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# Corporate presentation April 2023

# **Forward-Looking Statements**

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# **Executive Management Team**

- In-depth knowledge of regulatory affairs, market access and the capital markets; involved in > 80 approved drugs, executed >250 licensing transactions; established track record of shareholder value creation
- Our team consists of 37 people, 11 nationalities





# Rethinking, Reinventing, Optimising Existing Medications

### To improve overall therapy outcomes

### REFORMULATING



# Changing dose and/or route of administration

### REPURPOSING/ REPOSITIONING



### New therapeutic uses

For the benefit of patients, physicians, payors



# Patented Value-Added Medicines: Pharma's Sweet Spot

New indications, combinations, reformulations

**Unique Features** 

Patented value-added 505(b)(2) medicines: Optimised existing medicines

Efficacy, safety, new use, compliance, onset of action, drug titration, convenience

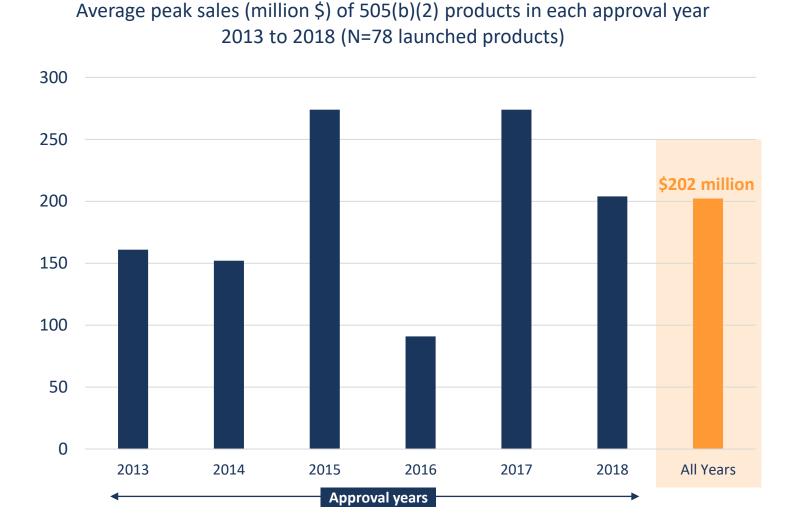
Key Benefits to Patients, Physicians and Payors New Chemical Entities & Biologicals

Off-patent ethical compounds and generics

Risk, Cost and Timelines

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# Average Peak Sales of Value-Added 505(b)(2) Products



	Product name	2019 Sales
	Avycaz	\$117M
	Belbuca	\$98M
REFORMULATED	Vasostrict	\$531M
NUL	Abraxane	\$1,200M
ORN	Restasis	\$1,188M
REF	Neoral	\$419M
	Kaletra	\$283M
	Viagra	\$2,000Mª
0	Thalomid	\$500M <sup>b</sup>
OSEI	Tecfidera	\$4,430M
REPURPOSED	Revatio	\$144M
	Propecia	\$447M <sup>c</sup>
-	Rituxan	\$1,200M <sup>d</sup>

# Putting Healthcare Needs at the Centre of Therapy Design





# To Drive Continuous Growth and Create Shareholders' Value

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 average cost** 

Min. NPV hurdle

Continuously growing diversified product portfolio characterised by



Fast market adoption



**Maximized ROI** 

**9**-•

Addressing clear unmet needs

Large potential

Ambition to become a leader in value-added medicines



## Broad, innovative cardiovascular portfolio

Product	Route of Adminstration	Indication	Formulation & Manufacturing	Clinical Development	Regulatory Filling	Target Market
Sotalol IV	Intravenous	Atrial fibrillation				
Aspirin IV	Intravenous	Acute coronary syndrome				GLOBAL
Milrinone	Extended-release capsule	Advanced heart failure (LVAD)				GLOBAL
Dofetilide IV	Intravenous	Atrial fibrillation				USA
Metolazone IV	Intravenous	Congestive heart failure				USA
HY-074	Intravenous	Acute coronary syndrome				GLOBAL
HY-075	Oral Liquid	Coronary heart disease				USA
Inte	ended to be commercialised by Hyl	oris in the U.S.				
Intended to be commercialised with partner						



LVAD: battery-operated, mechanical surgically implanted pump, which helps the left ventricle of the heart pump blood

and Fusidic Acid Cream have not been included in the above overview

## Value-added portfolio, commercialized with partners

Product	Route of Adminstration	Indication	Formulation & Manufacturing	Clinical Development	Regulatory Filling	Target Market
Maxigesic® IV	Intravenous	Post-operative pain	Licensed	in >100 countries		GLOBAL <b>AF</b> pharmaceuticals
Tranexamic Acid	Oral Mouth Rinse	(Dental) bleeding				GLOBAL
Miconazole - DB	Τορίcal	Recurring VVC				GLOBAL
Alenura	Instillation	IC/BPS				GLOBAL
Plecoid Agent	Intravenous	AML and SCLC				GLOBAL
Atomoxetine	Oral Liquid	ADHD				USA
HY-029	Oral Liquid	Viral Infection				USA
HY-083	Nasal Administration	Idiopathic Rhinitis				GLOBAL
HY-088	Oral Liquid	Hypophosphatemia				GLOBAL
	S and Fusidic Ad	<b>ier generic products, TXA R</b> c <b>id Cream have not been in</b> intravenous ; RTU: ready to use	cluded in the above overview	TXA: tranexamic acid ADHD: attention deficit hype Miconazole-DB: miconazole- rVVC: recurring vulvovaginal AML: Acute Myeloid Leukem SCLC: Small cell Lung Cancer	domiphen bromide candidiasis	



#### **Addressable market**

Market size	7% of population
Absolute numbers	~ 19 million patients in the US ~ 25,8 million patients in Europe
Seeks specialist treatment	13% of the above, following ~8 years of trial and error

### HY-083

Nasal Administration

Indication: Idiopathic rhinitis (chronic rhinitis without a known cause)

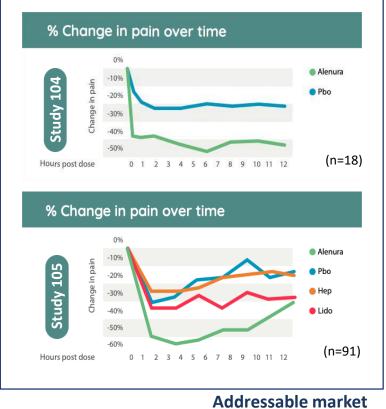
Unmet medical need: providing first reliable treatment

*Symptoms:* Runny nose, stuffy nose, sneezing fits without a medical diagnosis (allergies, infection, inflammation, ...)

- Impacting **quality of life** daily (sleep patterns, drowsiness, irritability, poor concentration)
- Molecule with known mechanism of action: block TRPV1 receptor in the nose
- Both rapid and sustainable relief
- Discovery of TRPV1-receptors was awarded the **2021 Nobel Prize**



### Proven pain reduction in 2 controlled Ph2 trials



# Patients/year >6 million (U.S.) Instillation procedures 3 million (U.S.)

### Alenura

### Instillation

### Indication: Interstitial Cystitis/Bladder Pain Syndrome Unmet medical need: no approved treatment for acute pain flares & restoration of bladder wall

- Defect in inner lining of the bladder = chronic, recurring discomfort & pain
- Alenura 15mL prefilled syringe with a dual mode of action:
  - Alkalinised lidocaine: penetrates bladder wall and provides immediate pain relief
  - Heparin: augments bladder mucous, anti-inflammatory and anti-bacterial properties = **prolonged pain relief**
  - Unique combination

#### More toxic metals in AML patients = higher mortality 1.00 Score 1-3 Score 4-6 Score >6 **Proportion surviving** 0.75 P=0.02 0.50 0.25 0.00 30 36 42 48 54 60 68 72 12 24 38 6 Overall survival in AML patients by groupings of metal scores <sup>1</sup>

#### Addressable market

Market size (AML)	158.400 cases of AML in 2018 <sup>2</sup>
5-year survival rate	Less than 30%
Market size (SCLC)	SCLC accounts for 13-15% of 2 million cases of lung cancer/year $\ ^3$

### **Plecoid Agents**

Intravenous infusion

### Indication: Acute Myeloid Leukemia & Small Cell Lung Cancer Unmet medical need: increase survival rate for leukemia patients undergoing chemotherapy

Based on breakthrough research

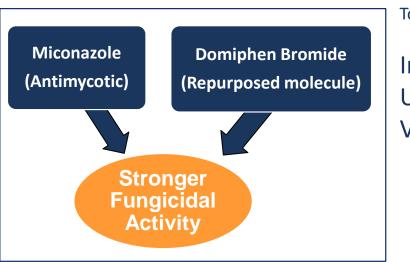
- Chelating agents bind to metal ions to extract them from the body
- Detoxifying the cancer-promoting micro-environment
  - Efficacy of chemo increased by 50% in micro-environment testing
- Potentially offering a boost and prolonged survival



1) M. Ohanian et al, American Journal of Hematology, January 2020

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- 2) Datamonitor Healthcare
- 3) Medscape Abid Irshad, MD Associate Professor, Department of Radiology, Medical University of South Carolina College of Medicine



#### Market size breakdown

Total number of drug products sold	± 175,000,000
Average annual growth rate	5.5%
Classification	Creams: 47% Pessaries: 34% Other: 19%

### **Miconazole and Domiphen Bromide**

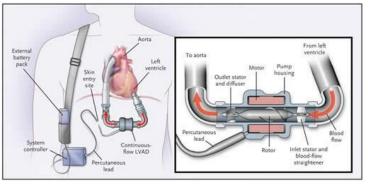
Topical cream

Indication: severe and recurrent **Vulvo Vaginal Candidiasis** (rVVC) Unmet medical need: no approved topical treatment options for <u>recurring</u> VVC

- Half of all women experience VVC in their lifetime
  - Severe or recurring cases get no benefit from regular Miconazole
- MCZ-DB adds Domiphen-Bromide, creating a **unique mode of action** 
  - Miconazole: a well-known antimycotic = reducing fungal growth
  - A repurposed molecule breaking down the yeast biofilm, hereby increasing efficacy
- Challenges with current SoC
  - Fluconazole



G. Pappas *et al.*, Clinical Infectious Diseases (2016); J.D. Sobel *et al.*, Expert Opinion on Pharmacotherapy (2018) J.D. Sobel et al., Expert Opinion on Pharmacotherapy (2018) Janssen-Cilag Ltd is the marketing authorisation holder of Gyno-Daktarin



### **Milrinone Extended Release**

Oral capsule

### Indication: Late-stage heart failure

*Unmet medical need:* patient-friendly oral formulation of Milrinone IV to improve quality of life and significantly reduce cost of care

- **Orphan drug** status in the U.S.
- #1 cause of hospitalization in people >65 years
- Potential of auto-administration (2 pills/day) at home providing constant and predictable drug exposure
  - Significantly reduces cost of care
  - Improves quality of life
- No approved competitors

#### Market size breakdown

Patients with an LVAD	~ 20.000 (U.S.)
Expected annual growth rate**	6%
Population with Right Heart Failure	30%



\*LVAD: battery-operated, mechanical surgically implanted pump, which helps the left ventricle of the heart pump blood \*\*Grand View Research Inc 2021

# Robust IP Portfolio: Extended Period of Exclusivity

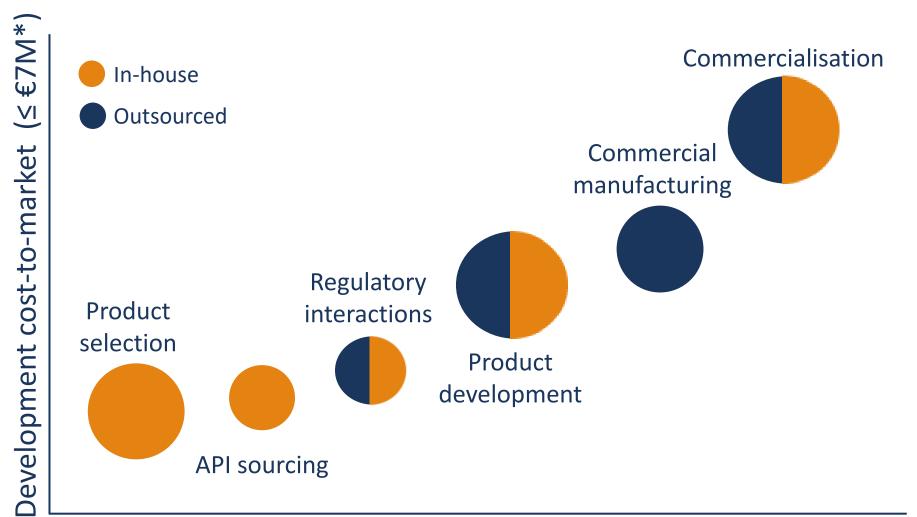


- Broad portfolio: exclusivity through 2039 in key pharma markets across the globe; orphan indications
- Wide range of protection: dosages, formulations, indications, methods for preparing a composition, manufacturing methods

• Additional layer of protection: knowhow, technological innovation and in-licensing



# Powerful R&D Engine: Leveraging our Network of Partners



### Time-to-market (≤ 7 years)



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

# Flexible, Hybrid Earnings and Commercialisation Model

### **CARDIOVASCULAR FRANCHISE**

- Lean and efficient U.S. sales team targeting ~2,700 hospital-affiliated cardiologists
- Exploit existing regulatory package for certain product candidates to partner in other key geographies
- Already a presence in the U.S. with Sotalol IV, via commercial partner AltaThera

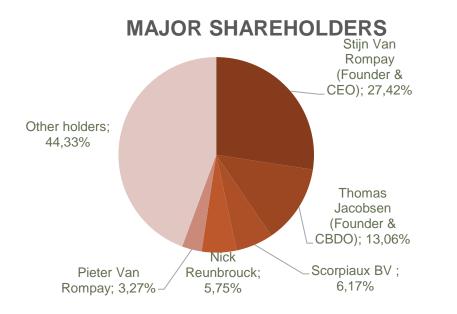
### **OTHER VALUE-ADDED PORTFOLIO**

- Out-licensing to commercial partners across various geographies
- Create ability to quickly monetise assets via upfront and milestone payments
- Retain a large minority or small majority of net profit realised by partners



The cardiovascular franchise for self-commercialisation excludes Sotalol IV, which is commercialised by our partner AltaTera and HY-075, which is envisaged to be commercialised by a partner (targeting the large retail market)

# Shareholders' Information



EUTICALS

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

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

H2 2022 cash position	€43.45 million
Capital raised end of March 2022 (gross proceeds)	€15.0 million
Total number of outstanding voting rights (= denominator)	28,000,374 <sup>1</sup>
Total number of securities carrying voting rights not yet issued (March 31 <sup>st</sup> 2023)	634,625

## Financial Highlights 2022

(in € thousand)	2022	2021	% change
Revenue	2,951	3,096	-4.7%
Cost of sales	-94	-107	/
R&D	(10,151)	(5,056)	100.8%
G&A	(3,517)	(2,900)	21.3%
Other (income/expenses)	173	(5,573)	/
Operating Result	-10,638	-10,541	0.9%
Result of the period	-10,770	-11,579	-7.0%
Cash and cash equivalents	43,457	50,012	-13.1%

### **Key Factors**

#### • Revenues:

- Increased royalties in 2022 contribute more to current topline
- Out-licensing fee of €1 million (HY-038)
- 2021 revenue impacted by upfront milestone payment (€1.8 million) (Maxigesic IV)
- Operating expenses:
  - Higher R&D expenses, following portfolio expansion
  - Headcount grew from 21 (YE 2021) to 37 today



## Anticipated Value Inflection Milestones in the next 12 months

### Clinical

- Alenura<sup>™</sup> starting multiple trials, among which four-arm phase 2 clinical trial
- Miconazole/DB: Phase 2 top line results in H1 2023
- Starting Phase 3 clinical trial on HY004 (Tranexamic Acid Oral Mouth Rinse)
- HY-029 and Dofetilide IV: start pivotal PK studies

### Regulatory

- Maxigesic<sup>®</sup> IV in the U.S. submitted in April 2023
- ➔ Potential NDA approval before end of 2023
- Global market authorizations for Maxigesic<sup>®</sup> IV

### Commercial

Commercial partnership(s)

- Out-licensing deal(s)
- In-licensing deal(s)

### Ambition to expand the product portfolio to ~30 assets before 2025



# Hyloris ESG: 3 Imperatives with 14 goals

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





8. No further Animal testing

# Potential Game Changer, Geared for Growth

### **MULTIPLE SHOTS ON GOAL**

**≤ 7 years** to market

**≤ €7 million** average cost to market

**Lower risk** as we start from existing drugs

**16<sup>1</sup> Innovative, patented, valueadded** drug candidates in the pipeline

### **COMMERCIAL PORTFOLIO**

2 patented products with partners

**Addressing unmet needs** 

Build **U.S. commercial** team

**Relevant improvements** for patients, physicians and the healthcare system

### Ambition to become the reference in value-added medicines over the coming years



<sup>1</sup> 14+2 commercialised products, excluding our high barrier generic products, TXA RTU, HY-016 and Fusidic Acid Cream.

Listed on Euronext Brussels ISIN-CODE: BE0974363955

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Q&A

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