

Hyloris

7 September 2023

# H1 results & business outlook



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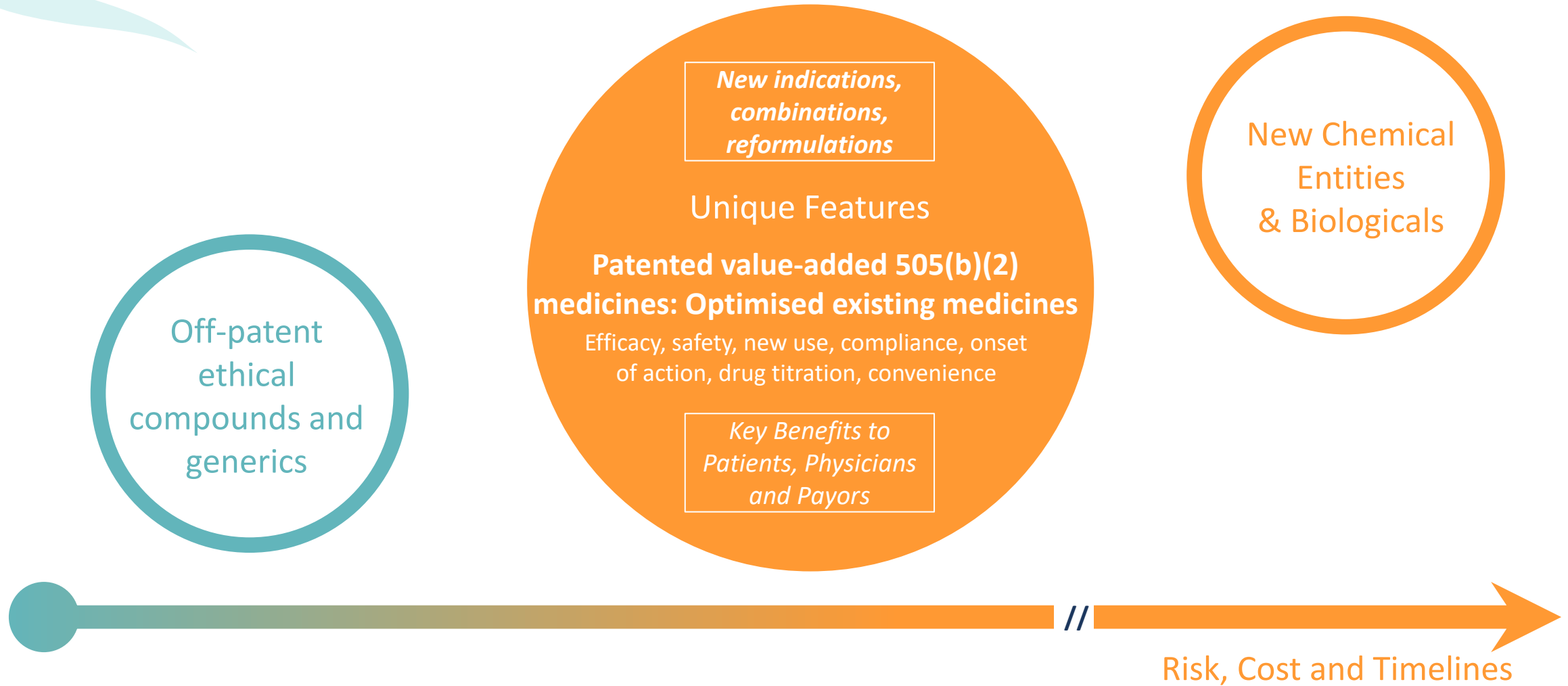
# Agenda for today's call

- Company strategy
- Commercial products
- R&D progress
- Financial position
- Selection of expected milestones
- Q&A





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



# Strategic pillars driving value

## Cardio portfolio

- Multiple targeted U.S. submission dates starting in 2024, making **2025 a pivotal year**
- Analyzing different go-to-market strategies
- Multiple clinical trials in preparation

## Value-added portfolio

- Multiple clinical trials, regulatory submissions and out-licensing deals ongoing or expected
- ➔ Strategic focus on downstream revenue over (upfront) milestone payments

## Pipeline expansion

- Exploring solutions to underserved medical needs
- Ambition to expand to 30 assets before 2025: **acceleration** of pipeline expansion
  - In-licensing deals
  - Internal projects

Significant near term value inflection points for the company

# Commercial products H1 2023

## Sotalol IV

- **Volume increase** year-over-year
- Royalty percentages attributed on an annually calculated **step-up basis** ensure higher percentage of product sales for Hyloris
- Hyloris taking steps to capture more of growth potential in the future

## Maxigesic<sup>®</sup> IV

- PDUFA goal date\* **17 October 2023**
- Opioid pandemic in the U.S.: chronic usage found in **9%\*\* of post-operative patients**
- First sales could follow shortly after approval: license and distribution deal with Hikma
- ~\$2 million in milestone payment subject to regulatory approval & first sales
- Further global roll-out

## Continued revenue growth expected

# Maxigesic IV: Significant Growth of Commercial Footprint



+ strong local distribution partners

| Countries            | H1 2023 | H1 2020 |
|----------------------|---------|---------|
| Licensed             | 100+    | 80      |
| Registered/ Approved | 40+     | 3       |
| Launches             | 20+     | -       |


















## Global roll-out:

- Increasing licenses and approvals worldwide

## United States (subject to FDA approval):

- Largest expected market opportunity + higher royalty percentage
- United States: potential market launch 2 to 3 months after approval

# 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.



# Other value-added portfolio

| Product            | Route of Administration | Indication                 | Formulation and Manufacturing                                 | Clinical Development  | Regulatory Filing | Target Market   |
|--------------------|-------------------------|----------------------------|---|---|-------------------|---|
|                    |                         |                            |   | Up to 7 years  |                   |   |
| 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            |   |   |                   |    |
| Plecoïd™ 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.*

# HY-083

## Nasal spray targeting widespread nasal symptoms

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<br>~ 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**

# HY-088

## No approved oral treatment available

Indication: **Phosphate deficiency (hypophosphatemia)**

- Severe condition can be **life threatening** (respiratory or heart failure)
- Rich body of clinical data exists of widely used but unapproved treatment
- Always linked to **underlying condition**
- **Direct treatment** for subpopulation during and/or after hospital stay

Market Size

5% of hospitalized patients\*



# 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

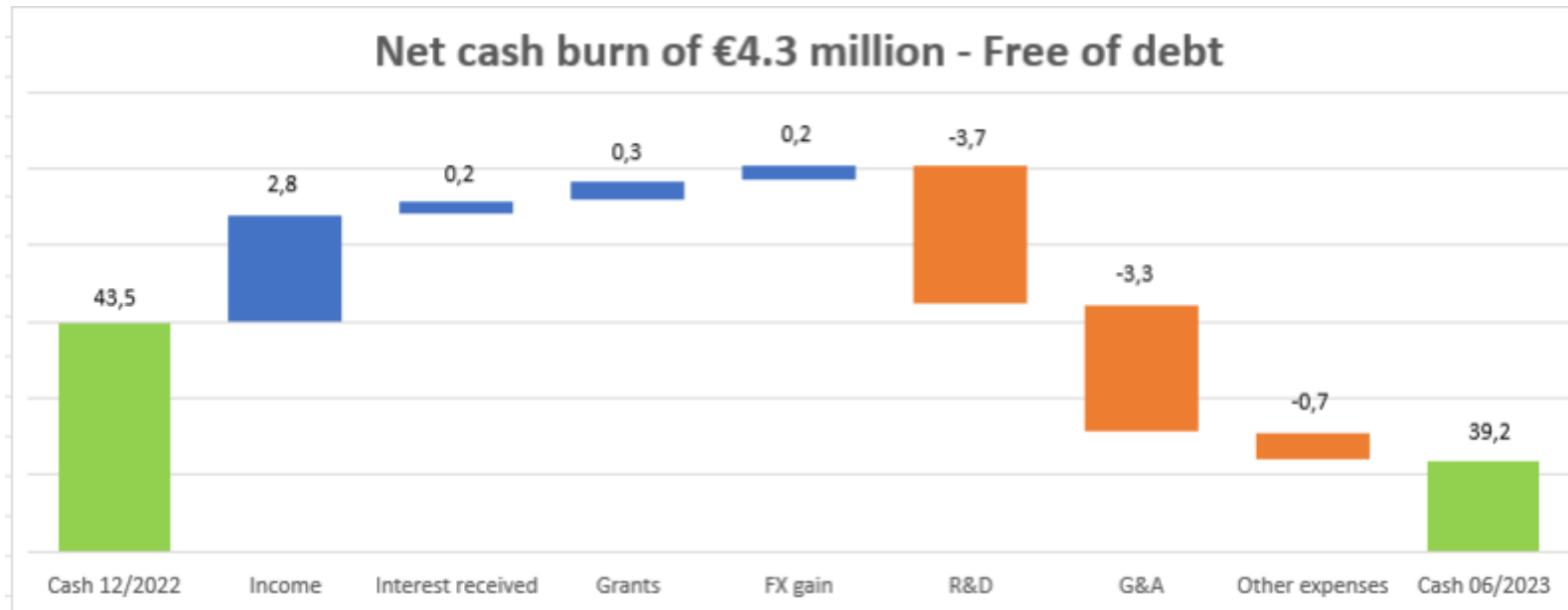
- Operating expenses:

- 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

# Cashflow H1 2023



- Net cash position of €39,2 million on 30 June 2023
- Sufficiently capitalized for all expected R&D expenditures related to the current product candidates\*

# Upcoming events – Interact with Hyloris' top management

| Date                 | Location            | Event                                   |
|----------------------|---------------------|---|
| 27-29 September 2023 | Munich, Germany     | Biotech on Tap 2023                     |
| 5 October 2023       | Paris, France       | Investor Day                            |
| 9 October 2023       | Antwerp, Belgium    | De Belegger On Tour                     |
| 24-25 October 2023   | Barcelona, Spain    | CPHI                                    |
| 6-8 November 2023    | Munich, Germany     | BIO-Europe                              |
| 14 November 2023     | Ghent, Belgium      | VFB Trefpunt Gent, Brussel              |
| 14-16 November 2023  | London, U.K.        | Jefferies Healthcare Conference         |
| 23 November 2023     | Paris, France       | Belgian Day in Paris (Degroof Petercam) |
| 8-11 January 2024    | San Francisco, U.S. | JP Morgan Healthcare Conference         |



# 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**





Q&A

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