Hyloris

Corporate Presentation

5 October 2023 – Paris

Speakers

Stijn Van Rompay
CEO, co-founder

Jean-Luc Vandebroek
CFO

Forward-Looking Statements

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Hyloris PHARMACEUTICALS

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

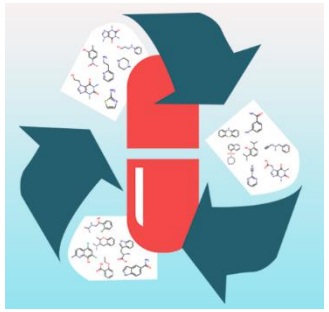
Rethinking, Reinventing, Optimising Existing Medications

To improve overall therapy outcomes

REFORMULATING

Changing dose and/or route of administration

REPURPOSING/
REPOSITIONING

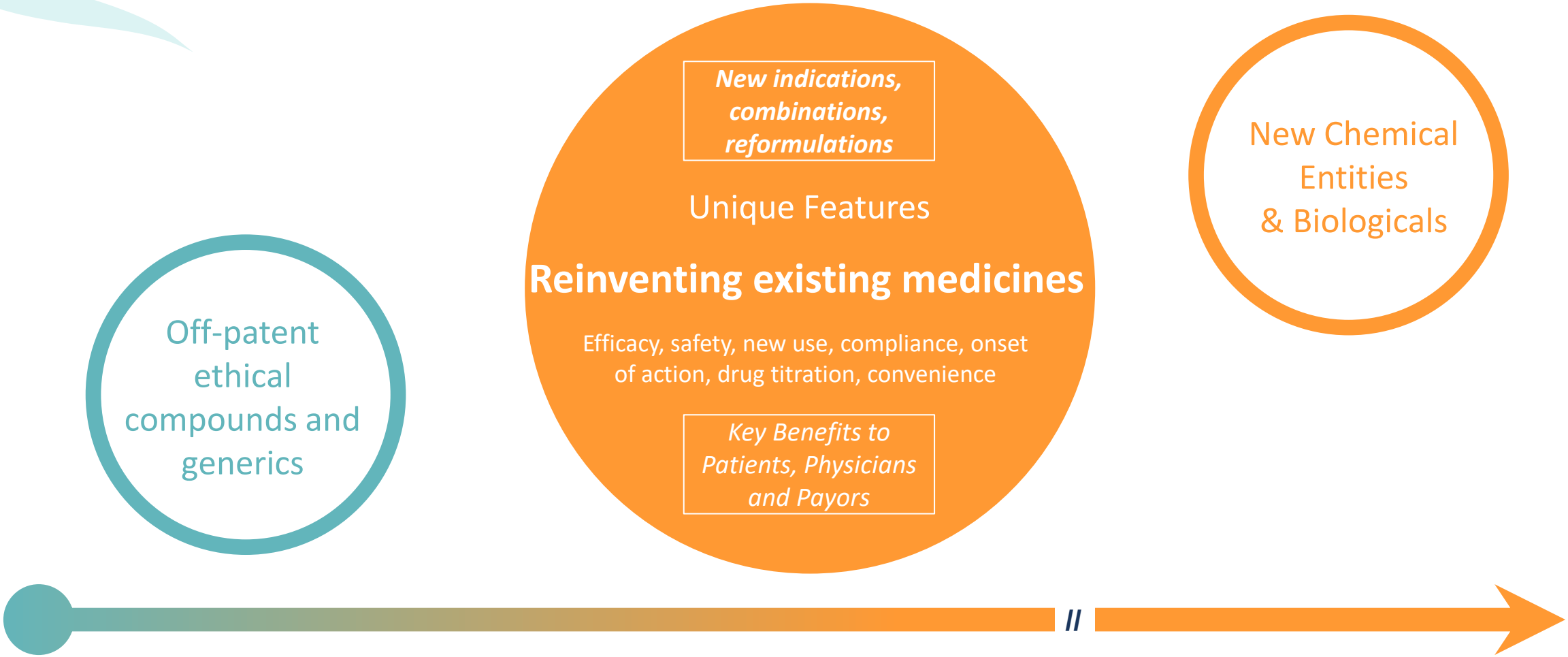


New therapeutic uses

For the benefit of patients, physicians, payors

Hyloris PHARMACEUTICALS

Our Focus: Patented Value-Added Medicines



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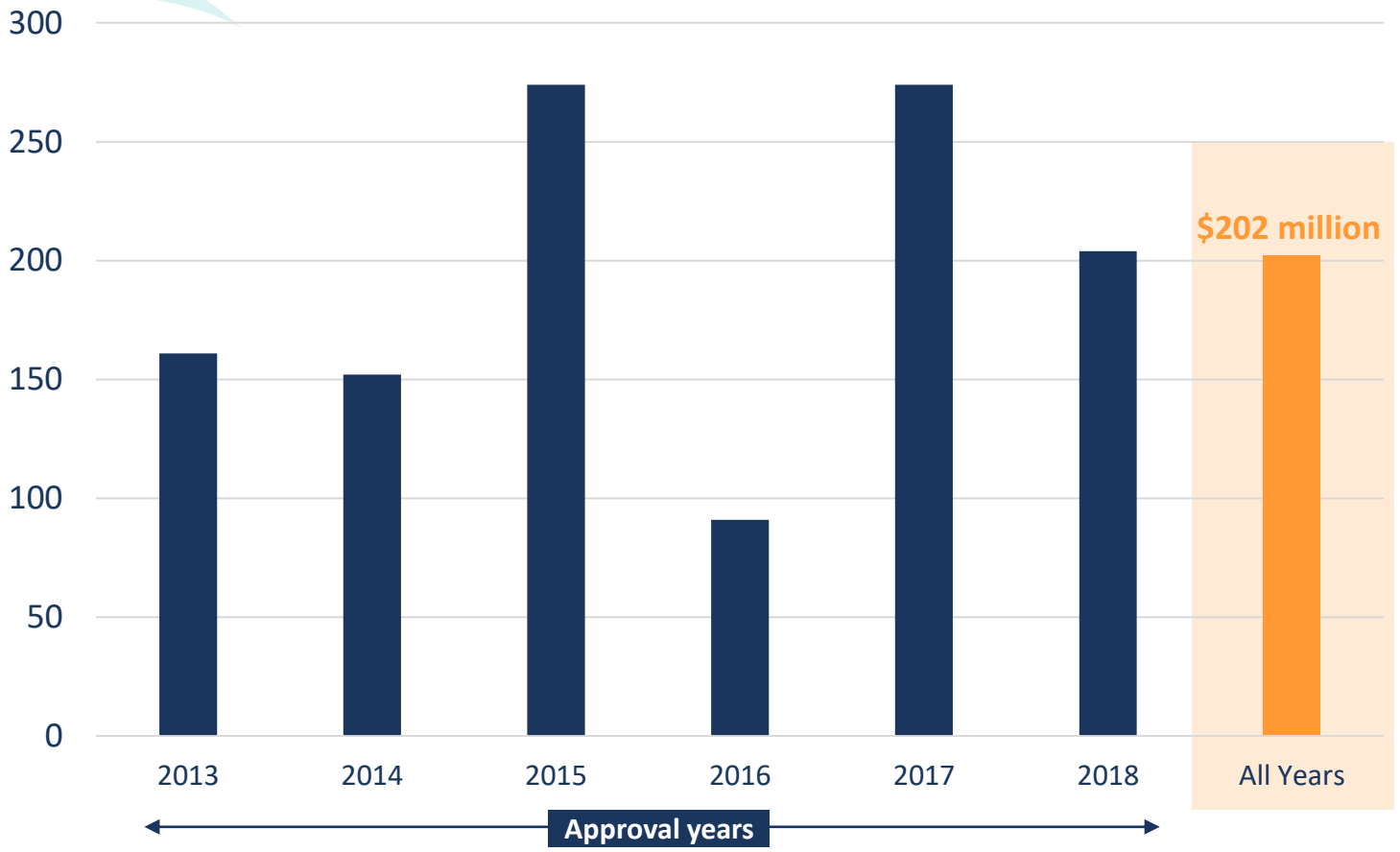
Average Peak Sales of Value-Added 505(b)(2) Products

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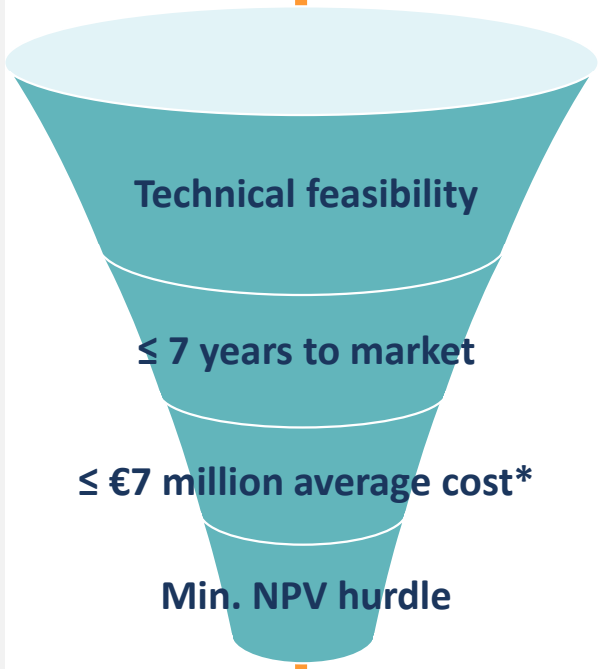
https://www.pharmexec.com/view/505b2-pathway-competitiveness-through-innovation-specialty-and-generic-companies

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

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*Not adjusted for inflation/exchange rate differences

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

Stijn Van Rompay - Chief Executive Officer

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

Alter Pharma · Actavis · UTERON PHARMA · Mylan · DOCPHARMA

Dietmar Aichhorn - Chief Operating Officer

- >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

Mylan · SANDOZ · polpharma · ViraTherapeutics

Thomas Jacobsen - Chief Business Development Officer

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

DOCPHARMA · Mylan · Alter Pharma · Alternova

Koenraad Van der Elst - Chief Legal Officer

- >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

Nikon · PUNCH · Koramic

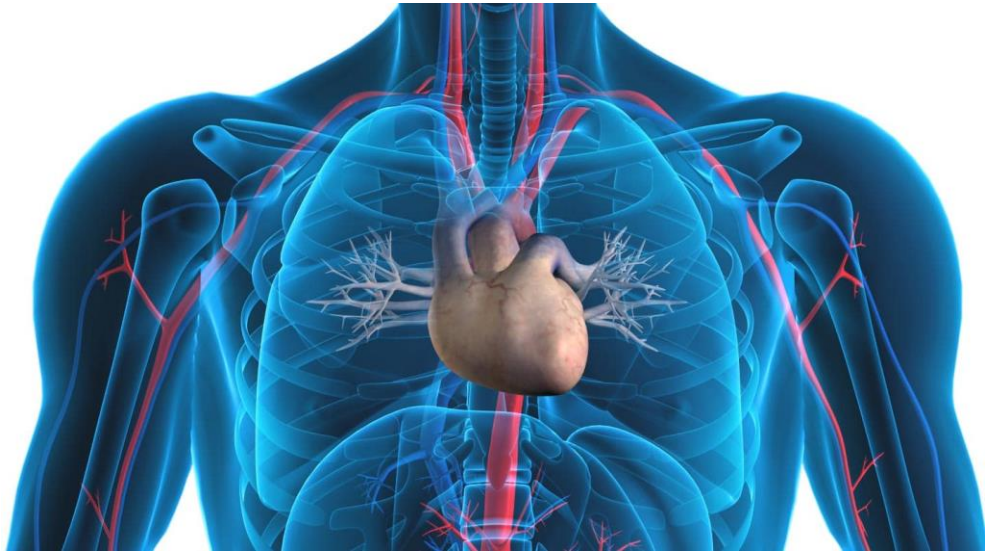
Jean-Luc Vandebroek - Chief Financial Officer

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

Bone Therapeutics · FLUXYS · ALCOPA · DELHAIZE

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

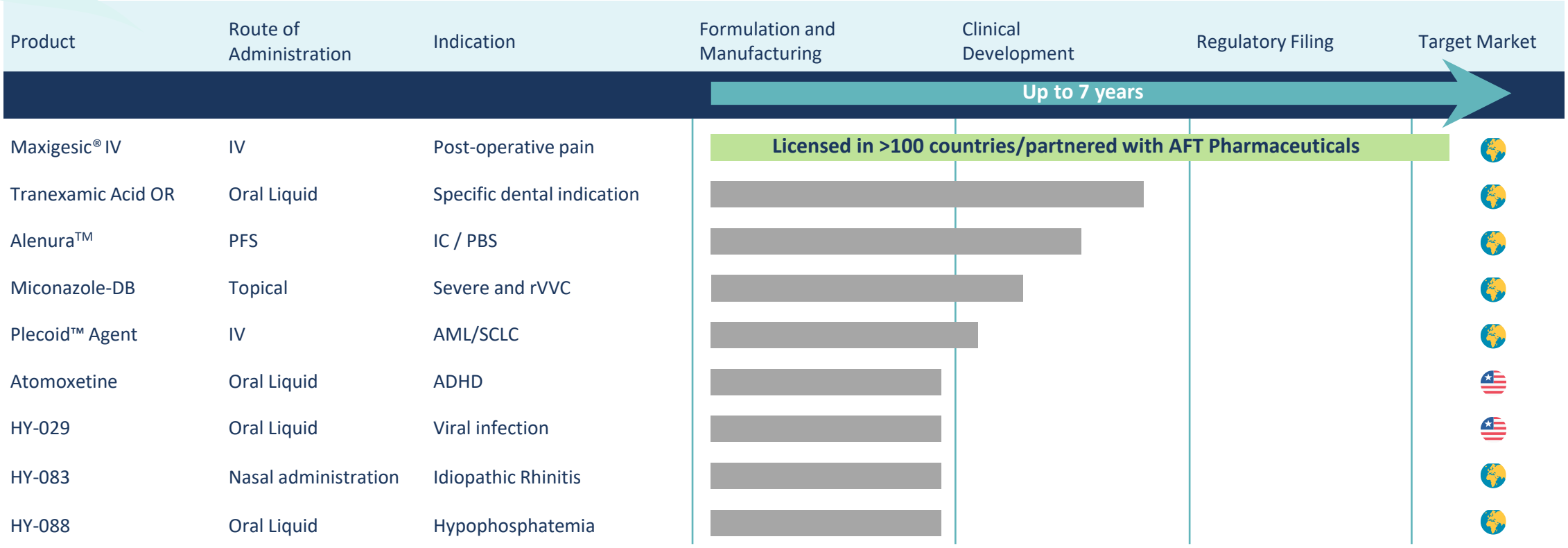
** Our high barrier generic products, TXA RTU, HY-016 and Fusidic Acid Cream have not been included in the above overview.*

Hyloris

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

Other value-added portfolio

Product	Route of Administration	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Target Market
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				
Plecoid™ 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.*

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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

Maxigesic IV

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

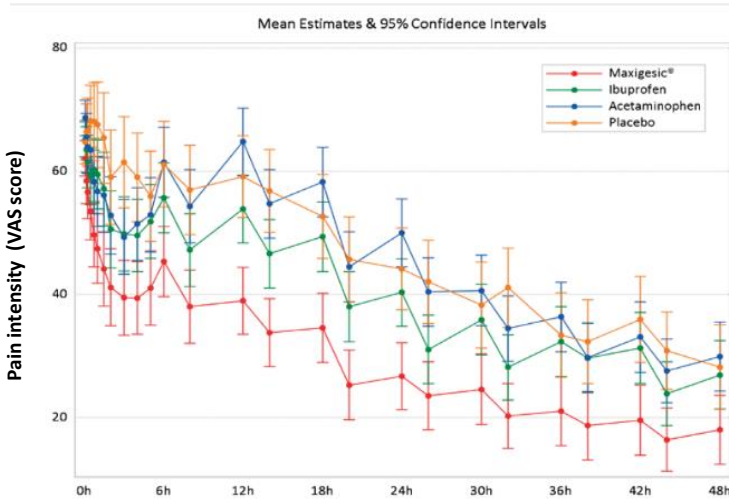
Indication: **Post-operative pain**

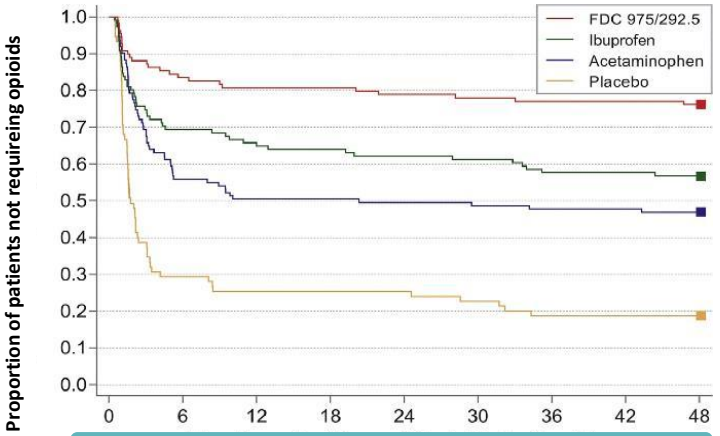
- Novel, unique intravenous combination of 1.000mg **Paracetamol** IV + 300mg **Ibuprofen** IV
- Alternative to opioid **pain relief** medicines
  - Potentially reducing opioid addiction and related costs
    - Health Care
    - Criminal justice
    - Lost productivity

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

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* Data Overview | Opioids | CDC

** Chronic Opioid Usage in Surgical Patients in a Large Academic Center - PubMed (nih.gov)

Alenura™

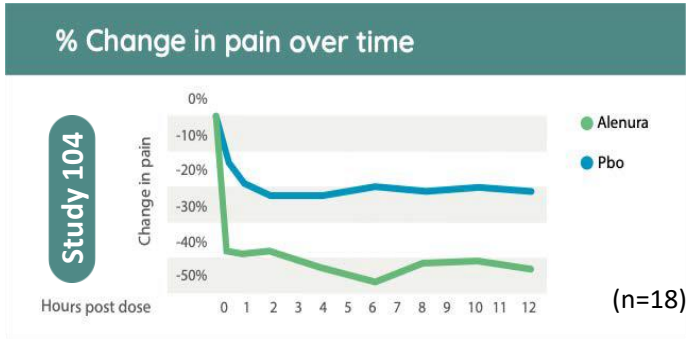
No approved treatment for acute pain flares & restoration of bladder wall

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



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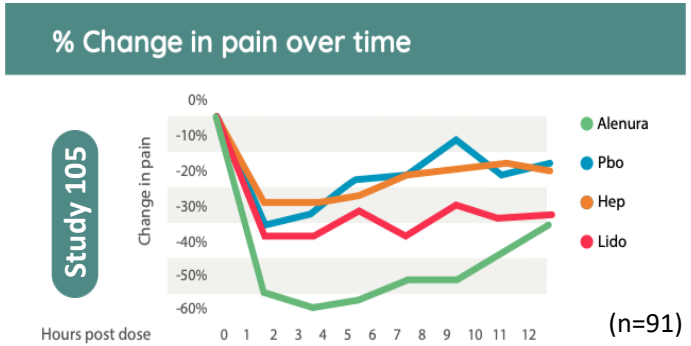

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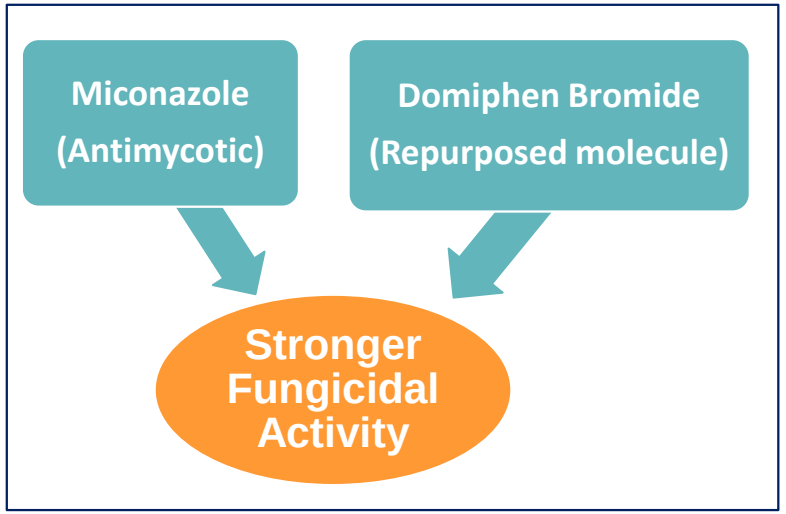
Miconazole and Domiphen Bromide

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



Phase 2 results expected in 2023

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

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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

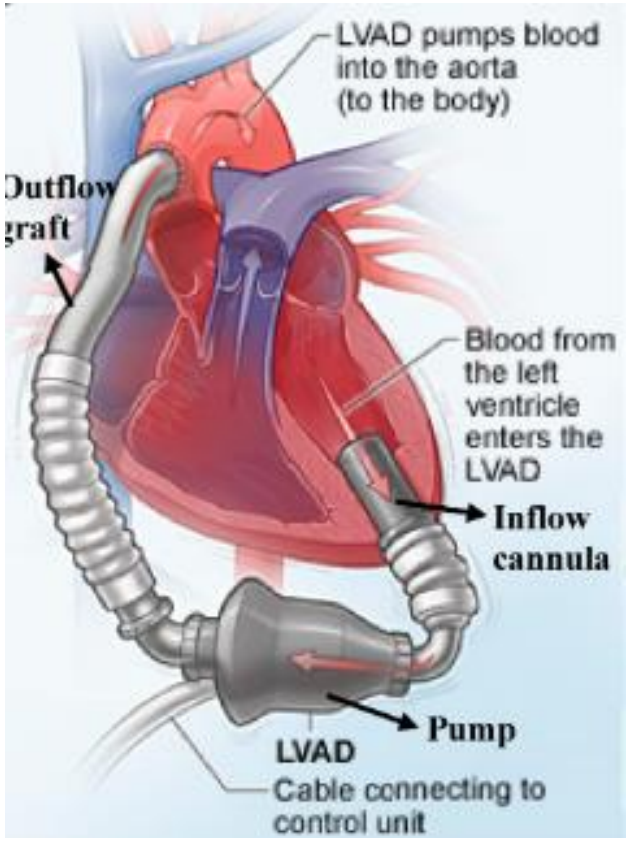
Milrinone Extended Release

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%



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

**Grand View Research Inc 2021

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

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Plecoid Agents

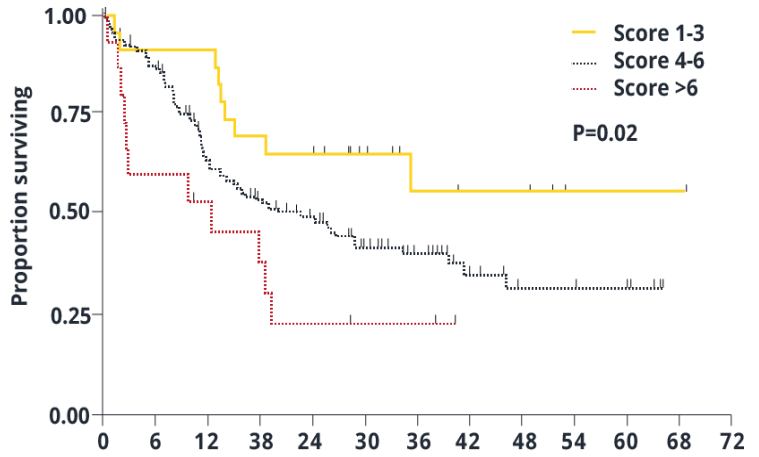
Increasing chemotherapy response rate for leukemia patients

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

More toxic metals in AML patients = higher mortality



Overall survival in AML patients by groupings of metal scores [1]

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]

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(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

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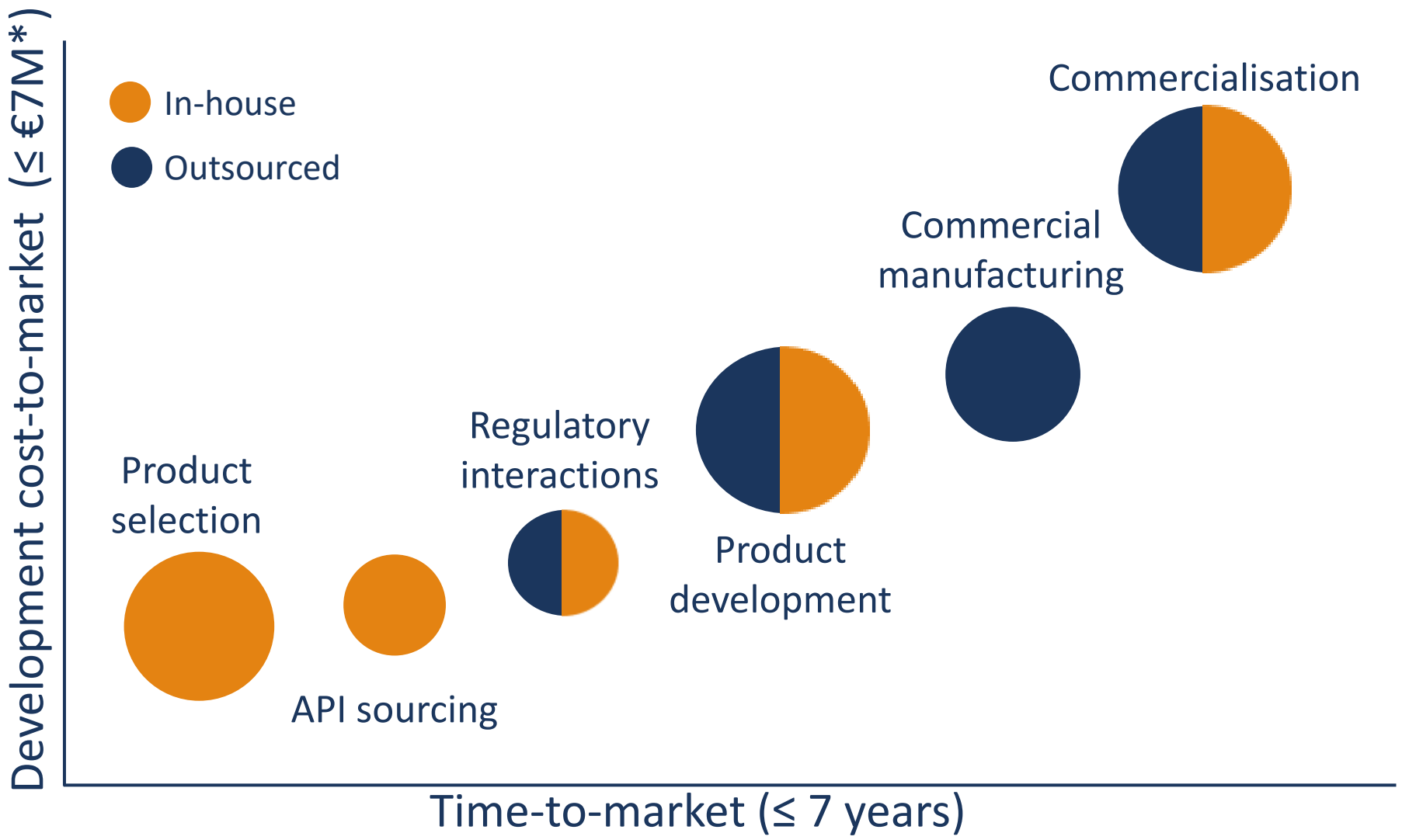
Powerful R&D Engine: Leveraging our Network of Partners



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

Financial Highlights H1 2023

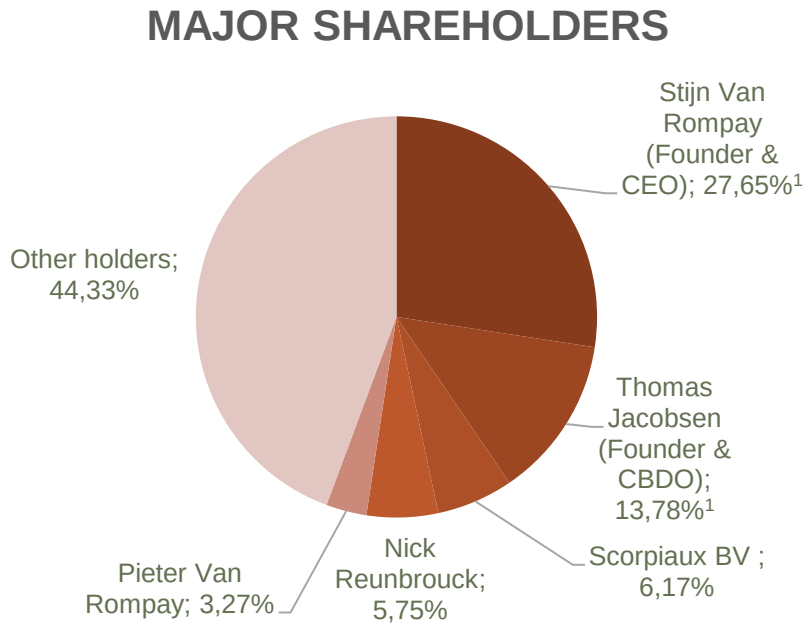
(in € thousand)	H1 2023	H1 2022	% change
Total revenue & other income	**2,391**	**1,229**	**+95%**
Cost of sales	**(46)**	**(61)**	**/**
R&D	(6,871)	(4,712)	+46%
G&A	(2,490)	(1,274)	+95%
Operating Result	**(7,100)**	**(4,876)**	**+46%**
Financial Income	**466**	**(66)**	**/**
Result of the period	**(6,634)**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



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

Bank	Analyst	Rating
Berenberg	Beatrice Allen	Buy
KBC Securities	Jacob Mekhael	Buy
Kempen	Suzanne van Voorthuizen	Buy
Degroof 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

H1 2023 cash position	€39,16 million
Total number of outstanding voting rights (= denominator)	28,000,374[1]
Total number of securities carrying voting rights not yet issued	711,125

(1) including capital raise in March 2022

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

16[1] 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

[1] 14+2 commercialised products, excluding our high barrier generic products, TXA RTU, HY-016 and Fusidic Acid Cream.

**Not adjusted for inflation/exchange rate differences*

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Q&A

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