



**2022 HALF-YEAR  
FINANCIAL REPORT**

**REFORMULATING THE FUTURE**



This report is prepared in accordance with article 13 of the Belgian Royal Decree of November 14, 2007. Hyloris publishes its Interim Financial Report in English and French. In the event of differences of interpretation between the English and the French versions of the Report, the original English version will prevail.

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## 1. BUSINESS PERFORMANCE REVIEW

### Key Highlights and Year-to-Date Events

#### Commercial products

- **Sotalol IV**, a novel, patented, IV formulation of oral 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.
- **Maxigesic® IV**, a novel, unique combination for the treatment of post-operative pain 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 2022, 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 the completion of the 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 and regulatory update

- **Aspirin IV** 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.

- **Oral Tranexamic Acid Solution formulation (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™:**  
The 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), and 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 6 months ago. Several discussions are being held with regulatory agencies to confirm and validate development plans.

#### Corporate 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.
- Renegotiated the Shareholder loan terms resulting in
  - Lower interest rate at 0.75% versus 4% as from 1 January 2022
  - Setup new credit line from shareholders covering the portion of reimbursed capital allowing to guarantee the same level of liquidity for the company.
- Hyloris' shareholders approved 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
<b>Total revenue and income</b>	<b>1,229</b>	<b>1,145</b>	<b>7%</b>
Revenues	1,033	838	23%
Other operating income	196	307 <sup>i</sup>	(36%)
<b>Cost of sales</b>	<b>(61)</b>	<b>(42)</b>	<b>45%</b>
<b>Operating expenses</b>	<b>(5,986)</b>	<b>(9,016)</b>	<b>(34%)</b>
Research and development expenses	(4,712)	(1,560)	202%
General and administration expenses	(1,274)	(1,608)	(21%)

Other operating expenses <b>(one-off)</b> <sup>ii</sup>	--	<b>(5,770)</b>	(100%)
<b>Operating result</b>	<b>(4,876)</b>	<b>(7,913)</b>	<b>(38%)</b>
<b>Net result</b>	<b>(4,942)</b>	<b>(8,240)</b>	<b>(40%)</b>
<b>Net cash (burn)/inflow</b> <sup>iii</sup>	<b>7,675</b> <sup>ivii</sup>	<b>(10,934)</b>	
<b>Cash and cash equivalents</b>	<b>57,687</b>	<b>53,465</b>	

<sup>i</sup> One-off income related to the unwinding of the license agreements with the Alter Pharma Group

<sup>ii</sup> One-off expenses related to the unwinding of the license agreements with the Alter Pharma Group

<sup>iii</sup> For the period 1 January to 30 June

<sup>ivii</sup> Including net proceeds from Capital Transactions

### Total revenue and other income

During the first six months of 2022, total revenue and other operating 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 R&D services rendered by the Group.

### Results

The Group realised 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.

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 €5,770 thousand 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 the costs related to outsourced and internal product development activities, which is driven by the pipeline expansion and the 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 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. 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).

A detailed overview and explanation of the condensed interim financial statements are available in the Notes of this report.

### **Outlook for the Remainder of 2022**

- **Pipeline expansion:** The Company re-stated that its goal remains to add at least four new reformulated or repurposed product candidates through in-licensing or joint ventures by

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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-U.S.: continue roll-out in Europe and Rest of World
- ii) Maxigesic IV for the U.S.: Submit requested additional information to the U.S. FDA in support of the new drug application (NDA)
- iii) Sotalol IV: accelerate roll-out in the U.S.

With cash and cash equivalents of €57.7 million at 30 June 2022, the Group 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.

### **Significant Events and Transactions**

On 1 April 2022 Hyloris announced that it has 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 20 June 2022 Hyloris successfully renegotiated the Shareholder loans which results in :

- Loans denominated in USD are converted in EUR;
- A new actual interest rate, effective as from 1 January 2022, of 0.75% instead of 4%;
- A payment of interests up to 20 June 2022 (€1,265 thousand);
- A reimbursement of the outstanding principal amount owed to Pieter Van Rompay (€1,059 thousand), who made a cash credit line available for the same amount with the same maturity (0.55% reservation fee);
- An one-off and non-cash expenses of €484 thousand corresponding to the impact of fair value and the exchange rate differences on these loans ).

On 22 June 2022 Hyloris increased Capital and Share Premium with respectively €6 thousand and €2,826 thousand through the exercise of 1,200,000 outstanding Transactions Warrants. As per 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.

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## 2. RESPONSABILITY STATEMENT

We hereby certify:

- that, to the best of our knowledge, the condensed consolidated financial statements for the six-month period ended 30 June 2022, which have been prepared in accordance with IAS 34 “Interim Financial reporting” as adopted by the European Union, gives a true and fair view of the financial position, comprehensive loss and cash flows of the Group and the undertakings included in the consolidation as a whole (the ‘Group’), and
- that the interim management report includes a fair review of the important events that have occurred during the first six months of the financial year and of the major transactions with the related parties, and their impact on the condensed consolidated financial statements, together with a description of the principal risks and uncertainties for the remaining six months of the financial year.

On behalf of the Board of Directors  
31 August 2022

Stefan Yee  
Chairman

Stijn Van Rompay  
CEO

### 3. CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

#### Condensed Consolidated Statement of Financial Position

ASSETS (in € thousand)	Note	30 June 2022	31 December 2021
<b>Non-current assets</b>		<b>10,229</b>	<b>9,485</b>
Intangible assets	6	3,080	2,944
Property, plant and equipment		138	122
Right-of-use assets		62	173
Investments in associates and joint ventures		4,021	4,079
Financial assets	7	1,505	453
Other non-current assets	8	1,424	1,714
<b>Current assets</b>		<b>62,738</b>	<b>53,959</b>
Inventories		-	-
Trade and other receivables	9	2,023	2,321
Other financial assets	7	314	528
Other current assets	10	2,714	1,098
Cash and cash equivalents		57,687	50,012
<b>TOTAL ASSETS</b>		<b>72,967</b>	<b>63,444</b>
<b>EQUITY AND LIABILITIES</b>			
(in € thousand)	Note	30 June 2022	31 December 2021
<b>Equity</b>	11	<b>60,586</b>	<b>48,056</b>
Share capital		140	129
Share premium		121,513	103,693
Retained earnings		(59,748)	(54,805)
Other reserves		(1,320)	(960)
<b>Liabilities</b>		<b>12,381</b>	<b>15,388</b>
<b>Non-current liabilities</b>		<b>538</b>	<b>409</b>
Borrowings	12	38	109
Other financial liabilities	12	500	300
<b>Current liabilities</b>		<b>11,843</b>	<b>14,978</b>
Current borrowings	12	28	65
Other current financial liabilities	12	9,823	11,815
Trade and other liabilities	13	1,980	2,749
Current tax liabilities	19	-	349
Other current liabilities		13	-
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>72,967</b>	<b>63,444</b>

## Condensed Consolidated Statement of Profit and Loss and Other Comprehensive Income

STATEMENT OF COMPREHENSIVE INCOME (in € thousand)	Note	30 June 2022	30 June 2021
Revenues	14	1,033	838
Cost of sales	15	(61)	(42)
<b>Gross profit</b>		<b>973</b>	<b>796</b>
Research and development expenses	15	(4,712)	(1,560)
Selling, General and administrative expenses	15	(1,274)	(1,608)
Share of result from Associates and joint ventures, net of taxes	15	(58)	(78)
Other operating income		196	307
Other operating expenses	15	-	(5,770)
<b>Operating profit/(loss) (EBIT)</b>		<b>(4,876)</b>	<b>(7,913)</b>
Financial income	16	555	20
Financial expenses	16	(621)	(347)
<b>Profit/(loss) before taxes</b>		<b>(4,942)</b>	<b>(8,240)</b>
Income taxes		-	-
<b>PROFIT/(LOSS) FOR THE PERIOD</b>		<b>(4,942)</b>	<b>(8,240)</b>
<b>Basic and diluted earnings/(loss) per share (in €)</b>	17	<b>(0.19)</b>	<b>(0.32)</b>

## Condensed Consolidated Statement of Changes in Equity

(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			
<b>Balance at 31 December 2020</b>	<b>129</b>	<b>103,693</b>	<b>1,814</b>	<b>(3,827)</b>	<b>476</b>	<b>(43,226)</b>	<b>59,059</b>	
Share-based payments	-	-	261	-	-	-	261	
Total comprehensive income	-	-	-	-	-	(8,240)	(8,240)	
<b>Balance at 30 June 2021</b>	<b>129</b>	<b>103,693</b>	<b>2,075</b>	<b>(3,827)</b>	<b>476</b>	<b>(51,466)</b>	<b>51,080</b>	
 <b>Balance at 31 December 2021</b>	 <b>129</b>	 <b>103,693</b>	 <b>2,391</b>	 <b>(3,827)</b>	 <b>476</b>	 <b>(54,805)</b>	 <b>48,056</b>	
Private Placement via ABB (note 11)	5	14,995	(634)				14,366	
Exercise of Warrants (note 11)	6	2,826					2,832	
Share-based payments			274				274	
Total comprehensive income						(4,942)	(4,492)	
<b>Balance at 30 June 2022</b>	<b>140</b>	<b>121,513</b>	<b>2,665</b>	<b>(4,460)</b>	<b>476</b>	<b>(59,748)</b>	<b>60,586</b>	

## Condensed Consolidated Statement of Cash Flow

(in € thousand)	Note	30 June 2022	30 June 2021
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>			
Operating result		(4,942)	(8,240)
<i>Adjustments to reconcile net loss to net cash provided by operating activities:</i>			
Depreciation, amortisation and impairments		92	50
Share-based payment expense	18	274	261
Derivatives financial instruments		(276)	
R&D tax credit		(137)	63
Interest expenses on shareholders loans		45	234
Loss on derecognition of shareholders loans		486	-
Equity transaction costs		29	-
Losses from associates and joint ventures		58	78
Other non-cash adjustments		(4)	99
<i>Changes in working capital:</i>			
Trade and other receivables		298	(1,830)
Other current and non-current assets		(1,221)	122
Trade and other liabilities		(769)	(625)
Other current and non-current liabilities		13	505
<b>Cash generated from operations</b>		<b>(6,054)</b>	<b>(9,282)</b>
Interest paid		1	-
Income Taxes paid	19	(349)	-
<b>Net cash generated from operating activities</b>		<b>(6,401)</b>	<b>(9,282)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>			
Purchases of property, plant and equipment		(30)	(4)
Purchases of Intangible assets		(182)	(150)
Investments in associates and joint ventures		-	(1,270)
Acquisition of other financial assets	7	(522)	(13)
Other		-	219
<b>Net cash provided by/(used in) investing activities</b>		<b>(734)</b>	<b>(1,218)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>			
Reimbursements of borrowings and other financial liabilities	12	(1,059)	(409)
Reimbursements of lease liabilities		(35)	(24)
Proceeds from Private Placement via ABB		14,337	-
Proceeds from Execution Transactions Warrants		2,832	-
Interest paid		(1,265)	-
<b>Net cash provided by/(used in) financing activities</b>		<b>14,810</b>	<b>(434)</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>		<b>7,675</b>	<b>(10,934)</b>
<b>CASH AND CASH EQUIVALENTS at beginning of the period</b>		<b>50,012</b>	<b>64,399</b>
<b>CASH AND CASH EQUIVALENTS at end of the period, calculated</b>		<b>57,687</b>	<b>53,465</b>

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## 4. NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

### 1. General Information

Hyloris Pharmaceuticals SA (the “Company” or “Hyloris”) is a limited liability company governed by Belgian law. The address of its registered office is Blvd Gustave Kleyer 17, 4000 Liège, Belgium.

Hyloris is a specialty biopharma Group focused on innovating, reinventing, and optimising 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 14 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives.

Two products are initial stages of commercialisation with partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. The Group’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.

#### Implication of the armed conflict between Russia and Ukraine

The geopolitical situation in Eastern Europe intensified on 24 February 2022, with Russia’s invasion of Ukraine. The war between the two countries continues to evolve as military activity proceeds and additional sanctions are imposed.

Although the Russia-Ukraine war is not expected to cause disruption in the Groups’ operations, (i) the Group continue to monitor the situation and (ii) is taking measures to mitigate the impact on her ability to conduct clinical development activities.

These interim condensed interim consolidated financial statements were authorized for issue by the Board of Directors on 31 August 2022 and are available on the [Hyloris website](#).

### 2. Summary of Significant Accounting Policies

#### ***Basis of preparation***

The Group’s condensed consolidated financial statements for the 6-month period ended 30 June 2022 have been prepared in accordance with International Accounting Standard 34 – Interim Financial Reporting as adopted by the European Union and comprise the Company and its subsidiaries (together to as ‘the Group’)

This condensed consolidated financial information does not include all the information required for full annual financial statements and should be read in conjunction with the consolidated financial statements as at and for the year ended 31 December 2021, which were prepared in accordance with IFRS, as adopted by the European Union. However, selected explanatory notes are included to explain events and transactions that are significant to the understanding of the changes in the Group’s financial position and performance since the last annual financial statements.

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The condensed consolidated financial statements are presented in Euro (€) and all values are rounded to the nearest thousand (€'000) which may result in minor discrepancies in the totals and sub-totals disclosed in the financial tables and percentages may not precisely reflect the absolute figures.

These financial statements are prepared on an accrual basis and on the assumption that the entity is in going concern and will continue in operation in the foreseeable future (see below).

The preparation of the interim financial statements in accordance with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise judgment in the process of applying the Group accounting policies. The areas involving a higher degree of judgment or complexity, or areas where assumptions and estimates are significant to the consolidated financial statements are disclosed in Note 3.

### ***Change in accounting policies***

The same accounting policies, presentation and methods of computation have been applied in these interim condensed financial statements as were applied in the preparation of the Group's financial statements for the year ended 31 December 2021, except for the impact of the adoption of new Standard and Interpretations as described below:

- Amendments to IFRS3 – Business Combinations (effective January 1, 2022, and endorsed in EU): These amendments update a reference in IFRS 3 to the Conceptual Framework for Financial Reporting without changing the accounting requirements for business combinations.
- Amendments to IAS 16 – Property, Plant and Equipment (effective January 1, 2022, and endorsed in EU): These amendments prohibit a company from deducting from the cost of property, plant and equipment amounts received from selling items produced while the company is preparing the asset for its intended use. Instead, a company will recognize such sales proceeds and related cost in profit or loss. The amendments also clarify that testing whether an item of PPE is functioning properly means assessing its technical and physical performance rather than assessing its financial performance.
- Amendments to IAS 37 – Provisions, Contingent Liabilities and Contingent Assets (effective January 1, 2022, and endorsed in EU): These amendments specify which costs a company includes when assessing whether a contract will be loss-making. The amendments clarify that the 'costs of fulfilling a contract' comprise both: the incremental costs; and an allocation of other direct costs.
- Annual Improvements to IFRS Standards 2018–2020 make minor amendments to IFRS 1 First-time Adoption of International Financial Reporting Standards, IFRS 9 Financial Instruments, IAS 41 Agriculture and the Illustrative Examples accompanying IFRS 16 Leases

The above mentioned IFRS pronouncement did not have a significant impact on the condensed consolidated interim financial statements.

Following the Group's mitigation of its foreign currency risk, a new accounting policy has been defined and described here below.

### ***Derivative Financial Instruments***

The Group holds derivative financial instruments to hedge its foreign currency. Derivatives are recognised initially at fair value at the date a derivative contract is entered into and are subsequently remeasured to their fair value at each reporting date. A derivative with a positive fair value is

recognised as a financial asset whereas a derivative with a negative fair value is recognised as a financial liability. Derivatives are not offset in the financial statements unless the Group has both legal right and intention to offset. A derivative is presented as a non-current asset or a non-current liability if the remaining maturity of the instrument is more than 12 months and it is not expected to be realised or settled within 12 months. Other derivatives are presented as current assets or current liabilities.

### 3. Critical Accounting Estimates and Judgments

In preparing the condensed consolidated financial statements for the 6-month period ended 30 June 2022, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources.

The significant judgments made by management in applying the Group's accounting policies and key sources of estimations uncertainty were the same as those described in the last annual financial statements.

### 4. Financial Instruments Fair Value Disclosures

The table below summarises all financial instruments by category in accordance with IFRS 9:

(in € thousand)	IFRS 9 Category	30-Jun-22	31-Dec-21
Non-current financial assets	FVTPL	1,012	453
Non-current financial assets	At amortised cost	481	
Trade receivables	At amortised cost	1,822	2,026
Other financial assets	FVTPL	314	528
Other (non-) current assets*	At amortised cost	1,453	1,490
Cash and cash equivalents	At amortised cost	57,687	50,012
<b>Total financial assets</b>		<b>62,741</b>	<b>54,509</b>
<i>Non-current financial liabilities</i>			
Lease liabilities	At amortised cost	38	109
Other financial liabilities	At amortised cost	500	300
<i>Current financial liabilities</i>			
Lease liabilities	At amortised cost	28	65
Other financial liabilities	At amortised cost	9,823	11,815
Trade payables	At amortised cost	1,824	2,622
<b>Total financial liabilities</b>		<b>12,213</b>	<b>14,911</b>

\* Other (non-) current assets that are not financial assets (pre-paid expenses / R&D tax credit receivables) are not included

The Group considers that the carrying amounts of financial assets and financial liabilities measured at amortized costs in the condensed interim consolidated financial statements approximate their fair values.

## 5. Operating Segments

According to IFRS 8, reportable operating segments are identified based on the “management approach”. This approach stipulates external segment reporting based on the Group’s internal organisational and management structure and on internal financial reporting to management.

The Group’s activities are managed and operated in one segment, pharmaceuticals. There is no other significant class of business, either individual or in aggregate. As such, management reviews the operating results and operating plans and makes resource allocation decisions on a Group wide basis.

Revenues generated during the six-month period ending 30 June 2022 mainly relates to royalties generated from one third party customer, Alta Thera, from out-licensing Maxigesic® IV by our partner AFT Pharmaceuticals and revenue for R&D, strategic advice and services rendered.

### **Geographical information**

Revenue reported in the consolidated statement of profit or loss, and other comprehensive income and non-current assets recorded in the consolidated statement of financial position are located in Belgium, country of domicile of the Group.

## 6. Intangible Assets

In the 6-month period ended 30 June 2022, the movements in intangible assets are mainly related to the patent and regulatory related expenses for Maxigesic® IV.

The intangible assets related to capitalised development are not amortised until the moment they are available for use as intended by management, i.e. ready for commercialization. The development costs of Sotalol IV, for which amortisation already started, have a remaining useful life of 2.5 years. As from January 1, 2022 the development costs of Maxigesic® IV incurred related (future) commercialisation outside the U.S. (Rest of the World), are subject to amortisation as our partner AFT Pharmaceuticals obtained Market Approval in 39 Countries (€ 19 thousand).

As long as the assets are not amortised, they are tested for any impairment losses on an annual basis or more frequently if required. No impairment triggering events have been identified. No impairment loss has been recognised during the period.

No intangible assets have been pledged in the context of financial liabilities.

## 7. (Other) Financial Assets

(in € thousand)	30 June 2022	31 December 2021
Shares Pleco Therapeutics BV	1,000	-
Automatically Convertible loan	-	500
Optional Convertible loan	481	441
Other Financial Assets	62	40
Derivatives financial Instruments	276	-
<b>Other Financial Assets</b>	<b>1,819</b>	<b>981</b>
<i>of which as:</i>		
Non-current financial assets	1,505	453
Current other financial assets	314	528

In 2021, the Group entered into a partnership with Pleco Therapeutics to develop a Plecoid™ Agent, a novel combination product of chelating agents for the treatment of Acute Myeloid Leukaemia (AML) and Small Cell Lung Cancer (SCLC). Under the terms of the agreement, Hyloris provided via a €1,000 thousand automatically non-interest bearing convertible loan (whereof as of per 31 December 2021 €500 thousand was paid to Pleco Therapeutics). On 1 June 2022, Pleco Therapeutics issued new shares and conform the agreement, the loan has been converted into shares. The Group received 7,944 preferred shares at an issuing price of €126 per share (which result in a 4.67% ownership of the company Pleco Therapeutics).

In the first 6 months of 2022, the Group actively mitigated its foreign exchange risk (USD exposure) utilizing forward foreign exchange contracts for a total nominal value of \$6 million, whereof as per end of June \$3 million is still outstanding. As a result and as per 30 June 2022, a derivative with a positive fair value is recognised as a current financial asset for € 276 thousand.

## 8. Other Non-Current Assets

The balance sheet as at 30 June 2022, held (i) a non-current receivable amounts € 808 thousand (€845 thousand 31 December 2021) and relates to fees, payable in 2023, for services rendered and (ii) a receivable from the Belgian Government for R&D incentives (R&D Tax Credit) for a total of €616 thousand (€474 thousand 31 December 2021). The decrease compared to last year is mainly explained by the transfer of the receivable towards Alter Pharma Group to current assets as due January 2023.

## 9. Trade Receivables and Other Receivables

(in € thousand)	30 June 2022	31 December 2021
Trade receivables	1,823	2,026
Less: allowance for impairment of trade receivables	-	-
<b>Trade receivables – Net</b>	<b>1,823</b>	<b>2,026</b>
Other receivables	200	295
<b>Other receivables</b>	<b>200</b>	<b>295</b>
<b>Trade and other receivables – Current</b>	<b>2,023</b>	<b>2,321</b>

The trade receivables as per 30 June 2022 mainly relate to (i) pre-commercial milestones and (ii) R&D and strategic advice rendered in the first 6 months of 2022. An impairment analysis of trade receivables is done on an individual level, and there are no individual significant impairments. The carrying amount of the Group's trade receivables (gross) is denominated in USD\$. During the period, the payment terms for the receivables have neither deteriorated nor been renegotiated. The maximum credit risk exposure at the end of the reporting period is the carrying value of each caption of receivables mentioned above. The Group does not hold any collateral as security. Other receivables mainly include recoverable VAT.

## 10. Other Assets

(in € thousand)	30 June 2022	31 December 2021
Pre-paid R&D expenses	1,943	756
Other pre-paid expenses	126	92
Other current assets	645	250
<b>Other current assets</b>	<b>2,714</b>	<b>1,098</b>

Pre-paid R&D expenses relate to payments made by the Group for research and development projects conducted by third parties and will be recorded in profit and loss when these incur. The increase of €1,187 thousand compared to 31 December 2021, is mainly related to the product candidate HY-084 Alenura.

Pre-paid R&D expenses per 30 June 2022 mainly relate to (i) the development agreement with Vaneltix Inc (see note 22) for the development of HY-084 Alenura and (ii) the development agreement with Generic Specialty Pharma Ltd for the clinical development of Fusidic Acid Cream

The other current assets of €645 thousand per 30 June 2022 relate to the termination of the development projects conducted by Alter Pharma and its subsidiaries, whereof € 250 thousand was paid on 1 July 2022.

## 11. Equity

The increase of Share Capital and Share premium over the period can be explained by (i) the successful Capital raise through an equity offering by means of a private placement via an accelerated bookbuild offering and (ii) the execution of transaction Warrants (see Significant Events and Transactions).

The movement of other reserves over the period can be explained by (i) the increase of €273 thousand resulting from the share-based payment expenses associated with the ESOP warrants and (ii) the recognition of cost of capital of €634 thousand as a result of the capital transactions conducted in the first 6 months of 2022.

## 12. Borrowings and Other Financial Instruments

### Borrowings

(in € thousand)	30 June 2022	31 December 2021
Lease liabilities	66	174
<b>Total borrowings</b>	<b>66</b>	<b>174</b>
<i>of which as:</i>		
Non-current borrowings	38	109
Current borrowings	28	65

The Group is not subject to financial covenants. The underlying leased assets such as the headquarter building and some cars, act as pledge in the context of the lease liabilities.

### Other financial Liabilities

The other financial liabilities are detailed as follows:

(in € thousand)	30 June 2022	31 December 2021
Loans from shareholders	6,823	8,615
Other financial liabilities	3,500	3,500
<b>Other financial liabilities</b>	<b>10,323</b>	<b>12,15</b>
<i>of which as:</i>		
Non-current other financial liabilities	500	300
Current other financial liabilities	9,823	11,815

### Loans from Shareholders

The Group successfully renegotiated its Shareholders loans during the reporting period. The changes in the terms of the loan agreements qualified for substantial modifications of the terms resulting in the derecognition of the carrying value of former loans replaced by the carrying value of the loans under the new terms (see Significant Events and Transactions). The loans from shareholders, are unsecured, bear as from 1 January 2022 a fixed nominal interest rate of 0.75% (4% previously) and are payable the earlier of 31 December 2022 or, if and when, the Group will generate a positive EBIT. Decrease of the outstanding Loans from Shareholders (€1,792 thousand) can be explained by (i) the reimbursement of the principal amount of one Shareholder (€1,059 thousand), (ii) payment of incurred interest up to 20 June 2022 (€1,264 thousand), partly compensated by (iii) the FX impact on the conversion of the loans denominated in USD into EUR (€ 256 thousand), (iv) the loss resulting from the derecognition of the former carrying value of the loan (€ 226 thousand) and (v) the interest of the period (€ 45 thousand).

#### *Other financial Liabilities*

The other financial liabilities consist of (i) milestone payments to Alter Pharma Group relating to the successfully renegotiated the license agreements for multiple lead products in 2021 and (ii) committed milestone related investments (contributions to the equity) in PFH BV. As of 30 June 2022, this is presented respectively, a non-current other financial liability of €500 thousand, and a current other financial liability of €3,000 thousand.

The non-current other financial liabilities of €500 thousand have a maturity of more than 1 year and less than 5 years.

### **13. Trade and Other Liabilities**

(in € thousand)	30 June 2022	31 December 2021
Trade payables	1,824	2,622
Employee benefit liabilities	97	80
Other payables	59	47
<b>Trade and other liabilities – Current</b>	<b>1,004</b>	<b>2,749</b>

Trade payables mainly relate to the R&D activities. Other payables mainly relate to the remuneration of the members of the Board of Directors.

### **14. Total Revenue and Other Income**

Revenues generated in the six-month period include recognised (i) income from royalty income on (1) net sales of Sotalol IV commercialised by AltaThera in the U.S, (2) on Net Income of Maxigesic® IV via Partner AFT Pharmaceuticals and (ii) income from Services rendered .

In the six-month period ending 30 June 2022, the Group realised other operating income of €196 thousand compared to €307 thousand over the same period last year:

(in € thousand)	30 June 2022	30 June 2021
Grants income related to exemption on withholding taxes	59	25
Grants income related to tax credit	137	281
Other income	-	1
<b>Other Operating Income</b>	<b>196</b>	<b>307</b>

## 15. Expenses by Nature

Expenses by nature represent an alternative disclosure for amounts included in the consolidated statement of comprehensive income. They are classified under “Cost of sales”, “Research and development expenses”, “Selling, General and administrative expenses” and “Other operating expenses” with respect to the six-month period ending 30 June 2022:

(in € thousand)	30 June 2022	30 June 2021
Amortisation expense of intangible assets	40	22
Depreciation expense of property, plant and equipment	15	4
Employee benefit expenses and management fees	1,749	1,212
Board related expenses	91	94
Share based payments	274	261
Out-sourced R&D	3,273	1,298
Renegotiation and unwinding Alter Pharma		5,770
Other General and Administrative Expenses	664	397
<b>Total operating expenses</b>	<b>6,105</b>	<b>9,058</b>
<i>of which as:</i>		
Cost of sales	61	42
Research and Development expense	4,712	1,560
Selling, General and Administrative expenses	1,274	1,608
Other operating expenses	-	5,770
Earnings/losses from Associates and Joint Ventures	58	78

In accordance with IAS 38, the Group does not capitalise its research and development expenses until it has strong evidence that the technical and product development feasibility condition is met (i.e. when filing for marketing approval from the relevant regulatory authorities for the applicable product candidate).

Research and Development expenditures incurred during the six-month period ending 30 June 2022 were accounted for as operating expenses and increased to €4,712 thousand, mainly driven by higher costs for outsourced product development activities (more product candidates in pipeline).

Employee benefit expenses and management fees incurred during the first half-year of 2022 increased to €1,749 thousand, driven by the enlargement of the Group’s structure and key hires.

Despite the enlargement of the Group’s structure and key hires, Selling, General and Administrative expenses decreased by 21% to €1,274 thousand during the six-month period ending 30 June 2022, compared to €1,608 thousand in the same period in 2021. The difference is related to the reclassification of employee benefit expenses from SG&A expenses to R&D expenses for workers that are now fully dedicated to the R&D activities.

In the six-month period ending 30 June 2022, no other operating expenses are recognized, compared to an amount of €5,770 thousand in the same period in 2021, which was driven by the successful renegotiation and unwinding of the license agreements for multiple lead products with the Alter Pharma Group.

## 16. Financial Result

The various items comprising the net financial result are as follows:

(in € thousand)	30 June 2021	30 June 2020
FV adjustment on FX forward instruments	276	-
Realised gain FX forward contracts	252	5
Other financial income	27	15
<b>Financial income</b>	<b>555</b>	<b>20</b>
Interest expense on other financial liabilities	45	234
Interest expense on lease liabilities	1	2
Interest expense on cash and cash equivalents	38	52
<b>Total interest expense</b>	<b>83</b>	<b>288</b>
Loss related to substantial modification of the shareholder loans	226	-
Exchange differences	247	45
Bank and other fees	27	14
Other financial expenses	37	-
<b>Total financial expenses</b>	<b>621</b>	<b>347</b>

## 17. Earnings per Share

Basic earnings per share are calculated by dividing net profit for the year attributable to ordinary equity holders of the parent by the weighted average number of ordinary shares outstanding during the year.

Diluted earnings per share are calculated by dividing the net profit attributable to ordinary equity holders of the parent (after adjusting for the effects of all dilutive potential ordinary shares) by the weighted average number of ordinary shares outstanding during the year plus the weighted average number of ordinary shares that would be issued on conversion of all the dilutive potential ordinary shares into ordinary shares. No effects of dilution affect the net profit attributable to ordinary equity holders of the Group. The table below reflects the income and share data used in the basic and diluted earnings per share computations for the six-month period ending 30 June 2022:

(in € thousand)	30 June 2022	30 June 2021
Basic earnings		
Profit from continuing operations attributable to owners of the parent	(4,942)	(8,240)
Diluted earnings		
Dilution effect of share-based payments		
Profit from continuing operations attributable to owners of the parent, after dilution effect	(4,942))	(8,240)

Earnings per share based on the existing number of ordinary shares:

Number of shares	30 June 2022	30 June 2021
Average number of ordinary shares outstanding during the period	26,384,191	25,832,632
Basic earnings per share	(0.19)	(0.32)

Diluted earnings per share	(0.19)	(0.32)
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## 18. Share-Based Payments

The Group has a stock option/warrants plan for its employees, consultants and Executive Directors of the Group and its subsidiaries for rendered services, to involve them more closely in the long-term development of the Group. In accordance with the terms of the plan, as approved by shareholders, employees may be granted warrants to purchase ordinary shares at an exercise price per ordinary share, as mentioned below.

Each employee warrant converts into one ordinary share of the Group upon exercise. No amounts are paid or payable by the recipient upon receipt of the warrant. The warrants carry neither rights to dividends nor voting rights. Warrants may be exercised at any time from the date of vesting to the date of expiry.

The share-based payment arrangements during the current and previous periods are presented below:

Expiry Date	Exercise Price per warrant (€)	Fair value at grant date (€)	Warrants per 30 June 2022	Warrants per 31 December 2021
<b>PLAN 2017</b>				
Warrants	Exercised	2.36	1.11	-
<b>PLAN 2019</b>				
Warrants	31/12/2024	5.34	2.47	311,125
<b>PLAN 2020</b>				
Warrants	27/11/2031	9.88	4.44	69,500
Warrants	27/11/2031	12.04	5.68	55,000
Warrants	27/11/2031	13.92	6.20	60,000
Warrants	27/11/2031	16.64	7.39	2,000

The 2017 plan was immediately fully vested as no vesting conditions were required. In the six-month period ending 30 June 2022, all 1,200,000 warrants were exercised (see Significant Events and Transactions).

On 31 December 2019, the Group issued a plan of 363,300 warrants in the context of an employee stock ownership plan (ESOP warrants). The 2019 plan is subject to conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month). The Group offered in total 353,000 warrants. As of 30 June 2022, all offered warrants were accepted and 41,875 warrants lapsed. The remaining warrants of the 2019 plan already lapsed as at 31 December 2020.

On 27 November 2020, the Group issued a new plan of 400,000 warrants. The 2020 plan is subject to conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month). As at 30 June 2022, 186,500 warrants were offered and all were accepted. The remaining warrants of the 2020 plan were cancelled and replaced by a new plan (2022 plan).

On 22 June 2022, the Group issued a new plan of 213,500 warrant by replacing the cancelled warrants from 2020 plan. The 2022 plan is subject to conditions so that it will vest gradually over the next four years (25% after 1 year, and 1/48 for every additional month). As at 30 June 2022, no warrants have been accepted and therefore it has no impact in the interim financial statements.

The fair value of the warrants has been determined based on the Black Scholes model. For the plans issued in 2017 and 2019, the expected volatility is based on the historical share price volatility over the past 5 years of listed peer companies. For new plan issued as from 2020, the expected volatility is based on the historical share price volatility since listing of the Group and bench marked with listed peer companies.

Below is an overview of all the parameters used in this model:

	PLAN 2017	PLAN 2019	PLAN 2020
Average Share price (€)	2.36	5.34	10.92
Average Exercise Price (€)	2.36	5.34	11.05
Expected volatility of the shares (%)	55%	55%	40%
Expected dividends yield (%)	0%	0%	0%
Risk free interest rate (%)	0.60%	0.10%	0.00%

The following reconciles the options outstanding at the beginning and end of the period:

	Average Exercise Price (€)	Numbers of Warrants
<b>Closing balance at 31 December 2018</b>	<b>2.36</b>	<b>1,200,000</b>
Warrants accepted in December 2019	5.34	118,000
<b>Closing balance at 31 December 2019</b>	<b>2.63</b>	<b>1,318,000</b>
Warrants accepted in 2020	5.34	235,000
Warrants lapsed in 2020	5.34	20,000
<b>Closing balance at 31 December 2020</b>	<b>3.01</b>	<b>1,533,000</b>
Warrants accepted in 2021	11.89	186,500
Warrants lapsed in 2021	5.34	20,000
<b>Closing balance at 31 December 2021</b>	<b>3.68</b>	<b>1,699,500</b>
Warrants exercised in H1 2022	2.36	1,200,000
Warrants lapsed in H1 2022	5.34	1,875
<b>Closing balance at 30 June 2022</b>	<b>7.78</b>	<b>497,625</b>

## 19. Contingencies

As of 30 June 2022, the Group was not involved in any claim or dispute incidental to its activities other than mentioned below.

### *Luxembourg Tax Claim*

In 2021, The Group received a request for payment of taxes related to taxable income realized in 2016 (when the Company was still located in Grand Duchy of Luxembourg) and recognized an additional Tax Expenses in 2021. Although the company filed timely her Tax Return related to income year 2016, the company did not receive any Tax Assessments prior to the request for payment.

In the six-month period ending 30 June 2022, management appointed a legal representative in Grand Duchy of Luxembourg, the Group paid the outstanding Taxes (see Cash Flow Statement), and filed an official appeal via her legal representative. As per 30 June 2022, the Company did not receive any official response related her Appeal.

## 20. Commitments and Contingent Liabilities

End of June 2022, the Group has contractual commitments and contingent liabilities for a maximum of €37,674 thousand (among which €300 thousand and \$38,820 thousand converted in EUR at a rate of 1.0387) related to asset purchase, licenses and development agreements recorded under intangible assets. The amounts due to the counterparties are due upon reaching certain milestones dependent on successful completion of development stages of the different product candidates (including FDA approval) or on meeting specified sales targets, and which represent the maximum that would be paid if all milestones and sales targets, however unlikely, are achieved. The amounts are not risk-adjusted or discounted.

The following table details the total maximum contractual commitments and contingent liabilities at 30 June 2022 per product candidates if such products are successfully marketed (in € thousand):

Product Candidate	\$	€	Converted in €
HY-004 Tranexamic Acid MR	225		217
HY-032 Metolazone IV	1,650		1,589
HY-033 Dofetilide IV	350		337
HY-030 Atomoxetine Liquid	150		144
HY-073	31,170		30,009
HY-074	175		168
HY-029		300	300
HY-085 Alenura (note 21)	5,100		4,910
<b>TOTAL</b>	<b>38,820</b>	<b>300</b>	<b>37,674</b>

## 21. Related Party Transactions

The reference shareholder is current CEO, Stijn Van Rompay.

As part of the business, the Group has entered into several transactions with related parties. Balances and transactions between the Group and its subsidiaries, which are related parties of the Group, have been eliminated on consolidation and are not disclosed in this note. Details of transactions between the Group and other related parties are disclosed below.

The related parties presented below are identified as:

- Shareholders: i) Mr. Stijn Van Rompay, CEO and executive member of the Board of Directors of the Group, and reference shareholder of the Group; ii) GRNR Invest BV, an entity controlled by Thomas Jacobsen, CBDO and executive member of the Board of Directors of the Group
- Vaneltix Inc and its affiliates, in which non-executive an independent member of the Board of directors, Carolyn Myers her partner, Dr. Dan Vickery is CEO and shareholder.
- The Executive Management Team is defined below.
- The Board of Directors (Non-Executive Directors).

### Transaction with Shareholders

#### Successful renegotiation Shareholder loans

In the six-month period ending 30 June 2022, the Group successfully renegotiated the Shareholder loans. In table below, an overview is provided of the impact of the renegotiation of the Shareholder loans with identified Related parties, as mentioned in note 12.

(in € thousand)	Other Current Financial Assets	Financial Expenses
FX exchange losses (conversion in EUR of Loans denominated in USD)		168
Interest saving H1 2022		(84)
Loss on derecognition of the SH loan	206	206
Interest payment as per 30 June 2022*	(1,265)	
<b>Net Impact</b>	<b>(1,059)</b>	<b>290</b>

\* The withholding Tax on paid interest (30%) of €432 thousand has been paid by the Group within 15 days after payment of Net Interest (payment 1 July 2022).

#### Capital Increase dated 22 June 2022

On 22 June 2022 Hyloris increased her Capital and accompanied her Share Premium with respectively €6 thousand and €2,826 thousand via the exercise of 1,200,000 outstanding Transactions Warrants. The table below represent the exercised warrants of related parties:

Related Party	Number of Transactions warrants exercised	Exercise Price in €
Stijn Van Rompay	852,096	2.36
Thomas Jacobsen	163,512	2.36
<b>Total</b>	<b>1,015,608</b>	<b>2.36</b>

#### **Transaction with Vaneltix, Inc.**

In 2021, the Group entered into a strategic collaboration with Vaneltix Pharma, Inc. for the development and commercialisation of Alenura as first-line drug treatment for acute pain in interstitial cystitis /bladder pain syndrome (IC/BPS). Under the terms of the agreement, Vaneltix will be responsible for the further development, manufacturing, regulatory affairs and commercialisation of Alenura in collaboration with Hyloris. In return, Hyloris will provide staged investments of in total maximum \$6,700 thousand for Phase 2, manufacturing and regulatory related activities related activities and a 6% interest bearing (potential convertible) loan of \$ 500 thousand (see note 8). Hyloris will be eligible to receive a tiered and incremental percentage of the product margin generated by Vaneltix. The table below provides an overview as per 30 June 2022

(in € thousand)	30 June 2022		
	Financial Position	Profit Loss	Commitments
Non-current financial assets (note 7)	493		
Prepaid R&D Expenses (note 10)	1,291		
Recognized R&D Expenses (-)		(159)	
Interest Income		12	
Commitments and Contingent Liabilities (see note 21)			4,910
<b>Total</b>	<b>2,058</b>	<b>(147)</b>	<b>4,910</b>

## Executive Management Team

Executive management team personnel include those persons having authority and responsibility for planning, directing and controlling the activities of the Group. As of 30 June 2022, members of the Executive Management Team are:

- SVR Management BVBA, an entity controlled by Stijn Van Rompay, an executive member of the board of the Company, CEO and reference shareholder of the Company
- Jacobsen Management BV, an entity controlled by Thomas Jacobsen, an executive member of the board of the Company and CBDO
- Finsys Management BV, an entity controlled by Jean-Luc Vandebroek, Chief Financial Officer
- Dr Dietmar Aichhorn, Chief Operating Officer
- Herault BVBA, an entity controlled by Koenraad Vanderelst, Chief Legal Officer

The table below presents the compensation of all members of Executive Management by type of compensation:

(in € thousand)	30 June 2022	30 June 2021
Short-term compensation	467	430
Share based payments	95	111
<b>Total</b>	<b>562</b>	<b>541</b>

## Transactions with the Board of Directors (Non-Executive Directors)

As of 30 June 2022, non-executive members of the Board of Directors are:

- Stefan Yee, Chairman
- Leon Van Rompay
- Marc Foidart
- Carolyn Myers
- James Gal
- Chris Buysse

The table below presents the compensation of all non-executive members of Board of Directors by type of compensation:

(in € thousand)	30 June 2022	30 June 2021
Board fees	55	47
Share based payments <sup>1</sup>	15	36
<b>Total</b>	<b>70</b>	<b>83</b>

<sup>1</sup> Only the Chair of the Board, Stefan Yee, holds 100,000 warrants, which were granted prior the date of the IPO – the Group does not consider these warrants to be variable compensation

## 22. Events after the End of the Reporting Period

### Maxigesic® IV

The FDA has informed Hyloris' development partner, AFT Pharmaceuticals, via a Complete Response Letter, that it was unable to complete its review of the NDA for Maxigesic IV® and has provided 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 more specifically to revise a risk assessment of the required leachable compound study.

Hyloris and her development partner will need to re-submit a toxicological risk assessment for all leachable compounds based on confirmed compounds quantified using validated methods. The request required by the FDA falls well within the parameters of our normal operational budget and can be completed expeditiously, requiring no additional clinical data to be generated. Hyloris remains committed to Maxigesic IV®, and ensuring the product fulfills its commercial potential in the U.S.

### Positive results from Phase 1 Study of HY-004

The study results showed that HY-004 was found to be well-tolerated under varied conditions with no serious adverse events following tooth extraction, while effectively controlling procedural bleeding without delaying clot formation. Hyloris also plans to investigate its use for broader related indications in patients undergoing oral surgical procedures with or without bleeding disorders that would benefit from a locally-acting antifibrinolytic agent.

### Potential litigation with AltaThera Pharmaceuticals LLC

AltaThera Pharmaceuticals LLC has filed a complaint before the District Court for the Northern District of Illinois (Eastern Division) against Academic Pharmaceuticals Inc, Dr. Somberg and Hyloris Pharmaceuticals, for (e.g.) alleged misappropriation of AltaThera's trade secrets and confidential information and breach of contract. Hyloris is fully confident in its defense to the litigation given the strength of its case and no contingencies have been established.

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## 5. STATUTORY AUDITOR'S REPORT

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## 6. GLOSSARY OF TERMS

### Atrial Fibrillation (AF)

An abnormal heart rhythm (arrhythmia) characterised by the rapid and irregular beating of the atrial chambers of the heart. It often begins as short periods of abnormal beating, which become longer or continuous over time

### Attention Deficit Hyperactivity Disorder (ADHD)

One of the most common neurodevelopmental disorders of childhood. It is usually first diagnosed in childhood and often lasts into adulthood. Children with ADHD may have trouble paying attention, controlling impulsive behaviours (may act without thinking about what the result will be), or be overly active

### Cardiovascular (CV)

A class of diseases that involves the heart or blood vessels

### Dose-range finding study

Phase 2 clinical study exploring the balance between efficacy and safety among various doses of treatment in patients. Results are used to determine doses for later studies

### Food and Drug Administration (FDA)

The agency responsible for protecting and promoting public health and in charge of American market approval of new medications

### FSMA

The Belgian market authority: Financial Services and Markets Authority, *Or Autoriteit voor Financiële Diensten en Markten; Autorité des Services et Marchés Financiers*

### Full-Time Equivalent (FTE)

A way to measure an employee's involvement in a project. For example, an FTE of 1.0 means that the equivalent work of one full-time worker was used on the project

### HY-004

Previously known as HY-REF-004, a liquid formulation of an established product for use following a specific dental procedure, to address a non-disclosed acute issue or possible procedural related complications

### HY-016

Previously known as HY-EMP-016, a high barrier generic of an off-patent reference product currently sold in the U.S. without generic competition

### HY-029

Previously known as HY-REF-029, a liquid formulation of an existing antiviral drug that is currently only available in oral solid form to treat a non-disclosed viral infection

### HY-038

Previously known as HY-REF-038, a prefilled syringe of a commonly used product to treat a specific, non-disclosed deficiency

### HY-073 and HY-074

Previously known as HY-CVS-073, HY-CVS-074, IV formulations of oral antiplatelet drugs, offering faster onset of action in patients suffering from coronary heart disease

### HY-075

Previously known as HY-CVS-075, a liquid formulation of a commonly used drug for the treatment of coronary heart disease requiring frequent dose adjustments

### Initial Public Offering (IPO)

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Refers to the process of offering shares of a private corporation to the public in a new stock issuance. A public share issuance allows a Group to raise capital from public investors. The transition from a private to a public Group can be an important time for private investors to fully realize gains from their investment as it typically includes share premiums for current private investors. Meanwhile, it also allows public investors to participate in the offering.

#### **Intellectual Property (IP)**

Creations of the mind that have commercial value and are protected or protectable, including by patents, trademarks or copyrights

#### **Intravenous (IV)**

Some medications must be given by an IV injection or infusion, meaning these medications are administered directly into the veins using a needle or tube

#### **Investigational New Drug (IND)**

A drug that is ready for clinical trials in humans. When a drug reaches this point, the drug developer submits an application to get the consent of the Food and Drug Administration (FDA) to begin these trials

#### **Pharmacokinetics (PK)**

The study of drug absorption, distribution, metabolism, and excretion. A fundamental concept in pharmacokinetics is drug clearance, i.e., elimination of drugs from the body, analogous to the concept of creatinine clearance

#### **Phase 1 studies**

First stage of clinical testing of an investigational drug designed to assess the safety and tolerability, pharmacokinetics of a drug, usually in a small number of healthy human volunteers

#### **Phase 2 studies**

Second stage of clinical testing of a investigational drug, usually performed in < several hundreds patients in order to determine efficacy, tolerability and drug dose

#### **Phase 3 studies**

Large clinical studies, usually conducted in hundred (and in some indications, thousand) patients to gain a definitive understanding of the efficacy and tolerability of the drug candidate – serves as a basis for approval

#### **Pivotal studies**

Registrational clinical studies

#### **Ready-to use (RTU)**

Pre-diluted medicines for intravenous use, known as "ready to use" preparations, help to reduce the amount of errors associated with the preparation and administration of medicines

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## Financial Calendar

16 March 2023 – 2022 Full Year Financial Results and Business Update

### Contact

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### Disclaimer And Other Information

These unaudited condensed consolidated interim financial statements were prepared in accordance with International Financial Reporting Standards as adopted by the European Union including IAS 34 – Interim Financial Reporting. In preparing this financial statement as of and for the six-month period ended 30 June 2022, the same accounting policies and accounting estimates were used as in the 31 December 2021 annual consolidated financial statements, unless indicated otherwise.

This interim report only provides an explanation of events and transactions that are significant to understand the changes in the financial position and financial performance since the last annual reporting period and should therefore be read in conjunction with the consolidated financial statements for the financial year ended on 31 December 2021, available on the Group's website: [www.hyloris.com](http://www.hyloris.com).

The Group has prepared its half-year report in English and provided a French translation in accordance with Belgian laws. Hyloris is responsible for the translation and conformity between the English and French versions. In case of consistency between the English and French versions, the English version will prevail.

### Forward-Looking Statements

Certain statements in this half-year report 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 Group makes concerning the intended results of its strategy. These statements relate to future events or the Group's future financial performance and involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Group's control, that may cause the actual results, levels of activity, performance or achievements of the Group or its industry to be materially different from those expressed or implied by any forward-looking statements. The Group undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law. You should not place undue reliance on forward-looking statements. Certain monetary amounts and other figures included in this annual report have been subject to rounding adjustments. Accordingly, any discrepancies in any tables between the totals and the sums of amounts listed are due to rounding.

