Hyloris Reports Full Year Results for 2023 & Provides Business Outlook

- Total revenue and other income amounted to €4.4 million
- Stronger growth expected in 2024 of both sales and gross margin, mainly fueled by the recent launch in the U.S. of Maxigesic® IV and Podofilox gel, the global roll out of Maxigesic IV® and commercial deals
- Increased operating R&D expenses while net operating cash outflow remained stable versus 2022
- Significant R&D progress including clinical and regulatory achievements with multiple NDA submissions expected within the next 15 months
- Attractive commercial deals, including an out-licensing deal for Atomoxetine Oral Liquid in Canada
- Promising new product candidates driving innovation, targeting a portfolio of 30 assets by 2025
- €30.2 million in cash & cash equivalents, no financial debt
- Webcast on 14 March 2024 at 1PM GMT / 2PM CET/ 9AM EST (Register here)

Liège, Belgium – 14 March 2024 – 7AM 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 its financial and operational results for the year ending on 31 December 2023, as well as its business outlook for 2024.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"Despite a challenging year for the global healthcare industry, 2023 proved to be a year of significant accomplishment for Hyloris. As a company built on the unique and successful strategy of repurposing and reformulating existing pharmaceuticals, we achieved a major milestone with the U.S. approval of Maxigesic® IV in partnership with AFT Pharmaceuticals, marking a crucial step in delivering this innovative pain management solution to American patients.*

Additionally, approval was secured for Podofilox gel, the first generic version of Condylox® Gel, expanding access to this medication. Our unwavering commitment to research and development yielded impressive progress across our diverse product pipeline. These advancements solidify our position as a leader in providing solutions to unmet medical needs in the years to come. We are incredibly proud of our team's dedication and resilience throughout this transformative year.

Looking ahead to 2024, Hyloris is poised for continued growth and innovation. We plan to significantly bolster our pipeline with the addition of several new product candidates addressing critical unmet medical needs. Recent additions, including treatments for Vulvar Lichen Sclerosus and Burning Mouth Syndrome, demonstrate our commitment to expanding our portfolio and addressing a wider range of patient needs. We remain confident in our ability to continue delivering value to patients, shareholders, and all stakeholders and expect continued growth beyond 2024.

Commercial Highlights

Maxigesic® IV is a patented, unique combination, intravenous formulation for the treatment of post-operative pain and is currently licensed to partners covering over 100 countries across the globe.

During 2023 and early 2024:

- A marketing authorization was granted by the United States Food and Drug Administration (FDA) in October 2023.
- Hikma Pharmaceuticals (Hikma), a leading supplier of complex injectable hospital products, has launched the product in the U.S. under the tradename Combogesic® IV. An exclusive license and distribution agreement had previously been signed between Hyloris' partner AFT Pharmaceuticals (AFT) and Hikma.
- Additional submissions for marketing authorization were made in 13 countries in the Middle East, Africa, Latin America, and Asia.
- Additional marketing authorizations have been granted in 8 countries including Poland, South Africa, and Spain. In early 2024, Health Canada granted approval bringing the total number of approvals to 50.
- Launches occurred in 14 countries including Norway, Singapore, Belgium, The Netherlands, the Czech Republic, and Romania. Imminent launches are expected in several additional countries, bringing the total number of countries where Maxigesic® IV will be available up to more than 30.

In the United States, chronic opioid usage in patients following surgery averages around 9%, ranging from 4% to 24% among various specialties. Drug overdoses involving opioids resulted in over 80.000 deaths in the U.S. in 2021. Patients who experienced an opioid overdose accounted for nearly $2 billion in annual hospital costs.

Sotalol IV is a patented, intravenous formulation of Sotalol for the treatment of atrial fibrillation, and life-threatening ventricular arrhythmias developed for the U.S. Sotalol IV potentially allows to significantly reduce the length of hospital stay and the overall cost of care and potentially improve patient outcomes.

Hyloris is taking further steps targeting to increase product related revenues in the future (see also: Ongoing Legal Proceedings).

Podofilox Gel (Product previously referenced as HY-016)

In December 2023, our partner Padagis US LLC (Padagis) received marketing authorization for Podofilox gel 0.5% from the FDA. Padagis launched the product in December 2023. It is the first generic for Condylox® Gel in the U.S.

Podofilox Gel is an antimycotic drug for the topical treatment of external genital and perianal warts caused by certain types of the Human Papilloma Virus (HPV). Around 1% of the sexually active

population in the U.S. presents with genital or perianal warts.[1] To date there is a vaccine for HPV but no cure.

For the 12 months period ending December 2022, Condylox® Gel had U.S. sales of approximately $9 million according to IQVIA Health.

Other Commercial Highlights

Tranexamic Acid RTU

Additional out-licensing agreements were signed for Tranexamic Acid RTU in 2023. These agreements cover a large European country and several major Asian countries, with a combined population of over 60 million people. Previous agreements have been signed in 2021 for Australia, New-Zealand and Canada. In 2023, our licensing partner for Canada submitted an application for approval by Health Canada. Additional regulatory submissions in the partnered territories are in progress, and more out-licensing agreements are expected going forward. An Abbreviated New Drug Application (ANDA) has been submitted to the U.S. FDA.

Tranexamic acid injection is an established antifibrinolytic agent used in emergency situations with major hemorrhages and is also used as a prophylactic agent in surgeries. Hyloris is developing a ready-to-use (RTU) formulation for infusion.

Atomoxetine Oral Liquid

An out-licensing agreement was signed with Kye Pharmaceuticals (Kye) in October 2023. Kye will exclusively commercialize the product in Canada where atomoxetine is currently not available as an oral liquid formulation. The introduction of an oral liquid formulation in the ADHD (Attention Deficit Hyperactivity Disorder) medication category has historically led to significant market share gains[2]. This suggests a strong potential for Atomoxetine Oral Liquid in Canada, where an estimated 1.8 million people (or 4-6% of adults and 5-7% of children) are diagnosed with ADHD[3]. ADHD is a chronic condition, with symptoms persisting into adulthood for 60-80% of patients[4].

Under the terms of the agreement, Hyloris will be eligible to receive attractive sales-related milestone payments (totaling up to USD 7.5 million), and a substantial share of the generated revenue.

New Pipeline Product Candidates

Our business development team leverages its expertise in existing products, real-world data, and a vast network to identify unmet medical needs. This includes collaborating with healthcare professionals, patient groups, insurers (payors), and industry partners. In 2023 over 87 opportunities were screened and 3 product candidates will meet our investment criteria of €7 million[5] in 7 years or less.

[1] https://www.aafp.org/pubs/afp/issues/2010/1115/p1209.html
[2] IQVIA
[3] https://caddac.ca/about-adhd/
[4] https://journals.sagepub.com/doi/10.1177/1060028013510699
[5] Not adjusted for inflation

For product candidates which Hyloris intends to out-license, the strategic goal is to capture a substantial part of the net product margin realized by our commercial partners. Hyloris aims to achieve this by partnering these assets close to regulatory submission, except in countries where additional local clinical trials are required. In general, we will prioritize in-market product sales or profit-based participation over (upfront) milestone payments.

We aim to increase our product portfolio to 30 assets by 2025, with a focus on accelerating pipeline growth in the near future.

HY-091, a novel topical treatment candidate for Vulvar Lichen Sclerosus (VLS) was announced in January 2024. VLS is a chronic inflammatory condition affecting an estimated 3% of women, causing severe pain, itching, and discomfort, significantly impacting their quality of life. HY-091 is being developed as a convenient and user-friendly treatment specifically designed to target these VLS symptoms.

Hyloris has partnered with AFT for co-development, registration, and worldwide commercialization.

HY-090, a promising new treatment candidate for Burning Mouth Syndrome (BMS) was announced in December 2023.

BMS is a chronic condition affecting millions, primarily postmenopausal women, causing a burning, tingling, or scalding sensation in the mouth for months at a time. While the mouth appears healthy, sufferers may also experience dry mouth or taste alterations, the exact cause of BMS remains unknown. Studies suggest that 0.7% to 5% of individuals in the U.S. might be affected[6].

Hyloris has partnered with AFT to co-develop and commercialize the product worldwide.

HY-088 was announced in January 2023. This novel, proprietary oral formulation will be administered to patients with hypophosphatemia – a condition where the blood level of phosphorus is lower than 2.5mg/dL. Patients can develop hypophosphatemia from either a genetic abnormality (such as Cushing Syndrome or osteomalacia) or an acquired condition (like long-term use of diuretics or phosphate binders).

It is estimated hypophosphatemia affects around 5% of hospitalized patients, and a subpopulation needs direct treatment during and/or after their hospital stay.

Treatment protocols for patients deficient in phosphate are well-established and have proven useful in other situations of bone mineral imbalance. Oral administration is the preferred way of treating hypophosphatemia, although in most countries no approved drugs exist. Currently, physicians mostly rely on compounded drugs which have, by definition, not been submitted for regulatory scrutiny regarding safety, efficacy, and quality.

R&D Update

Throughout 2023, Hyloris achieved significant advancements across the entire R&D portfolio, propelling the 18 product candidates and 3 high-barrier generics closer to commercialization. Key

[6] Based on combination of different sources: population-based study, clinical based study and key opinion leaders' estimation

milestones were met for multiple programs, and discussions with regulatory agencies and partners are underway to solidify development plans. As a result, Hyloris anticipates submitting multiple INDs (Investigational New Drug applications) and NDAs (New Drug Applications) throughout 2024 and early 2025.

Enhanced Capabilities Drive Efficiency

Further bolstering our R&D efforts, Hyloris officially opened its new and improved R&D lab at the Montlegia Science Park in June 2023. This on-site facility allows Hyloris to perform drug formulation and analytical activities in-house, streamlining processes and optimizing resource allocation for the expanding pipeline.

Cardiovascular Portfolio

Hyloris is actively engaged in advancing a comprehensive portfolio dedicated to addressing a wide range of conditions within the largest global treatment category – cardiovascular care. These products are currently progressing through or towards clinical trials, with the aim of significantly enhancing the quality of life for patients.

Main highlights for 2023 and selected expected milestones for 2024 include:

Aspirin IV: Registration batches have been manufactured and the stability study is ongoing. An NDA submission is planned for the U.S. as soon as all necessary data has been collected.

Aspirin IV is an intravenous (IV) formulation of acetylsalicylic acid (ASA) to be used in an emergency setting. Aspirin is not available in the U.S. as an IV product. Currently, most patients suspected of having an emergency cardiovascular event (such as a myocardial infarction or stroke) are immediately given oral aspirin to decrease their risk of morbidity and mortality.

Milrinone: The optimization of the extended-release formulation for alcohol resistance marked a significant development milestone. Preparations for a pilot pharmacokinetic (PK) study are in progress.

Oral milrinone is being developed as a novel, extended-release formulation offering convenient oral dosing for a selected population of end-stage heart failure (HF) patients who have Left Ventricular Assist Devices (LVADs).

HY-074: All non-clinical studies were completed in 2023**.** A patent application was filed through the Patent Cooperation Treaty (PCT) which allows an applicant to seek patent protection in several different countries – including the U.S. Hyloris is targeting an IND submission for Q2 2024 for the PK bridging study expected to start at the end of 2024.

HY-074 is an intravenous formulation of current standard of care treatment for acute coronary syndrome (ACS) to offer faster onset of action, more convenient administration, and dosage control. It is currently available in oral form, which should allow for an optimal switching strategy from the oral form to an IV in a hospital setting.

Dofetilide IV: Registration batches have been manufactured and the stability study is ongoing. A CRO has been selected for the required clinical study. An NDA submission is planned for the U.S. as soon as all necessary data has been collected.

A pivotal clinical study to support regulatory submission for Dofetilide IV is nearing completion, with results expected by Q3 2024. Additional U.S. patent applications have been filed to bolster the drug's intellectual property protection.

Other Value-Added Programs

Hyloris, in collaboration with its development partners, is achieving consistent progress on all stages of our value-added programs.

Main highlights for 2023 and expected milestones for 2024 include:

Tranexamic Acid Oral Mouth Rinse (previously HY-004): A Type A meeting with the FDA resulted in alignment on the phase 3 study protocol. The phase 3 trial began in November 2023, enrolling the first patient in early 2024. Completion of enrollment (Last Patient Last Visit - LPLV) is expected by year-end, with study results anticipated in the first half of 2025.

This rinse targets patients on blood thinners (anticoagulant therapies) undergoing dental procedures with a high risk of excessive bleeding. Additionally, Hyloris intends to explore the effectiveness in a wider range of related oral surgery procedures, encompassing both patients with and without bleeding disorders who could benefit from a localized treatment to reduce blood clotting.

Miconazole/Domiphen Bromide: Hyloris is co-developing Miconazole/Domiphen Bromide (MCZ/DB) with Purna Female Healthcare, a topical cream combining miconazole and domiphen bromide. This innovative treatment targets Recurrent Vulvovaginal Candidiasis (rVVC), a chronic and often debilitating vaginal yeast infection affecting nearly 1 in 10 women throughout their lives.

The Phase 2 clinical trial, completed in late 2023 (Q4), showed promising results. The low-dose group exhibited evidence of delayed disease recurrence at day 29. These findings will be used to design the next clinical trial, scheduled to begin by year-end 2024. MCZ/DB presents a strong scientific and commercial potential for addressing rVVC.

Alenura™: Hyloris is co-developing Alenura™ with Vaneltix. It is a first-in-class drug candidate designed to bring immediate pain relief to patients suffering from interstitial cystitis/bladder pain syndrome (IC/BPS). This chronic condition affects at least 6 million people in the U.S. alone.

Alenura™ stands out for its innovative dual mode-of-action. It combines a new, alkalinized form of lidocaine for fast pain relief with heparin to potentially aid in the regeneration of the bladder lining. This unique approach holds promise for providing both immediate symptom relief and long-term benefits for IC/BPS patients.

June 2023 marked a significant milestone with the enrollment of the first patient in the Phase 2 clinical trial of Alenura™**.** This pivotal study will compare the effectiveness of Alenura™ against its individual components (lidocaine and heparin) as well as a placebo.

PTX-252: PTX-252 is a novel chelating agent in development for the treatment of Acute Myeloid Leukemia (AML). This product candidate incorporates a novel molecular entity that is a derivative of a known established molecule. This advancement was followed by positive news: Hyloris' co-development partner, Pleco, secured Orphan Drug Designation from the FDA for PTX-252 specifically for AML.

PTX-252's potential lies in its ability to potentially improve the effectiveness of existing chemotherapy for AML patients. This is particularly significant as AML affects approximately 160,000 people globally. Previous research suggests a correlation between high levels of toxic metals and lower survival rates in AML patients.

A Pre-Investigational New Drug (PIND) meeting with the FDA is planned.

Valacyclovir: A successful study demonstrating bioequivalence was completed in 2023. An additional pivotal study can be expected to start and close in H1 of 2024. Registration batches have been manufactured to demonstrate pharmaceutical quality of the product and robustness of the manufacturing process**.**

Hyloris is developing a liquid formulation of valacyclovir which is currently only available in oral solid form. Valacyclovir is an antiviral drug commonly used to treat the Herpes Simplex Viruses (HSV) that cause cold sores, genital herpes, chicken pox, and shingles.

Management & Board changes

The total headcount of the Company grew to 42 people, with several key recruitments occurring over the summer. To enhance the development activities, only limited additional hiring is required. Both the C-level executives and all board members remained in their respective positions, providing continuity in the company's leadership.

Business Outlook

With 18 reformulated and repurposed molecules, and 3 high-barrier generics, several clinical trials are expected to start and/or finish within 2024. The Company is actively accelerating the growth of its product pipeline, aiming to reach 30 product candidates by 2025.

The company is expecting several clinical and regulatory achievements in the next 15 months. Several clinical studies will be initiated or completed. The Company is anticipating multiple NDA submissions to the U.S. FDA and other regulatory agencies.

Webcast Details

The Company will host a webcast conducted in English to present its 2023 annual results and 2024 Business Outlook, followed by a live Q&A session. The webcast will start on March 14th 2024 at 2PM CET / 1PM GMT / 9AM EST. To join the webcast, please register at the following link: Hyloris: 2023 Full Year Results, Outlook for 2024, and Q&A

For those unable to join via webcast, please find dial in information below:

Phone Conference ID: 598 167 742#

Belgium: +32 4 290 22 87
France: +33 1 73 24 00 56
Netherlands: +31 20 708 1382
Switzerland: +41 43 434 66 31
United Kingdom: +44 20 7660 8327

United States: +1 347 378 4531
Japan: +81 3 4540 5088

Financial Highlights 2023

	Year ended 31 December		
(in € thousand)	**2023**	**2022 Restated***	**Variance**
Total Revenues and Other income	**4,406**	**2,386**	**85%**
Revenues	2,814	1,951*	44%
Other operating income	1,592	435[7]	266%
Operating expenses	**(20,642)**	**(14,024)**	**47%**
Cost of sales	(93)	(94)	**(1%)**
Research and development expenses	(14,749)	(10,272)	**44%**
General and administration expenses	(5,653)	(3,517)	**61%**
Share of result of equity-accounted investees, net of tax	(147)	(130)	**13%**
Other operating expenses	-	(12)	
Operating result (EBIT)	**(16,236)**	**(11,638)***	**40%**
Net financial result	474	(127)	**-473%**
Income Taxes	-	(4)	
Profit/(Loss) for the period	**(15,762)**	**(11,770)***	**34%**
Net operating cash flow	**(12,726)**	**(12,499)[8]**	**2%**
Other investment	-	10,000	
Cash and cash equivalents	30,196	33,457	-10%
Total cash and Other investment	**30,196**	**43,457**	

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

Total Revenue and Other Income

In 2023, total revenue and other income increased to €4,406 thousand compared to €2,386 thousand in 2022, which is 85% higher compared to last year. The strong growth is mainly driven by increase of royalties of the 3 early-stage commercialized products, services provided to external partners and non-dilutive funding which we received from a US State Government and the Walloon region in Belgium.

Results

[7] Reclassification of the withholding tax on R&D salaries. (payroll tax rebates)
[8] Reclassification of the loan to third-party from Operating to Investing activities in the Cash flow statement

The Company realized a net loss of €15,762 thousand in 2023, compared to a net loss of €11,770 thousand last year. The net loss is mainly resulting from the increase in R&D expenditure and G&A expenses for supporting the development of the Company. R&D expenditure during 2023 amounted to €14,749 thousand, compared to €10,272 thousand in 2022. The increase was mainly driven by the progressive shift from early to late-stage development of several product candidates as well as the increased headcount of the research and development team leading to additional costs.

General and administrative expenses increased to €5,653 thousand in 2023 versus €3,517 thousand in 2022, mainly driven by higher legal costs related to the AltaThera's litigation compared to last year.

The net financial income in 2023 was €474 thousand compared to a net financial loss of €127 thousand in 2022. The positive evolution of the financial result is mainly due to the impact of an active cash management strategy in a context of high short term interest rates both in EURO and USD.

As a result, net losses in 2023 increased to €15,762 thousand versus €11,770 thousand in the same period of 2022.

Balance Sheet

The Company's non-current assets mainly consist of (1) investments in joint ventures of € 3,801 thousand, (2) intangible assets of €3,828 thousand including capitalized development, purchased assets and in-licensing costs, versus €3,600 thousand in 2022, (3) Right of use assets related to the leasing of the office, lab and cars, (4) shares in Pleco of €1,000 thousand, (5) a prepayment of future royalties to a third party of $700 thousand and (6) a tax credit. Hyloris does not capitalize research and development expenses until the filing for a marketing authorization for the applicable product candidate. Research and development expenditures incurred during the period were accounted for as operating expenses. When an intangible asset is acquired and capitalized, the amortization begins when the asset is available for commercialization.

The Company's current assets mainly consist of €30,196 thousand in cash and cash equivalents on total assets of €47.61 million, and trade and other receivables of €4.1 million.

The increase in Right-of-use assets and borrowings is due to the start of the lease for the new lab. The Company received an advance payment related to a government grant from the Walloon region. €43 thousand of this advance is a financial liability and €37 thousand is part of Trade and other liabilities.

Cash Position and Cash Flow

The Company maintains its strong cash position, with a current cash and cash equivalents totaled €30,196 thousand at the end of 2023, compared to €43,457 thousand at the end of 2022 (which includes a deposit for an amount of €10 million which has been reclassified to Other investment in 2022).

Net cash outflow generated from operating activities was €12,726 thousand in 2023, compared to a net operating cash outflow of €12,499 thousand in 2022. The stable net operating cash outflow is attributed to an internal control system implemented to oversee expenditure and cash flow, which includes effective management of working capital.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION FOR THE YEAR ENDED DECEMBER 31

ASSETS (in thousands of euros)	31-Dec-23	31-Dec-22 Restated*
Non-current assets	***12,336***	***11,063***
Intangible assets	3,828	3,607
Property, plant and equipment	429	176
Right-of-use assets	1,724	885
Equity accounted investments	3,801	3,948
Other investment, including derivatives	1,000	1,000
Trade and other receivables	1.554	1.447
Current assets	***35,276***	***49,801***
Trade and other receivables	4,100	4,127
Other investment, including derivatives	499	10,469[9]
Prepayments	481	1,748
Cash and cash equivalents	30,196	33,457[9]
TOTAL ASSETS	**47,612**	**60,864**

EQUITY AND LIABILITIES (in thousands of euros)	31-Dec-23	31-Dec-22 Restated*
Equity	***38.822***	***54.045***
Share capital	140	140
Share premium	121,513	121,513
Retained earnings, excluding profit (loss) for the reporting period	(65,246)	(53,476)
Result of the period, profit (loss) for the reporting period	(15,762)	(11,770)
Share based payment	2.161	1,621
Cost of Capital	(4,460)	(4,460)
Other reserves	476	476
Non-current liabilities	**1.853**	**1,047**
Borrowings	1,510	747
Other financial liabilities	344	300

[9] Reclassification of deposit from Cash and cash equivalents to Other investment including derivatives for an amount of €10 million in 2022

Current liabilities	**6,937**	**5,772**
Borrowings	241	138
Other financial liabilities	3,200	3,212
Trade and other liabilities	3,496	2,422
Current tax liabilities	-	-
TOTAL EQUITY AND LIABILITIES	**47,612**	**60,864**

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED DECEMBER 31

in € thousands	2023	2022 restated*	Variance
Revenue	2,814	1,951	47%
Other operating income	1,592	435[3]	252%
Operating income	**4,406**	**2,386**	**85%**
Cost of sales	(93)	(94)	(1%)
Research and development expenses	(14,749)	(10,272)[10]	44%
Selling, general and administrative expenses	(5,653)	(3,517)	61%
Share of result of equity-accounted investees, net of tax	(147)	(130)	13%
Other operating expenses	-	(12)	
Operating expenses	**(20,642)**	**(14,024)**	**47%**
Operating profit/(loss) (EBIT)	**(16,236)**	**(11,638)**	40%
Financial income	867	466	86%
Financial expenses	(393)	(594)	-34%

[10] Reclassification of the withholding tax on R&D salaries. (payroll tax rebates) for an amount of €120k

Profit/(loss) before taxes	**(15,762)**	**(11,766)**	34%
Income taxes	-	(4)	
PROFIT/(LOSS) FOR THE PERIOD	**(15,762)**	**(11,770)**	34%

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED DECEMBER 31 2023

	Attributable to equity holders of the Company						
			Other reserves				
(in thousands of euros)	Share capital	Share premium	Share-based payment reserve	Cost of Capital	Other reserves	Retained earnings	Total Equity
Balance at December 31, 2021	**129**	**103,693**	**2,391**	**(3,827)**	**476**	**(54,805)**	**48,056**
Private Placement Via an Accelerated Bookbuild Offering	5	14,995		(634)			14,366
Equity Transaction via Transaction Warrants	6	2,826	(1,329)			1,329	2,832
Share-based payments			560				560
Total comprehensive income						(11,770)	(11,770)
Balance at December 31, 2022	**140**	**121,513**	**1,622**	**(4,460)**	**476**	**(65,246)**	**54,045**
Share-based payments			539				539
Total comprehensive income						(15,762)	(15,762)
Balance at December 31, 2023	**140**	**121,513**	**2,161**	**(4,460)**	**476**	**(81,008)**	**38,822**

CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31 2023

in € thousands	**2023**	**2022 Restated***
CASH FLOW FROM OPERATING ACTIVITIES		
Net result	(15,762)	(11,770)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation, amortisation and impairments	349	196
Share-based payment expense	539	560

Derivatives financial instruments	(52)	52
Interest income on deposits and current accounts	-	164
Net finance result	(474)	-
Change in fair value of financial assets	311	-
Loss on derecognition of shareholders loans	-	486
Equity transaction costs	-	29
Share of profit of equity-accounted investees, net of tax	147	130
Losses on disposal of PPE	-	16
Other non-cash adjustments	(17)	16
Changes in working capital:		
Trade and other receivables	(293)	(921)
Other investment, including derivatives	(31)	4
Prepayments	1,268	(650)
Trade and Other liabilities	1,236	(468)
Cash generated from operations	**(12,779)**	**(12,157)**
Interest paid	52	7
Income Taxes paid	-	(349)
Net cash generated from operating activities	**(12,726)**	**(12,499)**
CASH FLOW FROM INVESTING ACTIVITIES		
Interest received	403	
Purchases of property, plant and equipment	(298)	(101)
Purchases of Intangible assets	(425)	(638)
Acquisition of Other Investments	(0)	(500)
Loans made to third parties	-	(655)
Deposits	10,000	(10,000)
Discontinued operations		
Net cash provided by/(used in) investing activities	**9,654**	**(11,894)**
CASH FLOW FROM FINANCING ACTIVITIES		
Reimbursements of borrowings and other financial liabilities	(12)	(7,376)
Proceeds from borrowings and other financial liabilities	44	-
Reimbursements of lease liabilities	(222)	(79)
Modifications/terminations Right of Use Assets	2	-

Proceeds from Private Placement via Accelerated Book Building	-	14,337
Proceeds from Execution Transactions Warrants	-	2,832
Interests paid	-	(1,877)
Net cash provided by/(used in) financing activities	**(188)**	**7,838**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(3,261)**	**(16,555)**
CASH AND CASH EQUIVALENTS at beginning of year	33,457	50,012
CASH AND CASH EQUIVALENTS at end of year, calculated	30,196	33,457*

RESTATEMENT OF THE YEAR 2022 and HALF-YEAR 2023

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.

(See Press Release dated 14th of March 2024 on the restatement for more information)

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 correction of error**		
	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 correction of error		
	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 correction of error**		
	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 EUR 1 million from the out-licensing of HY-038 and a cash outflow of EUR 1.2 million resulting from the in-licensing of HY-088, the transactions are presented in the consolidated statement of cash flows for the year ended per December 31, 2023 (i.e., EUR 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 per December 31, 2022, as no cash inflow occurred yet.

Audit Report

The statutory auditor, KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises, represented by Olivier Declercq, has informed us that the audit procedures were not yet completed.

ONGOING LEGAL PROCEEDINGS

In August 2022, AltaThera Pharmaceuticals LLC filed a complaint before the District Court for the Northern District of Illinois against Academic Pharmaceuticals Inc, Dr. Somberg and Hyloris Pharmaceuticals, for (a.o.) alleged misappropriation of AltaThera's trade secrets and confidential information, improper inventorship, and breach of contract, which seeks (punitive) damages and termination of the agreement whereby Hyloris licenses Sotalol IV to AltaThera (the "Litigation"). Hyloris moved to dismiss the complaint for improper service of process and lack of jurisdiction. Further, in November 2022, Hyloris initiated an arbitration against AltaThera for breach of the same licensing agreement between Hyloris and AltaThera in relation to Sotalol IV, including the failure of AltaThera to use commercially reasonable efforts in selling Sotalol IV as required under the licensing agreement, which seeks damages and termination of the licensing agreement (the "Arbitration"). AltaThera responded and counter-demanded, reasserting its claims from the Litigation.

At the end of August 2023, all parties agreed to stipulate to the dismissal of the Litigation and to consolidate the Litigation and the Arbitration before the American Arbitration Association ("AAA") in New York.

Hyloris contests the claims asserted by AltaThera and, based upon Hyloris' assessment of the documents and expert reports put forward to date by AltaThera to support its claims, Hyloris is of the

view that there is no convincing evidence supporting AltaThera's claims for liability or damages. On the other hand, Hyloris believes strongly in the merits of its claims against AltaThera, and that its position is well supported by its expert reports and other documents and evidence submitted to the arbitration panel.

Arbitration hearings are scheduled in April 2024 with a final decision expected by the end of H1 2024. Hyloris remains fully confident about the outcome of this litigation in its favor. Hyloris however cannot guarantee that the outcome of the litigation, even if in its favor, may not have a negative impact on future sales of Sotalol IV.

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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Disclaimer and forward-looking statements

Hyloris means “high yield, lower risk”, which relates to the 505(b)(2) regulatory pathway for product approval on which the Company focuses, but in no way relates or applies to an investment in the Shares.

Certain statements in this press release are “forward-looking statements.” These forward-looking statements can be identified using forward-looking terminology, including the words "believes", "estimates," "anticipates", "expects", "intends", "may", "will", "plans", "continue", "ongoing", "potential", "predict", "project", "target", "seek" or "should", and include statements the Company makes concerning the intended results of its strategy. These statements relate to future events or the Company’s future financial performance and involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Company’s control, that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by any forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.