

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 2023 – 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		
	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)

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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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.

