Press Release
Regulated information
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Hyloris Reports Full Year 2020 Financial Results

On track to fuel the pipeline with ≥4 new product candidates in 2021
Strong cash position of €64 million year-end to execute ambitious growth plan
14 commercial products expected by 2024

Conference call and webcast today at 3pm CET/9am ET (details below)

Liège, Belgium – 9 March 2021 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), a specialty biopharma company committed to bringing innovative treatments that offer added value to underserved patient populations, today reports its consolidated financial results and a business update for the year ended 31 December 2020, recent achievements, and an outlook for 2021.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: *"I am extremely proud of the significant progress we have made across all areas of our business, which has set a strong foundation to execute our ambitious growth plan. We are committed to changing the lives of patients by applying our knowhow and innovative technologies to develop novel, value added medicines based on real-world data and our knowledge of established products. To achieve this goal and uncover underserved medical needs, we are in continuous dialogue with healthcare professionals, patient groups, payors and partners as well as leveraging our extensive sourcing network and R&D capabilities."*

"In the coming months, we expect to further expand our diversified pipeline with the addition of at least three new product candidates, on top of the recently announced partnership with Purna Female Healthcare. Despite the global challenges brought on by the COVID-19 pandemic, all our pipeline programs are progressing well, and we are on track to report results from the pivotal study of Atomoxetine Oral Solution in ADHD later this year. Our commercial partners, AltaThera and AFT Pharmaceuticals, continue the roll-out of, respectively, Sotalol IV, a novel, patented IV solution to treat atrial fibrillation and Maxigesic® IV, a novel dual mode-of-action non-opioid pain treatment that, to date, is registered in 20 countries."

Hyloris will publish its 2020 Annual Report on 30 April 2021, which will be made available on the Investors section of the Company's website.

FINANCIAL HIGHLIGHTS 2020

	Year ended 31 December		
(in € thousand)	**2020**	**2019**	**Variance**
Revenues	**175**	**91**	**92%**
Research and development expenses	(3,413)	(4,577)	(25%)
General and administration expenses	(2,194)	(808)	172%
Shares' issuance related expenses	(1,468)	-	NA
Operating result	**(7,025)**	**(5,274)**	**(25%)**
Net financial result	(120)	(508)	76%
Net result	**(7,145)**	**(5,768)**	**(16%)**
Net operating cash flow	**(4,570)**	**(4,562)**	**(0.2%)**
Cash and cash equivalents	**64,399**	**205**	**NA**

OPERATIONAL REVIEW 2020

R&D and regulatory

- **Sotalol IV**, a novel, patented intravenous (IV) solution for the treatment of atrial fibrillation – **partnered with AltaThera in the U.S.**
  Sotalol IV is a novel IV formulation of Sotalol tablets that can dramatically reduce the length of hospital admission (three to one day), and potentially significantly reduce overall cost of care, while at the same time improve tolerability and patient outcomes. Moreover, the IV formulation allows for a faster onset of activity, which is crucial in acute hospital settings. The use of Sotalol IV is included in the "American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care"
    - March 2020: U.S. Food and Drug Administration (FDA) approval of 'Sotalol IV loading regimen label expansion' for use in all newly diagnosed adult patients (and not only in patients who are not eligible for oral treatment), thereby significantly broadening the product's potential beyond acute care and paediatric use only
- **Maxigesic IV**, a novel, patented, dual mode-of-action non-opioid pain treatment – **co-developed with AFT Pharmaceuticals ("AFT")**
  Maxigesic IV is a novel combination of Paracetamol 1000mg + Ibuprofen 300mg solution for infusion for use post-operatively in hospitals for patients for whom the use of oral analgesics is limited
    - Throughout 2020: obtained National Marketing Authorizations in 17 European countries
    - July 2020: successful completion of a second Phase 3 study in 232 subjects to support regulatory filing to the FDA. The submission of a scientific paper in a peer reviewed journal is currently being prepared
- **Other pipeline assets:** further advanced formulation and manufacturing activities, regulatory discussions, and preparations for clinical development

Commercial

- **Maxigesic IV** – licensed in 90 countries and launched in three countries
    - June 2020: launched by AFT in Australia, New Zealand and the United Arab Emirates; exclusive license and distribution agreement between AFT and Ever Pharma for commercialisation in Germany, France, Italy and Austria
    - July 2020: exclusive license and distribution agreement between AFT and Medochemie for commercialisation in Bulgaria, Cyprus, the Czech Republic, Hungary, Romania, and Slovakia
    - November 2020: exclusive distribution and supply agreement between AFT and EDGE Pharmaceuticals and its local UK Joint Venture partner, Kensington Pharma, for commercialisation in Hong Kong and the U.K.

Corporate update

- Successfully raised €79.54 million in gross proceeds:
    - March and April 2020: issuance of convertible bonds totalling €15.15 million
    - June 2020: successful Initial Public Offering (IPO) on Euronext Brussels, raising a total of €64.39 million (including over-allotment); all convertible bonds converted into equity
- Further built internal resources and capabilities, and expanded the management team with the appointments of Koenraad Van der Elst as Chief Legal Officer and Dr Dietmar Aichhorn as Chief Operating Officer
- Reinforced the Board of Directors with the appointments of Leon Van Rompay, Carolyn Myers, James Gale and Marc Foidart, and the nomination of Chris Buyse

POST-PERIOD HIGHLIGHTS

The year 2021 started with numerous value-enhancing events:

Pipeline expansion

- Signed a partnership with Purna Female Healthcare (spin-off founded by Purna Pharmaceuticals and Creafund) 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). Severe and rVVC are debilitating vaginal fungal infections for which there are no effective treatment options currently available. The Phase 2 dose-finding clinical study is expected to start later in 2021. Purna Female Healthcare has exclusively in-licensed MCZ-DB and associated Intellectual Property owned by KU Leuven and the University of Antwerp (Belgium)

Clinical

- **HY-004**[1] (indication not disclosed): initiated a Phase 1 study to evaluate the pharmacokinetics (PK) and safety of HY-004 oral solution – the study also includes exploratory efficacy endpoints

Regulatory

- **Tranexamic Acid RTU**[2], a ready-to-use IV administration of tranexamic acid to prevent excessive blood loss: submitted a marketing application to the FDA
  Tranexamic Acid RTU has potential to facilitate the use of antifibrinolytic therapies for haemophilia patients and patients with trauma injuries, and to save time for healthcare professionals by eliminating the need for additional dilution procedures and manipulations prior to administration

Commercial

- **Maxigesic IV**: exclusive licensing and distribution agreement between AFT and Aguettant in eight new European markets – thereby extending Maxigesic IV's footprint in the European Union to a total of 20 EU member states

Corporate

- Strengthened the management team with the appointments Thomas Jacobson as Chief Business Development Officer following the retirement of Ed Maloney, and Marieke Vermeersch as VP Investor Relations and Corporate Communications

OUTLOOK 2021

During the course of 2021, Hyloris anticipates delivering on key value inflection milestones within its strategic focus areas:

- **Pipeline expansion** with the addition of at least three new product candidates, in addition to the recently announced partnership with Purna Female Health for Miconazole-Domiphen Bromide
- **Atomoxetine oral solution**, a novel patented reformulation of Atomoxetine to allow titrated oral liquid doses of Atomoxetine for the treatment of Attention Deficit Hyperactivity Disorder (ADHD): start and results from pivotal study
- **Dofetilide IV**, a novel, patented IV formulation of Dofetilide to allow a faster loading regimen in patients with atrial fibrillation: start pivotal study

[1] Formerly known as HY-REF-004
[2] Ready-to-use

- **HY-004 oral solution** (indication not disclosed): results from Phase 1 PK / safety study and start preparations of the pivotal study to support the submission of a marketing application, which is on track for 2023
- **Miconazole-Domiphen Bromide**: start Phase 2 dose-finding study
- **Maxigesic IV**: submission of marketing application to the FDA by AFT Pharmaceuticals

Commercially, Hyloris' partners AFT Pharmaceuticals and AltaThera will continue the rollout of Maxigesic IV and Sotalol IV, with sales from these products expected to be the primary drivers of short-term revenue for the Company.

With cash and cash equivalents of €64.40 million at year-end, the Company is well-capitalised to advance all current pipeline assets as planned and execute on its ambitious growth strategy with 14 commercial products expected by 2024.

FINANCIAL REVIEW 2020

Income statement

In 2020, total revenues increased by 92% to €0.18 million (2019: €0.08 million), driven by higher royalties received from AltaThera on net sales from Sotalol IV. Cost of sales increased to €0.15 million (2019: €0.07 million) mainly as a result of higher licensing fees paid to Academic Pharmaceuticals in relation to higher sales of Sotalol IV and amortization expenses of the capitalized development costs of the commercialised products.

Research and development expenses decreased to €3.41 million in 2020 (2019: €4.58 million) mainly as a result of the lower impairment costs (€0.48 million in 2020 compared to €3.20 million in 2019). Excluding these impairment costs, research and development expenses increased by €1.60 million, in line with the budget and the progression and expansion of the product pipeline.

General and administrative expenses increased to €2.19 million in 2020 (2019: €0.81 million), primarily driven by the enlargement of the management and governance structure of the Company (€0.70 million), the vesting cost of the 2019 warrant plan (€0.49 million) and the increase of the headcount of the Company to support the development of the product pipeline (€0.39 million).

In 2020, the Company expensed €1.47 million in costs associated with the Initial Public Offering (IPO) closed in June 2020 and the convertible bonds issued in April and March 2020. The total transaction costs amounted to €5.30 million, of which €3.83 million was capitalised and recorded as cost of equity, and €1.47 was expensed.

As a result of the foregoing, the operating loss increased in 2020 to €7.03 million (2019: €5.27 million).

The net financial loss in 2020 was €0.12 million (2019: €0.51 million). Financial income amounted to €0.90 (2019: €0.01 million) and comprised mostly of gain related to extension of maturity of the shareholders loans and exchange differences. Financial expenses amounted to €1.02 million (2019: €0.52 million) and comprised mostly of interest expenses on shareholders loans and convertible bonds and the fair value adjustment on the shareholders' loans.

As a result of the foregoing, the net loss increased in 2020 to €7.15 million (2019: €5.77 million).

As the Company incurred losses in all relevant periods, the Company had no taxable income, and therefore paid no income taxes.

Statement of financial position

The Company's intangible assets of €2.38 million at year-end 2020 included capitalised development, purchased assets and in-licensing costs. In 2020, the Company capitalised development costs for a total of €0.6 million (2019: €0.5 million).

The Company's current assets mainly consist of €64.40 million in cash and cash equivalents, and prepaid development expenses on some product candidates of €1.88 million.

Current liabilities mainly compose of trade payables.

The non-current liabilities of €7.99 million mainly comprise of shareholders' loans. During the first semester of 2020, the Group contracted additional loans with its main shareholders for a total amount of €3.25 million, and reimbursed loans with part of the proceeds of the convertible bonds for a total of €8.05 million.

The Company's equity increased to €59.06 million, mainly as a result of the net proceeds of €74.25 million (excluding the cost recorded in profit and loss) from the successful IPO on Euronext Brussels in June 2020 and the convertible bonds issued in March and April 2020. The equity increase was partially offset by the net loss for the year of €7.15 million.

Cash flow statement

There was a net cash outflow from operating activities of €4.57 million, compared to a net outflow of €4.56 million in 2019. The cash outflows related to operating activities in 2020 amounted to €4.60 million (2019: €2.48 million). The working capital requirements at year-end 2020 amounted to €0.03 million.

There was a net cash outflow from investing activities of €0.63 million in 2020, as compared to €1.22 million in 2019, and primarily comprises the capitalisation of development expenses.

There was a net cash inflow from financing activities of €69.40 million in 2020, as compared to a net cash inflow of €3.31 million in 2019, mainly as a result of the net proceeds of €74.25 million from the successful IPO on Euronext Brussels in June 2020 and the convertible bonds issued in March and April 2020, offset by the net reimbursements of shareholders' loans of €4.80 million.

As at 31 December 2020, cash and cash equivalents amounted to €64.40 million, a significant increase compared to €0.21 million at 31 December 2019 as a result of the IPO and the issuance of convertible bonds in the first half of 2020.

AUDIT REPORT

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

EXPECTED FINANCIAL CALENDAR 2021 and UPCOMING IR EVENTS

11 March	BioCapital Europe 2021
24 April	VFB Virtual Expert Day
30 April	Publication Annual Report 2020
12 May	Annual Kempen Life Sciences Conference
8 June	Annual General Meeting of Shareholders
4 August	Half year 2021 financial results and business update

CONFERENCE CALL AND WEBCAST

Hyloris will host a conference call with live webcast today at 3pm CET/9am ET. The webcast may be accessed on the Events page of the company's website or by clicking here. A replay of the webcast will be available on the Hyloris website.

For more information, please contact:

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About Hyloris Pharmaceuticals SA

Hyloris is a specialty biopharma company identifying and unlocking hidden potential in existing medications for the benefit of patients and the healthcare system. Hyloris applies its knowhow and technological innovations to existing pharmaceuticals and has built a broad proprietary product pipeline that has the potential to offer significant advantages over currently available alternatives. Hyloris currently has two, partnered commercial-stage products, Sotalol IV, for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid analgesic for the treatment of pain. 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 has already been established. This pathway can reduce the clinical burden required to bring a product to market, and significantly shorten the development timelines and reduce costs and risks. Hyloris is based in Liège, Belgium. For more information, visit www.hyloris.com and follow-us on LinkedIn.

Disclaimer and forward-looking statements

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.

Certain statements in this press release are "forward-looking statements." These forward-looking statements can be identified by the use of 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

ASSETS (in € thousand)	**December 31 2020**	**December 31 2019**
Non-current assets	**2,569**	**2,245**
Intangible assets	2,381	2,138
Property, plant and equipment	24	32
Right-of-use assets	152	66
Financial assets	12	9
Current assets	**66,613**	**3,739**
Trade and other receivables	253	333
Other financial assets	7	-
Other current assets	1,954	3,200
Cash and cash equivalents	64,399	205
TOTAL ASSETS	**69,182**	**5,983**

EQUITY AND LIABILITIES (in € thousand)	**December 31 2020**	**December 31 2019**
Equity attributable to owners of the parent	**59,059**	**(10,188)**
Share capital	129	89
Share premium	103,693	23,982
Retained earnings	(43,226)	(36,081)
Other reserves	(1,537)	1,822
Non-current liabilities	**7,991**	**22**
Borrowings	106	22
Other financial liabilities	7,885	-
Current liabilities	**2,132**	**16,149**
Borrowings	46	44
Other financial liabilities	409	13,130
Trade and other liabilities	1,629	2,927
Current tax liabilities	47	47
Total liabilities	**10,123**	**16,171**
TOTAL EQUITY AND LIABILITIES	**69,182**	**5,983**

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME FOR THE YEAR ENDED DECEMBER 31

(in € thousand)	2020	2019
Revenues	175	91
Cost of sales	(145)	(66)
Gross profit	**30**	**25**
Research and development expenses	(3,413)	(4,577)
General and administrative expenses	(2,194)	(808)
Shares' issuance related expenses	(1,468)	-
Other operating income	21	86
Operating profit/(loss)	**(7,025)**	**(5,274)**
Financial income	901	10
Financial expenses	(1,021)	(158)
Profit/(loss) before taxes	**(7,145)**	**(5,782)**
Income taxes	(1)	14
PROFIT/(LOSS) FOR THE PERIOD	**(7,145)**	**(5,768)**
Other comprehensive income	-	-
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	**(7,145)**	**(5,768)**
Profit/(loss) for the period attributable to the owners of the Company	(7,145)	(5,373)
Profit/(loss) for the period attributable to the non-controlling interests	-	(395)
Total comprehensive income for the period attributable to the owners of the Company	(7,145)	(5,373)
Total comprehensive income for the period attributable to the non-controlling interests	-	(395)
Basic and diluted earnings/(loss) per share (in €)	(0.33)	(0.37)

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED DECEMBER 31

(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	Other reserves			Retained earnings			
			Share-based payment	Cost of Capital	Other reserves				
Balance at December 31, 2018	**89**	**23,982**	**1,329**	**-**	**450**	**(28,097)**	**(2,246)**	**(2,216)**	**(4,462)**
Issuance of shares									
Acquisition of non-controlling interest as part of business combination under common control						(2,611)	(2,611)	2,611	-
Contribution by shareholder					42		42		42
Total comprehensive income						(5,373)	(5,373)	(395)	(5,768)
Balance at December 31, 2019	**89**	**23,982**	**1,329**	**-**	**493**	**(36,081)**	**(10,188)**	**-**	**(10,188)**
Initial Public Offering	30	64,363		(3,725)			60,668		60,668
Issuance of convertible bonds					4,531		4,531		4,531
Conversion of convertible bonds	10	15,347		(102)	(4,585)		10,670		10,670
Contribution by shareholder					37		37		37
Share-based payments			485				485		485
Total comprehensive income						(7,145)	(7,145)		(7,145)
Balance at December 31, 2020	**129**	**103,693**	**1,814**	**(3,827)**	**476**	**(43,226)**	**59,059**	**-**	**59,059**

CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31

(in € thousand)	2020	2019
CASH FLOW FROM OPERATING ACTIVITIES		
Loss for the period	(7,145)	(5,768)
Adjustments for:		
Depreciation, amortisation and impairments	581	3,306
Equity-settled share-based payment expense	485	-
Cost of equity transactions	1,468	-
Interest expenses on Convertible Bonds	208	-
Amortized costs on shareholders loans	(139)	-
Borrowing costs on IPRD	(43)	-
Income taxes	-	(14)
Other non-cash adjustments	(17)	-
Changes in working capital:		
Trade and other receivables	81	808
Other current and non-current assets	1,246	(3,191)
Trade and Other Payables	(1,398)	(111)
Other financial liabilities	103	407
Other current liabilities	(1)	(2)
Cash generated from operations	*(4,571)*	*(4,565)*
Taxes paid	1	4
Net cash generated from operating activities	**(4,570)**	**(4,562)**
CASH FLOW FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	-	(8)
Purchases of Intangible assets	(623)	(1,222)
Purchases of other financial assets	(10)	-
Proceeds from other financial assets	-	3
Net cash provided by/(used in) investing activities	**(633)**	**(1,228)**
CASH FLOW FROM FINANCING ACTIVITIES		
Reimbursements of shareholders loans	(8,050)	-
Proceeds from shareholders loans	3,250	3,364
Reimbursements of borrowings	(51)	(52)
Net proceeds from the Initial Public Offering	59,254	-
Net proceeds from the Convertible Bonds	14,994	-
Net cash provided by/(used in) financing activities	**69,397**	**3,308**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**64,194**	**(2,482)**
CASH AND CASH EQUIVALENTS at beginning of the period	205	2,687
CASH AND CASH EQUIVALENTS at end of the period	**64,399**	**205**