



## **Hyloris Reports Half-Year 2020 Financial Results and Business Highlights**

**Successfully raised €80 million through public listing on Euronext Brussels and private placement**

**Funding of all development portfolio secured up until launch**

**Funding available for business development opportunities**

*Management to host a conference call at 2:00pm CEST today*

**Liège, Belgium – 6 August 2020 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL) (“Hyloris” and/or the “Company”)**, an early-stage innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals, today provides a business update and its consolidated financial results for the first half of 2020, prepared in accordance with IFRS as adopted by the European Union, and an outlook for the second half of 2020. The full interim condensed financial report is available on the Company’s website.

**Stijn Van Rompay, Chief Executive Officer of Hyloris, commented:** “Having successfully completed our public listing on Euronext Brussels, we are well positioned to deliver our goal to bring reformulated drugs with added value to the healthcare system to market as quickly as possible. We have a clear strategic vision to accomplish this and look forward to making progress through the development of our existing portfolio of product candidates, the establishment of a commercial team in the United States for our IV Cardiovascular portfolio and the potential organic or acquisition-driven expansion of our pipeline.”

### **First half 2020 operational highlights and relevant post-period events**

Hyloris continued to successfully develop its product portfolio over the first six months of 2020. The following elements were identified as key highlights:

#### **IV<sup>1</sup> Cardiovascular portfolio**

- In March, the US FDA approved a Sotalol IV label expansion to include rapid loading of patients starting on sotalol. The commercialization of this new label expansion in the United States will start in H2 2020.
  - o Oral Sotalol is a commonly used drug for the maintenance of sinus rhythm in patients with atrial fibrillation with a black box warning requiring patients to be continuously monitored for a period of days when initiating the therapy.
  - o This novel Sotalol IV loading indication can decrease the length of hospital admission and potentially significantly decrease overall cost of care, while improving patient satisfaction and safety.

#### **Other Reformulation portfolio**

- Maxigesic<sup>®</sup> IV<sup>2</sup> was launched in Australia, New Zealand and the UAE in June 2020 by Hyloris' partner AFT Pharmaceuticals ("AFT").
  - o Hyloris will receive a part of the margin generated in all countries where Maxigesic<sup>®</sup> IV will be commercialized except in Australia and New Zealand.
  - o Launch should support additional market approvals in the coming months.
- June – AFT signed an exclusive distribution agreement for the commercialization of Maxigesic<sup>®</sup> IV in four western European countries (Germany, France, Italy and Austria) with Austria's Ever Pharma.
  - o Commercialization could start in late 2020 in Germany and Austria.
- July – Completion of the enrolment of the open-label, multiple-dose, single arm exposure clinical Phase III trial of Maxigesic<sup>®</sup> IV in 232 patients with acute pain following orthopedic, general or plastic surgery.
  - o This second Phase III study was undertaken in New Zealand and the United States and aims at determining the tolerability of repeated doses of Maxigesic<sup>®</sup> IV over an extended period of exposure.
  - o An earlier Phase III clinical trial conducted in 276 patients (for the treatment of acute postoperative pain after foot surgery (bunionectomy)) found that Maxigesic<sup>®</sup> IV provided significantly better pain relief than either Paracetamol IV (acetaminophen) or Ibuprofen IV alone at the same doses.
- July – AFT signed a license and supply agreement for the commercialization of Maxigesic<sup>®</sup> for Bulgaria, Cyprus, the Czech Republic, Hungary, Romania and Slovakia with the Cyprus based multinational pharmaceutical company Medochemie.
  - o Commercialization in these countries is expected to start in 2021

#### **Established Market portfolio**

- February - Hyloris sold all rights, titles and interest in the product HY-REF-038 in vial form to Alter Pharma<sup>3</sup>, while retaining all rights to the Prefilled Syringe, for a consideration (of the

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<sup>1</sup> IV stands for intravenous

<sup>2</sup> Maxigesic<sup>®</sup> IV is a novel combination of paracetamol (also called acetaminophen in the United States) and ibuprofen in an intravenous form

<sup>3</sup> Hyloris and Alter Pharma have some common shareholders which don't have a controlling interest in Alter Pharma

transferred intellectual property rights) of € 1.4 million. The generic vial form is currently already commercially available in the United States.

- During the first quarter the ANDA<sup>4</sup> application for HY-EMP-016 was submitted by Hyloris' partner Perrigo at the FDA. Approval is expected in 2021.

### Corporate highlights

- Hyloris successfully raised €79.54 million gross proceeds.
  - o In March and April, the Company issued convertible bonds totaling €15.15 million.
  - o On June 29, the Company completed an Initial Public Offering on Euronext Brussels, raising a total of €61.81 million.
  - o All bonds were converted into equity on June 30, at a 30% discount of the IPO price.
  - o On July 30, the Company received an additional €2.58 million from the exercise of the over-allotment option, bringing the total gross proceeds of the IPO to €64.39 million.
- Hyloris expanded its senior management team with the recruitment of an experienced Chief Legal Officer and Chief Financial Officer, who both bring extensive industry expertise in strategic legal, finance and business development planning and execution.
- The Company also expanded its Board of directors with the addition of Leon Van Rompay and three independent directors, namely Carolyn Myers, James Gale and Marc Foidart.

### Selected financial information

In € thousand	June 30, 2020	June 30, 2019	December 31, 2019
<b>Revenue</b>	82	75	91
Research and development expenses	(1,172)	(819)	(4,577)
General and administration expenses	(2,454)	(316)	(808)
Other income/(expenses)	20	72	86
Operating loss	(3,633)	(1,026)	(5,274)
Loss of the period	(3,742)	(1,314)	(5,768)
<b>Net cash used in operations</b>	<b>95</b>	<b>(911)</b>	<b>(4,562)</b>
Net cash inflow/(outflow) of the period	66,578	(1,539)	(2,482)
Cash and cash equivalents	<b>66,783</b>	<b>1,147</b>	<b>205</b>

- Revenue over the period corresponded to royalties due on the sales of Sotalol IV made in the US by Hyloris' distribution partner, AltaThera.
- Research and development expenses amounted to €1.2 million for the first half of 2020, an increase of €0.3 million compared to the same period of 2019 resulting from additional outsourced product development, pre-clinical and clinical expenses on our product candidates.
- General and administrative expenses amounted to €2.4 million, compared to €0.3 million in H1 2019. The €2.1 million increase was mainly driven by transaction costs associated to fund raises completed in H1 2020 and, to a lesser extent, to expenses associated to the ESOP warrants and to the strengthening of the management structure of the Company.

<sup>4</sup> Abbreviated New drug Application; application for a US generic drug approval for an existing licensed medication or approved drug

- Net operating cash flow was marginally up for H1 2020 (€0.1 million) compared to a cash burn of €0.9 million for H1 2019. Higher operating expenses incurred in H1 2020 were compensated by the proceeds of the sale of the rights of HY-REF-038 (in vial form) to Alter Pharma.
- Cash and cash equivalents increased to €66.8 million on June 30, 2020 compared to €0.2 million on December 31, 2019, resulting mainly from the issuance of convertible bonds in March and April 2020 for respectively €10.8 million and €4.4 million, and from the IPO completed on June 29, 2020 for €61.8 million.

### **Outlook for the remainder of 2020**

Management believes that Hyloris is well positioned for the remainder of 2020 and beyond. The successful financing transactions undertaken during the first half of 2020 provide the Company with the required funding for: Development of the existing product portfolio until market release, the establishment of a commercial infrastructure in the United States for the commercialization of the IV Cardiovascular Portfolio under development, and the further expansion of the pipeline, both internally and through business development opportunities.

Hyloris Management anticipates several upcoming key milestones in the near term including:

- the commercial launch of Sotalol IV under the new extended label in the US
- the first European regulatory approvals of Maxigesic® IV
- FDA submission for market approval of Maxigesic® IV and Tranexamic Acid.

The Company's operations were not materially affected by the ongoing COVID-19 pandemic.

### **Audit report**

KPMG Réviseurs d'Entreprises represented by Olivier Declercq has reviewed the condensed consolidated interim financial statements of Hyloris SA as of and for the six-month period ended June 30, 2020. Their review was conducted in accordance with International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" and their unqualified review report dated August 5, 2020 is attached to the interim financial information.

## CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS (in € thousand)	June 30, 2020	December 31, 2019
<b>Non-current assets</b>	<b>2,757</b>	<b>2,245</b>
Intangible assets	2,648	2,138
Property, plant and equipment	28	32
Right-of-use assets	73	66
Financial assets	9	9
<b>Current assets</b>	<b>69,056</b>	<b>3,739</b>
Trade and other receivables	427	333
Other financial assets	6	-
Other current assets	1,839	3,200
Cash and cash equivalents	66,783	205
<b>TOTAL ASSETS</b>	<b>71,813</b>	<b>5,983</b>
<b>EQUITY AND LIABILITIES</b> (in € thousand)	<b>June 30, 2020</b>	<b>December 31, 2019</b>
<b>Equity attributable to owners of the parent</b>	<b>59,666</b>	<b>(10,188)</b>
Share capital	128	89
Share premium	101,114	23,982
Retained earnings	(39,823)	(36,081)
Other reserves	(1,753)	1,822
<b>Non-current liabilities</b>	<b>7,948</b>	<b>22</b>
Borrowings	26	22
Other financial liabilities	7,922	-
<b>Current liabilities</b>	<b>4,198</b>	<b>16,149</b>
Borrowings	47	44
Other financial liabilities	409	13,130
Trade and other liabilities	3,694	2,927
Current tax liabilities	47	47
<b>Total liabilities</b>	<b>12,147</b>	<b>16,171</b>
<b>TOTAL EQUITY AND LIABILITIES</b>	<b>71,813</b>	<b>5,983</b>

## CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE 6-MONTH PERIOD ENDED JUNE 30

in € thousand	2020	2019
Revenue	82	75
Cost of sales	(109)	(37)
<b>Gross profit</b>	<b>(27)</b>	<b>38</b>
Research and development expenses	(1,172)	(819)
General and administrative expenses	(2,454)	(316)
Other operating income	20	72
<b>Operating profit/(loss)</b>	<b>(3,633)</b>	<b>(1,026)</b>
Financial income	620	91
Financial expenses	(729)	(380)
<b>Profit/(loss) before taxes</b>	<b>(3,741)</b>	<b>(1,314)</b>
Income taxes	(1)	-
<b>PROFIT/(LOSS) FOR THE PERIOD</b>	<b>(3,742)</b>	<b>(1,314)</b>
Other comprehensive income	-	-
<b>TOTAL COMPREHENSIVE INCOME OF THE PERIOD</b>	<b>(3,742)</b>	<b>(1,314)</b>
Profit/(loss) for the period attributable to the owners of the Company	(3,742)	(1,078)
Profit/(loss) for the period attributable to the non-controlling interests	-	(237)
Total comprehensive income for the period attributable to the owners of the Company	(3,742)	(1,078)
Total comprehensive income for the period attributable to the non-controlling interests	-	(237)
Basic and diluted earnings/(loss) per share (in €)	(0.21)	(0.07)

## CONDENSED CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE 6-MONTH PERIOD ENDED JUNE 30, 2020

in € thousand	Attributable to equity holders of the Company					Equity attributable to owners of the parent	Non-controlling interests	Total Equity	
	Share capital	Share premium	Share-based payment reserve	Other reserves Cost of Capital	Other reserves				Retained earnings
<b>Balance at December 31, 2018</b>	<b>89</b>	<b>23,982</b>	<b>1,329</b>	<b>-</b>	<b>450</b>	<b>(28,097)</b>	<b>(2,246)</b>	<b>(2,216)</b>	<b>(4,462)</b>
Issuance of shares	-	-	-	-	-	-	-	-	-
Contribution by shareholder	-	-	-	-	28	-	28	-	28
Total comprehensive income	-	-	-	-	-	(1,078)	(1,078)	(237)	(1,314)
<b>Balance at June 30, 2019</b>	<b>89</b>	<b>23,982</b>	<b>1,329</b>	<b>-</b>	<b>478</b>	<b>(29,175)</b>	<b>(3,296)</b>	<b>(2,453)</b>	<b>(5,748)</b>
<b>Balance at December 31, 2019</b>	<b>89</b>	<b>23,982</b>	<b>1,329</b>	<b>-</b>	<b>493</b>	<b>(36,081)</b>	<b>(10,188)</b>	<b>-</b>	<b>(10,188)</b>
Initial Public Offering	29	61,784	-	(3,656)	-	-	58,156	-	58,156
Issuance of convertible bonds	-	-	-	-	4,531	-	4,531	-	4,531
Conversion of convertible bonds	10	15,347	-	(102)	(4,585)	-	10,671	-	10,671
Amortized costs on shareholders loans	-	-	-	-	(5)	-	(5)	-	(5)
Share-based payments	-	-	243	-	-	-	243	-	243
Total comprehensive income	-	-	-	-	-	(3,742)	(3,742)	-	(3,742)
<b>Balance at June 30, 2020</b>	<b>128</b>	<b>101,113</b>	<b>1,572</b>	<b>(3,758)</b>	<b>434</b>	<b>(39,823)</b>	<b>59,666</b>	<b>-</b>	<b>59,666</b>

## CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE 6-MONTH PERIOD ENDED JUNE 30

in € thousand	2020	2019
<b>CASH FLOW FROM OPERATING ACTIVITIES</b>		
Net result for the period	(3,742)	(1,314)
<i>Adjustments for:</i>		
Depreciation, amortization and impairments	52	51
Equity-settled share-based payment expense	243	-
Interest expenses on Convertible Bonds	235	-
Interest expenses on shareholders loans	317	193
Change in maturity of shareholders loans	(381)	-
Change in fair value of derivative instruments	(81)	-
Equity transaction costs	1,408	-
Income taxes	1	-
Other non-cash adjustments	(59)	28
<i>Changes in working capital:</i>		
Trade and other receivables	(94)	558
Other financial assets	(6)	3
Other current assets	1,361	(1)
Trade and Other Payables	723	(976)
Other current liabilities	-	1
Other financial liabilities	119	549
<i>Cash generated from operations</i>	<i>96</i>	<i>(911)</i>
Taxes paid	(1)	-
<b>Net cash generated from operating activities</b>	<b>95</b>	<b>(911)</b>
<b>CASH FLOW FROM INVESTING ACTIVITIES</b>		
Purchases of property, plant and equipment	-	-
Purchases of Intangible assets	(487)	(603)
Proceeds from other financial assets	-	-
<b>Net cash provided by/(used in) investing activities</b>	<b>(487)</b>	<b>(603)</b>
<b>CASH FLOW FROM FINANCING ACTIVITIES</b>		
Reimbursements of shareholders loans	(8,050)	-
Proceeds from shareholders loans	3,250	-
Reimbursements of borrowings	(26)	(26)
Net proceeds from the Initial Public Offering	56,803	-
Net proceeds from the Convertible Bonds	14,994	-
Interests paid	(1)	(1)
<b>Net cash provided by/(used in) financing activities</b>	<b>66,970</b>	<b>(26)</b>
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>66,578</b>	<b>(1,539)</b>
CASH AND CASH EQUIVALENTS at beginning of the period	205	2,687
CASH AND CASH EQUIVALENTS at end of the period	66,783	1,147



### Conference Call Details

Hyloris will host a conference call on Thursday, 6 August at 2:00pm CEST accessible through the following numbers:

Event Plus Passcode:	<b>2533728</b>
Belgium, Brussels	02 793 3847
Belgium	0800 48 471
United States, New York	1 646 741 3167
United States	1 877 870 9135
United Kingdom	08 444 819 752
France	08 0510 1465
Netherlands	0800 023 5015

To ensure a timely connection, it is recommended that users register at least 10 minutes prior the scheduled start timing.

-Ends-

### For more information, please contact:

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### About Hyloris Pharmaceuticals SA

Based in Liège, Belgium, Hyloris is an early-stage innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals. Hyloris develops proprietary products it believes offer significant advantages compared to currently available alternatives, with the aim to address the underserved medical needs of patients, hospitals, physicians, payors and other stakeholders in the healthcare system. Hyloris' portfolio spans three areas of focus: IV Cardiovascular, Other Reformulations and Established Market (high-barrier generics). Hyloris currently has two early commercial-stage products, Sotalol IV for the treatment of atrial fibrillation, commercialized through its partner AltaThera, and Maxigesic® IV, a non-opioid analgesic product for the treatment of pain, developed with the Company's partner, AFT Pharmaceuticals. Additionally, Hyloris has 12 product candidates in various stages of development across the Company's wider portfolio. Read more at [www.hyloris.com](http://www.hyloris.com). Hyloris stands for "high yield, lower risk" and relates to the 505(b)(2) regulatory pathway for product approval on which the Issuer focuses, but in no way relates or applies to an investment in the Shares.