financiele 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 realize 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 n medications are adm
Key Opinion Leader (KOL)	An influential physic
Investigational New Drug (IND)	A drug that is ready drug developer subr Administration (FDA)
In vivo	Animal models of dis
Net Present Value (NPV)	A tool of capital buc is calculated by taking present value of case
New Chemical Entity (NCE)	A compound, withou products
Pharmacokinetics (PK)	The study of drug at fundamental concep drugs from the body
Phase 1 studies	First stage of clinical and tolerability, phar human volunteers
Phase 2 studies	Second stage of clin several hundreds pa
Phase 3 studies	Large clinical studies thousand) patients to of the drug candidat
Pivotal studies	Registrational clinica
QT interval	A measurement mac electrical properties wave to the end of t cardiac ventricles st or abnormally short abnormal heart rhyt
Ready-to use (RTU)	Pre-diluted medicing help to reduce the a administration of me
Reference listed pharmaceutical drug (RLD)	An approved drug p that they are bioequ
Return on Investment (ROI)	A performance mea investment or comp tries to directly mea the investment's cos
Torsade de Pointes	An uncommon and o characterised by a g complexes around t torsade, is associate acquired. Torsade us degenerate into ven
Visual Analog Scale Pain (VAS) Score	a validated, subjection making a handwritte "no pain" and "worst

must be given by an IV injection or infusion, meaning these ministered directly into the veins using a needle or tube

cian or researcher who is held in high esteem by their colleagues

y for clinical trials in humans. When a drug reaches this point, the omits an application to get the consent of the Food and Drug A) to begin these trials

lisease

idgeting to analyse the profitability of a project or investment. It king the difference between the present value of cash inflows and ash outflows over a certain period

out any precedent among the regulated and approved drug

absorption, distribution, metabolism, and excretion. A ept in pharmacokinetics is drug clearance, i.e., elimination of dy, analogous to the concept of creatinine clearance

al testing of an investigational drug designed to assess the safety armacokinetics of a drug, usually in a small number of healthy

inical testing of a investigational drug, usually performed in < atients in order to determine efficacy, tolerability and drug dose

es, usually conducted in hundred (and in some indications, to gain a definitive understanding of the efficacy and tolerability ate – serves as a basis for approval

cal studies

de on an electrocardiogram used to assess some of the es of the heart. It is calculated as the time from the start of the Q the T wave, and approximates to the time taken from when the start to contract to when they finish relaxing. An abnormally long t QT interval is associated with an increased risk of developing thms and sudden cardiac death

nes for intravenous use, known as "ready to use" preparations, amount of errors associated with the preparation and redicines

product to which new generic versions are compared to show uivalent

asure used to evaluate the efficiency or profitability of an pare the efficiency of a number of different investments. ROI asure the amount of return on a particular investment, relative to ost

distinctive form of polymorphic ventricular tachycardia (VT) gradual change in the amplitude and twisting of the QRS the isoelectric line. Torsade de pointes, often referred to as ted with a prolonged QT interval, which may be congenital or usually terminates spontaneously but frequently recurs and may ntricular fibrillation

tive measure for acute and chronic pain. Scores are recorded by en mark on a 10-cm line that represents a continuum between st pain"

## **FINANCIAL CALENDAR**

June 14, 2022 General Assembly

September 1<sup>st</sup>, 2022 Half-year results 2022

## CONTACT

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Stijn Van Rompay CEO Hyloris



Jean-Luc Vandebroek CFO Hyloris

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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 Gustave-Kleyer 17, 4000 Liège, Belgium. 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 con-formity 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 state- ments 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-look- ing 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-look- ing statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law. You should not place undue reliance on forward-looking statements. Certain monetary amounts and other figures included in this annual report have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

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# Note



Hyloris Pharmaceuticals SA

Boulevard Gustave-Kleyer 17 4000 Liège, Belgium https://hyloris.com/