

A photograph of a man with a shaved head and a goatee, wearing a blue t-shirt and khaki pants, carrying a young child with curly hair on his shoulders. They are in a lush green forest. The man is looking up and smiling, and the child is also smiling. The background is filled with green foliage and trees.

# ANNUAL REPORT 2020

## REFORMULATING THE FUTURE





Specialty biopharma

### Attractive Risk-Reward



At the heart of Europe, Belgium

### Founded in 2012



### Build-out own, U.S., lean commercial organisation,

focused on cardiologists



### Raised ~€86 million since foundation

Euronext Brussels - HYL



### Broad pipeline<sup>1</sup>

with 11 innovative, value added candidates plus 2 approved products



### Extensive KOL & partners network

Strong IP and knowhow

<sup>1</sup> The two high barrier generic products within the “Established Markets Portfolio” not included



# ANNUAL REPORT 2020

This Annual Report 2020 includes the management report in accordance with article 12 of the Royal Decree of 14 November 2007 relating to the obligations of issuers of financial instruments admitted on a regulated market. All information required to be included in such management report pursuant to articles 3:6 and 3:32 of the Belgian Code of Companies and Associations is reported throughout all difference sections of this Annual Report.



# Contents

## Business Overview

7

## Corporate Governance

51

## Financial Statements

89

## Auditor's Report

161

## Glossary and Other Info

169





# Business Overview

At a glance .....	8
Letter from the Management.....	10
2020 in brief.....	14
Our Strategy and Strengths .....	16
Key to Our Success .....	24
Outlook 2021 .....	46
The Hyloris Share.....	48



## AT A GLANCE

*ADDING VALUE IS AT THE CORE OF WHAT WE DO*

We are 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, partnered commercial-stage products, Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a novel, dual mode-of-action non-opioid analgesic for the treatment of post-operative pain.

Our development strategy of reformulating and repurposing approved pharmaceuticals primarily utilises the 505(b)(2) regulatory pathway in the U.S. and similar pathways in other countries, which 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.



Specialty biopharma

### Attractive Risk-Reward



### Build-out own, U.S., lean commercial organisation,

focused on cardiologists

*Ambition to become a leading player in number of 505(b)(2) value-added products in the next few years*



At the heart of Europe, Belgium

### Founded in 2012



### Broad pipeline<sup>1</sup>

with 11 innovative, value added candidates plus 2 approved products



Euronext Brussels - HYL

### Raised ~€86 million since foundation



### Extensive KOL & partners network

Strong IP and knowhow

*Fuel the value-added pipeline with at least 4 new candidates in 2021*

*14 approved products expected by 2024*

<sup>1</sup> The two high barrier generic products within the “Established Markets Portfolio” not included





*“We develop products that offer clear benefits to patients, physicians and payors”*

— Stijn van Rompay, CEO Hyloris



## LETTER FROM THE MANAGEMENT

### DEAR SHAREHOLDERS, COLLEAGUES, AND PARTNERS,

It is a great pleasure to present Hyloris Pharmaceuticals' first annual report as a publicly listed company. Despite being set against the tragic backdrop of the global pandemic, 2020 was a momentous year for the Company, and we are extremely proud of the significant progress we have made across all areas of our business, securing a strong foundation to execute our ambitious plans for sustainable long-term growth and value for patients, physicians, payors and shareholders.

Hyloris is committed to changing the lives of patients by applying our extensive experience, industry expertise and innovative technologies to develop novel, 505(b)(2) value-added medicines based on real-world data and our knowledge of established products. To fulfil our goal of developing new ways

to address underserved medical needs, our team is in continuous dialogue with healthcare professionals, patient groups, payors and partners. We are also leveraging our extensive sourcing network and R&D to identify high potential opportunities for value creation.

Securing €79.54 million through an initial public offering on Euronext Brussels and the issuance of convertible bonds in 2020 has provided us with the funding required to execute our ambitious growth plans and we are well positioned to deliver on our goal to bringing our innovative treatments to market as quickly as possible, benefiting patients and providing value for healthcare systems.

Overall, we are pleased to report that we have continued to make progress in line with our stated strategic objectives across our pipeline of 11 value-added product candidates and two commercially available treatments, Maxigesic® IV and Sotalol IV, with sales from these products expected to be the primary drivers of short-term revenue for the Company.

Sotalol IV is a novel, patented intravenous (IV) solution for the treatment of atrial fibrillation, which is commercialised in the U.S. by our partner AltaThera. Oral sotalol is a commonly used drug for the maintenance of normal sinus rhythm in patients with atrial fibrillation. However, the label carries a black box warning requiring patients to be continuously monitored in the hospital for at least 3 days or until steady state drug levels are achieved.

The novel Sotalol IV loading indication can dramatically decrease the length of the hospital stay and potentially significantly decrease overall cost of care, while improving patient outcomes and safety, since the use of the IV formulation of this widely used drug allows for a faster onset of activity and hence the use of Sotalol IV has received strong support from the medical community.

In March 2020, the U.S. Food and Drug Administration (FDA) approved a label extension of Sotalol IV to include the initiation of loading on Sotalol IV in patients who are prescribed oral sotalol and for dose escalation for chronic administration of an increased dose of oral sotalol, thereby significantly broadening the product's potential. AltaThera has commenced the launch of the product under this newly expanded label and has significantly enlarged their sales force to support roll-out and commercialisation in the U.S.

Maxigesic IV, a novel, patented, dual mode-of-action non-opioid pain treatment, is a unique combination of Paracetamol (known as acetaminophen in the U.S.) 1000mg + Ibuprofen 300mg solution for infusion for use post-operatively in hospitals for patients for whom the use of oral analgesics is limited. Treatment options for post-operative pain have not substantially improved over the past 20 years, with the misuse of opioids remaining a key public health issue with globally more than 100,000 deaths annually due to opioid-involved overdoses. There is an urgent need for safer and more effective non-opioid pain treatments in the post-operative hospital setting, and thanks to its unique, dual mode-of-action, Maxigesic IV has the potential to become a valuable pain treatment option without the side effects and risk of addiction associated with opioids.

Throughout 2020, our partner AFT Pharmaceuticals has made significant progress and obtained National Marketing Authorisations for Maxigesic IV in 17 European countries, signed multiple license agreements in Europe and launched Maxigesic IV in New Zealand, Australia and the United Arab Emirates. In July we were pleased to see the successful completion of a second Phase 3 study in 232 subjects to support regulatory filing to the FDA. The submission of a scientific paper in a peer reviewed journal is currently being prepared by AFT and we anticipate the submission of the marketing application to the FDA in the first half of 2021.

In February 2021 we were pleased to announce a partnership with Purna Female Healthcare (“PFH”), a spin-off founded by Purna Pharmaceuticals NV and Creafund NV, to develop an innovative combination therapy for the treatment of severe and recurrent vulvovaginal candidiasis (rVVC). There is currently no cure for severe and rVVC and patients with these conditions suffer from pain, anxiety, shame, and depression.





*“Unique value propositions and potential first-in-class products”*

— Stefan Yee, Chairman Hyloris

We believe that our novel Miconazole-Domiphen Bromide (MCZ-DB) combination candidate therapy has significant potential to help women manage this underserved condition and demonstrates our ability to identify, reformulate and repurpose known products to substantially enhance current treatment practices.

During the next coming months, we expect to further expand our diversified pipeline with the addition of at least three new product candidates in addition to the recently announced partnership with PFH. Despite the global challenges brought on by the COVID-19 pandemic, all our pipeline programs are progressing well, and before the end of 2021, we anticipate multiple potential value-enhancing milestones, including the results from the pivotal study of Atomoxetine Oral Solution in ADHD, the start the pivotal study of Dofetilide IV in Atrial Fibrillation, the results from the PK and safety study of HY-004 (non-disclosed indication), and the start of the Phase 2 dose-finding study of MCZ-DB. We also expect additional licensing and commercial agreements and preparations to start several pivotal studies of our other value-added product candidates. By end 2024, we expect to have 14 approved products.

With cash and cash equivalents of €64.40 million at year-end 2020, the Company is well-capitalised to advance all current pipeline assets as planned and execute on our ambitious growth strategy to become a market leader in number of 505(b)(2) value-added products in the next few years. To support this growth, we strengthened the Company’s internal resources and capabilities and expanded the management team with the appointments of Koenraad Van der Elst as Chief Legal Officer and Dr.

Dietmar Aichhorn as Chief Operating Officer. We also reinforced the capabilities represented by our Board of Directors with the appointments of Leon Van Rompay, Carolyn Myers, James Gale and Marc Foidart, and the nomination of Chris Buyse.

Post period, we were further bolstered by the appointments of Thomas Jacobson as Chief Business Development Officer following the retirement of Ed Maloney, and Marieke Vermeersch as VP Investor Relations and Corporate Communications. Each of these individuals bring new expertise and skills that will enable us to continue the strong momentum we have already built throughout this transformational year for Hyloris.

*“Focused on changing the lives of patients and improve treatment outcomes”*



— Stijn van Rompay, CEO Hyloris

Our thanks go to our staff and all our stakeholders for their continued support. We are confident in the outlook for 2021 and beyond and look forward to providing further updates on our progress as we move through the year.

Stijn Van Rompay  
CEO

Stefan Yee  
Chairman





# 2020 IN BRIEF


STRONG FOUNDATION SET FOR FUTURE GROWTH

## Major Achievements


 **Successfully raised €79.54 million**  
in gross proceeds through the issuance of Convertible Bonds and our Initial Public Offering on Euronext Brussels

 **Strengthened our internal capabilities and management team**  
with the appointments of Koenraad van der Elst as Chief Legal Officer and Dr. Dietmar Aichhorn as Chief Operating Officer

 **Further expanded our Board of Directors**  
with the appointments of Leon Van Rompay, Carolyn Myers, James Gale and Marc Foidart, and the nomination of Chris Buyse

 **Sotalol IV**  
*novel intravenous (IV) loading formulation of oral sotalol to treat atrial fibrillation: partnered with AltaThera in the U.S.*

FDA approval of the expanded label of Sotalol IV for loading in all AF patients to potentially replace oral sotalol initiation regimen until steady state drug levels are achieved. Sotalol IV has potential to dramatically reduce hospital stay that is required with initiation, up-titration or re-initiation of oral sotalol, resulting in important potential cost savings, better patient outcomes and safety.

 **Maxigesic® IV**  
*novel dual mode-of-action non-opioid pain treatment: partnered with AFT Pharmaceuticals globally*

Obtained marketing authorisations in 17 European countries, launched in Australia, New Zealand and United Arab Emirates, and multiple license and distribution agreements signed to accelerate roll-out and commercialisation in Europe and Hong Kong. Second Phase 3 study successfully completed to support regulatory submission in the U.S.

## Financial Highlights

(in € thousand)	Year ended 31 December		
	2020	2019	Variance
<b>Revenues</b>	175	91	92%
Research and development expenses	(3,413)	(4,577)	(25%)
General and administration expenses	(2,194)	(808)	172%
Shares' issuance related expenses	(1,468)	-	NA
<b>Operating result</b>	<b>(7,025)</b>	<b>(5,274)</b>	<b>(25%)</b>
Net financial result	(120)	(508)	76%
<b>Net result</b>	<b>(7,145)</b>	<b>(5,768)</b>	<b>(16%)</b>
<b>Net operating cash flow</b>	<b>(4,570)</b>	<b>(4,562)</b>	<b>(0.2%)</b>
<b>Cash and cash equivalents</b>	<b>64,399</b>	<b>205</b>	<b>NA</b>

Well-capitalised to execute ambition growth plans



# OUR STRATEGY AND STRENGTHS

COMMITTED TO ADDRESSING UNDERSERVED NEEDS THROUGH INNOVATION

## Faster Innovation at a Much Lower Cost and Risk to Drive Continuous Growth and Create Shareholders' Value

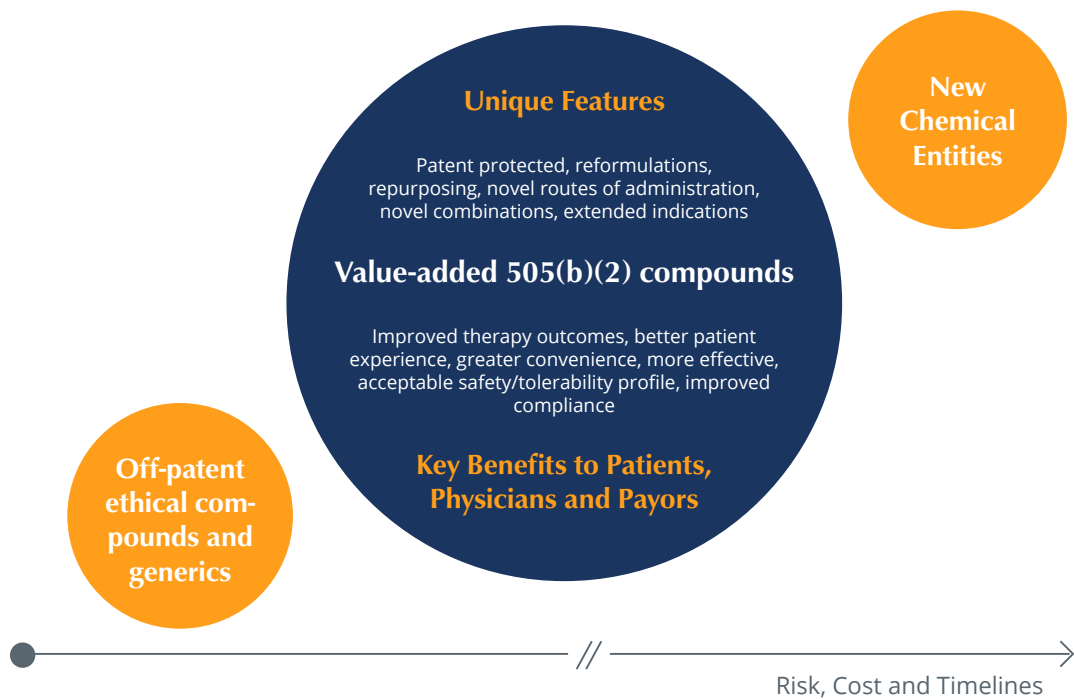
Since our inception, we have significantly strengthened our capabilities and skills, and expanded our focus from high barrier generics towards complex, reformulated and repurposed patented products, thereby further moving up the value chain.

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.

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.

To achieve our goal of becoming a leader in the number of 505(b)(2) value-added products in development, 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



### 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
- Added-value to the healthcare system

### Technical feasibility

≤ 7 years to market

≤ €7 million cost

Minimal NPV hurdle

### Continuously growing diversified product portfolio characterised by:

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

Ambition to become a leading 505(b)(2) company





**11<sup>1</sup>**  
**505(b)(2)**  
**differentiating product**  
**candidates in the pipeline**  
**and growing exponentially**

across various stages of  
development and indications

**2**  
**Marketed**  
**products**

via partners in the  
U.S. and RoW

**Acquisitions**  
**and in-licensing**

Scouting for strategic fits  
on an opportunistic  
basis

**Desk**  
**research**

Conducting extensive  
market studies and com-  
paring utilisation patterns  
and labels for ex-U.S.  
pharmaceuticals

**FDA-approvable**  
**off-label utilisation**

Uncovering usage opportuni-  
ties for indications that are not  
included in the current  
package insert

**Real-  
World Data**  
**and Surveys**

Polling KOLs and payors  
to find solvable problems  
and assess appetite for  
potential solutions

**Network**

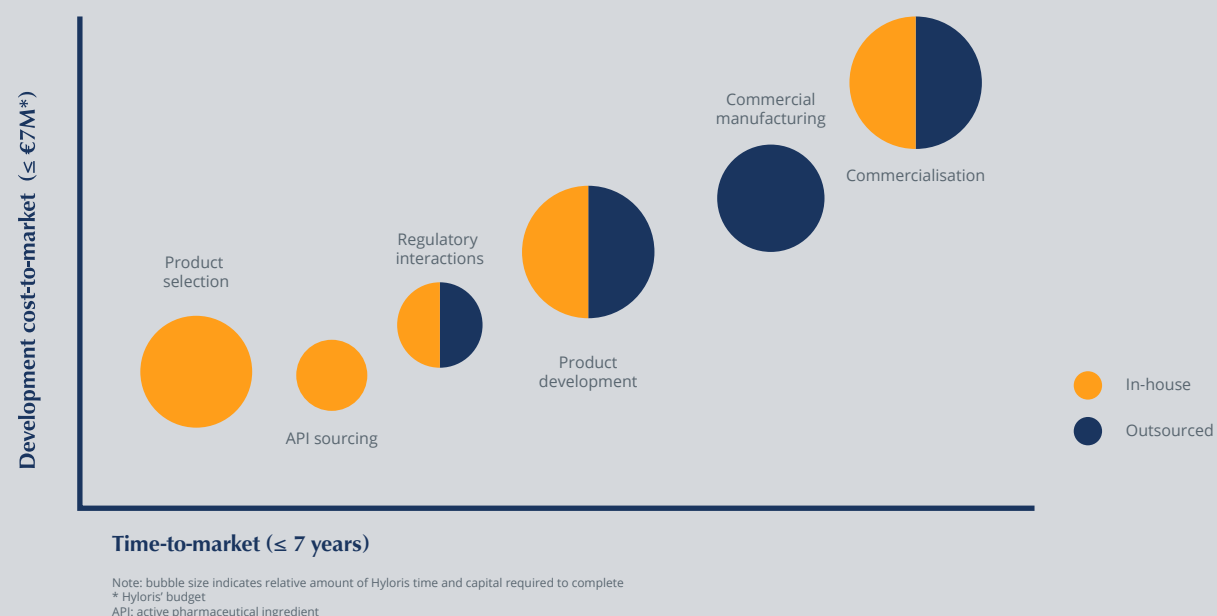
In-depth discussions  
with physicians and  
partners to uncover  
underserved needs

1 Our two high barrier generic products not included





## The Key Elements of Our Strategy Include:



- **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, 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.

- **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 14 approved products 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 long-term strategy to register and protect our intellectual property to maximise our products' commercial lifespan. Our patent portfolio (as owner, co-owner and/or licensee) provides a wide range of protection, including dosages and formulations, medical indications, methods for preparing a composition and improved methods of production.

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

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

More notably, there are currently 6,146 hospitals and less than 33,000 cardiologists in the U.S., with more than 70% of cardiologists employed by hospitals. We will commercially target sub-segments for the promotion of our products such as an estimated 3,200 electrophysiologists in the U.S. (with the exception of Sotalol IV, which is partnered with AltaThera and HY-075

which has potential in the larger retail market). We expect to have our U.S. specialist sales force on the ground when we are closer to the anticipated approval of our first, non-partnered cardiovascular product candidate, Dofetilide IV (for the treatment of atrial fibrillation), currently anticipated in 2023.

For our other product candidates, we intend to remain flexible and assess the optimal commercialisation strategy on a case-by-case basis to maximise the return on investment, including potential commercial opportunities outside the U.S. For our existing commercial products, Sotalol IV and Maxigesic IV, we already have agreements with strategic partners for the marketing, sale and distribution of these products, i.e. AltaThera and AFT Pharmaceuticals respectively.

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

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

By 2024, we anticipate having 14 approved and commercial products, marketed either alone or with strategic partners.

For the majority of our partnered products (with the exception of Sotalol IV, Maxigesic IV and Miconazole-Domiphen Bromide), we expect to retain a large minority or small majority of the net product margin (i.e., the gross profit after deduction of distribution and manufacturing related expenses, insurance, transport etc.) realised by our commercial partners. In general, we do not target substantial upfront milestone payments from our commercial partners as we prefer to retain more product sales related income.

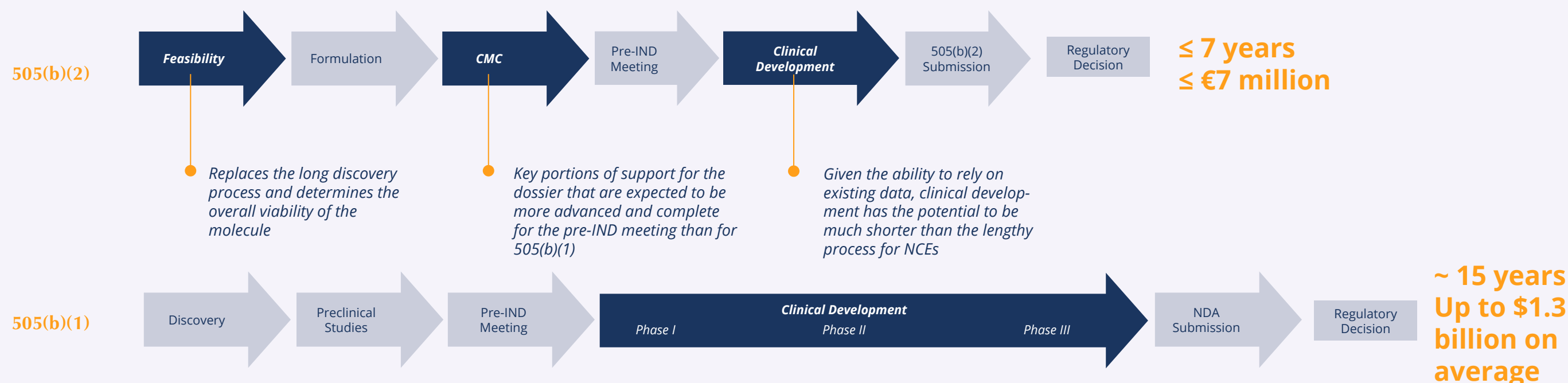


## The 505(b)(2) Regulatory Pathway Significantly Lowers Development Risks and Costs Compared to the Traditional 505(b)(1) Regulatory Pathway

The 505(b)(2) regulatory pathway is intended for molecules that have previously been approved by the FDA or that have been proven to be safe and effective outside the U.S.

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
- **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



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



## KEY TO OUR SUCCESS

### BUILDING A BROAD, PROPRIETARY INNOVATIVE PRODUCT PORTFOLIO

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

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

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

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

*Our goal is to fuel the pipeline with at least 4 new product candidates in 2021 with the ambition to have 14 approved products by end 2024*

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

Product	Route of Administration	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Expected Launch
<b>CARDIOVASCULAR PORTFOLIO</b>						
Sotalol IV	IV	Atrial fibrillation				'20 <sup>1</sup> 🇺🇸 with AltaThera
Dofetilide IV	IV	Atrial fibrillation				'23 🇺🇸
Metolazone IV	IV	Congestive heart failure				'24 🇺🇸
HY-073	IV	Coronary heart disease				'25 🇺🇸
HY-074	IV	Coronary heart disease				'25 🌐
HY-075	Oral Liquid	Coronary heart disease				'24 🇺🇸
<b>OTHER VALUE-ADDED PORTFOLIO</b>						
Maxigesic® IV	IV	Post-operative pain				'20 <sup>2</sup> 🌐 with AFT Pharmaceuticals
Tranexamic Acid RTU	IV	Excessive bleeding				'22 🌐
HY-038	IM	(specific) deficiency				'23 🇺🇸
HY-004	Oral Liquid	Non-disclosed				'24 🌐
Miconazole-DB	Topical	Severe and rVVC				TBD 🌐
Atomoxetine	Oral Liquid	ADHD				'23 🇺🇸
HY-029	Oral Liquid	Viral infection				'24 🇺🇸

The pipeline graph presented above does not include our to high barrier generics: HY-016 and Fusidic Acid Cream

1 Under the new expanded label

2 Marketing application in the U.S. currently being prepare

Partners: **AFT** pharmaceuticals  
**ALTATHERA** PHARMACEUTICALS

Intended to be commercialised by Hyloris

Intended to be commercialised with partner



## Benefits to Patients, Physicians and Payors

Adding value is at the core of everything we do.

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

Product	Route of Administration	IP	Indication	Potential Added Value
<b>CARDIOVASCULAR PORTFOLIO</b>				
<b>Sotalol</b>		'34-'38; granted	AF	Shorter hospital stay; fast onset of action; lower overall healthcare cost; facilitate antiarrhythmic therapy for patients unable to swallow tablets
<b>Dofetilide IV</b>		'39; pending	AF	Shorter hospital stay; lower overall healthcare cost; facilitate antiarrhythmic therapy for patients unable to swallow tablets
<b>Metolazone IV</b>		'38; pending	Congestive heart failure	Fast onset of action (essential in critical care) ; improved drug absorption and concomitant treatment possible
<b>HY-073</b>		<i>Confidential</i> - granted	Coronary heart disease	Fast onset of action (essential in critical care) with low drug-drug interaction risk; therapy possible in patients who are nauseous or unconscious
<b>HY-074</b>		<i>Confidential</i>	Coronary heart disease	Fast onset of action (essential in critical care) with low drug-drug interaction risk; therapy possible in patients who are nauseous or unconscious
<b>HY-075</b>		<i>Confidential</i>	Coronary heart disease	Possibility for drug titration, ease of administration and indicated dosage control
<b>OTHER VALUE-ADDED PORTFOLIO</b>				
<b>Maxigesic® IV</b>		'30-'38; granted & pending	Pain	Highly effective non-opioid; tolerable profile; dual MOA; greater pain relief
<b>Tranexamic Acid RTU</b>		'39; granted	Excessive bleeding	Improved convenience and ease of use; potential as critical care product
<b>HY-038</b>		<i>Unregistered</i>	ND Deficiency	Prefilled syringe; improved convenience and potential health economic benefits
<b>HY-004</b>		'39; granted & pending	ND	Address acute issues or possible procedural related complications in dental offices
<b>Miconazole-DB</b>		'38; pending	sVVC/rVVC	Dual MOA; addressing population for whom there is no cure available
<b>Atomoxetine</b>		'36; granted	ADHD	Possibility for drug titration, ease of administration and indicated dosage control; improved compliance and convenience
<b>HY-029</b>		<i>Confidential</i>	Viral infections	Ease of administration and dosage control; improved compliance and clinical benefit

ND = non-disclosed



## Our Commercial Portfolio

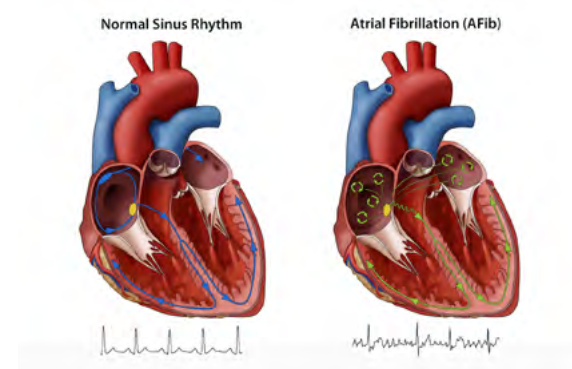


### Sotalol IV for the treatment of atrial fibrillation

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

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

Normally, the heart contracts and relaxes to a regular beat. In atrial fibrillation, the upper chambers of the heart (the atria) beat irregularly (quiver) instead of beating effectively to move blood into the ventricles. A clot that breaks off and enters the bloodstream and lodges in an artery leading to the brain results in a stroke.



Source: WebMD

#### 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 anti-arrhythmic drug, with the oral potassium channel blockers being the principal rhythm control drugs in the U.S. (including amiodarone, dronedarone, sotalol and dofetilide).

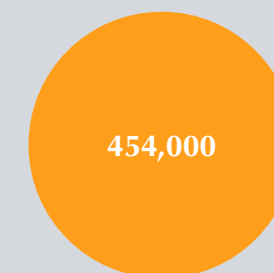
In 2019, about 730 million tablets and capsules of rhythm control drugs were sold in the U.S. with amiodarone and sotalol leading the space with 30% and 29% market share, respectively<sup>3</sup>.

#### >200 million Sotalol tablets/year in the U.S. despite FDA black box warning

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.



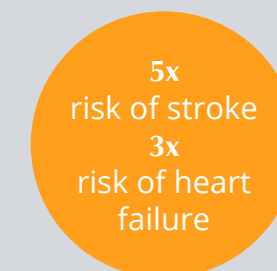
U.S. prevalence expected to double to 12 million by 2030<sup>1</sup>



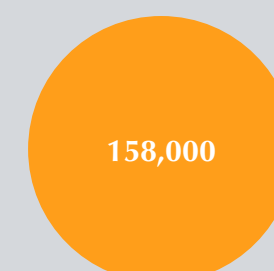
AF-related hospitalisations per year in the U.S. with majority receiving an anti-arrhythmic drug



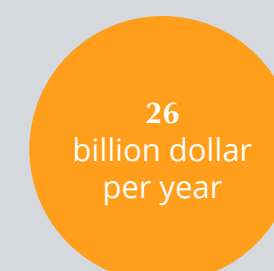
If left untreated, AF patients will die within five years following onset of symptoms



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>



deaths per year in the U.S. to which AF contributes



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>

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

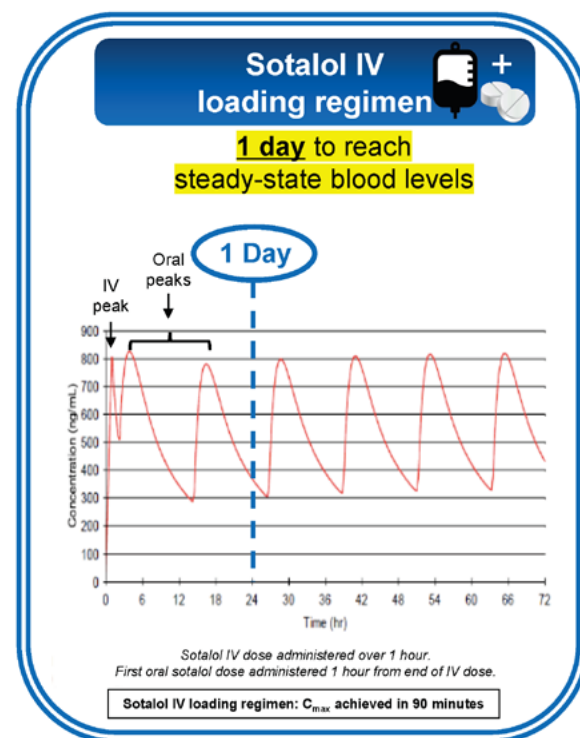
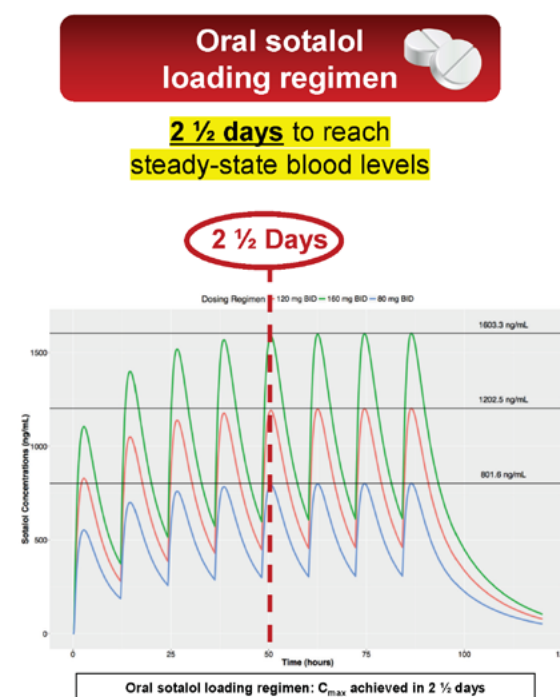


**Our solution: Sotalol IV: an innovative, patented, IV formulation of oral sotalol, the 2nd most widely used antiarrhythmic drug in the U.S.**

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 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 of Sotalol IV.

***Sotalol IV has potential to capture 18% of the market***



**2020 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.



## Maxigesic® IV for the treatment of post-operative pain - \$442M peak sales potential in U.S., Japan and EU5<sup>4</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 post-operative or non-operative. Post-operative pain is a response to tissue damage during surgery that stimulates peripheral nerves, which signal the brain to produce a sensory and emotional response.

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

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.

*“Reformulating and repurposing existing pharmaceuticals to benefit patients, physicians and payors”*

<sup>4</sup> DelveInsight market study (EU5: France, Germany, Italy, Spain, UK) (includes Maxigesic® in oral form)

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.

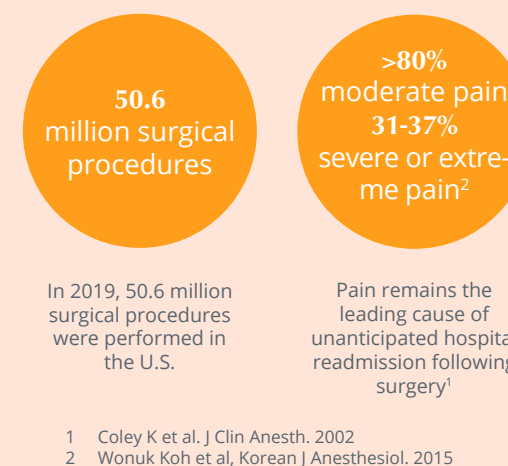
## Analgesics

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 health-care, 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. 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).<sup>5</sup>



<sup>5</sup> IQVIA and DelveInsight Market Research



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

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

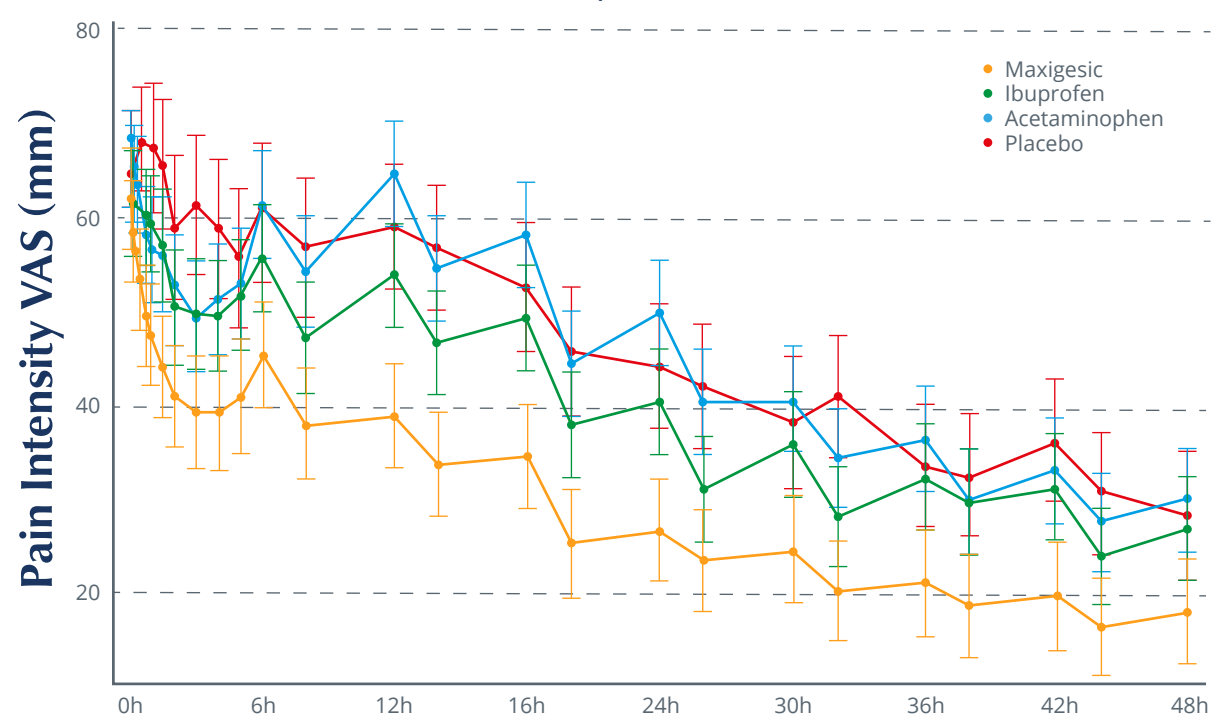
Maxigesic IV is a novel and unique combination of 1000mg paracetamol with 300mg ibuprofen solution for infusion for use post-operatively in a hospital setting.

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

Results from a randomised, double-blind, placebo-controlled Phase 3 trial in 276 patients following bunion surgery demonstrated that Maxigesic IV was well-tolerated and had a faster onset of action and offered higher pain relief compared to ibuprofen IV or paracetamol IV alone in the same doses. Moreover, the superior analgesic effect of Maxigesic IV was supported by a range of secondary endpoints, including reduced opioid consumption compared to the paracetamol IV and ibuprofen IV treatment groups ( $P < 0.005$ )<sup>6</sup>. An additional exposure study has demonstrated Maxigesic IV's efficacy and safety in an expanded population group over a longer treatment period<sup>7</sup>.



**Mean Estimates & 95% Confidence Intervals**



<sup>6</sup> Daniels et al, 2019, Clinical Therapeutics

<sup>7</sup> Maxigesic IV Phase 3 exposure study. Study ID No AFT-MXIV-11. NCT04005755. Submitted for publication

**2020 achievements**

Hyloris' partner AFT Pharmaceuticals launched Maxigesic IV in New Zealand, Australia and the United Arab Emirates. In addition, Maxigesic IV obtained approval in 17 European countries and is to date licensed in more than 90 countries. The preparations to submit a marketing application to the FDA progressed well and a submission is anticipated in the first half of 2021.



## Our Cardiovascular Product Pipeline Targeting Multi-Billion-Dollar End-Markets



At the date of this annual report, our cardiovascular product pipeline includes five 505(b)(2) reformulated product candidates in formulation and pilot production, and we anticipate that by 2022, all these products will be in clinical development or beyond.

We intend to build-out our own commercial organisation in the U.S. focused on specialist cardiologists and 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.

### Dofetilide IV

#### Indication

Atrial fibrillation, a life-threatening cardiac condition expected to affect more than 12 million people in the U.S. by 2030. See also section on Sotalol IV.

#### Unmet needs

On average, the duration of hospital stay required for dofetilide oral dosing is even longer than that of patients on oral sotalol, due to underlying weakness of the heart.

### Our potential solution

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, potentially 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 *Torsades de Pointes* happen gradually. In other words, the loading related risk is different.

### Metolazone IV

#### Indication

Congestive heart failure (CHF) is the most rapidly growing cardiovascular condition globally and the leading cause of hospitalisations, with 30% readmission rate.

Approximately 870,000 new cases per year in the U.S. and 8 million people in the U.S. are expected to suffer from CHF by 2030.<sup>8</sup>

By 2030, the total cost of heart failure is forecasted to reach \$69.8 billion.<sup>9</sup>

#### Unmet needs

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>10</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 oedema.

### Our potential solution

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.

### HY-073, HY-074 and HY-075

#### Indication

Coronary Heart Disease (CHD) is a serious condition usually caused by atherosclerosis, i.e. plaque (fatty deposits) build-up in the arteries, which may partially or totally block blood flow through large- or medium-sized arteries in the heart, brain, pelvis, legs, arms, or kidneys.

Plaque itself can pose a risk. A piece of plaque can break off and be carried by the bloodstream until it gets stuck. And plaque that narrows an artery may lead to a blood clot (thrombus) that sticks to the blood vessel's inner wall, which in return can provoke acute coronary syndrome (ACS).

<sup>8</sup> Benjamin et al, Circulation, 2019

<sup>9</sup> AHA association

<sup>10</sup> Ellison et al, NEJM 2017



In either case, the artery can be blocked, cutting off blood flow.

CHD can result in (i) a stable angina: episodic chest pain occurring on exertion and lasting two to five minutes, (ii) unstable angina: severe chest pain occurring at rest and lasting more than ten minutes, (iii) acute myocardial infarction: heart attack accompanied by a sensation of tightness, pressure or squeezing and (iv) sudden cardiac death: sudden death caused by loss of heart function.

The risk of coronary heart disease increases with family history of coronary heart disease before the age of 50, older age, smoking tobacco, high blood pressure, high cholesterol, diabetes, lack of exercise and obesity.

Heart attack is the leading cause of death in the U.S. with >370,000 deaths every year.<sup>11</sup> About 18.2 million adults in the U.S., aged >20 years old, had a CHD in 2017 and the estimated annual incidence of heart attacks in the U.S. amounted to 605,000 new attacks and 200,000 recurrent attacks between 2005 and 2014.<sup>12</sup>

#### Unmet needs

When ACS occurs, fast diagnosis and treatment is crucial and potentially lifesaving. The sooner treatment begins, the better the chances of survival.<sup>13</sup>

If the blood flow is not restored quickly, the damage to the heart muscle can be permanent or the patient may die.

Half of all deaths due to a heart attack occur in the first three to four hours after symptoms begin.

Despite the need for fast onset of action drugs is the majority of current standard of care treatments only available in oral form, resulting on a significant delay in treatment onset. Existing IV formulations are only used during percutaneous coronary intervention and require continuous infusion due to their short drug half-life. Furthermore, the optimal switching strategy from the IV to an oral therapy with another mode-of-action is a concern due to drug-drug interactions and lack of guideline recommendations.

#### Our potential solutions

HY-073 and HY-074 are intravenous formulations of current standard of care treatments to offer faster onset of action (and thereby potentially significantly reduce the risk of death), more convenient administration (more notably in patients who are nauseated or unconscious), and dosage control. In addition, our IV product candidates are currently available in oral form, which should allow for an optimal switching strategy from the IV to the oral form.

HY-075 is a novel liquid formulation of a commonly used drug for the treatment of specific cardiovascular diseases requiring frequent dosage changes and adjustments. This novel formulation is expected to significantly improve drug administration, ease of use, and dosage control, potentially resulting in potential better compliance and patient outcomes.

## Other Value-Added Products in the Pipeline Addressing Global Healthcare Challenges



**At the date of this annual report, six 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 commercialization of these assets.**

For competitive reasons, the indications of most 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

Severe and recurrent vulvovaginal candidiasis (VVC) are chronic and debilitating vaginal infections commonly caused by the yeast *Candida albicans*.

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.

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.

<sup>11</sup> American Heart Association, Heart Disease & Stroke Statistics (2016)

<sup>12</sup> American Heart Association, Heart Disease & Stroke Statistics (2019)

<sup>13</sup> The Complete Encyclopaedia of Medicine & Health, Johannes Schade

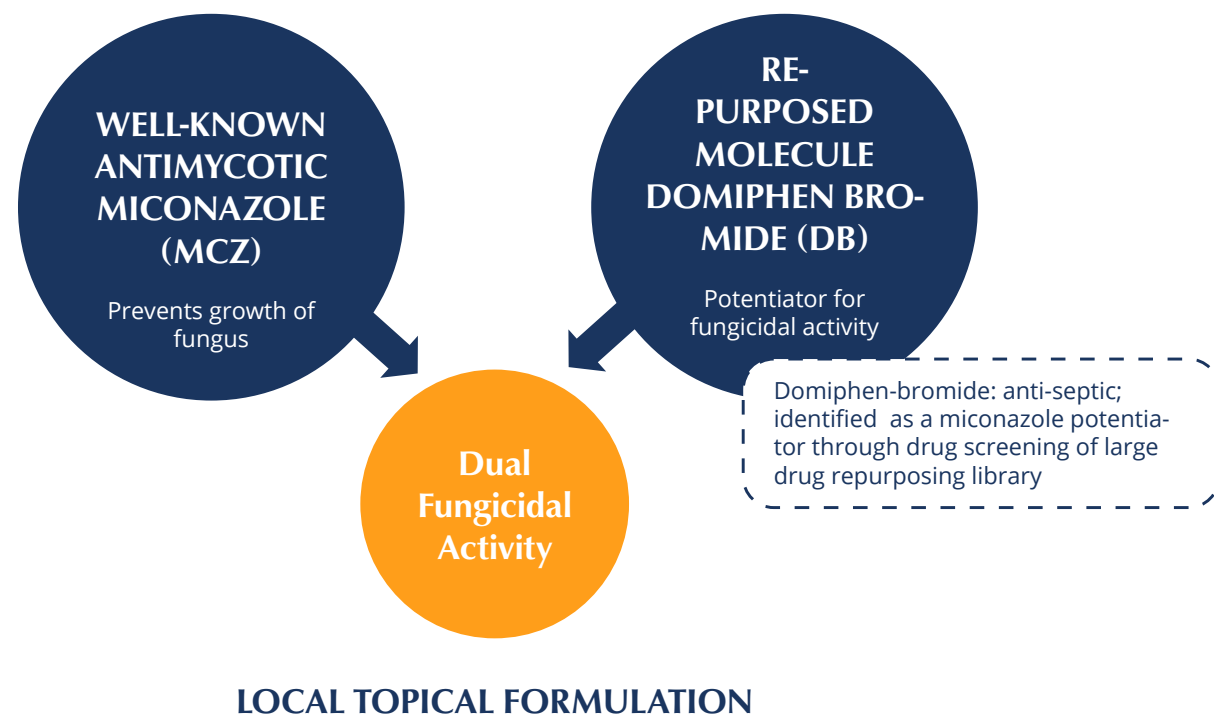
### Current treatments and their limitations

VVC treatments include topical and systemic anti-fungal treatments with about 175 million drug products sold annually.<sup>14</sup>



However, these are not effective and have severe side effects when used chronically to treat severe and recurrent VVC. With limited innovation over the past decades, there is a high unmet need for effective and safe treatment options for severe and recurrent VVC.

**For as many as 10% of all women globally, there is no effective treatment available**



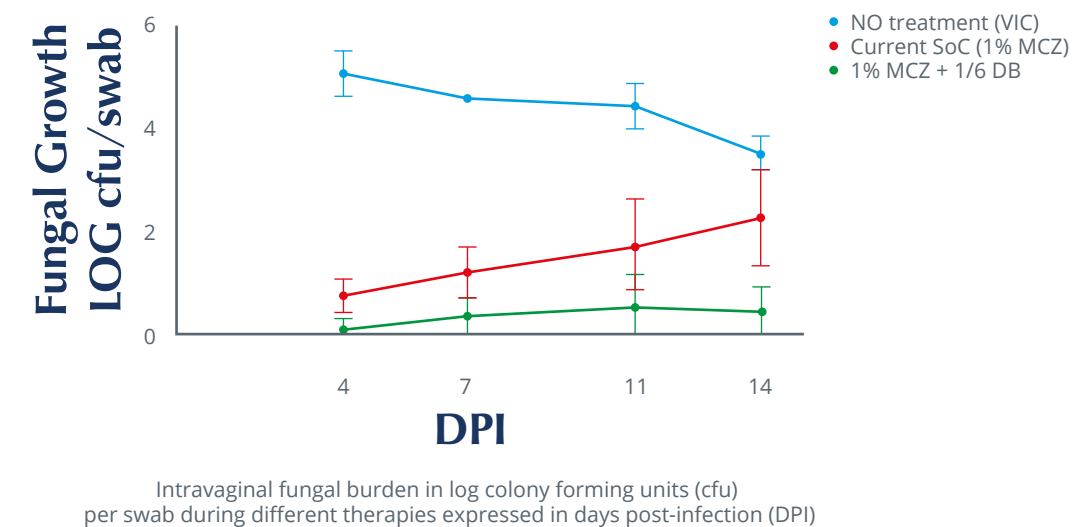
### Our potential solution: Miconazole-Domiphen Bromide, a novel, dual-mode-of-action locally administered emulsion

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

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* infection<sup>15</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.

**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>16</sup>**

The Phase 2 dose-finding study of MCZ-DB is expected to start later in 2021.



**Domiphen Bromide (DB) significantly enhances miconazole efficacy *in vivo***

<sup>15</sup> J Tits., J et al., Antimicrob. Agents Chemother (2020); K. De Cremer et al., Antimicrobial agents and chemotherapy (2015)  
<sup>16</sup> Manuscript for scientific paper submitted





## Tranexamic Acid Ready-to-Use (RTU), a reformulated RTU conversion containing tranexamic acid to treat or prevent excessive bleeding

### Indication

Tranexamic acid is approved for haemophilia, a rare genetic clotting disorder, affecting about 400,000 people worldwide. Tranexamic acid is also approved outside the U.S. in a range of other indications related to bleeding complications (e.g. haemorrhage and fibrinolysis).

Tranexamic acid is an anti-fibrinolytic drug that controls bleeding and sales of tranexamic acid injectable vials in the U.S. have grown significantly from 49,000 vials in 2007 to 4.04 million in 2018.

### Current treatments and their limitations

The preparation of the intravenous solution of tranexamic acid is cumbersome and requires multiple steps, resulting in treatment delays.

Recent scientific studies demonstrated that patients should be treated with tranexamic acid as soon as possible after injury as every 15 minutes in treatment delay decreases the drug's efficacy by 10%, with complete loss of effect after 3 hours.<sup>17</sup>

### Our potential solution

To optimise drug administration and avoid time wasted on pre-administration dilution manipulations and to avoid dosing errors, we have developed a ready-to-use, prediluted solution packed in infusion bottles with concentrations of 2.0 g (10 mg/ml, 200 ml), 1.0 g (10 mg/ml, 100 ml) and 0.5 g (5 mg/ml, 100 ml). No clinical studies were required for the regulatory submission as the FDA concluded that an *in vivo* bioequivalence study of an IV product intended solely for administration by injection is self-evident.

In April 2019, Exela Pharma Sciences obtained approval of a 10 mg/ml version of tranexamic acid RTU in 100 ml sodium chloride and is gaining market share.<sup>18</sup>

The marketing application for Tranexamic RTU, 1. g (10 mg/ml, 100 ml) product to obtain U.S. approval was submitted to the FDA in early 2021, but with increased competition from Exela Pharma Sciences, generics manufacturers of the vials and possible additional entrants, the market potential of Tranexamic Acid RTU will likely be impacted.

## 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, have lower grades and are more likely to drop out of school. In addition, ADHD often presents itself with one or more comorbidities such as oppositional defiant disorder, major depressive disorder, and anxiety disorders, thus bestowing additional challenges on these individuals.

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.<sup>19</sup>

### Current treatments and their limitations

Stimulants are the most widely used medications for ADHD. In most cases, non-stimulant medications are considered when stimulants do not work or have caused intolerable side effects.

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 commercialised by several companies.

In 2019, atomoxetine had more than 2 million prescriptions<sup>20</sup> in the U.S. and the number of atomoxetine capsules sold over the past few years has grown from 88.5 million in 2016 to 99.3 million in 2019.<sup>21</sup>

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 choking.<sup>22</sup>

### 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 its use 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 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.<sup>20</sup>

The start and results from the pivotal study of Atomoxetine Oral Liquid are anticipated later in 2021.

<sup>19</sup> Sharma and Couture, Ann Pharmacother. 2014

<sup>20</sup> "The Top 300 of 2019". clincalc.com. Archived from the original on 21 November 2018. Retrieved 22 December 2018

<sup>21</sup> IQVIA

<sup>22</sup> Van Riet Nales DA et al. Oral medicines for children in the European paediatric investigation plans. PLoS One 2014; 9(6): e98348.

<sup>17</sup> Roberts et al, The Lancet 2019; Gayet-Ageron et al, The Lancet 2018

<sup>18</sup> Hyloris IPO prospectus



High Barrier Generics Portfolio



Outside our core strategic focus, we have two high barrier generic products in late-stage 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.
- Fusidic acid cream, a generic of an off-patent reference product currently sold in Canada without generic competition, is expected to enter clinical development shortly.

HY-016 is partnered with Perrigo. For Fusidic acid cream, we intend to seek a commercial partner closer to approval of the product.

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 2021

## MULTIPLE VALUE INFLECTION MILESTONES AHEAD

### 2021-to-Date Achievements

The year 2021 started with numerous value-enhancing events:

#### Pipeline expansion

We signed a partnership with Purna Female Healthcare (“PFH”) (a spin-off founded by Purna Pharmaceuticals and Creafund) to develop Miconazole-Domiphen Bromide (MCZ-DB) a novel, topical, dual mode-of-action combination candidate treatment for severe and recurrent vulvovaginal candidiasis (VVC). Severe and rVVC are debilitating vaginal fungal infections for which there are no effective treatment options currently available. Under the terms of the agreement, Hyloris has committed to milestone related investments of up to €4.3 million in PFH (of which €1.27 million at signing) and will lead the commercialisation and out-licensing activities. Hyloris owns 20% of PFH and is eligible to receive up to a maximum of 45% of the net profits generated by PFH. The Phase 2 dose-finding clinical study of MCZ-DB is expected to start later in 2021. PFH has exclusively in-licensed MCZ-DB and associated Intellectual Property owned by KU Leuven and the University of Antwerp (Belgium).

#### Clinical

- **HY-004** (indication not disclosed): initiated a Phase 1 study to evaluate the pharmacokinetics (PK) and safety of HY-004 oral solution – the study also includes exploratory efficacy endpoints

#### Regulatory

- **Tranexamic Acid RTU**, a ready-to-use IV administration of tranexamic acid to prevent excessive blood loss: submitted a marketing application to the FDA

Tranexamic Acid RTU has potential to facilitate the use of antifibrinolytic therapies for haemophilia patients and patients with trauma injuries, and to save time for healthcare professionals by eliminating the need for additional dilution procedures and manipulations prior to administration

#### Commercial

- **Maxigesic IV**: commercial partner AFT signed an exclusive license and distribution agreement with Hikma in the U.S. and with Aguettant, Mercapharma and Vianex in Europe

#### Corporate

- Strengthened the management team with the appointment of Thomas Jacobsen as Chief Business Development Officer following the retirement of Ed Maloney, and of Marieke Vermeersch as VP Investor Relations and Corporate Communications

### Anticipated Upcoming Value Inflection Milestones in 2021

During 2021, we anticipate delivering on key value inflection milestones within our strategic focus areas:

- **Pipeline expansion** with the addition of at least three new product candidates, in addition to the recently announced partnership with Purna Female Health for Miconazole-Domiphen Bromide
- **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 and results from the pivotal study
- **Dofetilide IV**, a novel, patented IV formulation of dofetilide to allow a faster loading regimen in patients with atrial fibrillation: start pivotal study
- **HY-004 oral solution** (indication 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, which is on track for 2023
- **Miconazole-Domiphen Bromide**: start Phase 2 dose-finding study
- **Maxigesic IV**: submission of marketing application to the FDA

Commercially, Hyloris’ partners AFT Pharmaceuticals and AltaThera will continue the rollout of Maxigesic IV (with the aim to make it available in more than 100 countries - from three today) and Sotalol IV, with sales from these products expected to be the primary drivers of short-term revenue for the Company.

With cash and cash equivalents of €64.40 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 14 approved products expected by 2024.

# THE HYLORIS SHARE

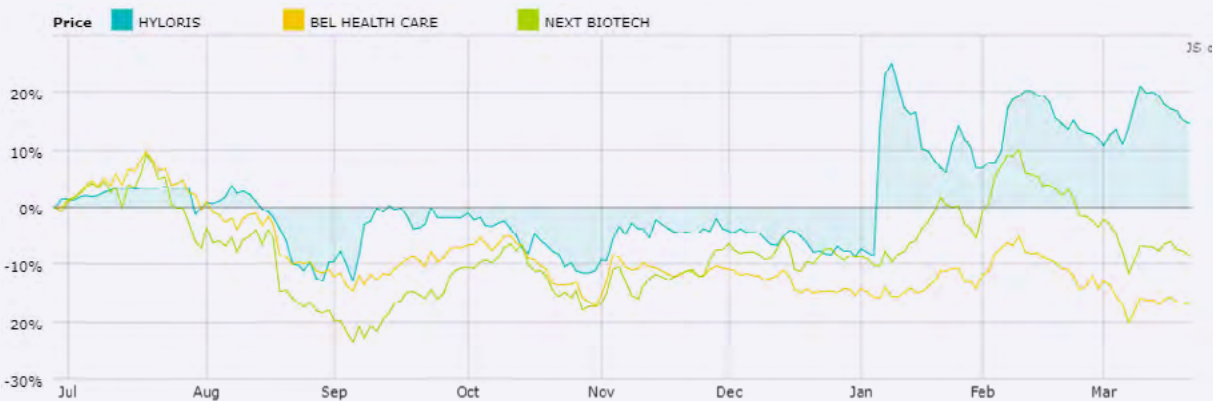
Hyloris Pharmaceuticals SA (ticker: HYL) is listed on Euronext Brussels since 29 June 2020.

## The Hyloris share

Absolute performance since IPO on 29 June 2020



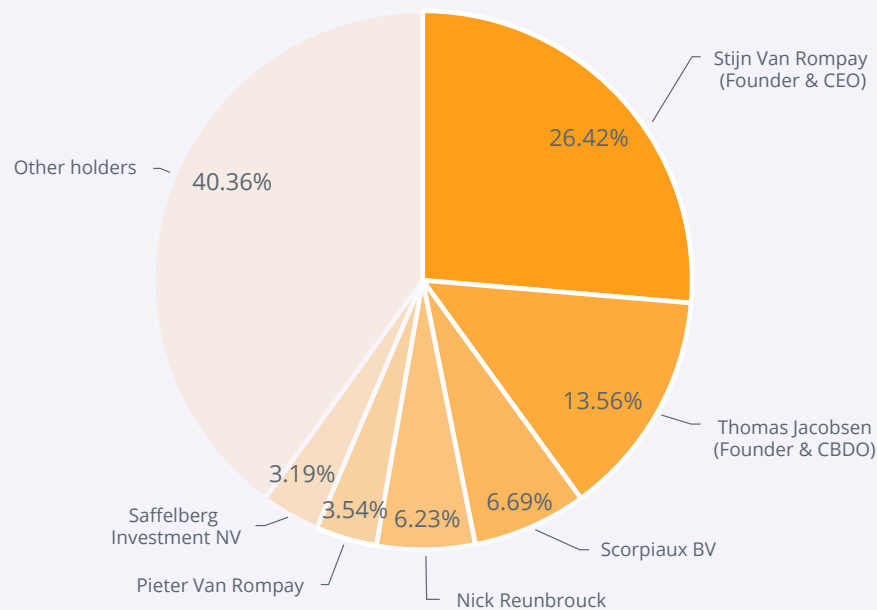
Performance versus sector indices since IPO on 29 June 2020



On 31 December 2020, there were 25,832,632 shares representing a total share capital of the Company of €129,163.16 (excluding share premium). The total number of voting rights (denominator) was 25,832,632 and the total number of securities carrying voting rights not yet issued was 1,933,000.

# Breakdown of Share Capital

## Major shareholders (status December 31, 2020)



Share capital (excluding share premium)	€129,163.16
Total number of outstanding voting rights (= denominator)	25,832,632
Total number of securities carrying voting rights not yet issued	1,913,000

# Analyst Coverage

Bank	Analyst	Rating
KBC Securities	Lenny Van Steenhuyse	Buy
Kempen	René Wouters	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





# Corporate Governance

Introduction .....	52
Compliance with the Corporate Governance Code .....	53
Board of Directors .....	54
Composition of the Board of Directors .....	54
Activity Report .....	58
Committees of the Board of Directors .....	58
Executive Committee .....	62
Remuneration Report .....	64
Remuneration Policy.....	64
Remuneration.....	70
Shares and Share Options - Warrants.....	72
Appraisals.....	72
Internal Control and Risk Management Systems .....	74
Internal Mechanism .....	74
Risk Analysis .....	74
Controls, Supervision and Correctives Actions .....	76
Market Abuse Regulations .....	78
Conflicts of interest and Related Parties.....	79
Conflicts of Interest.....	79
Related Party Transactions .....	80
Share Capital, Shares and Shareholders .....	82
History of Capital - Capital Increase and Issuance of Shares .....	82
Warrants Plans .....	83
Consequences in Case of a Public Take-Over Bid .....	85
Shareholders .....	86
Dividends and Dividend Policy .....	87



## 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://investors.hyloris.com/corporate-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. This deviation is explained by the fact that the members of the Executive Management perform their functions under the leadership of the CEO, to whom the day-to-day management and additional well-defined powers were delegated by the Board of Directors.
- **Provision 4.14:** no independent internal audit function has been established. This deviation is explained by the size of the Company. The Audit Committee will regularly assess the need for the creation of an independent internal audit function and, where appropriate, will consult external persons to conduct specific internal audit assignments and will inform the Board of Directors of their outcome.
- **Provision 7.6:** 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, also as some of them hold ESOP Warrants, the value of which is based on the value of the shares. Therefore, the payment in shares is not deemed necessary. However, the Company intends to review this provision in the future to align its corporate governance with the provisions of the Corporate Governance Code 2020.

- **Provision 7.9:** no minimum threshold of shares to be held by the members of the Executive Committee has yet been set. This deviation is explained by the fact that the interests of the members of the Executive Committee are currently considered to be sufficiently oriented to the creation of long-term value for the Company, also as some of them hold ESOP Warrants, the value of which is based on the value of the shares. Therefore, setting a minimum threshold of shares to be held by them is not deemed necessary. However, the Company intends to review this in the future to align its corporate governance with the provisions of the Corporate Governance Code 2020.

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 seven members (with a minimum of three as set out in the Articles of Association), two of whom are Executive Directors (as member of the Executive Management team) and five of whom are Non-Executive Directors, including three Independent Directors.

The Company's Board currently counts one female Director.

It was decided that when Board seats become available, special efforts will be 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	58	Non-Executive Director Chairman of the Board of Directors	2020	2024
Mr. Stijn Van Rompay <sup>1</sup>	45	Executive Director	2020	2024
Mr. Thomas Jacobsen <sup>2</sup>	46	Executive Director	2020	2024
Mr. Leon Van Rompay <sup>3</sup>	71	Non-Executive Director	2020	2024
Mr. Marc Foidart <sup>4</sup>	45	Independent Director	2020	2024
Mrs. Carolyn Myers	62	Independent Director	2020	2024
Mr. James Gale	72	Independent Director	2020	2024

<sup>1</sup> Acting through SVR Management BV

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

<sup>3</sup> Acting through Van Rompay Management BV

<sup>4</sup> Acting through Noshag Partners SCRL



#### Stefan Yee

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



#### Stijn Van Rompay

Stijn Van Rompay has over 20 years of experience in leadership positions in the pharmaceutical industry and is the co-founder and CEO of the Company. Stijn also co-founded, and was CEO of, Alter Pharma, a pharmaceutical company focused on the development of complex generics and pharmacy-related products. He was also co-CEO of Uteron Pharma, a company focused on innovative female healthcare products, which was sold to Watson for \$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 outlicensing of Docpharma's products. Thomas started his career in the Scandinavian-based generics company Alternova, where he was responsible for licensing, product registration and launches. Thomas holds a Master's Degree in Pharmacy from the University of Copenhagen and a Business Degree from Copenhagen Business School.



#### Leon Van Rompay

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



#### Marc Foidart

Marc Foidart is co-founder of EKLO ASBL, Member of the Executive Committee of Noshag SA in charge of the Life Sciences sector, CEO of B2H SA, the public company superseding the life sciences ecosystem in Liège, and 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. He is also co-founder and Executive Chairman of Eyed Pharma SA, a start-up company developing innovative controlled release microimplants in ophthalmology. 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 Principal of Bioensemble Ltd, a business strategy consulting firm that provides a comprehensive range of drug development, commercial and business development services to C-suite executives of small and medium sized companies. Carolyn's experience comes from having led many businesses in their growth strategies. At Allergan (formerly Actavis), she was the Vice President of Global Business Development and Alliance Management with a focus on expanding product portfolios. At Forest Laboratories (acquired by Actavis), Carolyn was the

Vice President of the CNS marketing group responsible for marketing and sales of established and new products. At Mylan she held two different leadership positions including President of Mylan Technologies, a division focused on developing generic transdermal systems and President of Dey Laboratories having full P&L responsibility to develop, manufacture and sell innovative respiratory products. Carolyn is also an advisor to several start-up organisations and investors. 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 Fund IV and is currently the Chairman of the Board of Alpex Pharma S.A., Knight Therapeutics Inc. (TSX: GUD), Teligent (NSDQ: TLGT, formerly IGI Laboratories), and also serves on the Board of Directors of Bionpharma, Chr. Olesen Synthesis A/S, CoreRx, Leon-Nanodrugs GmbH, Pharmaceuticals International (Pii), Advantice Health, 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).



## Activity Report

In 2020, in addition to discussing the financial reporting and the operational development of the Company, the Board of Directors devoted a great deal of attention to product development and business development, considering further expansion of the Company’s growth and strategy.

The Executive and Non-Executive members of the Board of Directors convened four times in 2020 (August 5, October 14, November 27 (before the Notary through proxy) and December 16). All Directors attended all Board Meetings, except for Mr. Foidart who was excused at the Board Meeting of 16 December.

## 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 consists of three Directors.

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.

As of the Initial Public Offering in June 2020, the Audit Committee comprises the following members:

Name	Position
<b>Mr. Marc Foidart<sup>5</sup></b>	Independent Director, Chairperson of the Audit committee
<b>Mr. Stefan Yee</b>	Non-Executive Director
<b>Mr. James Gale</b>	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 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 Management 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 three times in 2020: on August 3, October 22 and December 14.

### Remuneration and Nomination Committee

The Remuneration and Nomination Committee consists of three Directors.

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 chairperson of the Board of Directors or another Non-Executive Director is the Chair of the Remuneration and Nomination Committee.

<sup>5</sup> Acting through Noshag Partners SCRL

The Remuneration and Nomination committee consist of the following members:

Name	Position
<b>Mr. Stefan Yee</b>	Non-Executive Director Chairperson of the Remuneration and Nomination Committee
<b>Mrs. Carolyn Myers</b>	Independent Director
<b>Mr. Marc Foidart<sup>6</sup></b>	Independent Director

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 participates in the meetings of the Remuneration Committee in an advisory capacity every time the remuneration of another member of the Executive Management 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 Management 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 Management, including variable remuner-

ation and long-term performance bonuses, whether or not linked to shares, in the form of stock options (warrants) or other financial instruments, and severance pay, and, where applicable, the resulting proposals that the Board of Directors must submit to the General Shareholders' Meeting;

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

Pursuant to its function as Nomination Committee:

- make recommendations to the Board of Directors with regard to the appointment of Board members and members of Executive Management;
- prepare plans for the orderly succession of Board members;
- lead the re-appointment process of Board members;
- ensure that sufficient and regular attention is paid to the succession of members of Executive Management; and
- 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 two times in 2020: on August 4 and December 8.

## Scientific Committee

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

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

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

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

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

6 Acting through Noshag Partners SCRL



## EXECUTIVE COMMITTEE

The Board of Directors has established an “Executive Management”, which is an advisory committee to the Board of Directors. The Company’s Executive Management does not constitute a “conseil de direction” / “directieraad” per the definition of Article 7:104 CCA.

The Board of Directors appoints the members of the Executive Management in consultation with the CEO, based on the recommendations made by the Remuneration and Nomination Committee. The Board of Directors considers the need for a balanced Executive team.

On 31 December 2020, the Executive Management consisted of the following members:

Name	Position
<b>Mr. Stijn Van Rompay</b> <sup>7</sup>	Chief Executive Officer Acting Chief Financial Officer
<b>Mr. Thomas Jacobsen</b> <sup>8</sup>	Executive Director
<b>Mr. Koenraad Van der Elst</b> <sup>9</sup>	Chief Legal Officer
<b>Mr. Edward Maloney</b> <sup>10</sup>	Chief Business Development Officer
<b>Mr. Dietmar Aichhorn</b>	Chief Operating Officer



### Stijn Van Rompay

Stijn Van Rompay has over 20 years of experience in leadership positions in the pharmaceutical industry, and is the co-founder and CEO of the Company. Stijn also co-founded, and was CEO of, Alter Pharma, a pharmaceutical company, focused on the development of complex generics and pharmacy-related products. He was also co-CEO of Uteron Pharma, a company focused on innovative female healthcare products, which was sold to Watson for \$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 outlicensing 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.



### Koenraad Van der Elst

Koenraad Van der Elst has more than 30 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.



### Edward Maloney

Edward Maloney has 30 years of experience in the pharma industry in various roles. Before joining Hyloris, he was President United States of Milla Pharmaceuticals, a subsidiary of the Alter Pharma Group where he was responsible for the U.S. Operations; Vice President Operations at Paddock Laboratories, a manufacturer of solid, liquid and semi-solid products, where he was responsible for manufacturing, supply chain and facilities; and Vice President Business Development at Paddock Laboratories, where he was responsible for in-licensing, out-licensing and joint venture deals. Edward also served as a Board member of the Generic Pharmaceutical Association (GPhA-US), which was the Generic Drug Lobby organisation in the United States (since February 2017, the Generic Pharmaceutical Association was renamed

to Association for Accessible Medicines (AAM)). Edward holds a Bachelor of Science in Business Administration from the University of Minnesota.



### Dietmar Aichhorn

Dietmar Aichhorn has more than 20 years of experience in the pharmaceutical industry leading teams in a broad range of functions, including, development, regulatory, clinical development, product launch and logistics of small molecules, biologics and Advanced Therapy Medicinal Products. Before joining Hyloris in October 2020, Dietmar worked in clinical development at Polpharma Biologics and Vira Therapeutics, Innovacell Biotechnology as Head of Development. Dietmar’s experience also includes Strategic Planning, M&A and post-merger integration at Mylan and Novartis. Dietmar holds a degree in chemistry and a degree in economy from Vienna University of Economy and is a lecturer at the Medical University of Innsbruck and the Austrian Medical Association.

The Executive Committee has met every week since the listing of the Company on Euronext Brussels. It has also met on an informal basis through conference and video calls every time it was required for its proper functioning.

7 Acting through SVR Management BV  
8 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  
9 Acting through Herault BV  
10 Acting through Humara Kinetics LLC. Mr. Maloney has retired as of 28 February 2021



# 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 subject to the approval of the annual Shareholders' Meeting to be held on 8 June 2021.

For the period prior January 1, 2021, the remuneration package for the members of the Executive Management was approved at the General Shareholders Meeting of June 8, 2020 and is fully disclosed in the IPO prospectus, available on the Hyloris [website](#). In addition, the Remuneration Committee meeting of February 23, 2021 has performed the appraisal of the Board of Directors and of the members of the Executive Management and has also approved the bonuses of the members the Executive Management, in line with the principles as outlined in the Remuneration Policy 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. The Remuneration Policy was approved by the Board on April 21, 2021, upon the Remuneration Committee's recommendation.

The Remuneration Policy is submitted to the Shareholders' Meeting for approval at every material change and at least every four years.

### Objective of the Hyloris' Remuneration Policy

The objective of the Hyloris Remuneration Policy is to attract, motivate and retain diverse, qualified and expert individuals whom Hyloris need to achieve its corporate, strategic and operational objectives.

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 Remuneration Policy also aims to ensure consistency between the remuneration of executives and that of all staff members, while soundly and efficiently managing risks and controlling wage-related costs for Hyloris.

The Remuneration Policy is developed as follows: The Board requests the Remuneration Committee to evaluate the overall remuneration packages of Executive Directors, Non-Executive Directors, and Hyloris' employees. The Remuneration Committee consults and engages the Board on this subject matter.

The Remuneration Committee takes into consideration all the information on its workforce remuneration, its knowledge and research data about the relevant job market to ensure that all Hyloris employees are remunerated in a market-conform and sufficient manner to motivate and retain its employees.

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

### Remuneration Policy for Non-Executive Directors

The Board makes a Non-Executive Directors remuneration scheme proposal while considering the recommendations made by the Remuneration Committee. 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.

The Non-Executive Directors do not receive any variable remuneration i.e., performance-related pay such as bonuses.

As of the date of the IPO in June 2020, Hyloris no longer grants Non-Executive Directors a fixed number of Stock Options (warrants) as part of their remuneration package<sup>11</sup> to comply with the new Belgian Corporate Governance Code ('Code 2020'). Hyloris does not grant shares to Non-Executive Directors. It considers that its general policy and *modus operandi* already meet the objective of recommendation 7.6 of the Code 2020, which is to promote long-term value creation.

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

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

The remuneration scheme for Executive Committee members consists of short-term and long-term remuneration elements. The short-term remuneration elements have a fixed part (please see Fixed remuneration, 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.

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

<sup>11</sup> Only the Chair of the Board, Stefan Yee, holds 100,000 warrants, which were granted prior the date of the IPO – the Company does not consider these warrants to be variable compensation





### 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 of the remuneration to be linked to an individual's performance and to the performance of Hyloris. It also allows for the individual's interest to be aligned 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 achievement of individual targets (Personal Targets) and the overall performance of Hyloris (Corporate Targets).
3. Corporate Targets include factors related to progress in Hyloris' research activities, corporate development and budgetary requirements. The Corporate Targets focus on company growth and value creation for all shareholders.
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 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 deliberated by the Remuneration Committee and

finally decided by the Board. Appraisal is based on a weighted average of the achievement rate of the Personal Targets.

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 publiclisted 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. Stijn Van Rompay has been entered into between Mr. Stijn Van Rompay's Belgian incorporated management company SVR Management BV and the Company effective as from 1 September 2019, for an indefinite period. It can be terminated by both the Company upon six months' notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by SVR Management BV upon three months' notice or payment of a compensation equivalent

to the fixed remuneration of such three-month period. The agreement also provides for reasons for immediate termination because of a breach by either party (e.g., serious contractual breach, bankruptcy, insolvency, non-performance of the consultancy services for 25 consecutive days, etc.).

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

#### Mr. Thomas Jacobsen (Executive Director<sup>12</sup>)

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

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

12 Chief Business Development Officer as of 28 February 2021 following the retirement of Edward Maloney



**Mr. Edward Maloney (CBDO)**

The services agreement with Mr. Maloney was ended on 28 February 2021 upon mutual agreement as Mr. Maloney reached the retirement age.

**Mr. Dietmar Aichhorn (COO)**

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

In the event of termination of the services agreement, the agreement provides for a non-compete period of 12 months after termination against a payment of 50% of the fixed fee over such 12 months’ period. However, the Company is entitled to waive this non-compete payment if the services agreement is terminated at the initiative of Mr. Aichhorn. The non-compete payment will not be due if the Company terminates the services agreement for breach of contract imputable to Mr. Aichhorn.

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

The current services agreement with Mr. Koenraad Van der Elst has been entered into between Mr. Koenraad Van der Elst’s Belgian incorporated management company Herault BV and the Company effective as from 1 January 2020, for an indefinite period. It can be terminated by the Company upon six months’ notice or payment of a compensation equivalent to the fixed remuneration of a three-month period. It can be terminated by Herault BV upon three months’ notice period or payment of a compensation equivalent to the fixed remuneration

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

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

**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 (4th) calendar year following that of the Date of the Offer and this, only during the first fortnight. (the first fifteen (15) days) of each quarter. The first fortnight (the first fifteen (15) days) of the last quarter of the validity period of the Stock Option Warrants constitutes the last possible exercise period. Each fiscal period will end on the last business day of the relevant fiscal period.	Warrants which are definitively acquired (“vested”) may be exercised from the first (1) of January of the fourth (4th) calendar year following that of the Date of the Offer and this, only during the first fortnight. (the first fifteen (15) days) of each quarter. The first fortnight (the first fifteen (15) days) of the last quarter of the validity period of the Stock Option Warrants constitutes the last possible exercise period. Each fiscal period will end on the last business day of the relevant fiscal period.

Article 7:91, first paragraph of the BCCA states that a director—within three years from the date of the grant—may not definitively acquire shares by way of remuneration or exercise share options or any other right to acquire shares. The company’s articles of association may deviate from this rule. Article 3 of the Articles of Association of Hyloris explicitly allows the Board to deviate from this rule when proposing the variable remuneration scheme.





## Minimum Shareholding

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

## Clawback

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

## Pension Scheme

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

## Decision-making and Conflict of Interest

The Remuneration Committee is composed exclusively of Non-Executive Directors, and most of its members are also independent directors within the meaning of Article 7:87 of the Belgian Code of Companies and Associations. This composition helps to avoid conflicts of interest regarding the structure design, adjustment and implementation of the Remuneration Policy towards Executive Committee members. The CEO and Executive Committee members are not invited to participate in the Remuneration Committee's deliberations of their own individual compensation. Regarding the remuneration of Non-Executive Directors, all decisions are approved by the Shareholders' Meeting.

## Deviations from the Remuneration Policy

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

## Changes to the Remuneration Policy

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

## 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 8, 2020 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 a prorata has been applied for 2020 and the total remuneration amounted to € 54,940. The table below provides an overview of the remuneration per Non-Executive Director.

Name	Remuneration
Mr. Stefan Yee	13,542
Mr. Leon Van Rompay <sup>13</sup>	7,022
Mr. Marc Foidart <sup>14</sup>	13,542
Mrs. Carolyn Myers	11,042
Mr. James Gale	9,792

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, 2020.

Name	Warrants	
	Number	% <sup>15</sup>
Mr. Stefan Yee	100,000	6.52%
Mr. Leon Van Rompay <sup>13</sup>	0	0%
Mr. Marc Foidart <sup>14</sup>	0	0%
Mrs. Carolyn Myers	0	0%
Mr. James Gale	0	0%

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

## Remuneration of Executive Directors and Members of the Executive Committee

In 2020, the following remuneration and compensation was paid or accrued to the CEO (i.e., Mr. Stijn Van Rompay) and the other members of the Executive Management of Hyloris:

	CEO (€)	Other members of the Executive Management (€) <sup>16</sup>
Annual base salary	162,000	636,670
Annual variable salary	55,000	55,750
Supplementary pension plan (defined contribution)	n.a.	n.a.
Car lease/transport allowance	n.a.	n.a.
Medical plan	n.a.	n.a.

The 2020 ratio between the highest remuneration of the members of the Executive Committee and the lowest remuneration (in full-time equivalent) of Hyloris' employees amounted to 6-to-1. Share options (warrants) are excluded from the calculations.

<sup>13</sup> Acting through Van Rompay Management BV

<sup>14</sup> Acting through Noshag Partners SCRL

<sup>15</sup> Calculated as % of all outstanding warrants (1,533,000 warrants outstanding as at December 31, 2020)

<sup>16</sup> This includes remuneration and compensation of members of the Executive Management who left the Company in 2020 – no departure indemnity was paid to these members

Shares and Share Options - Warrants

The table below provides an overview of the shares and warrants held by the (former) members of the Executive Committee at the date of December 31, 2020.

Name	Shares	
	Number	% <sup>17</sup>
Mr. Stijn Van Rompay <sup>18</sup>	6,824,304	26.42%
Mr. Thomas Jacobsen <sup>19</sup>	3,504,089	13.56%
Mr. Koenraad Van der Elst <sup>20</sup>	27,443	0.11%
Mr. Edward Maloney <sup>21</sup>	428,828	1.66%
Mr. Dietmar Aichhorn	0	0%

Name	ESOP warrants	
	Number	% <sup>22</sup>
Mr. Stijn Van Rompay <sup>17</sup>	68,000	9.27%
Mr. Thomas Jacobsen <sup>18</sup>	0	0%
Mr. Koenraad Van der Elst <sup>19</sup>	50,000	6.8%
Mr. Edward Maloney <sup>20</sup>	0	0%
Mr. Dietmar Aichhorn	40,000	5.46%

17 Calculated as % of total number of voting rights at 31 December 2020 (25,832,632)  
18 Acting through SVR Management BV  
19 Acting through Jacobsen Management BV  
20 Acting through Herault BV  
21 Acting through Humara Kinetics LLC. Mr. Maloney has retired as of 28 February 2021  
22 Calculated as % of total number of warrants accepted at the date of this annual report (733,000)

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.

In addition, the Non-Executive Directors should regularly (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 Directors including the implementation of a reporting on key performance indicators.

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 Chairman of the Board and the performance of his role within the Board are also carefully evaluated.

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 21, 2021 under the leadership of the Chairman of the Board of Directors. This evaluation resulted in a positive assessment with several less significant working points.

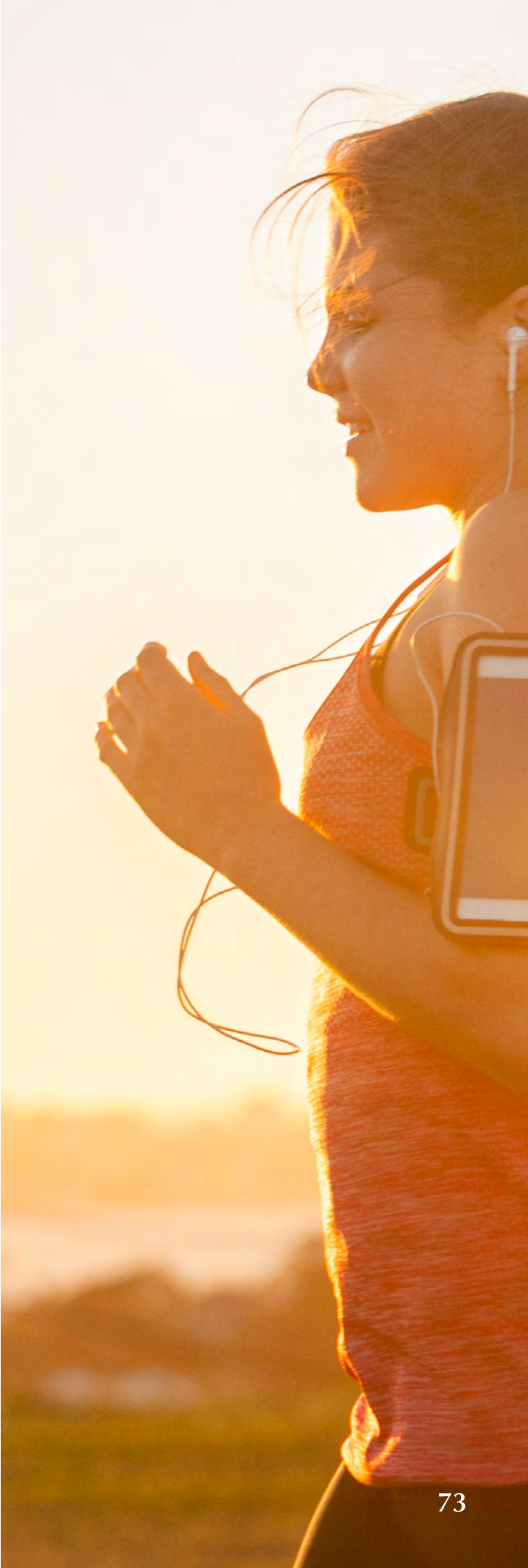
Executive Committee

The CEO and the Remuneration Committee assess the operation as well as the performance of the Executive Committee on an annual basis. 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 Board of Directors has assessed the performance and contributions of the CEO and the other members of the Executive Management on April 21, 2021.

The Board of Directors has taken note of the positive assessment by the Remuneration Committee in the context of the annual assessment of the performance and contribution of the members of the executive management. The Remuneration Committee has assessed (i) the successful listing of the Company on Euronext Brussels, and (ii) the achievement of the goals with respect to product development and business development.

Based on the information available to the Remuneration Committee, the Board determined that the corporate objectives for 2020, which were aimed at supporting the company’s long-term performance, had been achieved and on some aspects overachieved. The remuneration for 2020 has considered the contributions the members of the Executive Committee made to these achievements.







## 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' 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 two commercial products, Sotalol IV and Maxigesic 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 currently has no internal sales and marketing functions and it will be required to develop these capabilities in-house 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 but also for the future development and expansion of its portfolio.

The occurrence of a pandemic, epidemic or other health crisis, 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.

Hyloris has entered into arrangements with related parties and these arrangements present potential conflicts of interest.

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 deficit 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.

In 2020, a total amount of €285,000 was paid to the statutory auditor. This amount includes the following elements: €79,292 for audit fees, and €11,000 for audit related services legally assigned to the statutory auditor and €195,000 audit related services in the context of the IPO.

### Internal Control

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

The Executive Committee develops a long-term financial plan (5-year business plan) incorporating the Company strategy. This plan is monitored on a regular basis and updated twice a year to keep it in line with the strategy plans.

The Executive Committee also develops an annual budget which is approved by the Board and which is closely monitored during the year. Management reporting is prepared monthly, which details the variances between the actuals and the budget.

Internal control activities are performed by the Finance Department related to accounting and financial information and by all persons in charge for all matters related to the operational activities of the company. When deviations are identified, there are reported to the head of department.

As of the date of this report there is not yet a dedicated Internal Audit Function and this 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:

- The company has developed procedures relating to various business processes (procurement, payroll, IT, investments, cash management).
- The Company has developed a monthly reporting tool which allows a close monitoring of the financial information.
- 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 reporting is 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.

During the second half of 2020, the Company made the following improvements in its internal processes:

- The Company took measures to improve the internal controls by implementing procedures in the following cycles: expenditures, payroll, IT, cash management and books closing and reporting;
- A monthly reporting of the actual spending was also installed such that each department and the Executive Management Team could follow the actual income and expenses compared to their budgets creating an additional level of cost awareness;

- An adjusted budgeting process was implemented, and each department was involved in the implantation. The new budgeting procedure was designed to provide a stronger involvement to the departments of the Company providing a more accurate forecast of the spending on a more granular level.





## MARKET ABUSE REGULATIONS

With a view to preventing market abuse (insider dealing and market manipulation), and pursuant to the Market Abuse Regulation, the Board has established a Dealing Code which is available on the Hyloris [website](#).

The Dealing Code describes the declaration and conduct obligations of directors and members of the Executive Management with respect to transactions in shares and other financial instruments of the Company. The Dealing Code sets limits on carrying out transactions in shares and other financial instruments of the Company and allows dealing by the directors and the members of the Executive Management only during certain windows.

In its Governance Charter, the Company established several rules to prevent illegal use of inside information by Directors, shareholders, management members and employees, or the appearance of such use.

An insider can be given access to inside information within the scope of the normal performance of his duties. The insider has the strict obligation to treat this information confidentially and is not allowed to trade financial instruments of the Company to which this inside information relates.

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

## CONFLICTS OF INTEREST AND RELATED PARTIES

### Conflicts of Interest

There is a conflict of interest when the administrator has a direct or indirect financial interest adverse to that of the Company. In accordance with Article 7:96 of the Belgian Code on Companies and Associations, a Director of a limited company which “has, directly or indirectly, an interest of an economic nature in a decision or an operation under the Board of Directors” is held to follow a particular procedure. If members of the Board, or of the Executive Committee or their permanent representatives are confronted with possible conflicting interests arising from a decision or transaction of the Company, they must inform the Chairman of the Board thereof as soon as possible. Conflicting interests include conflicting proprietary interests, functional or political interests or interests involving family members (up to the second degree). If Article 7:96 of the Belgian Code on Companies and Associations is applicable, the Board member involved must abstain from participating in the deliberations and in the voting regarding the agenda items affected by such conflict of interest.

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

- One of the close relatives of the member concerned has a personal financial interest that is in conflict with a decision or transaction that falls within the authority of the Board or the Executive Management; or

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

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

### Conflicts of Interest of Directors and Members of Executive Management

None of the Directors or the members of the Executive Management have a conflict of interest within the meaning of Article 7:96 CCA that has not been disclosed to the Board of Directors. Where such a conflict of interest has occurred (in particular those with the Alter Pharma Group), Hyloris has applied (or ratified the application of) the statutory conflicts of interest procedure of Article 7:96 CCA.

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



### Board of Directors of June 8, 2020

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 had a direct or indirect financial interest with respect to a certain number of decisions to be taken by the Board, such as the approval of certain commercial contracts with the Alter Pharma Group, the approval of the consultancy agreements & remuneration package for SVR Management BV and Jacobsen Management BV, the acquisition of RTU Pharma, the approval of certain loan agreements between certain shareholders and the Company, the acquisition of Dermalis and the confirmation of the decisions to be taken by Hyloris' Group Companies with respect to a certain number of commercial contracts entered into by Hyloris' Group Companies.

Considering the above arguments, 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.

## 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.

In accordance with the procedure set out in Article 7:97, §3-4/1 CCA, 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 Management 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 Alter Pharma

The Alter Pharma Group is such a related party, and the procedure will be applied with respect to decisions and transactions that relate to the Alter Pharma Group as long as it remains such a related party, unless any of the exemptions apply.

No decisions relating to Alter Pharma have been taken by the Board in 2020.

### 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 €61,812,500 (including issue premium) with issuance of 5,750,000 new ordinary shares. The new shares were issued at a price of €10.75 per share (including issue premium). Following this capital increase, the capital of the Company amounted to €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, 2020, 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 363,300 ESOP warrants (under the 2019 ESOP plan of December 2019) and 400,000 ESOP warrants (under the ESOP plan of November 2020) which give right to subscribe to an equal number of shares. On the date of this Annual Report:
- Under the 2019 ESOP plan, a total of 333,000 warrants<sup>23</sup> were granted and accepted (with a total of 30,300 warrants being lapsed).
- Under the 2020 ESOP plan, a total of 89,500 ESOP warrants were granted and accepted, a total number of 55,000 warrants have been granted for which the acceptance period has not yet expired, and a total number of 255,500 ESOP warrants issued under the 2020 ESOP plan are still to be granted.
- Transaction warrants: the Company has issued 1,200,000 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.

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

Consequently, the Board is therefore authorised to increase the share capital of the Company within the framework of the authorised capital for a maximum amount of €115,758.84 (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 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 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 employees and 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.

<sup>23</sup> At December 31, 2020



### 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, 333,000 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, 144,500 ESOP Warrants are currently granted and outstanding.

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 (determined for each beneficiary separately): i.e., a first tranche of 25% vests on the first anniversary of the starting date and subsequently 1/48th vests each month. ESOP Warrants can only be exercised by the relevant holder of such ESOP Warrants, provided that they have effectively vested, as of the beginning of the fourth calendar year following the year in which the Company granted the ESOP Warrants to the holders thereof. As of that time, the ESOP Warrants can be exercised during the first fifteen days of each quarter. However, the terms and conditions of the ESOP Warrants provide that the ESOP Warrants can or must also be exercised, regardless of whether they have vested or not, in several specified cases of accelerated vesting set out in the issue and exercise conditions.

The terms and conditions of the ESOP Warrants contain customary good leaver and bad leaver provisions in the event of termination of the professional relationship between the beneficiary and Hyloris. The terms and conditions of the ESOP Warrants also provide that all ESOP Warrants (whether or not vested) will become exercisable during a special

exercise period to be organised by the Board in the event of certain liquidity events. These liquidity events include (i) a transfer of all or substantially all Shares of the Company; (ii) a merger, demerger or other corporate restructuring resulting in the shareholders 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.

### Consequences in Case of a Public Take-Over Bid

The General Meeting of Shareholders of June 8, 2020 decided to give the authorisation to the Board to increase the capital of the Company in case of reception by the Company of a communication by the Financial Services and Markets Authority (FSMA) stating that the FSMA has been informed of a public takeover bid regarding the Company, for all public take-over bids notified to the Company three years after June 8, 2020.

The Company may acquire and accept in pledge its own Shares in accordance with the Belgian Code of Companies and Associations and article 10 of its Articles of Association. The Company must inform the FSMA of any such contemplated transactions.

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 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 Board of Directors is furthermore authorised to transfer own Shares where such transfer is necessary to prevent serious imminent 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 authorisations referred to above also apply to the Company, the direct subsidiaries of the Company, insofar as necessary, the indirect subsidiaries of the Company, and, insofar as necessary, every third party acting in its own name but on behalf of those companies.

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





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

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

## Shareholders

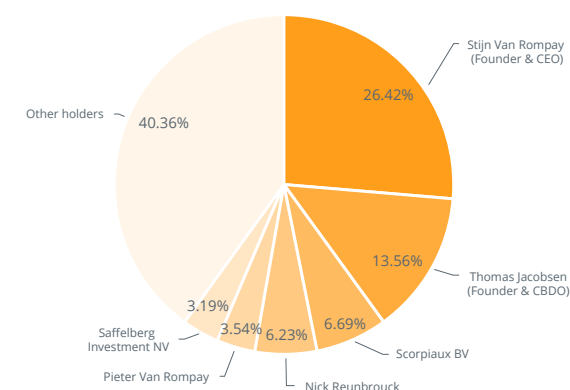
Belgian legislation (the Law of May 2, 2007 on the disclosure of major shareholdings in Companies whose shares are admitted to trading on a regulated market, and the Royal Decree of February 14, 2008 on the disclosure of major shareholdings) imposes disclosure requirements on each natural person or legal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

A notification duty applies also if (a) the voting rights (linked to securities) referred to in (i) or (b) the voting rights deemed to be linked to securities referred to in (ii) and (iii), taken separately, reaches, rises above or falls below the threshold.

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

The graph below provides an overview of the shareholders of Hyloris Pharmaceuticals SA, taking into account the transparency notifications received pursuant to the Law of May 2, 2007 on the disclosure of large shareholders (situation as per December 31, 2020):

### Major Shareholders



At December 31, 2020, 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 363,300 ESOP warrants (December 2019) and 400,000 ESOP warrants (November 2020) which give right to subscribe to an equal number of shares.

## Dividends and Dividend Policy

### Entitlement to Dividends

Pursuant to the Belgian Code of Companies and Associations, the shareholders can in principle decide on the distribution of profits with a simple majority vote at the occasion of the Annual General Shareholders' Meeting, based on the most recent statutory audited financial statements, prepared in accordance with Belgian GAAP and based on a (non-binding) proposal of the Company's Board of Directors. The Company's Articles of Association also authorise the Board of Directors to declare interim dividends without shareholder approval. The right to pay such interim dividends is, however, subject to certain legal restrictions.

The Company's ability to distribute dividends is subject to availability of sufficient distributable profits as defined under Belgian law based on the Company's stand-alone statutory accounts prepared in accordance with Belgian GAAP. In particular, dividends can only be distributed if following the declaration and issuance of the dividends the amount of the Company's net assets on the date of the closing of the last financial year as follows from the statutory non-consolidated financial statements (i.e., summarized, the amount of the assets as shown in the balance sheet, decreased with provisions and liabilities, all in accordance with Belgian accounting rules), and, save in exceptional cases, to be mentioned and justified in the notes to the annual accounts, decreased with the non-amortized costs of incorporation and extension and the non-amortized costs for research and development, does not fall below the amount of the paid-up capital (or, if higher, the issued capital), increased with the amount of non-distributable reserves (which include, as the case may be, the unamortized part of any revaluation surpluses). In addition, pursuant to Belgian law and the Company's Articles of Association, the Company must allocate an amount of 5% of its Belgian GAAP annual net profit ("bénéfices nets"/"nettowinst") to

a legal reserve in its stand-alone statutory accounts, until the legal reserve amounts to 10% of the Company's share capital. The Company's legal reserve currently does not meet this requirement. Accordingly, 5% of its Belgian GAAP annual net profit during future years will need to be allocated to the legal reserve, further limiting the Company's ability to pay out dividends to its shareholders.

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

### Dividend Policy

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

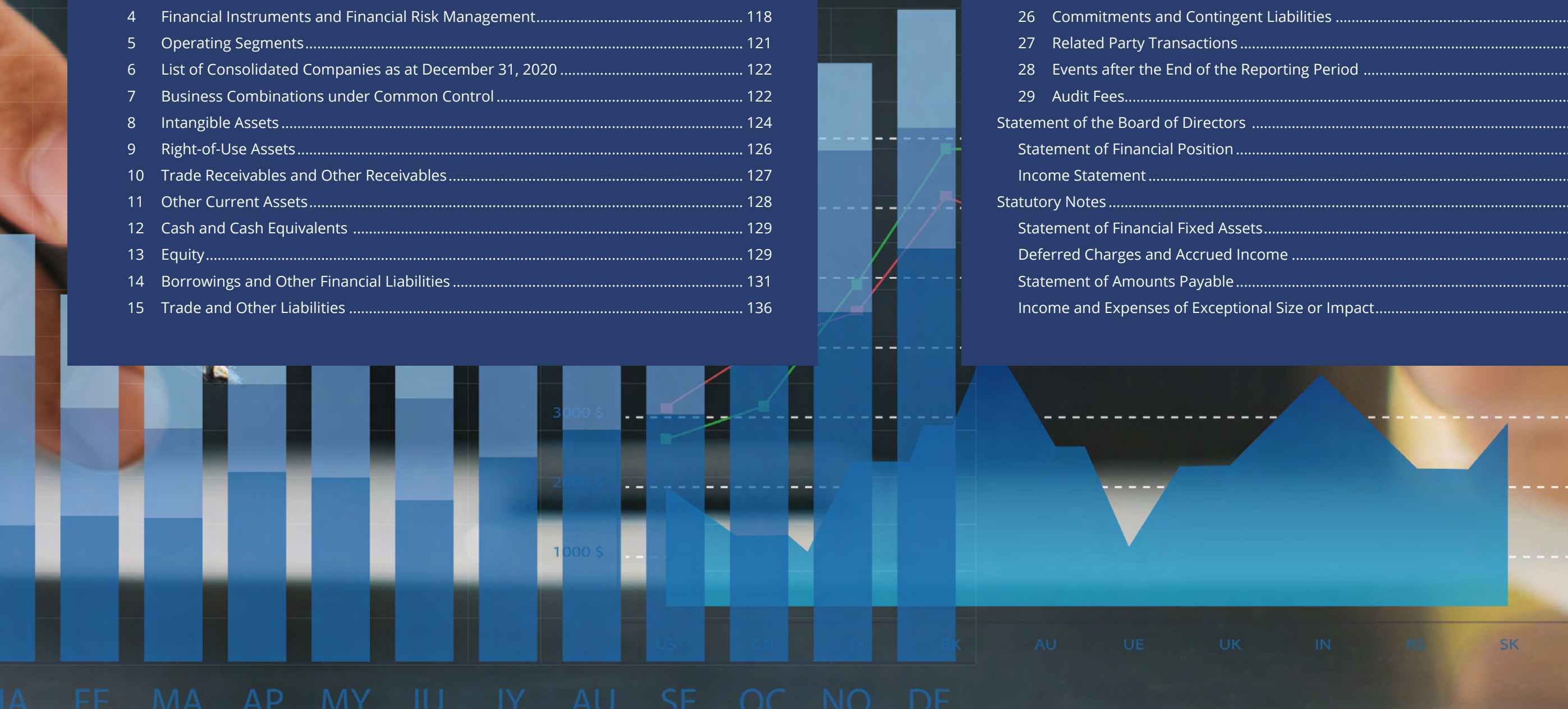
Currently, the Board of Directors of the Company expects to retain all earnings, if any, generated by the Company's operations for the development and growth of its business and does not anticipate paying any dividends to the shareholders in the foreseeable future.

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

# Financial Statements

Statement of the Board of Directors .....	90
Consolidated Financial Statements as of 31 December 2020.....	91
Consolidated Statement of Financial Position .....	91
Consolidated Statement of Profit or Loss and other Comprehensive Income .....	93
Consolidated Statement of Changes in Equity .....	94
Consolidated Statement of Cash Flow .....	96
Notes to the Consolidated Financial Statements .....	99
1 General Information .....	99
2 Summary of Significant Accounting Policies.....	99
3 Critical Accounting Estimates and Judgments.....	113
4 Financial Instruments and Financial Risk Management.....	118
5 Operating Segments.....	121
6 List of Consolidated Companies as at December 31, 2020 .....	122
7 Business Combinations under Common Control .....	122
8 Intangible Assets .....	124
9 Right-of-Use Assets.....	126
10 Trade Receivables and Other Receivables.....	127
11 Other Current Assets.....	128
12 Cash and Cash Equivalents .....	129
13 Equity.....	129
14 Borrowings and Other Financial Liabilities .....	131
15 Trade and Other Liabilities .....	136

16 Deferred Taxes .....	137
17 Revenue .....	138
18 Expenses by Nature .....	138
19 Employee Benefit Expenses.....	140
20 Other Operating Income .....	140
21 Financial Result.....	141
22 Income Tax Expense .....	141
23 Earnings per Share.....	142
24 Share-Based Payments .....	143
25 Contingencies .....	145
26 Commitments and Contingent Liabilities .....	145
27 Related Party Transactions .....	146
28 Events after the End of the Reporting Period .....	151
29 Audit Fees.....	152
Statement of the Board of Directors .....	153
Statement of Financial Position .....	154
Income Statement .....	156
Statutory Notes .....	157
Statement of Financial Fixed Assets.....	157
Deferred Charges and Accrued Income .....	158
Statement of Amounts Payable .....	158
Income and Expenses of Exceptional Size or Impact.....	159





## STATEMENT OF THE BOARD OF DIRECTORS

On April 21, 2021, we hereby confirm that, to the best of our knowledge

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

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

## CONSOLIDATED FINANCIAL STATEMENTS AS OF 31 DECEMBER 2020

### Consolidated Statement of Financial Position

ASSETS (in € thousand)	Note	December 31, 2020	December 31, 2019
<b>Non-current assets</b>		<b>2,569</b>	<b>2,245</b>
Intangible assets	8	2,381	2,138
Property, plant and equipment		24	32
Right-of-use assets	9	152	66
Financial assets		12	9
<b>Current assets</b>		<b>66,613</b>	<b>3,739</b>
Trade and other receivables	10	253	333
Other financial assets		7	-
Other current assets	11	1,954	3,200
Cash and cash equivalents	12	64,399	205
<b>TOTAL ASSETS</b>		<b>69,182</b>	<b>5,983</b>

EQUITY AND LIABILITIES (in € thousand)	Note	December 31, 2020	December 31, 2019
<b>Equity attributable to owners of the parent</b>		<b>59,059</b>	<b>(10,188)</b>
Share capital	13	129	89
Share premium	13	103,693	23,982
Retained earnings		(43,226)	(36,081)
Other reserves	13	(1,537)	1,822
<b>Non-current liabilities</b>		<b>7,991</b>	<b>22</b>
Borrowings	14	106	22
Other financial liabilities	14	7,885	
<b>Current liabilities</b>		<b>2,132</b>	<b>16,149</b>
Borrowings	14	46	44
Other financial liabilities	14	409	13,130
Trade and other liabilities	15	1,629	2,927
Current tax liabilities		47	47
<b>Total liabilities</b>		<b>10,123</b>	<b>16,171</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>69,182</b>	<b>5,983</b>

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

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

(in € thousand)	Note	2020	2019
Revenue	17	175	91
Cost of sales	18	(145)	(66)
<b>Gross profit</b>		<b>30</b>	<b>25</b>
Research and development expenses	18	(3,413)	(4,577)
General and administrative expenses	18	(2,194)	(808)
Shares issuance related expenses	18	(1,468)	-
Other operating income	20	21	86
Other operating expenses		-	-
<b>Operating profit/(loss)</b>		<b>(7,025)</b>	<b>(5,274)</b>
Financial income	21	901	10
Financial expenses	21	(1,021)	(518)
<b>Profit/(loss) before taxes</b>		<b>(7,145)</b>	<b>(5,782)</b>
Income taxes	22	(1)	14
<b>PROFIT/(LOSS) FOR THE PERIOD</b>		<b>(7,145)</b>	<b>(5,768)</b>
Other comprehensive income		-	-
<b>TOTAL COMPREHENSIVE INCOME OF THE PERIOD</b>		<b>(7,145)</b>	<b>(5,768)</b>
Profit/(loss) for the period attributable to the owners of the Company		(7,145)	(5,373)
Profit/(loss) for the period attributable to the non-controlling interests		-	(395)
Total comprehensive income for the period attributable to the owners of the Company		(7,145)	(5,373)
Total comprehensive income for the period attributable to the non-controlling interests		-	(395)
Basic and diluted earnings/(loss) per share (in €)	23	<b>(0.33)</b>	(0.37)

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



## Consolidated Statement of Changes in Equity

(in € thousand)	Attributable to equity holders of the Company					Equity attributable to owners of the parent	Non-controlling interests	Total Equity	
	Share capital	Share premium	Other reserves		Retained earnings				
			Share-based payment	Cost of capital (Note 3.5)					Other reserves
Balance at January 1, 2019	89	23,982	1,329		450	(28,097)	(2,246)	(2,216)	(4,462)
Contribution by shareholder – low-interest loans	-	-	-		42	-	42		42
Acquisition of non-controlling interest as part of business combination under common control (Note 7)	-	-	-		-	(2,611)	(2,611)	2,611	-
Total comprehensive income	-	-	-		-	(5,373)	(5,373)	(395)	(5,768)
Balance at December 31, 2019	89	23,982	1,329		493	(36,081)	(10,188)	-	(10,188)
Initial Public Offering (Note 13)	30	64,363		(3,725)			60,668		60,668
Issuance of convertible bonds					4,531		4,531		4,531
Conversion of convertible bonds (Note 13)	10	15,347		(102)	(4,585)		10,670		10,670
Contribution by shareholders – low-interest loans					37		37		37
Share-based payments			485				485		485
Total comprehensive income						(7,145)	(7,145)		(7,145)
Balance at December 31, 2020	129	103,693	1,814	(3,827)	476	(43,226)	59,059	-	59,059

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

## Consolidated Statement of Cash Flow

(in € thousand)	Note	2020	2019
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Loss for the period		(7,145)	(5,768)
<i>Adjustments for:</i>			
Depreciation, amortisation and impairments	18	581	3,306
Equity-settled share-based payment expense	18	485	
Cost of equity transactions	18	1,468	
Interest expenses on convertible bonds		208	
Income tax expenses		-	(14)
Amortized costs on shareholders loans		(139)	-
Borrowing costs on IPRD		(43)	
Other		(17)	
<i>Changes in working capital:</i>			
Trade and other receivables		81	808
Other current and non-current assets		1,246	(3,191)
Trade and other payables		(1,398)	(111)
Other financial liabilities		103	407
Other current liabilities		(1)	(2)
<b>Cash generated from operations</b>		<b>(4,571)</b>	<b>(4,565)</b>
Interest paid		1	4
<b>Net cash generated from operating activities</b>		<b>(4,570)</b>	<b>(4,562)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchases of property, plant and equipment		-	(8)
Purchases of intangible assets	8	(623)	(1,222)
Purchase of other financial assets		(10)	-
Proceeds from other financial assets		-	3
<b>Net cash provided by/(used in) investing activities</b>		<b>(633)</b>	<b>(1,228)</b>

<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Reimbursements of shareholders loans	14.3	(8,050)	-
Reimbursements of borrowings	14.3	(51)	(52)
Proceeds from shareholders loans	14.3	3,250	3,364
Interests paid		-	(4)
Proceeds from convertible bonds (net of issue costs)	3.5	14,994	
Proceeds from issue of equity instruments of the Company (net of issue costs)	3.5	59,254	-
<b>Net cash provided by/(used in) financing activities</b>		<b>69,397</b>	<b>3,308</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>			
Cash and cash equivalents at beginning of year		205	2,687
Cash and cash equivalents at end of year		64,399	205

Presentation of 2019 figures was adapted to match 2020 presentation. The accompanying notes are an integral part of these consolidated financial statements.





## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

### 1 General Information

Hyloris Pharmaceuticals SA (the “Company” or “Hyloris”) is a limited liability company governed by Belgian law. The address of its registered office is Boulevard 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, commercial-stage products: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid analgesic for the treatment of pain.

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

These consolidated financial statements should be read in conjunction with the audited financial information and the notes thereto included in the Initial Public Offering Prospectus issued on June 16, 2020 and available on the Company’s website. The consolidated financial statements were authorised for issue by the Board of Directors on April 21, 2021.

### 2 Summary of Significant Accounting Policies

#### 2.1 Basis of Preparation

These consolidated financial statements of the Group for the year ended December 31, 2020 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, 2020. 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 2020*

The following new IFRS standards, interpretations and amendments have been applied to the IFRS financial statements closed on 31 December 2020:

- Amendments to IFRS 3 – Definition of a Business (effective January 1, 2020): The amendments aim to assist companies to determine whether it has acquired a business or a group of assets.
- Amendments to IFRS 9, IAS 39 and IFRS 7 – Interest Rate Benchmark Reform (effective January 1, 2020): The amendments deal with issues affecting financial reporting in the period before the replacement of an existing interest rate benchmark with an alternative interest rate and address the implications for specific hedge accounting requirements.
- Amendments to IAS 1 and IAS 8 – Definition of Material (effective January 1, 2020): The amendments clarify the definition of “material” and to align the definition used in the Conceptual Framework and the standards.
- Amendment to IFRS 16 – Covid-19-Related Rent Concessions (effective May 28 2020): The amendment provides a practical expedient that permits lessees not to assess whether rent concessions that occur as a direct consequence of the covid-19 pandemic and meet specified conditions are lease modifications and, instead, to account for those rent concessions as if they were not lease modifications.

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 2021 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 2020:

- 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 37 – Provisions, Contingent Liabilities and Contingent Assets (effective January 1, 2022, but not yet 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.

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 unrealised gains on transactions between group companies are eliminated. Unrealised losses are also eliminated but considered an impairment indicator of the asset transferred.

### *Business combinations*

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

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

### *Transactions under common control*

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

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

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

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

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

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

### *Non-controlling interests*

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





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

## 2.3 Goodwill

Goodwill represents the excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the net identifiable net assets acquired at the date of acquisition. Goodwill is tested annually for impairment and carried at cost less accumulated impairment losses. Impairment losses on goodwill are not reversed. Gains and losses on the disposal of a CGU include the carrying amount of goodwill relating to the entity disposed.

## 2.4 Foreign Currencies

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

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

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

1 EUR =	Closing rate	Average rate
December 31, 2020	1.2271	1.1142
December 31, 2019	1.1234	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 recognised. Expenditure on research is recognised as an expense when it is incurred.

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

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

With respect to the technical feasibility condition, a strong evidence is achieved only when Phase 3 (i.e. final stage before filing for marketing approval) of the related development project is successfully completed, i.e. when filing for marketing approval from the relevant regulatory authorities. Consequently, internally generated development expenses arising before this point, mainly the cost of clinical trials, are expensed as incurred within Research and development expenses.

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

The cost of an internally-generated intangible asset is the sum of the expenditure incurred from the date when the intangible asset first meets the recognition criteria. The cost of an internally-generated intangible asset comprises all directly attributable costs necessary to create, produce and prepare the asset to be capable of operating in the manner intended by management, including any fees to register legal rights (patent costs) and borrowing costs.

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

### *Separately acquired research and development*

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

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

The second condition for capitalisation (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 (capitalisation) or related to outsourced research and development. The latter will be recognised as research and development expenses when they occur.

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

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

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

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

#### Other intangible assets acquired separately

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

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

- the cost of the asset can be measured reliably.

Intangible assets (research and development costs or other intangible assets as referred above) with finite useful lives that are acquired separately are measured at cost less accumulated amortisation and accumulated impairment losses. The cost of a separately acquired intangible asset comprises its purchase price, including import duties and non-refundable purchase taxes, after deducting trade discounts and rebates. Any directly attributable cost of preparing the asset for its intended use is also included in the cost of the intangible asset.

#### Amortisation

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

The estimated useful life and amortisation method are reviewed at the end of each reporting period, with the effect of any changes in estimate being accounted for on a prospective basis. Intangible assets with indefinite useful lives that are acquired separately are carried at cost less accumulated impairment losses.

Intangible assets are amortised on a systematic basis over their useful life, using the straight-line method, and amortisation are presented as Cost of Sale in the Profit or Loss Statement. The applicable useful lives are determined based on the period during which the Company expects to receive benefits from the underlying project. Key factors considered to determine the useful life comprises the duration of the patent protection and access of competitors to the market.

#### Derecognition

An intangible asset is derecognised on disposal, or when no future economic benefits are expected from use or disposal. Gains or losses arising from derecognition of an intangible asset, measured as the difference between the net disposal proceeds and the carrying amount of the asset, are recognised in profit or loss when the asset is derecognised.

## 2.6 Property, Plant and Equipment

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

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

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

- Furniture and equipment 10 years
- IT equipment 3 years

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

## 2.7 Leases

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

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

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

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

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

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





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

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

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

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

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

## 2.8 Impairment of Non-Financial Assets

Intangible assets with indefinite useful lives and intangible assets not yet available for use are not subject to amortisation, but are tested annually for impairment, and whenever events or changes in circumstances

indicate that the carrying amount may not be recoverable. Other assets which are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

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

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

## 2.9 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 recognised when the Company transfers control over the product to the customer; control of an asset refers to the ability to direct the use of, and obtain substantially all of the remaining benefits from, that asset. For the vast majority of contracts, revenue is recognised when the product is physically transferred, in accordance with the delivery and acceptance terms agreed with the customer.

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

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

A license will either provide:

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

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

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

## 2.10 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. Currently, the Group holds only financial assets at amortised cost.

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.

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

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



Financial assets (such as loans, trade and other receivables, cash and cash equivalents) 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.

Trade and other receivables (current and non-current) are recognised initially at fair value and subsequently measured at amortised cost, i.e. at the net present value of the receivable amount, using the effective interest rate method, less allowances for impairment.

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

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

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

rewards of ownership and continues to control the transferred asset, the Group recognises its retained interest in the asset and an associated liability for amounts it may have to pay. If the Group retains substantially all the risks and rewards of ownership of a transferred financial asset, the Group continues to recognize the financial asset and also recognises 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 recognised in profit or loss.

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

## 2.11 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.

## 2.12 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.

## 2.13 Government Grants

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

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

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

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

### *Recoverable cash advances*

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

### *R&D Tax Credit*

In Belgium, companies that invest in environmentally 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 capitalising its R&D expenses under tax reporting framework, the Group may either (i) get a reduction of its taxable income (if any) corresponding to 13.5% of the capitalised R&D expenses, or (ii) if no sufficient taxable income is available, apply for the refund of 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.

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





## 2.14 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.

## 2.15 Share-Based Payments

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

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

## 2.16 Provisions

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

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

## 2.17 Income Taxes

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

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

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

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

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

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

However, the deferred tax is not recognised for:

- the initial recognition of goodwill (in case of taxable temporary differences arising);
- the initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss and
- deferred tax is recognised on temporary differences arising on investments in subsidiaries and associates, except for deferred income tax liabilities where the timing of the reversal of the temporary difference is controlled by the

Group and it is probable that the temporary difference will not reverse in the foreseeable future.

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

Deferred tax assets are recognised for deductible temporary differences and unused tax losses and tax credits to the extent that it is probable that taxable profits will be available against which they can be 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. Unrecognised deferred tax assets are reassessed at each reporting date and recognised to the extent that it has become probable that future taxable profits will be available against which they can be used.

Deferred taxes are calculated at the level of each fiscal entity in the Group. The Group is able to offset deferred tax assets and liabilities only if the deferred tax balances relate to income taxes levied by the same taxation authority and it intends either to settle on a net basis, or to realize the asset and settle the liability simultaneously.



## 2.18 Financial Liabilities

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

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

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

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

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

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

### *Compound financial instruments*

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

## 2.19 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.

## 2.20 Contractual Commitments

Hyloris has contractual commitments related to asset purchase, licenses and development agreements. The amounts are due upon reaching certain milestones dependent on successful completion of development stages of the different product candidates (including FDA approval) or on meeting specified sales targets.

The Company disclosed as commitments the maximum that would be paid if all milestones and sales targets are achieved. The amounts are not risk-adjusted or discounted

## 2.21 Statement of Cash Flows

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

# 3 Critical Accounting Estimates and Judgments

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

## 3.1 Going Concern

The 2020 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 2021 and 2022. 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) but believes that the cash position of the Group at year end 2020 (i.e. €64 million) is sufficient to cover the cash needs of the Company at least until a 12-month period following the approval of this report.





After due consideration of the above, 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, and hence it is appropriate to prepare the financial statements on a going concern basis.

The impact of COVID-19 on the Company's business and operations are uncertain and will depend on future developments, which are highly uncertain and cannot be predicted. The Company is of the opinion that although there are uncertainties, it does not materially impact the Company's ability to continue operations. As of the date of authorization for issue of the consolidated financial statements, we have encountered limited delays in the development of our product candidates, and we do not believe this will result in major deviation in our planned activities and in the assumptions of our business plan. As a conclusion, the uncertainty raised by the COVID-19 pandemic is not impacting the going concern and the Company's ability to continue its operations.

### 3.2 Business Combinations under Common Control

There were no acquisitions in 2020.

The Group acquired in late 2019 Dermax SA. The acquisition of Dermax consists of acquisitions of businesses as defined by IFRS 3 – Business Combinations.

Considering that both Hyloris and Dermax were ultimately controlled by the same group of shareholders before and after the business combination, the acquisition is considered to be transactions under common control (business combination under common control). A business combination under common control is a business combination in which all of the combining entities or businesses are ultimately controlled by the same party or parties both before and after the business combination, and that control is not transitory. As such, considering

that both Hyloris and the acquired companies were ultimately controlled by the same parties both before and after the business combinations, the transaction is considered business combinations under common control which falls outside the scope of IFRS 3. Factors considered to conclude the common control situation includes:

- Existence of shareholders agreements;
- The composition of the boards of directors;
- Financing of Dermax operations by Hyloris.

Considering that there is no other specific guidance on such transactions elsewhere in IFRS, management developed an accounting policy that provides relevant and reliable information in accordance with IAS 8 to account for the acquisitions. As such, Hyloris applies the predecessor approach ('pooling of interests') to the acquisitions and elected for the following accounting policy choice:

- apply book value accounting in recognizing the assets acquired and liabilities assumed using the book values in the financial statements of the acquiree. The difference between the consideration paid and the capital of the acquire is recognised in retained earnings;
- 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. However, this restatement does not extend to periods during which the entities were not under common control;
- account for the capital increase used as financing of the acquisition as if the acquisition occurred before the start of the earliest period presented as the acquired companies are considered to be part of the Group as from the moment common control is established.

Reference is made to Note 7 for description of the acquisition of Dermax.

### 3.3 Share-Based Payments

In accordance with IFRS 2 – Share-based Payment, the fair value of the warrants at grant date is recognised as an expense in the consolidated statement of comprehensive income over the vesting period, the period of service. Subsequently, the fair value is not re-measured.

The fair value of each warrant granted during the year is calculated using the Black-Scholes pricing model. This pricing model requires the input of subjective assumptions, which are detailed in Note 24.

### 3.4 Automatically Convertible Bonds

On March 31, 2020, the Company issued automatically convertible bonds for an amount of €10,800 thousand. On April 30, 2020, the Company issued additional convertible bonds of an amount of €4,350 thousand, bringing the total subscription to €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. €7.53 per share (Note 3.5 and 13.3).

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 recognised 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 recognised in equity (€4,531 thousands in total).

The transaction costs amounting to €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 recognised in equity, as cost of capital (€102 thousand). The remaining part of the transaction costs were expensed.

An embedded derivative was recognised 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 (Note 21). At conversion, embedded derivatives were offset against equity (other reserves) and the difference between interest accrued and interest paid in shares were recognised as 'other reserves' in equity (€37 thousand – Note 3.3).

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

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	Capitalised costs related to issuance of new shares	Costs 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
<b>Total</b>	<b>79,542</b>	<b>(3,827)</b>	<b>(1,468)</b>	<b>74,248</b>

### 3.6 Effective Interest Rate of Shareholders' Loans

The Group was granted several shareholders' loans as disclosed in Note 14.2. 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. As such, based on the principles of IFRS 9 Financial Instruments, the Company remeasured the shareholders' loans at fair value (at the date the loan has been originated or at transition date). Subsequently the loans are measured at amortised cost based on the market-related rate. As such the Group recognises the interest expense it would need to pay if it would finance itself on the market. The differential between the fair value of the loans and the nominal amount is considered as a capital contribution, which is recognised immediately in equity, net of tax.

#### *Change of maturity of the shareholder's loans*

In March 2020, the Company and the lenders agreed to review the terms of the shareholder loans. The loans were originally repayable by year end 2020. Following the terms of the new agreements, the Company shall reimburse €8.1 million and repay the remaining part of the loans (including interest) the earlier of year end 2022 or when the Company will generate an operating profit.

For a reconciliation, we refer to Note 14.2.

### 3.7 Recognition of Deferred Tax Assets

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

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

Since inception, the Company has reported losses, and as a consequence, the Company has unused tax losses. Management has therefore concluded that deferred tax assets should not be recognised as of 31 December 2020 considering uncertainties regarding future taxable profits relating to the commercialisation of the development projects. Deferred tax assets will be recognised, over time, when management will have more visibility on the profitability of the Group.

### 3.8 COVID-19

On March 11, 2020 the World Health Organization declared the novel strain of coronavirus (COVID-19) a global pandemic and recommended containment and mitigation measures worldwide. The length or severity of this pandemic cannot be predicted, and although there have been vaccines developed, the Group anticipates that there may still be a potential impact from COVID-19 on the planned development activities of the Group.

With COVID-19 continuing to spread in Europe and in the United States, the business operations of the Group could be delayed, particularly with third-party organizations (such as hospitals, CRO's and CMO's) located in affected geographies that the Group relies upon to carry out its preclinical and clinical trials. The spread of COVID-19, or another infectious disease, could also negatively affect the operations at its third-party suppliers, which could result in delays or disruptions in the supply of drug product used in its preclinical and clinical trials. In addition, the Group is taking temporary precautionary measures intended to help minimize the risk of the virus to its employees, including temporarily requiring all employees to work remotely, suspending all travel worldwide for its employees.

Further, timely enrolment in clinical trials is reliant on clinical trial sites which may be potentially affected by the COVID-19 pandemic. Most of the Group's and CRO's clinical trial sites are located in the United States, currently being afflicted by COVID-19.

Some factors from the COVID-19 outbreak that the Group believes would affect enrolment in its trials at least on a temporary basis include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of physicians serving as Group's clinical trial investigators, hospitals serving as its clinical trial sites and hospital staff supporting the conduct of its clinical trials;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- employee absences that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

As of the date of authorization for issue of the consolidated financial statements, the Board considers that the limited delays encountered in the development of our product-candidates will not result in major deviation in our planned activities and in the assumptions of our business plan. As stated in Note 3.1, the uncertainty raised by the COVID-19 pandemic is not impacting the going concern and the Company's ability to continue its operations.



## 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, 2020	December 31, 2019
Non-current financial assets	At amortised cost	12	9
Trade receivables	At amortised cost	48	58
Other financial assets	At amortised cost	7	-
Cash and cash equivalents	At amortised cost	64,399	205
<b>Total financial assets</b>		<b>64,466</b>	<b>272</b>
<i>Non-current financial liabilities</i>			
Lease liabilities	At amortised cost	106	22
Other financial liabilities	At amortised cost	7,885	-
<i>Current financial liabilities</i>			
Lease liabilities	At amortised cost	46	44
Other financial liabilities	At amortised cost	409	13,130
<i>Trade and other liabilities</i>			
Trade payables	At amortised cost	1,595	2,866
<b>Total financial liabilities</b>		<b>10,041</b>	<b>16,062</b>

Currently, no financial instrument is carried at fair value in the consolidated statement of financial position.

The Company considers that the carrying amounts of financial assets and financial liabilities recognised 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 U. S. Dollar.

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, 2020	December 31, 2019
<b>Assets</b>	2,469	173
<b>Liabilities</b>	(3,487)	(3,216)

At December 31, 2020, 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 10 thousand respectively.

### 4.4 Interest Rate Risk

The Company is currently not exposed to significant interest rate risk as the interest-bearing financial liabilities 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 receivables, cash and cash equivalents and short-term deposits.

The Company believes that the credit risk is limited as the Company has currently limited trade receivables considering the limited revenue. Furthermore, the Company is not exposed to any material credit risk with regard to any individual customer or counterparty, as no single customer claims a dominant part of total revenue. As such, no impairment is recognised for these receivables. Cash and cash equivalent and short-term deposits are invested with highly reputable banks and financial institutions.

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

Based on the ongoing credit evaluation performed, impairment on financial assets is considered as insignificant.

## 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.

31/12/2020 (in € thousand)	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
<i>Borrowings</i>					
Lease liabilities	48	112			160
<i>Other financial liabilities</i>					
Loans from shareholders		8,861			8,861
Other loans	409				409
<b>Total</b>	<b>457</b>	<b>8,973</b>	-	-	<b>9,431</b>

31/12/2019 (in € thousand)	Within one year	>1 and <5 years	>5 and <10 years	>10 years	Total
<i>Borrowings</i>					
Lease liabilities	44	22	-	-	66
<i>Other financial liabilities</i>					
Loans from shareholders	12,721	-	-	-	12,721
Other loans	409	-	-	-	409
<b>Total</b>	<b>13,174</b>	<b>22</b>	-	-	<b>13,196</b>

## 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.

### 5.1 Geographical Information

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





## 6 List of Consolidated Companies as at December 31, 2020

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%

The voting rights equal the percentage of financial interest held.

## 7 Business Combinations under Common Control

On December 31, 2019, the Company acquired Dermax for a total consideration of €18,260 thousand. The consideration is fully settled in equity instruments (issue of 855,409 shares). The consideration settled in equity instruments was determined based on a pre-money valuation of the company resulting from the weighted average of a discounted cash flow approach and EBITDA multiple approach minus net debt. This valuation was confirmed by the board of directors of Hyloris and was in accordance with the report as provided by the external auditor (i.e. PKF-VMB Réviseurs d’Entreprises SCRL) of the Company.

Dermax is a company founded in Liège in December 2016 and similarly as the Company focused on 505 (b) (2) approvals as well as complex generics. It is specialized in the development of products in various therapeutic areas such as antibiotic for skin-related diseases, hormone therapy and anti-viral medicine and has on-going discussion with third-parties that could result in addition of new products in the pipeline. Dermax is

a strategic contributor to the future success of Hyloris through the addition of a strong network of partners which will reinforce the group in the future.

Considering that both the Company and Dermax were ultimately controlled by the same parties both before and after the business combination, the acquisition is considered as a business combination under common control which falls outside the scope of IFRS 3 (see also Note 3.2. above). At incorporation of Dermax in December 2016, Stijn Van Rompay and Thomas Jacobsen, who are key management and shareholders of Hyloris, were the only shareholders of Dermax. The other shareholders entered the capital of Dermax during the capital increase done in 2018. As such, Hyloris’ ultimate controlling party did not hold the majority of the shares in Dermax, but the other shareholders agreed to take any decisions with prior approval of Hyloris’ ultimate controlling party. Furthermore, Dermax’ management and board of directors consisted of Stijn Van Rompay and Thomas Jacobsen, who are key management of Hyloris. Hyloris’ involvement was not only limited to the shares held and the shared management, but Hyloris also granted financing for the activities of Dermax.

As the acquisition is considered a common control transaction, the business combination is not in scope of IFRS 3 Business Combinations. Based on this, the Group selected the accounting policy choice to account for the acquisition by applying the predecessor approach.

The application of the predecessor approach to the acquisition of Dermax consisted of the following accounting steps:

- Restated and adjust the comparative statements as if the acquisition 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. Based on this, Dermax has been included in these consolidated financial statements as from January 1st, 2017.
- Considering that, accounting wise, Dermax is included in these financial statements as from January 1st, 2017, the share issue done legally in December 2019 to finance the acquisition is also accounted for as from the start of the earliest period presented.
- As Hyloris’ controlling shareholders only held part of the shares of Dermax till December 2019, the Group recognised non-controlling interests (52.94%) for the shares in Dermax not held by Hyloris’ shareholders as from October 30th 2018, date at which the non-controlling interests entered into the equity of Dermax. The capital increase was subscribed by Hyloris Pharmaceuticals in cash (€250 thousand).
- At the date of the legal acquisition (i.e. December 31, 2019), the balance of non-controlling interests is reclassified to the Group retained earnings.

Acquisition-related costs were not significant and included only notary fees.





## 8 Intangible Assets

(in € thousand)	Development costs	Assets Purchase	In Licencing	Total
<b>Year ended December 31, 2020</b>				
Opening carrying amount	712	1,026	401	2,138
Additions	622	-	100	722
Borrowing costs capitalised	18	25	-	43
Amortisation expense	-	(43)	-	(43)
Impairment losses	(480)	-	-	(480)
Closing carrying amount	872	1,008	501	2,381
<b>At December 31, 2020</b>				
Cost	1,352	4,483	501	6,336
Accumulated amortisation and impairment	(480)	(3,475)	-	(3,955)
Carrying amount	872	1,008	501	2,381

(in € thousand)	Development costs	Assets Purchase	In Licencing	Total
<b>Year ended December 31, 2019</b>				
Opening carrying amount	245	3,704	-	3,949
Additions	461	400	401	1,262
Borrowing costs capitalised	5	168	-	173
Amortisation expense	-	(43)	-	(43)
Impairment losses	-	(3,203)	-	(3,203)
Closing carrying amount	712	1 026	401	2 138
<b>At December 31, 2019</b>				
Cost	712	4,458	401	5,570
Accumulated amortisation and impairment	-	(3,432)	-	(3,432)
Carrying amount	712	1,026	401	2,138

In 2020, the Company acquired intangible assets for a total of €722 thousand, of which (i) €622 thousand related to the development costs of product-candidates (mainly Maxigesic® and HY-016), (ii) and (ii) €100 thousand of in-licensing fees related to HY-029.

Capitalised development expenses of the product HY-039 were fully impaired end of 2020 (€0.5 million) as the development of this product was halted following the recent regulatory approval of a competitive product in markets contemplated by the Company.

Borrowing costs are calculated on 'Assets Purchase' and on Capitalised Development costs using a 6% annual interest rate, in line with the weighted average borrowing rate applicable to the Group.

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 5 years. The Company expects to start the amortisation of the development costs of Maxigesic IV in 2021.

The amortisation expenses are included in "Cost of sales" in the consolidated statement of profit or loss and other comprehensive income.

Therefore, as long as the assets are not fully amortised, they are tested for impairment losses on an annual basis or more frequently if specific indicators require it. The impairment test conducted is performed by product and consists in measuring the recoverable amount. The recoverable amount of the product is estimated based on the forecasted future cash flows discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset. The time horizon used for the impairment testing is based on the period during which the Company expects to generate cash flows from the project, which period does not exceed 10 years in the management estimates.

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

Based on the impairment tests conducted at year-end, except for the impairment loss recorded on product-candidate HY-039, 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 2.8, the discount rate reflecting current market assessments of the time value of money and the risks specific to the asset, and which was used for the impairment test, is estimated at 12.43% (was 12.77% in 2019).

The main variables that lead to a discount rate of 12.43% are:

- a risk free rate of -0.34% (corresponding to the 10-year OLO rate as of December 31, 2020)
- a beta factor of 1.31
- a market risk rate of 5.96%
- a Company specific risk premium of 7%
- a cost of debt before tax of 6%

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 2019).

We tested the sensitivity analysis of the impairment tests by increasing the discount rate by 4%, leading the discount rate to 16.43%. 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.





## 9 Right-of-Use Assets

(in € thousand)	Land and buildings	Vehicles and equipment	Total
<b>Year ended December 31, 2020</b>			
Opening carrying amount	51	15	66
Additions	134	32	166
Depreciation expense	(40)	(11)	(51)
Disposals	-	(29)	(29)
<b>Closing carrying amount</b>	<b>145</b>	<b>7</b>	<b>152</b>
<b>At December 31, 2020</b>			
Cost	242	69	311
Accumulated depreciation and impairment	(97)	(62)	(159)
<b>Carrying amount</b>	<b>145</b>	<b>7</b>	<b>152</b>
<b>Year ended December 31, 2019</b>			
Opening carrying amount	88	31	119
Additions	-	-	-
Depreciation expense	(36)	(16)	(53)
<b>Closing carrying amount</b>	<b>51</b>	<b>15</b>	<b>66</b>
<b>At December 31, 2019</b>			
Cost	109	66	175
Accumulated depreciation and impairment	(58)	(51)	(109)
<b>Carrying amount</b>	<b>51</b>	<b>15</b>	<b>66</b>

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.

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

(in € thousand)	2020	2019
Depreciation expense of right-of-use assets	(51)	(53)
Interest expense on lease liabilities	(3)	(4)
Expenses relating to low-value leases	(2)	(1)
<b>Total amount recognised in profit or loss</b>	<b>(56)</b>	<b>(58)</b>
of which as:		
General and administrative expenses (Note 18)	(53)	(54)
Financial expenses (Note 21)	(3)	(4)

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.

The undiscounted potential future rental payments relating to periods following the exercise date of termination options that are not included in the lease term amount to €131 thousand.

## 10 Trade Receivables and Other Receivables

(in € thousand)	December 31, 2020	December 31, 2019
Trade receivables	48	58
Less: allowance for impairment of trade receivables	-	-
<b>Trade receivables - net</b>	<b>48</b>	<b>58</b>
Prepayments	-	-
Other amounts receivable	205	275
<b>Prepaid expenses and other receivables</b>	<b>205</b>	<b>275</b>
<b>Trade and other receivables - Current</b>	<b>253</b>	<b>333</b>

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 Euro.

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.

## 11 Other Current Assets

(in € thousand)	December 31, 2020	December 31, 2019
Pre-paid R&D expenses	1,882	3,150
Other pre-paid expenses	72	50
Accrued income	-	-
<b>Other current assets</b>	<b>1,954</b>	<b>3,200</b>

Pre-paid R&D expenses relate to payments made by the Company for research and development projects conducted by third parties and will be recorded in profit and loss when incurred.

Pre-paid R&D expenses of €1,882 thousand in 2020 related to:

- €800 thousand (same as in 2019): development agreement with Stasisport Pharma (a subsidiary of the Alter Pharma group, a related party of Hyloris) to run the clinical development of the Fusidic Acid cream product candidate.
- €572 thousand (was €2,000 thousand in 2019): Development agreement with Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group, a related party of Hyloris), pursuant to which GSP agreed to carry out all development activities required for the acquisition/ registration of ANDA/ NDA approval for the product HY-038 in the form of prefilled syringes. The variance with 2019 is explained by the sale to Alter Pharma of the vial form of the HY-038 product.
- €350 thousand (same as in 2019): On 21 December 2018, Generic Specialty Pharma (GSP) (a subsidiary of the Alter Pharma group, a related party of Hyloris) entered into an

Asset purchase and development agreement with Hyloris Developments, pursuant to which GSP assigned and transferred to Hyloris Developments all intellectual property rights, title and interests in a product that has since been discontinued. In consideration of the amount paid by Hyloris, GSP will develop the (patentable) product, will be responsible for the patent application and for the submission of the NDA with the FDA. In 2019, Hyloris made a pre-payment of €350 thousand. As of 31 December 2020, no decision was made on the selection of a new product, hence no expenses have been incurred yet on that project. Therefore, the full amount paid is recognised as pre-paid R&D expenses.

## 12 Cash and Cash Equivalents

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

(in € thousand)	December 31, 2020	December 31, 2019
Cash at bank	44,399	205
Short-term deposit	20,000	-
<b>Total cash and cash equivalents</b>	<b>64,399</b>	<b>205</b>

The carrying amount of the cash and cash equivalents is a reasonable approximation of their fair value.

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.

## 13 Equity

### 13.1 Overview

(in € thousand)	December 31, 2020	December 31, 2019
Share capital	129	89
Share premium	103,693	23,982
Retained earnings	(43,226)	(36,081)
Other reserves	(1,537)	1,822
<b>Total Equity attributable to owners of the parent</b>	<b>59,059</b>	<b>(10,188)</b>

### 13.2 Capital Management

The Company manages its capital to maintain a strong level of capital in order to sustain development of the business and confidence of creditors while optimizing return on capital for shareholders. This ensures that entities in the Group will be able to continue as going concerns while maximizing the return to stakeholders through the optimization of its debt and equity balance. Also refer to Note 3.1 for further details on going concern.

The Group is not subject to any externally imposed capital requirements except those provided for by law. The Group's management reviews the capital structure of the Group on a regular basis. As part of this review, management considers the cost of capital and the risks associated with each financing options. The Group's objectives, policies and processes for managing capital have remained unchanged over the past few years.





### 13.3 Share Capital and Share Premium

#### Share Capital

As per December 31, 2020, the share capital of the Company amounts to €129,163.16 represented by 25.832.632 shares, without nominal value, each representing 1/25.832.632th of the share capital of the Company. The share capital of the Company is fully and unconditionally subscribed for and is fully paid up. All shares rank equally with regard to the

Company'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 Company.

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

The following capital transactions have taken place since the foundation of the Company:

Date	Transaction	Increase of share capital (incl. share premium) (€)	Number of securities issued	Issue price / share (rounded, incl. share premium) (€)	Number of Shares after the transaction
7 June 2012	Incorporation	50,000	10,000 Shares	5.00	10,000
31 March 2017	Capital increase	11,500	2,300 Shares	5.00	12,300
12 May 2017	Share split	-		-	3,075,000
31 May 2018	Capital increase	2,750,000	248,711 Shares	11.06	3,323,711
31 May 2018	Capital increase	3,000,000	271,322 Shares	11.06	3,595,033
31 December 2019	Capital increase	18,259,783 <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 2020	Over allotment option	2,580,000	240,000 Shares	10.75	25,832,632

On June 29, 2020, the Company completed its Initial Public Offering (IPO) on Euronext Brussels, resulting in the issuance of 5,750,000 new shares at €10.75 per share for a total gross proceeds of €61,821,500. The completion of the IPO triggered the conversion of the convertible bonds issued on March 31 2020

and April 30 2020 for respectively €10,800,000 and €4,350,000. The bonds were converted using a €7.525 value per share, corresponding to a 30% discount to the IPO price as contractually agreed at the issuance of the bonds. The Bonds bear a 6% interest rate as from their issue date. Accrued interest

as of the date of the conversion were paid in shares, together with the principal amount, totaling together €15,358,025.

On July 31, 2020, the Company exercised the over-allotment option in connection with its initial public offering. The exercise of the option resulted in the issuance of 240,000 new shares at €10.75 per share for a total gross proceeds of €2,580,000.

#### Share premium

As a result of the IPO and the conversion of the convertible bonds, the share premium increases by €79,711 thousand

#### Other reserves

(in € thousand)	December 31, 2020	December 31, 2019
Share based payment	1,814	1,329
Cost of Capital	(3,827)	-
Other	476	493
<b>Total Other reserves</b>	<b>(1,537)</b>	<b>1,822</b>

The main movement of the other reserves over the period can be explained as follow:

- An increase of €485 thousand resulting from the share based payment expenses associated with the ESOP Warrants issued in December 2019 and accepted in 2020;
- A decrease of €3,827 thousand resulting from the transaction costs associated to the issuance of new shares resulting from the conversion of the convertible bonds (€102 thousand) and the IPO (€3,725 thousand) (cfr Note 3.5).

## 14 Borrowings and Other Financial Liabilities

### 14.1 Borrowings

(in € thousand)	December 31, 2020	December 31, 2019
Bank borrowings	-	-
Lease liabilities	152	66
Other borrowings	-	-
<b>Total borrowings</b>	<b>152</b>	<b>66</b>
of which as:		
Non-current borrowings	106	22
Current borrowings	46	44

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.

<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

## 14.2 Financial Liabilities

The other financial liabilities can be detailed as follows:

(in € thousand)	December 31, 2020	December 31, 2019
Loans from shareholders	7,885	12,721
Recoverable cash advance	409	409
<b>Other financial liabilities</b>	<b>8,294</b>	<b>13,130</b>
of which as:		
Non-current other financial liabilities	7,885	-
Current other financial liabilities	409	13,130

### 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 Company 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.

During the first quarter of 2020, the Company received additional loans from its shareholders for a total of €3.3 million. In March 2020, the Company and the lenders agreed to review the terms of the shareholder loans. The loans were originally repayable by year end 2020. Following the terms of the new agreements, the Company shall reimburse €7.5 million in Q2 2020 (on top of the earlier reimbursement of €0.6 million made in Q1 2020) and repay the remaining part of the loans (including interest) the earlier of year end 2022 or when the Company will generate an operating profit.

*Quantitative assessment* - The net present value of the cash flows under the new terms differs by less than 10% from the present value of the remaining cash flow under the original terms. Hence, the changes in the contractual terms were not considered as a substantial modification of the terms of the shareholders loans.

The revised amortised cost of the shareholders loans was recalculated by discounting the revised estimated future cash flows at the loan's original effective interest rate and the difference was recognised as a financial income in the statement of profit or loss (€532 thousand – Note 21).

The anticipated reimbursement of €8.1 million made during the first half of 2020 led to the recognition of a financial expense in the statement of profit or loss (€151 thousand – Note 21).

Pursuant to the new loan agreements, the shareholders loans are presented as a non-current other financial liabilities

### Sensitivity analysis of the shareholders loans

A variance of 1% of the interest rate will have a €78 thousand impact on the statement of profit or loss of the Company (on an annual basis).

### Recoverable cash advance

The recoverable cash advance ('RCA') received by the Company from the Walloon Region which gives rise to a financial liability in the scope of IFRS 9 Financial Instruments as the advance needs to be settled by paying back the cash received or transfer all relating intellectual property rights and titles. As at year-end December 31, 2020, the research program for which the advance was granted was abandoned due to unsatisfactory results. The Company judges that the financial liability of the effectively received €488 thousand will be settled by paying back the unutilized cash received for an amount of €409 thousand.

Subsequent to the initial recognition, the financial liability is measured at amortised cost using the effective interest method on the basis of the estimated contractual cash flows with changes in value due to a change in estimated cash flows recognised in profit or loss, in accordance with IFRS 9.



### 14.3 Liquidity and Cash Flow Reconciliation

The maturity table of the borrowings and the other financial liabilities is presented in Note 4.6 on the liquidity risk.

The following tables reconcile the movements of the financial liabilities to the cash flows arising from financing activities:

31/12/2020 (in € thousand)	Opening carrying amount	Cash flows	Non-cash movements						Closing carrying amount	
			Acquisition	Modification	Termination	Capital contribution	Re-classes	Accrued interests and exchange differences		
Non-current financial liabilities										
Lease liabilities	22	-	32	134	(29)	-	(53)	-	106	
Other financial liabilities			-			-	7,540	345	7,885	
Current financial liabilities										
Lease liabilities	44	(51)					53	1	46	
Other financial liabilities	13,130	(4,800)		(532)	151		(7,540)		409	
<b>Total liabilities from financing activities</b>	<b>13,196</b>	<b>(4,851)</b>	<b>32</b>	<b>(398)</b>	<b>122</b>	<b>-</b>	<b>-</b>	<b>246</b>	<b>8,447</b>	
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)								

31/12/2019 (in € thousand)	Opening carrying amount	Cash flows	Non-cash movements					Closing carrying amount	
			Acquisition			Capital contribution	Re-classes		Accrued interests and exchange differences
Non-current financial liabilities									
Lease liabilities	66	-	-			-	(44)	-	22
Other financial liabilities	9,243	-	-			-	(9,243)	-	-
Current financial liabilities									
Lease liabilities	52	(52)	-			-	44	-	44
Other financial liabilities	-	3,364	-			(57)	9,243	580	13,130
<b>Total liabilities from financing activities</b>	<b>9,361</b>	<b>3,312</b>	<b>-</b>			<b>(57)</b>	<b>-</b>	<b>580</b>	<b>13,196</b>
Presented in the statement of cash flows (financing activities) as follows:									
Proceeds from borrowings and other financial liabilities		3,364							
Repayment of borrowings and other financial liabilities		(52)							

## 15 Trade and Other Liabilities

(in € thousand)	December 31, 2020	December 31, 2019
Trade payables	1,595	2,866
Employee benefit liabilities	25	52
Other payables	9	8
<b>Trade and other liabilities - Current</b>	<b>1,629</b>	<b>2,927</b>

The trade payables relate mainly to the R&D activities. Other payables relate to VAT payables.

The fair value of trade payables approximates their carrying amount.

Liquidity and currency risk are detailed in Note 4.

## 16 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:

(in € thousand)	December 31, 2020		December 31, 2019	
	Deferred tax asset	Deferred tax liability	Deferred tax asset	Deferred tax liability
Intangible assets	827		503	-
Financial liabilities		(173)	-	(71)
Tax losses	6,007		1,990	-
<b>Total deferred tax assets &amp; liabilities</b>	<b>6,834</b>	<b>(173)</b>	<b>2,493</b>	<b>(71)</b>
Net deferred tax assets not recognised	(6,661)		(2,422)	-
Offsetting	(173)	173	(71)	71
<b>Total deferred tax assets &amp; liabilities</b>			<b>-</b>	<b>-</b>

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

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

(in € thousand)	December 31, 2020	December 31, 2019
Deductible temporary differences	2,616	1,727
Tax losses	24,026	7,960
<b>Total</b>	<b>26,642</b>	<b>9,687</b>

The deductible temporary differences disclosed above would reverse over a period ranging between 5 to 10 years.

The tax losses carried forward, however, are available indefinitely.





## 17 Revenue

Currently, the Group generates only limited revenue as its main projects are in the development pipeline and are not yet commercialised. The limited revenue currently presented in the consolidated statement of comprehensive income relates to royalty income from our commercialised product, Sotalol IV.

## 18 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)	2020	2019
Out-sourced R&D	(2,128)	(971)
Employee benefit expenses (Note 19)	(771)	(377)
Management consultancy fees	(996)	(353)
Board related expenses	(116)	-
Share based payments	(485)	-
IPO related fees (Note 3.5)	(1,413)	-
Convertible bonds related fees (Note 3.5)	(55)	-
Legal & paralegal fees	(143)	(219)
Audit and related consultancy fees	(102)	(34)
Hiring fees	(73)	-
Office equipment, rent and utilities	(235)	(101)
Other expenses	(123)	(89)
Amortisation expense of intangible assets (Note 8)	(43)	(43)
Impairment losses on intangible assets (Note 8)	(480)	(3,203)
Depreciation expense on PPE and Right-of Use	(58)	(60)
<b>Total operating expenses</b>	<b>(7,220)</b>	<b>(5,451)</b>
<b>of which as:</b>		
Cost of sales	(145)	(66)
Research and development expense	(3,413)	(4,577)
General and administrative expenses	(2,194)	(808)
Share issuance related expenses	(1,468)	-

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)	2020	2019
Research and development expenses	(2,933)	(1,374)
Impairment of assets	(480)	(3,203)
<b>Total R&amp;D costs</b>	<b>(3,413)</b>	<b>(4,577)</b>

Hyloris’ research and development expenses increased by 113%, from €1,374 thousand in 2019 to €2,933 thousand in 2020. 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.

Capitalised development expenses of the product HY-039 were fully impaired end of 2020 as the development of this product was halted following unfavorable market information. In 2020, the Company capitalised developments costs for a total of €0.6 million (was €0.5 million in 2019).

Hyloris’ General and administrative expenses increased by 172% (or €1,386 thousand), from €808 thousand in 2019 to €2,194 thousand in 2020. The increase was principally driven by the vesting cost of the 2019 ESOP warrants (€485 thousand - refer to Note 24), and the enlargement of the management and governance structure of the Company (€698 thousand).

Expenses related to the financing activities for the Company in 2020 amounted in total to €1,468 thousand and related to the issuance of convertible bonds in March and April, and the Initial Public Offering completed in June. As detailed in Note 3.5, costs associated to equity transactions such as investment bank, legal and audit fees are expensed when incurred and recorded as General and Administrative expenses. Only the one-time costs related to the issuance of new shares are capitalised in the equity as costs of capital. When transactions costs are related to all shares, then such costs are recognised in both equity and profit and loss account using the new shares/exiting shares ratio.

## 19 Employee Benefit Expenses

(in € thousand)	2020	2019
Wages and salaries	(682)	(277)
Social security costs	(64)	(58)
Defined contribution costs	(9)	(9)
Other employee benefit expenses	(16)	(33)
<b>Total employee benefit expense</b>	<b>(771)</b>	<b>(377)</b>
<i>in full-time equivalents</i>		
Average number of total employees	8.1	5.5

## 20 Other Operating Income

(in € thousand)	2020	2019
Capital gain on sale of assets	21	-
Recoverable cash advance	-	86
<b>Total Other Operating Income</b>	<b>21</b>	<b>86</b>

In 2020, the Group realised a capital gain of €21 thousand on the sale of the HY-038 asset (vial form).

In 2019, the income recognised by the Company corresponded to the amount of expenses allocated to the research program partially financed by the RCA.

## 21 Financial Result

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

(in € thousand)	2020	2019
Gain related to the extension of the maturity of the shareholder loans (Note 14.2)	532	
Change in fair value of the embedded derivatives (Note 3.4)	81	
Interest income on current assets	11	-
Exchange differences	277	10
<b>Financial income</b>	<b>901</b>	<b>10</b>
Interest expense on lease liabilities	(3)	(4)
Interest expense on other financial liabilities	(567)	(407)
Other interest expense	(271)	(411)
<b>Total interest expenses</b>	<b>(841)</b>	<b>(822)</b>
Fair value adjustment on the shareholder loans (Note 14.2)	(151)	-
Bank fees	(21)	(4)
Exchange differences	-	(103)
Other	(8)	-
<b>Total financial expenses</b>	<b>(1,021)</b>	<b>(518)</b>

## 22 Income Tax Expense

### 22.1 Amounts recognised to profit and loss

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

(in € thousand)	2020	2019
Current tax (expense)/income	(1)	-
Deferred tax (expense)/income	-	14
<b>Total tax income</b>	<b>(1)</b>	<b>14</b>

### 22.2 Reconciliation of effective tax

The income tax expense can be reconciled as follows:

(in € thousand)	2020	2019
Loss before income tax	(7,145)	(5,782)
Income tax expense calculated at domestic tax rates	1,626	1,446
Disallowed expenses	-	-
Effect of unused tax losses not recognised as deferred tax assets	(1,627)	(1,432)
<b>Total tax income</b>	<b>(1)</b>	<b>14</b>



## 23 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)	2020	2019
<i>Basic earnings</i>		
Loss from continuing operations attributable to owners of the Company	(7,145)	(5,373)
<i>Diluted earnings</i>		
Dilution effect of share-based payments	-	-
Loss from continuing operations attributable to owners of the parent, after dilution effect	(7,145)	(5,373)

*Earnings per share based on the existing number of ordinary shares*

	2020	2019 <sup>2</sup>	2019
Weighted average existing number of ordinary shares outstanding during the period	21,818,814	14,389,508	3,597,377
Basic earnings per share (in €)	(0.33)	(0.37)	(1.49)
Diluted earnings per share (in €)	(0.33)	(0.37)	(1.49)

*Earnings per share based on the number of shares as adjusted for the common control of Dermax SA*

	2020	2019 <sup>2</sup>	2019
Weighted average number of ordinary shares outstanding during the period as adjusted for the common control of Dermax SA	21,818,814	17,801,768	4,450,442
Basic earnings per share (in €)	(0.33)	(0.30)	(1.21)
Diluted earnings per share (in €)	(0.33)	(0.30)	(1.21)

As the Company incurs 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.

<sup>2</sup> When applying the share split occurred on June 8 2020 to the weighted average number of shares of 2019

## 24 Share-Based Payments

The Company has a stock option (warrants) 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 warrants to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

Each employee warrant converts into one ordinary share of the Company on exercise. No amounts are paid or payable by the recipient on receipt of the warrant. The warrants carry neither rights to dividends nor voting rights. Warrants 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 stock warrant (€) (before stock split)	Fair value at grant date (€) (before stock split)	Warrants per December 31, 2020	Warrants per December 31, 2019 (as adjusted by stock split of June 8, 2020)	Warrants per December 31, 2019 (before stock split)
<b>PLAN 2017</b>						
Transaction warrants	04/05/2022	9.44	4.43	1,200,000	1,200,000	300,000
<b>PLAN 2019</b>						
ESOP warrants	31/12/2024	21.35	9.88	333,000	313,000	78,250

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

On December 31, 2019, the Company issued a new plan of 363,300 warrants (90,825 warrants before stock split) in the context of an employee stock ownership plan (ESOP Warrants). 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 Company offered in total 353,000 warrants (88,250 warrants before stock split) to the beneficiaries. As of 31 December 2020, all warrants offered were accepted and 20,000 warrants (5,000 warrants before stock split) lapsed. The remainder warrants of the 2019 plan (2,575 warrants before stock split) lapsed as at December 31, 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 December 31 2020,

74,500 warrants were offered to new employees but none were accepted end of 2020. This new plan has hence no impact on the 2020 profit or loss.

The fair value of the warrants has been determined based on the Black Scholes model. Expected volatility is based on the historical share price volatility over the past 5 years of listed peer companies.

Below is an overview of all the parameters used in this model:

	2017 Plan	2019 Plan
Share price (€) (before stock split)	9.44	21.35
Exercise Price (€) (before stock split)	9.44	21.35
Expected volatility of the shares (%)	55%	55%
Expected dividends yield (%)	0%	0%
Risk free interest rate (%)	0.60%	0.10%

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

	Average exercise price (€) (after stock split)	Number of warrants (after stock split)	Average exercise price (€) (before stock split)	Number of warrants (before stock split)
<b>Closing balance at December 31, 2018</b>	<b>2.36</b>	<b>1,200,000</b>	<b>9.44</b>	<b>300,000</b>
Warrants accepted in December 2019	5.34	118,000	21.35	29,500
<b>Closing balance at December 31, 2019</b>	<b>2.63</b>	<b>1,318,000</b>	<b>10.51</b>	<b>329,500</b>
Warrants accepted in 2020	5.34	235,000	21.35	58,750
Warrants lapsed in 2020	5.34	20,000	21.35	5,000
<b>Closing balance at December 31, 2020</b>	<b>3.01</b>	<b>1,533,000</b>	<b>12.03</b>	<b>383,250</b>

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.

## 25 Contingencies

At closing 2020, the Group was not involved in any claim or dispute incidental to the activities of the Group (nor in 2019 and 2018).

## 26 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 December 31, 2020, Hyloris has contractual commitments and contingent liabilities for a maximum amount of €3.6 million (among which €0.55 million and \$3.7 million converted in EUR at a rate of 1.2271) related to asset purchase, licenses and development agreements recorded under intangible assets.



The accounting treatment of the contractual commitments and contingent liabilities will vary per nature of triggering event. Development milestones up until commercialisation will be expensed. 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 December 31, 2020 per product candidates if such products are successfully marketed:

Product-Candidate	in \$ thousand	in € thousand	Converted in € (in € thousand)
Metolazone IV	1,650		1,345
HY-073	525		428
Dofetilide IV	350		285
Atomoxetine Liquid	250		204
HY-004	225		183
HY-074	225		183
To be assigned		150	150
HY-075		100	100
HY-029		300	300
<b>TOTAL</b>	<b>3,225</b>	<b>550</b>	<b>3,178</b>

As of December 31, 2020, out of the total value of €3.6 million, \$1.8 million (or €1.5 million) should be considered as contingent liabilities as they are not triggered by a performance obligation from the counterparty (\$1.3 million for Metolazone IV, \$0.3 million for Atomoxetine Liquid and \$0.2 million for HY-004).

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.

## 27 Related Party Transactions

The reference shareholder is 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' Chief Executive Officer, Mr. Stijn Van Rompay, and board member and executive director, Mr. Thomas Jacobsen, have material ownership interests.
- 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

### 27.1 Transactions with the Alter Pharma Group

The following table presents the total amount of transactions made with the Alter Pharma Group occurred during 2020. The underlying assets of the transactions made with related parties are presented as intangibles or prepaid expenses in the Consolidated Statement of Financial Position.

(in € thousand)	2020	2019
Licensing	-	175
Asset Purchase	-	750
Development services	(804)	2,801
<b>Total</b>	<b>(804)</b>	<b>3,726</b>

The transactions made with the Alter Pharma Group in 2020 were the following:

- Sale of the Vial form of HY-038 product for €1,400 thousand
- Development expenses on the product HY-028 for €432 thousand (the development of the product was abandoned and fully impaired in 2019). This amount is currently disputed by the Company.
- Development expenses on Maxigesic IV for €165 thousand, of which €131 thousand were capitalised as Intangibles

The transactions made with the Alter Pharma Group in 2019 were the following:

- In-licensing costs of €175 thousand associated to the License agreement with Stasisport Pharma (a subsidiary of the Alter Pharma group) and related to the granted personal, sub-

licensable and exclusive right to use all available development data and registration documents concerning Fusidic Acid Cream, in order to obtain (one or multiple) marketing authorisations for Fusidic Acid Cream in Canada, and to subsequently market, sell and distribute Fusidic Acid Cream in that territory.

- The Asset Purchase of €750 thousand are related to:

€350 thousand: an Asset purchase and development agreement with GSP (a subsidiary of the Alter Pharma group), pursuant to which GSP assigned and transferred all (intellectual property) rights, title and interests in a product that, whereof the final selection still has to be made, as well as in all related data and documentation. The balance can be offset against another existing project in place between Hyloris, GSP or an affiliated company of GSP. Therefore, the full amount is recognised as pre-paid R&D.

€400 thousand: an Asset purchase and development agreement with Nordic Specialty Pharma BVBA (NSP, a subsidiary of the Alter Pharma group), pursuant to which NSP divest all of its rights with respect to HY-075 (a product currently being developed by NSP for the United States market and subject to NSP's approval any market, that will accept the US Formulation.

- The Development agreement of €2,800 thousand are to pre-paid expenses related to

€2,000 thousand: Development Agreement with Generic Specialty Pharma Ltd (GSP, a subsidiary of the Alter Pharma group), pursuant to which GSP agreed to carry out all development activities required for (the acquisition/ registration of ANDA/NDA approval for) the product HY-038.



€800 thousand: Development Agreement with Statistport Pharma (a subsidiary of the Alter Pharma group) to run the clinical development of the Fusidic Acid cream product candidate.

#### Prepaid expenses

At December 31, 2020, there were prepaid expenses related to transactions with Alter Pharma and its subsidiaries:

(in € thousand)	2020	2019
Fusidic Acid Cream	800	800
HY-038	572	2,000
Unallocated	350	350
<b>Total</b>	<b>1,722</b>	<b>3,150</b>

The main variance with 2019 is explained by the sale in 2020 of the HY-038 vial form to Alter Pharma.

#### Trade payables

At December 31, 2020, there were outstanding trade payables related to transactions with Alter Pharma and its subsidiaries:

(in € thousand)	2020	2019
Licensing	-	175
Asset Purchase	-	-
Development Agreement	432	1,700
<b>Total</b>	<b>432</b>	<b>1,875</b>

The outstanding trade payables at December 31, 2020 related to development costs of HY-028 owned to Neogen NV.

#### Trade receivables

At December 31 2020, there were no outstanding trade receivables related to transactions with related parties.

#### Contractual commitments

Hyloris has contractual commitments for a maximum amount of €0.25 million with related parties related to licenses and development agreements recorded under intangible assets. 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, and which represent the maximum that would be paid if all milestones and sales targets, however unlikely, are achieved. The amounts are not risk-adjusted or discounted.

The following table details the total maximum contractual commitments (milestone payments only) at 31 December 2020 per product candidates if such products are successfully marketed. The profit split and royalties, which percentage varies based on achieved profit, are not included in the table:

Product-Candidate	Related party	(in € thousand)
To be assigned	Neogen (subsidiary of Alter Pharma)	150
HY-075	Nordic Speciality Pharma (subsidiary of Alter Pharma)	100
<b>Total</b>		<b>250</b>

## 27.2 Transactions with the Shareholders

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

(in € thousand)	2020	2019
Stijn Van Rompay	4,092	10,069
GRNR Invest BVBA (an entity controlled by Thomas Jacobsen)	1,039	382
Pieter Van Rompay	828	997
Stijn and Ellen Van Rompay-Delimon	416	204
<b>Total</b>	<b>6,375</b>	<b>11,651</b>

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 €1,410 thousand for 2020 (2019: €1,069 thousand).

Agreements with Shareholders were modified during the first half of 2020. Part of the loans were reimbursed. The remaining part of the loans (including interests) will be repaid the earlier of year end 2022 or when the Company will generate an operating profit (cfr Note 14.2).

#### Interest income and expenses

(in € thousand)	2020	2019
Gain related to the extension of the maturity of the shareholder loans (Note 14.2)	532	-
Exchange differences	96	-
<b>Financial income</b>	<b>628</b>	<b>-</b>
Interest expense on shareholder loans	(567)	(407)
Fair value adjustment on the shareholder loans (Note 14.2)	(151)	-
<b>Total financial expenses</b>	<b>(718)</b>	<b>(407)</b>

## 27.3 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 2020, 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, acting CFO and reference shareholder of the Company;

- Jacobsen Management BV, an entity controlled by Thomas Jacobsen, an executive member of the board of the Company
- Herauld BVBA, an entity controlled by Koenraad Van der Elst, Chief Legal Officer
- Mr Dietmar Aichhorn, Chief Operating Officer
- Humara Kinetics LLC, an entity controlled by Edward J Maloney, Chief Business Development Officer<sup>3</sup>

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 2020, ie Mr Antoine Carlhian (former CFO), Mrs Astrid Heiremans (former interim CFO) and Mr Maurizio Passanisi (former Head of clinical development)):

(in € thousand)	2020	2019
Short-term compensation (including management fees)	909	350
Post-employment benefits	1	2
Other long-term benefits	-	-
Share-based payments	201	-
<b>Total</b>	<b>1,111</b>	<b>352</b>

At December 31, 2020, there were outstanding trade payables related to transactions with the Executive Management Team:

(in € thousand)	2020	2019
Management fees	320	550
<b>Total</b>	<b>320</b>	<b>550</b>

3 Edward Maloney retired as of February 28, 2021



As of December 31, 2020, 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	26.24	920,096	60.02
Mr. Thomas Jacobsen	3,504,089	13.56	163,512	10.67
Mr. Koenraad Van der Elst	27,443	0.11	50,000	3.26
Mr. Edward Maloney <sup>4</sup>	428,828	1.66	-	-
Mr. Dietmar Aichhorn	-	-	-	-
<b>TOTAL</b>	<b>10,784,664</b>	<b>41.75</b>	<b>1,133,608</b>	<b>73.95</b>

In March and April 2020, Mr Van Rompay and Mr Van der Elst subscribed to the Convertible Bonds issued by the Company for respectively €1.0 million and €0.1 million, giving right to respectively 134,240 shares and 13,490 shares at the conversion of the bonds on June 30, 2020.

Total outstanding shares and warrants existing as of December 31, 2020 are respectively 25,832,632 and 1,533,000.

## 27.4 Transactions with the Board of directors (Non-Executive Directors)

As of December 31, 2020, non-executive members of the Board of directors are:

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

<sup>4</sup> Mr. Maloney has retired and left the Company on 28 February 2021

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

(in € thousand)	2020	2019
Board fees	55	-
Share-based payments	146	-
<b>Total</b>	<b>201</b>	<b>-</b>

At December 31, 2020, there were outstanding trade payables related to transactions with the non executive members of the Board of directors:

(in € thousand)	2020	2019
Board fees	7	-
<b>Total</b>	<b>7</b>	<b>-</b>

As of 31 December 2020, non-executive members of the Board of directors owned the following securities of the Company:

	Shares		Warrants	
	Number (#)	Pct. (%)	Number (#)	Pct. (%)
Stefan Yee	-	-	100,000	6.52
Leon Van Rompay	-	-	-	-
Marc Foidart	-	-	-	-
Carolyn Myers	-	-	-	-
James Gale	-	-	-	-
<b>Total</b>	<b>-</b>	<b>-</b>	<b>100,000</b>	<b>6.52</b>

## 28 Events after the End of the Reporting Period

### Purna Female Healthcare

On February 5 2021, the Company announced a partnership with Purna Female Healthcare (PFH) to develop and commercialise an innovative combination therapy for the treatment of severe and recurrent vulvovaginal candidiasis (rVVC).

PFH is a special purpose vehicle founded to exclusively develop a local topical combination formulation of the well-known antifungal Miconazole with Domiphen Bromide (MCZ-DB). Under the terms of the agreement, Hyloris has committed to milestone related investments of up to €4.3 million in PFH (of which €1.27 million at signing) and will lead the commercialisation and out-licensing activities. Hyloris owns 20% of PFH and is eligible to receive up to a maximum of 45% of the net profits generated by PFH.

Purna Female Healthcare has exclusively in-licensed MCZ-DB and associated IP owned by KU Leuven and the University of Antwerp (Belgium).

### Maxigesic IV

On March 5 2021, Hyloris' commercial partner AFT Pharmaceuticals announced an exclusive licensing and distribution agreement with Aguettant for Maxigesic IV in eight additional European countries. The agreement with Aguettant means that Maxigesic IV is now licensed in 20 out of the 27 EU member states (including the major pharma markets in the EU: Germany, France, Italy, and Spain) as well as the UK. Aguettant gains the exclusive rights to Maxigesic IV in the Nordics (Finland, Norway, Denmark, Sweden and Iceland), Spain, Portugal, and the Netherlands. AFT Pharmaceuticals expects sales of Maxigesic IV in these territories to commence in early 2022.

On April 8, 2021, Hyloris announced that its commercial partner AFT Pharmaceuticals signed exclusive licensing and distribution agreements with Mercapharm and Vianex for the commercialisation of Maxigesic IV in Poland and Greece respectively. AFT expects to receive regulatory approval in these countries in mid-2022, with sales expected to begin shortly thereafter.

On April 28, 2021, Hyloris announced that its commercial partner AFT Pharmaceuticals signed an exclusive licensing and distribution agreement with Hikma Pharmaceuticals in the U.S. Hyloris is eligible to receive \$4 million in regulatory milestones, as well as commercial milestones and a share of net profit.

### Tranexamic Acid RTU

Early 2021, Hyloris submitted a marketing application to the Food and Drug Administration for Tranexamic Acid RTU, a ready-to-use IV administration of tranexamic acid to prevent excessive blood loss.

### Strengthening of the management team

In February 2021, Hyloris announced the appointments of Thomas Jacobson as Chief Business Development Officer following the retirement of Ed Maloney, and Marieke Vermeersch as VP Investor Relations and Corporate Communications.

There were no other subsequent events that occur between 2020 year-end and the date of this report.

## 29 Audit Fees

During 2020, the statutory auditor provided services for the group Hyloris which fees were as follows:

(in € thousand)	2020
Audit services	79
Audit related services – legal engagement	11
Audit related services (IPO)	195
<b>Total</b>	<b>285</b>

## STATEMENT OF THE BOARD OF DIRECTORS

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, 2020 give a true and fair view of the Company’s equity and financial position as at December 31, 2020 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 €)	2020	2019
<b>ASSETS</b>		
<b>FIXED ASSETS</b>	<b>60,935,829</b>	<b>36,538,011</b>
II. Intangible fixed assets	0	
III. Tangible fixed assets	0	
IV. Financial fixed assets	<b>60,935,829</b>	<b>36,538,011</b>
Affiliated companies - Participations	39,174,782	22,674,782
Affiliated companies - Receivables	21,761,047	13,863,229
<b>CURRENT ASSETS</b>	<b>44,591,693</b>	<b>763,197</b>
VII. Amounts receivable within one year	<b>150,603</b>	<b>24,016</b>
Trade debtors	69,519	8,449
Others amounts receivable	81,084	15,567
VIII. Cash Investment	<b>20,000,000</b>	
IX. Cash at bank and in hand	<b>22,976,295</b>	<b>4,526</b>
X. Deferred charges and accrued income	<b>1,464,795</b>	<b>734,655</b>
<b>TOTAL ASSETS</b>	<b>105,527,522</b>	<b>37,301,208</b>
<b>CAPITAL AND RESERVES</b>	<b>97,077,677</b>	<b>23,950,531</b>
I. Capital	<b>10,821,808</b>	<b>89,009</b>
Issued capital	129,163	89,009
Uncalled capital (-)		
II. Share Premium	<b>103,692,645</b>	<b>23,982,274</b>
IV. Reserves	<b>5,000</b>	<b>5,000</b>
Legal Reserve	5,000	5,000
V. Accumulated profits (losses)	<b>(6,749,161)</b>	<b>(125,752)</b>

<b>PROVISIONS AND DEFERRED TAXES</b>		
<b>CREDITORS</b>	<b>8,449,845</b>	<b>13,350,677</b>
VIII. Amounts payable after more than one year	<b>6,902,269</b>	
Other financial loans	6,902,269	
IX. Amounts payable within one year	<b>432,593</b>	<b>12,080,965</b>
Current portion of amounts payable after one year	0	11,942,990
Suppliers	378,247	90,651
Taxes, remuneration and social charges	54,346	47,324
X. Accrued charges and deferred income	<b>1,114,983</b>	<b>1,269,712</b>
<b>TOTAL LIABILITIES</b>	<b>105,527,522</b>	<b>37,301,208</b>

## Income Statement

(in €)	2020	2019
<b>Operating income</b>	<b>80,611</b>	<b>50,882</b>
Turnover	0	0
Capitalisation of development costs	0	0
Other operating income	80,611	50,882
Non-recurring operating income	0	0
<b>Operating charges</b>	<b>(6,811,486)</b>	<b>(536,253)</b>
Supplies and goods	0	0
Services and other goods	(1,514,597)	(535,170)
Remuneration; social security and pensions	0	0
Depreciation of and other amounts written off formations expenses; intangible and tangible fixed assets (-)	0	0
Write-downs on inventories, on orders in progress and on trade receivables (appropriations -; write-backs +)	0	0
Provisions for liabilities and charges (appropriations -; use and write-backs +)	0	0
Other operating charges (-)	(2,702)	(1,080)
Non-recurring operating expenses	(5,294,127)	0
<b>Operating profit (loss)</b>	<b>(6,730,875)</b>	<b>(485,371)</b>
<b>Financial income</b>	<b>701,916</b>	<b>44,432</b>
Income from financial fixed assets	684,608	444,387
Other financial income	17,308	45
<b>Financial charges (-)</b>	<b>(591,184)</b>	<b>(394,562)</b>
Interest on financial debts	(576,587)	(383,735)
Other financial charges	(14,597)	(10,827)
<b>Profit (Loss) for the period before taxes (-)</b>	<b>(6,620,143)</b>	<b>(435,501)</b>
<b>Income taxes (-)</b>	<b>(3,236)</b>	<b>0</b>
<b>Profit (loss) for the period available for appropriation</b>	<b>6,623,379</b>	<b>(435,501)</b>

## STATUTORY NOTES

### Statement of Financial Fixed Assets

(in €)	2020	2019
<b>Affiliated companies - Participations</b>		
Acquisition value at the end of the preceding period		22,674,782
Movements during the period		
Acquisitions, included produced fixed assets	16,500,000	
Acquisition value at the end of the period		
Depreciation and amounts written down at end of the preceding period		
Movements during the period		
Recorded		
Depreciation and amounts written down at end of the period		
<b>Net book value at the end of the period</b>	<b>39,174,782</b>	
<b>Affiliated companies - Receivables</b>		
Net book value at the end of preceding period		13,863,229
Movements during the period		
Additions	7,897,818	
Reimbursement		
<b>Net book value at the end of the period</b>	<b>21,761,047</b>	

Company	Participation held		Data extracted from the last available annual accounts			
	Nature	Number	Direct	By subsidiaries	Annual Accounts at	Currency Code
			%	%		Capital
<b>Hyloris Developments SA</b> Blvd Gustave Kleyer 17 4000 Liège Belgium					31/12/2020	EUR
542,737,368						2,434,760
	Shares	74,066	99.99%	0%		(2,931,856)
<b>RTU Pharma SA</b> Blvd Gustave Kleyer 17 4000 Liège Belgium					31/12/2020	EUR
669,738,676						(1,185,097)
	Shares	62,000	100 %	0%		(659,044)
<b>Dermax SA</b> Blvd Gustave Kleyer 17 4000 Liège Belgium					31/12/2019	EUR
667,730,677						2,966,329
	Shares	65,875	100%	0%		286,693

## Deferred Charges and Accrued Income

(in €)	2020
<b>Deferred Charges and accrued income</b>	
Interest earned on receivables from related companies	1,357,510

## Statement of Amounts Payable

(in €)	2019
<b>Analysis by current position of amounts initially payable after more than one year, maturing in 1 year</b>	
Other debts (Shareholder loans)	6,902,269
<b>Other debt</b>	
<b>Tax, wage and social amounts payable</b>	
<b>Taxes</b>	
Estimated taxes payable	47,325
<b>Accrued charges and deferred income</b>	
Accrued Interests on other financial loans	1,064,983
Accrued Management fees	50,000

## Income and Expenses of Exceptional Size or Impact

(in €)	2020	2019
<b>Non-recurring income</b>		
<b>Non-recurring expenses</b>	5,294,127	
Other non-recurring expenses (Cost of capital transactions)	5,294,127	



# Auditor's report







## Statutory auditor's report to the general meeting of Hyloris Pharmaceuticals SA on the consolidated financial statements as of and for the year ended 31 December 2020

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 2020, 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 2 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 2020, 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 2020, 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 69.182.000 and the consolidated statement of profit or loss and other comprehensive income shows a loss for the year of EUR 7.145.000.

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 2020 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.

KPMG Bedrijfsrevisoren - KPMG Réviseurs d'Entreprises, a Belgian BV/SRL and a member firm of the KPMG global organization of independent member firms affiliated with KPMG International Limited, a private English company limited by guarantee. All rights reserved.  
Document Classification: KPMG Public

Zetel - Siège:  
Luchthaven Brussel Nationaal 1K  
B-1930 Zaventem

KPMG Bedrijfsrevisoren - KPMG  
Réviseurs d'Entreprises BV/SRL  
Ondernemingsnummer / Numéro  
d'entreprise 0419.122.548  
BTW - TVA BE 0419.122.548  
RPR Brussel - RPM Bruxelles  
IBAN : BE 95 0018 4771 0358  
BIC : GEBABEBB



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 2020

#### 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 test of intangible assets

We refer to note 8 of the consolidated financial statements.

##### — Description

The Group has recognized individual intangible assets (EUR 2.381.000) relating to development costs, asset purchases and in-licensing as at 31 December 2020. 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 2020

— Our audit procedures

We performed among others the following procedures:

- We evaluated the process by which management's business plan per product candidate was prepared.
- We inspected relevant internal information such as board of directors' minutes and project status minutes prepared by Management and external parties engaged in the development phases of the product candidates.
- We obtained the annual impairment test and analyzed the consistency of the underlying data used in the impairment test with data from the business plan approved by the board of directors.
- We evaluated the appropriateness of Management's assessment for the determination of the value-in-use per product candidate, including the assumptions used in the discounted cash flow model and the mathematical accuracy of this model.
- We assessed whether any matters arising after the end of the reporting period were relevant to the impairment testing and management's measurement of the value-in-use supporting the carrying value of these intangible assets.
- We assessed the appropriateness of the disclosures in respect of impairment testing, which are included in note 8 of the consolidated financial statements.

**Board of directors' responsibilities for the preparation of the consolidated financial statements**

The board of directors is responsible for the preparation of these consolidated financial statements that give a true and fair view in accordance with 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.



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 2020

**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. 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;





*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 2020*

- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements represent the underlying transactions and events in a manner that achieves fair presentation;
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express an opinion on the consolidated financial statements. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinion.

We communicate with the audit committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide the audit committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

For the matters communicated with the audit committee, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter.

#### **Other legal and regulatory requirements**

##### ***Responsibilities of the Board of directors***

The board of directors is responsible for the preparation and the content of the board of directors' annual report on the consolidated financial statements and the other information included in the annual report.

##### ***Statutory auditor's responsibilities***

In the context of our engagement and in accordance with the Belgian standard which is complementary to the International Standards on Auditing as applicable in Belgium, our responsibility is to verify, in all material respects, the board of directors' annual report on the consolidated financial statements and the other information included in the annual report, and to report on these matters.

##### ***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.



*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 2020*

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:

- Our business – 2020 in brief;
- Our governance; and
- Abbreviated Statutory Financial Statements of the Company

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.

#### ***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 2021

KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises  
Statutory Auditor  
represented by

Olivier Declercq  
Bedrijfsrevisor / Réviseur d'Entreprises





## Glossary and Other Info



# GLOSSARY OF TERMS

Active pharmaceutical ingredient (API)	A substance used in a finished pharmaceutical
Atherosclerosis	The build-up of fats, cholesterol and other substances in and on the artery walls. This build-up is called plaque, which can cause the arteries to narrow, blocking blood flow
Atrial Fibrillation (AF)	An abnormal heart rhythm (arrhythmia) characterised by the rapid and irregular beating of the atrial chambers of the heart. It often begins as short periods of abnormal beating, which become longer or continuous over time
Attention Deficit Hyperactivity Disorder (ADHD)	One of the most common neurodevelopmental disorders of childhood. It is usually first diagnosed in childhood and often lasts into adulthood. Children with ADHD may have trouble paying attention, controlling impulsive behaviours (may act without thinking about what the result will be), or be overly active
Bioavailability	Assessment of the amount of product candidate that reaches the body's systemic circulation after administration
Cardiovascular (CV)	A class of diseases that involves the heart or blood vessels
Chemistry, Manufacturing and Controls (CMC)	To appropriately manufacture a pharmaceutical or biologic, specific manufacturing processes, product characteristics, and product testing must be defined in order to ensure that the product is safe, effective and consistent between batches. These activities are known as CMC
Dose-range finding study	Phase 2 clinical study exploring the balance between efficacy and safety among various doses of treatment in
patients. Results are used to determine doses for later studies	
Food and Drug Administration (FDA)	The agency responsible for protecting and promoting public health and in charge of American market approval of new medications
FSMA	The Belgian market authority: Financial Services and Markets Authority, Or Autoriteit voor Financiële Diensten en Markten; Autorité des Services et Marchés Financiers
Full-Time Equivalent (FTE)	A way to measure an employee's involvement in a project. For example, an FTE of 1.0 means that the equivalent work of one full-time worker was used on the project
HY-004	Previously known as HY-REF-004, a liquid formulation of an established product for use following a specific dental procedure, to address a non-disclosed acute issue or possible procedural related complications
HY-016	Previously known as HY-EMP-016, a high barrier generic of an off-patent reference product currently sold in the U.S. without generic competition
HY-029	Previously known as HY-REF-029, a liquid formulation of an existing antiviral drug that is currently only available in oral solid form to treat a non-disclosed viral infection
HY-038	Previously known as HY-REF-038, a prefilled syringe of a commonly used product to treat a specific, non-disclosed deficiency
HY-073 and HY-074	Previously known as HY-CVS-073, HY-CVS-074, IV formulations of oral antiplatelet drugs, offering faster onset of action in patients suffering from coronary heart disease

HY-075	Previously known as HY-CVS-075, a liquid formulation of a commonly used drug for the treatment of coronary heart disease requiring frequent dose adjustments
Initial Public Offering (IPO)	Refers to the process of offering shares of a private corporation to the public in a new stock issuance. A public share issuance allows a company to raise capital from public investors. The transition from a private to a public company can be an important time for private investors to fully 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 must be given by an IV injection or infusion, meaning these medications are administered directly into the veins using a needle or tube
Key Opinion Leader (KOL)	An influential physician or researcher who is held in high esteem by their colleagues
Investigational New Drug (IND)	A drug that is ready for clinical trials in humans. When a drug reaches this point, the drug developer submits an application to get the consent of the Food and Drug Administration (FDA) to begin these trials
In vivo	Animal models of disease
Net Present Value (NPV)	A tool of capital budgeting to analyse the profitability of a project or investment. It is calculated by taking the difference between the present value of cash inflows and present value of cash outflows over a certain period
New Chemical Entity (NCE)	A compound, without any precedent among the regulated and approved drug products
Pharmacokinetics (PK)	The study of drug absorption, distribution, metabolism, and excretion. A fundamental concept in pharmacokinetics is drug clearance, i.e., elimination of drugs from the body, analogous to the concept of creatinine clearance
Phase 1 studies	First stage of clinical testing of an investigational drug designed to assess the safety and tolerability, pharmacokinetics of a drug, usually in a small number of healthy human volunteers
Phase 2 studies	Second stage of clinical testing of a investigational drug, usually performed in < several hundreds patients in order to determine efficacy, tolerability and drug dose
Phase 3 studies	Large clinical studies, usually conducted in hundred (and in some indications, thousand) patients to gain a definitive understanding of the efficacy and tolerability of the drug candidate – serves as a basis for approval
Pivotal studies	Registrational clinical studies
QT interval	A measurement made on an electrocardiogram used to assess some of the electrical properties of the heart. It is calculated as the time from the start of the Q wave to the end of the T wave, and approximates to the time taken from when the cardiac ventricles start to contract to when they finish relaxing. An abnormally long or abnormally short QT interval is associated with an increased risk of developing abnormal heart rhythms and sudden cardiac death



Ready-to use (RTU)	Pre-diluted medicines for intravenous use, known as "ready to use" preparations, help to reduce the amount of errors associated with the preparation and administration of medicines
Reference listed pharmaceutical drug (RLD)	An approved drug product to which new generic versions are compared to show that they are bioequivalent
Return on Investment (ROI)	A performance measure used to evaluate the efficiency or profitability of an investment or compare the efficiency of a number of different investments. ROI tries to directly measure the amount of return on a particular investment, relative to the investment's cost
<i>Torsade de Pointes</i>	An uncommon and distinctive form of polymorphic ventricular tachycardia (VT) characterised by a gradual change in the amplitude and twisting of the QRS complexes around the isoelectric line. Torsade de pointes, often referred to as torsade, is associated with a prolonged QT interval, which may be congenital or acquired. Torsade usually terminates spontaneously but frequently recurs and may degenerate into ventricular fibrillation
Visual Analog Scale Pain (VAS) Score	a validated, subjective measure for acute and chronic pain. Scores are recorded by making a handwritten mark on a 10-cm line that represents a continuum between "no pain" and "worst pain"

## FINANCIAL CALENDAR

June 8, 2021

Annual General Meeting of Shareholders

August 4, 2021

Half year 2021 Financial Results and Business Update

## CONTACT



**Marieke Vermeersch**

Vice President Investor Relations and Corporate Communications  
Hyloris Pharmaceuticals SA  
Boulevard Gustave-Kleyer 17  
4000 Liège, Belgium  
Tel: +32 (0)479 490 603  
Email: [marieke.vermeersch@hyloris.com](mailto:marieke.vermeersch@hyloris.com)

## 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 conformity between the French and English versions. In case of inconsistency between the French and the English versions, the English version shall prevail.

This report, including the statutory financial statements of Hyloris Pharmaceuticals SA, is available on the Company's website, [www.hyloris.com](http://www.hyloris.com).

### Forward-Looking Statements

Certain statements in this annual report are "forward-looking statements." These forward-looking statements can be identified using forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. These statements relate to future events or the Company's future financial performance and involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Company's control, that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by any forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law. You should not place undue reliance on forward-looking statements. Certain monetary amounts and other figures included in this annual report have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding

Concept & lay-out:  
[www.cantilis.be](http://www.cantilis.be)

