

**Reformulating the Future** 

# 2021 Half-Year Results 4 August 2021

### **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, 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.



## Agenda for Today's Call

- Hyloris: geared for growth
- Business update year-to-date
- Financial results first half 2021
- Outlook for the remainder of the year
- Q&A



### Rethinking, Reinventing, Optimising Existing Medications

#### To improve overall therapy outcomes

#### REFORMULATING



# Changing dose or route of administration

#### REPURPOSING/ REPOSITIONING



#### Finding new indications

For the benefit of patients, physicians, payors



### Faster Innovation at Considerably Lower Costs and Risks

Discovery, pre-	Regulatory
clinical Clinical Development	submission &
development	decision

15 YEARS ON AVERAGE \$1.3 BILLION COSTS ON AVERAGE



Traditional R&D model: Wouters *et al*, Journal of the American Medical Association, 2020 \* Hyloris budget

"Traditional Pharma-Biotech Model"

### 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



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

Product	RoA	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing		ected unch
CARDIOVASCU	ILAR (CV) PORTF	OLIO		Maximum 7 yea	ars	\ 	$\rangle$
Sotalol IV	IV	Atrial fibrillation	Launche	d in U.S./partnered with A	AltaThera		'20 <sup>1</sup>
Dofetilide IV	IV	Atrial fibrillation				۲	'23
Metolazone IV	IV	Congestive heart failure				۲	'24
HY-073	IV	Acute coronary syndrome				<b>_</b>	'25
HY-074	IV	Acute coronary syndrome					'25
HY-075	Oral Liquid	Coronary heart disease				۹	'24
OTHER VALUE-	ADDED PORTFO	LIO		Maximum 7 ye	ars		$\rangle$
Maxigesic <sup>®</sup> IV	IV	Post-operative pain	Licensed in >100 c	ountries/partnered with A	NFT Pharmaceuticals		'20 <sup>2</sup> 🗸
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				۲	'23
HY-029	Oral Liquid	Viral infection				<b></b>	'24

<sup>1</sup> Under the new expanded label

<sup>2</sup> Preparations to submit the NDA to the FDA ongoing

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

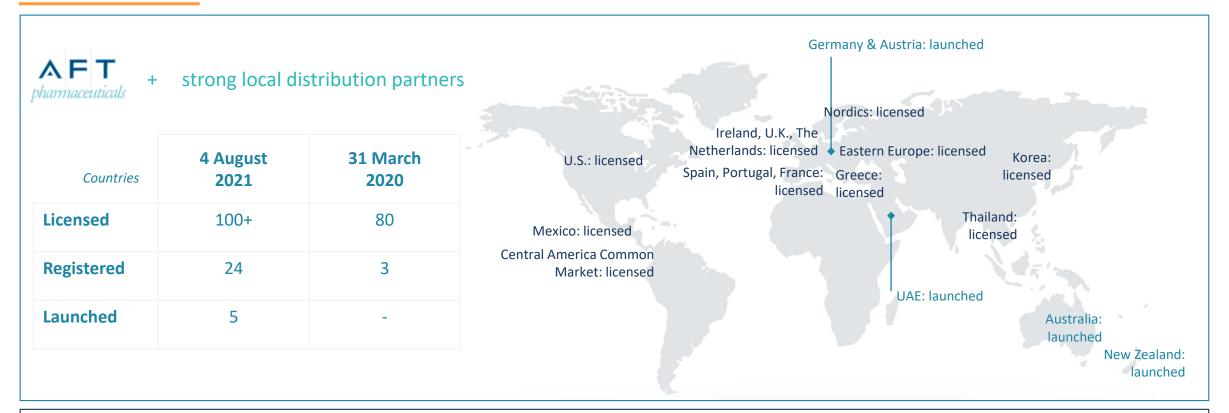
EUTICALS

Intended to be commercialised by Hyloris

Intended to be commercialised with partner

IV: intravenous ; RTU: ready to use; IM: intra-muscular

### Maxigesic IV: Significant Growth of Commercial Footprint



#### Year-to-date achievements:

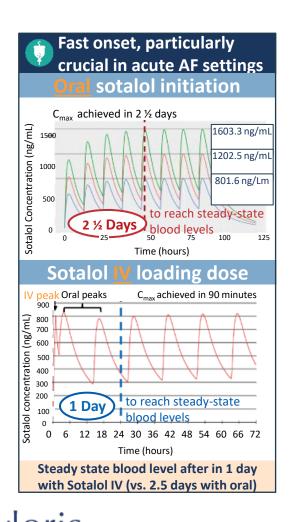
- Launches in Germany and Austria
- Expansion of license agreement in South America
- License agreement with Hikma in the U.S.

- Europe: expansion of existing license plus additional licenses
- Patents granted across multiple jurisdictions
- Preparations to submit an NDA to the FDA progressing well

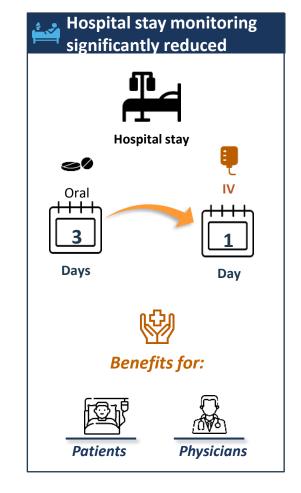
### Sotalol IV: Expanded Sales Force to Foster Growth

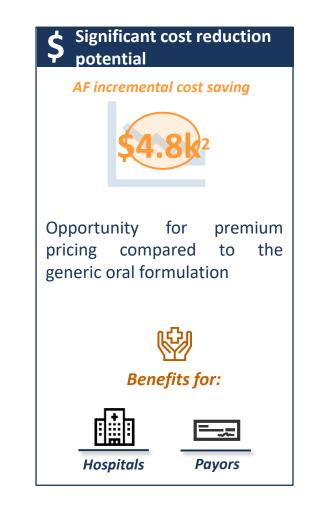
• Expansion of AltaThera's sales force to accelerate roll-out in the U.S.

PHARMACEUTICALS



EUTICALS





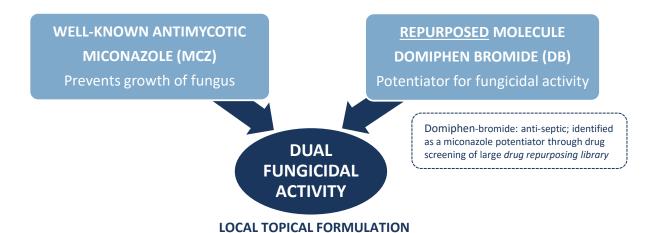
### Unique Partnership with Purna Female Health (PFH)

#### To address unmet needs in severe and recurring VVC

- Infection caused by *Candida* sp. yeast
- 10% of all women globally
- No effective treatments due to drug-resistant biofilm of yeast
- \$14.4 Bn annual estimated economic burden

UTICALS





Milestone-related investments of up to €4.27M in PFH – of which €1.27M paid at signing

20% ownership of PFH – eligible to receive up to 45% of net profits generated by PFH



### Past & Future Obligations towards Alter Pharma Group Waived

Products	Terms	Results
• Maxigesic <sup>®</sup> IV	• €5.25M <u>one-time lump sum</u> payment	<ul> <li>Acquires all royalty rights for Maxigesic IV (partnered with AFT)</li> </ul>
• HY-075	• Potential €500K future earn-out	<ul> <li>Assumes sole responsibility for HY- 075 and HY-038; future profit split</li> </ul>
<ul><li>HY-038</li><li>Fusidic Acid Cream (Canada)</li></ul>	<ul> <li>Hyloris CEO and CBDO resigned from Alter Pharma's Board of Directors</li> </ul>	<ul> <li>Obtains a higher profit margin for Fusidic Acid Cream</li> </ul>

 Resolving potential risk of conflict of interest risk and related-party transactions

#### Financially attractive – business further streamlined – focus on execution



### Additional Achievements Year-to-Date

### **R&D** and Regulatory

- Phase 1 start HY-004, an oral solution for use in specific dental procedures
- Marketing application filed in U.S. for Tranexamic Acid RTU discussions ongoing to address questions raised by FDA

#### Corporate

- Strengthened the organisation with key hires and lab space
- Unanimous adoption of all resolutions at 2021 AGM



### 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 <sup>i</sup>	(10,934)	66,578	NA
Cash and cash equivalents	53,465	66,783	(20%)

<sup>i</sup> 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)

### Core Assets: Anticipated Value Inflection Milestones in 2021

#### Clinical

- 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

• Maxigesic IV: marketing application in U.S.

#### Commercial

- Commercial partnership(s)
- In-licensing agreement(s)
- Out-licensing agreement(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 3 new candidates still expected before end 2021





## Q&A



## Contact us: investorrelations@hyloris.com