



# Corporate Presentation

March 28 2022

# Forward-Looking Statements

---

This presentation has been prepared by, and is the sole responsibility of, Hyloris Pharmaceuticals SA (the "Company") for discussions with investors in relation to the Company and its group. For the purposes of this notice, "presentation" means this document, oral presentation, any question and answer session and any written or oral material discussed or distributed during the presentation meetings. This presentation (or any part of it) may not be reproduced or redistributed, passed on, or the contents otherwise divulged, directly or indirectly, to any other person (whether inside or outside such person's organization or firm) or published for any purpose or under any circumstances.

This presentation does not constitute an offer or invitation to sell or issue, or any solicitation of an offer to purchase or subscribe for, any securities of the Company in any jurisdiction and neither it nor any part of it shall form the basis of, or be relied upon in connection with, any contract or commitment whatsoever. This presentation does not contain all the information that a prospective purchaser of securities of the Company may desire or require in deciding whether or not to purchase such securities nor does it constitute a due diligence review and should not be construed as such. This presentation is not directed to, or intended for distribution to or use by, any person or entity that is a citizen or resident in any jurisdiction where such distribution or use would be contrary to law or regulation or would require any registration or licensing within such jurisdiction. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction. Any person into whose possession this presentation comes should inform themselves about, and observe, any such restrictions.

This presentation includes market, economic and industry data, which were obtained by the Company from scientific journals, industry publications, press releases, data published by government agencies, industry reports prepared by consultants and other market data providers. While the information has been accurately reproduced, and in as far as the Company is aware and is able to ascertain from such third-party information, no facts have been omitted which would render the reproduction of this third-party information inaccurate or misleading, the Company cannot guarantee its accuracy or completeness. Accordingly, you should not place reliance on any of the market, economic and industry data contained in this presentation.

This presentation includes statements that are, or may be deemed to be, "forward-looking statements" which are based on current expectations and projections about future events. These forward-looking statements can be identified by the use of forward-looking terminology, including the words 'believe', 'estimate', 'anticipate', 'expect', 'intend', 'may', 'will', 'plan', 'continue', 'ongoing', 'possible', 'predict', 'plans', 'target', 'seek', 'would' or 'should', and contain statements made by the company regarding the intended results of its strategy. By their nature, these forward-looking statements involve risks and uncertainties because they relate to events and depend on circumstances that may or may not occur in the future. Forward-looking statements are not guarantees of future performance. A number of factors could cause actual results or outcomes to differ materially from those expressed, projected or implied in any forward-looking statements. In light of these risks, uncertainties and assumptions, the events or circumstances referred to in the forward-looking statements may not occur. None of the future projections, expectations, estimates or prospects in the materials should be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such future projections, expectations, estimates or prospects have been prepared are correct or exhaustive or, in the case of the assumptions, fully stated in the materials. No one undertakes to publicly update or revise any such forward-looking statement, whether as a result of new information, future events or otherwise. As a result of these risks, uncertainties and assumptions, you should not place undue reliance on these forward-looking statements as a prediction of actual results or otherwise.

By attending and otherwise accessing this presentation you will be deemed to have read and understood the contents of this disclaimer. In making an investment decision, you must rely on your own assessment, examination, analysis and enquiry of the Company.

# 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
- Hyloris currently employs 23 people, 7 nationalities



**Stijn Van Rompay - Chief Executive Officer**

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



**Thomas Jacobsen - Chief Business Development Officer**

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



**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



**Jean-Luc Vandebroek - Chief Financial Officer**

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



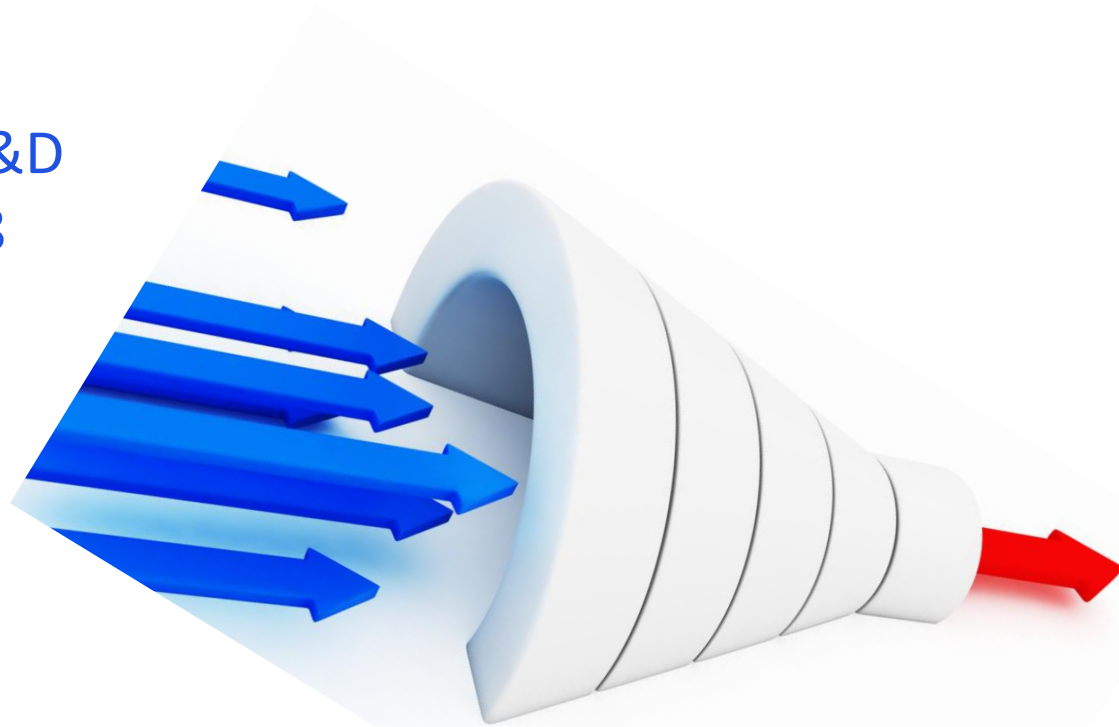
**Koenraad Van der Elst - Chief Legal Officer**

- >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



# New Drug Development: an Expensive, Slow, and Risky Process

15,000 drugs in R&D  
pipeline in 2018



60 new drugs  
hit the market  
in 2018

~15 years and ~\$1Bn cost on average

~10% of candidates entering clinical development eventually make it to market

High Unmet Medical Needs





# Rethinking, Reinventing, Optimising Existing Medications

To improve overall therapy outcomes

REFORMULATING



Changing dose and/or route of administration

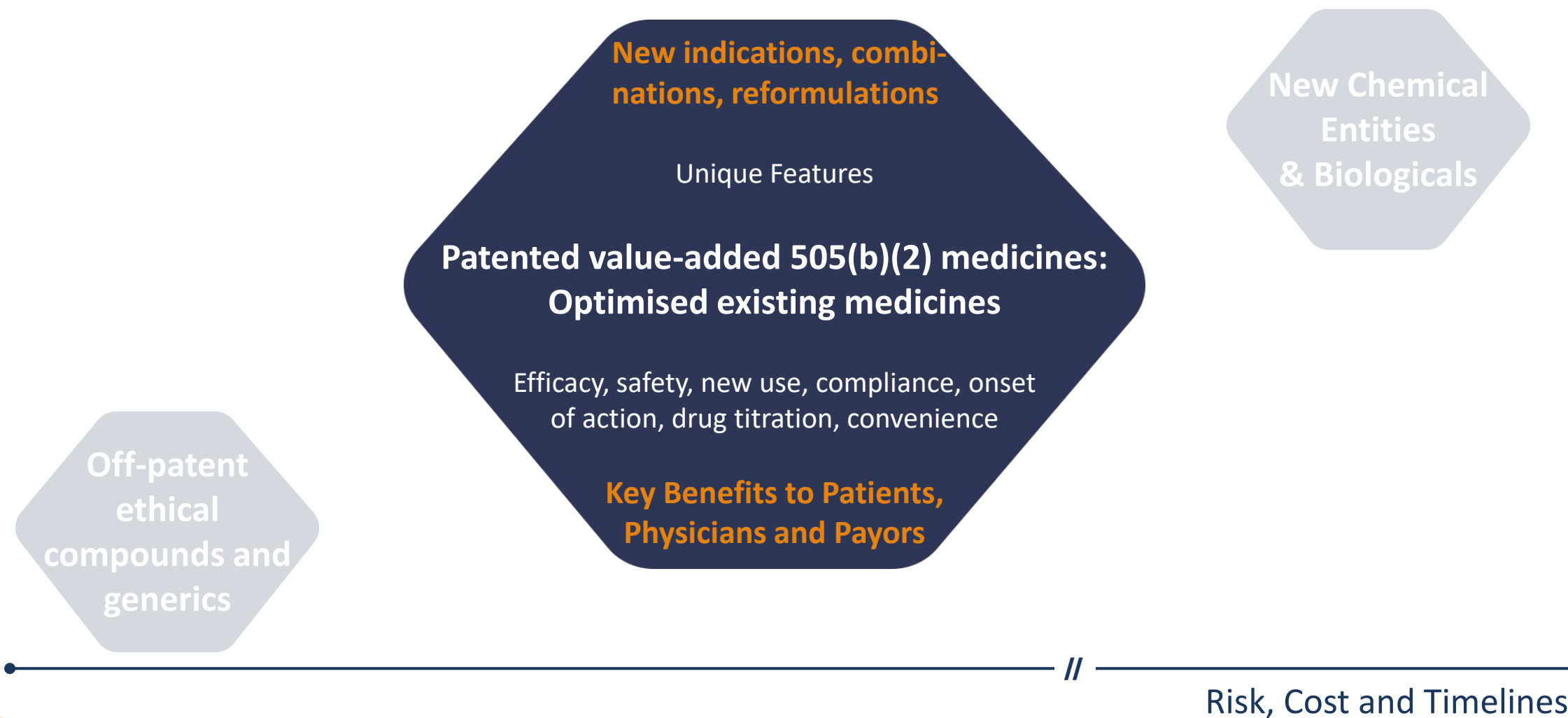
REPURPOSING/  
REPOSITIONING



New therapeutic uses

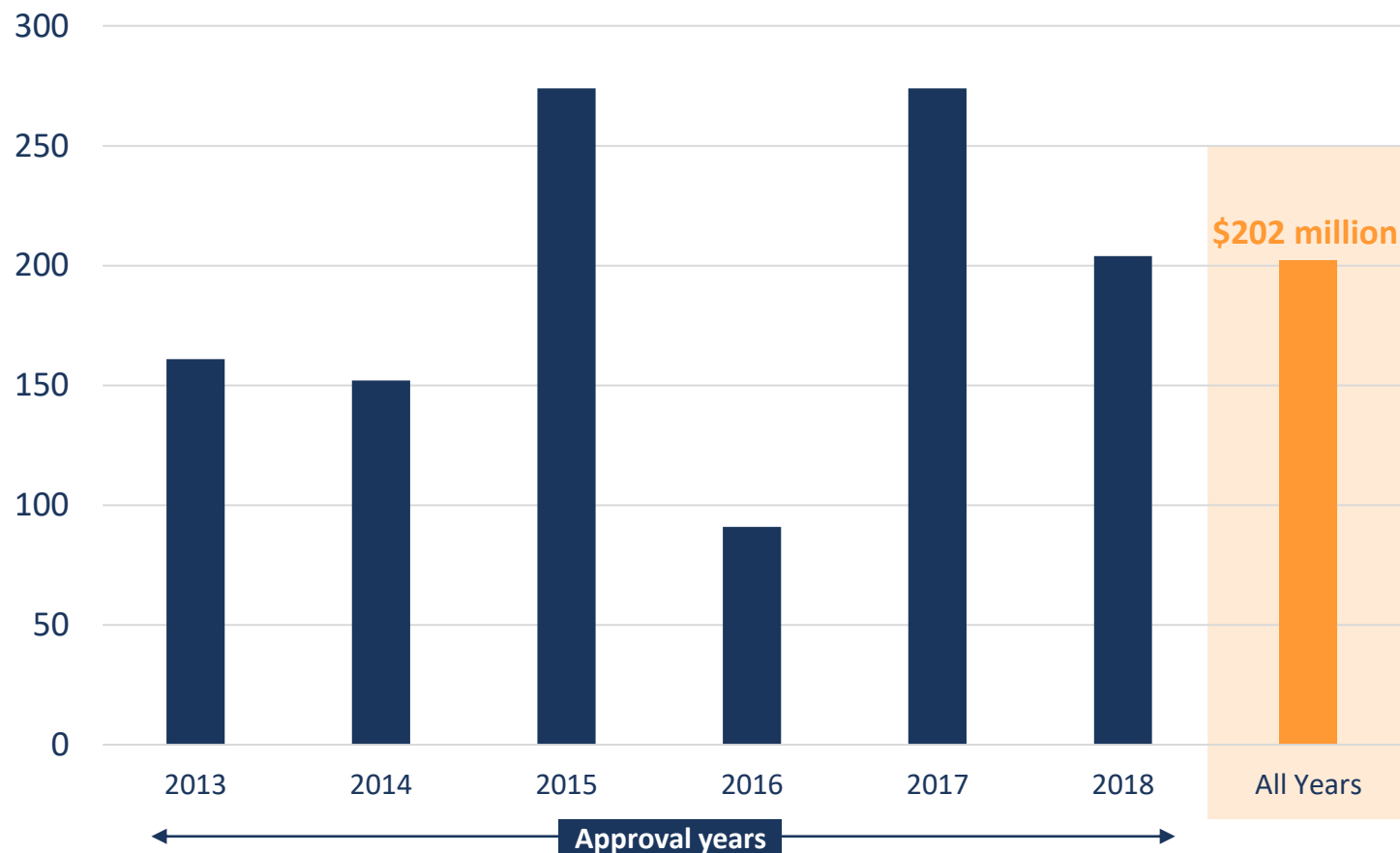
For the benefit of patients, physicians, payors

# Patented Value-Added Medicines: Pharma's Sweet Spot



# 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)



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 <sup>a</sup>
Thalomid	\$500M <sup>b</sup>
Tecfidera	\$4,430M
Revatio	\$144M
Propecia	\$447M <sup>c</sup>
Rituxan	\$1,200M <sup>d</sup>



# Hyloris: Key Investment Highlights

## Growth Pillars

**14**<sup>1</sup> patented product candidates in the pipeline

Spread across stages and indications

Expand with 4 products on average per year

**MULTIPLE SHOTS ON GOAL**

**2** products on the market with partners

Build own, lean, commercial organisation in the U.S.

Addressing large areas of unmet medical needs

**COMMERCIAL PORTFOLIO**

Patients, partners, physicians and KOLs

Real-world data and payors' input

Outsourcing of non-core activities

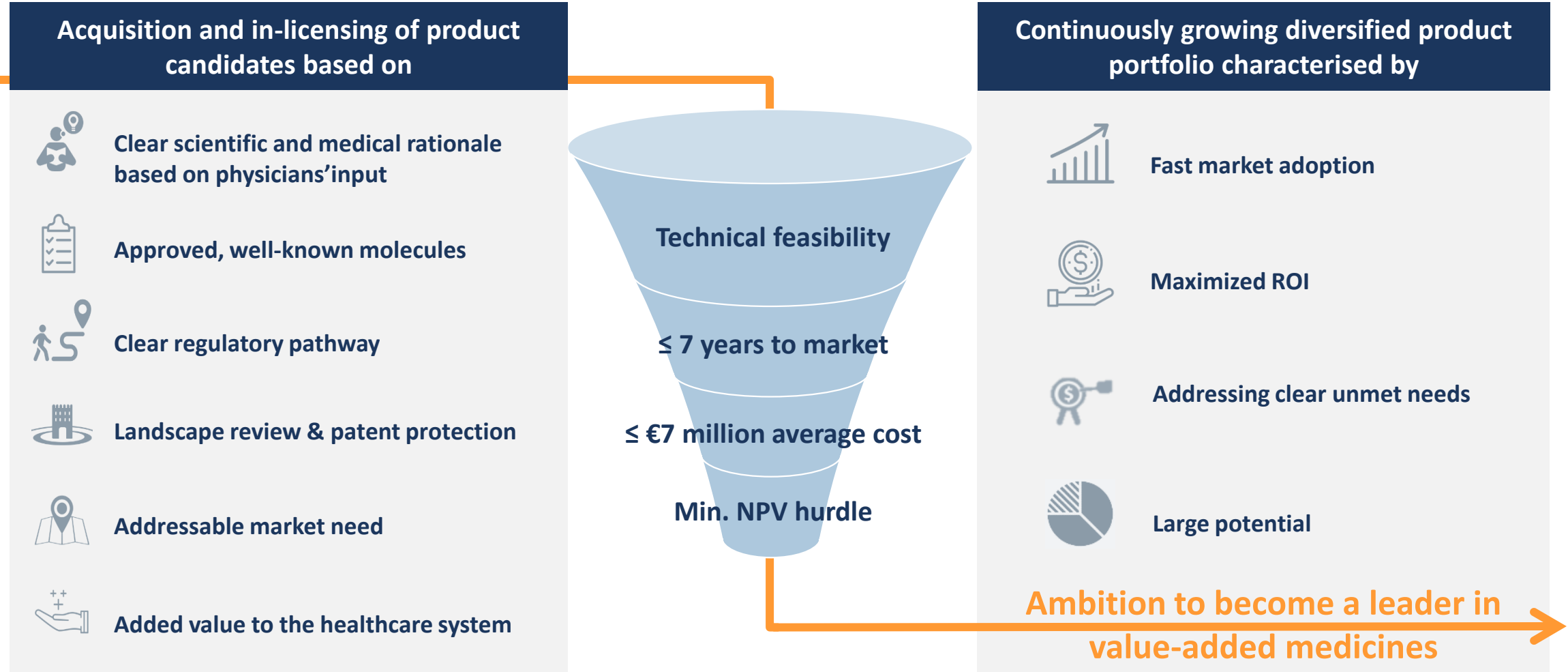
**VALUED PARTNERS**

# Putting Healthcare Needs at the Centre of Therapy Design















UNMET  
MEDICAL  
NEEDS



# To Drive Continuous Growth and Create Shareholders' Value



# Broad, Innovative Portfolio\*: Expand to ~30 Assets by 2024

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 U.S.	IV	Acute coronary syndrome				
Milrinone	Extended Release Capsule	Advanced heart failure (LVAD)				
Dofetilide IV	IV	Atrial fibrillation				
Metolazone IV	IV	Congestive heart failure				
HY-074	IV	Acute coronary syndrome				
HY-075	Oral Liquid	Coronary heart disease				
OTHER VALUE-ADDED PORTFOLIO			Up to 7 years			
Maxigesic® IV	IV	Post-operative pain	Licensed in >100 countries/partnered with AFT Pharmaceuticals			
HY-004	Oral Liquid	Specific dental indication				
Miconazole-DB	Topical	Severe and rVVC				
Plecoid™ Agent	IV	AML/SCLC				
Alenura™	PFS	IC / PBS				
Atomoxetine	Oral Liquid	ADHD				
HY-029	Oral Liquid	Viral infection				

\* Our high barrier generic products, TXA RTU, HY-038, HY-016 and Fusidic Acid Cream have not been included in the above

# 2021 Pipeline Expansion : All Unmet Medical Needs

## 1) **Miconazole and Domiphen Bromide** in recurring Vulvo Vaginal Candidiasis (topical cream)

- Dual fungicidal activity based on a known antimycotic and a repurposed potentiator
- Unique mode of action
- Ongoing clinical trial with FPFV in November 2021

## 2) **Milrinone Extended Release** in late-stage heart failure (oral)

- New, long term use indication for LVAD patients who have developed Right Heart Failure
- Potential to significantly reduce cost of care and improve QoL
- No approved competitors

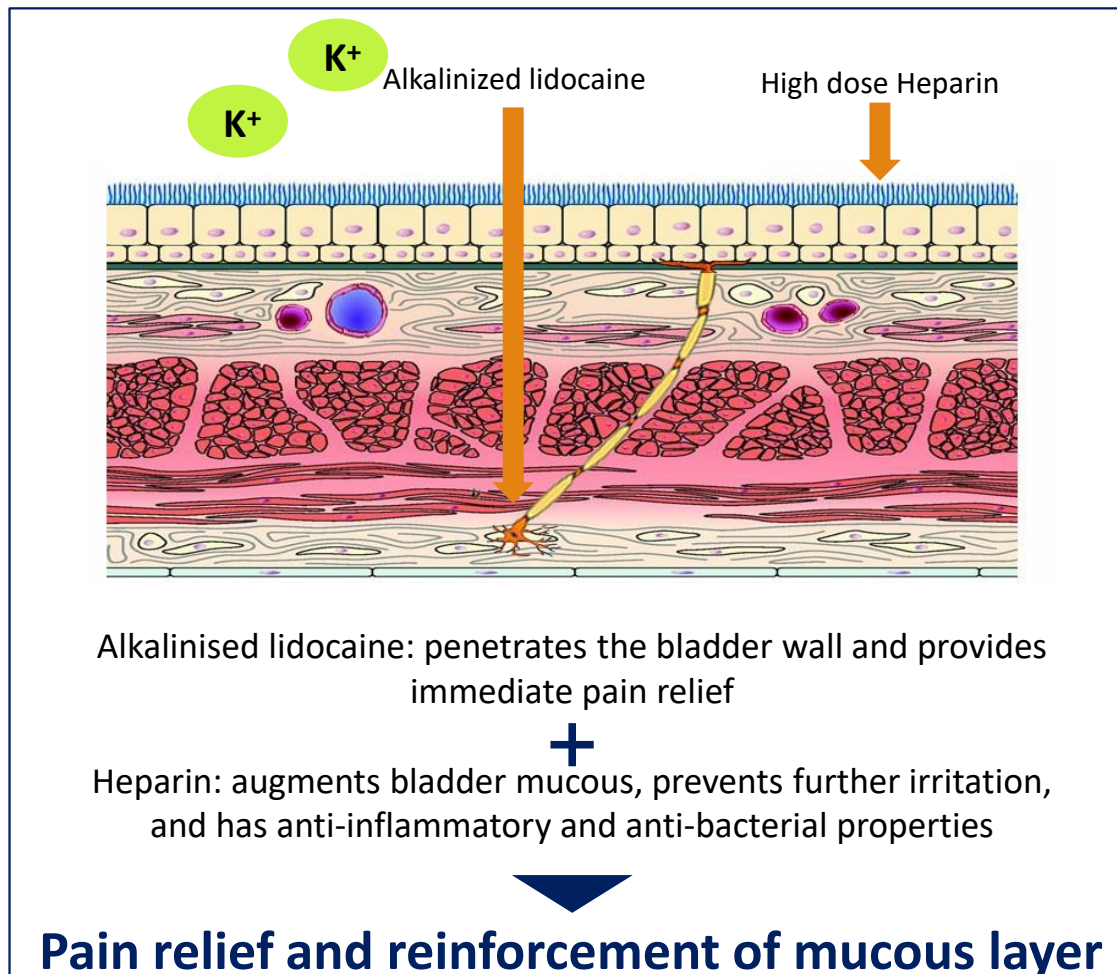
## 3) **Plecoid Agents (IV)** in Acute Myeloid Leukemia and Small Cell Lung Cancer

- Chelating agents to detoxify the cancer-promoting micro-environment
- Concomitant with SOC chemotherapy, potentially offering a boost and prolonged survival

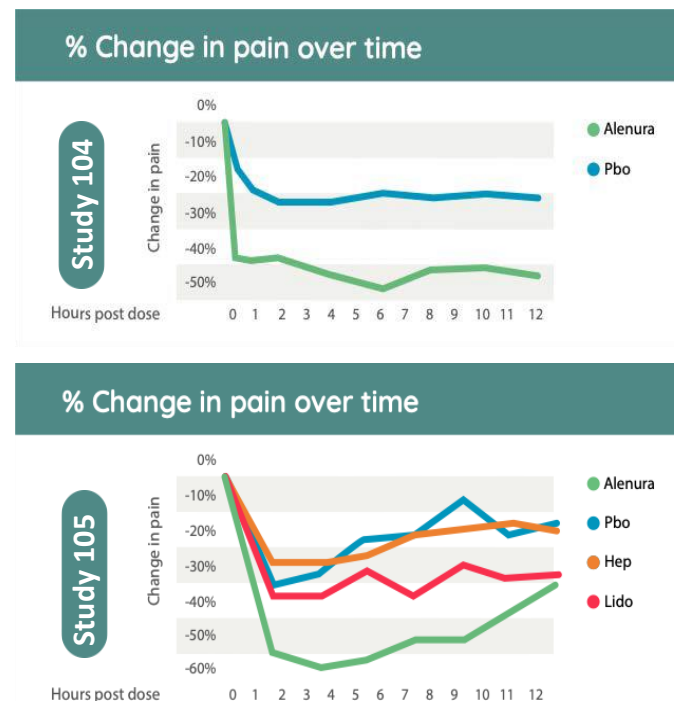
## 4) **Alenura** - See next slide



## 4) Alenura: Novel, Dual MOA Candidate to IC/PBS



- Alenura 15mL prefilled syringe: unique combination of alkalinised lidocaine + heparin to use as instillation product
- Proven efficacy in 2 controlled Phase 2 trials



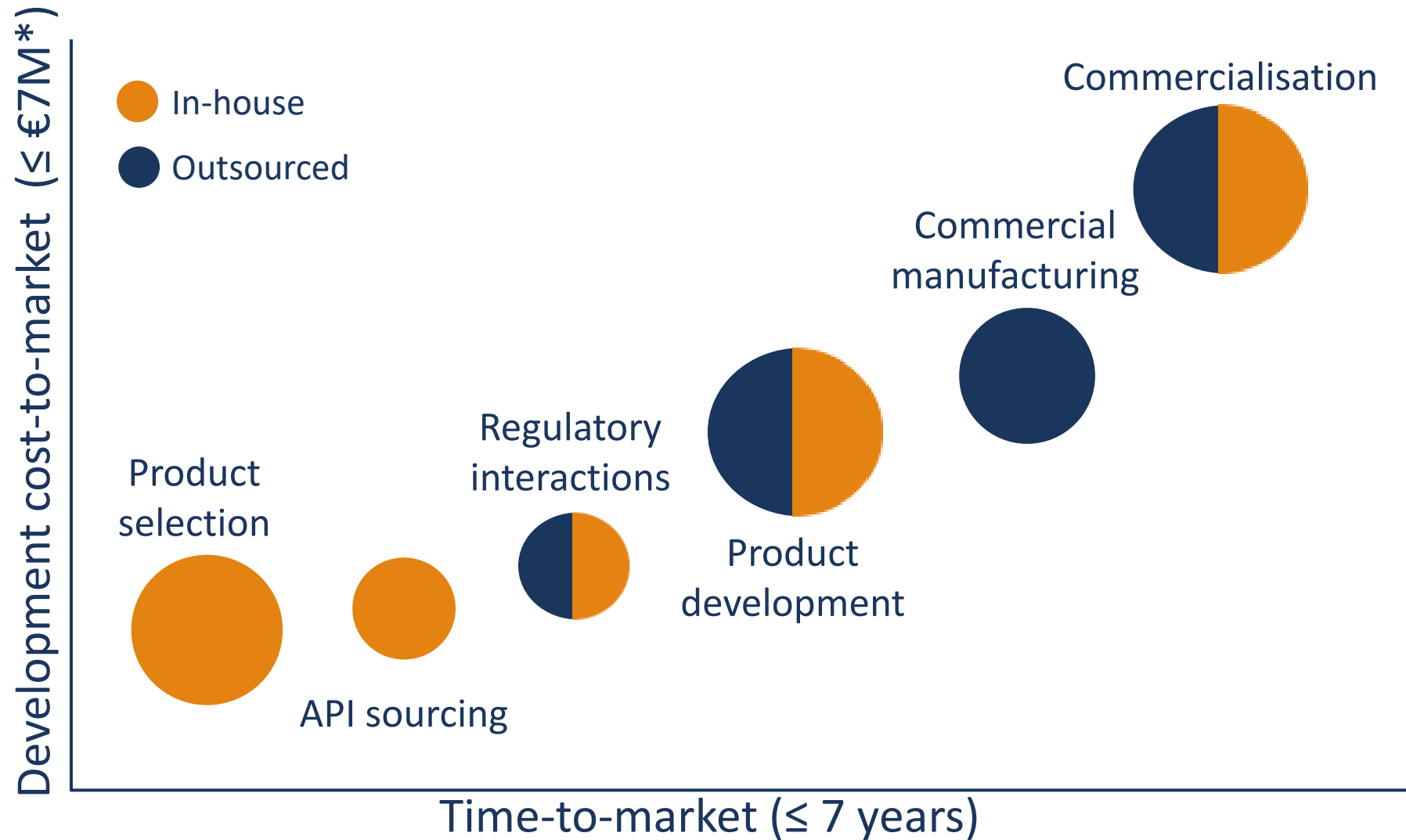
Potential to address unmet needs of patients suffering from acute pain in IC/PBS

# 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



# Flexible, Hybrid Earnings and Commercialisation Model

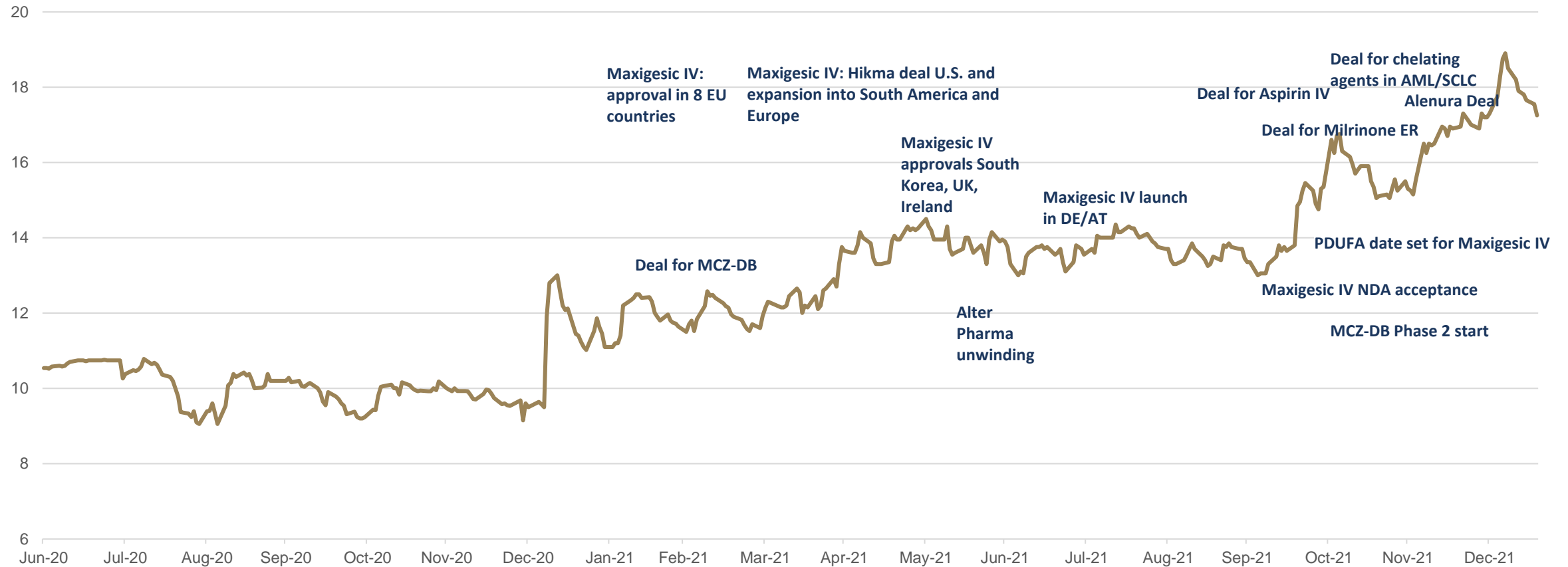
## CARDIOVASCULAR FRANCHISE

- Lean and efficient U.S. sales team targeting ~2,700 hospital-affiliated cardiologists
- Exploit existing regulatory package for certain product candidates to partner in other key geographies
- Already a presence in the U.S. with Sotalol IV, via commercial partner AltaThera

## OTHER VALUE-ADDED PORTFOLIO

- Out-licensing to commercial partners across various geographies
- Create ability to quickly monetise assets via upfront and milestone payments
- Retain a large minority or small majority of net profit realised by partners

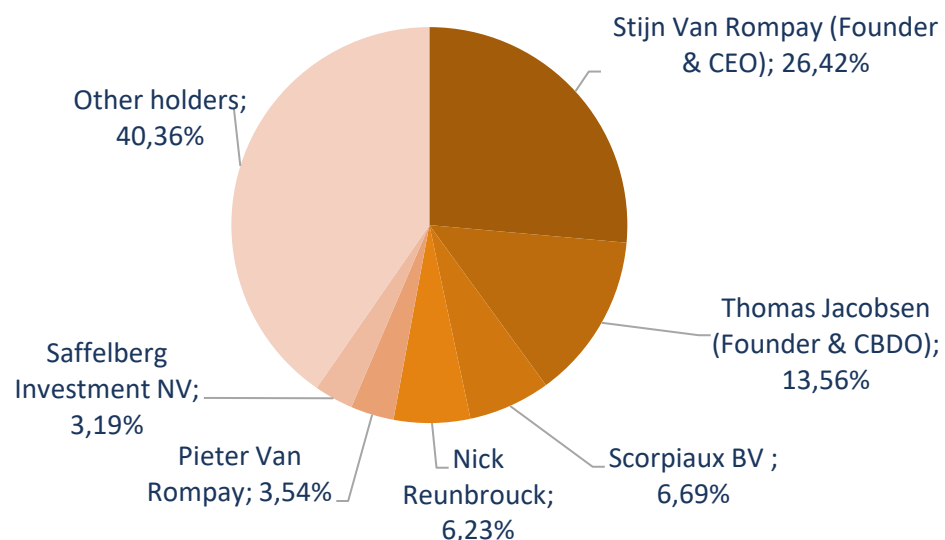
# Consistently Delivered on Our Promises since IPO in June 2020





# Shareholders' Information

## Major shareholders



Bank	Analyst	Rating
Berenberg	Beatrice Allen	Buy
KBC Securities	Jeroen Van den Bossche	Buy
Kempen	René Wouters	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*

HY21 cash position

€53.46 million

Total number of outstanding voting rights (= denominator)

25,832,632

Total number of securities carrying voting rights not yet issued

1,908,000

# Financial Highlights: Year end 2021

(in € thousand)	FY 2021	FY 2020	% change
<b>Revenues</b>	<b>3,096</b>	<b>175</b>	<b>1669%</b>
<b>Operating expenses</b>	<b>(13,337)</b>	<b>(3,626)</b>	<b>149%</b>
R&D expenses	(5,056)	(3,413)	48%
G&A expenses	(2,900)	(3,662)	(20.8%)
Other (one-off expenses)	(5,381)	21	NA
<b>Net cash (burn)/inflow<sup>i</sup></b>	<b>(14,387)</b>	<b>64,194</b>	<b>NA</b>
<b>Cash and cash equivalents</b>	<b>50,012</b>	<b>64,399</b>	<b>(22.34%)</b>

- **Revenues:** growth mainly driven by Maxigesic IV and Sotalol IV

- **Operating expenses:**
  - R&D expenses according to plan
  - G&A 2020 impacted by IPO costs
  - One-off expense related to unwinding of agreements with the Alter Pharma Group

- **Cash burn:**

- HY21: impacted by one-off cash outflow related to unwinding of agreements with Alter Pharma Group
- HY20: positively impacted by financing activities (convertible bonds and IPO)

<sup>i</sup> For the period 1 January to 31 December

# Core Assets: Anticipated Value Inflection Milestones in 2022

## Clinical

- Starting and completing pivotal PK clinical trial for Aspirin IV
- Starting pivotal PK clinical trial for Dofetilide IV and HY-029
- Starting Phase 2 clinical trial for Alenura™
- Completing Phase 2 clinical trial for Miconazole-DB in H2 2022
- Starting Phase 3 clinical trial on HY-004

## Regulatory

- Maxigesic® IV: PDUFA date 30 June 2022
- Atomoxetine: implementing changes to taste masking technology – FDA scientific feedback

## Commercial

- Commercial partnership(s)
- Continue roll-out of Maxigesic® IV and Sotalol IV with our partners

**Ambition to expand the product portfolio to ~30 assets by 2024, of which min 4 new candidates in 2022**

# 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

**14<sup>1</sup> 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**

<sup>1</sup> excluding our high barrier generic products, TXA RTU, HY-038, HY-016 and Fusidic Acid Cream.

# Unique Value Proposition

- Two commercial products with long runway for growth.
- Broad product candidate portfolio (6 cardiovascular and 7 other value added) supporting long-term growth.
- Strategic objective to expand to ~30 product (candidates) by 2024, primarily repurposed.
- Lean and smart operating model based on stringent 7-7 development criteria expected to provide strong return on investment.
- EUR 50 million cash to fund product portfolio development.





[investorrelations@hyloris.com](mailto:investorrelations@hyloris.com)

