

## Hyloris Reports 2021 Half-Year Results: Multiple Potential Value Inflection Points Ahead

On target to grow the broad product pipeline with at least 3 additional programmes before end 2021

Significant expansion of commercial footprint of non-opioid pain treatment Maxigesic® IV

Expected to start 2 clinical studies and to report the results from 2 clinical studies before year-end

€53.47 million in cash and cash equivalents to execute ambitious growth strategy

Conference call and [webcast](#) today at 3pm CEST/9am EST (details below)

Liège, Belgium – 4 August 2021 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today reports its condensed consolidated financial results for the six-month period ending 30 June 2021, a year-to-date business update, and an outlook for the remainder of the year.

**Stijn Van Rompay, Chief Executive Officer of Hyloris, commented:** “On 29 June we celebrated our first anniversary as a publicly traded company on Euronext Brussels, and we would like to thank all our stakeholders for their continued support. We are very pleased with the progress we have made over the past few months as we are successfully executing our business strategy and gradually moving up the value chain through our increased focus on repurposed medicines to offer meaningful improvements for patients, physicians, and payors.”

“We promised to grow our pipeline with four new candidate products this year, and we are on track to deliver on that promise. In addition, during the next coming months we expect that two programmes will enter clinical development and to communicate the results from two clinical studies. Finally, our commercial partners are making progress with the roll-out of Sotalol IV in atrial fibrillation and Maxigesic® IV, a novel, potent, non-opioid pain medication, which is now licensed in more than 100 countries and launched in five countries. We look forward to updating the market as we expect to report on multiple potential value inflection points before the end of the year.”

### FINANCIAL HIGHLIGHTS: SIX-MONTH PERIOD ENDING 30 JUNE 2021

| (in € thousand)  | Period ended 30 June |                              |               |
|--|----------------------|------------------------------|---------------|
|  | 2021                 | 2020                         | Variance      |
| <b>Total revenue and other income</b>                  | <b>1,145</b>         | <b>102</b>                   | <b>1,023%</b> |
| Revenues   | 838                  | 82                           | 922%          |
| Other income   | 307                  | 20                           | 1,435%        |
| <b>Cost of sales</b>                                   | <b>(42)</b>          | <b>(109)</b>                 | <b>(61%)</b>  |
| <b>Operating expenses</b>                              | <b>(9,016)</b>       | <b>(3,626)</b>               | <b>149%</b>   |
| Research and development expenses                      | (1,560)              | (1,172)                      | 33%           |
| General and administration expenses                    | (1,608)              | (2,454)                      | (34%)         |
| Other operating expenses <i>(one-off)</i> <sup>i</sup> | (5,770)              | --                           | --            |
| <b>Operating result</b>                                | <b>(7,913)</b>       | <b>(3,633)</b>               | <b>(118%)</b> |
| <b>Net result</b>                                      | <b>(8,240)</b>       | <b>(3,742)</b>               | <b>(120%)</b> |
| <b>Net cash (burn)/inflow</b> <sup>ii</sup>            | <b>(10,934)</b>      | <b>66,578</b> <sup>iii</sup> | --            |
| <b>Cash and cash equivalents</b>                       | <b>53,465</b>        | <b>66,783</b>                | <b>(20%)</b>  |

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

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

<sup>iii</sup> Including net proceeds from the IPO and issuance of convertible bonds



## OPERATIONAL REVIEW YEAR-TO-DATE

### Commercial products

- **Maxigesic IV**, a novel, patented, potent, intravenous (IV) non-opioid treatment for post-operative pain – commercialised globally with AFT Pharmaceuticals (AFT) and local distribution partners:
  - Start of European roll-out with launches in Germany, the largest pharmaceutical market in Europe, and Austria.
  - Expansion of exclusive license and distribution agreement with Pharma Bavaria International for commercialisation in South America, thereby broadening the addressable market for Maxigesic IV in Latin America and the Caribbean to 17 countries.
  - Major partnership in the U.S. with Hikma Pharmaceuticals whereby Hyloris is eligible to a license fee and regulatory and commercial-based milestone payments of up to USD\$10 million plus a share of any additional product-related income received by AFT in the U.S.
  - Significant enlargement of European footprint through multiple exclusive license agreements for commercialisation in Poland, Greece, the Nordics, Spain, Portugal, and The Netherlands.
- **Sotalol IV**, a novel, patented, IV formulation of oral sotalol for the treatment of atrial fibrillation – commercialised by AltaThera in the U.S.: significant expansion of AltaThera’s sales force to accelerate commercial roll-out and inclusion in hospital drug formularies.

### R&D and regulatory update

- **Maxigesic IV:**
  - Preparations to submit a new drug application (NDA) to the FDA further advanced, with filing in the U.S. expected shortly.
  - Obtained additional national marketing authorisations in Europe and Rest of the World, thereby further broadening the geographical base where Maxigesic IV is approved to 24 countries today.
  - Patents granted (exclusivity to 2035-2038) across multiple jurisdictions, including Japan, Singapore, Canada, Mexico, and the Republic of China.
- **HY-004:** initiated a Phase 1 study to evaluate the pharmacokinetics (PK) and safety of HY-004 oral solution – the study also includes exploratory efficacy endpoints.
- **Pipeline expansion:** signed a partnership with Purna Female Healthcare (PFH) to develop and commercialise Miconazole-Domiphen Bromide (MCZ-DB) a novel, topical, dual mode-of-action combination treatment for severe and recurrent vulvovaginal candidiasis (VVC), a debilitating vaginal fungal infection for which there is currently no effective treatment available.
- **Other:** regulatory interactions ongoing to address questions raised by the FDA following the submission of the marketing applications for Tranexamic Acid RTU and HY-016.

### Corporate update

- Successfully renegotiated and unwound the license agreements with the Alter Pharma Group for Maxigesic IV, HY-075, HY-038, and Fusidic Acid Cream. Hyloris paid the Alter Pharma Group a total one-off lump sum of €5.25 million with an additional €0.5 million in potential earn-out payments, thereby waiving all past commitments and any further future financial obligations towards the Alter Pharma Group.
- Rental agreement for laboratory space to perform drug formulation and analytical activities and further streamline processes and more effectively capitalise on internal resources.
- Hyloris’ shareholders unanimously approved all resolutions at the 2021 Annual General Meeting, including the appointment of Chris Buyse to the Board of Directors.
- Further strengthened the team and built internal capabilities with key hires in management and clinical and regulatory affairs.



## OUTLOOK FOR THE REMAINDER OF 2021

Hyloris anticipates delivering on key value inflection milestones within its strategic focus areas:

- **Pipeline expansion:** addition of at least three new reformulated or repurposed product candidates through in-licensing or joint ventures
- **Clinical development:**
  - **Study results:** i) pivotal study of Atomoxetine oral solution (attention deficit hyperactive disorder); ii) Phase 1 PK/safety study of HY-004 oral solution (indication not disclosed)
  - **Study starts:** i) pivotal study of Atomoxetine oral solution; ii) Phase 2 dose-finding study of Miconazole Domiphen-Bromide (severe and recurrent VVC)
- **Commercial products:** i) Maxigesic IV: continue roll-out in Europe and Rest of World, and submission of a new drug application to the FDA; ii) Sotalol IV: accelerate roll-out in the U.S.

With cash and cash equivalents of €53.47 million at 30 June 2021, the Company 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 candidate - and marketed products by 2024.

## FINANCIAL REVIEW FOR THE SIX-MONTH PERIOD ENDING 30 JUNE 2021

### Total revenue and other income

During the first six months of 2021, total revenue and other income increased to €1,145 thousand compared to €102 thousand in the first half-year of 2020.

Revenues increased by 922% to €838 thousand, compared to €82 thousand for the first six months of 2020. The significant growth was mainly driven by recognised income from a pre-commercial milestone payment related to Maxigesic IV, partnered with AFT Pharmaceuticals.

Other income amounted to €307 thousand compared to €20 thousand for the same period in 2020 thanks to higher R&D related incentive income from the Federal government.

### Results

The Company realised a net loss of €8,240 thousand for the six-month period ending 30 June 2021, compared to a net loss of €3,742 thousand for the first half-year of 2020. The higher loss is mainly driven by the one-off lump sum of €5,250 thousand and €500 thousand future potential earn-out payments related to the [successful renegotiation and unwinding of the license agreements](#) with the Alter Pharma Group for lead products, Maxigesic IV, HY-075 and HY-038, and the high-barrier generic, Fusidic Acid Cream in Canada. This transaction was recognised as other operating expenses.

Operating loss amounted to €7,913 thousand for the first half-year of 2021, compared to an operating loss of €3,633 thousand for the first half-year of 2020, mainly impacted by the [successful renegotiation and unwinding of the license agreements](#) for the lead products with the Alter Pharma Group.

R&D expenditure during the first six months of 2021 amounted to €1,560 thousand, compared to €1,172 thousand for the first half-year of 2020. The increase was mainly driven by the costs related to outsourced product development activities.

Despite the further expansion of the Company's Group Structure and key hires, general and administration expenses decreased to €1,608 thousand, compared to €2,454 thousand for the first half-year of 2020. The difference is mainly driven by the transaction costs in 2020 related to the successful IPO on Euronext Brussels and the issuance of convertible bonds.



## Cash Position

Current cash and cash equivalents totalled €53,465 thousand on 30 June 2021, compared to €66,783 thousand on 31 December 2020.

A net decrease of €10,934 thousand in cash and cash equivalents was recorded for the six-month period ending 30 June 2021, compared to a net increase of €66,578 thousand during the first half-year of 2020. The net decrease was mainly 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), compared to a net cash inflow for the same period in 2020 of €66,970 thousand, driven by the net proceeds from financing activities from the IPO on Euronext Brussels and the issuance of convertible bonds.

## AUDIT REPORT

The statutory auditor, KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises, represented by Olivier Declercq, has reviewed the condensed consolidated interim financial statements for the six-month period ended June 30, 2021. Its 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 its unqualified review report dated August 3, 2021 is attached to the 2021 half-year financial report which is available on the [Hyloris website](#).

## CONFERENCE CALL AND WEBCAST

Hyloris will host a conference call with audio webcast today at 3pm CEST/9am EST, followed by a Q&A session. The webcast may be accessed on the [Events](#) page of the company's website or by clicking [here](#). To participate in the Q&A session, please dial one of the following numbers, ten minutes prior to the start of the live call:

|                |                  |
|----------------|------------------|
| Belgium        | +32 2 79 338 47  |
| France         | +33 1 70 700 781 |
| Netherlands    | + 31 20 795 6614 |
| United Kingdom | +44 2071 928 338 |
| United States  | +1 646 741 3167  |

Confirmation code 2687826

A replay will be available on the [events](#) page of the Hyloris website.

## UPCOMING IR EVENTS 2021 AND PRELIMINARY FINANCIAL CALENDAR 2022

|                  |  |
|------------------|--|
| 9 September 2021 | Annual KBC Securities Life Science Conference        |
| 23 October 2021  | VFB Happening  |
| 16 March 2022    | Full Year 2021 Financial Results and Business Update |

## About Hyloris Pharmaceuticals

Hyloris is a specialty biopharma company 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 13 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Two products are currently in initial phases of commercialisation 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](http://www.hyloris.com) and follow-us on [LinkedIn](#).

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**Disclaimer and forward-looking statements**

Hyloris means “high yield, lower risk”, which relates to the 505(b)(2) regulatory pathway for product approval on which the Issuer focuses, but in no way relates or applies to an investment in the Shares.

Certain statements in this press release are “forward-looking statements.” These forward-looking statements can be identified using forward-looking terminology, including the words “believes”, “estimates”, “anticipates”, “expects”, “intends”, “may”, “will”, “plans”, “continue”, “ongoing”, “potential”, “predict”, “project”, “target”, “seek” or “should”, and include statements the Company makes concerning the intended results of its strategy. These statements relate to future events or the Company’s future financial performance and involve known and unknown risks, uncertainties, and other factors, many of which are beyond the Company’s control, that may cause the actual results, levels of activity, performance or achievements of the Company or its industry to be materially different from those expressed or implied by any forward-looking statements. The Company undertakes no obligation to publicly update or revise forward-looking statements, except as may be required by law.



## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

| <b>ASSETS</b><br><b>(in € thousand)</b>                 | <b>30 June</b><br><b>2021</b> | <b>31 December</b><br><b>2020</b> |
|---|-------------------------------|-----------------------------------|
| <b>Non-current assets</b>                               | <b>7,323</b>                  | <b>2,569</b>                      |
| Intangible assets                                       | 2,228                         | 2,381                             |
| Property, plant and equipment                           | 23                            | 24                                |
| Right-of-use assets                                     | 129                           | 152                               |
| Investments in associates and joint ventures            | 4,192                         | -                                 |
| Financial assets  | 12                            | 12                                |
| Other non-current assets                                | 739                           | -                                 |
| <b>Current assets</b>                                   | <b>56,661</b>                 | <b>66,613</b>                     |
| Inventories   | -                             | -                                 |
| Trade and other receivables                             | 2,082                         | 253                               |
| Other financial assets                                  | 20                            | 7                                 |
| Other current assets                                    | 1,093                         | 1,954                             |
| Cash and cash equivalents                               | 53,465                        | 64,399                            |
| <b>TOTAL ASSETS</b>                                     | <b>63,984</b>                 | <b>69,182</b>                     |
| <b>EQUITY AND LIABILITIES</b><br><b>(in € thousand)</b> | <b>30 June</b><br><b>2021</b> | <b>31 December</b><br><b>2020</b> |
| <b>Equity</b>   | <b>51,080</b>                 | <b>59,059</b>                     |
| Share capital   | 129                           | 129                               |
| Share premium   | 103,693                       | 103,693                           |
| Retained earnings                                       | (51,466)                      | (43,226)                          |
| Other reserves  | (1,276)                       | (1,537)                           |
| <b>Liabilities</b>                                      | <b>12,904</b>                 | <b>10,123</b>                     |
| <b>Non-current liabilities</b>                          | <b>10,301</b>                 | <b>7,991</b>                      |
| Borrowings  | 83                            | 106                               |
| Other financial liabilities                             | 10,218                        | 7,885                             |
| <b>Current liabilities</b>                              | <b>2,603</b>                  | <b>2,132</b>                      |
| Current borrowings                                      | 47                            | 46                                |
| Other current financial liabilities                     | 1,500                         | 409                               |
| Trade and other liabilities                             | 1,004                         | 1,629                             |
| Current tax liabilities                                 | 47                            | 47                                |
| Other current liabilities                               | 5                             | -                                 |
| <b>TOTAL EQUITY AND LIABILITIES</b>                     | <b>63,984</b>                 | <b>69,182</b>                     |

## CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

| STATEMENT OF COMPREHENSIVE INCOME<br>(in € thousand)      | 30 June<br>2021 | 30 June<br>2020 |
|---|-----------------|-----------------|
| Revenues  | 838             | 82              |
| Cost of sales   | (42)            | (109)           |
| <b>Gross profit</b>                                       | <b>796</b>      | <b>(27)</b>     |
| Research and development expenses                         | (1,560)         | (1,172)         |
| General and administrative expenses                       | (1,608)         | (2,454)         |
| Earnings/losses from Associates and joint ventures        | (78)            | -               |
| Other operating income                                    | 307             | 20              |
| Other operating expenses                                  | (5,770)         | -               |
| <b>Operating profit/(loss) (EBIT)</b>                     | <b>(7,913)</b>  | <b>(3,633)</b>  |
| Financial income  | 20              | 620             |
| Financial expenses  | (347)           | (729)           |
| <b>Profit/(loss) before taxes</b>                         | <b>(8,240)</b>  | <b>(3,741)</b>  |
| Income taxes  | -               | (1)             |
| <b>PROFIT/(LOSS) FOR THE PERIOD</b>                       | <b>(8,240)</b>  | <b>(3,742)</b>  |
| <b>Basic and diluted earnings/(loss) per share (in €)</b> | <b>(0.32)</b>   | <b>(0.21)</b>   |

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

| (in € thousand)                       | Attributable to equity holders of the Company |                |                             |                 |                | Retained earnings | Total Equity    |
|---------------------------------------|---|----------------|-----------------------------|-----------------|----------------|-------------------|-----------------|
|                                       | Share capital                                 | Share premium  | Other reserves              |                 |                |                   |                 |
|                                       |   |                | Share based payment reserve | Cost of Capital | Other reserves |                   |                 |
| <b>Balance at 31 December 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> |
| Initial public offering               | 29  | 61,783         |                             | (3,656)         | -              | -                 | 58,156          |
| Share-based payments                  | -   | -              | 243                         | -               | -              | -                 | 243             |
| Issuance of convertible bonds         |   |                |                             | -               | 4,531          |                   | 4,531           |
| Conversion of convertible bonds       | 10  | 15,348         |                             | (102)           | (4,585)        | -                 | 10,671          |
| Amortised costs on shareholders loans | -   | -              |                             | -               | (5)            | -                 | (5)             |
| Total comprehensive income            | -   | -              |                             |                 | -              | (3,742)           | (3,742)         |
| <b>Balance at 30 June 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>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>   |



## CONSOLIDATED STATEMENT OF CASH FLOWS

| (in € thousand)  | 30 June<br>2021 | 30 June<br>2020 |
|--|-----------------|-----------------|
| <b>CASH FLOW FROM OPERATING ACTIVITIES</b>   |                 |                 |
| Operating result   | (8,240)         | (3,742)         |
| <i>Adjustments to reconcile net loss to net cash provided by operating activities:</i> |                 |                 |
| Depreciation, amortisation and impairments   | 50              | 52              |
| Share-based payment expense  | 261             | 243             |
| R&D tax credit   | 63              | -               |
| Interest expenses on convertible bonds   | -               | 235             |
| Interest expenses on shareholders loans  | 234             | 317             |
| Change in maturity of shareholders loans   | -               | (381)           |
| Change in fair value of derivative instruments   | -               | (81)            |
| Equity transaction costs   | -               | 1,408           |
| Income taxes   | -               | 1               |
| Losses from associates and joint ventures  | 78              | -               |
| Other non-cash adjustments   | 99              | (59)            |
| <i>Changes in working capital:</i>   |                 |                 |
| Trade and other receivables  | (1,830)         | (94)            |
| Other financial assets   | -               | (6)             |
| Other current assets   | 861             | 1,361           |
| Other non-current assets   | (739)           | -               |
| Trade and other liabilities  | (625)           | 723             |
| Other current liabilities  | 5               | -               |
| Other financial liabilities  | -               | 119             |
| Other non-current liabilities  | 500             | -               |
| <b>Cash generated from operations</b>  | <b>(9,282)</b>  | <b>96</b>       |
| Taxes paid   | -               | (1)             |
| <b>Net cash generated from operating activities</b>                                    | <b>(9,282)</b>  | <b>95</b>       |
| <b>CASH FLOW FROM INVESTING ACTIVITIES</b>   |                 |                 |
| Purchases of property, plant and equipment   | (4)             | -               |
| Purchases of Intangible assets   | (150)           | (487)           |
| Investments in associates and joint ventures   | (1,270)         | -               |
| Acquisition of other financial assets  | (13)            | -               |
| Other  | 219             | -               |
| <b>Net cash provided by/(used in) investing activities</b>                             | <b>(1,218)</b>  | <b>(487)</b>    |
| <b>CASH FLOW FROM FINANCING ACTIVITIES</b>   |                 |                 |
| Reimbursements of borrowings and other financial liabilities                           | (409)           | (8,050)         |
| Proceeds from borrowings and other financial liabilities                               | -               | 3,250           |
| Reimbursements of lease liabilities  | (24)            | (26)            |
| Proceeds from convertible bonds  | -               | 56,803          |
| Proceeds from IPO  | -               | 14,994          |
| Interests paid   | -               | (1)             |
| <b>Net cash provided by/(used in) financing activities</b>                             | <b>(434)</b>    | <b>66,970</b>   |
| <b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>                            | <b>(10,934)</b> | <b>66,578</b>   |
| <b>CASH AND CASH EQUIVALENTS at beginning of the period</b>                            | <b>64,399</b>   | <b>205</b>      |
| <b>CASH AND CASH EQUIVALENTS at end of the period, calculated</b>                      | <b>53,465</b>   | <b>66,783</b>   |