



Hyloris[®]



Investor Presentation

25 September 2025

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 is our DNA
patient-centric developments



Founded in 2012
Based in Liège in Belgium



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

Executive Management Team

Our team consists of 50+ people, 15 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



Dietmar Aichhorn
COO

- >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



Christophe Maréchal
CFO

- >25 years of executive financial leadership
- Expertise in corporate finance and risk management and access to large, global network of investors and financial institutions



Ann De Jaeger
CLO

- > 25 years of international leadership experience in legal, governance, and corporate affairs.
- Senior executive and board-facing roles at multinational, listed, and family-owned companies in the FMCG and B2B sectors



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

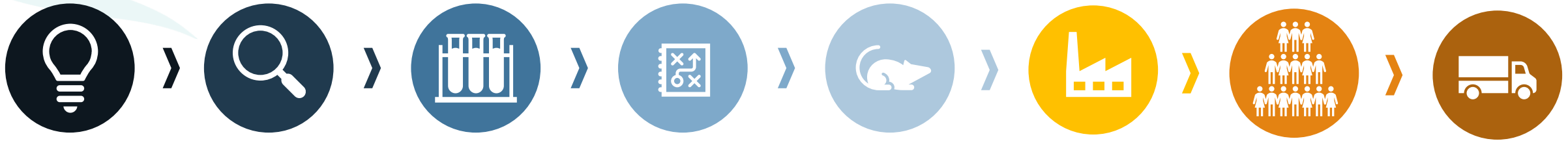
"Traditional drug discovery is a time-consuming, laborious, expensive and a high-risk process"

"No risk of failure, low barriers to entry"

Off-patent ethical compounds and generics

Development risk, costs, and 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

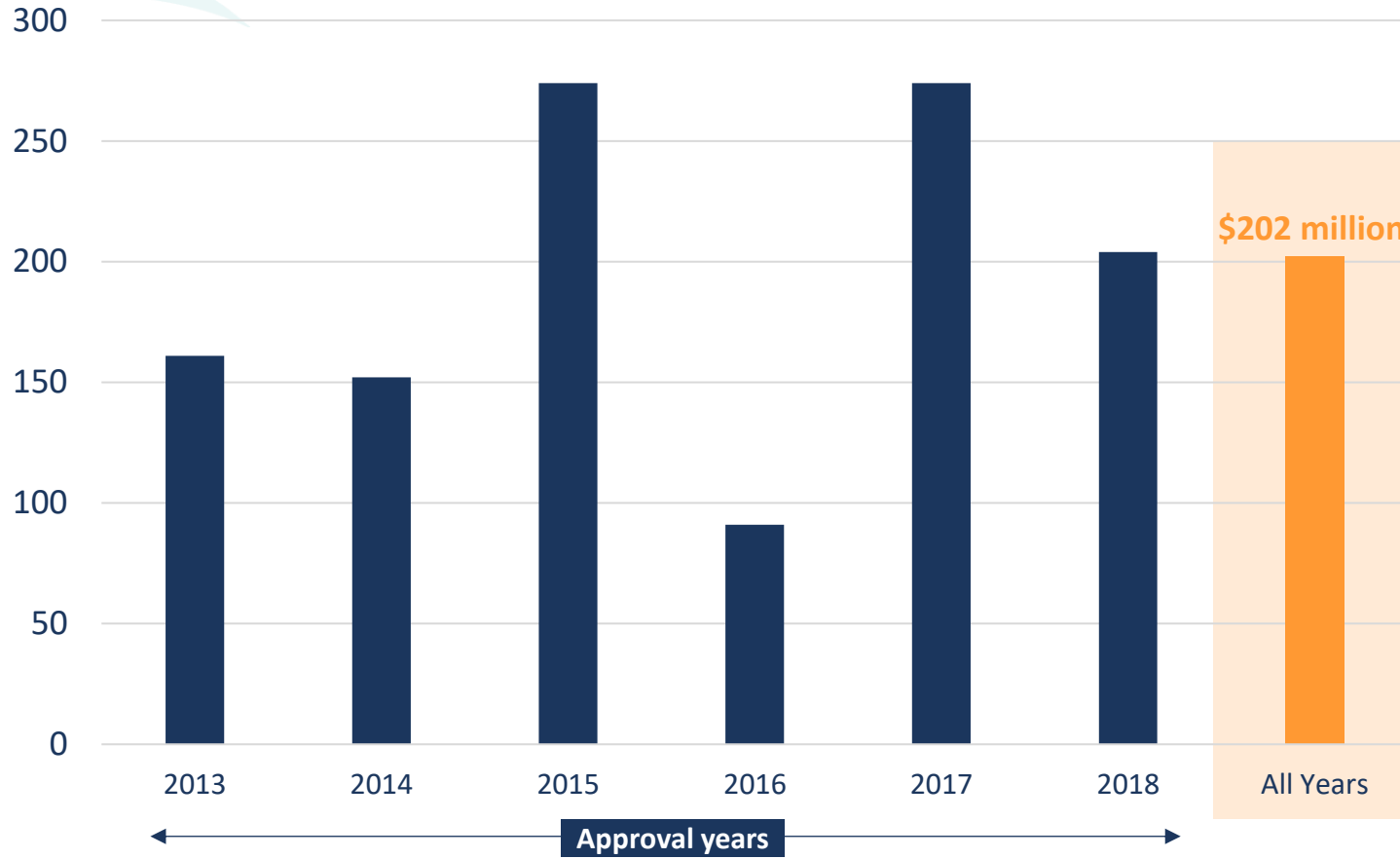
Hyloris®



- ✓ Pharmacology characterized
- ✓ Safety established for the compound
- ✓ 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)

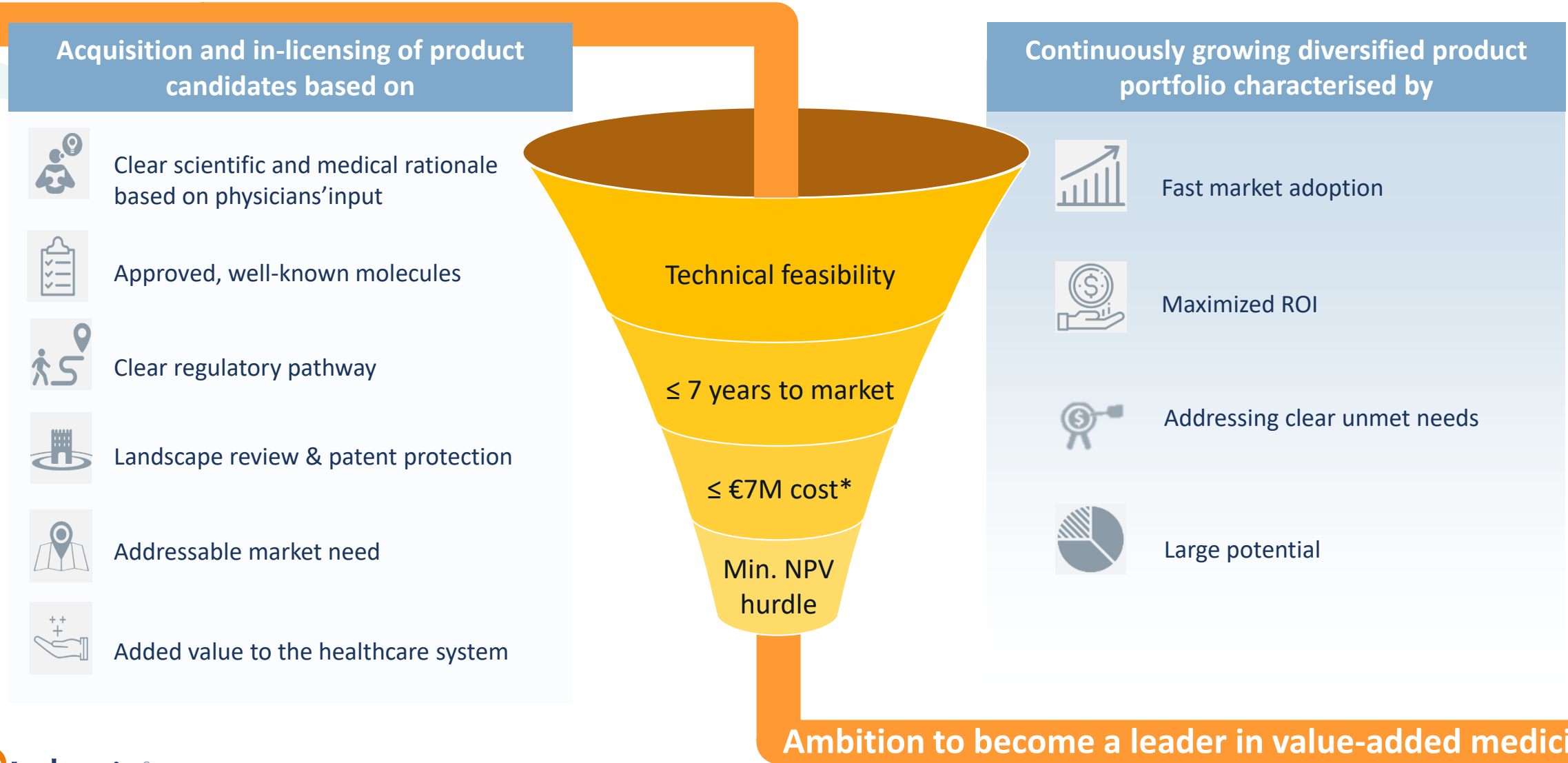


REFORMULATED

REPURPOSED

Product name	2019 Sales
Avycaz	\$117M
Belbuca	\$98M
Vasostriect	\$531M
Abraxane	\$1,200M
Restasis	\$1,188M
Neoral	\$419M
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

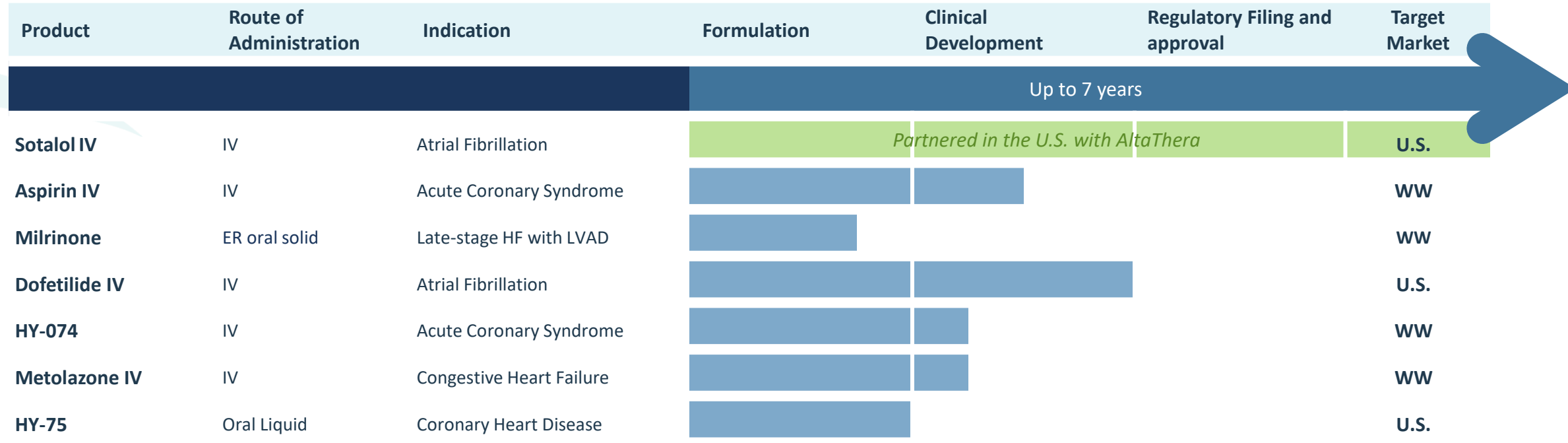


Optimal commercialization strategy currently under evaluation.

Commercialized with partner

Intended to be commercialised with partner

Broad, innovative cardiovascular portfolio



ER: Extended-Release

HF: Heart Failure

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

Commercialized with partner

Intended to be commercialised with partner

Other value-added portfolio


Product	Route of Administration	Indication	Formulation	Clinical Development	Regulatory Filing and approval	Target Market
			Up to 7 years			
Maxigesic® IV	IV	Post-operative pain	<i>Co-development with AFT Pharmaceuticals</i>			WW
Podofilox Gel	Topical	Ext. genital and perianal warts	<i>Partnered in the U.S. with Padagis</i>			U.S.
Tranexamic Acid OR	Oral Liquid	Specific dental indication				WW
Alenura™	PFS	IC / PBS				WW
Miconazole-DB	Topical	Severe and rVVC				WW
Plecoïd™ Agent	IV	AML/SCLC				WW
Atomoxetine	Oral Liquid	ADHD				WW
Valacyclovir	Oral Liquid	Viral infection				WW
HY-083	Nasal spray	Idiopathic Rhinitis				WW
HY-088	Oral Liquid	Hypo Phosphatemia				WW
HY-090	Local-acting dose	Burning Mouth Syndrome		<i>Co-development with AFT Pharmaceuticals</i>		WW
HY-091	Mucoadhesive form	Vulvar Lichen Sclerosus		<i>Co-development with AFT Pharmaceuticals</i>		WW
HY-095	Long-acting Injectable	Equine Gastric Ulcer Syndrome				WW



Other than Podofilox Gel, our high barrier generic products, TXA RTU and Fusidic Acid Cream have not been included in the above overview. ADHD: attention deficit hyperactivity disorder; Miconazole-DB: miconazole-domiphen bromide; rVVC: recurring vulvovaginal candidiasis; AML: Acute Myeloid Leukemia; SCLC: Small cell Lung Cancer

Other value-added portfolio, cont'd

Product	Route of Administration	Indication	Formulation	Clinical Development	Regulatory Filing and approval	Target Market
			Up to 7 years			
Pantoprazole	RTU Injection	GERD and EE				WW
Ondansetron	E.R. Tablet	Prevention of nausea/vomiting				WW*
HY-095	Injection	Iron Deficiency Anemia	<i>Co-development with AFT Pharmaceuticals</i>			WW
Suramin IV	Injection	Human African Trypanosomiasis**				U.S.

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 pieces of equipment and a whiteboard with orange sticky notes.

**Recent
pipeline
additions**

HY-090

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 started in December 2023
- ✓ **Targeting to provide the first reliable and approved treatment**

Prevalence¹²

0.7% to 5% in the U.S.



HY-091

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 started in January 2024
- No cure exists
- ✓ **Aiming to provide a user-friendly, mildly occluding dosage form containing a known drug substance to provide a targeted therapy while optimizing 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 approved long-acting injection of PPI drug, providing a reliable dose while minimizing the frequency of administrations by injection**
- ✓ **Estimated Development cost: Well below 7 MEUR**

Overall prevalence	30%
Prevalence in sports horses	60%
Prevalence in racehorses	90%

Brand leader
188 MUSD
in sales



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

Pantoprazole RTU injection

Indication: **Gastroesophageal reflux disease (GERD) and Erosive Esophagitis (EE)**

- Key option in managing severe acid related conditions, including bleeding peptic ulcers and erosive esophagitis
- Currently only available as a lyophilized product for infusion
- Hyloris' version is RTU, and does not require dilution or reconstitution
- Valuable in high-demand and time-sensitive environments
- Targeting a launch by of before 2028
- Patents filed
- In 2024, the global injectable (IV) pantoprazole market was value at USD 450 million, projected to expand at a compound annual growth rate (CAGR) of 6.5% and reach USD 750 million by 2033¹.

Use of pantoprazol IV Lyophilisate ²

Over 395 million vials in 2024



Ondansetron Extended-Release Tablet

Indication: **Prevention of nausea related to CINV/RINV**

- Once-daily, proprietary, bimodal extended-release oral tablet formulation of ondansetron (covering 24 hours)
- Sustained relief from nausea and vomiting associated with chemotherapy, radiotherapy, and post-operative recovery (CINV/RINV)
- Targeting the world outside of North America
- Supported by a successful Phase 3 study (GUARD) in patients with acute gastroenteritis and gastritis and positive Phase 2 study for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D)
- The global CINV/RINV 5-HT₃ antagonist market was estimated at USD 1,5 billion in 2024 and is growing at a compound annual growth rate (CAGR) of approximately 5,3%².

Use of IR Ondansetron¹

1.13 Bn tablets (+8%)



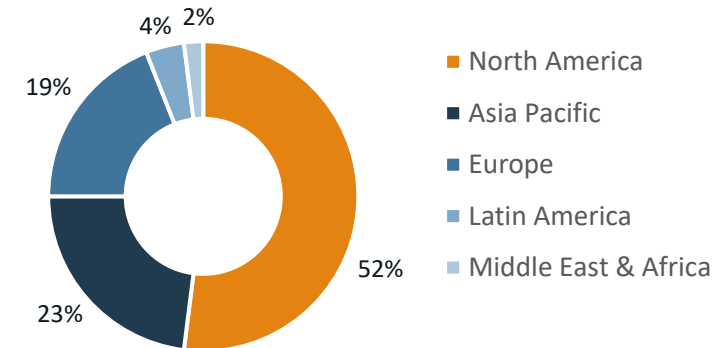
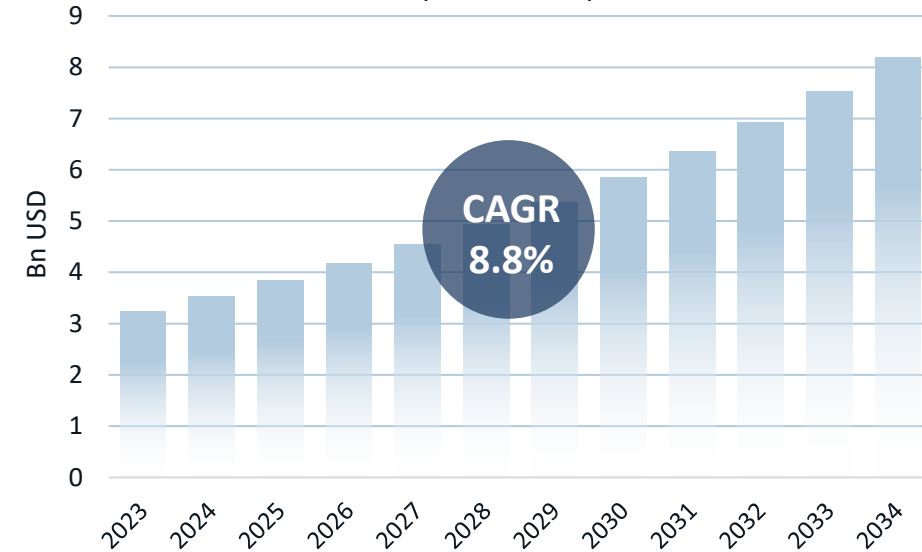
HY-094 Ferric for injection

Indication: Iron Deficiency Anemia (IDA)

- Innovative NCE injectable iron therapy designed to overcome limitations of current treatments for better convenience and tolerability
- Targeting global intravenous iron drug market forecasted to more than USD 7.41 billion by 2033¹
- Co-development deal with AFT Pharmaceuticals in March 2025
- Data shows potential reduction in dosing needs, fewer side effects, and lower toxicity vs. standard care
- 146-patient trial demonstrated fewer complications (2.7% vs. 29.7%) and no hypophosphatemia risk
- IND filing with FDA underway; ~1,000-patient global Phase III trial starting soon
- Hyloris' estimated development costs below EUR 7 million

25% of the global population are anemic ²	Corresponding to ~ 1.9 billion people
66% of the anemic burden due to IDA ²	Corresponding to ~ 1.3 billion people
Market for intravenous iron drugs ³	USD 3.2 bn in 2023 growing to >USD 7.4bn in 2033.

Global Intravenous Iron Drugs Market Size 2023 to 2034 (USD Billion)



Suramin IV

Indication: Human African Trypanosomiasis (HAT)

- An acute neglected parasitic disease transmitted by tsetse flies, fatal if left untreated. Also known as East-African Sleeping Sickness
- Suramin IV has been the standard of care in Africa for >100 years but was never approved in the U.S.
- FDA approval goal for 2027 could result in the grant of a Tropical Disease Priority Review Voucher (PRV) that can be monetized through sale to a third party
- Hyloris provides milestone-based R&D funding and equity investment (USD 3.6M total). Hyloris is entitled to royalties, >50% of PRV sale proceeds and just below 20% of Kuvatris, the development partner.
- Phase 2 on Autism Spectrum Disorder conducted as potential label extension (3.2 million patients in the U.S. in 2024¹)

Incidence of rHAT

Less than 1.000 cases/year worldwide. U.S. cases extremely rare

Recent PRV values

USD 150m to USD 160m²



 Hyloris[®]



**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**
- Combogesic® IV **received a J-code in October 2024**

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 Condyllox® 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

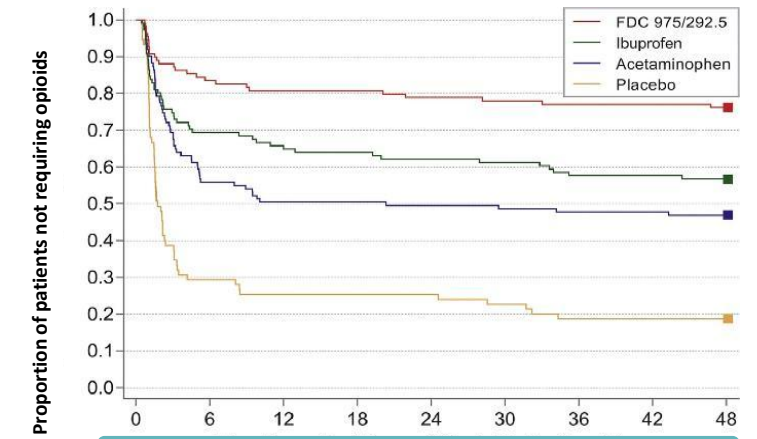
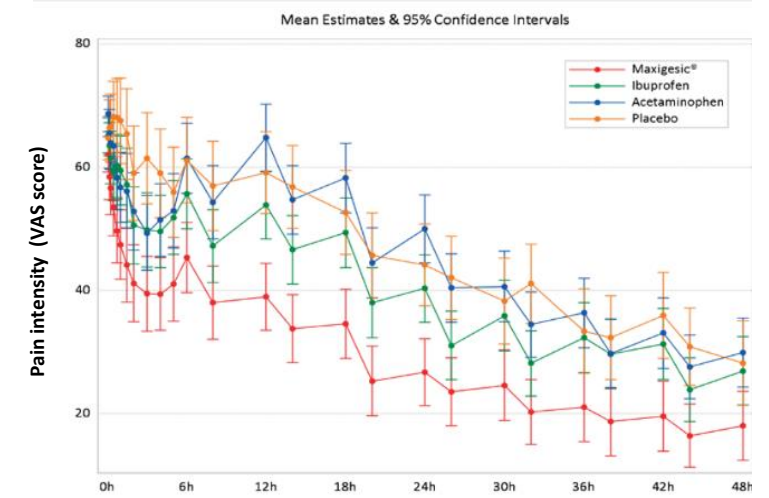
Indication: **Short-term management of mild to moderate acute pain**

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	USD 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>



**Other
portfolio
highlights**



Indication: Interstitial Cystitis/Bladder Pain Syndrome

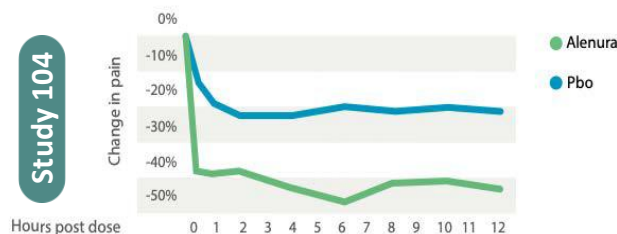
- Defect in inner lining of the bladder = chronic, recurring discomfort & pain
- Alenura 15 mL container targeting a dual mode of action:
 - Alkalinized lidocaine: penetrates bladder wall and provides **immediate pain relief**
 - Heparin: potentially augments bladder mucous, anti-inflammatory and anti-bacterial properties
 - **Unique combination, developed in partnership**
- 4-arm (controlled double-blind multi-center) clinical trial in the U.S. ongoing (by development partner), FPFV in June 2023.

✓ Targeting first treatment for acute pain flares

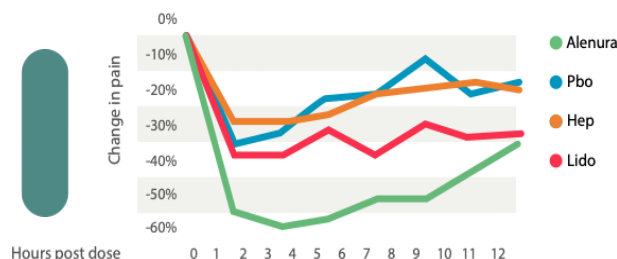
Patients/year (U.S.)	>6 million
Instillation procedures (U.S.)	3 million

Proven pain reduction in 2 controlled Ph2 trials

% Change in pain over time



% Change in pain over time





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 targeting known mechanism of action: downregulates TRPV1 receptor in the nose and ablates signaling pathways
 - Both rapid and sustainable relief
- ✓ **New Chemical Entity (NCE) is being developed as potential first-in-class treatment**

Market size	7% of population
Absolute numbers	~ 19 million patients in the U.S. ~ 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*

*) Not performed on final product.



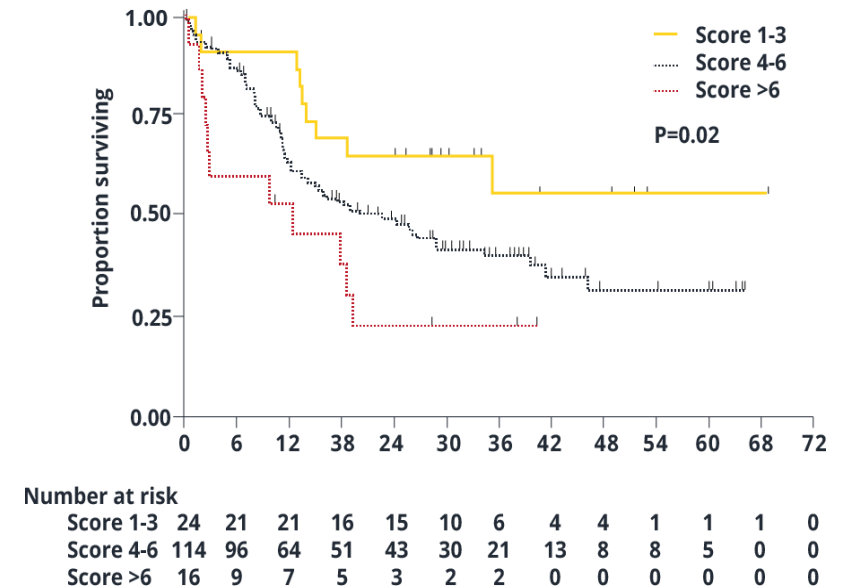
Indication: Acute Myeloid Leukemia & Small Cell Lung Cancer

- Developed in collaboration with Pleco Therapeutics, PTX 252 is a small molecule designed to extract heavy metals from the body
 - Metals are involved in the pathophysiology of AML and can impact the effectiveness of chemotherapy in AML
 - Targeting to improve the functioning of the tumor suppressor protein p53, thus increasing the sensitivity of cancer cells to chemotherapy
 - Early clinical development, formulation completed
 - Granted Orphan Drug Designation by the FDA for the treatment in AML
- ✓ **Targeting New Chemical Entity (NCE) that could increase 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

(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

More toxic metals in AML patients = higher mortality

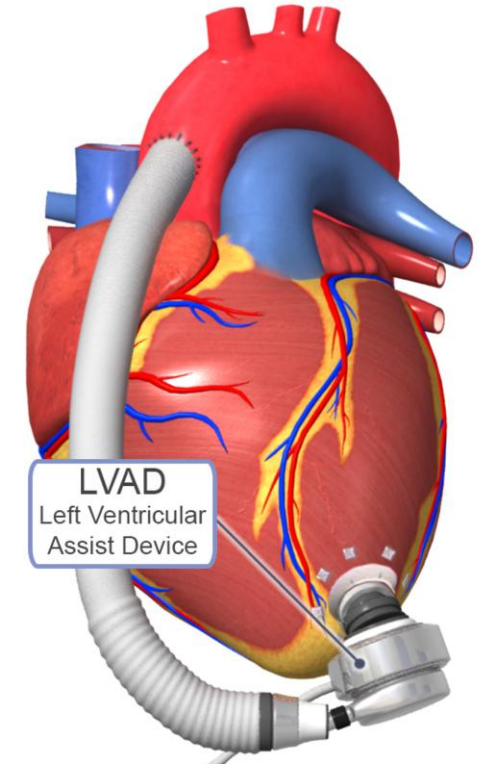


Milrinone Extended Release



Indication: Late-stage heart failure

- **Orphan drug** status in the U.S., **targeting patients with right heart failure with an 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
 - Markedly reduces **cost of care**
 - Significantly improves **quality of life**



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
- (4) LVAD = Left Ventricular Assist Device



**Investment
highlights**

Financial highlights

(in € thousand)	HY 2025	HY 2024	% change
Revenues	3,018	4,153	-27%
Other operating income	765	487	57%
Operating income	3,784	4,640	-18%
Cost of sales	(128)	(108)	18%
R&D expenses	(4,975)	(5,313)	-6%
G&A expenses	(2,203)	(3,150)	-30%
Other operating expenses	(12)	(45)	-74%
Operating expenses	(7,318)	(8,616)	-15%
Operating result	(3,534)	(3,976)	-11%
Net financial result	(183)	491	-137%
Income taxes	162	-	N.A.
Net result	(3,555)	(3,486)	2%

 Equity	28,889	32,143
 Cash and cash equivalents	18,615	23,594*

*includes €10M short term deposits on 30 June 2024

Operating income

- Operating income of €3.8 million, down 18% versus H1 2024 due to the temporary absence of milestone payments compared to 2024 (USD 2.1 million milestone relating to Maxigesic® IV in the U.S.), partly offset in Revenues by a 30% increase in royalties to €2.9 million across the three commercialized products and a 57% increase in other operating income.

Operating expenses

- R&D expenses are 6% lower than last year despite sustained R&D activity and progress achieved with several positive study results obtained.
- General and administrative expenses amounted to €2.2 million, down 30%, mainly due to much lower legal and investigation fees (Alta Thera litigation) partly compensated by higher employee benefits and share based payment expenses.

Financial result

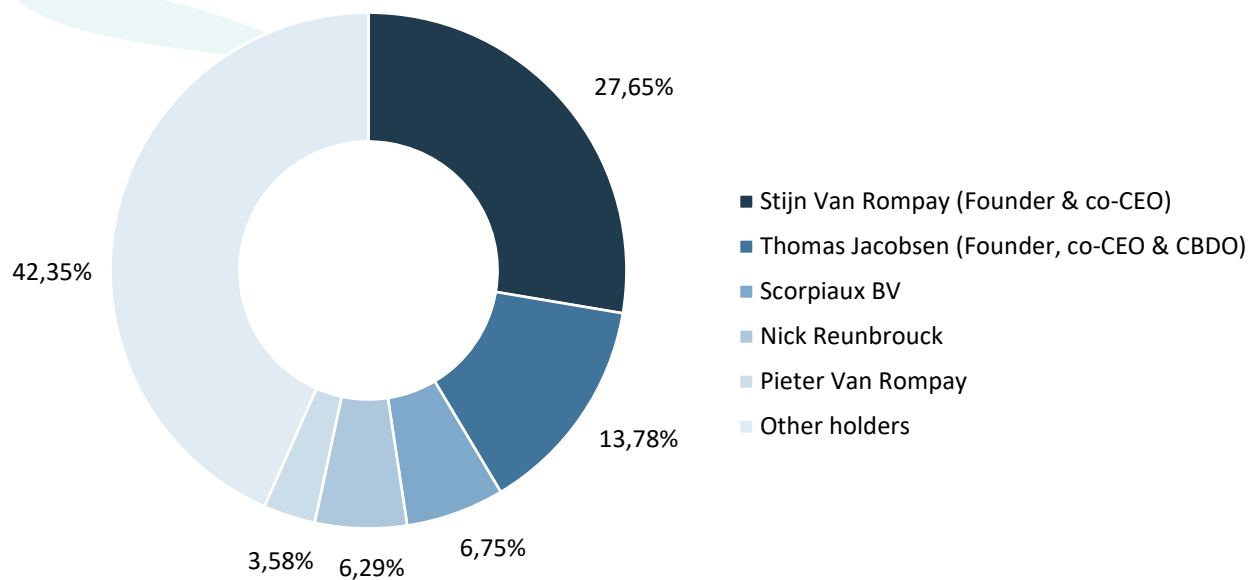
- Net financial result for the first half of 2025 amounted to €-183 thousand, compared with €491 thousand in 2024. The decline mainly reflects lower interest income on cash placements due to reduced interest rates in 2025, and foreign exchange losses on USD financial assets and royalties following the weakening of the USD against the EUR in H1 2025.

Net result

- Net result stable at €3.6 million, reflecting continued cost discipline, while R&D activities progressed steadily, resulting in a contained impact with equity reported at €28.9 million

The Hyloris Share

Major shareholdings



Recalculation of shareholder overview and latest denominator is based on latest transparency declaration and online notification (FSMA website) of managers transactions as per September 24, 2025. A shareholder overview as per 31 December, based on the transparency notifications received, is included in the annual report.

Total number of outstanding voting rights (denominator)	28,000,374
Total number of securities carrying voting rights not yet issued	309,313
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

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

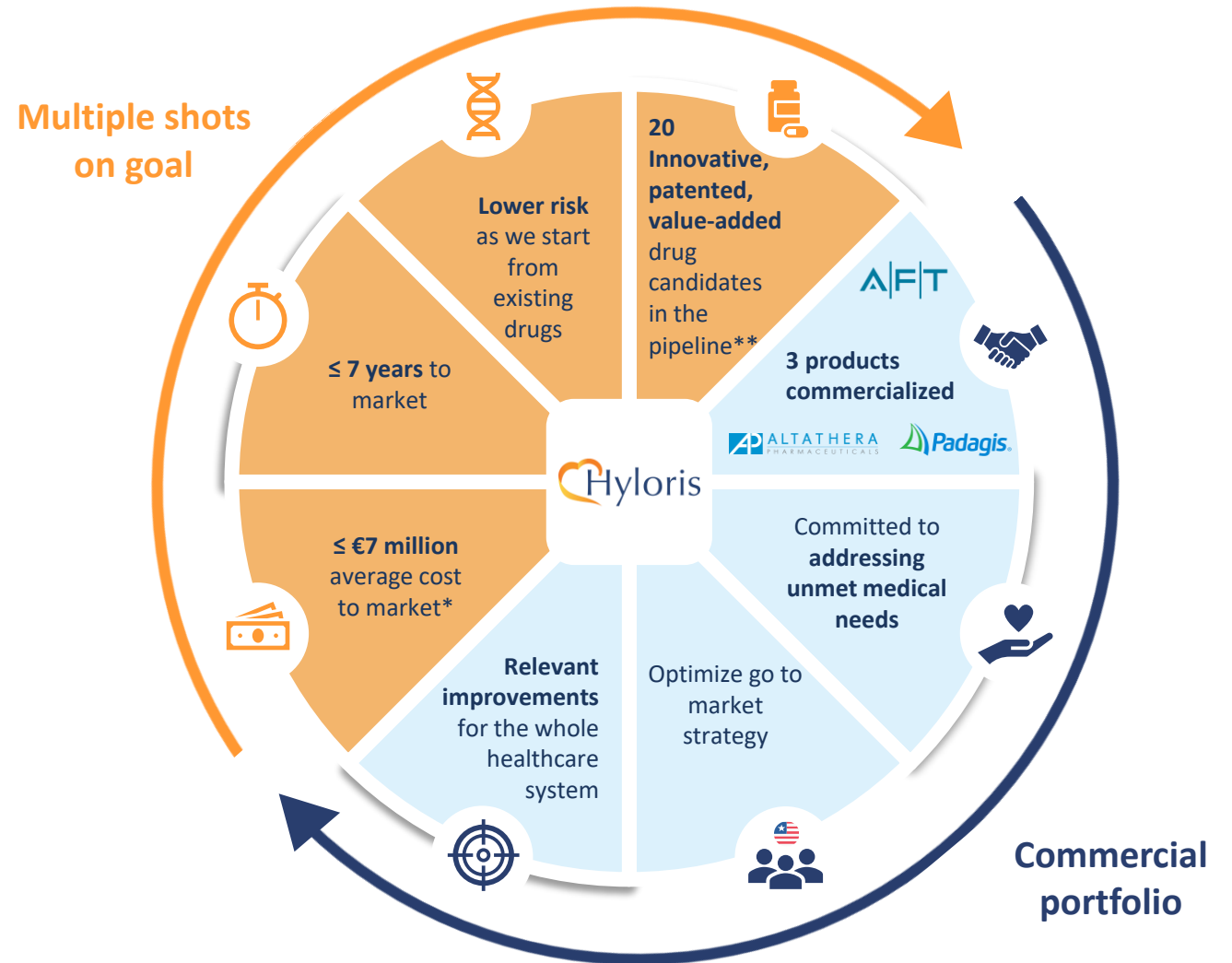
Latest News and Anticipated Value Inflection Milestones

	Clinical	Regulatory	Commercial
Completed	<ul style="list-style-type: none"> Dofetilide IV: positive results pivotal clinical study Alenura: Positive IDMC recommendation following interim assessment Atomoxetine OS positive results (U.S.) 	<ul style="list-style-type: none"> Regulatory submission in the U.S. completed for Valacyclovir liquid Approval of Tranexamic acid RTU in Portugal and the U.S. 	<p>Maxigesic® IV</p> <ul style="list-style-type: none"> Launched. J-code in October 2024 <p>Commercial partnership(s)</p> <ul style="list-style-type: none"> Out-licensing deal(s) <ul style="list-style-type: none"> Huons ,AFT and Colonis for XTRAZA in South Korea, Canada, Australia, New Zealand, Singapore, Hong-Kong and UK Kuvatris Therapeutics for Suramin IV in the U.S. Rosemont for Valacyclovir Oral susp. in the U.S. Avenacy for Tranexamic RTU in the U.S. In-licensing deal(s)
Expected	<ul style="list-style-type: none"> Tranexamic Acid OR: Phase 3 clinical trial LPLV ongoing Initiating multiple other trials 	<ul style="list-style-type: none"> Up to 9 products to be filed in 2025 and 2026, including Dofetilide IV, Valacyclovir liquid (outside the U.S.), Tranexamic Oral Mouth Rinse and others 	

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

**Excluding Generics



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