Hyloris Pharmaceuticals Reports 2022 Half-Year Results and Provides Corporate Update

- On track to broaden product pipeline to meet a target portfolio of 30 programs by 2024

- Continued commercial rollout of Sotalol IV in US and Maxigesic® IV

- Focused entry into US market with Maxigesic® IV for non-opioid pain treatment; continuing to work with the FDA to support the application review

- Positive clinical data reported for Tranexamic Acid Oral Mouth rinse program (HY-004), for patients on anti-coagulant therapies undergoing dental procedures that have a risk of bleeding complication

- Progressing on all added-value programs

- €57,687 million in cash and cash equivalents allows for incremental growth in line with Hyloris' business strategy to acquire and develop additional products to improve the lives of patients

Liège, Belgium – 1 September 2022 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today reported its condensed consolidated financial results for the six-month period ending 30 June 2022, along with a year-to-date business update and an outlook.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented, *"Over the last two years as a publicly traded company, we have progressed our core cardiovascular product candidates aggressively in parallel with the other product candidates in our portfolio, and acquired a diverse range of product candidates that we believe will add value. We are actively evaluating many promising potential product candidates. Our strategic objective is to pursue opportunities to repurpose and reformulate medicines that offer meaningful improvements for patients, physicians, and payors. With cash and cash equivalents of €57,687 million at 30 June 2022, Hyloris remains well-capitalized to advance all value-added assets and execute on this accretive business strategy to expand its portfolio to 30 product candidates and marketed products by 2024."*

Mr Van Rompay continued, *"During the first six months of 2022, via our commercial partners, we further enlarged our commercial footprint including the first launches in the European market for Maxigesic IV and pursued the roll-out of Sotalol IV for the US market."*

MARKETED AND COMMERCIAL-STAGE PROGRAMS

Sotalol IV is a novel, patented, intravenous formulation of Sotalol for the treatment of atrial fibrillation, and life-threatening ventricular arrhythmias developed for the US.

During the first six months of 2022, the partner expanded medical and sales teams in order to accelerate commercial roll-out, inclusion in hospital drug formularies and clinical education of hospital staff.

Additional Value-Driving Programs

Maxigesic® IV is a novel, 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 the first six months of 2022, the geographical base where Maxigesic IV is approved has been broadened to 40 countries and additional marketing authorizations have been granted in Italy, Norway, Greece, Indonesia, Oman, Netherlands, Portugal, Finland, Bahrain, Kosovo, Singapore and Hong-Kong.

Marketing authorisations are pending in several additional countries including Canada, Mexico and the US.

Maxigesic® IV (for the US):

In July, the United States Food and Drug Administration (FDA) informed Hyloris' development partner, AFT Pharmaceuticals, via a Complete Response Letter (CRL), that it was unable to complete its review of the NDA for Maxigesic® IV and provided specific recommendations needed to address the application's deficiency. Importantly, the agency did not report any issues related to data generated during Maxigesic® IV's clinical development program, and the deficiency is confined solely to the Quality section of the application dossier and related to drug product packaging. Hyloris will generate additional data on extractables and leachables from the packaging components to respond to the FDA's information request. Both parties remain committed to Maxigesic® IV and ensuring the product fulfils its commercial potential in the US. Additional studies as requested by FDA are under preparation and expected to begin in Q4 2022 and will take a few months to complete. Upon completion of these studies, the submission to FDA will be made.

Other Developments Related to Maxigesic® IV:

Additional patents were granted across multiple jurisdictions including Japan, Singapore, Canada, Mexico, China and the US, which range in exclusivity from 2035-2038.

R&D UPDATE

<u>Cardiovascular Programs</u>

Aspirin IV US is a first-in-class intravenous (IV) formulation of acetylsalicylic acid that could significantly improve treatment outcomes of patients with acute coronary syndromes, or ACS). Hyloris and its partner have completed the clinical phase of the study to assess the

pharmacokinetics of this product candidate. Hyloris has contracted with a manufacturing organization to produce registration batches in preparation for an NDA submission to the FDA.

Milrinone is a novel, patented, extended-release capsule that has been developed for twice-a-day, convenient oral dosing for end-stage heart failure (HF) patients with an implanted left ventricular assist device (LVAD) who have developed right HF. The extended-release formulation of milrinone in an oral form would provide a steady and predictable exposure of milrinone as well as allow for longer term use in a capsule form. The Company reported it held a successful Type C meeting with the FDA, confirming development plans for an extended-release milrinone capsule in this patient population with a high unmet need.

Additional Value-Driving R&D Programs

Tranexamic Acid Oral Mouth Rinse program (HY-004): The program is being developed for patients on anti-coagulant therapies undergoing dental procedures that have a risk of bleeding complication, is progressing to a Phase 3 clinical trial after positive data reported from healthy subjects undergoing tooth extraction.

Alenura™: Hyloris' partner has written and soon will submit to FDA several protocols for the next clinical trials as part of the development of Alenura™, a first-line drug treatment for acute pain in interstitial cystitis /bladder pain syndrome (IC/BPS). The first of these clinical trials should start later this year.

Miconazole/DB: Hyloris is co-developing a topical synergistic combination treatment for Recurrent Vulvovaginal Candidiasis (rVVC), a condition that affects nearly 10 % of women during their lifetime. MCZ/DB has a strong scientific and business rationale. A Phase 2 clinical trial is ongoing and recruitment should be completed by the end of the year.

Other programs: These added-value programs are on track as planned as stated six months ago. Several discussions are being held with regulatory agencies to confirm and validate development plans.

FINANCE AND OPERATIONAL UPDATE

- Successfully raised a total of €17.8 million in gross proceeds, from new and existing, local and international investors, through (1) an equity offering by means of a private placement via an accelerated bookbuild and (2) execution of transaction warrants.
    - On 1 April 2022 Hyloris announced that it successfully raised an amount of € 15 million in gross proceeds, from new and existing, local and international investors, through an equity offering by means of a private placement via an accelerated bookbuild offering of 967,742 new shares (being approximately 3.7% of the Group's outstanding shares (pre-transaction)) at an issue price of EUR 15.50 per share (the "Offering"), representing a discount of 1.6% to the 30-day VWAP.

- On 22 June 2022 Hyloris increased its capital and share premium with €2.8 million through the exercise of 1.2 million outstanding transactions warrants. As per the date of this report, the total number of shares with voting rights that can be issued following the exercise of the attributed warrants is 711,125.

- Received shareholder approval of all resolutions at the 2022 Annual General Meeting.
- Further strengthened the team and built internal capabilities with key hires.

Key Financial Highlights and Analysis of Results of Operations

	Period ended 30 June		
(in € thousand)	**2022**	**2021**	**Variance**
Total revenue and income	**1,229**	**1,145**	**7%**
Revenues	1,033	**838**	23%
Other income	196	**307** [i]	(36%)
Cost of sales	**(61)**	**(42)**	**45%**
Operating expenses	**(5,986)**	**(9,016)**	**(34%)**
Research and development expenses	(4,712)	**(1,560)**	202%
General and administration expenses	(1,274)	**(1,608)**	(21%)
Other operating expenses ***(one-off)*** [ii]	--	**(5,770)**	(100%)
Operating result	**(4,876)**	**(7,913)**	**(38%)**
Net result	**(4,942)**	**(8,240)**	**(40%)**
Net cash (burn)/inflow [iii]	**7,675** [iiii]	**(10,934)**	
Cash and cash equivalents	**57,687**	**53,465**	

[i] One-off income related to the unwinding of the license agreements with the Alter Pharma Group

[ii] One-off expenses related to the unwinding of the license agreements with the Alter Pharma Group

[iii] For the period 1 January to 30 June

[iiii] Including net proceeds from Capital Transactions

Total Revenue and Other Income

During the first six months of 2022, total revenue and other income increased to €1,229 thousand compared to €1,145 thousand in the first half-year of 2021. The continuous growth is mainly driven by royalty related income from commercialized products and research and development (R&D) services rendered by the Company.

Results

The Company realized a net loss of €4,942 thousand for the six-month period ending 30 June 2022, compared to a net loss of €8,240 thousand for the first half-year of 2021, which is approximately 40% lower compared to last year.

While last year net loss was mainly driven by the renegotiation and unwinding of the license agreements with the Alter Pharma Group (one-off Other Operating expenses of €5.7 million), in the first half of this year the net loss is mainly resulting from the increase in R&D expenditure.

R&D expenditure during the first six months of 2022 amounted to €4,712 thousand, compared to €1,560 thousand for the first half-year of 2021. The increase was mainly driven by costs related to outsourced and internal product development activities, driven by ongoing pipeline expansion and further development of current product candidates.

Cash Position

The Group maintains its strong cash position, with a current cash and cash equivalents totalled €57,687 thousand on 30 June 2022, compared to €53,465 thousand on 30 June 2021.

A net increase of €7,675 thousand in cash and cash equivalents was recorded for the six-month period ending 30 June 2022, compared to a net decrease of €10,934 thousand during the first half-year of 2021. The net increase was mainly driven by net proceeds from a capital transaction of €17,169 thousand off set by (1) net cash out generated from operating activities of €6,401 thousand and (2) cash out due to partial reimbursement of shareholders' loans and payment of interests of €2,324 thousand. This is compared to a net cash outflow for the same period in 2021 of €10,934 thousand, driven by the net operational cash burn of €9,282 thousand, impacted by one-time other expenses, and committed milestone investments in joint ventures (net cash used in investing activities).

Business Outlook

- **Pipeline expansion**: The Company re-stated that its goal remains to add four new reformulated or repurposed product candidates by the end of 2022 in line with its goal to build a portfolio of 30 products and product candidates by 2024.

- **Commercial products**:
  - i) Maxigesic IV, ex-US: continue roll-out in Europe and Rest of the World
  - ii) Maxigesic IV for the US: Submit requested additional information to the US FDA in support of the new drug application (NDA)
  - iii) Sotalol IV: accelerate roll-out in the US

With cash and cash equivalents of €57.7 million at 30 June 2022, the Company believes that it is well-capitalised to advance all current pipeline assets as planned and execute its current business plan with the expectation to expand the portfolio to 30 product candidates - and marketed products by 2024.

UPCOMING PRELIMINARY FINANCIAL CALENDAR FOR 2023

16 March 2023 Full Year 2022 Financial Results and Business Update

About Hyloris Pharmaceuticals
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. Hyloris has built a broad, patented portfolio of fourteen reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Outside of its core strategic focus, the Company also has four high barrier generic products in development. Two products are currently in initial phases of commercialization with partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. The Company's development strategy primarily focuses on the FDA's 505(b)2 regulatory pathway, which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This pathway can reduce the clinical burden required to bring a product to market, and significantly shorten the development timelines and reduce costs and risks. 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 Issuer 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.