Hyloris

2023 Annual Results and 2024 Outlook

Presented by Stijn Van Rompay, CEO and Jean-Luc Vandebroek, CFO

14 March 2024

Forward-Looking Statements

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Agenda

- Company Overview
- Commercial Highlights
- Research and Development Updates
- Financial Position
- Anticipated Milestones (15 months)
- Q&A

Stijn Van Rompay
Chief Executive Officer

Jean-Luc Vandebroek
Chief Financial Officer

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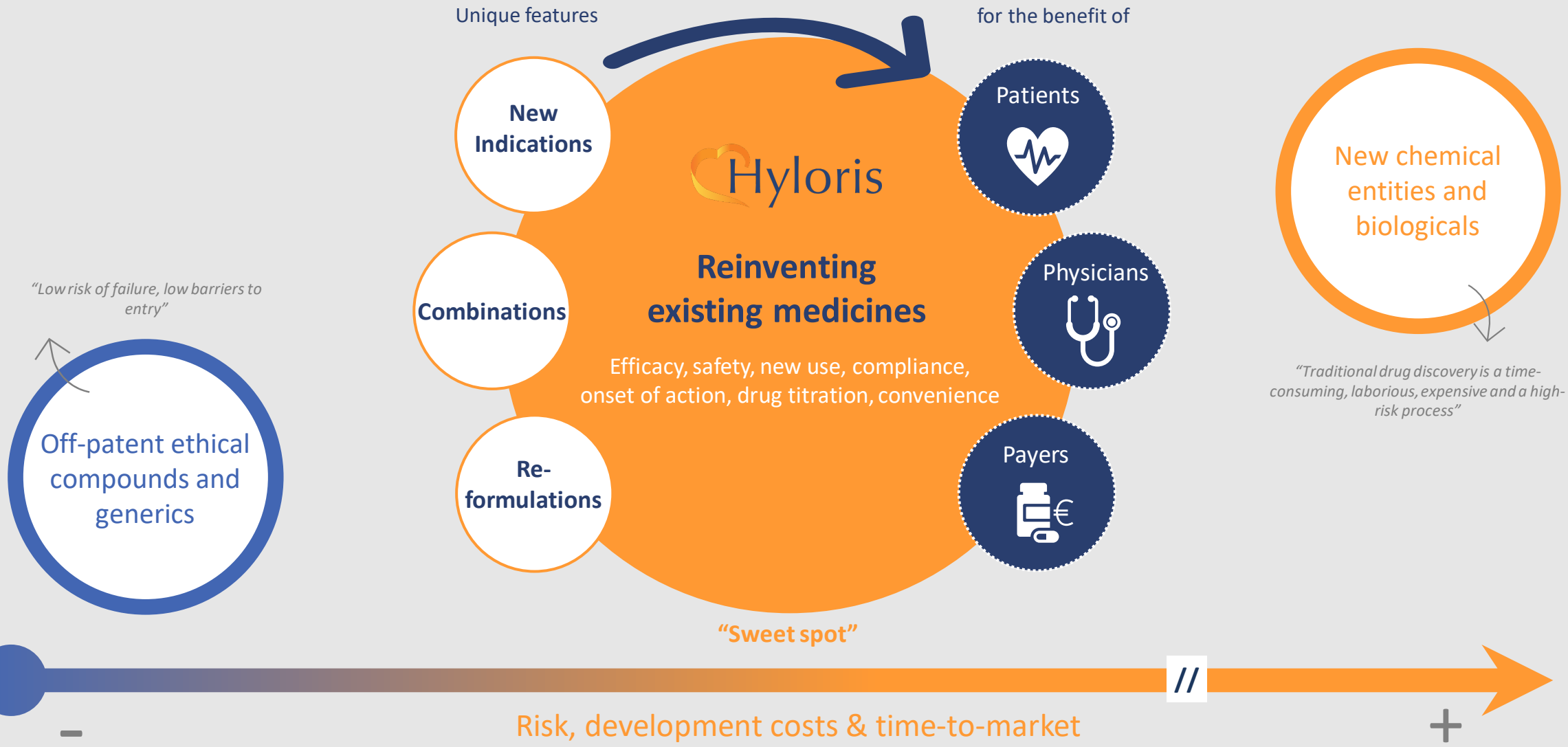
Corporate Overview

Focus on patented value-added medicines



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	Partnered in the US 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				

LVAD: battery-operated, mechanical surgically implanted pump, which helps the left ventricle of the heart pump blood

Commercialized with partner

Intended to be commercialised by Hyloris in the US

Intended to be commercialised with partner

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Other value-added portfolio

Product	Route of Administration	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Target Market
OTHER VALUE-ADDED (OVA) PORTFOLIO*			Up to 7 years			
Maxigesic® IV	IV	Post-operative pain	Partnered with AFT Pharmaceuticals			
Podofilox Gel	Topical	Ext. genital and perianal warts	Partnered in the US with Padagis			
Tranexamic Acid OR	Oral Liquid	Specific dental indication				
Alenura™	PFS	IC / PBS				
Miconazole-DB	Topical	Severe and rVVC				
PTX-252	IV	AML/SCLC				
Atomoxetine	Oral Liquid	ADHD				
HY-029	Oral Liquid	Viral infection				
HY-083	Nasal administration	Idiopathic Rhinitis				
HY-088	Oral Liquid	Hypo Phosphatemia				
HY-090	Oral Liquid	Burning Mouth Syndrome				
HY-091	Topical	Vulvar Lichen Sclerosus				

Commercialized with partner

Intended to be commercialised with partner

*Our high barrier generic products, fusidic acid cream and TXA RTU have not been included in the above overview

TXA: tranexamic acid | ADHD: attention deficit hyperactivity disorder | Miconazole-DB: miconazole-domiphen bromide | rVVC: recurring vulvovaginal candidiasis | AML: Acute Myeloid Leukemia | SCLC: Small cell Lung Cancer

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Commercial Highlights

A year of U.S. FDA approvals, strategic out-licensing deals, and commercial sales

Podofilox Gel 0.5% / Genital and Perianal Warts

- Hyloris' development partner, Padagis US LLC, **received marketing authorization by the U.S. FDA** in December 2023
- First generic option for Condylox® 0.5% ($9M in U.S. sales in 2022[1)]. There is currently an HPV vaccine available but **no cure exists**

Atomoxetine Oral Liquid / ADHD

- Out-licensed Canadian commercial rights to Kye Pharmaceuticals in October 2023
- No oral liquid formulation of atomoxetine exists in the Canadian market which consists of an **estimated 1.8 million people** diagnosed with ADHD

Tranexamic Acid RTU / Antifibrinolytic

- Out-licensing agreements signed in 2023 cover a major European country and several Asian countries
- Licensing partner in Canada submitted an application to Health Canada
- ANDA **submitted to the U.S. FDA** in September 2023

Sotalol IV / Atrial Fibrillation

- Continued to see steady sales in the U.S.
- Taking further steps to potentially capture more of the growth potential

1. IQVIA Health

Maxigesic® IV expands into new markets in 2023

9
Marketing Authorizations

13
Marketing Applications

14
Commercial Launches

U.S. Highlights

- Marketing authorization granted by U.S. FDA in October 2023
- Launched early 2024 under the tradename **Combogesic® IV** by Hikma Pharmaceuticals
- Milestone Payment of $2.1M in 2024

Three candidates within the €7M[1]/7 years criteria added to pipeline

HY-091

a novel topical treatment candidate for Vulvar Lichen Sclerosus (VLS)
VLS is a chronic inflammatory condition affecting an estimated 3% of women, causing severe pain, itching, and discomfort, significantly impacting their quality of life
Co-development with AFT

HY-090

a promising new treatment candidate for Burning Mouth Syndrome (BMS)
Studies suggest that 0.7% to 5% of individuals in the U.S. might be affected with this chronic condition that causes a burning, tingling, or scalding sensation in the mouth for months at a time
Co-development with AFT

HY-088

proprietary oral formulation for hypophosphatemia
Hypophosphatemia is estimated to affect around 5% of hospitalized patients, and a subpopulation needs direct treatment during and/or after their hospital stay

[1] not adjusted for inflation – on average €7M / product candidate

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Research & Development Updates

Enhanced capabilities drive efficiency

- R&D lab at the Montlegia Science park was officially opened in June 2023
- Several key recruitments made to optimize the R&D team

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Cardiovascular product candidates steadily progressing towards submission

Aspirin IV / Reduced Morbidity and Mortality from Cardiovascular Events

- Manufacturing of registration batches completed
- Stability study is ongoing

Milrinone ER / Advanced Heart Failure Patients with Left Ventricular Devices (LVADs)

- Optimization of the extended-release formulation for alcohol resistance
- Plans for pilot PK are in preparation

HY-074 / Acute Coronary Syndrome (ACS)

- All non-clinical studies completed
- Patent Cooperation Treaty (PCT) patent application filed seeking additional protection in a number of different countries – including the U.S.
- IND planned

Dofetilide IV / Atrial Fibrillation

- Registration batches have been manufactured
- Stability study is ongoing
- CRO selected for the clinical study and IND submitted in early 2024

2023 Highlights for other value-added programs

Tranexamic Acid Oral Mouth Rinse / Excessive Bleeding in a Select Population

- Phase 3 trial began in November 2023
- First patient was enrolled in early 2024
- LPLV expected around year-end

Miconazole/Domiphen Bromide / Recurrent Vulvovaginal Candidiasis (rVVC)

- Phase 2 trial completed in Q4 2023 with promising results

Alenura™ / Interstitial Cystitis/Bladder Pain Syndrome (IC/BPS)

- Pivotal 4-arm Phase 2 clinical study ongoing comparing Alenura™ against each of the separate components and a placebo

PTX-252 / Acute Myeloid Leukemia (AML)

- Received Orphan Drug Designation (ODD) for AML
- NCE – Pre-IND expected in 2024

Valacyclovir / Herpes Simplex Viruses

- Bioequivalence study completed in 2023
- Registration batch manufacturing

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Financial Position 2023

Financial Highlights

(in € thousand)	2023	2022*	% change
Total revenue & other income	**4,406**	**2,386**	**+85%**
Revenues	2,814	1,951*	+44%
Other revenue & income	1,592	435[1]	266%
Total operating expenses	**(20,641)**	**(14,024)**	**+47%**
Cost of sales	(93)	(94)	-1%
R&D expenses	(14,749)	(10,272)	+44%
G&A expenses	(5,653)	(3,517)	+61%
Operating result	**(16,236)**	**(11,638)***	**+40%**
Financial income	474	(127)	-473%
Result of the period	**(15,762)**	**(11,770)***	**+34%**
Cash and cash equivalents	**30,196** (FY 2023)	**33,457** (FY 2022)	

Key factors

Revenue

- Increased royalties and out-licensing income
- 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

Financial income

- Proactive treasury management leads to increased interest income and currency exchange gains in H1

*Restatement of the year 2022 and Press Release date 14th of March 2024 related to restatement for additional information on HY-038 and HY-088

[1]Reclassification of the withholding tax on R&D salaries (payroll tax rebates)

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Restatement* and clarification of HY-088 acquisition and HY-038 divestment

Divested HY-038 to QliniQ for €1 million in December 2022

- HY-038 considered a high-barrier generic outside of our core portfolio
- Limited development before divestment
- Encountered challenges in identifying a suitable CMO capable of manufacturing HY-038 at a desired cost

Acquired HY-088 from QliniQ for €1 Million in January 2023

- Acquired the global rights of ongoing development from Dutch company QliniQ who maintained the rights to commercialize the product candidate in its home country and a select number of Middle Easter and developing countries

Accounting Treatment of the Transactions with QliniQ

- Initially recognized €1 million in 2022 from the sale of HY-038 along with a €1 Million R&D expense and a €0.2 million intangible asset for buying HY-088
- Unreliable fair value determination for both products due to development stage and simultaneous negotiation
- Transactions were reclassified as a non-monetary exchange (IAS 38)
- Reversed €1 million revenue and offset the €1 Million HY-088 R&D expense with the received €1 Million

Consolidated statement of financial position

Per 31 December 2022 (in € thousands)	Impact of Restatement		
	As previously reported	Adjustment	As restated
Current assets	50.801	-1.000	49.801
Trade and other receivables	5.127	-1.000	4.127
Total assets	61.864	-1.000	60.864
Equity	55.045	-1.000	54.045
Result of the period	(10.770)	-1.000	(11.770)
Total equity and liabilities	61.864	-1.000	60.864

Consolidated statement of profit or loss and other comprehensive income

For the year ended 31 December 2022 (in € thousands)	Impact of Restatement		
	As previously reported	Adjustment	As restated
Revenues	2.951	-1.000	1.951
Gross profit	2.857	-1.000	1.857
Operating profit/(loss) (EBIT)	(10.638)	-1.000	(11.638)
Profit (loss) before taxes	(10.766)	-1.000	(11.766)
PROFIT (LOSS) FOR THE PERIOD	(10.770)	-1.000	(11.770)
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD	(10.770)	-1.000	(11.770)

For the year ended 31 December 2022 (in €)	Impact of Restatement		
	As previously reported	Adjustment	As restated
Basic/diluted earnings/(loss) per share	(0.380)	(0.035)	(0.435)

*See appendix for press release on restatement

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Anticipated Selected Milestones (15 Months)

Anticipated value inflection milestones

Ambition to expand the product portfolio to ~30 assets by 2025

Hyloris pathway

Clinical

- Miconazole/DB: second clinical trial to begin by year end
- Tranexamic Acid OS: Phase 3 clinical trial LPLV expected around end of 2024
- Initiating multiple pivotal (PK) studies, including Alenura™, Dofetilide and Milrinone

Regulatory

Expecting to submit **several INDs** in the US

Anticipating **multiple NDAs** both in the U.S. and elsewhere

PIND for PTX-252 by YE 2024

Commercial

Maxigesic®IV

- First sales in the US in **Q1 2024**

Commercial partnership(s)

- Out-licensing deal(s)
- In-licensing deal(s)

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Q&A

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Appendix

Restatement* and clarification of HY-088 acquisition and HY-038 divestment

Communication at the request of the FSMA on the transactions with Qliniq

- Revision of 2022 and half-year of 2023 (HY 2023) financial statements following a correction of a non-cash error in the accounting treatment of the transactions with Qliniq announced on 20 January 2023
- HY-088 and HY-038 considered as a non-monetary exchange under IAS 38.45 in 2023
- No impact on the cash flow and cash position

Liège, Belgium – 14 March 2024 – 07:00AM CET – Regulated Information – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces it has issued a restatement of fiscal year 2022 and half year 2023 results. Following discussions with the Belgian Financial Services and Markets Authority (FSMA) and Hyloris' statutory auditor, the Board of Directors has revised the financial statements due to the correction of a non-cash accounting error regarding the divestment of HY-038 and acquisition of HY-088.

Clarification on the press release of 20 January 2023 on the transactions with Qliniq

On 20 January 2023 Hyloris announced that the global rights of the ongoing development of HY-088 was licensed-in from a Dutch company, Qliniq, who maintained the rights to commercialize the product candidate in its home country, and a selected number of Middle Eastern and developing countries. In the same press release, Hyloris announced that it had divested HY-038 to the same company, Qliniq, for a price of EUR 1 million.

As detailed in the 2022 Annual Report, HY-038 falls under the category of high-barrier generics and thus lies beyond Hyloris' core portfolio of assets. Limited development activities had occurred for HY-038 since the IPO and the product was no longer under development at the time of the closing of the transaction with Qliniq. Hyloris encountered challenges in identifying a suitable Contract Manufacturing Organization (CMO) capable of producing HY-038 at a desired cost. The transaction price of € 1 million was received on 16 February 2023.

HY-088 is a ready-to-administer oral liquid formulation designed for addressing hypophosphatemia. Presently, physicians utilize compounded products for treating this condition, which have not undergone regulatory evaluation regarding their safety, effectiveness, and quality. At the time of the transaction, QliniQ held no exclusive rights to develop the oral liquid formulation and had not initiated any significant development activities on HY-088.

It is expected that Hyloris will submit HY-088 for registration in the course of 2025. The transaction price of €1.2 million (including €200 thousand designated as prepaid expenses), was paid by Hyloris on 13 February 2023.

QliniQ is a Dutch company which develops and in-licenses drugs and medical supplies in various therapeutic domains and commercializes these in the Netherlands. QliniQ nurtures cooperation and long-lasting business relationships with international companies as part of its successful market

approach. At December 31, 2022, Qliniq had a balance sheet total of € 0.8 million, a cash balance of € 0.2 million and 2 FTE's. Qliniq's shareholders have previously successfully developed several pharmaceutical companies.

Accounting treatment of the transactions with Qliniq

Hyloris initially recognized (a) €1 million in revenue in 2022 from the divestment of HY-038, and (b) € 1 million in R&D expenses and € 0,2 million in intangible assets in H1 2023 for the purchase of HY-088. A reassessment determined that both transactions qualify as a non-monetary exchange because negotiations and valuations occurred simultaneously. Due to the development stage of the products exchanged, the fair value of neither the asset received, nor the asset given up can be reliably determined. As a result of this reassessment, the restated financials for 2022 will reverse the €1 million revenue from the divestment of HY-038. This adjustment will also affect the half-year 2023 financial statements, resulting in a reversal of €1 million in R&D expenses for HY-088. These expenses are offset against the €1 million received by Hyloris for HY-038.

The following tables summarize the impact of the restatement on the consolidated financial statements.

Consolidated statement of financial position

Per 31 December 2022 *(in € thousands)*	**Impact of Restatement**		
	As previously reported	**Adjustment**	**As restated**
Current assets	**50.801**	**-1.000**	**49.801**
Trade and other receivables	5.127	-1.000	4.127
Total assets	**61.864**	**-1.000**	**60.864**
Equity	**55.045**	**-1.000**	**54.045**
Result of the period	(10.770)	-1.000	(11.770)
Total equity and liabilities	**61.864**	**-1.000**	**60.864**

Consolidated statement of profit or loss and other comprehensive income

For the year ended 31 December 2022 *(in € thousands)*	**Impact of Restatement**		
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Revenues	**2.951**	**-1.000**	**1.951**
Gross profit	**2.857**	**-1.000**	**1.857**
Operating profit/(loss) (EBIT)	**(10.638)**	**-1.000**	**(11.638)**
Profit (loss) before taxes	**(10.766)**	**-1.000**	**(11.766)**
PROFIT (LOSS) FOR THE PERIOD	**(10.770)**	**-1.000**	**(11.770)**
TOTAL COMPREHENSIVE INCOME FOR THE PERIOD	**(10.770)**	**-1.000**	**(11.770)**

For the year ended 31 December 2022 *(in €)*	**Impact of Restatement**		
	As previously reported	**Adjustment**	**As restated**
Basic/diluted earnings/(loss) per share	(0.380)	(0.035)	(0.435)

Consolidated statement of cash flows

Even though there was an actual cash inflow of € 1 million from the divestment of HY-038 and a cash outflow of € 1.2 million resulting from the in-licensing of HY-088, the transactions are presented in the net consolidated cash flow statement for the year ended per December 31, 2023 (i.e., € 200k prepaid expenses), as this most faithfully presents the substance of the transactions. There is no impact on the consolidated statement of cash flows for the year ended on December 31, 2022, as there is no cash impact.

About Hyloris Pharmaceuticals SA

Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimizing existing medications to address important healthcare needs and deliver relevant improvements for patients, healthcare professionals and payors.

The Company's development strategy primarily focuses on leveraging established regulatory pathways, such as the FDA's 505(b)2 pathway in the U.S or equivalent regulatory frameworks in other regions which are specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This approach can reduce the clinical burden required for market entry, and significantly shorten the development timelines, leading to reduced costs and risks.

Hyloris has built a broad, patented portfolio of 18 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over existing alternatives. Two products are currently in early phases of commercialization in collaboration with commercial partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. In addition to its core strategic focus, the Company has 1 approved high barrier generic product launched in the U.S. and 2 high barrier generic products in development.

Hyloris is based in Liège, Belgium. For more information, visit www.hyloris.com and follow-us on LinkedIn.

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