Source: *Hyloris Pharmaceuticals SA*

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Hyloris reports results for the full year 2021

Added 4 additional innovative product candidates

Strong growth in H2 leading to total revenues of €3.1 million (€0.2 million in 2020)

Significant expansion of commercial footprint of Maxigesic® IV

Tranexamic RTU licensing extended beyond U.S.

€50 million in cash and cash equivalents to execute ambitious growth strategy

LIÈGE, Belgium, March 16, 2022 (GLOBE NEWSWIRE) -- **Hyloris Pharmaceuticals SA (Euronext Brussels: HYL)**, a specialty biopharma company committed to addressing unmet medical needs through reinventing existing medications, today announces its financial and operational results for the year ending 31 December 2021.

"*The past year has validated the business model that Hyloris outlined at IPO - to deliver pragmatic and commercially attractive medical innovations that address unmet needs - while consistently endeavoring to grow shareholder value. All this has occurred during a challenging period for the life science sector."* said **Stijn Van Rompay, Chief Executive Officer of Hyloris.** During the year, the company has bolstered its emphasis on innovation and on value creation. *''We retain our core focus on cost efficient development of products through the 505(b)(2) pathway. The company has also shifted its focus towards repurposed product candidates, adding value and longevity to its portfolio with the addition of four exciting and innovative product candidates. During the year, Hyloris has invested more in in-house R&D including the opening of our laboratory in Liege. Carrying this momentum into 2022, the company expects to extend the reach of its commercialized products and bring a least 4 new exciting product candidates into Hyloris.*"

Increased roll out of commercial products

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 2021 and early 2022:

- An exclusive license and distribution agreement was signed with Hikma (LSE: HIK.L) for commercialization in the U.S. has been signed. The PDUFA date has been set on June 30, 2022. The market for post-operative pain is growing rapidly and is forecasted to reach $2.6 billion by 2028 (up from $1.1 billion in 2019)[1].
- Marketing authorizations have been granted in additional countries including: Israel, Panama, Albania, South Korea, UK, Cyprus, France, Luxembourg, Denmark, Iceland, Ireland, Italy, Greece and Norway.
- Submission has been done in further countries including : Pakistan, Oman, Bahrain, Thailand, Hong-Kong, Malaysia, US, Spain, Netherlands, Canada and Mexico.
- The product has been launched in 4 additional markets : Germany, Austria, South Korea and Panama. More launches are planned in the near future.
- Additional patents have been granted.

[1] IQVIA and DelveInsight Market Research

Sotalol IV, a novel, patented, IV formulation of oral Sotalol for the treatment of atrial fibrillation, and life-threatening ventricular arrhythmias developed for the U.S.

- Significant expansion of AltaThera's sales force mid 2021 in order to accelerate commercial roll-out and inclusion in hospital drug formularies.
- Post expansion sales performance has been impacted by COVID 19-related restrictions of access to hospitals. Mitigating measures have been implemented.
- Currently Sotalol IV is investigated in two clinical studies. The first study is investigating a shorter loading regimen and is expected to be completed in 2022. The second study is a patient registry capturing real-world experience on loading and is expected to be completed in 2023.

4 new innovative product candidates

Underlining the incremental lean and mean value-creation of Hyloris, the company announced the successful addition of four new innovative product candidates to its portfolio during 2021. Each of the product candidates addresses a clear unmet need and has the potential to bring substantial value to patients, physicians and payors.

- **February 2021: Miconazole + Domiphen Bromide (MCZ/DB**): Through a development and commercialization deal with Purna Female Healthcare, Hyloris will co-develop 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 with results expected in H2 2022.
- **October 2021: CRD-102 (modified release Milrinone capsule**): a novel, clinical-stage, extended-release long term use Milrinone capsule in late-stage heart failure (HF) patients with an implanted left ventricular assist device (LVAD). Heart failure is a severe and chronic condition in which the heart muscle is unable to pump enough blood to meet the body's need for blood and oxygen. Earlier studies have demonstrated that treatment with CRD-102 resulted in improved quality of life and functional status of late-stage HF patients and it has the potential to address the current unmet needs of late-stage LVAD patients with right HF. Orphan drug designation has been granted in the US.
- **November 2021: Plecoid agents:** Through its global exclusive co-development rights and future joint commercialization rights with Pleco Therapeutics, Hyloris will co-develop a chelating agent or agents - chemical compounds that capture metal ions - to detoxify the cancer promoting cellular micro-environment and improve the effectiveness of chemotherapy in patients with acute myeloid leukemia (AML: 160,000 patients[2] globally) and small cell lung cancer (SCLC: which accounts for approximately 13-15%[3] of 2 million cases of lung cancer per year). Previous studies demonstrate that elevated levels of toxic metals are associated with inferior survival in patients with AML. Exploratory clinical studies are currently ongoing in AML patients to evaluate the metal rebalancing effect of chelating agents administered concomitantly with chemotherapy.
- **December 2021: Alenura™:** Hyloris' strategic collaboration with Vaneltix Pharma aims to develop and commercialize Alenura™, a patented, innovative, clinical-stage bladder instillation product candidate that combines lidocaine[4] in a new alkalinized form with heparin. Thanks to the novel dual mode-of-action, Alenura™ has the unique potential to i) immediately relieve pain, and ii) augment the mucous layer of the bladder. The product candidate treats acute pain in interstitial cystitis/bladder pain syndrome (IC/BPS), a condition that affects at least 6 million[5] people in the US. Currently, there are 3 million instillation procedures per year in the US. A Phase 2 clinical trial is expected to start by mid-2022 with results potentially available by late 2023.

Repurposing and reformulation

These new innovative product candidates added in 2021 reflect a continued shift in emphasis for Hyloris on repurposing of existing drugs reaching beyond reformulation. Repurposing is the development of a pharmaceutical product, based on a well know molecule, but in a completely new indication. Repurposing can have important business advantages, it represents a more robust business strategy which is anchored in the demands of the healthcare system that are reflected in the unmet medical needs of patients, physicians and payors.

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2 Datamonitor Healthcare April 2021; Leukemia & Lymphoma Society, 2019; WHO classification of AML, 2016

3 Medscape - Abid Irshad, MD Associate Professor, Department of Radiology, Medical University of South Carolina College of Medicine

4 Lidocaine is a local anesthetic that works by causing temporary numbness/loss of feeling in the skin and mucous membranes; Heparin is a component of the mucous layer of the bladder wall and is an anticoagulant (blood thinner) that prevents the formation of blood clots

5 Data on the female population is from the RAND Study: J Urol. 2011 August, 186(2): 540–544. doi:10.1016/j.juro.2011.03.132
Data on the male population is from the RICE Study: J Urol. 2013 January, 189(1): 141–145. doi:10.1016/j.juro.2012.08.0

Development pipeline

The company opened its own laboratory facilities in Liège, Belgium, bringing drug formulation and analytical activities in-house to further streamline processes and accelerating the R&D activities.

Hyloris has 15 products in development[6] of which two are commercialized. For all current 505(b)2 products, we have made significant progress in 2021. Some of the achievements, milestones and adjustments are noted below.

Hyloris expanded the commercial potential of Tranexamic RTU beyond the U.S. with licensing deals in Australia, New Zealand and Canada, realizing an upside that was not anticipated at the IPO. In the US, Hyloris will optimize the go-to-market model for Tranexamic RTU by positioning it as a generic product, which significantly reduces regulatory costs but resulting in later approval. Although it remains an added value product outside of the US, it will be reported as established market product candidate.

Hyloris obtained a worldwide exclusive license related to an Aspirin IV formulation and technology, bringing forward the development timeline of Aspirin IV in acute coronary syndrome. The Aspirin IV pivotal PK study is currently ongoing.

HY-004: Phase 1 study completed with top line results becoming available in Q2 2022. As the product moves towards its pivotal study, the company may seek to expand and optimize the label claims to increase the commercial potential of the product through further evolving regulatory and clinical strategies that could extend the timeline.

Miconazole/Domiphen Bromide: A Phase 2 clinical trial ongoing with results expected in H2 2022.

Atomoxetine OS: Implementing changes to taste masking technology as per FDA scientific advice received.

HY-029: Scientific advice from the regulatory agency has been requested with the aim to start a pivotal PK study.

For the established market product candidates, patient recruitment for the Fusidic Acid Cream trial is ongoing in multiple territories and the company is evaluating its response to an FDA request relating to HY-016 for additional clinical data.

COVID-19-related restrictions affected several of the company’s programs during 2021 with minor impacts on timelines. None of these timeline revisions is expected to impact substantially on the company's cash position or financial projections. The development pipeline of added value products currently has no direct exposure relating to the current geopolitical situation in Eastern Europe.

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[6] Excluding high barrier generic products, HY-038, HY-016 and Fusidic Acid Cream

Management and Board changes

Hyloris' strengthened its senior management team during 2021. Thomas Jacobsen was appointed as Chief Business Development Officer in February, and Jean-Luc Vandebroek joined as Chief Financial Officer in September.

The company also appointed Chris Buyse as an independent member of the Board of Directors. Chris is an experienced investor, currently Managing Director of Fund+, the largest Belgian life science venture capital fund.

Outlook 2022

During 2022 Hyloris anticipates delivering on key value inflection milestones within its strategic focus areas, including conducting 6 clinical studies on its pipeline products, the further roll out of its commercial products and the addition of at least 4 new product candidates through internal innovation, in-licensing or joint ventures.

With cash and cash equivalents of €50 million at 30 December 2021, the Company is well-capitalized to advance all current pipeline assets as planned and execute its current business plan with the expectation to expand the portfolio to about 30 candidate and marketed products by 2024.

Conference Call

The Company will host a conference call and webcast, conducted in English, to present the results, followed by a live Q&A session.

The webcast will be held on 16 March 2022 at 2pm CET / 1pm GMT / 9am EST. To join the webcast, please pre-register here.

To dial-in for the conference call, please use the following details:

US: 877-407-0792

International: +1 -201-689-8263

Conference ID: 13727870

FINANCIAL HIGHLIGHTS 2021

(in € thousand)	Year ended 31 December 2021	2020	Variance
Revenues	**3,096**	**175**	**1,669%**
Research and development expenses	(5,056)	(3,413)	48%
General and administration expenses	(2,900)	(2,194)	32%
Shares' issuance related expenses	-	(1,468)	
Other operating income/expenses	(5,381)	21	
Operating result	**(10,541)**	**(7,025)**	**(50%)**
Net financial result	(741)	(120)	518%
Income Taxes	(297)		-
Net result	**(11,579)**	**(7,145)**	**(62%)**
Net operating cash flow	**(11,692)**	**(4,570)**	**(156%)**
Cash and cash equivalents	**50,012**	**64,399**	**(22%)**

FINANCIAL REVIEW 2021

Income statement

In 2021, total revenues increased to €3.10 million versus €0.18 million in 2020, driven by the strong growth from out-licensing Maxigesic® IV by our partner AFT Pharmaceuticals and a continuously increasing royalties received from AltaThera on net sales from Sotalol IV.
Cost of sales amounts to €0.11 million versus €0.15 million in 2020 and is mainly due to fees paid to Academic Pharmaceuticals in relation to sales of Sotalol IV and amortization expenses of the capitalized development costs of commercialized products.

Research and development expenses increased to €5.06 million in 2021 versus €3.41 million in 2020, in line with the progression and the expansion of the product candidates pipeline and the enlargement of the research and development team.

General and administrative expenses increased to €2.90 million in 2021 versus €2.19 million in 2020, primarily driven by the strengthening of the management team of the Company.

In 2021, the Company successfully renegotiated and unwound several license agreements with the Alter Pharma Group for the following products: Maxigesic® IV, HY-075, HY-038 and the high-barrier generic Fusidic Acid Cream for the Canadian market. Renegotiating and unwinding resulted in a one-time other operating expense of €5.77 million.

As a result, the operating loss increased in 2021 to €10.54 million versus an operating loss of €7.03 million in 2020.

The net financial loss in 2021 was €0.74 million (2020: €0.12 million). Financial income amounted to €0.32 million, comprising mostly of interest received on deposits, versus €0.90 million last year. The figure in 2020 had been positively impacted by non-recurring gains from the extension of the maturity of the Shareholders loans (€0.53 million). Financial expenses amounted to €0.77 million versus €1.02 million in 2020 and comprised mostly interest expenses on shareholders loans and exchange differences.

As a result, net losses in 2021 increased to €11.58 million versus €7.15 million in 2020.

Statement of financial position
The Company's non-current assets mainly consist of (1) investments in joint ventures of € 4.1 million at year-end 2021 and (2) intangible assets of €2.94 million at year-end 2021 including capitalized development, purchased assets and in-licensing costs, versus €2.38 million in 2020.

The Company's current assets mainly consist of €50.01 million in cash and cash equivalents on total assets of € 63.44 million, and trade and other receivables of € 2.32 million primarily resulting from out-licensing revenue from Maxigesic® IV.

Current liabilities mainly comprise shareholders' loans of € 11.82 million with maturity date end of December 2022.

The Company's equity decreased to €48.06 million, mainly as a result of the net loss for the year of € 11.58 million.

Cash flow statement
Net cash outflow from operating activities was €11.25 million in 2021, compared to €4.57 million in 2020. The cash outflows related to operating activities in 2021 amounted to €10.48 million (2020: €4.60 million).

Net cash outflow from investing activities was €2.13 million in 2021, compared to €0.63 million in 2020, and mainly related to investments in joint ventures and capitalization of development expenses.

The financing activities amounted to a net cash outflow of €1.00 million in 2021 compared to a net cash inflow of €69.40 million in 2020 from the net proceeds of the successful IPO on Euronext Brussels in June 2020 and the convertible bonds issued in March and April 2020.

As at 31 December 2021, cash and cash equivalents amounted to €50.01 million, down from €64.40 million at the end of 2020 as a result of progression and the expansion of the product candidates pipeline, and the successful renegotiation and unwinding of the license agreements with the Alter Pharma Group for lead product candidates of about €5.25 million.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION FOR THE YEAR ENDED DECEMBER 31

ASSETS (in € thousand)	31-Dec 2021	31-Dec 2020
Non-current assets	**9,485**	**2,569**
Intangible assets	2,944	2,381
Property, plant and equipment	122	24
Right-of-use assets	173	152
Investments in associates and joint ventures	4,097	-
Financial assets	453	12
Other non-current assets	1,714	-
Current assets	**53,959**	**66,613**
Inventories	-	-
Trade and other receivables	2,321	253
Other financial assets	528	7
Other current assets	1,098	1,954
Cash and cash equivalents	50,012	64,399
TOTAL ASSETS	**63,444**	**69,182**

EQUITY AND LIABILITIES (in € thousand)	31-Dec 2021	31-Dec 2020
Equity	**48,056**	**59,059**
Share capital	129	129
Share premium	103,693	103,693
Retained earnings	-54,805	-43,226
Other reserves	-960	-1,537
Liabilities	**15,388**	**10,123**
Non-current liabilities	**409**	**7,991**

Borrowings	109	106
Other financial liabilities	300	7,885
Current liabilities	**14,924**	**2,132**
Current borrowings	65	46
Other current financial liabilities	11,815	409
Trade and other liabilities	2,749	1,629
Current tax liabilities	349	47
TOTAL EQUITY AND LIABILITIES	**63,444**	**69,182**

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

(in € thousand)	**31-Dec 2021**	**31-Dec 2020**
Revenues	3,096	175
Cost of sales	(107)	(145)
Gross profit	**2,988**	**30**
Research and development expenses	(5,056)	(3,413)
General and administrative expenses	(2,900)	(2,194)
Shares issuance related expenses	0	(1,468)
Earnings/losses from Associates and joint ventures	(191)	
Other operating income	389	21
Other operating expenses	(5,770)	-
Operating profit/(loss) (EBIT)	**(10,541)**	**(7,025)**
Financial income	32	901
Financial expenses	(773)	(1,021)
Profit/(loss) before taxes	**(11,282)**	**7,145**
Income taxes	(297)	(1)
PROFIT/(LOSS) FOR THE PERIOD	**(11,579)**	**(7,145)**
Other comprehensive income	-	-
TOTAL COMPREHENSIVE INCOME OF THE PERIOD	**(11,579)**	**(7,145)**
Profit/(loss) for the period attributable to the owners of the Company	(11,579)	(7,145)
Profit/(loss) for the period attributable to the non-controlling interests		-
Total comprehensive income for the period attributable to the owners of the Company	(11,579)	(7,145)
Total comprehensive income for the period attributable to the non-controlling interests		-
Basic and diluted earnings/(loss) per share (in €)	(0.45)	(0.33)

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

	Attributable to equity holders of the Company					**Total Equity**
	Share capital	**Share premium**	**Other reserves**			**Retained earnings**
(in € thousand)			**Share based payment reserve**	**Cost of Capital**	**Other reserves**	

Balance at 31 December 2019	**89**	**23,982**	**1,329**	**-**	**493**	**(36,081)**	**(10,188)**
Initial public offering	30	64,363		(3,725)	-	-	60,668
Issuance of convertible bonds				-	4,531		4,531
Conversion of convertible bonds	10	15,347		(102)	(4,585)	-	10,671
Amortised costs on shareholders loans	-	-		-	37	-	37
Share-based payments	-	-	485	-	-	-	485
Total comprehensive income	-	-			-	(7,145)	(7,145)
Balance at 31 December 2020	**129**	**103,693**	**1,814**	**(3,827)**	**476**	**(43,226)**	**59,059**

Balance at 31 December 2020	**129**	**103,693**	**1,814**	**(3,827)**	**476**	**(43,226)**	**59,059**
Share-based payments	-	-	576	-	-	-	576
Total comprehensive income	-	-		-	-	(11,579)	(11,579)
Balance at 31 December 2021	**129**	**103,693**	**2,391**	**(3,827)**	**476**	**(54,805)**	**48,056**

CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31

(in € thousand)	**Note**	**31-Dec 2021**	**31-Dec 2020**
CASH FLOW FROM OPERATING ACTIVITIES			
Operating result		(11,579)	(7,145)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation, amortisation and impairments		137	581
Equity settled share-based payment expense		576	485
Cost of equity transactions			1,468
Interest expenses on convertible bonds			208
Amortized costs on shareholders loans		198	(139)
Borrowing costs on IPRD			(43)
Losses from Associates and joint ventures		191	
Other non-cash adjustments		(1)	(17)
Changes in working capital:			
Trade and other receivables		(2,068)	81
Other current and non-current assets		(771)	1,246
Trade and other liabilities		1,138	(1,398)
Other current and non-current financial liabilities		623	103
Other current and non-current liabilities		301	(1)
Cash generated from operations		**(11,253)**	**(4,571)**
Taxes paid		3	1
Net cash generated from operating activities		**(11,250)**	**(4,570)**
CASH FLOW FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment		(107)	-
Purchases of Intangible assets		(954)	(623)
Proceeds (from disposal) of intangible assets		219	

Investments in associates and joint ventures	(1,270)	-
Acquisition of other financial assets	(21)	(10)
Other		-
Net cash provided by/(used in) investing activities	**(2,133)**	**(633)**
CASH FLOW FROM FINANCING ACTIVITIES		
Reimbursements of borrowings and other financial liabilities		(8,050)
Proceeds from borrowings and other financial liabilities		3,250
Reimbursements of borrowings	(62)	(51)
Repayment received from other financial assests	216	
Payment of other financial assests	(1,157)	
Net proceeds from Initial Public Offering		59,254
Net proceeds from convertible bonds		14,994
Net cash provided by/(used in) financing activities	**(1,004)**	**69,397**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	**(14,387)**	**64,194**
CASH AND CASH EQUIVALENTS at beginning of the period	**64,399**	**205**
CASH AND CASH EQUIVALENTS at end of the period, calculated	**50,012**	**64,399**

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.

About Hyloris Pharmaceuticals

Hyloris is a specialty biopharma company focused on innovating, reinventing, and optimizing existing medications to address important healthcare needs and deliver relevant improvements for patients, healthcare professionals and payors. Hyloris has built a broad, patented portfolio of 15 reformulated and repurposed value-added medicines that have the potential to offer significant advantages over available alternatives. Outside of its core strategic focus, the Company also has 3 high barrier generic products in development and registration phase. Two products are currently in initial phases of commercialization with partners: Sotalol IV for the treatment of atrial fibrillation, and Maxigesic® IV, a non-opioid post-operative pain treatment. The Company's development strategy primarily focuses on the FDA's 505(b)2 regulatory pathway, which is specifically designed for pharmaceuticals for which safety and efficacy of the molecule have already been established. This pathway can reduce the clinical burden required to bring a product to market, and significantly shorten the development timelines and reduce costs and risks. Hyloris is based in Liège, Belgium. For more information, visit www.hyloris.com and follow-us on LinkedIn.

For more information contact :

Hyloris Pharmaceuticals, Investors and Media

investorrelations@hyloris.com

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.