

Hyloris

Corporate Presentation

4 October 2023 – Geneva



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CEO, co-founder



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Forward-Looking Statements

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Hyloris at a glance



Becoming a market leader in value-added medicines, focusing on unmet medical needs



Global portfolio growing to 30 cardio and other value-added assets



Reformulating and Repurposing existing chemical entities



High yield, lower risk, patient-centric developments



€350 mio market cap

Quoted on Euronext Brussels



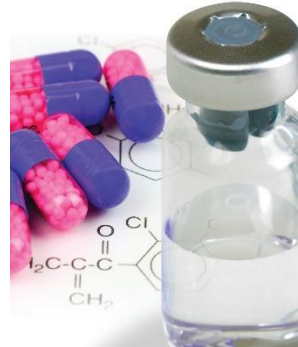
Based in Liège, Belgium

Founded in 2012, co-founders hold 41% of the shares

Rethinking, Reinventing, Optimising Existing Medications

To improve overall therapy outcomes

REFORMULATING



Changing dose and/or route of administration

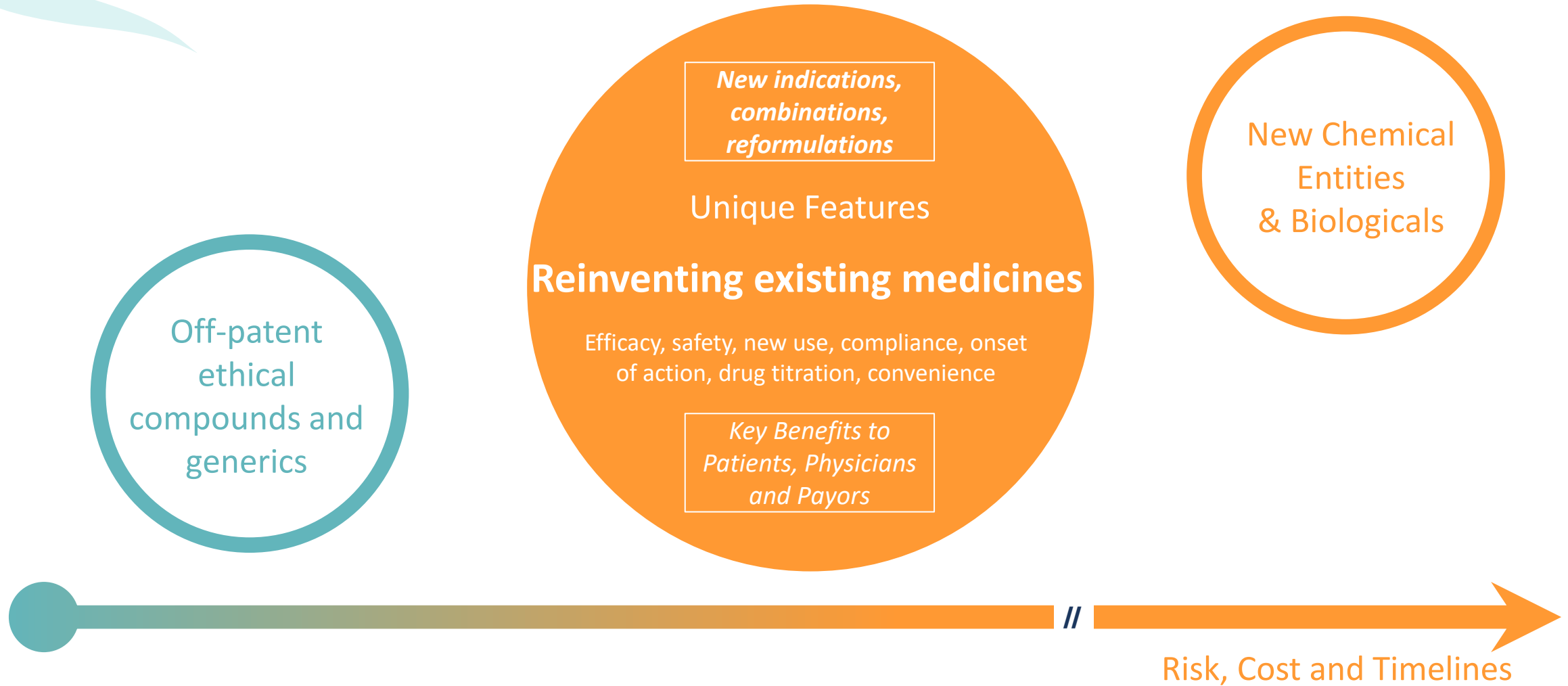
REPURPOSING/
REPOSITIONING



New therapeutic uses

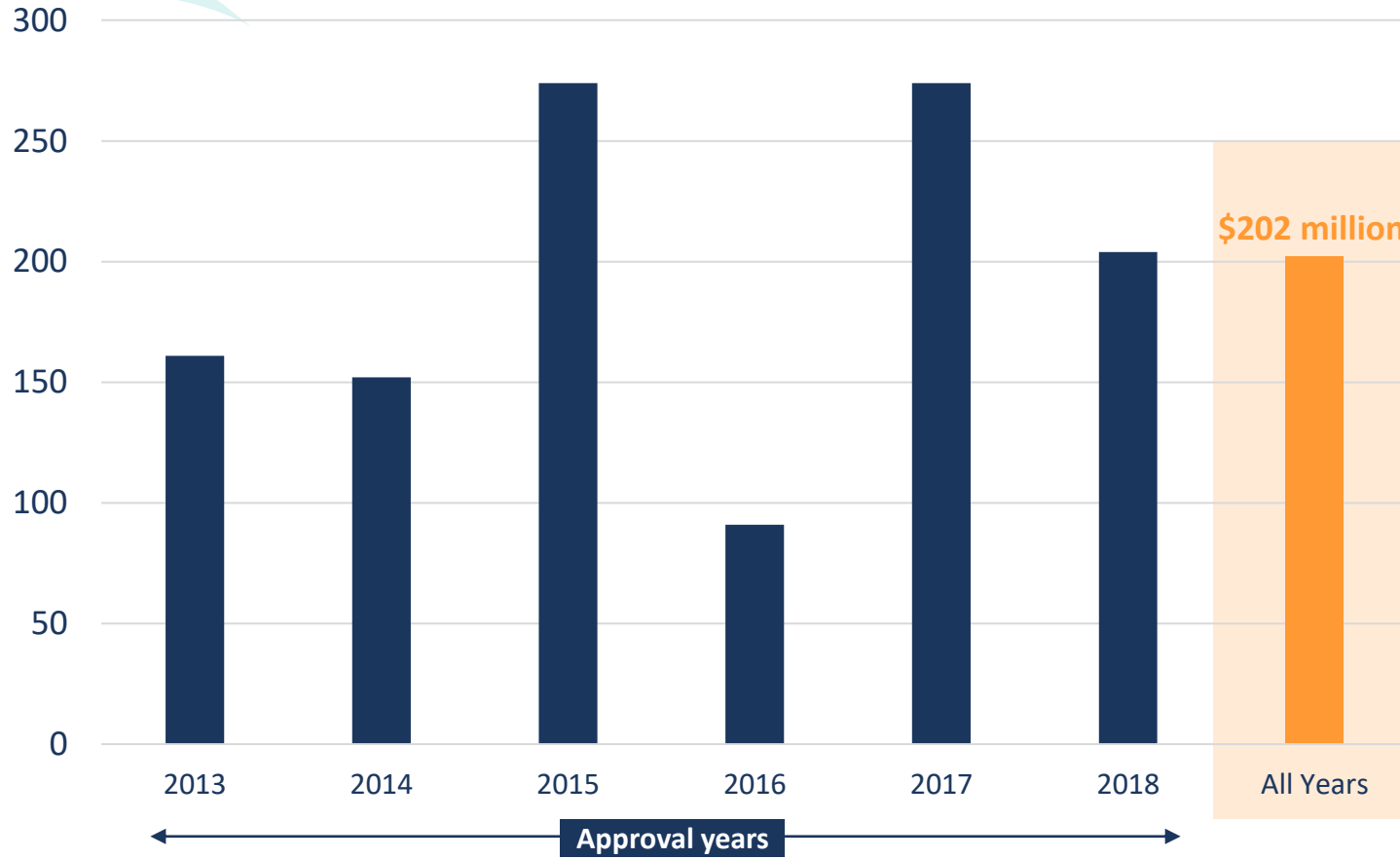
For the benefit of patients, physicians, payors

Our Focus: Patented Value-Added Medicines



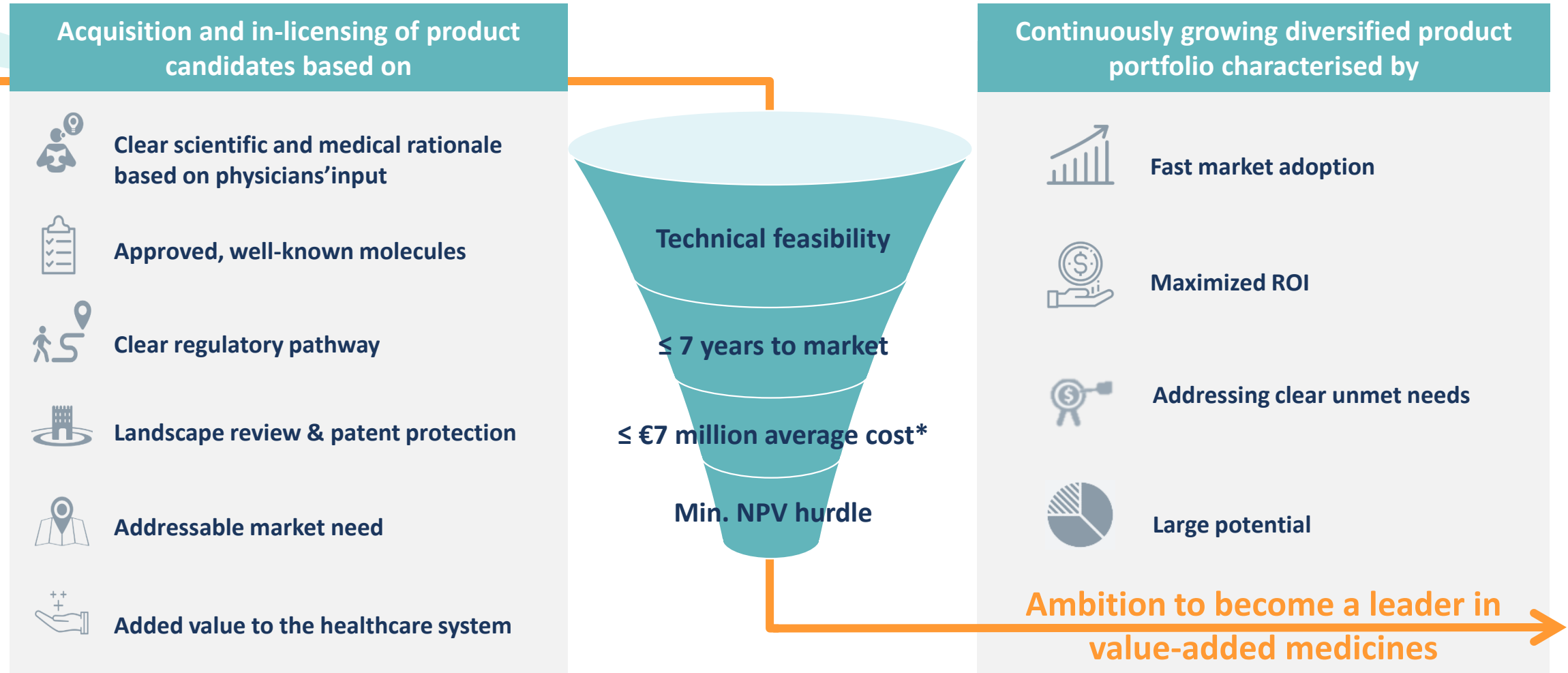
Average Peak Sales of Value-Added 505(b)(2) Products

Average peak sales (million \$) of 505(b)(2) products in each approval year 2013 to 2018 (N=78 launched products)



	Product name	2019 Sales
REFORMULATED	Avycaz	\$117M
	Belbuca	\$98M
	Vasostriect	\$531M
	Abraxane	\$1,200M
	Restasis	\$1,188M
	Neoral	\$419M
REPURPOSED	Kaletra	\$283M
	Viagra	\$2,000M ^a
	Thalomid	\$500M ^b
	Tecfidera	\$4,430M
	Revatio	\$144M
	Propecia	\$447M ^c
	Rituxan	\$1,200M ^d

To Drive Continuous Growth and Create Shareholders' Value



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 40+ people, 11 nationalities

 <p>Stijn Van Rompay - Chief Executive Officer</p> <ul style="list-style-type: none"> • >20 years of experience in leadership positions in pharma • Co-founded, managed, and exited multiple pharma companies 	 <p>Thomas Jacobsen - Chief Business Development Officer</p> <ul style="list-style-type: none"> • >20 years of experience in pharma • Expertise in operational management, and business & product development 
 <p>Dietmar Aichhorn - Chief Operating Officer</p> <ul style="list-style-type: none"> • >20 years of experience in various scientific roles in pharma • Expert in technical and clinical development and regulatory affairs in the U.S., EU and other key geographies 	 <p>Jean-Luc Vandebroek - Chief Financial Officer</p> <ul style="list-style-type: none"> • >25 years of executive financial leadership • large, global network of investors and financial institutions 
 <p>Koenraad Van der Elst - Chief Legal Officer</p> <ul style="list-style-type: none"> • >30 years of experience as external and in-house legal and general counsel at various listed companies • Involved in numerous capital and M&A transactions worldwide 	

Tackling the #1 cause of death in the world















Cardiovascular portfolio



- Focus on the **American market**
- Hospital products used by a **limited number of specialists**
 - ➔ Relatively **small salesforce**
 - ➔ Commercial approach: cost efficiency throughout
- Multiple pivotal clinical studies to be started in 2023 and 2024
 - ➔ Last study phase before submission
- Multiple FDA submissions planned as from 2024

2025 will be a transformational year for Hyloris











Broad, innovative cardiovascular portfolio

Product	Route of Administration	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Target Market
CARDIOVASCULAR (CV) PORTFOLIO			Up to 7 years 			
Sotalol IV	IV	Atrial fibrillation	Launched in U.S./partnered with AltaThera			
Aspirin IV	IV	Acute coronary syndrome				
Milrinone	Extended Release Capsule	Advanced heart failure (LVAD)				
Dofetilide IV	IV	Atrial fibrillation				
HY-074	IV	Acute coronary syndrome				
Metolazone IV	IV	Congestive heart failure				
HY-075	Oral Liquid	Coronary heart disease				

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

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

Other value-added portfolio

Product	Route of Administration	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Target Market
				Up to 7 years 		
Maxigesic® IV	IV	Post-operative pain	Licensed in >100 countries/partnered with AFT Pharmaceuticals			
Tranexamic Acid OR	Oral Liquid	Specific dental indication				
Alenura™	PFS	IC / PBS				
Miconazole-DB	Topical	Severe and rVVC				
Plecoïd™ Agent	IV	AML/SCLC				
Atomoxetine	Oral Liquid	ADHD				
HY-029	Oral Liquid	Viral infection				
HY-083	Nasal administration	Idiopathic Rhinitis				
HY-088	Oral Liquid	Hypophosphatemia				

 Intended to be commercialised with partner

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

Maxigesic IV

Marketed in over 20 countries, U.S. approval expected very soon

Indication: **Post-operative pain**

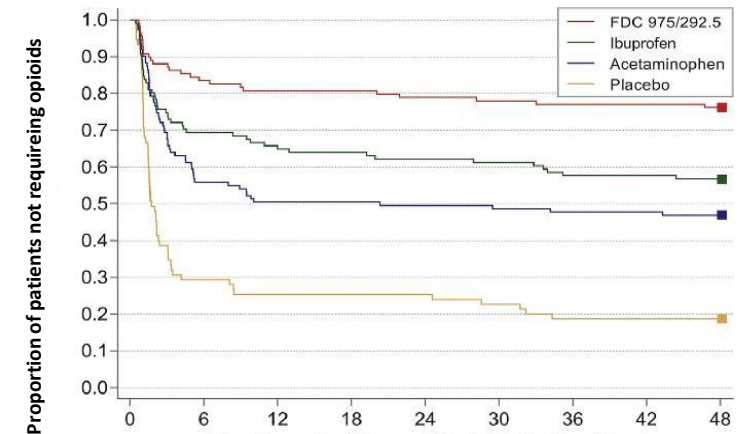
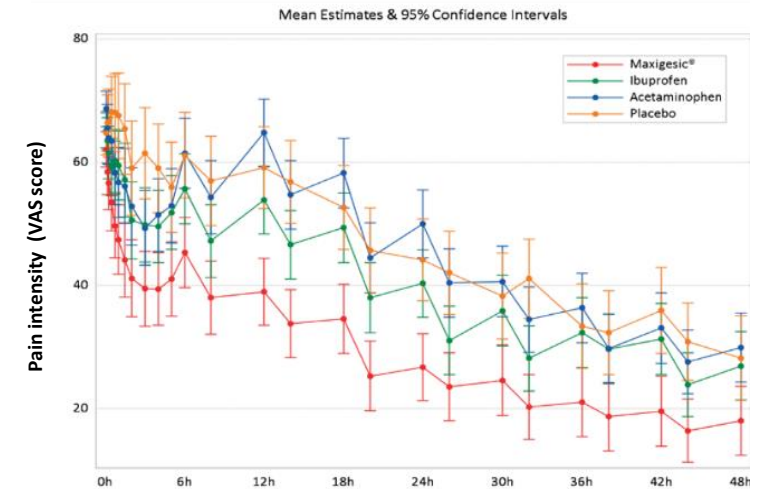
- Novel, unique intravenous combination of 1.000mg **Paracetamol IV** + 300mg **Ibuprofen IV**
- Alternative to opioid **pain relief** medicines
 - Potentially reducing opioid addiction and related costs
 - Health Care
 - Criminal justice
 - Lost productivity

Drug overdoses involving opioids (U.S.)* 80.000/year *

Chronic opioid use following surgery (U.S.)** 9%

Potential U.S. approval date: 17 October 2023

Higher pain relief with faster onset than SoC



Drastic reduction in opioid use

Alenura™

No approved treatment for acute pain flares & restoration of bladder wall

Indication: Interstitial Cystitis/Bladder Pain Syndrome

- 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**
- 4-arm (controlled double-blind multi-center) clinical trial in the U.S. ongoing, FPFV in June 2023

Patients/year (U.S.)

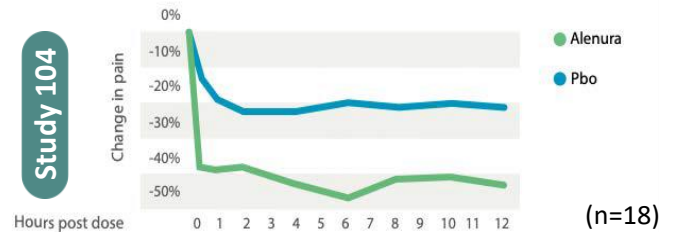
>6 million

Instillation procedures (U.S.)

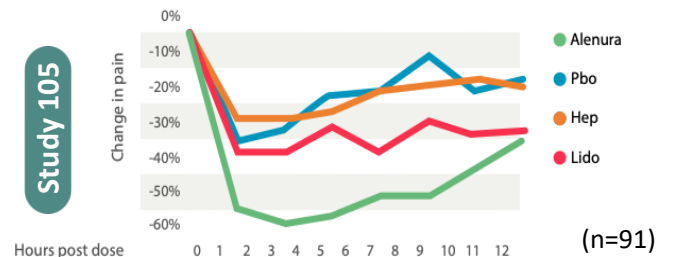
3 million

Proven pain reduction in 2 controlled Ph2 trials

% Change in pain over time



% Change in pain over time



Miconazole and Domiphen Bromide

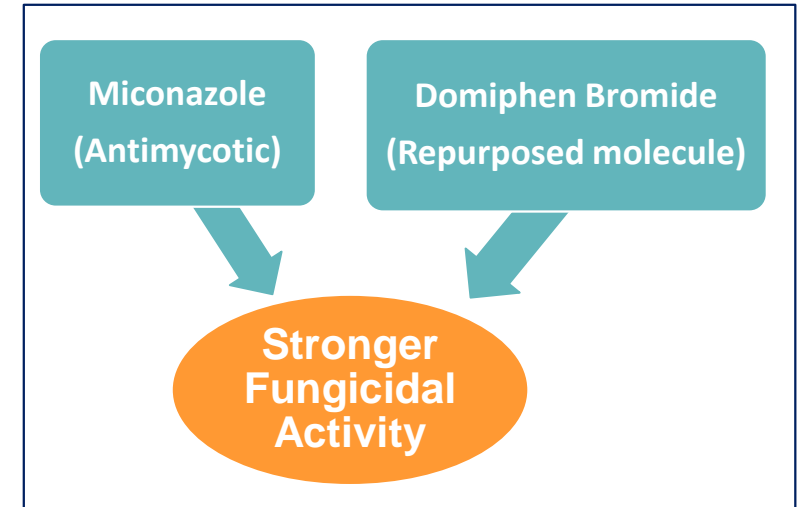
No approved topical treatment options for severe VVC

Indication: severe and recurrent **Vulvo Vaginal Candidiasis (rVVC)**

Half of all women experience VVC in their lifetime

- Severe or recurring cases - 20% of patients - 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

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



Phase 2 results expected in 2023

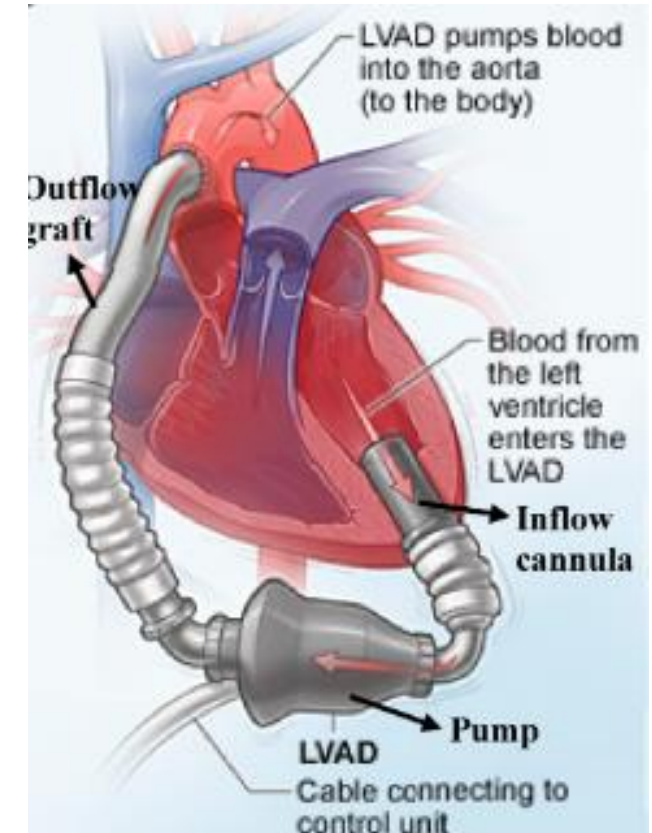
Milrinone Extended Release

Patient-friendly oral capsule of Milrinone IV

Indication: **Late-stage heart failure**

- **Orphan drug** status in the U.S. (patients with LVAD)
- #1 cause of hospitalization in people >65 years
- Shortcomings of Milrinone IV
 - High cost of care, low quality of life (repeated hospital admission)
 - Not approved for long term use
- Potential of auto-administration (2 pills/day) at home providing constant and predictable drug exposure
 - Significantly reduces **cost of care**
 - Improves **quality of life**

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



HY-083 for Idiopathic Rhinitis

Providing the first reliable treatment starting from a known molecule

Indication: Idiopathic rhinitis - chronic rhinitis **without a known cause**

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: blocks TRPV1 receptor in the nose
- Both **rapid** and **sustainable** relief
- Discovery of TRPV1-receptors was awarded the **2021 Nobel Prize**

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



**No systemic exposure
detected in Phase 1 trial**

Plecoïd Agents

Increasing chemotherapy response rate for leukemia patients

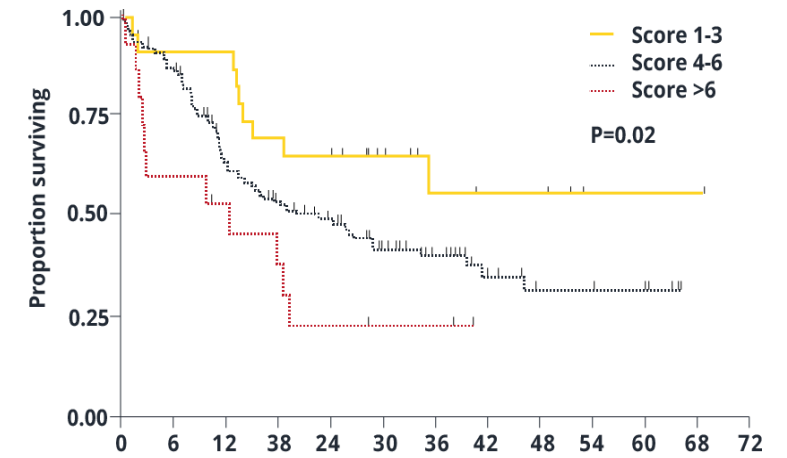
Indication: **Acute Myeloid Leukemia & Small Cell Lung Cancer**

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

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

More toxic metals in AML patients = higher mortality



Overall survival in AML patients by groupings of metal scores ¹

(1) [M. Ohanian et al, American Journal of Hematology, January 2020](#)

(2) Datamonitor Healthcare

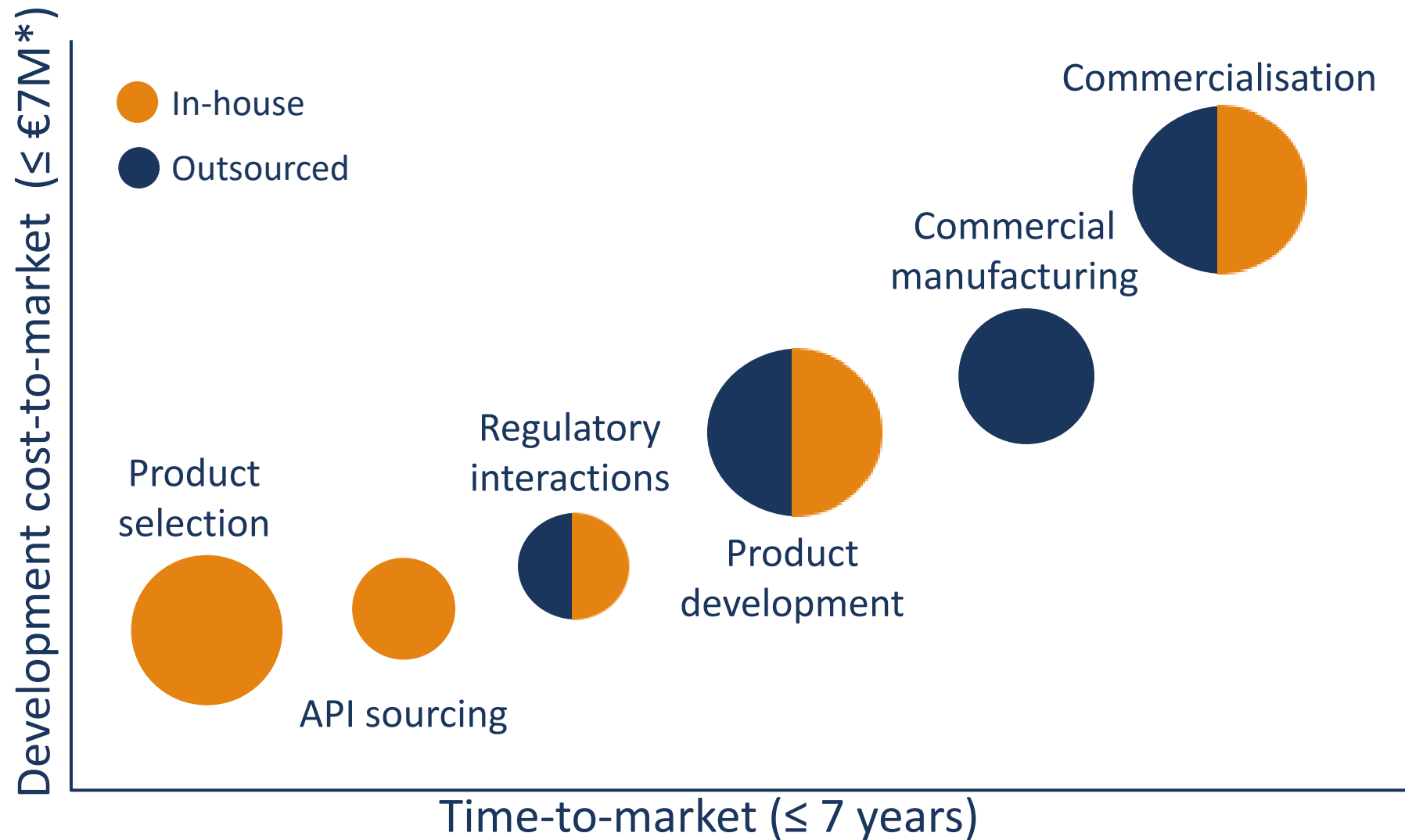
(3) Medscape - Abid Irshad, MD Associate Professor, Department of Radiology, Medical University of South Carolina College of Medicine

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



Financial Highlights H1 2023

(in € thousand)	H1 2023	H1 2022	% change
Total revenue & other income	2,391	1,229	+95%
Cost of sales	(46)	(61)	/
R&D	(6,871)	(4,712)	+46%
G&A	(2,490)	(1,274)	+95%
Operating Result	(7,100)	(4,876)	+46%
Financial Income	466	(66)	/
Result of the period	(6,634)	(4,942)	+34%

(in € thousand)	H1 2023	FY 2022
Cash and cash equivalents	39,159	43,457

Key Factors

Revenues:

- Increased royalties and out-licensing income contribute more to current topline
- Additional non-dilutive funding from a U.S. state government and the Walloon Region

Operating expenses:

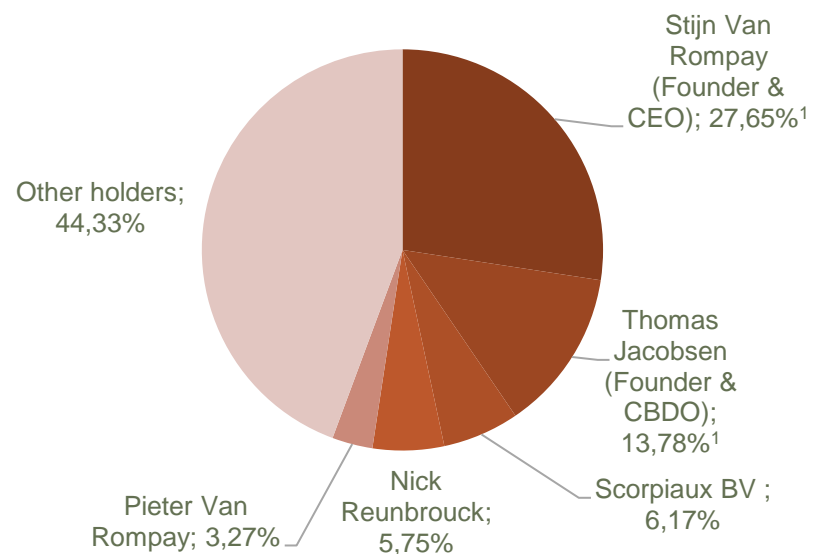
- Higher R&D expenses, following increased R&D activities & portfolio expansion
- Headcount grew to 43 (Sept 2023)

Financial income:

- Proactive treasury management leads to increased interest income and currency exchange gains in H1

Shareholders' Information

MAJOR SHAREHOLDERS



¹ based on the latest transparency notifications – published on FSMA.be - dated 5th and 15th of May 2023

H1 2023 cash position

€39,16 million

Total number of outstanding voting rights (= denominator)

28,000,374¹

Total number of securities carrying voting rights not yet issued

711,125

Bank	Analyst	Rating
Berenberg	Beatrice Allen	Buy
KBC Securities	Jacob Mekhael	Buy
Kempen	Suzanne van Voorthuizen	Buy
Degroef Petercam	David Seynnaeve	Buy
Kepler Cheuvreux	Christophe Dombu	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

Anticipated Value Inflection Milestones

Clinical

- Alenura™ : ongoing recruitment for 4-arm clinical study
- Miconazole/DB: Phase 2 read-out of results in H2 2023
- Tranexamic Acid OS: Phase 3 clinical trial starting in September 2023
- Initiating multiple pivotal (PK) studies, including HY-029 and Dofetilide IV

Regulatory

- Maxigesic® IV PDUFA goal date: 17 October 2023
- Multiple regulatory submissions expected, both inside and outside the U.S.

Commercial

- First sales of Maxigesic® IV in the U.S. leading to ~\$2 million milestone payment

Commercial partnership(s)

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

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

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

16¹ Innovative, patented, value-added 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



Q&A

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