



Investor Presentation

September 2024

Forward-Looking Statements

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Hyloris at a glance



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



Reformulating and Repurposing existing chemical entities



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



High yield, lower risk, patient-centric developments



Based in Liège, Belgium
Founded in 2012



Quoted on Euronext Brussels, co-founders hold 41% of the shares

Executive Management Team

Our team consists of 40+ people, 11 nationalities

In-depth knowledge of regulatory affairs, market access and the capital markets; involved in > 80 approved drugs, executed >300 licensing transactions; established track record of shareholder value creation



Stijn Van Rompay
Co-CEO
& Founder

- >20 years of experience in leadership positions in pharma
- Co-founded, managed, and exited multiple pharma companies



Thomas Jacobsen
Co-CEO, CBDO
& Founder

- >20 years of experience in pharma
- Expertise in operational management, and business & product development



Jean-Luc Vandebroek
CFO

- >25 years of executive financial leadership
- large, global network of investors and financial institutions



Dietmar Aichhorn
COO

- >20 years of experience in various scientific roles in pharma
- Expert in technical and clinical development and regulatory affairs in the US, EU and other key geographies



Koenraad Van der Elst
CLO

- >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



Our Focus: Patented Value-Added Medicines

Unique features

to the benefit of

New Indications

Patients



Reinventing existing medicines

Physicians



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

Combinations

Payers



Re-formulations

Hyloris

"Sweet spot"

NCEs and biologicals

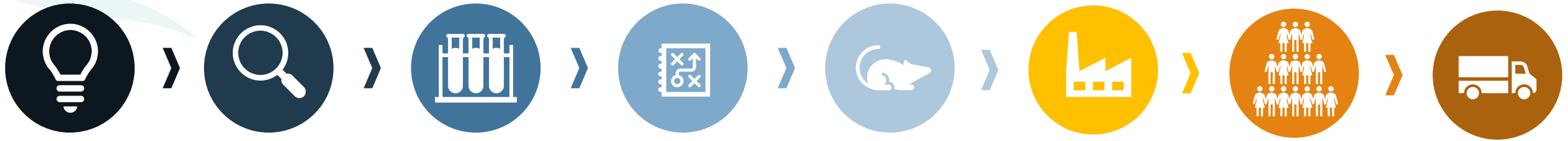
"Traditional drug discovery is a time-consuming, laborious, expensive and a high-risk process"

"No risk of failure, low barriers to entry"

Off-patent ethical compounds and generics

Risk, development costs & time-to-market

Faster innovation



Traditional model for NCEs and Biologics

Drug discovery & Preclinical development

Clinical development

Regulatory submission & Approval

Average

15 years

Repurposing model

Feasibility, formulation & production

Pre-clinical & Clinical development

Regulatory submission & Approval

Up to

7

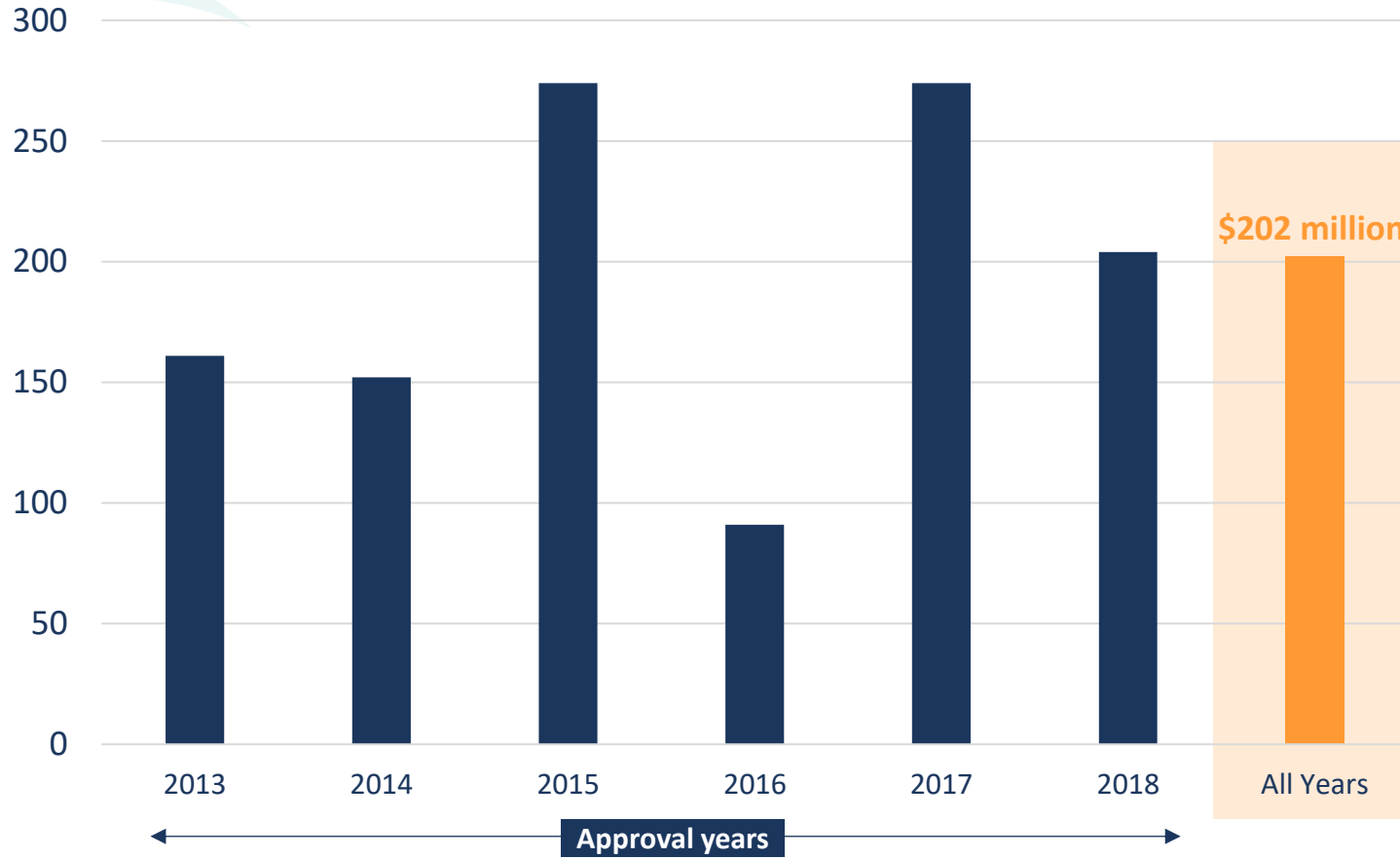
years



- ✓ Pharmacology characterized
- ✓ Safety established for the compound
- ✓ Only bridging studies needed
- ✓ Focus on efficacy

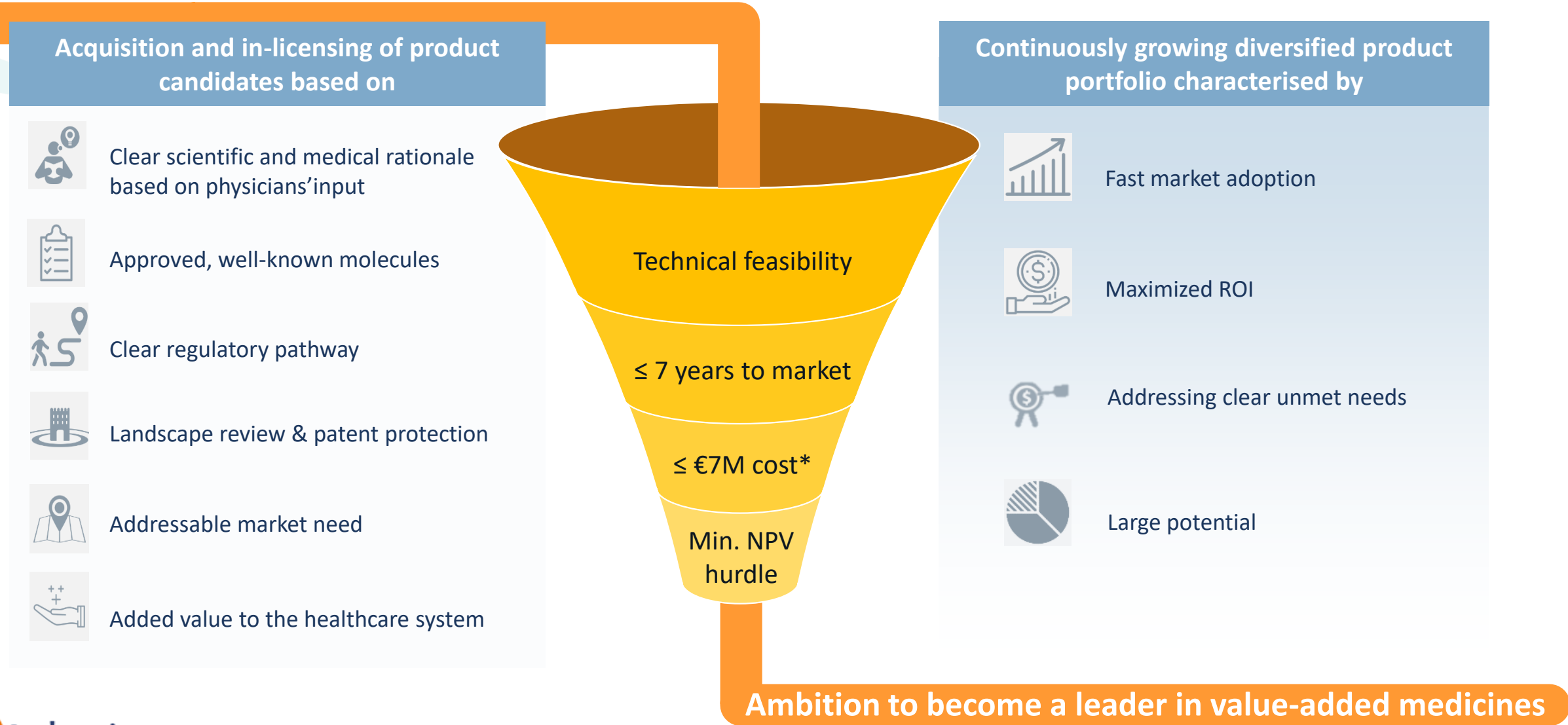
Peak Sales of Value-Added 505(b)(2) Products

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



Broad, innovative cardiovascular portfolio


Product	Route of Administration	Indication	Formulation	Clinical Development	Regulatory Filing	Target Market
CARDIOVASCULAR (CV) PORTFOLIO			Up to 7 years 			
Sotalol IV	IV	Atrial fibrillation	Partnered in the US with AltaThera			
Aspirin IV	IV	Acute coronary syndrome				
Milrinone	Extended Release oral solid	Late stage heart failure with 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				

Other value-added portfolio

Product	Route of Administration	Indication	Formulation	Clinical Development	Regulatory Filing	Target Market
Maxigesic® IV	IV	Post-operative pain	Co-development with AFT Pharmaceuticals			Global
Podofilox Gel	Topical	Ext. genital and perianal warts	Partnered in the US with Padagis			USA
Tranexamic Acid OR	Oral Liquid	Specific dental indication	Intended to be commercialised with partner	Intended to be commercialised with partner		Global
Alenura™	PFS	IC / PBS	Intended to be commercialised with partner	Intended to be commercialised with partner		Global
Miconazole-DB	Topical	Severe and rVVC	Intended to be commercialised with partner	Intended to be commercialised with partner		Global
Plecoïd™ Agent	IV	AML/SCLC	Intended to be commercialised with partner			Global
Atomoxetine	Oral Liquid	ADHD	Intended to be commercialised with partner	Intended to be commercialised with partner		Global
Valaciclovir	Oral Liquid	Viral infection	Intended to be commercialised with partner	Intended to be commercialised with partner		Global
HY-083	Nasal spray	Idiopathic Rhinitis	Intended to be commercialised with partner			Global
HY-088	Oral Liquid	Hypo Phosphatemia	Intended to be commercialised with partner			Global
HY-090	Local-acting dose	Burning Mouth Syndrome	Intended to be commercialised with partner	Co-development with AFT Pharmaceuticals		Global
HY-091	Mucoadhesive form	Vulvar Lichen Sclerosus	Intended to be commercialised with partner	Co-development with AFT Pharmaceuticals		Global
HY-095	Long-acting Injectable	Equine Gastric Ulcer Syndrome	Intended to be commercialised with partner			Global

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

TXA: tranexamic acid; ADHD: attention deficit hyperactivity disorder; Miconazole-DB: miconazole-domiphen bromide; rVVC: recurring vulvovaginal candidiasis; AML: Acute Myeloid Leukemia; SCLC: Small cell Lung Cancer



**Recent
pipeline
additions**



Indication: **Burning Mouth Syndrome (BMS)**

- BMS is a **complex chronic** disorder characterized by pain in the oral cavity without clinically causative lesions
- Other symptoms are burning sensation, dysgeusia (distorted taste), xerostomia (dry mouth), itching and other dysesthesias (pruritus, burning, tingling, stinging)
- The reported prevalence ranges from 0.7 to 5% and occurs more frequently in women than men, with a female to male ratio of 7:1
- **Equal partnership with AFT Pharmaceuticals**
- ✓ **Targeting to provide the first reliable and approved treatment**

Prevalence¹²

0.7% to 5% in the US





Indication: **Vulvar Lichen Sclerosus (VLS)**

- Chronic, inflammatory disease with an enormous impact on quality of life with an increased risk of depression, anxiety, and suicidal thoughts
- Pruritic white plaques with epidermal atrophy and scarring of the anogenital area. Patients experience discomfort, itching, and pain
- Increased risk of vulvar squamous cell carcinoma where 60% of the cases occur on the background of Lichen Sclerosus
- Massively underdiagnosed and affects 0.1% to 3% of the population, highest prevalence in postmenopausal women
- **Equal partnership with AFT Pharmaceuticals** for the development of the product candidate
- No cure exists
- ✓ **Providing a user-friendly muco-adhesive dose form containing a known drug designed to provide targeted therapy while ensuring compliance and relief**

Prevalence

0.1% to 3%



(1) <https://www.uptodate.com/contents/vulvar-lichen-sclerosus-beyond-the-basics>
(2) <https://www.uptodate.com/contents/vulvar-lichen-sclerosus-management>
(3) [https://www.jogc.com/article/S1701-2163\(21\)00890-2/fulltext](https://www.jogc.com/article/S1701-2163(21)00890-2/fulltext)
(4) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5496281/>
(5) <https://academic.oup.com/bjd/article/178/4/839/6602656>
(6) https://journals.lww.com/ijwd/fulltext/2024/10000/suicidal_ideation_in_patients_with_vulvar_lichen.6.aspx

HY-095

Indication: **Equine Gastric Ulcer Syndrome (EGUS)**

- Very prevalent condition: Ulcers in the lining of the stomach
- 30% of all horses (up to 90% in racehorses)
- Current standard of care: Oral administration daily for 4 to 6 weeks of a proton pump inhibitor (PPI)
- Resistance from the horse, inconsistent dosing, low bioavailability that eventually leads to suboptimal treatment
- No injectable product approved by regulators
- ✓ **Aiming to develop the first Long-acting injection of approved PPI drug candidate providing a reliable dose while minimizing the frequency of dosing**
- ✓ **Estimated Development cost: Well below 7 MEUR**

Overall prevalence	30%
Prevalence in sportshorses	60%
Prevalence in racehorses	90%

(1) <https://www.westvets.com.au/gastic-ulcers-in-the-performance-horse/>

Brand leader
188 MUSD
in sales





**Marketed
products**

3 commercial products

1

Maxigesic® IV

Novel combination of paracetamol & ibuprofen for short-term management of mild to moderate acute pain

- Marketing authorization granted by U.S. FDA in October 2023 and **launched early 2024** under the tradename **Combogesic® IV** by **Hikma Pharmaceuticals**

Phase 3 Trial

- Maxigesic® IV, when compared to ibuprofen IV or paracetamol IV alone in equivalent doses, demonstrated
 - Well-tolerated effects
 - Faster onset of action
 - Higher pain relief
 - Reduced opioid consumption



Marketing approvals in **50 countries**

Commercial launches in more than **30 countries**

2

Sotalol IV

Intravenous formulation of sotalol for atrial fibrillation

- Approved **March 2020** and marketed by **AltaThera Pharmaceuticals** in the U.S.
- Used for loading patients with atrial fibrillation before transitioning to oral sotalol for maintenance therapy
- Reduces hospital stay (1 day instead of 3)

3

Podofilox Gel

Topical formulation for treatment of genital warts

- Padagis US LLC (Hyloris' development partner) received U.S. FDA marketing authorization in December 2023
- \$9 million in U.S. sales in 2022
- First generic option for Condylox® 0.5%
- HPV vaccine available but no cure exists

Maxigesic IV

- ✓ **Licensed** in over 100 countries
- ✓ **Approved** in over 50 countries
- ✓ **Marketed** in over 30 countries

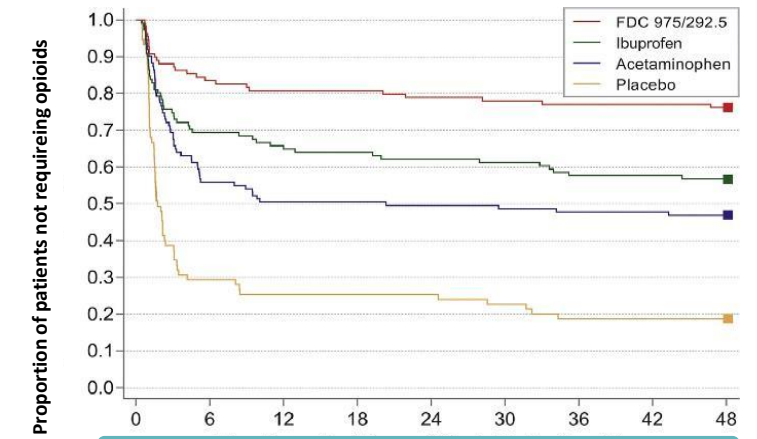
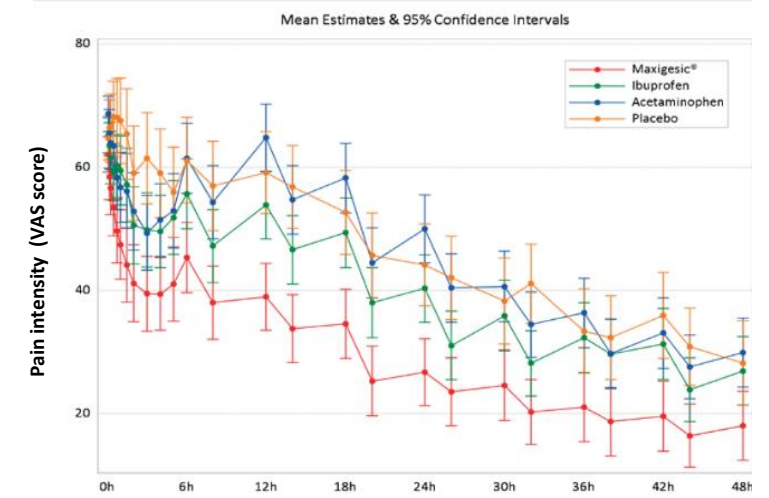
Indication: **Short-term management of mild to moderate acute pain**

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 to
 - Health Care
 - Criminal justice
 - Lost productivity

Healthcare care costs related to opioid abuse (U.S.) ¹	\$11 billion/year
Drug overdoses involving opioids (U.S.) ²	80.000/year
Chronic opioid use following surgery (U.S.) ³	~6%

Higher pain relief with faster onset than SoC



Drastic reduction in opioid use

(1) <https://www.premierinc.com/newsroom/press-releases/opioid-overdoses-costing-u-s-hospitals-an-estimated-11-billion-annually>

(2) [Data Overview | Opioids | CDC](#)

(3) <https://jamanetwork.com/journals/jamasurgery/fullarticle/2618383>

A circular inset image showing a female scientist in a white lab coat, blue surgical cap, and blue face mask. She is wearing blue nitrile gloves and is holding a test tube containing a red liquid. She is looking down at the test tube. In the background, there is a laboratory setting with various equipment and a whiteboard with orange sticky notes.

**Other
portfolio
highlights**

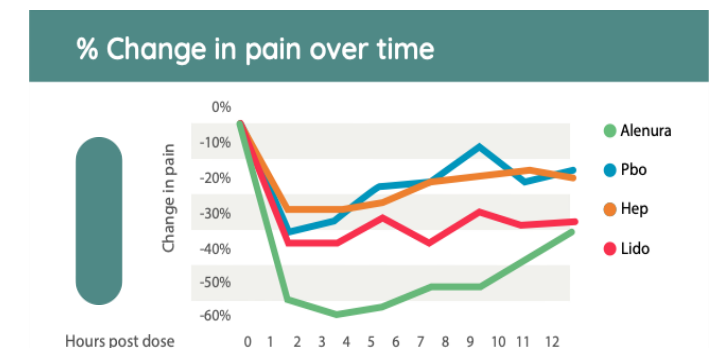
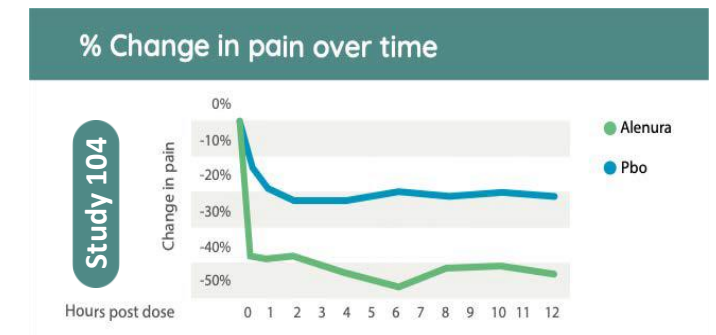


Indication: Interstitial Cystitis/Bladder Pain Syndrome

- 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
- ✓ **Targeting first treatment for acute pain flares**

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

Proven pain reduction in 2 controlled Ph2 trials





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

✓ **Targeting the first reliable treatment**

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

PTX-252

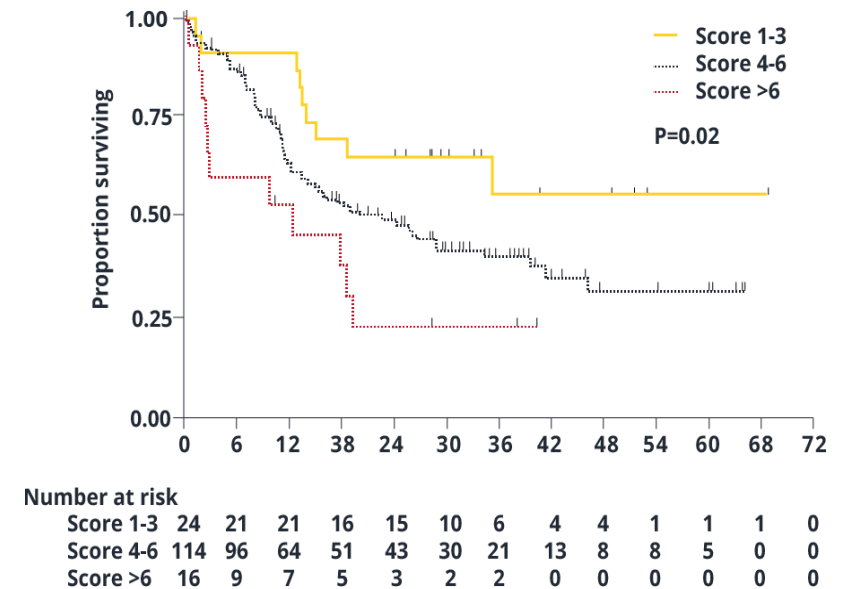


Indication: Acute Myeloid Leukemia & Small Cell Lung Cancer

- 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
- ✓ **Increasing chemotherapy response rate for Acute Myeloid Leukemia patients**

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



(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

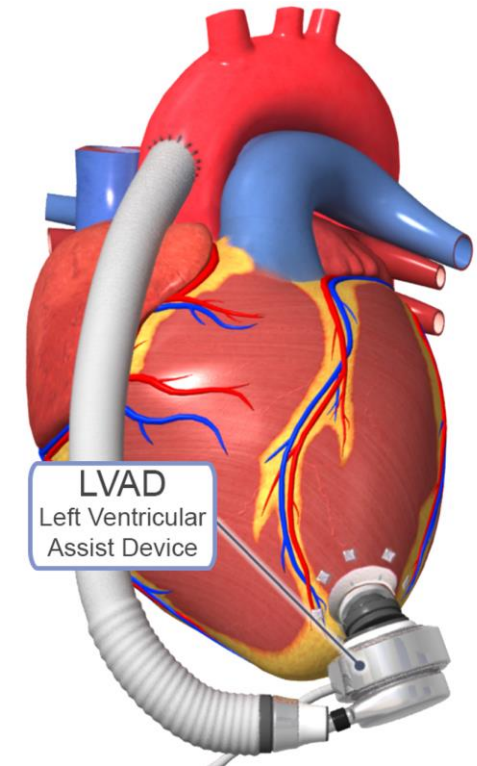
Milrinone Extended Release

Indication: Late-stage heart failure with LVAD

- **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 units/day) at home providing constant and predictable drug exposure
 - Significantly reduces **cost of care**
 - Improves **quality of life**
- ✓ **Patient-friendly oral solid form of Milrinone IV**

Patients with an LVAD	~ 20,000 (U.S.)
Expected annual growth rate**	6%
Population with Right Heart Failure	30%

- (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



A circular inset image showing a female scientist in a white lab coat, blue surgical cap, and blue face mask. She is wearing blue nitrile gloves and is holding a test tube containing a red liquid. She is looking down at the test tube. The background is a laboratory setting with various equipment and a whiteboard with orange sticky notes.

**Investment
highlights**

Financial highlights

(in € thousand)	2023	2022*	% change
Revenues	2,087	900	+132%
Other revenue & income	2,127	1,487	+43%
Total revenue & other income	4,214	2,387	+77%
Cost of sales	(93)	(94)	-1%
R&D expenses	(14,421)	(10,272)	+40%
G&A expenses	(5,693)	(3,659)	+155%
Total operating expenses	(20,207)	(14,024)	+44%
Operating result	(15,993)	(11,638)*	+37%
Financial income	613	(264)	-
Result of the period	(15,380)	(11,906)*	+29%

 Cash and cash equivalents	30,406 (FY 2023)	43,457** (FY 2022)
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Key factors

Revenue

- 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

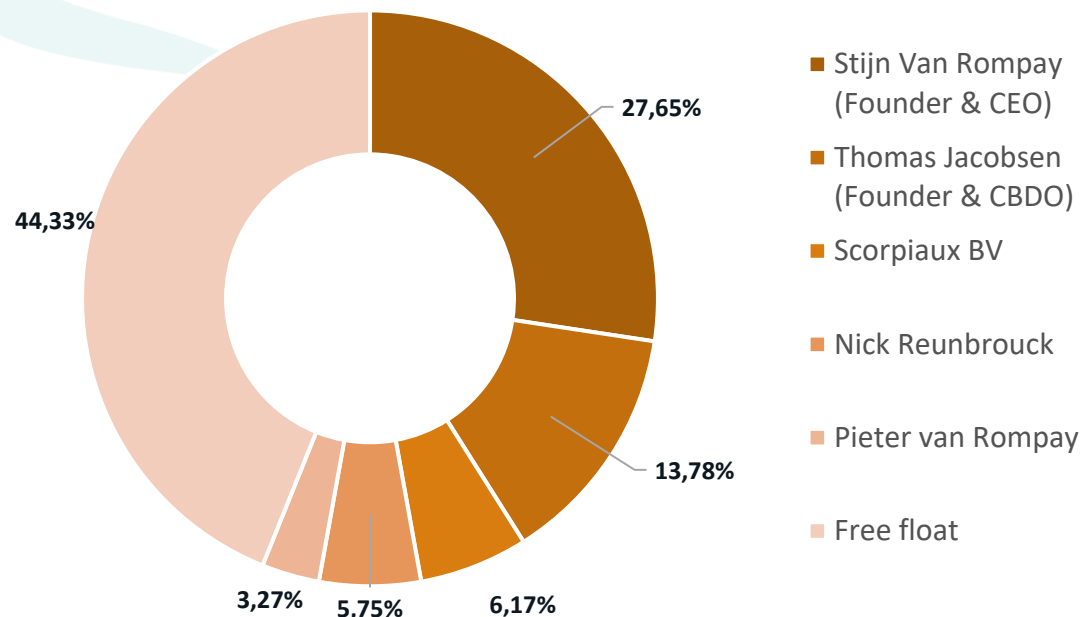
- Higher R&D expenses, following increased R&D activities & portfolio expansion
- Headcount grew to 43

Financial income

- Proactive treasury management leads to increased interest income and currency exchange gains in 2023

The Hyloris Share

Major shareholdings



based on transparency notifications and latest denominator
based on online notification (FSMA website) of managers' transactions

Total number of outstanding voting rights (denominator)	28,000,374
Total number of securities carrying voting rights not yet issued	627,271
Share capital (excluding share premium)	€140,001

Analyst coverage

Broker	Analyst	Rating
Degroef Petercam	David Seynnaeve	BUY
Kepler Cheuvreux	Christophe Dombu	BUY
KBC Securities	Jacob Mekhael	HOLD
Van Lanschot Kempen	Suzanne van Voorthuizen	Under Review
Berenberg	Beatrice Allen	BUY

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

Latest News and Anticipated Value Inflection Milestones

Clinical

- Miconazole/DB: positive Phase 2 -
- Valaciclovir OS positive results – expanded rights
- Dofetilide: Results from clinical study expected in 2024
- Tranexamic Acid OS: Phase 3 clinical trial LPLV expected H1 2025
- Initiating multiple other trials

Regulatory

Multiple regulatory submissions expected (IND & NDA), both in and outside the US such as Dofetilide IV, Valaciclovir liquid and Tranexamic Oral Mouth Rinse

Commercial

Maxigesic®IV

- U.S. launch in February 2024

Commercial partnership(s)

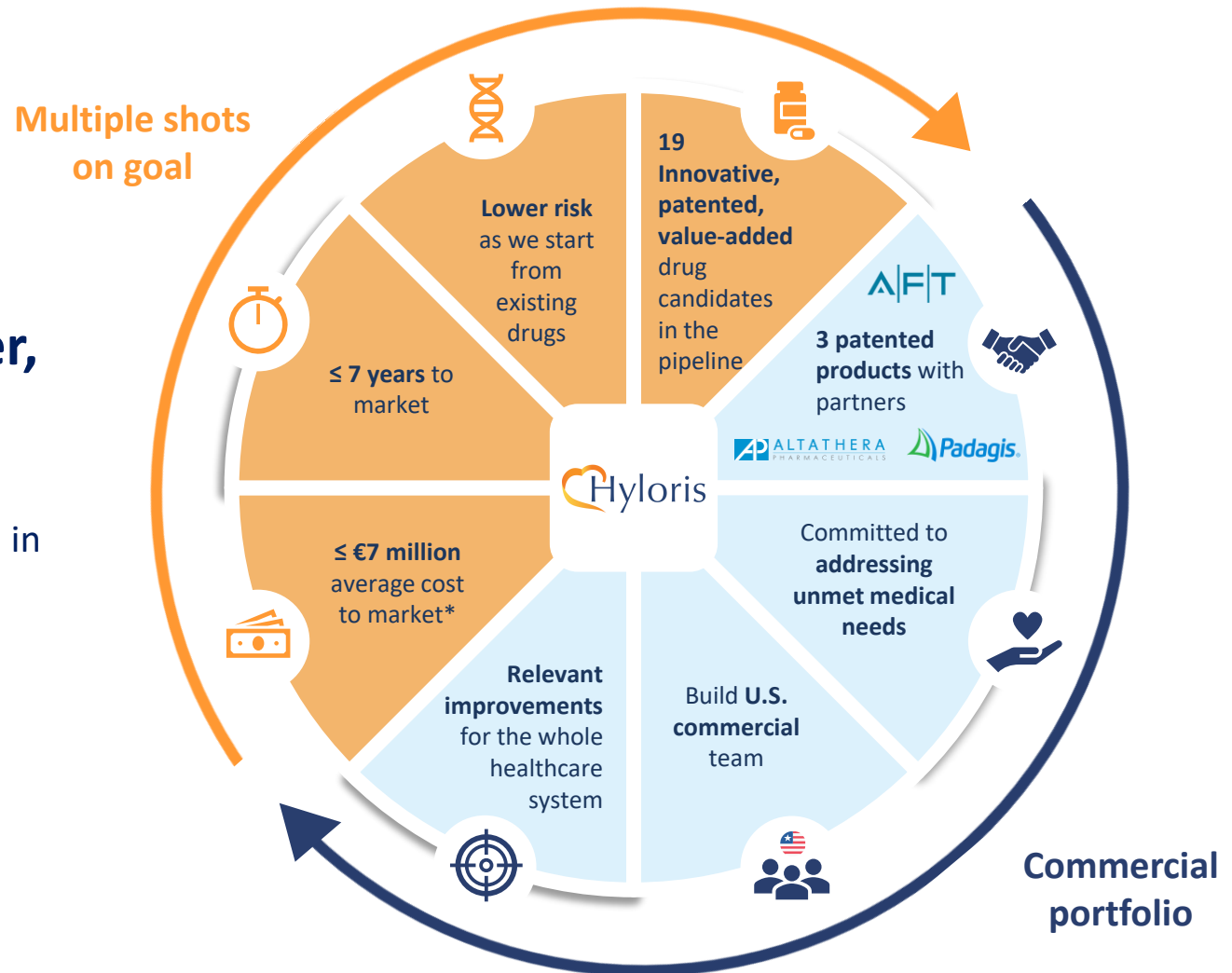
- Out-licensing deal(s)
- In-licensing deal(s)

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

Investment case

Potential game changer, geared for growth

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



**Not adjusted for inflation/exchange rate differences*



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Q&A