

Forward-Looking Statements

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Investment Highlights

Our Mission

Creating value by rethinking and reinventing existing medications

Our Vision

Become the reference in valueadded medicines

Our Values

Entrepreneurship, patientcentred care, commitment, mutual respect

Growth Pillars

11 patented product candidates in the R&D 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, U.S. commercial team

Addressing unmet medical needs

COMMERCIAL PORTFOLIO

Patients, partners, physicians and KOLs

Real-world data and payors' input

Outsourcing of non-core activities

VALUED PARTNERS



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

Reinventing existing medications to improve therapy outcomes

Unique Features

New indication, combination, reformulation

Patented value-added medicines:
Optimised existing medicines

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

Key Benefits to Patients, Physicians and Payors

New Chemical
Entities
& Biologicals

Off-patent
ethical
compounds and
generics



Faster Innovation at Considerably Lower Costs and Risks

Discovery, preclinical development

Clinical Development

Regulatory submission & decision

15 YEARS ON AVERAGE \$1.3 BILLION COSTS ON AVERAGE

"Traditional Pharma-Biotech Model"

Feasibility, formulation, production

Clinical Development

Regulatory submission & decision

≤ 7 YEARS







Putting Healthcare Needs at the Centre of Therapy Design

UNMET MEDICAL NEEDS





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



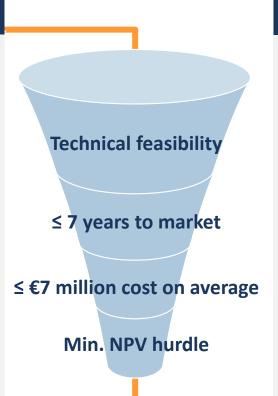
Landscape review & patent protection



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

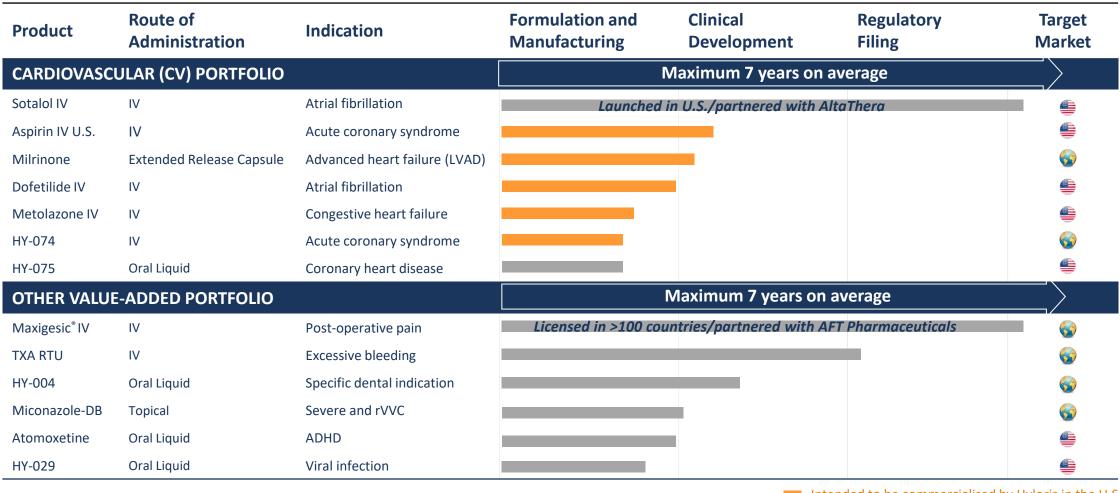


Large potential

Ambition to become a leader in value-added medicines



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



^{*} Our high barrier generic products, HY-038, HY-016 and Fusidic Acid Cream have not been included in the above overview



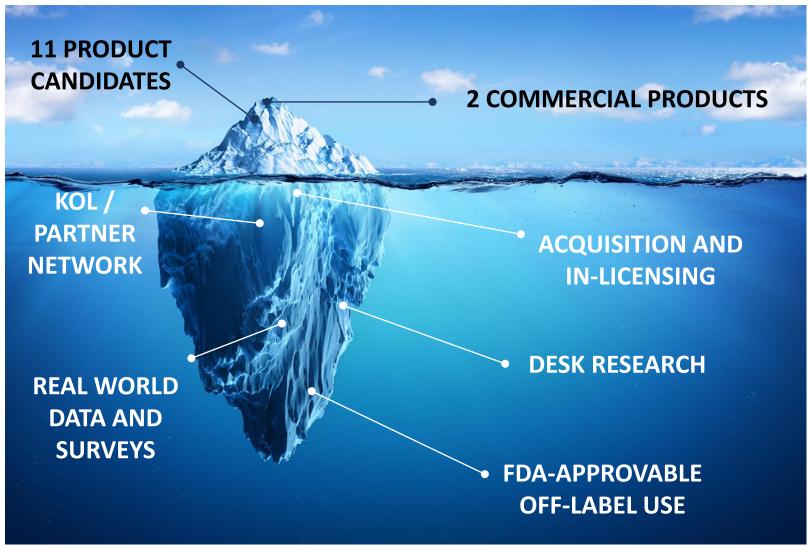
Intended to be commercialised by Hyloris in the U.S.Intended to be commercialised with partner

Our Portfolio*: Added-Value for all Stakeholders

•	Product	IP	Indication	Key Benefits and Value Proposition	
CALLOLIO	Sotalol IV	'34-'38; granted	Atrial fibrillation	Shorter hospital stay; fast onset of action; lower overall healthcare cost; facilitate antiarrhythmic therapy for patients unable to swallow tablets	
	Milrinone Oral	Confidential	Advanced heart failure	Extended release capsule with potential in LVAD patients who have developed right HF which could improve QoL and significantly reduce cost of care (lower readmission rates, faster discharge, at home administration for longer term use	
	Dofetilide IV	'39; pending	Atrial fibrillation	Shorter hospital stay; lower overall healthcare cost; facilitate antiarrhythmic therapy for patients unable to swallow tablets	
300	Metolazone IV	'38; pending	Congestive heart failure	Fast onset of action (essential in critical care); improved drug absorption and concomitant treatment possible	
CANDIOVASCULAN	Aspirin IV U.S.	'38, granted; pending	Acute Coronary Syndrome	Fast onset of action (essential in critical care) with low drug-drug interaction risk; prolonged, consistent effect; less intra- and interindividual metabolisation variabilities; therapy possible in patients who are nauseous or unconsciou	
	HY-074	Confidential	Acute Coronary Syndrome	Fast onset of action (essential in critical care) with low drug-drug interaction risk; therapy possible in patients who are nauseous or unconscious	
	HY-075	Confidential	Coronary heart disease	Possibility for drug titration, ease of administration and indicated dosage control	
) - -	Maxigesic [®] IV	'30-'38; granted & pending	Pain	Highly effective non-opioid; tolerable profile; dual MOA; greater pain relief	
י סוויס י	Miconazole-DB	'38; pending	sVVC/rVVC	Dual MOA; addressing population for whom there is currently no cure available	
AUUEU	HY-004	'39; granted & pending	Non-disclosed	Address acute issues or possible procedural related complications in dental offices	
i I	Atomoxetine	'36; granted	ADHD	Possibility for drug titration, ease of administration and indicated dosage control; improved compliance and convenience	
עאר ע	HY-029	Confidential	Viral infections	Possibility for drug titration; ease of administration and dosage control; improved compliance and clinical benefit	
JI IIEN	Tranexamic Acid RTU	'39; granted	Excessive bleeding	Improved convenience and ease of use; potential as critical care product	

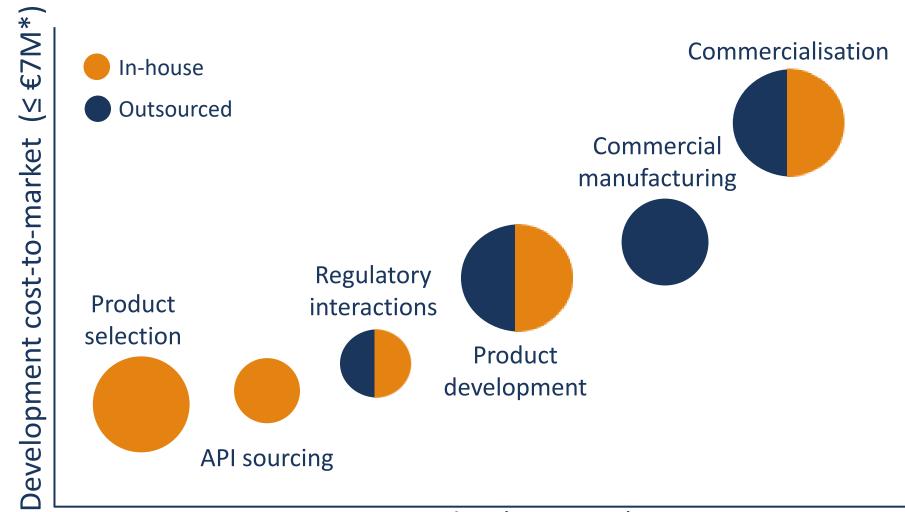


Sourcing Product Opportunities Via Multiple Channels





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



Financial Highlights: Period Ending 30 June 2021

(in € thousand)	HY 2021	HY 2020	% change
Revenue and other income	1,145	102	1,023%
Revenues	838	82	922%
Other income	307	20	1,435%
Operating expenses	(9,016)	(3,626)	149%
R&D	(1,560)	(1,172)	33%
G&A	(1,608)	(2,454)	(34%)
Other (one-off expenses)	(5,770)		NA
Net cash (burn)/inflow i	(10,934)	66,578	NA
Cash and cash equivalents	53,465	66,783	(20%)

For the period 1 January to 30 June

Key Factors

- Revenues: growth mainly driven by Maxigesic IV recognised income from milestones
- Operating expenses: impacted by <u>one-off</u> expense related to unwinding of agreements with the Alter Pharma Group

Cash burn:

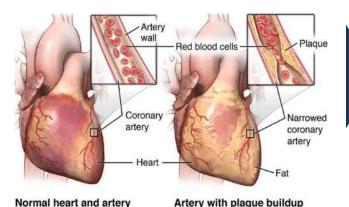
- HY21: impacted by one-off cash outflow related to unwinding of agreements with Alter Pharma Group
- HY20: positively impacted by financing activities (convertible bonds and IPO)





Coronary Artery Disease and Acute Coronary Syndrome

Coronary Artery Disease



Normal heart and artery
© University of Chicago
Medicine

#1 cause of death in the U.S.

Acute Coronary Syndrome (ACS)



~2 million patients/year in U.S.

- Acute myocardial infarction (heart attack)
- Unstable angina (chest pain)





Current SoC



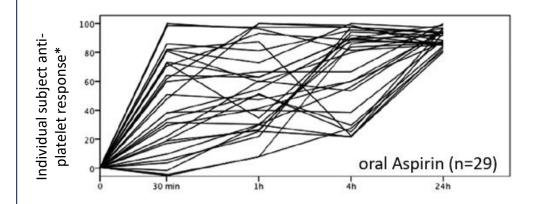
<u>Start ASAP</u> treatment with oral Aspirin to stop platelet aggregation and avoid further damage to heart tissue: mortality risk is <26% in patients who receive SoC within 3 hours post ACS event



Potential Solution to Overcome Limitations of oral Aspirin

Oral Aspirin

- Slow onset of action: max. effect only after 1-2 hours
- Bioavailability of 40-50% and highly variable across patients: significant delayed effect or no effect
- Not suitable for patients who are unconscious/vomiting

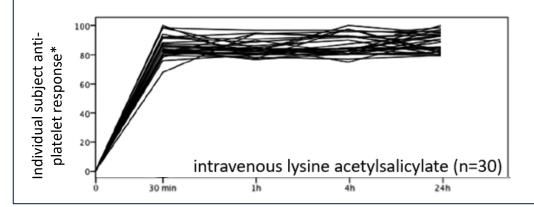


Unpredictable onset of effect and risk of poor or delayed clinical response, which can be fatal



Aspirin IV: first-in-class IV acetylsalicylic acid

- Fast onset of action: avoid further heart tissue damage
- 100% bioavailability: immediate, consistent effect
- Higher inhibition of platelet aggregation
- Can be administered to all ACS patients



Major clinical benefits thanks to its fast, consistent anti-platelet effect, which is crucial in ACS

Aspirin IV in U.S.: start of pivotal study expected early 2022



Aspirin IV U.S.: Partnership with Rhoshan Pharmaceuticals

To address unmet needs in acute coronary syndrome (ACS):

- Can result in heart attack or unstable angina
- Higher risk of mortality 24 hours post heart attack
- Need for novel products with fast onset of action and consistent effect



- HYL to acquire worldwide rights to Rhoshan's novel, patented, breakthrough IV formulation technology
- Enables accelerated development of Aspirin IV in the U.S. (formerly known as HY-073, acetylsalicylic acid IV)

Financial terms

- HYL to provide maximum \$7.5M funding up to launch (\$750K at signing), of which 20% is reimbursable the first 3 years post launch
- Rhoshan eligible to receive up to \$1.25M development and regulatory milestones; plus commercial milestones and doubledigit royalties



Responsibilities

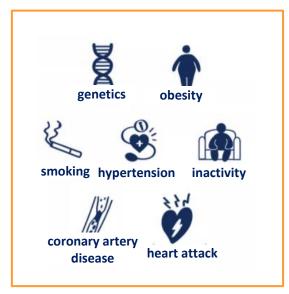
- HYL responsible for manufacturing and commercialisation
- Rhoshan to continue product development and regulatory affairs activities



Heart Failure: #1 Cause of Hospitalisation in people >65 years

Heart failure (HF) occurs when the heart is unable to pump enough blood through the body

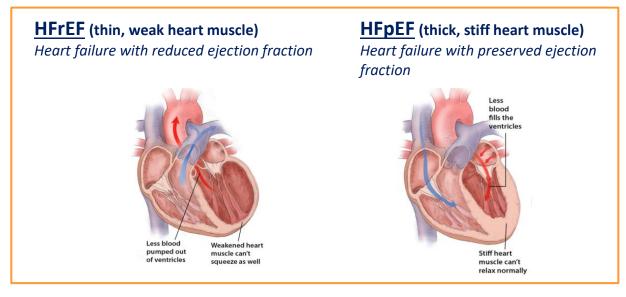
Causes and Risk Factors



Symptoms



2 Types



By 2030, the annual HF-related cost in the U.S. is expected to be \$70 Bn



50% incurred in the hospital



HF Classification and Disease Management

As the condition gets worse, the heart muscle pumps less blood to the organs, and the patient moves toward the next stage of heart failure

STAGE

MANAGEMENT STRATEGY



• Urge lifestyle modification (e.g. diet, weight loss, exercise)





STAGE B:



Asymptomaticwith structural heart disease



STAGE C:



Symptomatic *Prior or current HF symptoms*





- Continue to treat comorbidities and recommend lifestyle changes
- Monitor for development of HF symptoms

Additional treatment for reduced EF patients only

- Initiate beta blockers and ACE inhibitors or ARBs
- Use implantable cardioverter-defibrillators (ICD) in post-MI patients
- Continue to treat comorbidities and recommend lifestyle changes
- Educate patients on self-care (e.g. salt restriction and HF symptoms)

Additional treatment for reduced EF patients only

- Initiate beta blockers and ACE inhibitors or ARBs with diuretics
- ICDs or cardiac resynchronisation therapy
- Refer to cardiology for advanced therapies such as left ventricular assist device (LVAD) or heart transplant
- In-patient, short-term use of IV inotropes (such as IV Milrinone) for severe decompensated HF patients
- Discuss end-of-life treatment goals as appropriate



IV Milrinone: Positive Inotrope = Increases Contractility

CARDIOPULMONARY EFFECTS:

- Increased contractibility and heart rate
- Increased stroke volume and ejection fraction
- Increased cardiac output
- Decreased peripheral and pulmonary vascular resistance
- <u>Currently approved</u> for use as an intermittent or continuous infusion for treatment of up to 48 hours for acute decompensated heart failure
- Longer term off-label use exceeding 48 hours of treatment duration has been reported, requiring nursing support
- Market: >12 million vials and infusion bags sold in 2020, of which >2 million in the U.S. alone

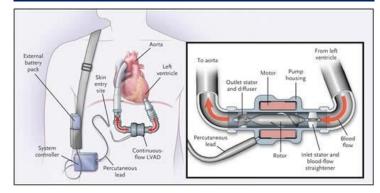


Oral Milrinone: Our Potential Solution in LVAD RHF Patients

Epidemiology







- Cumbersome, limiting patients' QoL
- High readmission rates post discharge
- High cost of care
- Not approved for long term use

~20,000 patients with an LVAD; 6% average annual growth rate expected over next years¹

30% will develop



- Associated with very poor outcomes, including increased morbidity and mortality
- May require IV inotropic treatment



Oral Milrinone Orphan Drug Status in U.S. in LVAD RHF

- Novel, orally administered extended-release capsule
- Positive results from earlier clinical studies: linear dose-response PK; well-tolerated and encouraging signs of effect in prolonged compassionate use phase*

This could potentially:

- Improve QoL
- Significantly reduce cost of care: lower readmission rates and faster discharge; administer at home by the patient for longer term use

Start of pivotal study in LVAD RHF patients expected end 2022/early 2023 Peak sales potential of \$50-\$80M in the U.S. in orphan LVAD right HF indication



¹ Grand View Research Inc 2021; ² Triangle Insights 2016

^{*} Nanayakkara et al. Am J Cardiol. 2018; Nanayakkara et al. J. Am. Heart Assoc. 2020; LVAD study results: publication pending

Oral Milrinone: Partnership with The Baker Institute

To develop and commercialise a novel, patient-friendly oral formulation of Milrinone to meaningfully improve the lives of patients with advanced HF and significantly reduce cost of care



Scope

- HYL to acquire worldwide rights to CRD-102, a novel oral formulation of Milrinone in patients with advanced HF
- Potential to replace Milrinone IV and overcome current shortcomings to significantly improve the lives of patients with advanced HF and reduce cost of care

Financial terms

HYL to pay the Baker Institute:

- \$50K upfront signing fee
- In markets where HYL will selfcommercialise: i) tiered single digit net profit share; ii) sales-based milestone payments
- In markets where HYL will seek commercial partnerships: tiered net profit share of net sub-license income

Responsibilities

- HYL responsible for product development, manufacturing, regulatory affairs and commercialisation
- The Baker Institute to provide R&D support



Unmet Needs in Severe and rVVC



Current medicines have limitations



Treatment of acute VVC episodes - side effects

Vulvovaginal candidiasis (VVC)

- Infection caused by *Candida* sp. yeast
- Causes irritation, vaginal discharge and intense itchiness
- Affects 50% of all women during their life
- ~175 million drug products sold/year

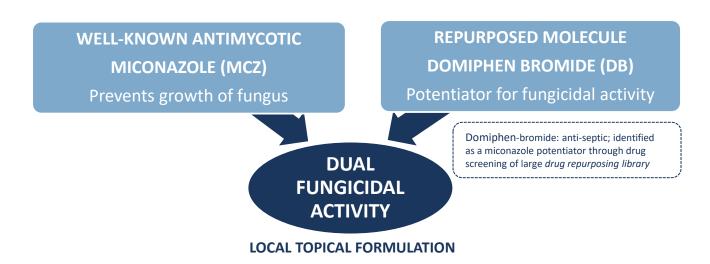
Severe and recurring VVC

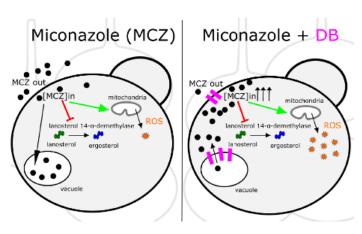
- 10% of all women globally
- No effective treatments: drug-resistant biofilm
- \$14.4 Bn annual estimated economic burden

No innovation over the past few decades



Miconazole-DB has Potential to Cure Severe and rVVC





Unique mode-of-action

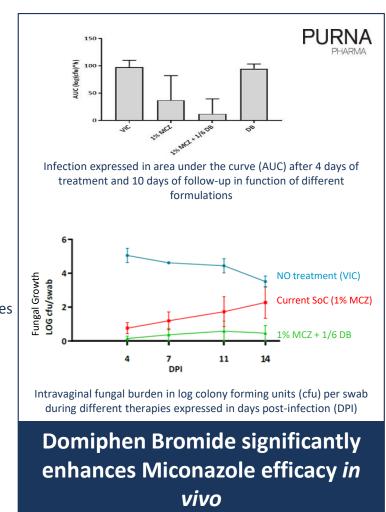
Domiphen Bromide (DB):

- Enables increased MCZ uptake in Candida cells at low doses
- Alters cytoplasmatic distribution of high azole doses
- Negatively affects vacuole integrity, thereby releasing vacuole-sequestered MCZ



Increased intracellular azole availability results in

- Increased ROS* generation = apoptosis
- Fungicidal antibiofilm activity



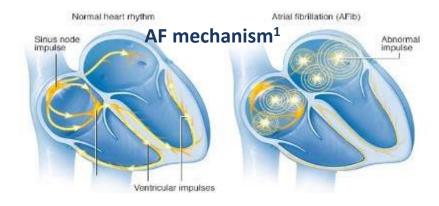


^{*} ROS = reactive oxygen species

High Unmet Needs in Atrial Fibrillation (AF)

Atrial Fibrillation: a life-threatening disease

Characterised by an irregular and often abnormal high heart rate



- Complications: 5x higher risk of stroke², 3x higher risk of heart failure³
- Contributes to about 158,000 deaths each year in the U.S.⁴
- U.S prevalence expected to double to 12M by 20304
- **454,000**⁴ AF-related **hospitalisations** per year in the U.S.
- Majority of hospitalised patients receives an antiarrhythmic drug

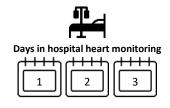
Current treatments could be improved

- Blood thinners
- Heart rate medicines
- Heart rhythm medicines



Rhythm control drugs have life-threatening side effects

FDA Oral sotalol carries black box warning

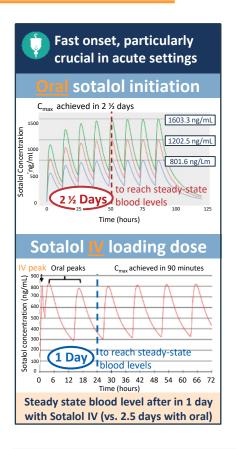


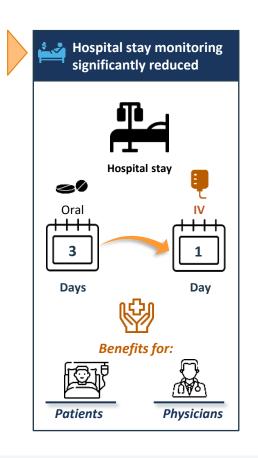
Incidence of *Torsade de Pointes (abnormal heart rhythm – a serious side effect)* is 0.5-5.8%⁵ on oral sotalol (dose-related)

Need for safer and more effective treatments



Sotalol IV Offers Benefits to Patients, Physicians and Payors







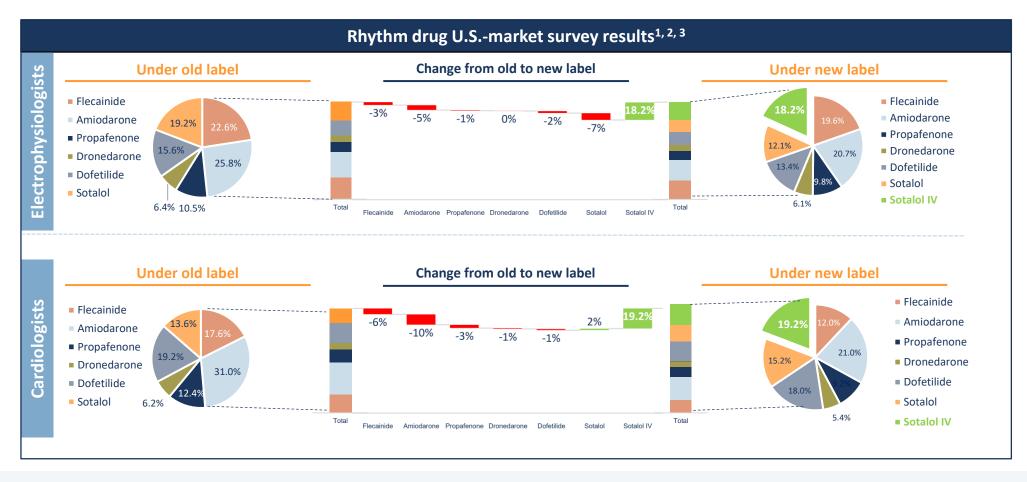


Hyloris eligible to receive:

- Increasing sales-related fees on net sales derived from Sotalol IV in the U.S.
- Five one-time sales-related milestone payments of increasing amounts, totalling maximum \$18M
- First milestone to materialise when annual net sales are ≥ \$20M



Sotalol IV New Label, Strong Support From Medical Community

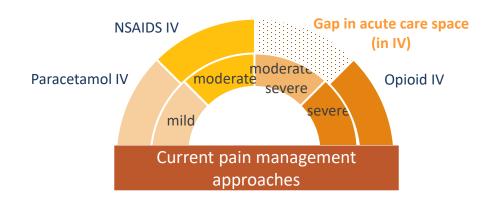


Sotalol IV under its new label has potential to take an important share in the antiarrhythmic market



High Unmet Needs in Post-Operative Pain Management

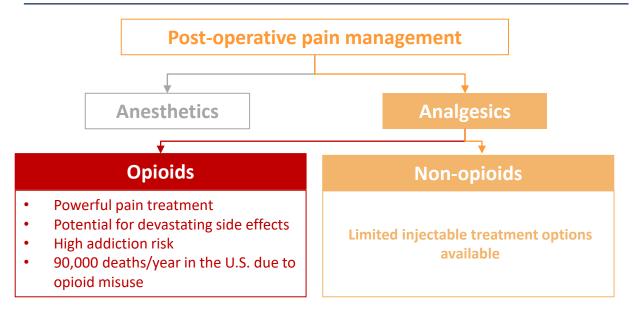
Gap in moderately severe pain care space



Market size breakdown

Maxigesic® platform expected to generate peak sales of \$442M in U.S., Japan and EU5¹ (incl. Maxigesic® in oral form)²

Current treatment options are suboptimal



Need for safer and more effective non-opioid treatment options

Hyloris entitled to a share on any revenues³ generated by commercial partner AFT





Maxigesic® IV has Potential to Combat the Opioid Crisis

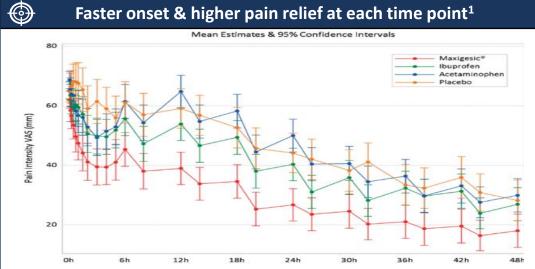
Maxigesic® IV: a <u>novel combination</u> of 1000mg paracetamol and 300mg ibuprofen solution for infusion, working in a complementary way to reduce both pain and inflammation and lower the use of opioid rescue medication

Paracetamol blocks the pain message at the source

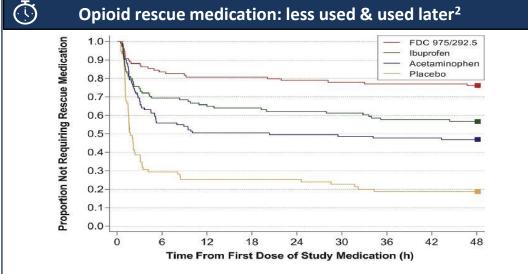








- Double-blind, randomised, placebo-controlled Phase 3 study of Maxigesic IV in 276 patients following bunion surgery
- Onset of pain relief (VAS score) was significantly faster compared to placebo, paracetamol or ibuprofen alone and 30% less opioid consumption in the Maxigesic IV group
- At every time interval measurement, the VAS score was statistically better in the Maxigesic IV group



- Double-blind, randomised, placebo-controlled Phase 3 of Maxigesic oral tablets in moderate to severe post-operative dental pain
- Mean total dose of rescue medication (oxycodone) in the Maxigesic oral group was significantly lower than in the other groups
- 87.2% of subjects in Maxigesic oral group achieved at least a 50% reduction in baseline VAS pain compared to the other groups without the use of rescue medication (p<0.05)





Core Assets: Anticipated Value Inflection Milestones in 2021

Clinical



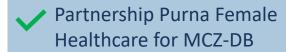
HY-004: start Phase 1

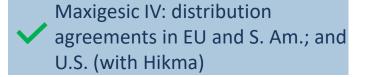
- Atomoxetine: start + results pivotal study
- HY-004: Phase 1 safety results and preparations pivotal study
- MCZ-DB: start Phase 2 study
- Other assets: preparations to start pivotal studies

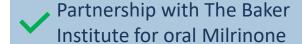
Regulatory

- ✓ Tranexamic Acid RTU: marketing application in U.S.
- Maxigesic IV: FDA acceptance of marketing application in U.S.
- Maxigesic IV: additional approvals in key markets

Commercial







- Maxigesic IV further roll-out
- Sotalol IV U.S. roll-out
- Commercial partnership(s)
- Out-licensing agreement(s)
- Expand R&D pipeline with 2 additional product candidates



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

Innovative, patented, valueadded drug candidates

COMMERCIAL PORTFOLIO

2 patented products with partners

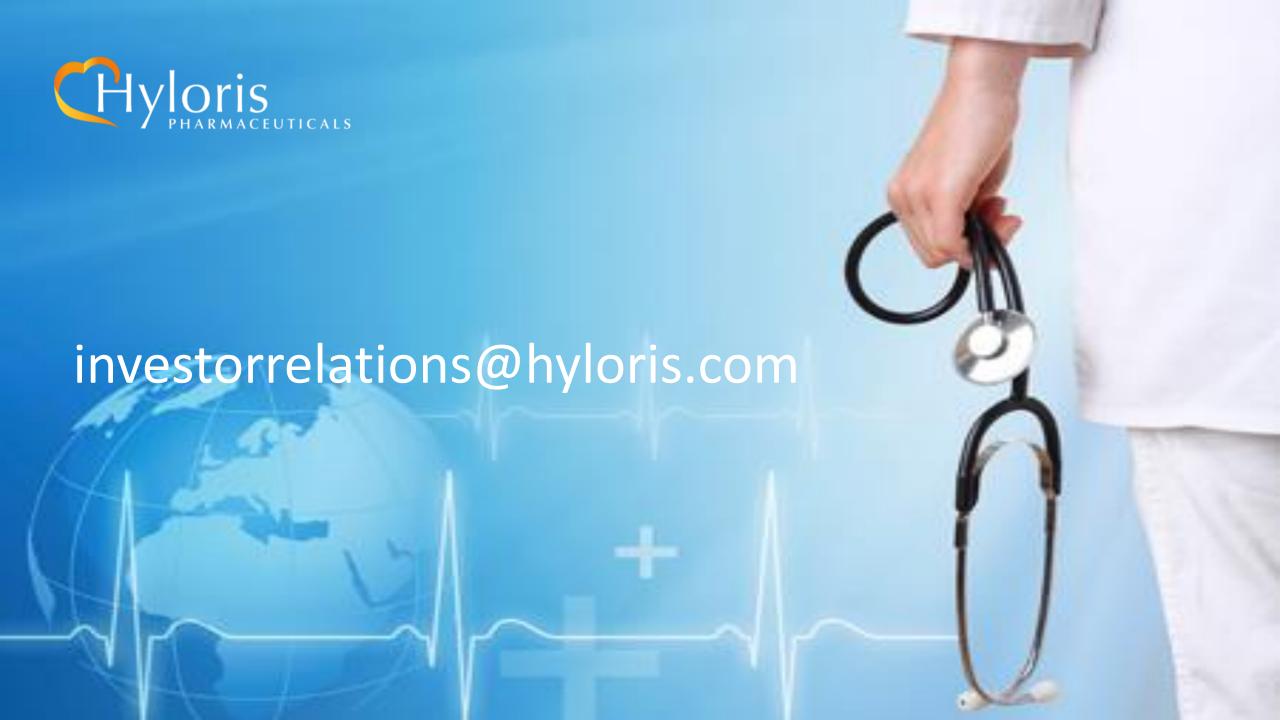
Addressing unmet needs

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

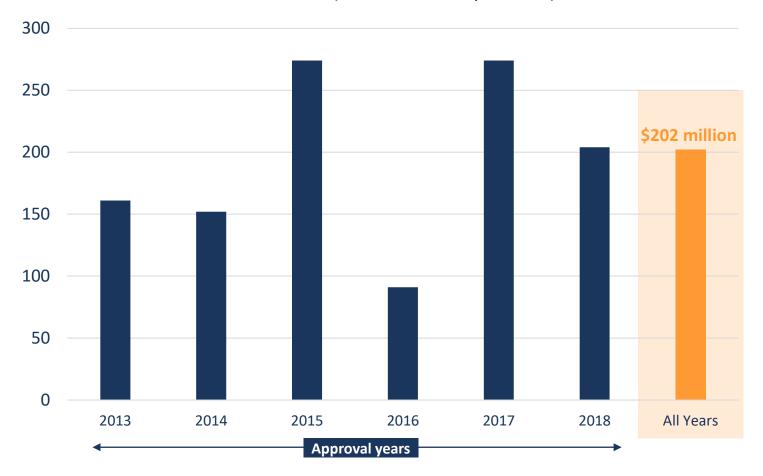






Average Peak Sales of Value-Added 505(b)(2) Products

Average peak sales (million \$) of 505(b)(2) products in each approval year 2013 to 2018 (N=78 launched products)





REFORMULATED

Performance of Select Number of 505(b)(2) Products

Product name	What changed in 505(b)(2)	Indication	Company	2019 Sales
Avycaz	New combination	Complicated intra-abdominal and urinary tract infections	Allergan (AbbVie)	\$117M
Belbuca	New dosage form	Chronic pain	BioDelivery Sciences	\$98M
Vasostrict	New dosage form	Hypotension in adults with vasodilatory shock	Endo	\$531M
Abraxane	New formulation	Metastatic breast cancer	Celgene (BMS)	\$1,200M
Restasis	New route of administration	Chronic dry eye syndrome	Allergan (AbbVie)	\$1,188M
Neoral	New formulation	Immunosuppressant to prevent organ rejection after kidney, heart or liver transplant	Sandoz (Novartis)	\$419M
Kaletra	New combination and formulation	HIV infections	Abbott (AbbVie)	\$283M
Viagra	New indication	Erectile dysfunction	Pfizer	\$2,000M ^a
Thalomid	New indication	Multiple myeloma	Celgene (BMS)	\$500M ^b
Tecfidera	New indication	Multiple sclerosis	Biogen	\$4,430M
Revatio	New indication	Pulmonary arterial hypertension	Pfizer	\$144M
Propecia	New indication	Male pattern baldness	Merck	\$447M ^c
Rituxan	New indication	Rheumatoid arthritis	Biogen & Roche	\$1,200M ^d



^a Sales in 2012, prior to generic entrants

^b Sales in 2008 prior introduction of Thalomid analogue drug Revlimid (Celgene)

^c Sales in 2010, prior to generic entrants

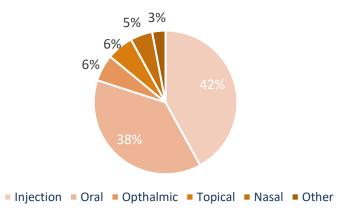
^d Sales in 2013, prior to biosimilar entrants

Increasing Use of 505(b)(2) Pathway in the Industry

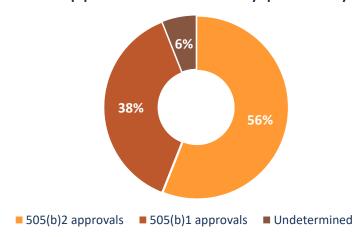
505(b)(2) approvals (2003-2019)



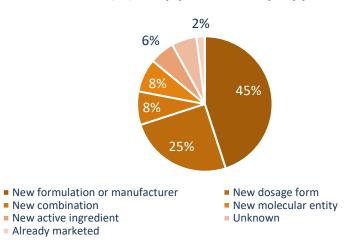
505(b)(2) approvals by route of administration



NDA approvals in 2019 by pathway

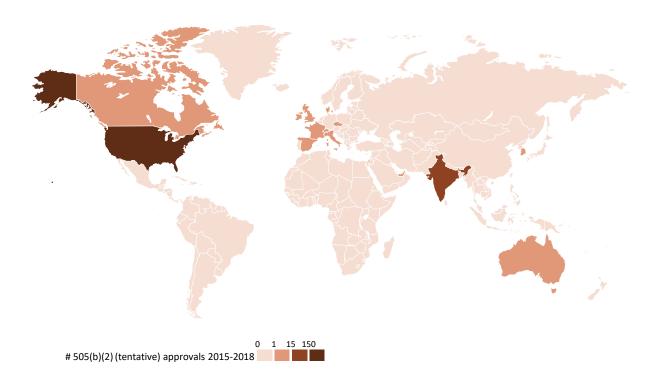


505(b)2 approvals by type



Value-Added 505(b)(2) Landscape

Geographical spread of 505(b)(2) (tentative) approvals 2015-2018 (# 221)



Top-3 applicants 2015-2018:

Country	Company	# of 505(b)(2) approvals
	FRESENIUS KABI	12
-	SUN PHARMA	7
Wa .	EXELA PHARMA SCIENCES	4

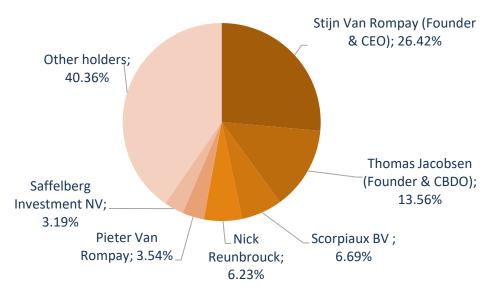
Select Listed Competitors:

Country	Company	# of 505(b)(2) approvals 2011 - 2019	Formulation route
	EAGLE PHARMACEUTICALS	3	IV (infusion)
	THERAPEUTICS' Dwellighing Bedrin-Class Medicine Emproving Units'	2	Injection, injectable emulsion
	eTon PHARMACEUTICALS	1	RTU injectable
	PACIRA PHARMACEUTICALS, INC.	1	Injectable suspension
	Pharmaceuticals, Inc.	Acquired a portfolio of 505(b)(2 product candidates from Coept	



Shareholders' Information

Major shareholders



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

Share capital (excluding share premium)

Total number of outstanding voting rights (= denominator)

Total number of securities carrying voting rights not yet issued

€53.46 million

€129,163.16

25,832,632

1,908,000



Hyloris Founders have an Impressive Industry Track Record



Combined transactions created additional shareholder value of >€550 million



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









Board of Directors



Stefan Yee Chairman, Non-Executive Director

PE Group











Marc Foidart⁴ **Independent Director**







Stijn Van Rompay¹ Chief Executive Officer, Executive Director













Carolyn Myers Independent Director

Bioensemble Ltd.







Thomas Jacobsen² Chief Business Development Officer, Executive Director













James Gale Independent Director











Leon Van Rompay³ Non-Executive Director





Belgian Pharmaceutical Industry Association





Chris Buyse⁵ **Independent Director**









2020 has Set Strong Foundations for Value-Creation

R&D - Regulatory

- Sotalol IV: U.S. approval expanded label
- Maxigesic IV: approvals in 17 EU countries; Phase 3 completed
- Further advanced all other pipeline assets

Commercial

Maxigesic IV:

- Licensed in >100 countries
- Launched in 3 countries

Corporate

- Raised €79.54M
- Strengthened management team
- Further built internal resources
- Reinforced Board of Directors



