



KBC Securities Life Sciences Conference

9 September 2021

Forward-Looking Statements

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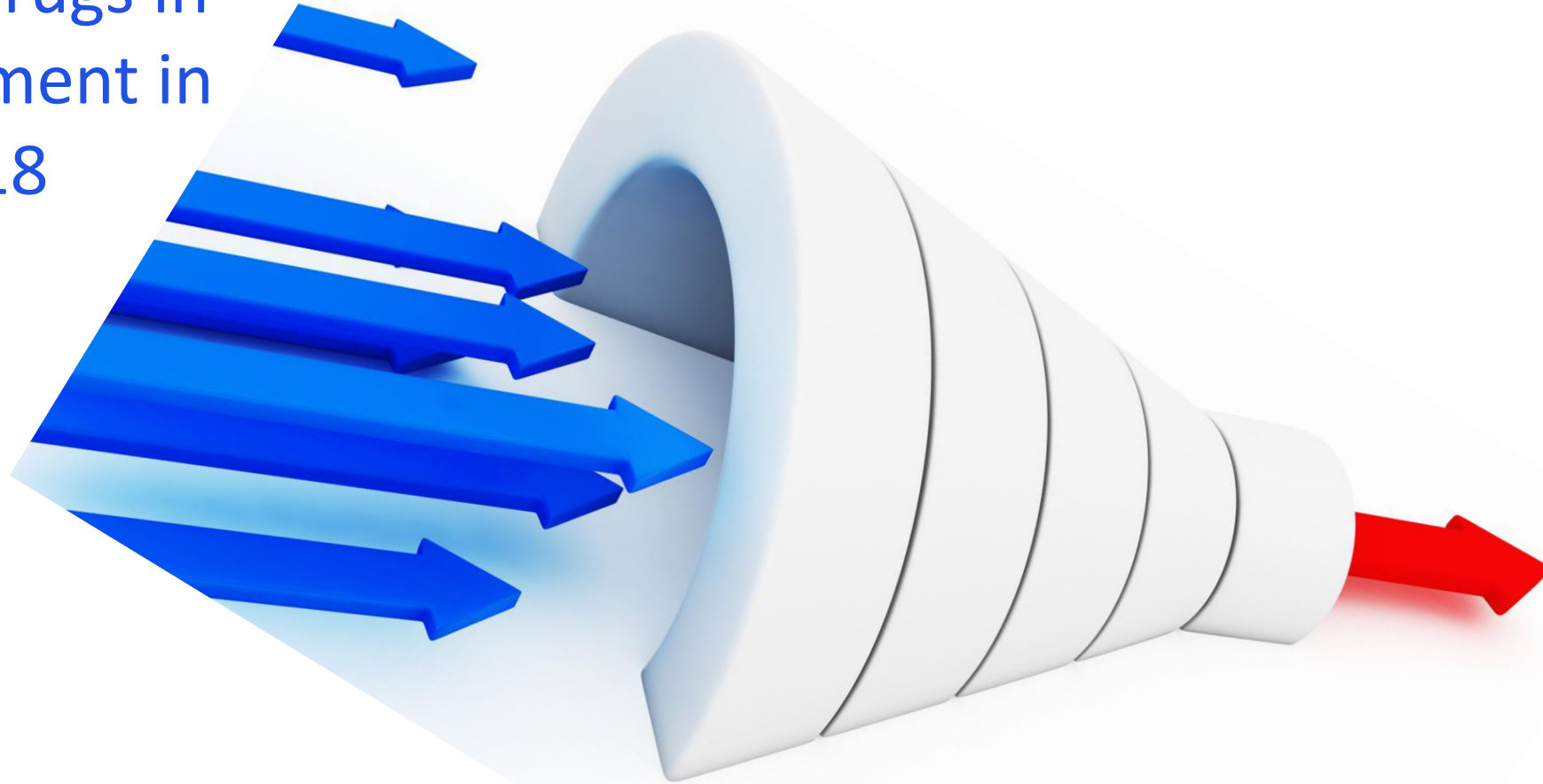
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15,000 drugs in
development in
2018



60 new
drugs hit
the
market
in 2018

High Unmet Medical Needs



Rethinking, Reinventing, Optimising Existing Medications

To improve overall therapy outcomes

REFORMULATING



Changing dose or mode of administration

REPURPOSING

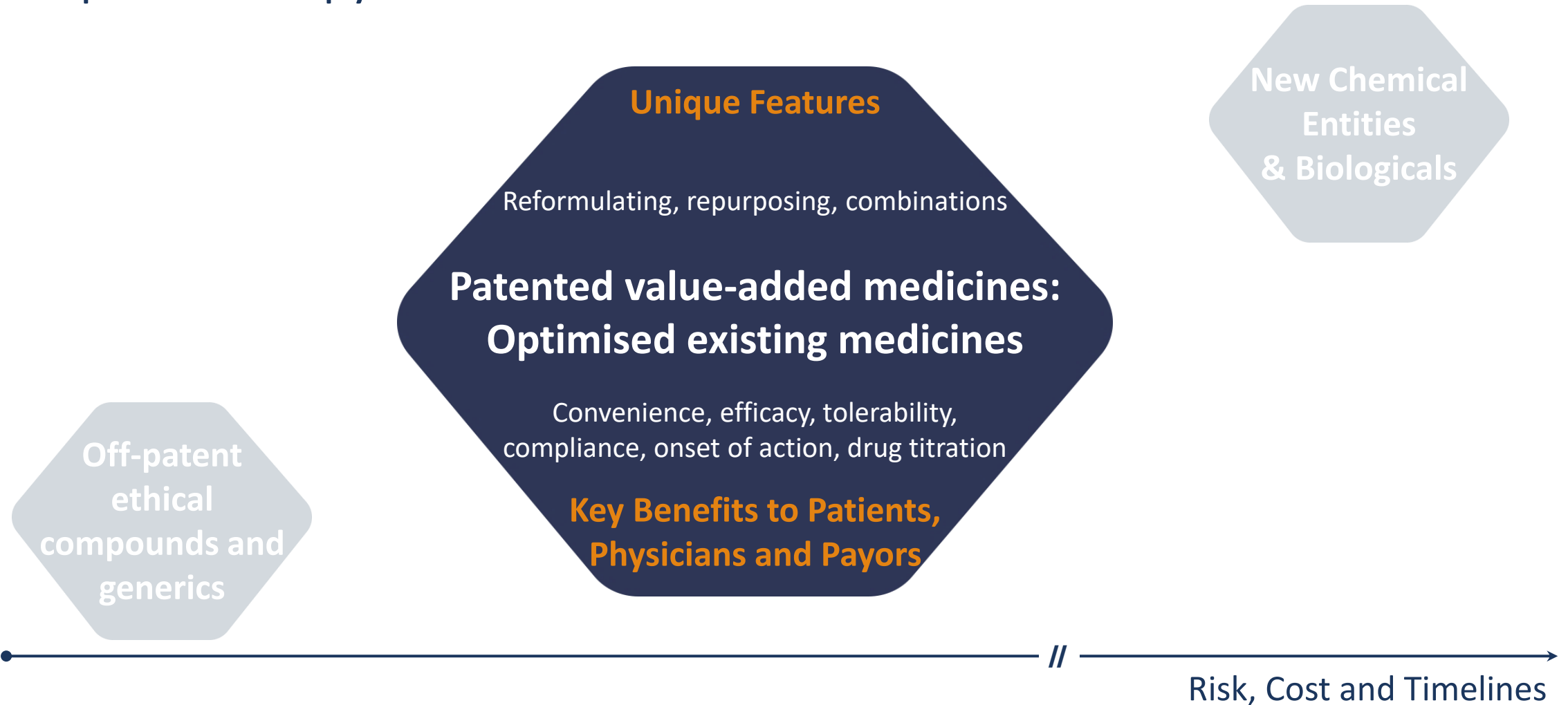


New therapeutic uses

For the benefit of patients, physicians, payors

Patented Value-Added Medicines: Pharma's Sweet Spot

To improve therapy outcomes



Faster Innovation at Much Lower Costs and Risks

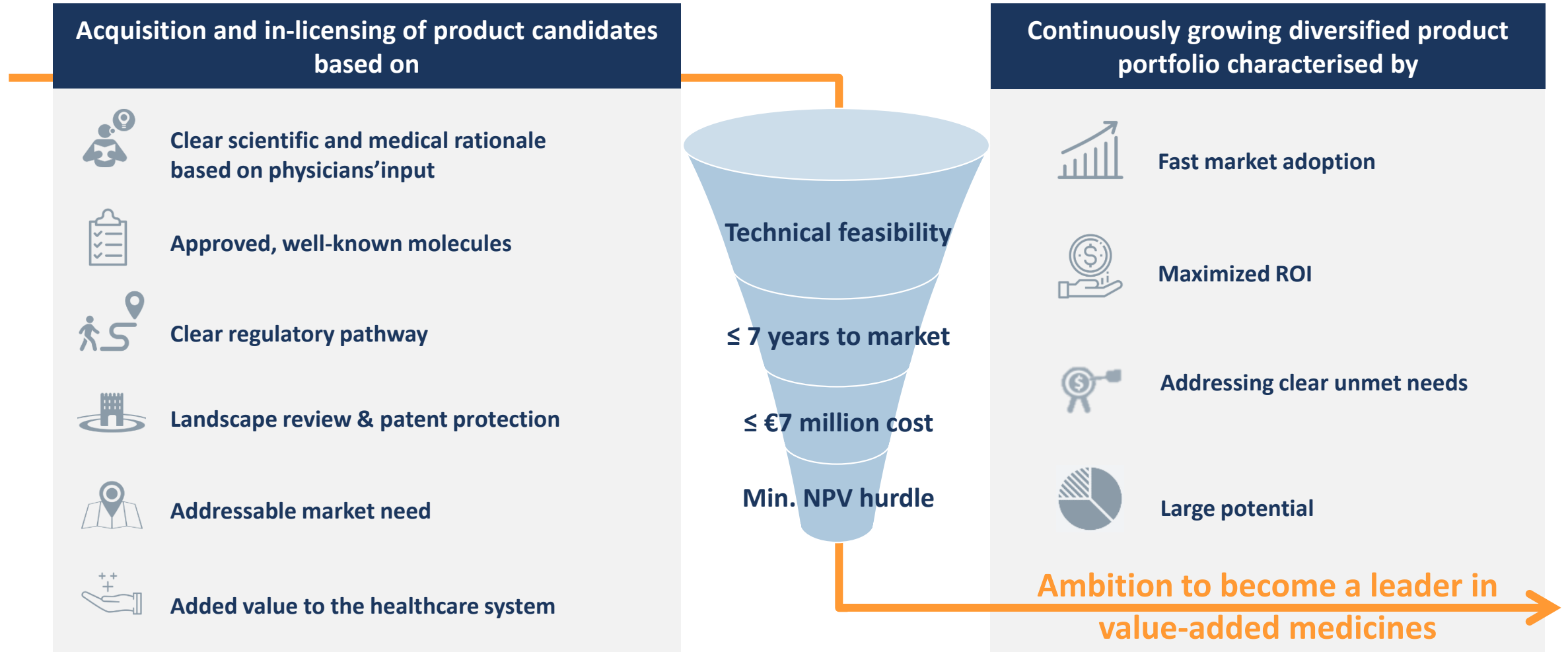


Putting Healthcare Needs at the Centre of Therapy Design

UNMET
MEDICAL
NEEDS



To Drive Continuous Growth and Create Shareholders' Value



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

Product	RoA	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Expected Launch
CARDIOVASCULAR (CV) PORTFOLIO			Maximum 7 years			
Sotalol IV	IV	Atrial fibrillation	Launched in U.S./partnered with AltaThera			'20 ¹ ✓
Dofetilide IV	IV	Atrial fibrillation				'23
Metolazone IV	IV	Congestive heart failure				'24
HY-073	IV	Acute coronary syndrome				'25
HY-074	IV	Acute coronary syndrome				'25
HY-075	Oral Liquid	Coronary heart disease				'24
OTHER VALUE-ADDED PORTFOLIO			Maximum 7 years			
Maxigesic® IV	IV	Post-operative pain	Licensed in >100 countries/partnered with AFT Pharmaceuticals			'20 ² ✓
TXA Acid RTU	IV	Excessive bleeding				'22
HY-038	IM	(Specific) deficiency				'23
HY-004	Oral Liquid	Specific dental indication				'24
Miconazole-DB	Topical	Severe and rVVC				TBD
Atomoxetine	Oral Liquid	ADHD				'23
HY-029	Oral Liquid	Viral infection				'24

¹ Under the new expanded label

² Marketing application to the U.S. FDA currently being prepared

Our two high barrier generic products, HY-016 and Fusidic Acid Cream have not been included

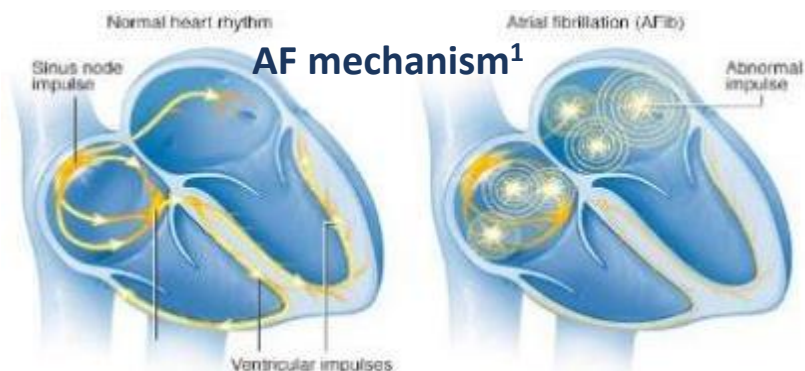
Intended to be commercialised by Hyloris

Intended to be commercialised with partner

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 2030**⁴
- 454,000**⁴ AF-related **hospitalisations** per year in the U.S.
- Majority** of hospitalised patients **receives** an **antiarrhythmic drug**

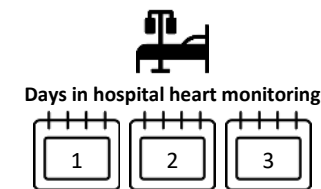
Current treatments could be improved

- Blood thinners
- Heart rate medicines
- Heart rhythm medicines**

LIMITATIONS

Rhythm control drugs have **life-threatening side effects**

FDA Oral sotalol carries black box warning

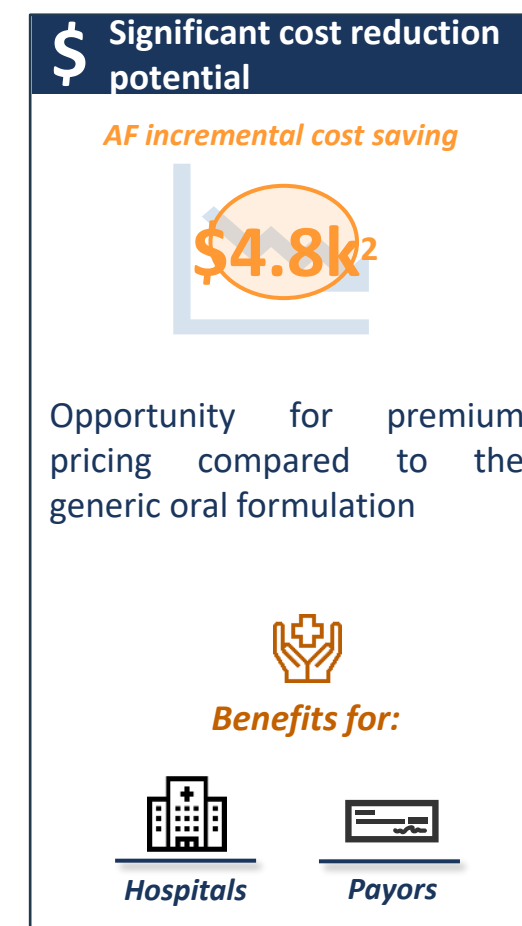
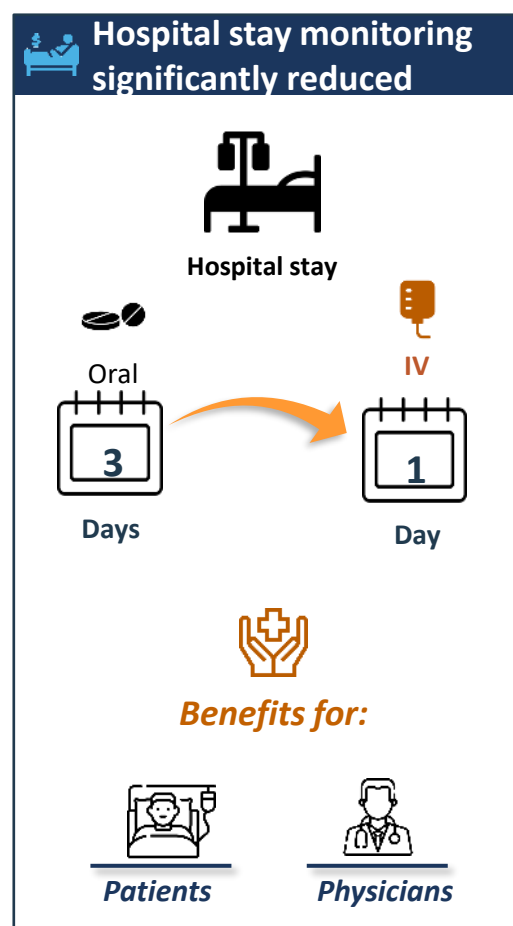
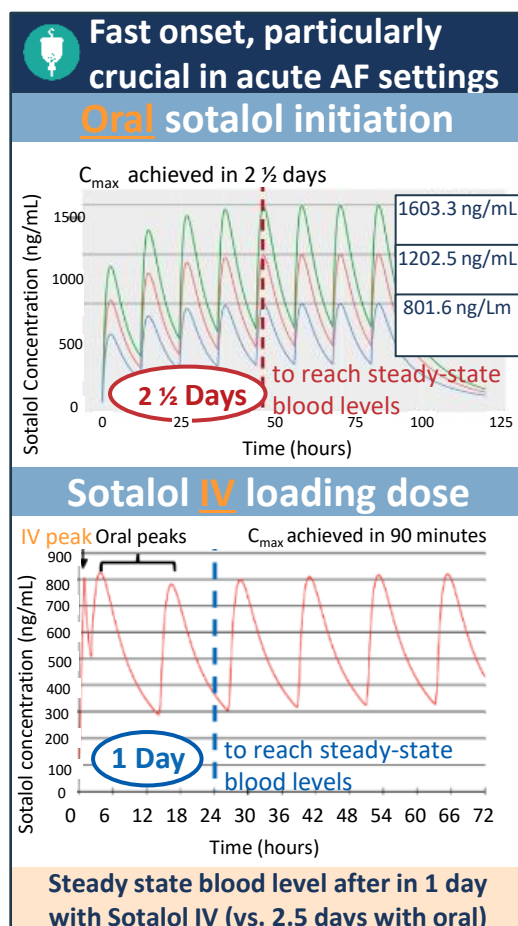


Incidence of *Torsade de Pointes* (abnormal heart rhythm – a serious side effect) is 0.5-5.8%⁵ on oral sotalol (dose-related)

Need for safer and more effective treatments

Sotalol IV Offers Benefits to Patients, Physicians and Payors

Commercial partner AltaThera expanded their sales force in 2021 to accelerate roll-out in the U.S.

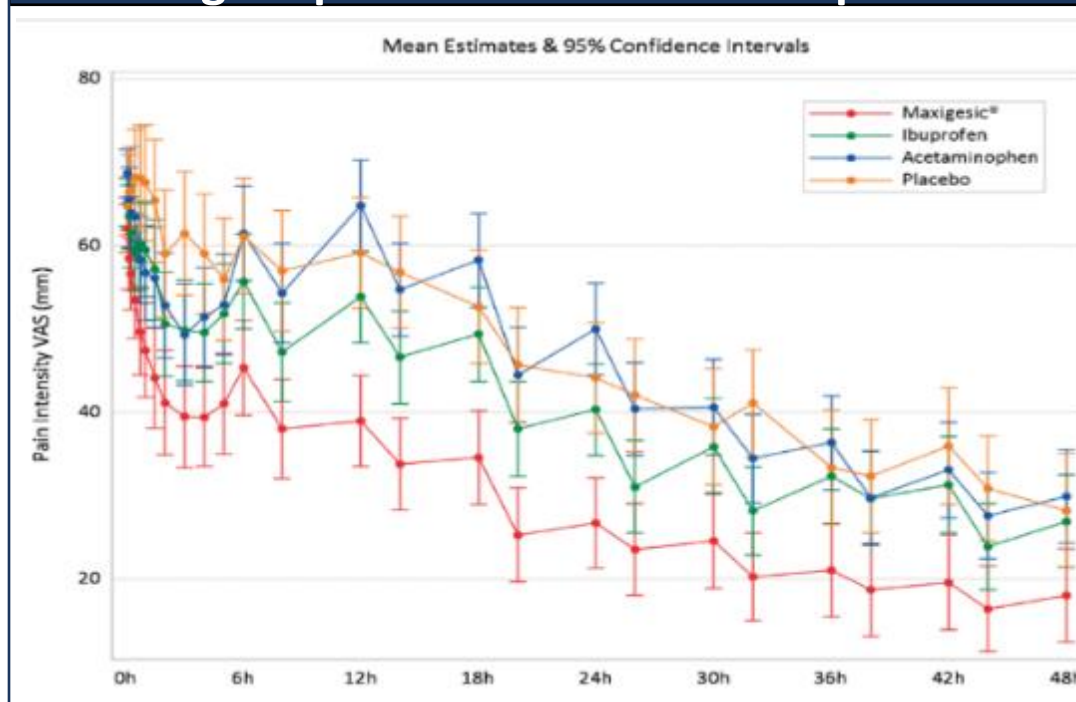


Maxigesic® IV has Potential to Combat the Opioid Crisis

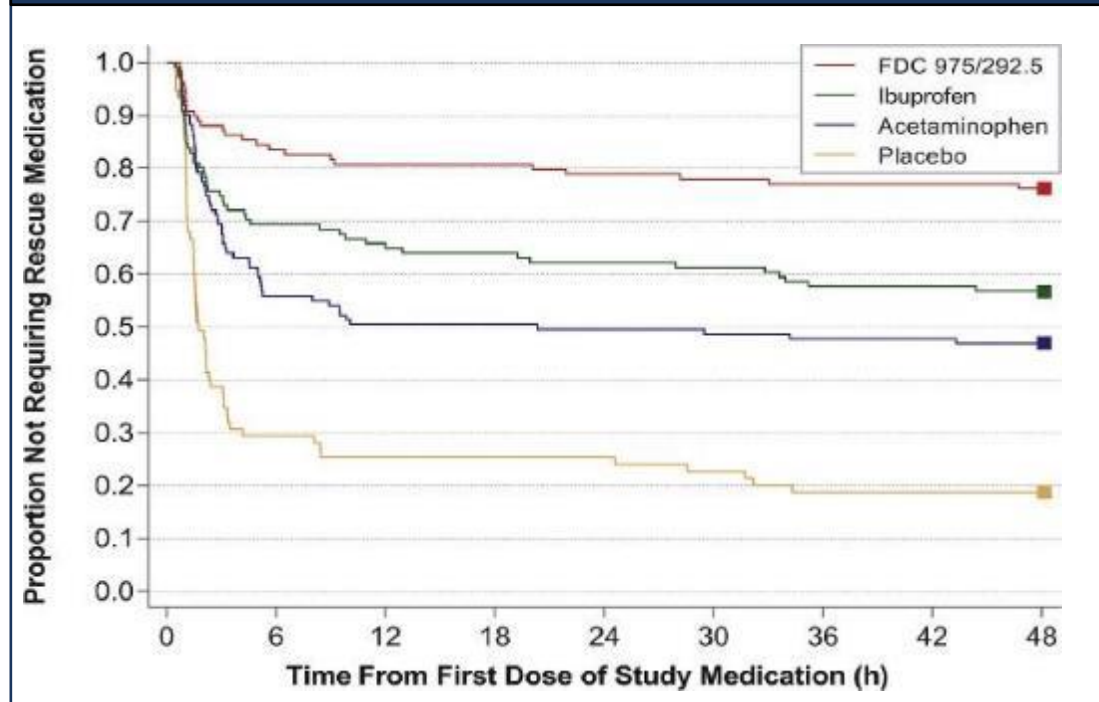
Maxigesic® IV: a novel combination of 1000mg paracetamol and 300mg ibuprofen solution for infusion



Phase 3 study results: Faster onset & higher pain relief at each time point¹



Phase 3 study results: Opioid rescue medication: less used & used later²

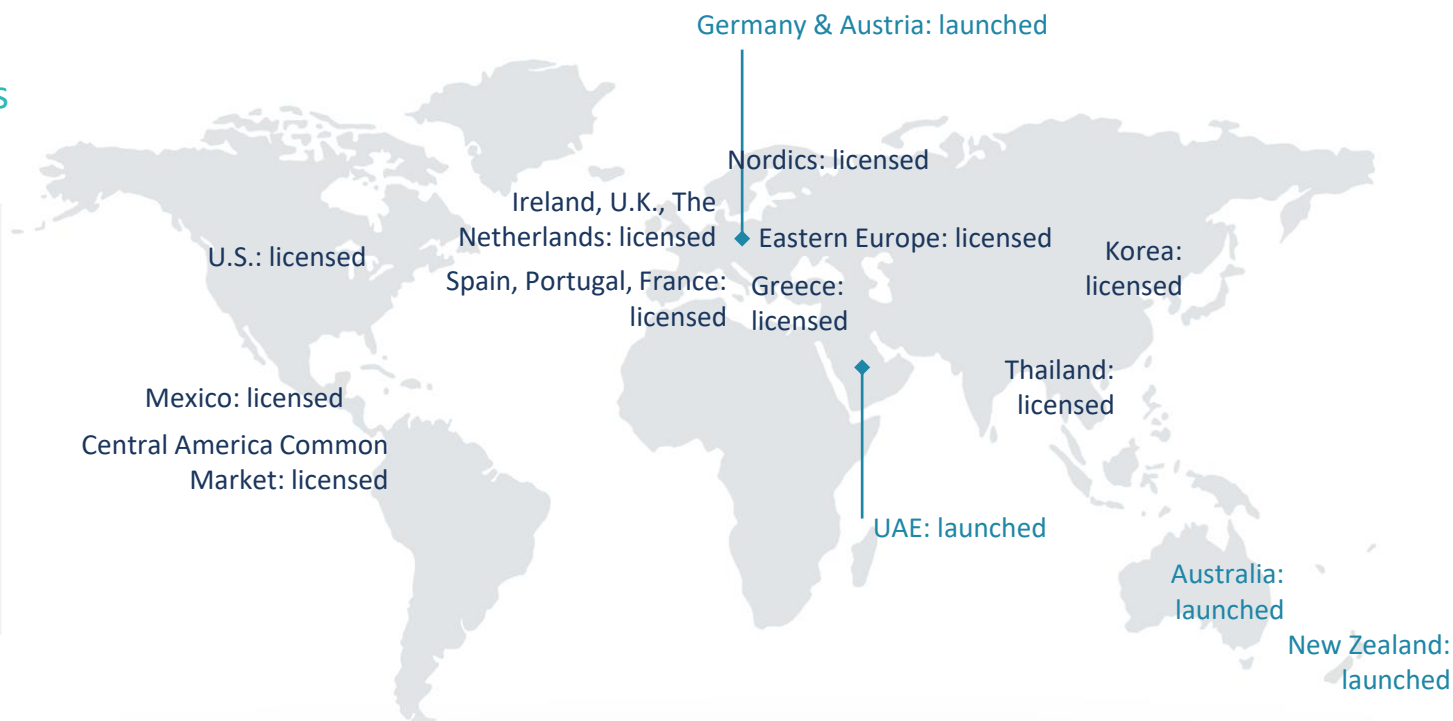


Maxigesic IV: Significant Growth of Commercial Footprint



+ strong local distribution partners

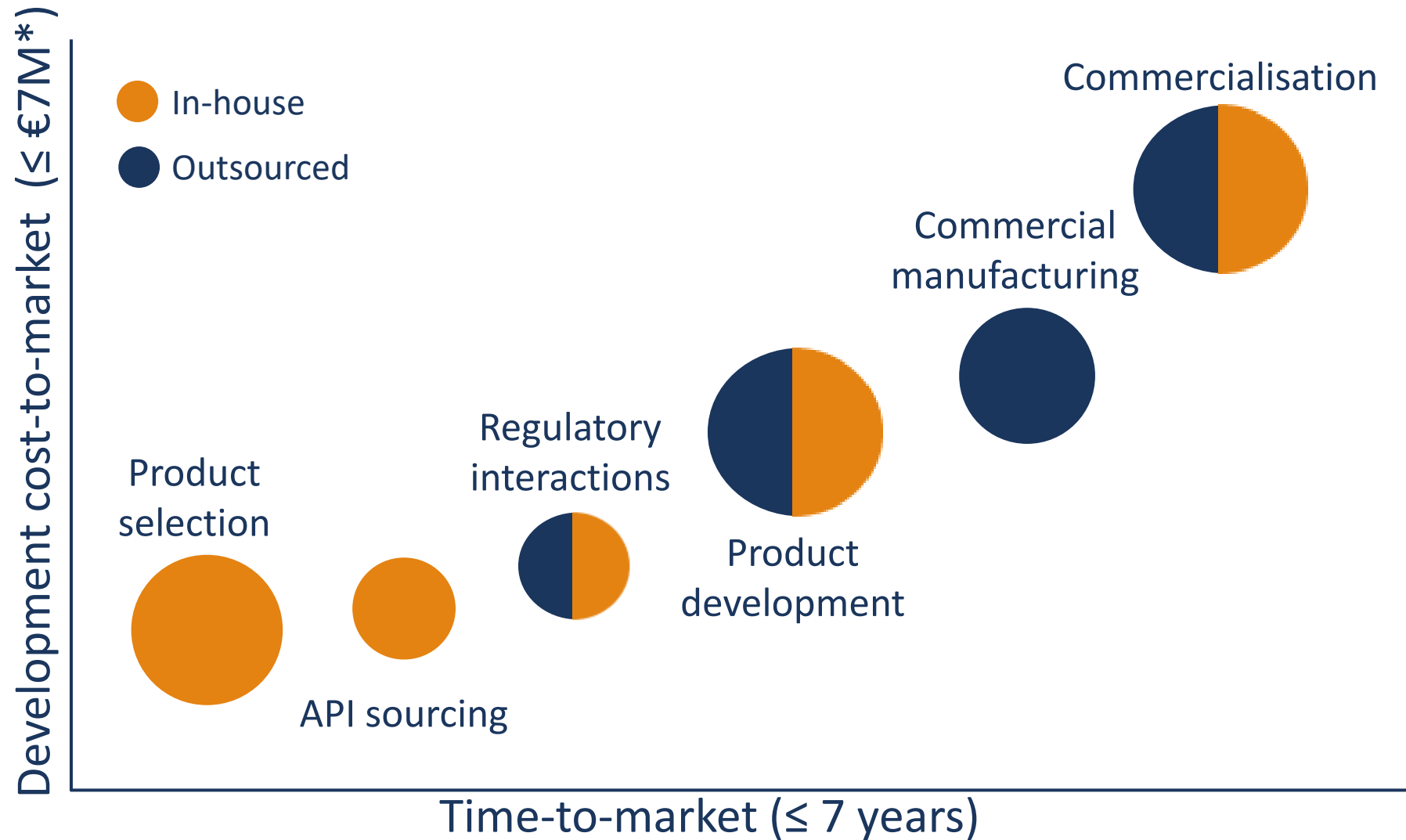
Countries	4 August 2021	31 March 2020
Licensed	100+	80
Registered	24	3
Launched	5	-



2021 year-to-date achievements:

- Launches in Germany and Austria
- Expansion of license agreement in South America
- License agreement with Hikma in the U.S.
- Europe: expansion of existing license plus additional licenses
- Patents granted across multiple jurisdictions
- Submission of NDA to the FDA ongoing

Powerful R&D Engine: Leveraging our Network of Partners



Flexible, Hybrid Earnings and Commercialisation Model

1. CARDIOVASCULAR FRANCHISE

- Lean speciality U.S. sales team targeting 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, commercialised by our partner AltaThera

2. OTHER 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 a small majority of net sales realised by partners

Launch of Own IV Cardiovascular Portfolio in the U.S.

- Build the right commercial team and manufacturing capabilities
- Focus on specialist cardiologists employed by hospitals in key sales territories



Robust IP Portfolio: Extended Period of Exclusivity



- Broad portfolio: exclusivity through 2039 in key pharma markets across the globe
- Wide range of protection: dosages, formulations, indications, methods for preparing a composition, manufacturing methods
- Additional layer of protection: knowhow, technological innovation and in-licensing

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%)

ⁱ For the period 1 January to 30 June

Key Factors
<ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> ▪ 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)

Core Assets: Anticipated Value Inflection Milestones in 2021

Clinical



HY-004: start Phase 1

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

Regulatory



Tranexamic Acid RTU: marketing application in U.S.

- Maxigesic IV: marketing application in U.S.
- Maxigesic IV: additional approvals in key markets

Commercial



Partnership Purna Female Healthcare



Maxigesic IV: distribution agreements in EU and S. America



Maxigesic IV: agreement with Hikma in the U.S.



Maxigesic IV further roll-out

- Sotalol IV U.S. roll-out
- Commercial partnership(s)
- Out-licensing agreement(s)
- Expand R&D pipeline with 3 new 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, value-added 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

Questions?



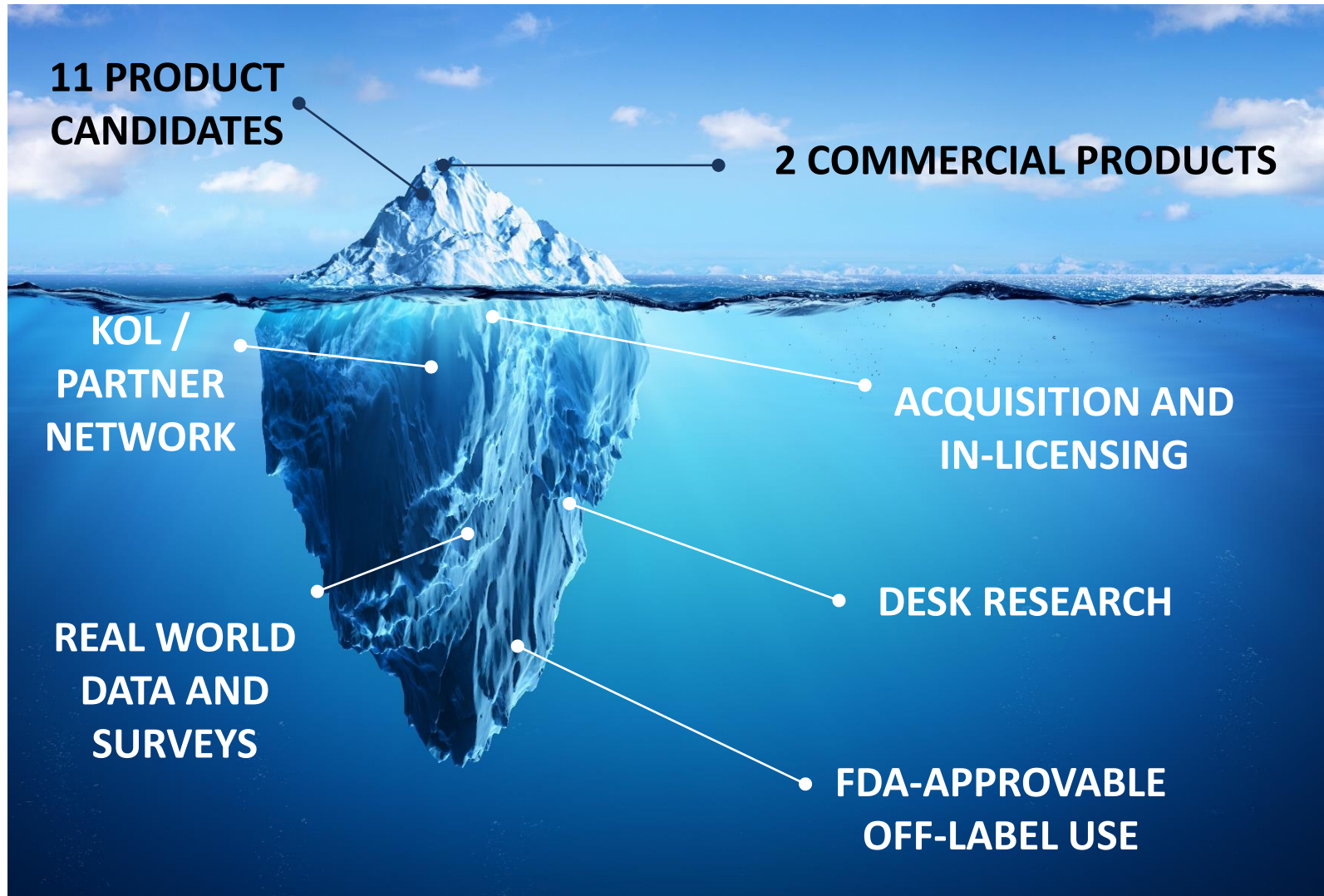
investorrelations@hyloris.com



Addendum:

- Background Info Product Pipeline
- 505(b)(2) Landscape
- Shareholders and Corporate Info

Sourcing Product Opportunities Via Multiple Channels



A photograph of a man with a shaved head and a goatee, wearing a blue t-shirt, carrying a young child with curly hair on his shoulders. The child is wearing a grey shirt and orange pants. They are in a lush green forest with tall trees and dense foliage in the background. The man is looking up and smiling, and the child is also smiling at the camera.

Selected Case Studies



Unmet Needs in Severe and rVVC



Pain,
depression, shame,
isolation, fear

Current medicines have limitations



Side effects – Not efficacious in rVVC

Vulvovaginal candidiasis (VVC)

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

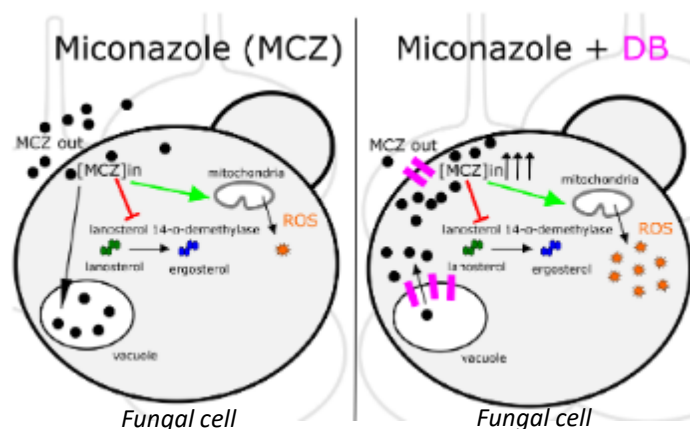
WELL-KNOWN ANTIMYCOTIC
MICONAZOLE (MCZ)
Prevents growth of fungus

REPURPOSED MOLECULE
DOMIPHEN BROMIDE (DB)
Potentiator for fungicidal activity

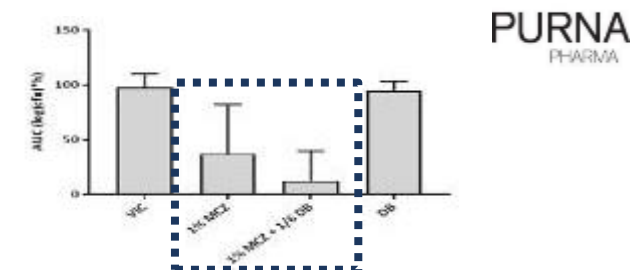
**DUAL
FUNGICIDAL
ACTIVITY**

Domiphen-bromide: anti-septic; identified as a miconazole potentiator through drug screening of large drug repurposing library

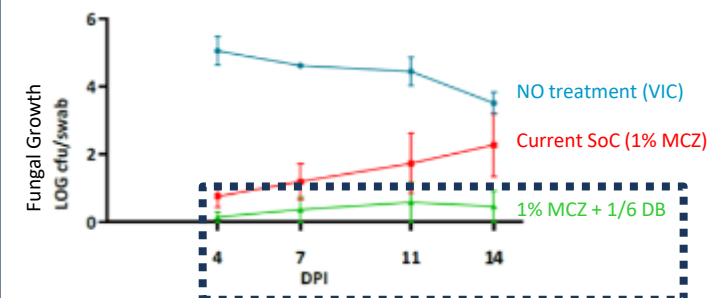
LOCAL TOPICAL FORMULATION



Unique mode-of-action



Infection expressed in area under the curve after 4 days of treatment and 10 days of follow-up in function of different formulations



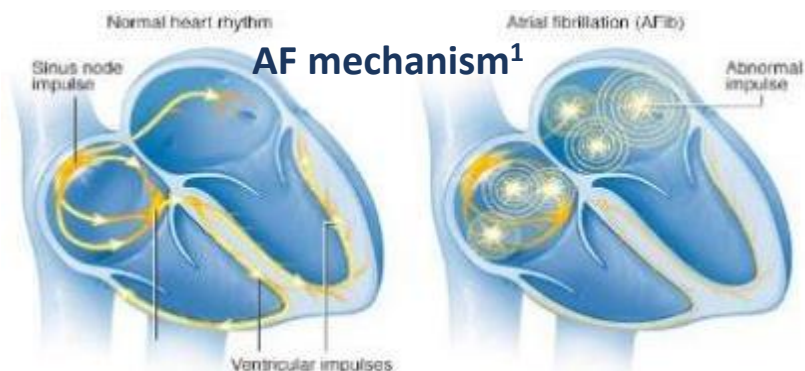
Intravaginal fungal burden in log colony forming units (cfu) per swab during different therapies expressed in days post-infection (DPI)

Domiphen Bromide significantly enhances Miconazole efficacy *in vivo*

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- 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 2030**⁴
- **454,000**⁴ AF-related **hospitalisations** per year in the U.S.
- **Majority** of hospitalised patients **receives** an **antiarrhythmic drug**

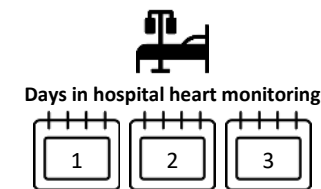
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- Heart rate medicines
- **Heart rhythm medicines**

LIMITATIONS

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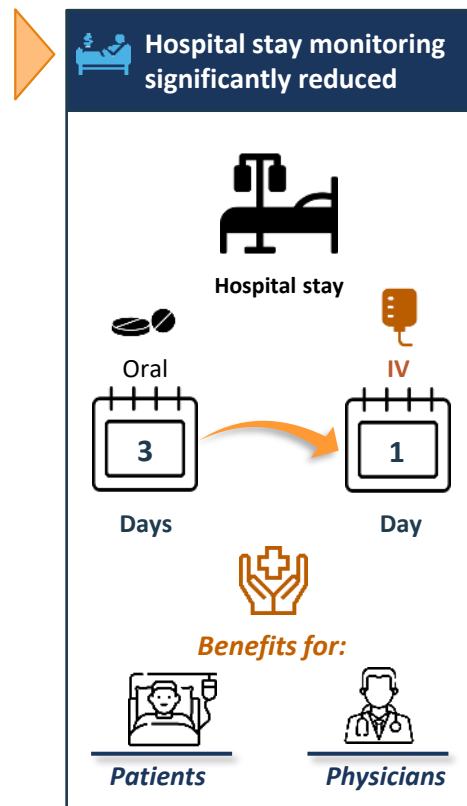
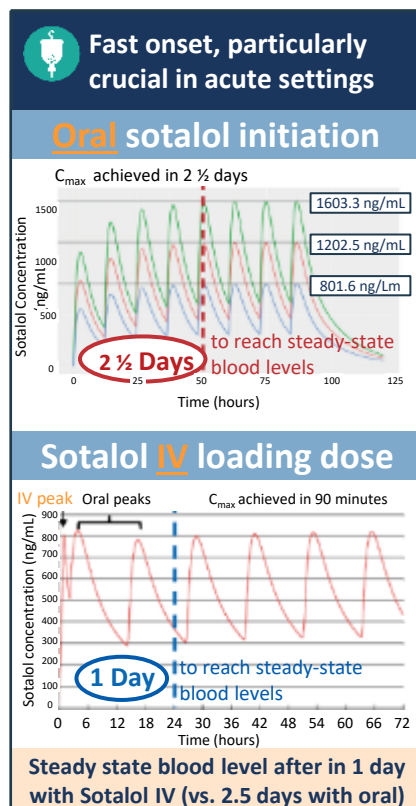
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Need for safer and more effective treatments

Sotalol IV Offers Benefits to Patients, Physicians and Payors



Approval Sotalol IV New Label (label extension)

NEW SOTALOL IV™
sotalol hydrochloride injection
10mL vial (15mg/mL)

New Dosing Information

American Heart Association

March 2020: FDA approval label extension to include the **initiation of loading** on Sotalol IV in patients who are prescribed oral sotalol and for **dose escalation** for chronic administration of an increased dose of oral sotalol

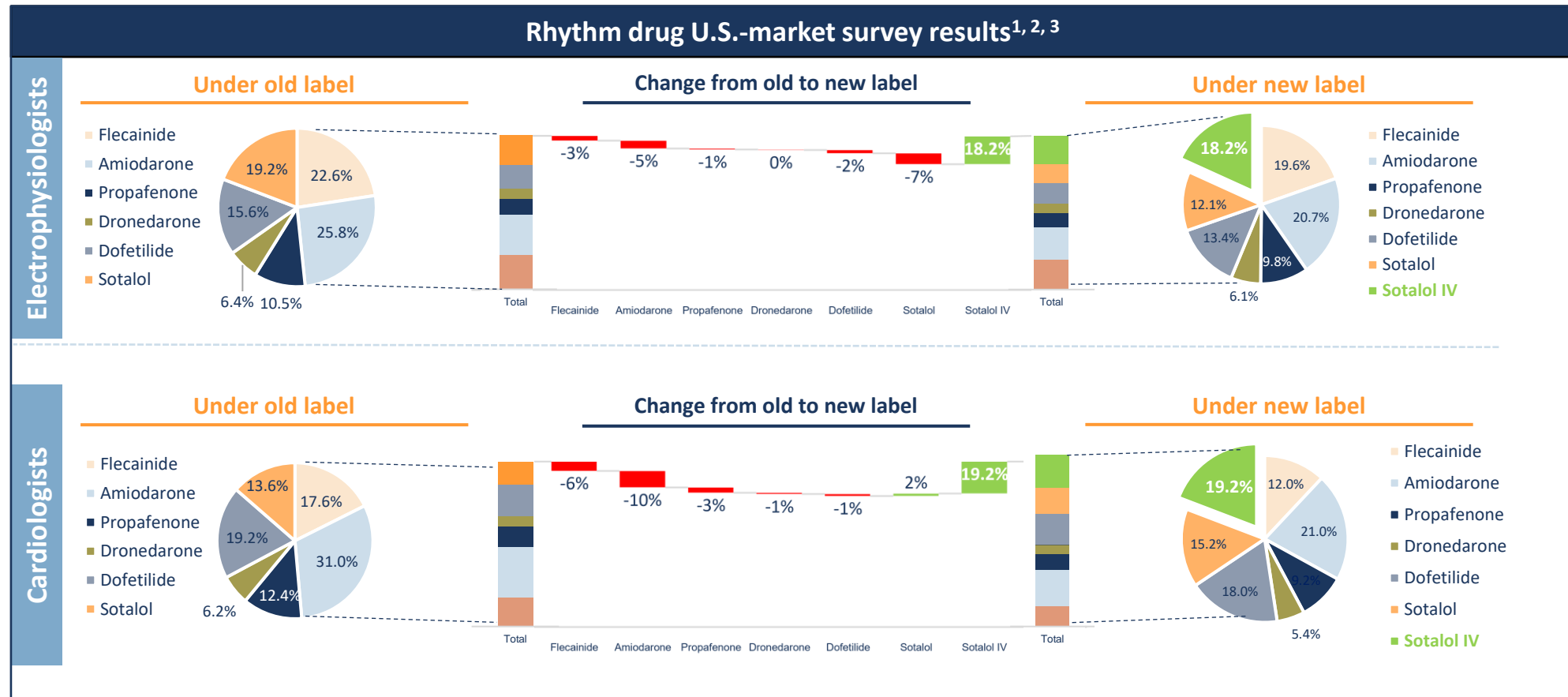
Commercialisation in the U.S. by Hyloris' partner

ALTATHERA PHARMACEUTICALS

Hyloris eligible to receive from its partner AltaThera:

- 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 \geq \$20M

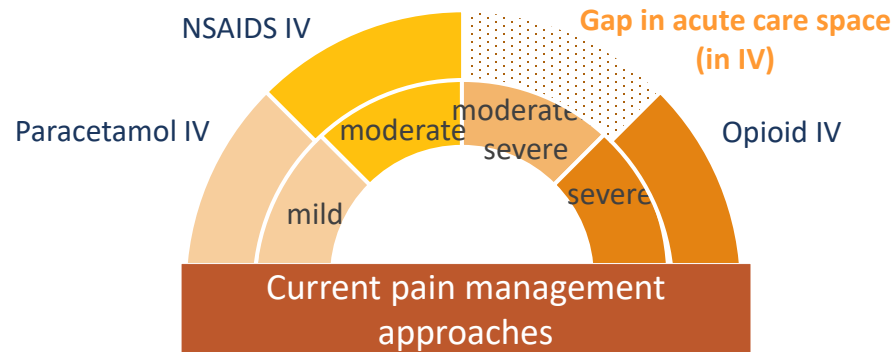
Sotalol IV New Label, Strong Support From Medical Community



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

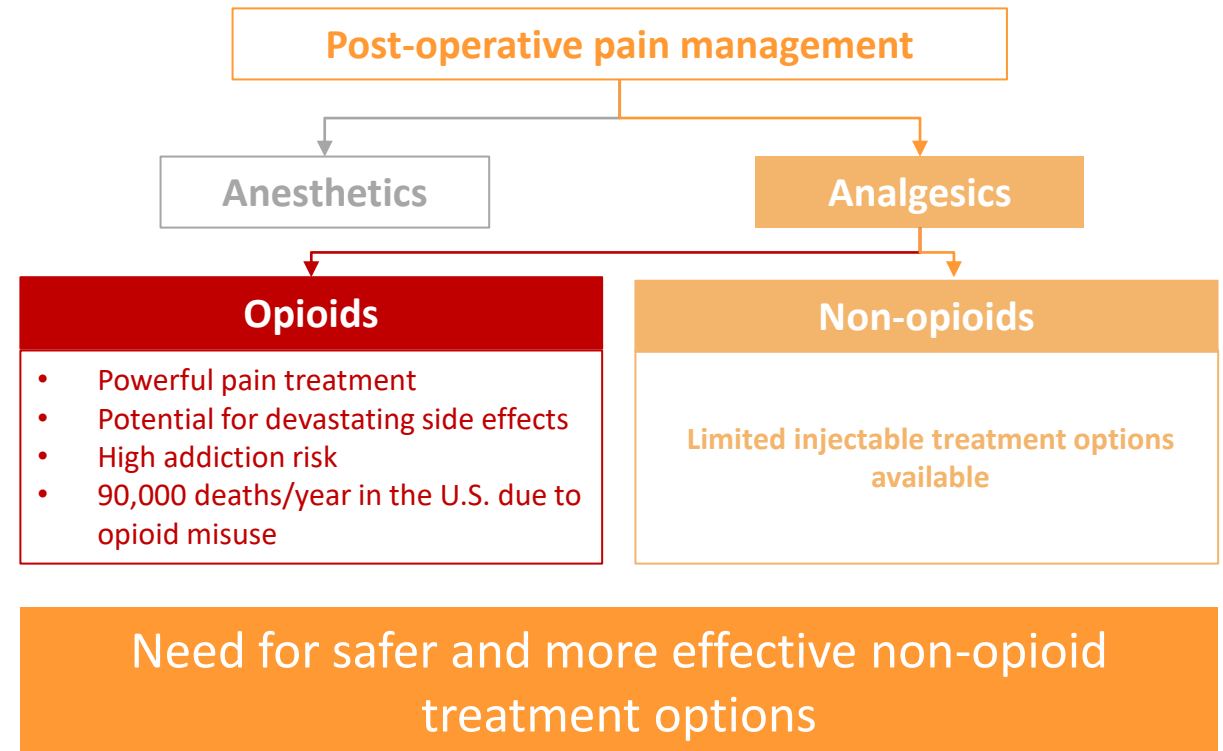
Gap in moderately severe pain care space



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



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

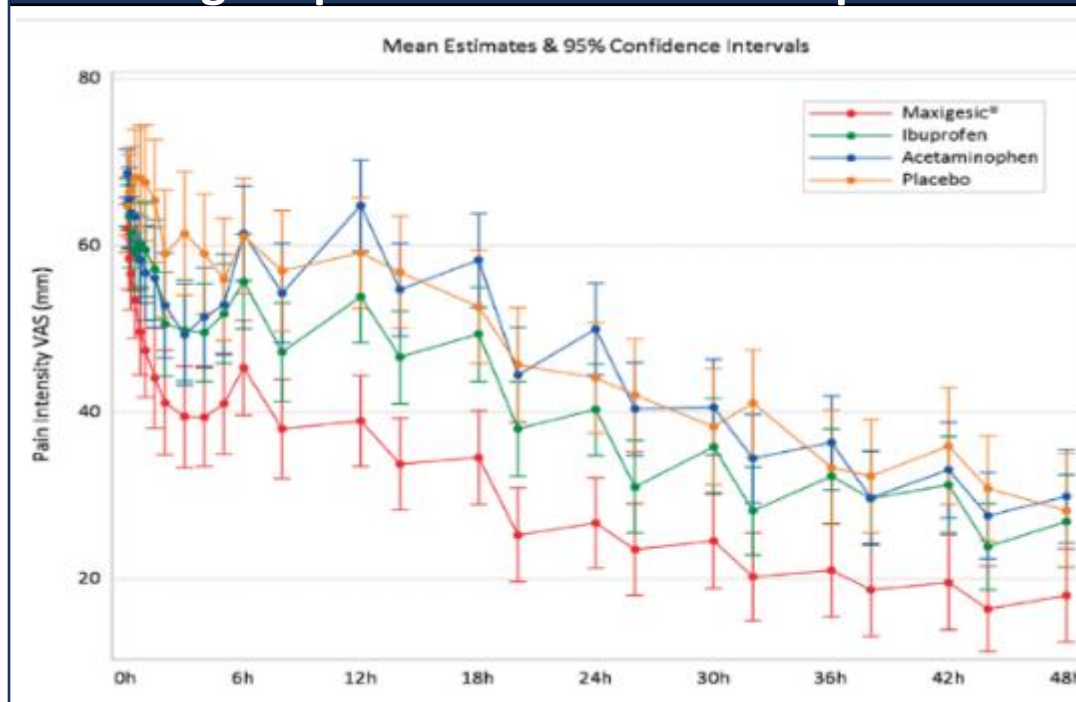


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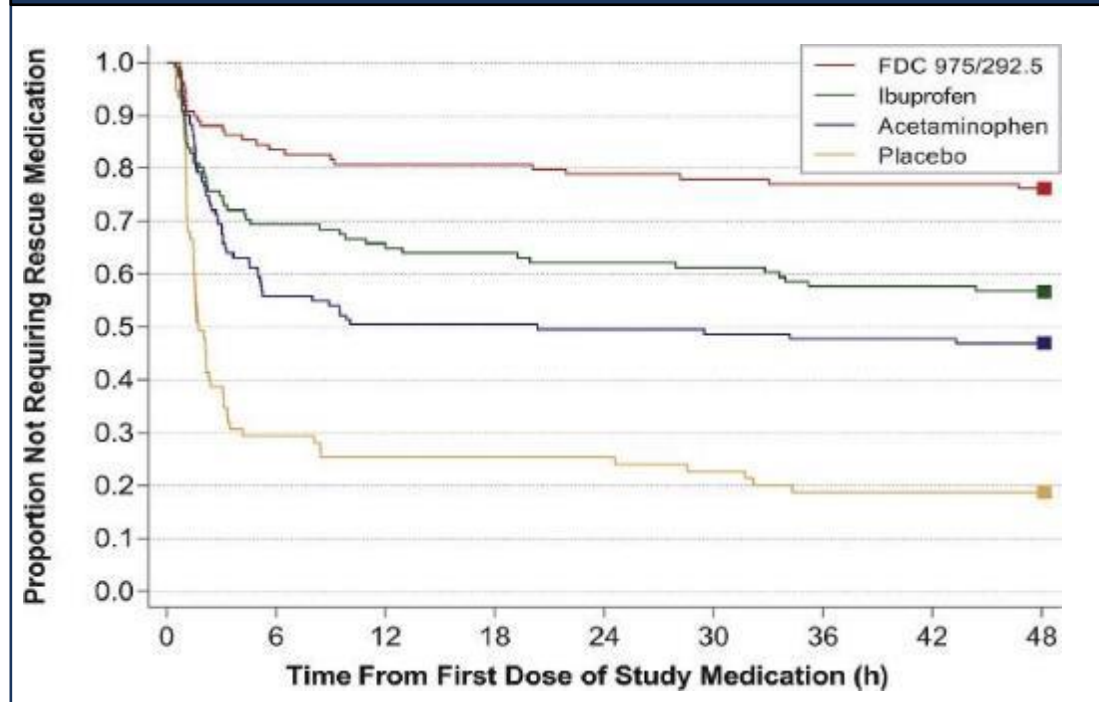
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Phase 3 study results: Faster onset & higher pain relief at each time point¹



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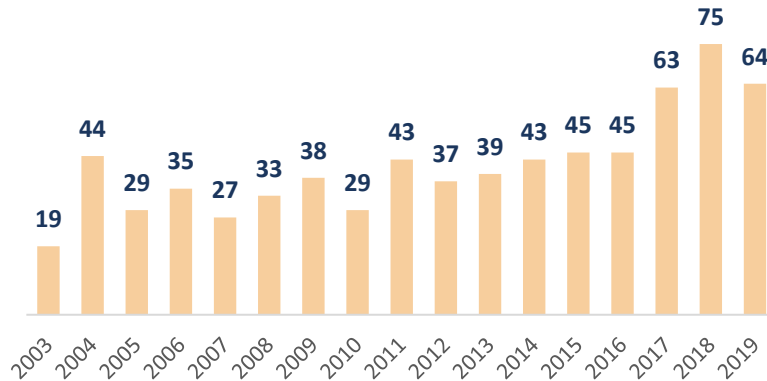
A person is running away from the camera on a wooden boardwalk that stretches into the distance. The scene is set at sunset, with a bright sun low on the horizon to the right, creating a strong lens flare and casting a warm, golden glow over the entire scene. The sky is filled with soft, wispy clouds. On either side of the boardwalk, there are lush green plants and some small pink flowers. The person running is wearing a light-colored long-sleeved shirt, light-colored leggings, and running shoes.

Market Landscape Value-Added 505(b)(2) Medicines



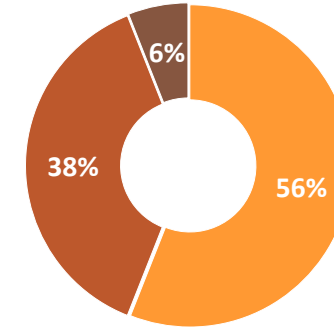
Increasing Use of 505(b)(2) Pathway in the Industry

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



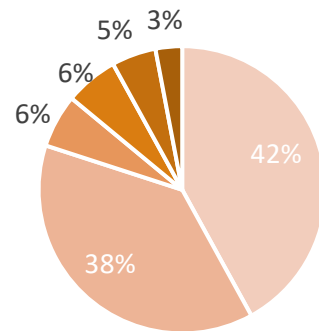
*Repurposed drugs have 150% higher chance of success to reach the market compared to NCEs**

NDA approvals in 2019 by pathway



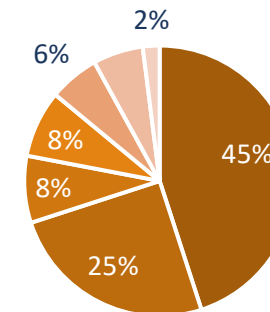
■ 505(b)2 approvals ■ 505(b)1 approvals ■ Undetermined

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



■ Injection ■ Oral ■ Ophthalmic ■ Topical ■ Nasal ■ Other

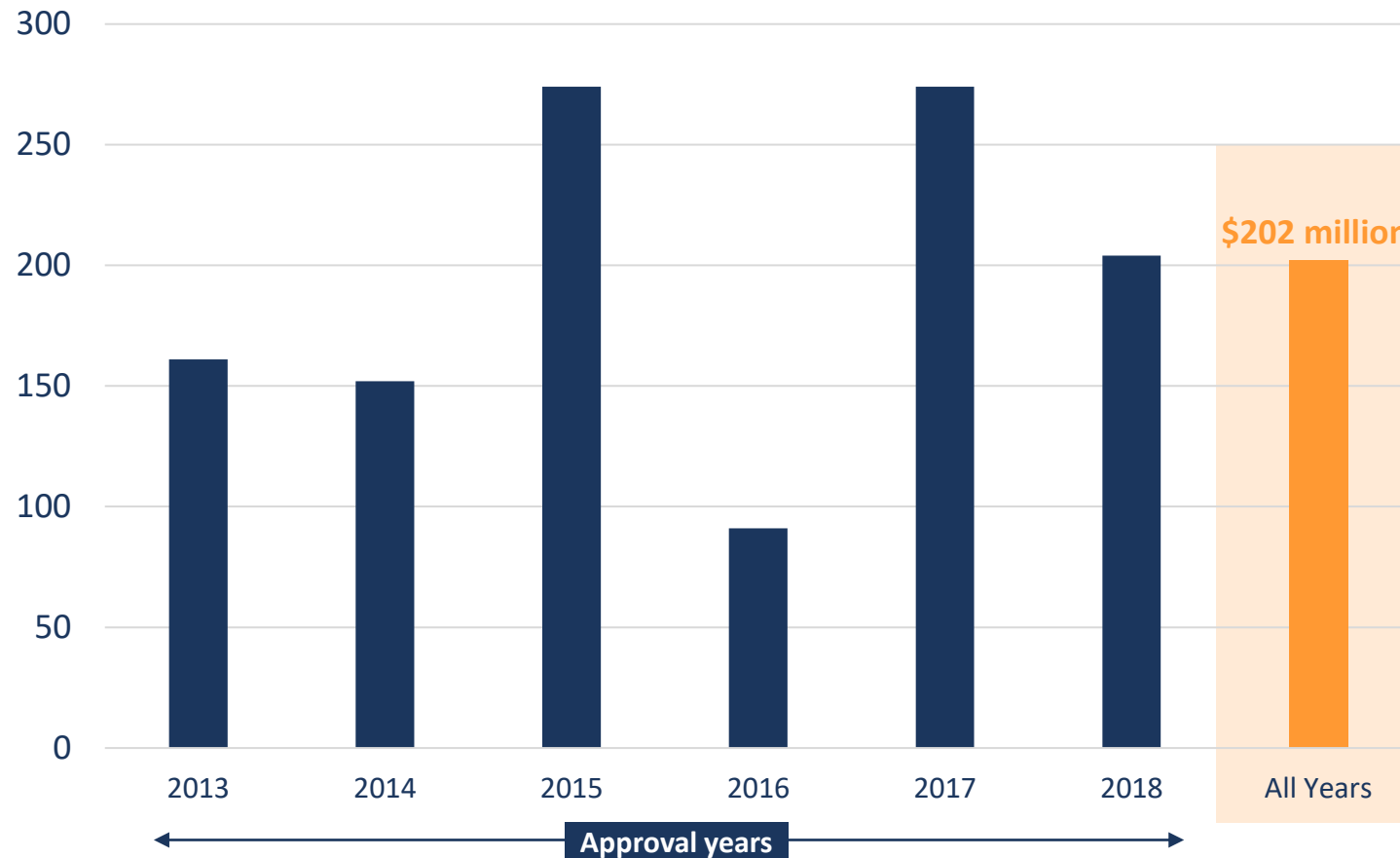
505(b)2 approvals by type



■ New formulation or manufacturer ■ New dosage form
■ New combination ■ New molecular entity
■ New active ingredient ■ Unknown
■ Already marketed

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)



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

	Product name	What changed in 505(b)(2)	Indication	Company	2019 Sales
REFORMULATED	Avycaz	New combination	Complicated intra-abdominal and urinary tract infections	Allergan (AbbVie)	\$117M
	Belbuca	New dosage form	Chronic pain	BioDelivery Sciences	\$98M
	Vasostriect	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
REPURPOSED	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

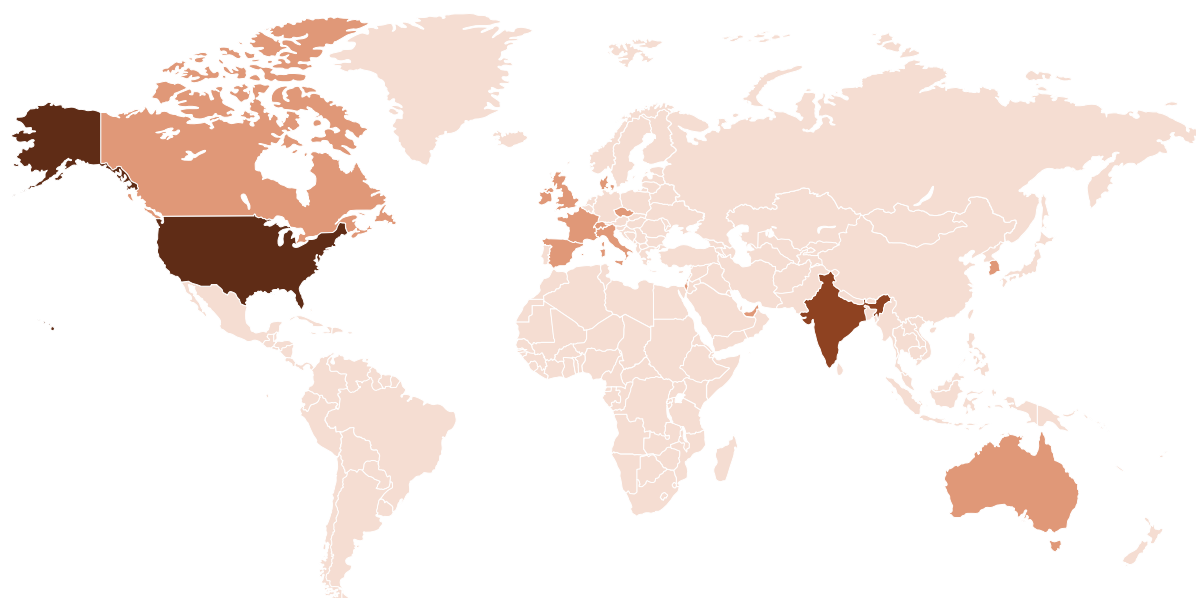
^b Sales in 2008 prior introduction of Thalomid analogue drug Revlimid (Celgene)

^c Sales in 2010, prior to generic entrants

^d Sales in 2013, prior to biosimilar entrants

Value-Added 505(b)(2) Landscape

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













505(b)(2) (tentative) approvals 2015-2018

0 1 15 150

Top-3 applicants 2015-2018:

Country	Company	# of 505(b)(2) approvals
		12
		7
		4

Select Listed Competitors:

Country	Company	# of 505(b)(2) approvals 2011 - 2019	Formulation route
		3	IV (infusion)
		2	Injection, injectable emulsion
		1	RTU injectable
		1	Injectable suspension
		Acquired a portfolio of 505(b)(2) product candidates from Coeptis	

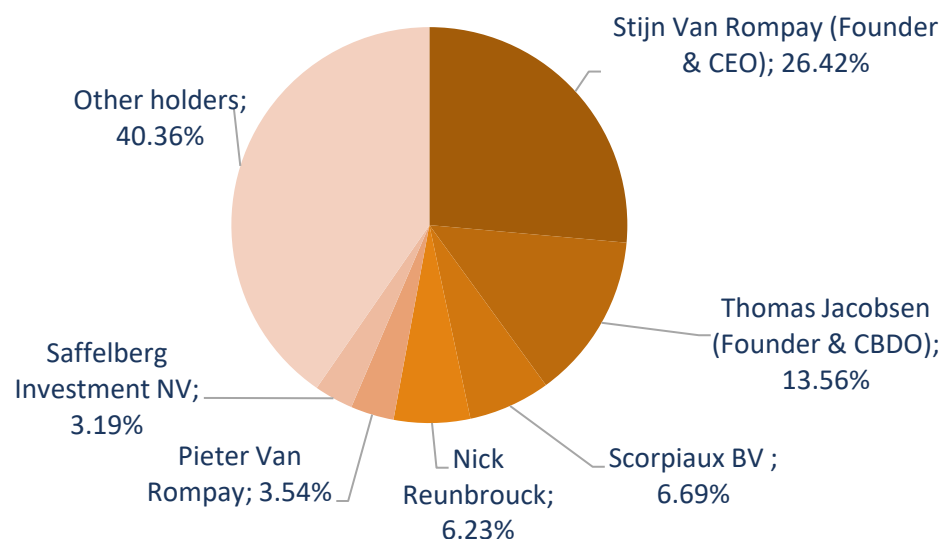


Shareholders and Corporate Information



Shareholders' Information

Major shareholders



Bank	Analyst	Rating
KBC Securities	Lenny Van Steenhuyse	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

€53.47 million

Share capital (excluding share premium)

€129,163.16

Total number of outstanding voting rights (= denominator)

25,832,632

Total number of securities carrying voting rights not yet issued

1,908,000

Founders with Impressive Track Record and Industry Expertise

2005



Founded by Leon & Stijn Van Rompay
Generics and Pharmacy Sales & Devices

acquired for €218M

by



2013



Founded by Stijn Van Rompay & François Fornieri
Women's Health

acquired for up to \$305M

by



2015

Uteron shareholders

sold Estelle® for >€250M

to



2016

Novalon

Co-founded by Stijn Van Rompay
Controlled Release Implants

50% stake acquired for €9.4M

by



2017



Alter Pharma

Founded by Stijn Van Rompay & Thomas Jacobsen
Generics and Pharmacy Sales Products

partially acquired

by



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

 <p>Stijn Van Rompay - Chief Executive Officer</p> <ul style="list-style-type: none">• >20 years of experience in leadership positions in pharma• Co-founded, managed, and exited multiple pharma companies <p>    </p>	 <p>Thomas Jacobsen - Chief Business Development Officer</p> <ul style="list-style-type: none">• >20 years of experience in pharma• Expertise in operational management, and business & product development <p>   </p>
 <p>Dietmar Aichhorn - Chief Operating Officer</p> <ul style="list-style-type: none">• >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 <p>   </p>	 <p>Chief Financial Officer</p> <p><i>Active search ongoing</i></p>
 <p>Koenraad Van der Elst - Chief Legal Officer</p> <ul style="list-style-type: none">• >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 <p>  </p>	

Board of Directors



Stefan Yee

Chairman, Non-Executive Director



Marc Foidart⁴

Independent Director



Stijn Van Rompay¹

Chief Executive Officer, Executive Director



Carolyn Myers

Independent Director



Thomas Jacobsen²

Chief Business Development Officer, Executive Director



James Gale

Independent Director



Leon Van Rompay³

Non-Executive Director



Chris Buyse⁵

Independent Director

