

Consolidated 2026 Half-Year Results and Outlook:

Hyloris Delivers 56% Revenue Growth and Its Lowest Half-Year Net Loss Since IPO, Advances Its Mavericks, Core Drivers and Promising Seeds

Liège, Belgium – 24 September 2026 – 07:00 AM CET – Regulated information – Inside information - Hyloris Pharmaceuticals SA (“Hyloris”) (Euronext Brussels: HYL), the specialty pharma group committed to addressing unmet medical needs through reinventing existing medicines and smart NCE developments, today announces its financial results and operational progress for the first half of 2026. Revenue grew 56% to €4.7 million, Operating Income grew 47% to €5.6 million and the net loss narrowed to €1.9 million, the lowest half-year loss reported since the Company’s IPO. These results were accompanied by continued execution across its three strategic focus groups – Mavericks, Core Drivers and Promising Seeds – including a new European licensing agreement for its ready-to-use Pantoprazole IV, remediation and further steps on its Valacyclovir oral suspension program in the U.S., and, after the reporting period, a new exclusive licensing agreement for Maxigesic® IV in China.

Hyloris organizes its broad development portfolio of more than 30 products and product candidates into three strategic focus groups reflecting each product’s stage of development and value-creation profile: **Core Drivers**, products with a comparatively predictable, capital-efficient path to near- and medium-term value, including Hyloris’ four commercialized products; **Mavericks**, high-potential products backed by clinical evidence and significant commercial potential; and **Promising Seeds**, earlier-stage opportunities pending further clinical or regulatory validation. During the first half of 2026, Hyloris advanced its position across all three groups, notably through a new European licensing agreement for its ready-to-use Pantoprazole IV with Orion Corporation, continued progress on its Valacyclovir oral suspension program in the U.S., and the submission of the U.S. NDA for Atomoxetine Oral Liquid. Following a portfolio review, Hyloris also discontinued the HY-075 and HY-091 programs, as well as the XTRAZA™ Phase 3 clinical trial and further U.S. development for that product, sharpening its focus on its most promising assets. After the reporting period, AFT Pharmaceuticals entered into a new exclusive licensing agreement for Maxigesic® IV in Mainland China.

Stijn Van Rompay, CEO of Hyloris, commented: *“The first half of 2026 was a period of disciplined execution. Revenue grew 56% and our net loss narrowed to its lowest half-year level since our IPO, while our commercialised Core Drivers continued to build a growing recurring revenue base and our Mavericks advanced toward key clinical and regulatory milestones. Our new partnership with Orion for ready-to-use Pantoprazole IV in Europe, and AFT’s new licensing agreement for Maxigesic® IV in China, reinforce the long-term commercial reach of our portfolio. We also sharpened our focus through selected program discontinuations.”*

Thomas Jacobsen, Chief Business Development Officer of Hyloris, added: *“Business development remained very active in the first half of 2026 and beyond. Following the new agreement for Pantoprazole IV in Europe, our partner AFT Pharmaceuticals re-established a pathway to Mainland China for Maxigesic® IV and is finalizing discussions with a commercialization partner for Japan, one of the largest remaining territories for the product. We continue to see strong partner interest across our Mavericks and Promising Seeds, and we are progressing our efforts to define the best go-forward commercialization strategy for our U.S. cardiovascular portfolio.”*

PRODUCT OVERVIEW: THREE STRATEGIC FOCUS GROUPS**Core Drivers – Building Recurring Revenue**

Core Drivers offer a comparatively predictable and capital-efficient pathway to near- and medium-term value creation, combining Hyloris' four commercialized products – Maxigesic® IV, Sotalol IV, Podofilox Gel and Tranexamic Acid IV RTU – with later-stage development programs progressing toward regulatory submission, approval or commercial launch, including Pantoprazole IV RTU, Valacyclovir Oral Suspension, Atomoxetine Oral Liquid, Dofetilide IV, Metolazone IV and the European XTRAZA® (tranexamic acid oromucosal solution) program. In the first half of 2026, Hyloris entered into an exclusive license and supply agreement with Orion Corporation for its ready-to-use Pantoprazole IV in the European Union, the UK, Switzerland and Norway. Tranexamic Acid IV RTU, Hyloris' newest commercialized product, was launched in the U.S. and Switzerland during the period. Commercial partner Rosemont Pharmaceuticals filed the U.S. NDA for Atomoxetine Oral Liquid, and Dofetilide IV progressed through a productive FDA interaction confirming its regulatory strategy. For Valacyclovir Oral Suspension, the FDA issued a Complete Response Letter tied to manufacturing observations at the Greek-based contract manufacturer, with no product-specific deficiencies raised; the manufacturer has stated that it is working on a remediation plan, while Hyloris and its partner are progressing the qualification of an additional manufacturing source. Royalties from the commercialized products continue to underpin the growth of this group.

Mavericks – Advancing High-Potential Assets

Mavericks are high-potential products backed by clinical evidence, offering significant commercial potential as they advance toward decisive clinical, regulatory or partnering milestones. The group includes HY-094 (IV Iron), Milrinone ER, Miconazole DB, Suramin IV and Alenura™. In the first half of 2026, IND clearance to initiate the Phase 3 program was obtained for HY-094, Hyloris' next-generation intravenous iron therapy developed in collaboration with AFT Pharmaceuticals. Milrinone ER, which holds FDA Orphan Drug Designation for LVAD-associated right-heart failure, entered human Phase 1 pharmacokinetic development. The Alenura-111 Phase 2 study in interstitial cystitis/bladder pain syndrome completed patient enrollment following an Independent Data Monitoring Committee recommendation to continue; if supportive, the results are expected to form the basis for an End-of-Phase 2 meeting with the U.S. FDA.

Promising Seeds – Expanding the Early-Stage Pipeline

Promising Seeds are early-stage products pending further clinical or regulatory validation, carrying relatively higher risk but offering significant long-term potential. This group includes HY-083, HY-095, HY-098, HY-089, HY-086 (PTX-252) and HY-106 (Methanobactin) for Wilson's disease. Following the exclusive European and Turkish license obtained at the end of 2025, the Methanobactin program continued to progress, while HY-095, a long-acting injectable proton pump inhibitor for Equine Gastric Ulcer Syndrome, advanced further prototype testing. Following a portfolio review intended to sharpen capital allocation, Hyloris discontinued the HY-075 and HY-091 programs. The remaining Promising Seeds early programs continue to expand the long-term optionality of Hyloris' pipeline.

SUBSEQUENT EVENTS

After the reporting period, Hyloris' commercial partner AFT Pharmaceuticals entered into a new exclusive licensing agreement with Chengdu Tongde Pharmaceuticals Co., Ltd. for the development, manufacture and commercialization of Maxigesic® IV in Mainland China, replacing the previous, since-terminated distribution arrangement and re-establishing a pathway to this important market. AFT Pharmaceuticals is also finalizing discussions with a commercialization partner for Japan, one of the

largest remaining territories for Maxigesic® IV, with the parties currently expecting to sign before the end of September 2026.

OUTLOOK FOR THE REMAINDER OF 2026

Looking ahead, Hyloris remains focused on disciplined execution, good governance and continued progress across its pipeline. The Company is preparing regulatory submissions for Aspirin IV and Dofetilide IV in the second half of 2026, and advancing Alenura™, HY-094, Metolazone IV, Milrinone ER and other priority programs toward meaningful clinical and regulatory milestones. A key strategic priority remains to further define the Company's go-forward commercialization strategy for its U.S. cardiovascular portfolio, which may include licensing agreements or other strategic partnerships. Beyond 2026, Hyloris believes its diversified, three-tier portfolio and flexible partnering model will continue to provide multiple pathways for value creation, while its development model continues to target new products at an average cost of less than EUR 7 million (non-inflation adjusted) over development timelines of up to seven years.

HUMAN RESOURCES AND GOVERNANCE

In March 2026, the Board of Directors approved the issuance of 250,000 new warrants under the ESOP Warrant Plan 2026, intended for key employees, consultants, members of the management team and certain directors, reinforcing long-term alignment between the Company and its people.

FINANCIAL HIGHLIGHTS

(in € thousands)	30 June 2026	30 June 2025	Variance in %
Revenue	4,696	3,018	56%
Other operating income	877	765	15%
Operating income	5,573	3,784	47%
Cost of sales	(298)	(128)	133%
Research and development expenses	(4,161)	(4,975)	(16%)
General and administrative expenses	(2,529)	(2,203)	15%
Other operating expenses	(591)	(12)	n.m.
Operating expenses	(7,579)	(7,318)	4%
Operating profit (loss) / EBIT	(2,006)	(3,534)	(43%)
Financial income & expenses	131	(183)	N.A.
Income taxes	-	162	N.A.
Profit (loss) for the period	(1,875)	(3,555)	(47%)

(in € thousands)	30 June 2026	31 December 2025	Variance in %
Equity	24,943	26,475	(6%)
Cash & cash equivalent	8,735	13,775	(37%)

Operating income

Total revenue and other operating income increased by 47% to €5,573 thousand in the first half of 2026, compared to €3,784 thousand in the same period of 2025. Revenue grew 56% to €4,696

thousand, mainly driven by higher milestone income, including a regulatory milestone on Atomoxetine Oral Liquid and the upfront payment received under the license and supply agreement for Pantoprazole IV. Royalties from Hyloris' commercialized products remained broadly stable at €2,917 thousand (with Podofilox Gel back in market in Q2), and the first half of 2026 saw the first royalties and profit share on Tranexamic Acid IV RTU, the Group's fourth commercialized product. Further details on revenue and other operating income can be found in the notes to the half-year report.

Results

R&D expenses were 16% lower than last year, mainly reflecting the phasing of projects, while R&D activity remained strong and several positive study results were achieved.

General and administrative expenses amounted to €2,529 thousand, up 15% compared to €2,203 thousand in 2025, mainly due to higher management consultancy and audit fees, partly offset by lower legal and paralegal fees. Operating expenses also reflect a €474 thousand impairment on a receivable related to the Group's collaboration with Pleco Therapeutics, following a delay in additional financing for that program.

Further details on the operating expenses can be found in the notes to the half-year report

Net financial income and expenses for the first half of 2026 turned positive at €131 thousand, compared to negative €183 thousand for the same period of 2025. The improvement mainly reflects the stabilization of the USD against the EUR, which resulted in a net exchange gain of €95 thousand in the first half of 2026, compared to a net exchange loss of €419 thousand in the same period of 2025, partly offset by lower interest income following reduced cash balances and interest rates.

The net loss for the period narrowed to €1,875 thousand, compared to €3,555 thousand in the first half of 2025 – a reduction of almost half, and the lowest half-year loss reported since the Company's IPO.

Equity and cash position

Hyloris' equity amounted to €24,943 thousand as of 30 June 2026, compared to €26,475 thousand as of 31 December 2025, reflecting the net loss for the period.

Cash and cash equivalents amounted to €8,735 thousand as of 30 June 2026, compared to €13,775 thousand as of 31 December 2025.

In line with the development profile of many pharma companies at this stage, Hyloris has reported net losses since inception, including for the first half of 2026. The Board approved the Company's 10-year strategic business plan in December 2025 and has since reviewed and approved an update reflecting the latest timing of commercial opportunities and revised R&D and G&A spending. Taking into account cash and cash equivalents of €8.7 million as of 30 June 2026, anticipated revenues from its commercialized products, expected out-licensing proceeds in 2026, 2027 and beyond, the flexibility to phase certain R&D activities and if needed call on a CEO Stijn Van Rompay's comfort letter in favour of Hyloris, unconditionally and irrevocably committing to provide financial support up to €2.5 million for a period till end September 2027. While the Company may not need to call on this support, in full or at all, it further reinforces Hyloris' financial flexibility. On this basis, the interim financial statements have been prepared on a going-concern basis, with no material uncertainty identified (IAS 1.25–26).

As a key strategic priority, Hyloris continues to explore and define its go-forward strategy for its U.S. cardiovascular portfolio, including (potential) financial and commercialization partnerships to optimize both value creation and market & patient access.

REPORT

The auditor, BDO Réviseurs d'Entreprises SRL, represented by Christophe Pelzer, has performed a limited review of the condensed consolidated interim financial statements on which he issued an unmodified opinion concluding as follow: "Based on our limited review, we have not identified any matters that lead us to believe that the accompanying condensed consolidated interim financial information has not been prepared, in all material respects, in accordance with IAS 34 'Interim Financial Reporting' as adopted by the European Union.". The Group's half-year financial report can be found at www.hyloris.com in the "Events and Presentations" section within the section dedicated to Investors.

FINANCIAL CALENDAR

March 25, 2027	2026 Annual Results
April 30, 2027	2026 Annual Report
June 8, 2027	Annual General Meeting of Shareholders
September 23, 2027	Half-Year Results 2027

About Hyloris Pharmaceuticals

Hyloris is a specialty pharma group focused on reinventing and optimizing existing medications through reformulation and repurposing to address important healthcare needs and deliver meaningful improvements for patients, healthcare professionals, and payers. 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 and regulatory burden required for market entry, and significantly shorten development timelines, leading to reduced costs and risks. Hyloris has announced a broad development portfolio including more than 25 value-added medicines of which two are currently in early stages 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 two high-barrier generic products approved and commercialized in the U.S.: Podofilox Gel and Tranexamic Acid RTU. Beyond its announced portfolio, Hyloris has initiated several additional internal early-stage development activities, bringing the total pipeline to more than 30 products and product candidates, and continues to evaluate further product opportunities to support future growth. ***Where others stop, Hyloris starts and adds value through Reinventing Existing Medicines for unmet patient needs worldwide.*** Hyloris is based in Liège, Belgium and since 2020 listed on Euronext Brussels (XBR: HYL) with about 54 people across 13 nationalities, targeting time-to-market of 7 years at an average cost of EUR 7 million per product (non-inflation adjusted).

For more information, visit www.hyloris.com and follow-us on [LinkedIn](#).

Contacts Hyloris Pharmaceuticals :

Ann De Jaeger, CLO
legal representative of Impact WITH Empathy BV
Ann.dejaeger@hyloris.com
32 (0)475 20 13 44 - 32 (0)4 346 02 07



Press Release

Regulated information – Inside information

Stijn Van Rompay, CEO
legal representative of SVR Management BV
stijn.vanrompay@hyloris.com
32 (0)4 346 02 07

Christophe Maréchal, CFO
legal representative of CMM&C srl
Christophe.Marechal@hyloris.com
32 (0)4 346 02 07

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.

This press release contains information about products under development and is not intended as a promotional statement. The product mentioned is subject to regulatory approval and is not currently available for sale. Please consult licensed medical professionals for healthcare decisions.