Hyloris®

Investor Presentation

March 2025

Forward-Looking Statements

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Hyloris®

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 **y**ield, **lo**wer **ris**k, patient-centric developments

Based in Liège, Belgium
Founded in 2012

HYL LISTED EURONEXT

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

Hyloris®

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

Alter Pharma, Uteron Pharma, Mylan, Actavis, DOC Pharma

Thomas Jacobsen
Co-CEO, CBDO
& Founder

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

Alter Pharma, Alternova, Mylan, DOC Pharma

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

mithra, AGC, orange, SMBC, Hamon

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

Mylan, Sandoz, polpharma, ViraTherapeutics

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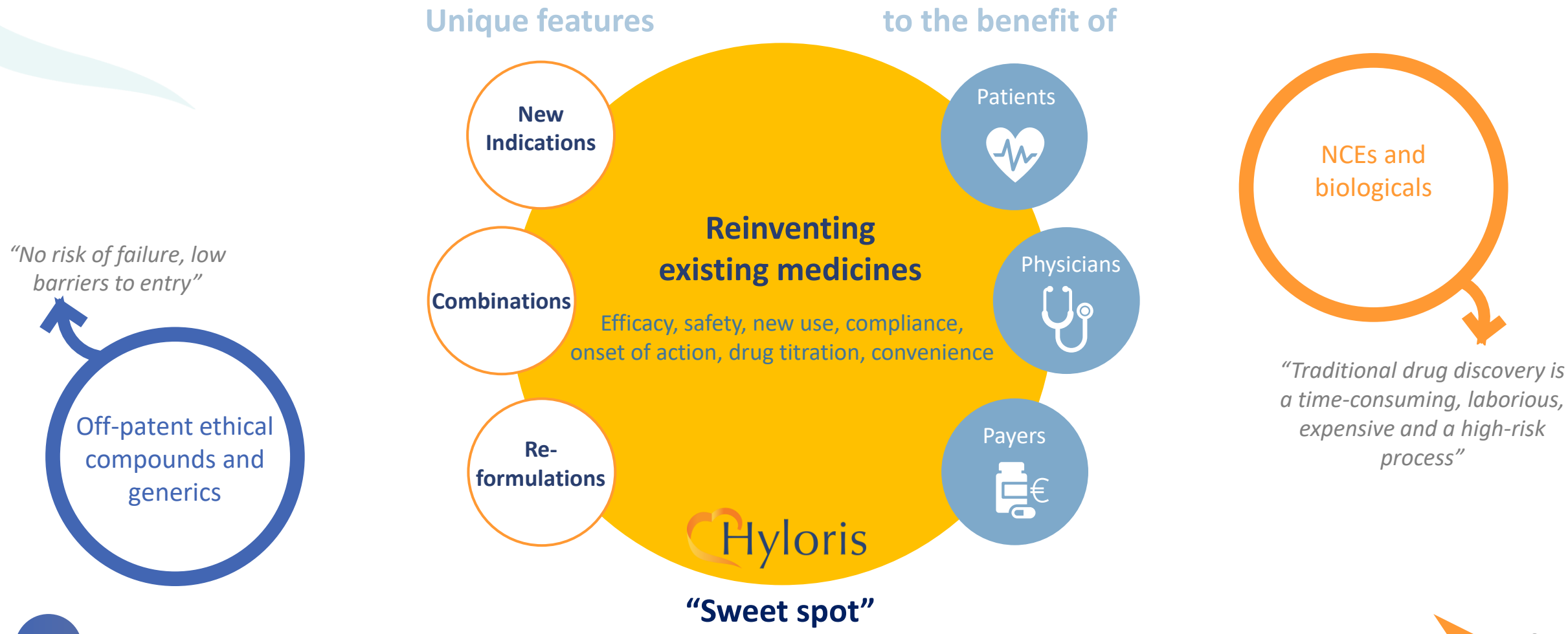
Our Focus: Patented Value-Added Medicines



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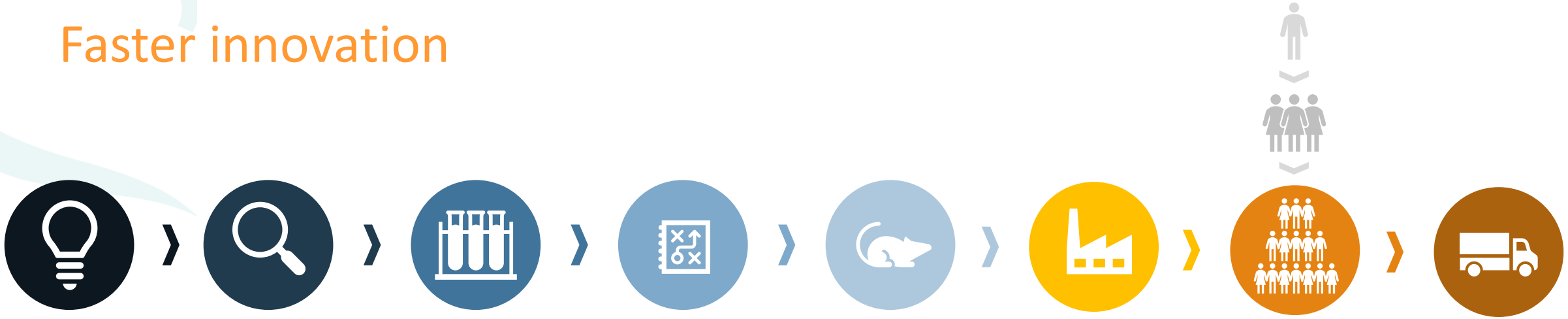
Faster innovation



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

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- ✓ Pharmacology characterized
- ✓ Safety established for the compound
- ✓ Focus on efficacy

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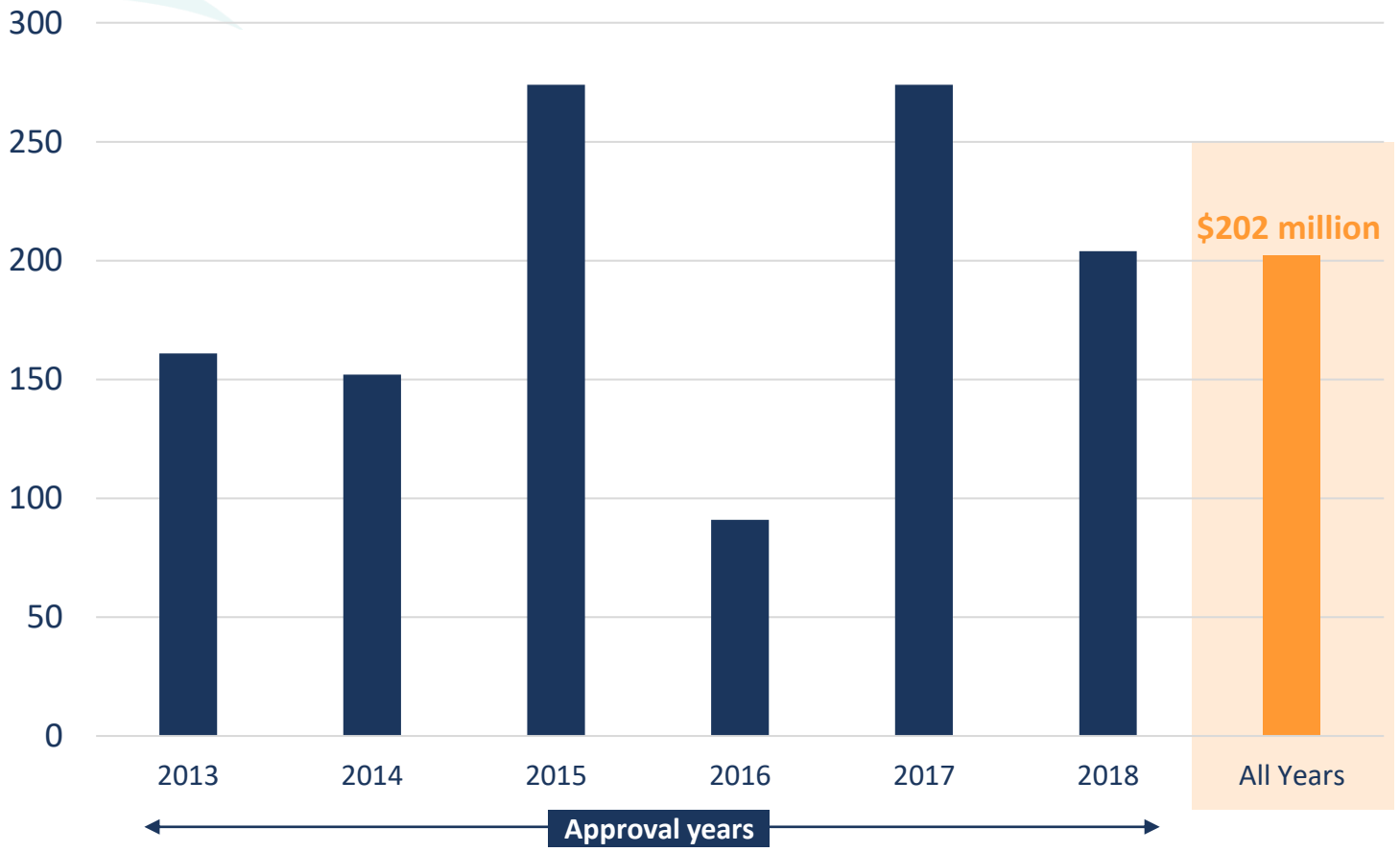
Peak Sales of Value-Added 505(b)(2) Products

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
	Vasostrict	$531M
	Abraxane	$1,200M
	Restasis	$1,188M
	Neoral	$419M
	Kaletra	$283M
REPURPOSED	Viagra	$2,000M[a]
	Thalomid	$500M[b]
	Tecfidera	$4,430M
	Revatio	$144M
	Propecia	$447M[c]
	Rituxan	$1,200M[d]

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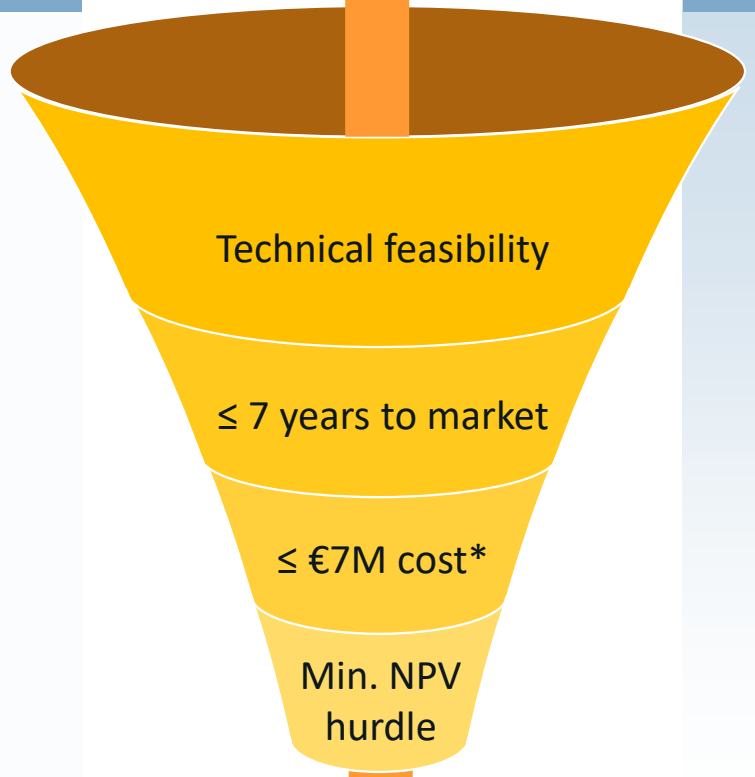
https://www.pharmexec.com/view/505b2-pathway-competitiveness-through-innovation-specialty-and-generic-companies

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



Continuously growing diversified product portfolio characterised by

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

Ambition to become a leader in value-added medicines

*Not adjusted for inflation/exchange rate differences

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Optimal commercialization strategy currently under evaluation.

Commercialized with partner

Intended to be commercialised with partner

Broad, innovative cardiovascular portfolio

Product	Route of Administration	Indication	Formulation	Clinical Development	Regulatory Filing	Target Market
			Up to 7 years			
Sotalol IV	IV	Atrial Fibrillation	*Partnered in the US with AltaThera*			**US**
Aspirin IV	IV	Acute Coronary Syndrome				**WW**
Milrinone	ER oral solid	Late-stage HF with LVAD				**WW**
Dofetilide IV	IV	Atrial Fibrillation				**US**
HY-074	IV	Acute Coronary Syndrome				**WW**
Metolazone IV	IV	Congestive Heart Failure				**WW**
HY-75	Oral Liquid	Coronary Heart Disease				**US**

ER: Extended-Release
HF: Heart Failure
LVAD: battery-operated, mechanical surgically implanted pump, which helps the left ventricle of the heart pump blood

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Commercialized with partner

Intended to be commercialised with partner

Other value-added portfolio

Product	Route of Administration	Indication	Formulation	Clinical Development	Regulatory Filing	Target Market
			Up to 7 years			
Maxigesic® IV	IV	Post-operative pain	*Co-development with AFT Pharmaceuticals*			**WW**
Podofilox Gel	Topical	Ext. genital and perianal warts	*Partnered in the US with Padagis*			**US**
Tranexamic Acid OR	Oral Liquid	Specific dental indication				**WW**
Alenura™	PFS	IC / PBS				**WW**
Miconazole-DB	Topical	Severe and rVVC				**WW**
Plecoid™ 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	*Co-development with AFT Pharmaceuticals*			**WW**
HY-091	Mucoadhesive form	Vulvar Lichen Sclerosus	*Co-development with AFT Pharmaceuticals*			**WW**
HY-095	Long-acting Injectable	Equine Gastric Ulcer Syndrome				**WW**

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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

Commercialized with partner

Intended to be commercialised with partner

Other value-added portfolio, cont'd

Product	Route of Administration	Indication	Formulation	Clinical Development	Regulatory Filing	Target Market
			Up to 7 years			
Pantoprazole	RTU Injection	GERD and EE				**WW**
Ondansetron	E.R. Tablet	Prevention of nausea/vomiting				**WW***

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* Worldwide, except USA, Canada, and Mexico

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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**

✓ **Targeting to provide the first reliable and approved treatment**

Prevalence[12]	0.7% to 5% in the US

(1) based on combination of different sources: population-based study, clinical based study and key opinion leaders' estimation
(2) prevalence increases with age in both men and women, with the highest prevalence reported in postmenopausal women aged 60–69 years

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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
- 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
(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

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HY-095

Brand leader
188 MUSD
in sales

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 administrations by injection**

✓ **Estimated Development cost: Well below 7 MEUR**

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

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

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Pantoprazole RTU injection

Indication: **GERD and EE**

- Key option in managing severe acid related conditions, including bleeding peptic ulcers and erosive esophagitis
- Currently only available as a lyo product for infusion
- Hyloris' version is RTU, and doesn’t require dilution or reconstitution
- Valuable in high-demand and time-sensitive environments
- Targeting a global launch by of before 2028
- Patents filed
- In 2023, over 351 million vials of lyophilized pantoprazole IV (+10%) were sold worldwide, generating a global revenue estimated of over USD 454 million

Use of panto IV Lyo [1]	Over 351 million vials

(1) IQVIA, As IQVIA does not report the hospital sales of major countries, the current market is substantially larger

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 Ondansetron[1]	1.13 Bn tablets (+8%)

(1) IQVIA 2023 (targeted territory only)
(2) Globenewswire.com

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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 Condylox® 0.5%
- HPV vaccine available but no cure exists

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Maxigesic IV

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

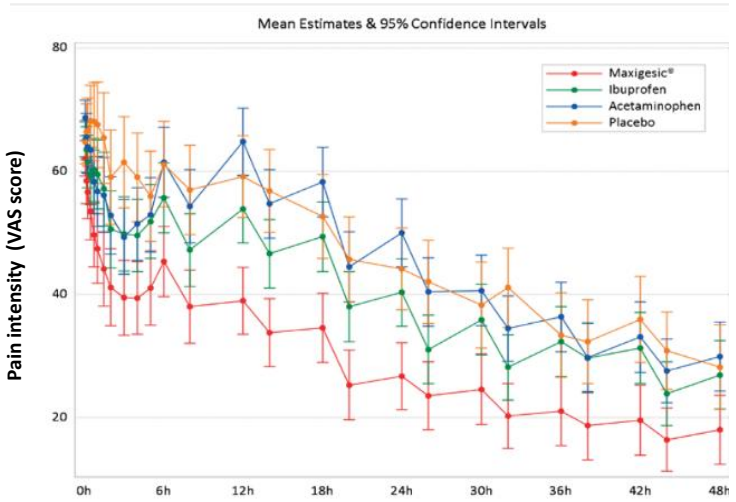
Indication: **Short-term management of mild to moderate acute pain**

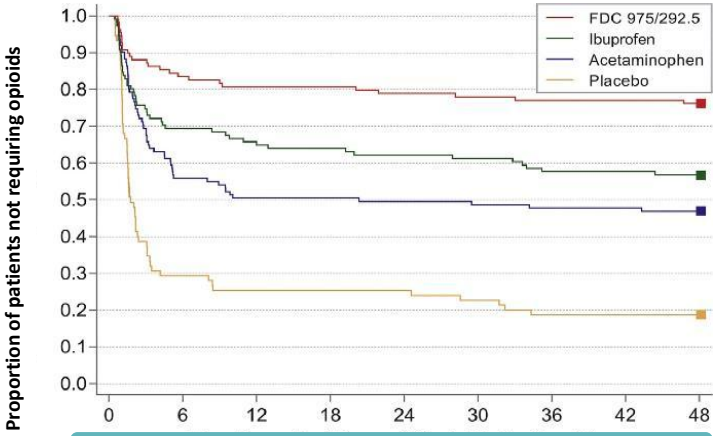
Novel, unique intravenous combination of 1.000mg **Paracetamol** IV + 300mg **Ibuprofen** IV

- 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

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Other portfolio highlights

Alenura™

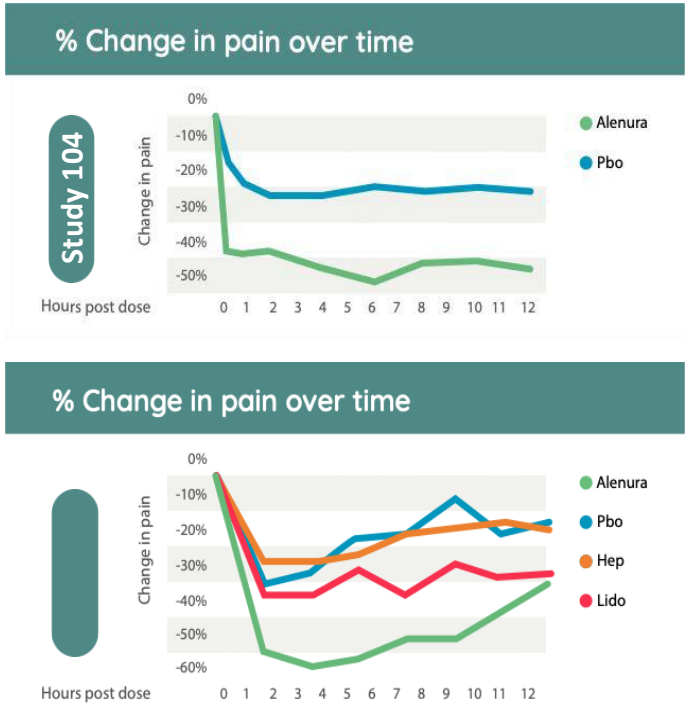
Indication: **Interstitial Cystitis/Bladder Pain Syndrome**

- 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: 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



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HY-083

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: downregulates TRPV1 receptor in the nose and ablates signaling pathways
  - 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*

*) Not performed on final product.

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PTX-252

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

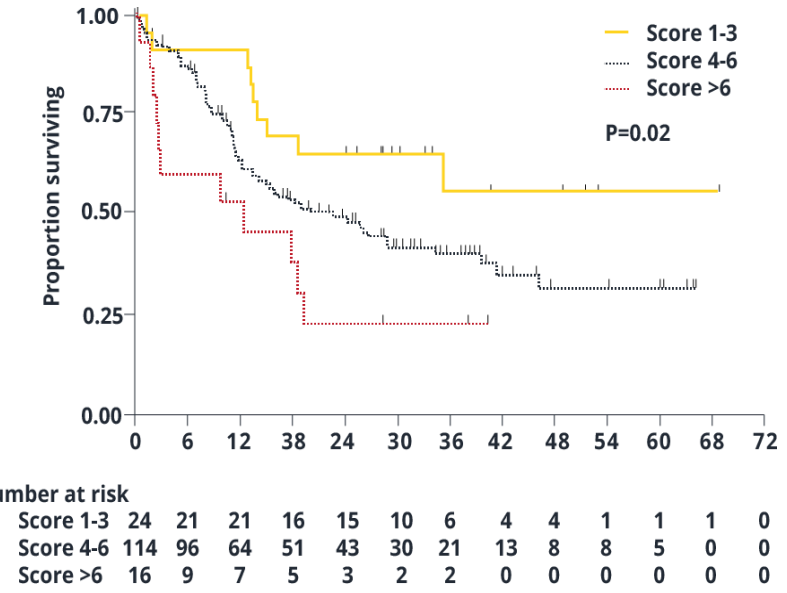
- Based on exciting insights
  - Chelating agents bind to metal ions to extract them from the body
  - Detoxifying the cancer-promoting micro-environment
  - Efficacy of chemo increased by 50% in micro-environment testing

- Potentially offering a boost and prolonged survival

✓ **Targeting to 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]

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

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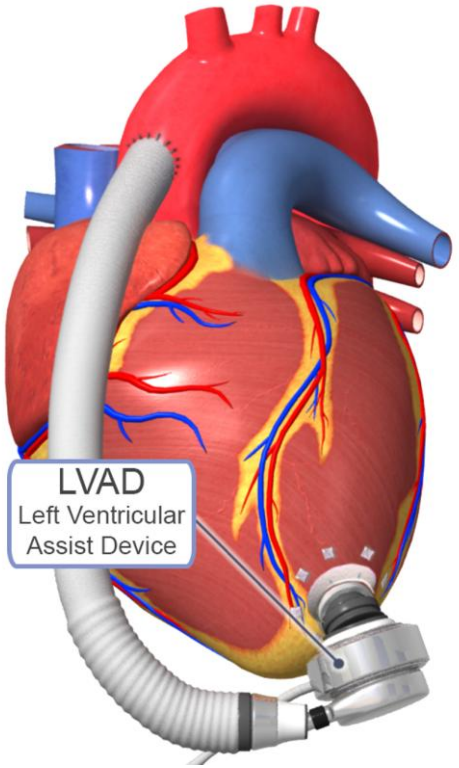
Milrinone Extended Release

Indication: **Late-stage heart failure with LVAD**

- **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

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Investment highlights

Financial highlights

(in € thousand)	2024	2023	% change
Revenues	8,458	2,087	305%
Other operating income*	1,584	2,127	-26%
Total revenue & other income	**10,043**	**4,214**	**138%**
Cost of sales	(227)	(93)	144%
R&D expenses	(10,265)	(14,421)	-29%
G&A expenses	(5,627)	(5,546)	1%
Share of result of equity-investees	(81)	(147)	-45%
Impairment on equity accounted investees	(972)	-	-
Total operating expenses	**(16,946)**	**(20,114)**	**-16%**
Operating result	**(7,130)**	**(15,993)**	**55%**
Net financial result	**788**	**613**	**+29%**
Net result	**(6,342)**	**(15,380)**	**-59%**
Cash and cash equivalents	**23,594**	**30,406****	

Key factors

Revenue

- Increased royalties from the commercialized products and includes a milestone payment of USD 2.1 million relating to the commercial launch of Maxigesic® IV in the U.S

Operating expenses

- R&D expenses decreased primarily due to the timing and phasing of development projects
- G&A expenses remained stable, reflecting elevated investigation fees and legal costs, the latter related to the now-concluded (and successfully resolved) AltaThera arbitration.

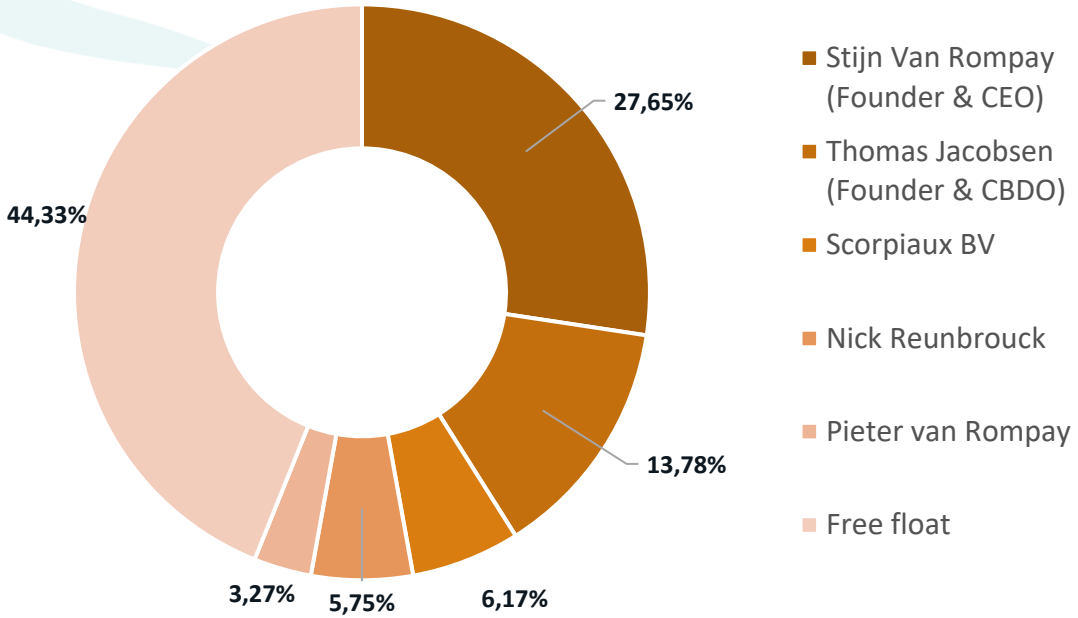
Financial result

- Net financial result increase primarily due to foreign exchange gains, improved cash management and higher short-term interest rates.

*the company corrected the R&D tax credit calculation for 2023 by applying the amended deduction rate of 20.5% instead of the 13.5% rate that had been incorrectly used in 2023, representing an additional other income of €225 thousands
**includes €10M short term deposits on 30 June 2024 and €10.2M on 30 June 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	309,313
Share capital (*excluding share premium*)	€140,001

Analyst coverage

Broker	Analyst	Rating
Degroof 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	• Valaciclovir OS positive results (Europe and U.S.) – expanded rights
	• Dofetilide IV: positive results clinical study
	• Alenura: Positive IDMC recommendation following interim assessment
		• Regulatory submission in the U.S completed for Valaciclovir liquid
		• Approval of Tranexamic acid RTU in Portugal
			Maxigesic®IV
			• U.S. launch in February 2024
			• J-code in October 2024
			
			Commercial partnership(s)
			• Out-licensing deal(s)
			  ○ Rosemont for Valaciclovir Oral susp. in the US
			  ○ Avenacy for Tranexamic RTU in the US
			  ○ Maxigesic IV in China
			• In-licensing deal(s)

Expected	• Tranexamic Acid OS: Phase 3 clinical trial LPLV ongoing • Initiating multiple other trials	• Up to 9 regulatory submissions in 2025 and 2026, including Dofetilide IV, Valaciclovir liquid (outside the US), Tranexamic Oral Mouth Rinse and others	

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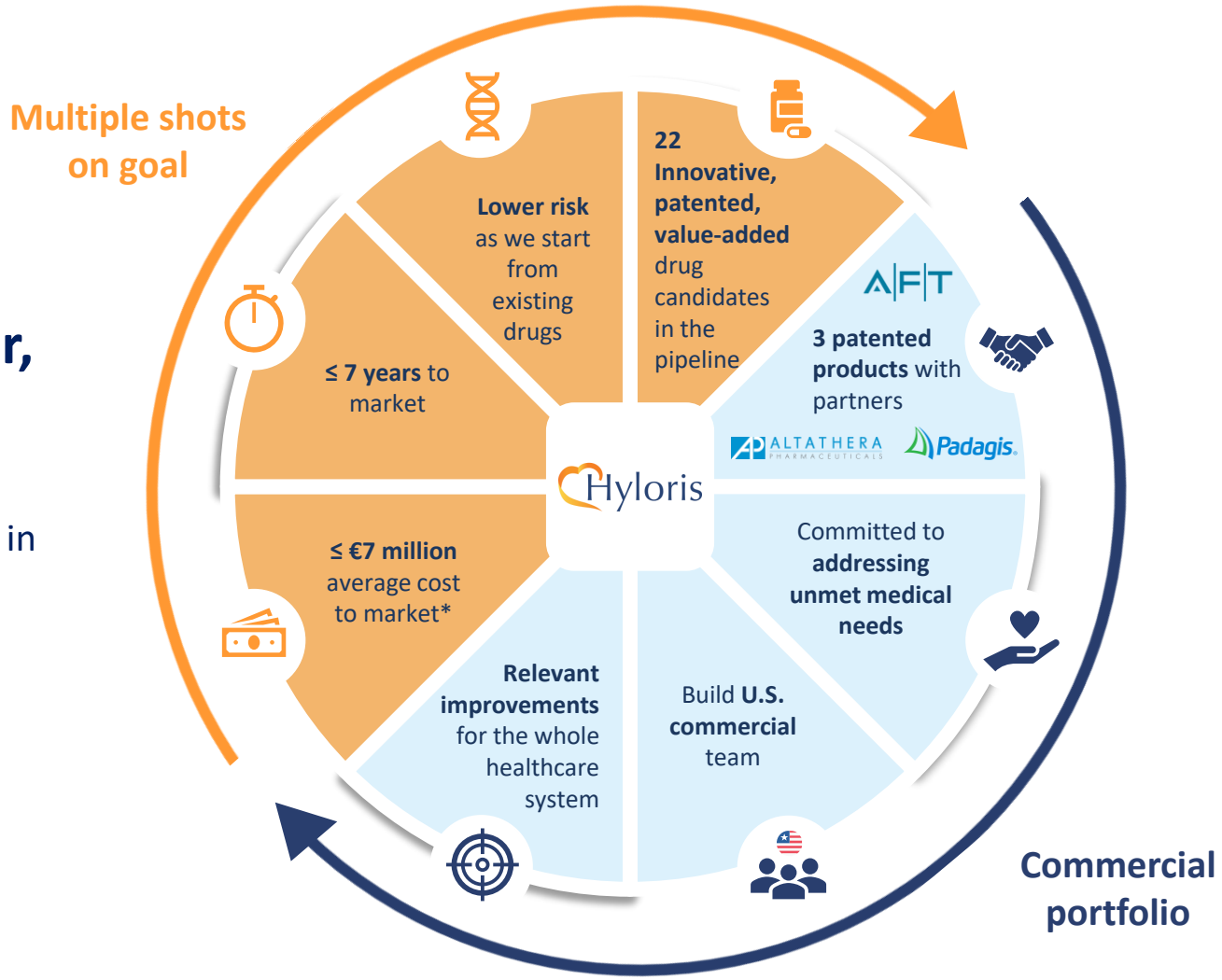
Ambition to expand the product portfolio to ~30 assets by end of 2025

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*

Q&A

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