Hyloris Pharmaceuticals Reports 2023 Half-Year Results and provides Business Outlook

- Total revenue and other income nearly doubled (€2,4 million, +95%)
- R&D progress across the board, including initiation of the 4-arm Phase 2 clinical trial for Alenura™, targeting IC/BPS, a condition affecting at least 6 million U.S. patients
- PDUFA goal date for Maxigesic® IV set for 17 October 2023 by the U.S. FDA[1]
- Evaluating external product candidates & advancing internal projects to reach 30 key assets before 2025
- Multiple NDA[2] submissions expected within the next 18 months
- Analyzing different go-to-market strategies for commercial launch of a range of cardiovascular product candidates in the U.S. healthcare market
- Net cash position of €39,2 million, sufficiently capitalized for all expected R&D expenditures related to the current product candidates[3]

Webcast 7 September at 3PM CET / 2PM GMT / 10AM EST (register here)

Liège, Belgium – 6 September 2023 – Regulated information - 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 2023, along with recent achievements and a business outlook.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"Progress on all fronts is what we have demonstrated during the first half of the year, and what we will continue to pursue in the future."*

Our unwavering ambition to offer innovative and improved treatment outcomes starting from existing medicines resulted in progress for the existing portfolio. R&D progress was marked by the enrolment of the first patients in a 4-arm Phase 2 clinical trial of Alenura™, a product candidate targeting acute interstitial cystitis/bladder pain syndrome (IC/BPS). This huge unmet medical need affects at least 6 million people in the U.S. alone."

"Another major expected milestone, only weeks away, is the potential approval for Maxigesic® IV by the US Food & Drug Administration. Such an NDA approval would be a rare occurrence for a Belgian company, and would demonstrate the strength of our R&D capabilities. Maxigesic® IV, our valueable non-opioid intravenous pain treatment for use post-operatively in hospitals has the potential to offer

[1] The Prescription Drug User Fee Act (PDUFA) date is the date by which the U.S. FDA expects to complete the review process for 90% of submitted drug applications. It is a potential approval date after which a drug product candidate could be commercialized in the U.S. healthcare market.
[2] NDA: New Drug Application
[3] Assuming continued strategic out-licensing, commercial success for Maxigesic® IV and Sotalol IV, additional non-dilutive funding and milestone payments.

pain relief and reduce the use of opioids in the U.S. The U.S. is the world's largest healthcare market, where Maxigesic® IV can contribute to improving patient's lives."

"Financially, our rigorous focus on costs and cash management resulted in a healthy balance sheet with no financial debt and a cash position of close to €40 million. This is a significant advantage in today's buyer's market as we are in advanced discussions on multiple product candidates, driving innovation for better patient outcomes."

COMMERCIAL VALUE DRIVERS

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.

The number of countries in which Maxigesic® IV has been approved has increased to more than 40. So far, launches have occurred in around 20 countries.

A potential approval date for the US market was set for 17 October 2023 by the U.S. Food & Drug Administration. The U.S. regulatory body confirmed that it had received a complete response in relation to the additional data on E&L (extractables and leachables) it had requested in July 2022.

Maxigesic® IV aims to provide an alternative, non-opioid treatment option for post-operative pain. In the United States, chronic opioid usage in patients following surgery averages around 9%, ranging from 4% to 24% among various specialties[4]. Drug overdoses involving opioids resulted in over 80.000 deaths in the U.S. in 2021[5]. Patients who experienced an opioid overdose accounted for nearly $2 billion in annual hospital costs[6].

On the condition of FDA approval, sales of Maxigesic® IV could start soon, with an exclusive license and distribution agreement already signed between Hyloris' partner AFT Pharmaceuticals and Hikma Pharmaceuticals, a leading supplier of complex, injectable hospital products in the U.S.

Under the terms of the development collaboration agreement between Hyloris and AFT, Hyloris is eligible to receive a share on any product-related revenues, such as license fees, royalties, milestone payments, received by AFT.

Subject to market approval by the FDA and the first U.S. sales, Hyloris will be be entitled to to a milestone of approximately $2 million as revenue.

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. Sotalol IV allows to significantly reduce the length of hospital stay and potentially the overall cost of care potentially improving patient outcomes.

Hyloris is taking further steps to capture more of the growth potential in the future. In addition, Hyloris will capture a larger share of the product sales in the second half of the year as the royalty percentages are attributed to the Company on a step-up basis.

[4] https://pubmed.ncbi.nlm.nih.gov/27163960/
[5] Data Overview | Opioids | CDC
[6] Premier | Opioid Overdoses Costing U.S. Hospitals an Estimated $11… (premierinc.com)

COMMERCIAL ROLL-OUT PREPARATION

Out-licensing agreements were signed for Tranexamic Acid RTU in early 2023, covering an important European country and a major Southeast Asian country, with a combined population of over 60 million people. Earlier agreements have been signed in 2021 for Australia, New-Zealand and Canada. Regulatory submissions in the partnered territories are in progress, and additional out-licensing agreements are expected going forward.

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. The Company 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.

Cardiovascular portfolio

Hyloris is actively analyzing different go-to-market strategies to bring its range of cardiovascular product candidates to the U.S healthcare market in the most efficient way.

The strategic grouping of submission dates targeted by Hyloris makes 2025 a pivotal year for the Company, with several launches anticipated or in in preparation for the U.S. market by that year. These product candidates will be promoted primarily to electrophysiologists, and a subset of cardiologists in hospitals.

Other value-added product candidates

With a growing portfolio and multiple product candidates progressing towards commercialization, the Company intends to sign partnerships with leading companies in their respective territories.

PIPELINE EXPANSION

The business development team applies its knowledge of established products and real-world data in the search for solutions to underserved medical needs. Inhouse knowhow is supplemented by leveraging dialogues with healthcare professionals, patient groups, payors and partners as well as our extensive sourcing network and R&D capabilities. We aim to create value by expanding our portfolio to 30 assets before 2025, and expect to accelerate pipeline expansion in the coming months.

In January 2023, Hyloris in-licensed **HY-088**, a product candidate targeting hypophosphatemia, a serious condition causing patients to have low level of phosphate in the blood. While mild hypophosphatemia is common and many patients are asymptomatic, severe hypophosphatemia can be life-threatening and requires medical treatment. Treatment protocols for patients deficient in phosphate are well-established and have proven useful in other situations of bone mineral imbalance, but in most countries no approved oral drugs exist.

By definition, the compounded drugs currently administered to patients have not been submitted for regulatory scrutiny regarding safety, efficacy and quality. Hyloris intends to achieve market access with an approved treatment in European countries.

R&D UPDATE & OUTLOOK

Swift & steady progress was made in the first half of 2023 to bring 14 repurposed and reformulated product candidates closer to patients in need, as well as 3 high barrier generics.

Our new and improved R&D lab is now operational at Légiapark in Liège (Belgium), the life sciences hub where Hyloris moved its head office at the end of 2022. Expanded R&D facilities and expertise will allow the Company to perform drug formulation and analytical activities in-house for its growing pipeline, further streamlining processes and more effectively deploying internal resources.

A non-exhaustive list of R&D achievements as well as selected milestones can be found below.

Cardiovascular portfolio

Progress has been made on all cardiovascular assets in the first half of 2023.

- For **Dofetilide IV**, the results of the pivotal clinical study, allowing regulatory submission, are expected by the summer of 2024. Additional U.S. patent applications have been submitted.
  Dofetilide IV aims to reduce hospitalization stays and related risks and costs. Currently, Dofetilide is only available as an oral capsule, and Dofetilide formulated as an IV could be used as an initial loading dose with subsequent oral Dofetilide dosing to reduce the time to reach steady state and hospital discharge.
- **Metolazone IV**: The process of manufacturing the final registration batches is currently in progress, with stability testing expected to be initiated as soon as October 2023. The pivotal clinical trial is currently in preparation and an additional U.S. patent application has been submitted.
  Metolazone tablets are used in patients with congestive heart failure, the most rapidly growing cardiovascular condition globally and the leading cause of hospitalization. The potential benefits of Metolazone IV include accelerating onset of action, allowing simultaneous administration with furosemide IV (the most frequently used intravenous hospital diuretic), and improving drug absorption for patients with concomitant gastrointestinal oedema. The intravenous formulation will also allow drug administration in patients who are too ill to receive oral medications or who are unconscious.
- **Aspirin IV:** The transfer to a new contract manufacturing organization (CMO), required following a strategic review, has been successfully concluded. Discussions with the FDA on the drug development program are ongoing.
  Aspirin IV is an intravenous formulation of acetylsalicylic acid (aspirin) targeting Acute Coronary Syndrome (ACS). When ACS occurs, fast diagnosis and treatment is crucial and potentially lifesaving.
- **HY-074**: Regulatory submission for the U.S. market is expected shortly after submissions related to the other cardiovascular assets mentioned in this list. For HY-074, Hyloris is exploring additional indications outside of the cardiovascular space.
  HY-074 is an IV formulation of a current standard of care treatment significantly reducing risk of death in ACS patients. HY-074 aims to offer faster onset of action, more convenient administration (more notable in patients who are nauseated or unconscious) and dosage control.

Other value-added product candidates

Notable points of progress for our these product candidates are described below. Other product candidates have advanced in line with the timelines previously indicated.

- **Alenura**™ : At the start of the summer, the first patients entered a 4-arm study which is part of an ambitious adaptive phase 2 program. The 4-arm trial is currently targeting to enroll 120 patients across multiple sites in the U.S. Each subject will receive a single blinded dose of Alenura™, placebo, lidocaine, or heparin by random assignment. Alenura™ is being developed as a ready-to-use instillation to be administered intra-vesicularly. The product candidate targets acute pain flares in patients with IC/BPS, which affects at least 6 million people in the US alone.
- **HY-083:** A Phase 1 study was conducted demonstrating no systemic exposure could be detected following intranasal administration of the molecule using a nasal spray. HY-083 targets idiopathic rhinitis, a medical disorder characterized by a collection of nasal symptoms that resemble nasal allergies and hay fever (allergic rhinitis) but are not caused by a known cause like allergens or infectious triggers.
- **Tranexamic Acid Oral Suspension**: FDA agreement to proceed with the Phase 3 study was obtained, with the enrolment of the first patient expected in September 2023. TXA oral mouth rinse aims to reduce oral bleeding in patients undergoing dental procedures.
- **Miconazole-Domiphen Bromide:** A full read-out of the Phase 2 dose-finding study can be expected shortly, with the results guiding the company for the design of the next clinical trial.
  Miconazole-DB is a topical synergistic combination treatment for vulvovaginal candidiasis .
- **HY-029**: Subject to a successful outcome of the planned pivotal clinical study, regulatory filing to the U.S. FDA can be expected by mid-2024.
  HY-029 is a liquid formulation of an existing non-disclosed antiviral drug that is currently only available in oral solid form. Hyloris aims to improve ease of administration and dosage control, and thus potentially improving clinical outcome.

The total headcount of the Company grew to slightly over 40 people, with several key recruitments occurring over the summer. To enhance the development activities, only limited additional hiring is required.

With a net cash position of €39,2 million and assuming continued strategic out-licensing, commercial success for Maxigesic® IV and Sotalol IV, additional non-dilutive funding and milestone payments, the Company believes it is sufficiently capitalized to fund all expected R&D expenditures of the current product candidates (14 product candidates & 3 generics).

FINANCIAL HIGHLIGHTS AND RESULTS OF OPERATIONS

	Period ended 30 June		
(in € thousands)	**2023**	**2022**	**Variance**
Total revenue and other income	**2,391**	**1,229**	**95%**
Revenues	1,160	1,033	**12%**
Other income	1,231	196	**528%**
Cost of sales	**(46)**	**(61)**	**(25%)**
Operating expenses	**(9,361)**	**(5,986)**	**56%**
Research and development expenses	(6,871)	(4,712)	**46%**
General and administration expenses	(2,490)	(1,274)	**95%**
Operating result	**(7,100)**	**(4,876)**	**46%**
Net financial result	**466**	**(66)**	**(806%)**
Net result	**(6,634)**	**(4,942)**	**34%**
Net operating cashflow	**(4,129)**	**(6,401)**	**-35%**
Cash and cash equivalents	**39,159**	**57,687**	**-32%**

Total Revenue and Other Income

During the first six months of 2023, total revenue and other income increased to €2,391 thousand compared to €1,229 thousand in the first half year of 2022, which is approximately 95% higher compared to last year. The strong growth is mainly driven by increase of royalties, out-licensing income for Maxigesic IV and non-dilutive funding which we received from a US State Government and the Walloon region in Belgium.

Results

The Company realized a net loss of €6,634 thousand for the six-month period ending 30 June 2023, compared to a net loss of €4,942 thousand for the first half year of 2022.
In the first half of this year, the net loss is mainly resulting from the increase in R&D expenditure and G&A expenses
R&D expenditure during the first six months of 2023 amounted to €6,871 thousand, compared to €4,712 thousand for the same period of 2022. The increase was mainly driven by intensified activities to progress product candidates through the drug development stages.

General and administrative expenses increased to €2,490 thousand in the first half-year of 2023 versus €1,274 thousand in 2022, primarily driven by the enlargement of the Group's structure, additional recruitments, increased IP costs and higher legal costs compared to last year.

The net financial income in the first six months of 2023 was €466 thousand compared to a net financial loss of €66 thousand in the same period of 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 the first-half year of 2023 increased to €6,634 thousand versus €4,942 thousand in the same period of 2022.

Balance Sheet

Compared to the end of 2022, the Group is free of debt. The increase in right-of-use assets and borrowings is due to the start of the lease agreement related to the new inhouse R&D lab. The Company received an advance payment related to a government grant from the Walloon region, supporting the drug development of the product candidate HY-083. €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 current cash and cash equivalents totaling €39,159 thousand on 30 June 2023, compared to €43,457 thousand on 31 December 2022.

Net cash outflow generated from operating activities was €4,158 thousand during the first six months of 2023, compared to a net operating cash outflow of €6,401 thousand in the same period of 2022. The decrease of 35% in the operating cash outflow is the result of revenue growth and good working capital management.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION FOR THE FIRST HALF-YEAR OF 2023

ASSETS (in € thousands)	30-Jun-23	31-Dec-22
Non-current assets	***12,258***	***11,063***
Intangible assets	3,785	3,607
Property, plant and equipment	275	176
Right-of-use assets	1,667	885
Equity accounted investments	3,863	3,948
Other investment, including derivatives	1,000	1,000
Trade and other receivables	1,667	1,447
Current assets	***45,015***	***50,801***
Trade and other receivables (current)	4,541	5,127
Other investment, including derivatives (Current)	489	469
Prepayments	826	1,748
Cash and cash equivalents	39,159	43,457
TOTAL ASSETS	**57,273**	**61,863**

EQUITY AND LIABILITIES (in € thousands)	30-Jun-23	31-Dec-22
Equity attributable to owners of the parent	***48,723***	***55,045***
Share capital	140	140
Share premium	121,513	121,513
Retained earnings	(64,246)	(53,476)
Result of the period	(6,634)	(10,770)
Share based payment	1,934	1,622
Cost of Capital	(4,460)	(4,460)
Other reserves	476	476
Total equity	***48,723***	***55,045***
Non-current liabilities	***1,822***	***1,047***
Borrowings	1,478	747
Other financial liabilities	344	300
Current liabilities	***6,728***	***5,772***
Borrowings (current)	195	138
Other financial liabilities (current)	3,200	3,212
Trade and other liabilities	3,332	2,422
Total liabilities	**8,550**	**6,819**
TOTAL EQUITY AND LIABILITIES	**57,273**	**61,863**

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE FIRST HALF-YEAR OF 2023

in € thousands	30-Jun-23	30-Jun-22
Revenue	1,160	1,033
Cost of sales	(46)	(61)
Gross profit	**1,114**	**973**
Research and development expenses	(6,871)	(4,712)
Selling, general and administrative expenses	(2,490)	(1,274)
Share of result of equity-accounted investees	(85)	(58)
Other operating income	1,231	196
Operating profit/(loss) (EBIT)	**(7,100)**	**(4,876)**
Financial income	566	55
Financial expenses	(100)	(621)
Profit/(loss) before taxes	**(6,634)**	**(4,942)**
PROFIT/(LOSS) FOR THE PERIOD	**(6,634)**	**(11.579)**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE FIRST HALF-YEAR OF 2023

(in € thousand)	Attributable to equity holders of the Company						Total Equity
	Share capital	Share premium	Other reserves			Retained earnings	
			Share based payment reserve	Cost of Capital	Other reserves		
Balance at 31 December 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					2,832
Share-based payments			274				274
Total comprehensive income						(4,942)	(4,942)
Balance at 30 June 2022	**140**	**121,513**	**2,665**	**(4,460)**	**476**	**(59,748)**	**60,586**
Exercise of warrants			(1,329)			1,329	-
Share-based payments			286				286
Total comprehensive income						(5,828)	(5,828)
Balance at 31 December 2022	**140**	**121,513**	**1,622**	**(4,460)**	**476**	**(64,246)**	**55,045**
Share-based payments			313				313
Total comprehensive income						(6,634)	(6,634)
Balance at 30 June 2023	**140**	**121,513**	**1,935**	**(4,460)**	**476**	**(70,880)**	**48,724**

CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE FIRST HALF-YEAR OF 2023

in € thousands	30-Jun-23	30-Jun-22
CASH FLOW FROM OPERATING ACTIVITIES		
Profit/(loss) for the period	(6,634)	(4,942)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation, amortisation and impairments	163	92
Share-based payment expense	313	274
Derivatives financial instruments	(80)	(276)
R&D Tax Credit	(211)	(137)
Interest expenses on shareholder loans	-	(45)
Interest income on deposits and current accounts	(396)	-
Loss on drecognition of shareholders loans	-	486
Equity transaction costs	-	29
Share of profit of equity-accounted investees, net of tax	85	58
Other non-cash adjustments	(12)	(4)
Changes in working capital:		
Trade and other receivables	834	298
Other investment, including derivatives	9	(1.221)
Prepayments	923	-
Trade and Other liabilities	849	(769)
Other current and non-current liabilities	-	13
Cash generated from operations	**(4,158)**	**(6.054)**
Interest paid	17	1
Interest received	12	-
Income Taxes paid	-	(349)
Net cash generated from operating activities	**(4,129)**	**(6,401)**
CASH FLOW FROM INVESTING ACTIVITIES		
Interests received	148	-

Purchases of property, plant and equipment	-	(30)
Purchases of intangible assets	(236)	(182)
Acquisition of other financial assets	-	(522)
Net cash provided by/(used in) investing activities	**(88)**	**(734)**
CASH FLOW FROM FINANCING ACTIVITIES		
Reimbursements of borrowings and other financial liabilities	-	(1.059)
Reimbursements of lease liabilities	(112)	(35)
Proceeds from borrowings and other financial liabilities	44	-
Proceeds from Private Placement via ABB	-	14.337
Proceeds from Execution Transactions Warrants	-	2.832
Interests paid	(12)	(1.265)
Net cash provided by/(used in) financing activities	**(80)**	**14.810**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(4,297)**	**7,675**
CASH AND CASH EQUIVALENTS at beginning of year	43,457	50,012
CASH AND CASH EQUIVALENTS at end of year, calculated	39,159	57.687

AUDIT REPORT

The statutory auditor, KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises, represented by Olivier Declercq, has confirmed that the audit procedures, which have been substantially completed, have not revealed any material misstatement in the accounting information included in the Company's annual announcement.

WEBCAST DETAILS

The Company will host a webcast conducted in English to present its 2023 Half-Year results and Business Outlook, followed by a live Q&A session. The webcast will start on September 7th at 3PM CET / 2PM GMT / 10 AM EST. To join the webcast, please register at Hyloris.com/webcast

EXPECTED FINANCIAL CALENDAR

14 March 2024	**Annual Results 2023**
25 April 2024	**Annual Report 2023**
4 June 2024	**Annual General Meeting of Shareholders**

UPCOMING EVENTS

Hyloris regularly takes part in events to interact with investors, partners and other stakeholders. We look forward to meeting you on one of the following occasions, and will be adding new events to our website under **events & presentations**.

Date	Location	Event
27-29 September 2023	Munich, Germany	Biotech On Tap 2023
5 October 2023	Paris, France	Investor Day
9 October 2023	Antwerp, Belgium	De Belegger On Tour
24-25 October 2023	Barcelona, Spain	CPHI
6-8 November 2023	Munich, Germany	BIO-Europe
14-16 November 2023	London, U.K.	Jefferies Healthcare Conference
23 November 2023	Paris, France	Belgian Day in Paris (Degroof Petercam)
8-11 January 2024	San Francisco, U.S.	JP Morgan Healthcare Conference

About Hyloris
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 16 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 3 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 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.