Hyloris

2023

Half-year Report

Reinventing existing medications

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

BUSINESS PERFORMANCE REVIEW

Key Highlights and Year-to-Date events

COMMERCIAL VALUE DRIVERS

Maxigesic® IV is a novel, unique combination, intravenous formulation for the treatment of post-operative pain and is currently licensed to partners covering over 100 countries across the globe.

The number of countries in which Maxigesic® IV has been approved has increased to more than 40. So far, launches have occurred in around 20 countries.

A potential approval date for the US market was set for 17 October 2023 by the U.S. Food & Drug Administration. The U.S. regulatory body confirmed that it had received a complete response in relation to the additional data on E&L (extractables and leachables) it had requested in July 2022.

Maxigesic® IV aims to provide an alternative, non-opioid treatment option for post-operative pain. In the United States, chronic opioid usage in patients following surgery averages around 9%, ranging from 4% to 24% among various specialties[1]. Drug overdoses involving opioids resulted in over 80.000 deaths in the U.S. in 2021[2]. Patients who experienced an opioid overdose accounted for nearly $2 billion in annual hospital costs[3].

On the condition of FDA approval, sales of Maxigesic® IV could start soon, with an exclusive license and distribution agreement already signed between Hyloris' partner AFT Pharmaceuticals and Hikma Pharmaceuticals, a leading supplier of complex, injectable hospital products in the U.S.

Under the terms of the development collaboration agreement between Hyloris and AFT, Hyloris is eligible to receive a share on any product-related revenues, such as license fees, royalties, milestone payments, received by AFT.

Subject to market approval by the FDA and the first U.S. sales, Hyloris will be be entitled to to a milestone of approximately $2 million as revenue.

Sotalol IV is a novel, patented, intravenous formulation of Sotalol for the treatment of atrial fibrillation, and life-threatening ventricular arrhythmias developed for the US. Sotalol IV allows to significantly reduce the length of hospital stay and potentially the overall cost of care potentially improving patient outcomes.

Hyloris is taking further steps to capture more of the growth potential in the future. In addition, Hyloris will capture a larger share of the product sales in the second half of the year as the royalty percentages are attributed to the Company on a step-up basis.

COMMERCIAL ROLL-OUT PREPARATION

Out-licensing agreements were signed for Tranexamic Acid RTU in early 2023, covering an important European country and a major Southeast Asian country, with a combined population of over 60 million people. Earlier agreements have been signed in 2021 for Australia, New-Zealand and Canada. Regulatory submissions in the partnered territories are in progress, and additional out-licensing agreements are expected going forward.

[1] https://pubmed.ncbi.nlm.nih.gov/27163960/
[2] Data Overview | Opioids | CDC
[3] Premier | Opioid Overdoses Costing U.S. Hospitals an Estimated $11... (premierinc.com)

For product candidates which Hyloris intends to out-license, the strategic goal is to capture a substantial part of the net product margin realized by our commercial partners. The Company aims to achieve this by partnering these assets close to regulatory submission, except in countries where additional local clinical trials are required. In general, we will prioritize in-market product sales or profit-based participation over (upfront) milestone payments.

Cardiovascular portfolio

Hyloris is actively analyzing different go-to-market strategies to bring its range of cardiovascular product candidates to the U.S healthcare market in the most efficient way.

The strategic grouping of submission dates targeted by Hyloris makes 2025 a pivotal year for the Company, with several launches anticipated or in in preparation for the U.S. market by that year. These product candidates will be promoted primarily to electrophysiologists, a subset of cardiologists in hospitals.

Other value-added product candidates

With a growing portfolio and multiple product candidates progressing towards commercialization, the Company intends to sign partnerships with leading companies in their respective territories.

PIPELINE EXPANSION

The business development team applies its knowledge of established products and real-world data in the search for solutions to underserved medical needs. Inhouse knowhow is supplemented by leveraging dialogues with healthcare professionals, patient groups, payors and partners as well as our extensive sourcing network and R&D capabilities. We aim to create value by expanding our portfolio to 30 assets before 2025, and expect to accelerate pipeline expansion in the coming months.

In January 2023, Hyloris in-licensed **HY-088**, a product candidate targeting hypophosphatemia, a serious condition causing patients to have low level of phosphate in the blood. While mild hypophosphatemia is common and many patients are asymptomatic, severe hypophosphatemia can be life-threatening and requires medical treatment. Treatment protocols for patients deficient in phosphate are well-established and have proven useful in other situations of bone mineral imbalance, but in most countries no approved oral drugs exist.

By definition, the compounded drugs currently administered to patients have not been submitted for regulatory scrutiny regarding safety, efficacy and quality. Hyloris intends to achieve market access with an approved treatment in European countries.

R&D UPDATE & OUTLOOK

Swift & steady progress was made in the first half of 2023 to bring 14 repurposed and reformulated product candidates closer to patients in need, as well as 3 high barrier generics.

Our new and improved R&D lab is now operational at Légiapark in Liège (Belgium), the life sciences hub where Hyloris moved its head office at the end of 2022. Expanded R&D facilities and expertise will allow the Company to perform drug formulation and analytical activities in-house for its growing pipeline, further streamlining processes and more effectively deploying internal resources.

A non-exhaustive list of R&D achievements as well as selected milestones can be found below.

Cardiovascular portfolio

Progress has been made on all cardiovascular assets in the first half of 2023.

- For **Dofetilide IV**, the results of the pivotal clinical study, allowing regulatory submission, are expected by the summer of 2024. Additional U.S. patent applications have been submitted.
  Dofetilide IV aims to reduce hospitalization stays and related risks and costs. Currently, Dofetilide is only available as an oral capsule, and Dofetilide formulated as an IV could be used as an initial loading dose with subsequent oral Dofetilide dosing to reduce the time to reach steady state and hospital discharge.
- **Metolazone IV**: The process of manufacturing the final registration batches is currently in progress, with stability testing expected to be initiated as soon as October 2023. The pivotal clinical trial is currently in preparation and an additional U.S. patent application has been submitted.
  Metolazone tablets are used in patients with congestive heart failure, the most rapidly growing cardiovascular condition globally and the leading cause of hospitalization. The potential benefits of Metolazone IV include accelerating onset of action, allowing simultaneous administration with furosemide IV (the most frequently used intravenous hospital diuretic), and improving drug absorption for patients with concomitant gastrointestinal oedema. The intravenous formulation will also allow drug administration in patients who are too ill to receive oral medications or who are unconscious.
- **Aspirin IV:** The transfer to a new contract manufacturing organization (CMO), required following a strategic review, has been successfully concluded. Discussions with the FDA on the drug development program are ongoing.
  Aspirin IV is an intravenous formulation of acetylsalicylic acid (aspirin) targeting Acute Coronary Syndrome (ACS). When ACS occurs, fast diagnosis and treatment is crucial and potentially lifesaving.
- **HY-074**: Regulatory submission for the U.S. market is expected shortly after submissions related to the other cardiovascular assets mentioned in this list. For HY-074, Hyloris is exploring additional indications outside of the cardiovascular space.
  HY-074 is an IV formulation of a current standard of care treatment significantly reducing risk of death in ACS patients. HY-074 aims to offer faster onset of action, more convenient administration (more notable in patients who are nauseated or unconscious) and dosage control.

Other value-added product candidates

Notable points of progress for our these product candidates are described below. Other product candidates have advanced in line with the timelines previously indicated.

- **Alenura**™ : At the start of the summer, the first patients entered a 4-arm study which is part of an ambitious adaptive phase 2 program. The 4-arm trial is currently targeting to enroll 120 patients across multiple sites in the U.S. Each subject will receive a single blinded dose of Alenura™, placebo, lidocaine, or heparin by random assignment.
  Alenura**™** is being developed as a ready-to-use instillation to be administered intra-vesicularly. The product candidate targets acute pain flares in patients with IC/BPS, which affects at least 6 million people in the US alone.
- **HY-083:** A Phase 1 study was conducted demonstrating no systemic exposure could be detected following intranasal administration of the molecule using a nasal spray.
  HY-083 targets idiopathic rhinitis, a medical disorder characterized by a collection of nasal symptoms that resemble nasal allergies and hay fever (allergic rhinitis) but are not caused by a known cause like allergens or infectious triggers.
- **Tranexamic Acid Oral Suspension**: FDA agreement to proceed with the Phase 3 study was obtained, with the enrolment of the first patient expected in September 2023.
  TXA oral mouth rinse aims to reduce oral bleeding in patients undergoing dental procedures.

- **Miconazole-Domiphen Bromide:** A full read-out of the Phase 2 dose-finding study can be expected shortly, with the results guiding the company for the design of the next clinical trial. Miconazole-DB is a topical synergistic combination treatment for vulvovaginal candidiasis.
- **HY-029**: Subject to a successful outcome of the planned pivotal clinical study, regulatory filing to the U.S. FDA can be expected by mid-2024.
  HY-029 is a liquid formulation of an existing non-disclosed antiviral drug that is currently only available in oral solid form. Hyloris aims to improve ease of administration and dosage control, and thus potentially improving clinical outcome.

The total headcount of the Company grew to slightly over 40 people, with several key recruitments occurring over the summer. To enhance the development activities, only limited additional hiring is required.

With a net cash position of €39,2 million and assuming continued strategic out-licensing, commercial success for Maxigesic® IV and Sotalol IV, additional non-dilutive funding and milestone payments, the Company believes it is sufficiently capitalized to fund all expected R&D expenditures of the current product candidates (14 product candidates & 3 generics).

FINANCIAL HIGHLIGHTS AND RESULTS OF OPERATIONS

	Period ended 30 June		
(in € thousands)	**2023**	**2022**	**Variance**
Total revenue and other income	**2,391**	**1,229**	**95%**
Revenues	1,160	1,033	**12%**
Other income	1,231	196	**528%**
Cost of sales	**(46)**	**(61)**	**(25%)**
Operating expenses	**(9,361)**	**(5,986)**	**56%**
Research and development expenses	(6,871)	(4,712)	**46%**
General and administration expenses	(2,490)	(1,274)	**95%**
Operating result	**(7,100)**	**(4,876)**	**46%**
Net financial result	**466**	**(66)**	**(806%)**
Net result	**(6,634)**	**(4,942)**	**34%**
Net operating cashflow	**(4,129)**	**(6,401)**	**-35%**
Cash and cash equivalents	**39,159**	**57,687**	**-32%**

Total Revenue and Other Income

During the first six months of 2023, total revenue and other income increased to €2,391 thousand compared to €1,229 thousand in the first half year of 2022, which is approximately 95% higher compared to last year. The strong growth is mainly driven by increase of royalties, out-licensing income for Maxigesic IV and non-dilutive funding which we received from a US State Government and the Walloon region in Belgium.

Results

The Company realized a net loss of €6,634 thousand for the six-month period ending 30 June 2023, compared to a net loss of €4,942 thousand for the first half year of 2022.
In the first half of this year, the net loss is mainly resulting from the increase in R&D expenditure and G&A expenses
R&D expenditure during the first six months of 2023 amounted to €6,871 thousand, compared to €4,712 thousand for the same period of 2022. The increase was mainly driven by intensified activities to progress product candidates through the drug development stages.

General and administrative expenses increased to €2,490 thousand in the first half-year of 2023 versus €1,274 thousand in 2022, primarily driven by the enlargement of the Group's structure, additional recruitments, increased IP costs and higher legal costs compared to last year.

The net financial income in the first six months of 2023 was €466 thousand compared to a net financial loss of €66 thousand in the same period of 2022. The positive evolution of the financial

result is mainly due to the impact of an active cash management strategy in a context of high short term interest rates both in EURO and USD.

As a result, net losses in the first-half year of 2023 increased to €6,634 thousand versus €4,942 thousand in the same period of 2022.

Balance Sheet

Compared to the end of 2022, the Group is free of debt. The increase in right-of-use assets and borrowings is due to the start of the lease agreement related to the new inhouse R&D lab. The Company received an advance payment related to a government grant from the Walloon region, supporting the drug development of the product candidate HY-083. €43 thousand of this advance is a financial liability and €37 thousand is part of Trade and other liabilities.

Cash Position and cash flow

The Company maintains its strong cash position, with current cash and cash equivalents totaling €39,159 thousand on 30 June 2023, compared to €43,457 thousand on 31 December 2022.

Net cash outflow generated from operating activities was €4,158 thousand during the first six months of 2023, compared to a net operating cash outflow of €6,401 thousand in the same period of 2022. The decrease of 35% in the operating cash outflow is the result of revenue growth and good working capital management.

STATEMENT OF THE BOARD OF DIRECTORS

On September 6, 2023, we hereby confirm that, to the best of our knowledge

- the condensed consolidated financial statements for the six-month period ended 30 June 2023, which have been prepared in accordance with IAS 34 “Interim Financial reporting” as adopted by the European Union, gives a true and fair view of the financial position, comprehensive loss and cash flows of the Group and the undertakings included in the consolidation as a whole (the ‘Group’), and
- that the interim management report includes a fair review of the important events that have occurred during the first six months of the financial year and of the major transactions with the related parties, and their impact on the condensed consolidated financial statements, together with a description of the principal risks and uncertainties for the remaining six months of the financial year.

On behalf of the Board of Directors

Stijn Van Rompay (CEO)

Stefan Yee (Chairman)

CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

Condensed Consolidated Statement of Financial Position

ASSETS (in € thousand)	Note	30 June 2023	31 December 2022
Non-current assets		**12,258**	**11,063**
Intangible assets	7	3,785	3,607
Property, plant and equipment		275	176
Right-of-use assets		1,667	885
Equity accounted investees		3,863	3,948
Other investment, including derivatives	9	1,000	1,000
Trade and other receivables	10	1,667	1,447
Current assets		**45,015**	**50,801**
Trade and other receivables	10	4,541	5,127
Other investment, including derivatives	9	489	469
Prepayments	11	826	1,748
Cash and cash equivalents	12	39,159	43,457
TOTAL ASSETS		**57,273**	**61,864**

EQUITY AND LIABILITIES (in € thousand)	Note	30 June 2023	31 December 2022
Equity		**48,723**	**55,045**
Share capital		140	140
Share premium		121,513	121,513
Retained earnings		(64,246)	(53,476)
Result of the period		(6,634)	(10,770)
Share based payment reserve		1,934	1,622
Cost of Capital		(4,460)	(4,460)
Other reserves		476	476
Liabilities		**8,550**	**6,819**
Non-current liabilities		**1,822**	**1.047**
Borrowings	13	1,478	747
Other financial liabilities	13	344	300
Current liabilities		**6,728**	**5,772**
Borrowings	13	195	138
Other financial liabilities	13	3,200	3,212
Trade and other liabilities	14	3,332	2,422
TOTAL EQUITY AND LIABILITIES		**57,273**	**61,864**

The accompanying notes are an integral part of these consolidated interim financial statements.

Condensed Consolidated Statement of Profit and Loss and Other Comprehensive Income

STATEMENT OF COMPREHENSIVE INCOME (in € thousand)	Note	30 June 2023	30 June 2022
Revenues	15	1,160	1,033
Cost of sales		(46)	(61)
Gross profit		**1,114**	**973**
Research and development expenses	16	(6,871)	(4,712)
General and administrative expenses	16	(2,490)	(1,274)
Share of result of equity-accounted investees, net of tax	16	(85)	(58)
Other operating income	17	1,231	196
Operating profit/(loss) (EBIT)		**(7,100)**	**(4,876)**
Financial income		566	555
Financial expenses		(100)	(621)
Profit/(loss) before taxes		**(6,634)**	**(4,942)**
Income taxes		-	-
PROFIT/(LOSS) FOR THE PERIOD		**(6,634)**	**(4,942)**
Other comprehensive income		-	-
TOTAL COMPREHENSIVE INCOME OF THE PERIOD		**(6,634)**	**(4,942)**
Profit/(loss) for the period attributable to the owners of the Company		(6,634)	(4,942)
Profit/(loss) for the period attributable to the non-controlling interests			
Total comprehensive income for the period attributable to the owners of the Company		(6,634)	(4,942)
Total comprehensive income for the period attributable to the non-controlling interests			
Basic and diluted earnings/(loss) per share (in €)		(0.24)	(0.19)

Total outstanding shares at the end of June 30, 2023: 28,000,374

The accompanying notes are an integral part of these consolidated interim financial statements

Condensed Consolidated Statement of Changes in Equity

(in € thousand)	Attributable to equity holders of the Company						Total Equity
	Share capital	Share premium	Other reserves			Retained earnings and result of the period	
			Share based payment reserve	Cost of Capital	Other reserves		
Balance at 31 December 2021	**129**	**103,693**	**2,391**	**(3,827)**	**476**	**(54,805)**	**48,056**
Private Placement Via an Accelerated Bookbuild Offering	5	14,995		(634)			14,366
Equity Transaction via Transaction Warrants	6	2,826					2,832
Share-based payments			274				274
Total comprehensive income						(4,942)	(4,942)
Balance at 30 June 2022	**140**	**121,513**	**2,665**	**(4,460)**	**476**	**(59,748)**	**60,586**
Transfer of SBP reserves to retained earnings			(1,329)			1,329	-
Share-based payments			286				286
Total comprehensive income						(5,828)	(5,828)
Balance at 31 December 2022	**140**	**121,513**	**1,622**	**(4,460)**	**476**	**(64,246)**	**55,045**
Share-based payments			313				313
Total comprehensive income						(6,634)	(6,634)
Balance at 30 June 2023	**140**	**121,513**	**1,935**	**(4,460)**	**476**	**(70,880)**	**48,724**

The accompanying notes are an integral part of these Consolidated interim financial statements.

Condensed Consolidated Statement of Cash Flow

(in € thousand)	Note	30 June 2023	30 June 2022
CASH FLOW FROM OPERATING ACTIVITIES			
Profit/(loss) for the period		(6,634)	(4,942)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation, amortisation and impairments	16	163	92
Share-based payment expense	18	313	274
Change in fair value - Derivatives financial instruments	9	(80)	(276)
R&D Tax Credit	10	(211)	(137)
Interest income on deposits and current accounts		(396)	-
Interest expenses on shareholders loans		-	45
Loss on derecognition of shareholder loans		-	486
Equity transaction costs		-	29
Share of profit of equity-accounted investees, net of tax		85	58
Other non-cash adjustments		(12)	(4)
Changes in working capital:			
Trade and other receivables	10	834	298
Other investment, including derivatives		9	(1,221)
Prepayments	11	923	-
Trade and other liabilities	14	849	(769)
Other current and non-current liabilities		-	13
Cash generated from operations		**(4,158)**	**(6,054)**
Interest paid		17	1
Interest received		12	
Taxes paid		-	(349)
Net cash generated from operating activities		**(4,129)**	**(6,401)**
CASH FLOW FROM INVESTING ACTIVITIES			
Interest received		148	-
Purchases of property, plant and equipment		-	(30)
Purchases of Intangible assets	7	(236)	(182)
Repayment received from other financial assets		-	(522)
Net cash provided by/(used in) investing activities		**(88)**	**(734)**
CASH FLOW FROM FINANCING ACTIVITIES			
Reimbursements of borrowings and other financial liabilities	13	-	(1,059)
Reimbursements of lease liabilities		(112)	(35)
Proceeds from borrowings and other financial liabilities		44	-
Proceeds from Private Placement via ABB		-	14,337
Proceeds from Execution Transactions Warrants		-	2,832
Interests paid		(12)	(1,265)
Net cash provided by/(used in) financing activities		**(80)**	**14,810**
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS		**(4,297)**	**7,675**
CASH AND CASH EQUIVALENTS at beginning of the period		**43,457**	**50,012**
CASH AND CASH EQUIVALENTS at end of the period, calculated		**39,159**	**57,687**

The accompanying notes are an integral part of these consolidated interim financial statements.

NOTES TO THE CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

1. GENERAL INFORMATION

Hyloris Pharmaceuticals SA (the "Company" or "Hyloris") is a limited liability company governed by Belgian law. The address of its registered office is Boulevard Patience et Beaujonc N°3/1, 4000 Liège, Belgium.

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.

Armed conflict between Russia and Ukraine

The geopolitical situation in Eastern Europe with Russia's invasion of Ukraine and the war between the two countries continues to evolve as military activity proceeds and additional economic sanctions are imposed.

Although the Russia-Ukraine war is not expected to cause disruption to the Groups' operations directly related to the military conflict, the Group continues to monitor the situation and is taking measures to mitigate the impact on her ability to conduct clinical development activities.

Current economic climate

In 2023, the outlook of the worldwide economy has several downside risks including higher costs in general due to inflation, tighter monetary policy leading to higher interest rates in both euro and usd, financial stress and rising geopolitical tensions. The company evaluated the impact of the current economic climate and concluded that mainly, the R&D and G&A costs increased due to impact of inflation but with limited impact.

The consolidated financial statements were authorized for issue by the Board of Directors on September 6, 2023.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

2.1 BASIS OF PREPARATION

These condensed interim consolidated financial statements of the Group for the 6-month period ended June 30, 2023 have been prepared in accordance with International Accounting Standard 34 - Interim Financial Reporting as adopted by the European Union and comprise the Company and its subsidiaries (together to as 'the Group').

The condensed interim financial statements should be read in conjunction with the Group's last annual consolidated financial statements as at and for the year ended 31 December 2022. They do not include all of the information required for a complete set of financial statement prepared in accordance with IFRS Accounting Standards. However, selected explanatory notes are included to explain the events and transactions that are significant to an understanding of the changes in the Group's financial position and performance since last annual financial statements.

These consolidated financial statements are presented in euro, which is the Company's functional currency. All amounts in this document are represented in thousands of euros (€ thousands), unless noted otherwise. Due to

rounding, numbers presented throughout these Consolidated Financial Statements may not add up precisely to the totals provided and percentages may not precisely reflect the absolute figures.

These financial statements are prepared on an accrual basis and on the assumption that the entity is in going concern and will continue in operation in the foreseeable future (see also Note 3.1 below).

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

Change in accounting policies

The accounting policies applied in these condensed interim financial statements are the same as those applied in the Group's consolidated financial statements as at and for the year ended 31 December 2022.

Accounting standards issued but not yet effective

A number of new accounting standards, amendments to standards and interpretations are effective for annual periods beginning after 1 January 2023. The Group has not early adopted any of the forthcoming new or amended accounting standards in preparing these condensed consolidated interim financial statements.

The Group is also not planning on early adopting the new or amended accounting standards and the impact of the initial application is not expected to be material.

Amendments to IAS 1 Presentation of Financial Statements:

- Classification of Liabilities as Current or Non-current Date (issued on 23 January 2020);
- Classification of Liabilities as Current or Non-current - Deferral of Effective Date (issued on 15 July 2020); and
- Non-current Liabilities with Covenants (issued on 31 October 2022)

Amendments to IAS 1 Presentation of Financial statements: Classification of Liabilities as Current or Non-current, issued on 23 January 2020, clarify a criterion in IAS 1 for classifying a liability as non-current: the requirement for an entity to have the right to defer settlement of the liability for at least 12 months after the reporting period.

The amendments:

- specify that an entity's right to defer settlement must exist at the end of the reporting period;
- clarify that classification is unaffected by management's intentions or expectations about whether the entity will exercise its right to defer settlement;
- clarify how lending conditions affect classification; and
- clarify requirements for classifying liabilities an entity will or may settle by issuing its own equity instruments.

On October 31, 2022, the IASB issued **Non-current liabilities with Covenants**, which amends IAS 1 and specifies that covenants (i.e. conditions specified in a loan arrangement) to be complied with after the reporting date do not affect the classification of debt as current or non-current at the reporting date. Instead, the amendments require a company to *disclose* information about these covenants in the notes to the financial statements.

All of the amendments are effective for annual reporting periods beginning on or after 1 January 2024, with early adoption permitted. The amendments have not yet been endorsed by the EU.

Amendments to IFRS 16 Leases: Lease Liability in a Sale and Leaseback, issued on 22 September 2022, introduce a new accounting model which will

impact how a seller-lessee accounts for variable lease payments in a sale-and-leaseback transaction.

Under this new accounting model for variable payments, a seller-lessee will:

— include estimated variable lease payments when it initially measures a lease liability arising from a sale-and-leaseback transaction; and
— after initial recognition, apply the general requirements for subsequent accounting of the lease liability such that it recognizes no gain or loss relating to the right of use it retains

These amendments will not change the accounting for leases other than those arising in a sale and leaseback transaction.

The amendments apply retrospectively for annual periods beginning on or after 1 January 2024 with early application permitted. These amendments have not yet been endorsed by the EU.

Amendments to IAS 12 Income taxes: International Tax Reform – Pillar Two Model Rules, issued 23 May 2023, provide a temporary mandatory relief from accounting for deferred tax that arises from legislation implementing the GloBE model rules. Under the relief, companies are effectively exempt from providing for and disclosing deferred tax related to top-up tax. However, they need to disclose that they have applied the relief. The relief is effective immediately and applies retrospectively. It will apply until the IASB decides either to remove it or to make it permanent.

The amendments also require new disclosures once tax law is enacted but before top-up tax is effective and after top-up tax is effective. These new disclosures apply from 31 December 2023. The amendments do not introduce new disclosure requirements in the financial statement in interim periods ending on or before 31 December 2023.

These amendments have not yet been endorsed by the EU.

Amendments to IAS 7 Statement of Cash Flows and IFRS 7 Financial Instruments: Disclosures: Supplier Finance Arrangements, issued on 25 May 2023, introduce additional disclosure requirements for companies that enter into supplier finance arrangements. The amendments are effective for periods beginning on or after 1 January 2024, with early application permitted. However, some relief from providing certain information in the year of initial application is available. These amendments have not yet been endorsed by the EU.

3. CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

In the application of the Group's accounting policies, management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates. The followings are areas where key assumptions concerning the future, and other key sources of estimation uncertainty at the end of the reporting period, have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

3.1 GOING CONCERN

The half year 2023 consolidated results of the Group present a negative result, and the consolidated statement of financial position includes a loss carried forward.

Management has prepared detailed budgets and cash flow forecasts for the years 2023 and 2024. These forecasts reflect the strategy of the Group and include significant expenses and cash outflows in relation to the development of the ongoing products candidates, including additional product candidates for the next two years. The

development of new product candidates does not require a lot of cash in the first year.

With a cash position of the Group at the end of June 2023 (i.e. €39 million), the Board of Directors held in September, 6 2023 is of the opinion that it has an appropriate basis to conclude on the business continuity over the next 12 months. The Board of Directors can decide to postpone development of new product candidates and has different options to manage the cash burn and the runway of the cash including the acceleration of out-license agreements and access to shareholders and new investors.

3.2 SHARE-BASED PAYMENTS

In accordance with IFRS 2 – Share-based payment, the fair value of the warrants at grant date is recognized as an expense in the consolidated statement of comprehensive income over the vesting period, the period of service. Subsequently, the fair value is not re-measured.

The fair value of each warrant granted during the year is calculated using the Black-Scholes pricing model. This pricing model requires the input of subjective assumptions, which are detailed in Note 18.

4. FINANCIAL INSTRUMENTS AND FINANCIAL RISK MANAGEMENT

4.1 OVERVIEW OF FINANCIAL INSTRUMENTS

The table below summarizes the carrying amounts of all financial instruments by category in accordance with IFRS 9:

Pleco - Other investment, including derivatives (non current) – Level 3: the valuation is based on last capital increase and decided by Pleco's general assembly and is considered as market value. No change with last year assessment and measurement.

Vaneltix – Other investment, including derivatives – Level 2: Discounted cash flows: the valuation model considers the present value of expected payments, discounted using a risk-adjusted rate. No significant change in the FV compared to last year.

FX forward contracts – Trade and other liabilities – Derivatives & Other investment, including derivatives – Level 2: Forward pricing: the fair value is determined using the spot FX exchange rates at the reporting date and FX forward price in the contract.

(in € thousand)	IFRS 9 Category	Input level	June 30, 2023	December 31, 2022
Other investment, including derivatives (Note 9)	FVTPL	2	489	469
Other investment, including derivatives – Pleco (Note 9) (non current)	FVOCI	3	1,000	1,000
Trade receivables (Note 10)	At amortised cost		4,743	5,615
Cash and cash equivalents	At amortised cost		39,159	43,457
Total financial assets *			**46,217**	**52,289**
Borrowings (Note 13.1)	At amortised cost		1,673	885

Other financial liabilities (Note 13.2)	At amortised cost		3,544	3,512
Trade and other liabilities (Note 14)			3,332	2,422
Trade payables	At amortised cost		3,216	2,302
Derivative	FVTPL	2	-	52
Total financial liabilities *			**8,549**	**6,819**

Trade and Other receivables (VAT / R&D tax credit receivables), prepayments and trade and other liabilities (deferred income and employee benefit liabilities) that are not financial assets / liabilities are not included

The Company considers that the carrying amounts of financial assets and financial liabilities measured at amortized cost in the consolidated financial statements approximate their fair values.

5. OPERATING SEGMENTS

According to IFRS 8, reportable operating segments are identified based on the "management approach". This approach stipulates external segment reporting based on the Group's internal organizational and management structure and on internal financial reporting to the chief operating decision maker.

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

Total revenue including other operating income represent an amount of €2,39 million. The revenue related to products (royalties, milestones, out-license revenues), represents €614 thousand, revenue for services rendered is €547 thousand and other operating income (subsidies, R&D tax credits, payroll tax exemption and settlement agreement) is €1,23 million.

1. GEOGRAPHICAL INFORMATION

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

6. LIST OF CONSOLIDATED COMPANIES AS AT JUNE 30, 2023

Company name	Company number	Location	% financial interest
Hyloris Pharmaceuticals SA	BE 0674.494.151	Blvd Patience et Beaujonc N°3/1, 4000 Liège	Parent
Hyloris Developments SA	BE 0542.737.368	Blvd Patience et Beaujonc N°3/1, 4000 Liège	99.99%
Hyloris Supply SA	BE 0669.738.676	Blvd Patience et Beaujonc N°3/1, 4000 Liège	100.00%
Dermax SA	BE 0667.730.677	Blvd Patience et Beaujonc N°3/1, 4000 Liège	100.00%
Purna Female Healthcare BV	BE 0762.693.578	Scheldestraat 31, 2880 Bornem	20.00%*

** equity accounted investee.*

The voting rights equal the percentage of financial interest held.

7. INTANGIBLE ASSETS

In the 6-month period ended 30 June 2023, the Company acquired intangible assets for a total of €236 thousand, of which (i) €36 thousand related to the development costs of product-candidate Maxigesic® IV and (iii) €200 thousand related to the development costs of HY-088.

The intangible assets are not amortised until the moment they are available for use as intended by management, i.e. ready for commercialisation. The company is amortizing since 2014 the development costs of Sotalol IV, an asset for which regulatory approval had been obtained. The development costs of Sotalol IV have a remaining useful life of 1.5 years. In 2022 the Company has started the amortisation of the development costs of Maxigesic® IV for the 38 countries outside the United States of America where market approval is obtained. Once the product is available for use in the United States of America, the amortisation will start for that market as well.

The amortisation expenses are included in "Cost of sales" in the consolidated statement of profit or loss and other comprehensive income.

As long as the assets are not fully amortised, they are tested for impairment losses on an annual basis or more frequently if specific indicators require it. No impairment triggering events have been identified. No impairment loss has been recognized during the period.

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

8. RIGHT-OF-USE ASSETS

During the six months ended 30 June 2023, the Group entered into a new lease agreement for use of a lab for 9 years. The Group makes fixed payments and additional variable payments depending on the usage of the asset during the contract period. On lease commencement, the Group recognized €818 thousand of right-of-use asset and lease liability. There is no renewal or purchase option at the end of the lease agreement.

9. OTHER INVESTMENT, INCLUDING DERIVATIVES

The other investment, including derivatives can be detailed as follows:

(in € thousand)	June 30, 2023	December 31, 2022
Shares Pleco Therapeutics BV	1,000	1,000
Optional convertible loan	460	469
Derivatives	29	-
Other Investment, including derivatives	**1,489**	**1,469**
of which as:		
Non-current	1,000	1,000
Current	489	469

Automatically converted loan into shares of Pleco

In 2021, the Group entered into a partnership with Pleco Therapeutics to develop a Plecoid™ Agent, a novel combination product of chelating agents for the treatment of Acute Myeloid Leukaemia (AML) and Small Cell Lung Cancer (SCLC). Under the terms of the agreement, Hyloris provided via a €1,000 thousand automatically non-interest bearing convertible loan (whereof as of per 31 December 2021 €500 thousand was paid to Pleco Therapeutics). On 1 June 2022, Pleco Therapeutics issued new shares and conform to the agreement, the loan has been converted into shares. The Group received 7,944 preferred shared at an issuing price of €126 per share (which result in a 4.67% ownership of the company Pleco Therapeutics). See note 4.1 for the valuation.

Subject to feedback from the FDA on the feasibility of the clinical development requirements, the Group may commit to fund (not convertible into equity) up to an additional €7,700 thousand pre-defined R&D activities through to submission for approval in AML, plus initial exploratory development work in SCLC. Pleco will fund all activities that are outside the scope of the maximum €7,700 thousand funding commitment from Hyloris. Hyloris will be eligible to receive up to 65% of the net gross product margin generated worldwide in AML and SCLC.

Optional convertible loan

On 13 December 2021, the Group entered into a collaboration with Vaneltix Pharma, Inc. (a related party of Hyloris) for the development and commercialisation of Alenura as first-line drug treatment for acute pain in interstitial cystitis /bladder pain syndrome (IC/BPS). Under the terms of the agreement, the Group granted a 6% interest bearing loan of $500 thousand.

The Loan will be reimbursed at the earliest of i) 31 December 2023 or ii) sale of equity or other equity-linked instruments by the Borrower to unaffiliated third parties for financing purposes for an amount of at least USD $5 million (the “Capital Increase”). In case Capital Increase on or prior to the reimbursement of the Loan in full, Hyloris shall have the option to convert the entire principal amount of the loan and all interest accrued into shares. Also under the terms of the agreement, the Group will provide staged investments of in total maximum $ 6,700 thousand for Phase 2, manufacturing and regulatory related activities (see note 21.1).

Derivatives

In the first 6 months of 2023, the Group actively mitigated its foreign exchange risk (USD exposure) utilizing forward foreign exchange contracts for a total nominal value of $4 million and €924 thousand whereas as per end of June $2 million is still outstanding. As a result and as per 30 June 2023, a derivative with a positive fair value is recognized as a current financial asset for €29 thousand.

10. TRADE RECEIVABLES AND OTHER RECEIVABLES

(in € thousand)	June 30, 2023	December 31, 2022
Trade receivables	3,627	4,527
API	622	625
Alter Pharma	-	395
R&D Tax Credits	1,034	811
Accrued interests on deposits	236	57
Other amounts receivable	322	159
Government Tax credit	368	-
Total trade and other receivables	**6,209**	**6,574**
of which as:		
Current	4,541	5,127
Non Current	1,668	1,447

An impairment analysis of trade receivables is done on an individual level, and there are no individual significant impairments.

The carrying amount of the Group's trade receivables (gross) is mainly denominated in EUR, primarily resulting from out-licensing revenues and service revenues in EUR.

During the year, the payment terms for the receivables have neither deteriorated nor been renegotiated. The maximum credit risk exposure at the end of the reporting period is the carrying value of each caption of receivables mentioned above. The Group does not hold any collateral as security.

Other amounts receivable mainly includes recoverable VAT.

Trade Receivables for Maxigesic IV

Hyloris should collect a receivable of €1,4 million recognized as revenue in 2021 after market approval by the FDA and first U.S. commercial sales (PDUFA date is set as 17 October 2023 by the U.S. FDA).

API

A loan of €644 thousand is granted by Hyloris to API, carrying a 0.1% interest per year. This loan is presented as non-current. As soon as the royalties (or other payments) of 3 product candidates, or any other product parties may develop together in

the future, exceed $200 thousand in a calendar year then the amount exceeding $200 thousand will be used to repay the loan. Hyloris can then withhold this amount from royalty payments. The loan has been measured at FVTPL using an interest market rate and appropriate credit risk. The change in FV compared to last year resulted in the initial recognition of a profit for the period of k€ 9 recognized as financial income.

R&D Tax Credits

Government Tax Credit

A Tax Credit of €368 thousand was granted from an American state government for the clinical development of the Alenura product candidate.

11. PREPAYMENTS

Pre-paid R&D expenses relate to payments made by the Group for research and development projects conducted by third parties and will be recorded in profit and loss when incurred.

In H1 2023, the prepayments outstanding as at 31 December 2022 have been fully used and mainly driven by the clinical development of the Alenura product candidate (see note 21.1). The outstanding prepayments as at 30 June 2023 are the results of the actual prepayments made during the period.

The Group applies for R&D tax credit incentives set-up by the Federal government and obtained reasonable assurance in the current reporting period that the Group will comply with the conditions attached to the grant and that the grant will be received. During the period, the Group recognized R&D tax credits for a total of €223 thousand in Other Operating Income (€211 thousand - see note 17 and in Intangible assets (€11 thousand).

12. CASH AND CASH EQUIVALENTS

The net cash position as presented in the consolidated statement of cash flows is as follows:

(in € thousand)	June 30, 2023	December 31, 2022
Cash at bank	14,159	13,457
Short-term deposit	25,000	30,000
Total cash and cash equivalents	**39,159**	**43,457**

The term of three deposits are from 13 December 2022 to 13 September 2023, from 3 January 2023 to 3 July 2023, and from 3 January 2023 to 3 January 24. It is classified as short term deposit as available for use by the group within a 32 days' notice period.

13. BORROWINGS AND OTHER FINANCIAL LIABILITIES

13.1 BORROWINGS

(in € thousand)	June 30, 2023	December 31, 2022
Lease liabilities	1,673	885
Total borrowings	**1,673**	**885**
of which as:		
Non-current borrowings	1,478	747
Current borrowings	195	138

The main increase in the lease liabilities is mainly due to the leasing of the new lab which is in use since June 2023. The incremental borrowing rate used for the measurement of this new lease liabilities is 3.95%. The Group is not subject to financial

covenants. The underlying leased assets act as pledge in the context of the lease liabilities.

13.2 OTHER FINANCIAL LIABILITIES

The other financial liabilities can be detailed as follows:

(in € thousand)	June 30, 2023	December 31, 2022
Advance on government grant	43	-
Other financial liabilities	3,501	3,512
Other financial liabilities	**3,544**	**3,512**
of which as:		
Non-current other financial liabilities	344	300
Current other financial liabilities	3,200	3,212

Other financial Liabilities

In June 2023 an advance payment related to the government grant for HY-083 was received from the Walloon region. A part of this advance payment is a standard government grant (€88 thousand) and the other part is refundable to the Walloon region (€169 thousand). 30% of the refundable part is a fix amount (€51 thousand) and is according to the accounting policy a financial liability initially measured at fair value. The variable part (70%) of the refundable advance (€118 thousand) is also treated as a government grant and recognized in profit or loss when the related costs are incurred. If the development of the product candidate is successful and will be commercialized the Group has to reimburse the advance: a fix amount and a variable amount depending on the sales of the product. If the product candidate is not successful the Group is not required to refund the advance but only if the Group decides to transfer the IP rights of the product candidate to the Walloon region. In case the Group decides to keep the IP rights, the fix part of the advance has to be reimbursed and the financial liability will be derecognized.

The Group has with the Alter Pharma Group related license agreements: a non-current other financial liability of €300 thousand and a current financial liability of each €200 thousand.

Committed to milestone related investments (contributions to the equity) in Purna Female Healthcare the Group has a current other financial liability of €3 million.

14. TRADE AND OTHER LIABILITIES

(in € thousand)	June 30, 2023	December 31, 2022
Trade payables	3,216	2,302
Employee benefit liabilities	79	68
Other payables	-	52
Deferred income	37	-
Trade and other liabilities - Current	**3,332**	**2,422**

The trade payables relate mainly to the R&D activities.

The fair value of trade payables approximates their carrying amount.

15. REVENUE

The revenues can be detailed as follows:

(in € thousand)	June 30, 2023	June 30, 2022
Sales-based royalties, milestone payments and out-licensing agreement	614	433
Services rendered	547	600
Revenues	**1,160**	**1,033**

Revenues generated in the six-month period include royalty income on net sales of the Group's commercialized products, Sotalol IV and Maxigesic® IV, income from services rendered and income from out-licensing agreements.

For Sotalol IV, while the unit sales increased versus last year, the calculation of the royalties provided by Alta Thera reflects the full impact of the royalty reduction based on the disputed unilateral termination of the license agreement by Alta Thera which is currently under litigation (see note 19). It also reflects Alta Thera's position of the impact of two acts passed by the U.S. Congress in 2022, effective as from January 1st 2023:

- The Inflation Reduction Act (IRA) which requires drug manufacturers to pay a rebate to the U.S. Federal Government if prices for single source drugs increased faster than the rate of inflation.
- The Infrastructure Act which requires drug manufacturers to provide a rebate for the total amount of the discarded medication recorded for single use package drugs (wasted or leftover medication).

Revenue from sales-based royalties is recognized when the subsequent sale occurs. Revenue from sales milestone is recognized when the performance obligation has been met (i.e. sales threshold reached).

Revenue for milestone payment in exchange for a license of intellectual property is only recognized when the performance obligation to which some or all of the milestones payments has been allocated has been satisfied.

Income from out-licensing is recognized at the point in time that the license is granted.

Revenue from services rendered in the first half year of 2023 primary consists of strategic advices incurred by the Group to support a co-developer. Revenue for services rendered is recognized when the service is rendered.

16. EXPENSES BY NATURE

Expenses by nature represent an alternative disclosure for amounts included in the consolidated statement of comprehensive income. They are classified under "Cost of sales", "Research and development expenses", "General and administrative expenses" and "Other operating expenses" in respect of the years ended December 31:

(In € thousand)	30 June 2023	30 June 2022
Amortisation expense of intangible assets	46	40
Depreciation expense of property, plant and equipment and RoU assets	124	15
Employee benefit expenses	1,719	1,383
Management fees	598	366
Legal & paralegal fees	665	85
Audit & audit related consultancy fees	47	8
Board related expenses	88	91
Other equipment, rent and utilities	258	112
Share based payments	313	274
R&D	4,992	3,273
Other General and Administrative Expenses	642	458
Total operating expenses	**(9,492)**	**(6,105)**
of which as:		
Cost of sales	46	61
Research and development expense	6,871	4,712
Selling, General and Administrative expenses	2,490	1,274
Earnings/losses from Associates and Joint Ventures	85	58

In accordance with IAS 38, we do not capitalize our research and development expenses until we file for marketing authorization for the applicable product candidate. Research and development expenditures incurred during the period were accounted for as operating expenses.

The Groups' research and development expenses incurred during the six-month period ending 30 June 2023 were accounted for as operating expenses and increased to €6,871 thousand compared to €4,712 thousand in the same period in 2022, mainly driven by more product candidates in development.

Employee benefit expenses and management fees incurred during the first half-year of 2023 increased to €2,317 thousand, driven by the enlargement of the Group's structure and additional recruitments.

Selling, General and Administrative expenses increased due to the enlargement of the Group's structure, legal costs, travel and accruals for the end of year bonuses.

17. OTHER OPERATING INCOME

(in € thousand)	June 30, 2023	June 30, 2022
Grants income related to exemption on withholding taxes	80	59
R&D tax credit	211	137
Government grants	545	-
Other income	395	-
Other Operating Income	**1,231**	**196**

In the six-month period ending 30 June 2023, the Group realized other operating income of €1,231 thousand compared to €196 thousand over the same period last year. The big increase is mainly related to:

- a tax credit from an American State government for the clinical development of the Alenura product candidate of €369 thousand

- an advance payment from the Walloon region related to a grant for the research and development of product candidate HY-083 of €177 thousand. Total amount of the grant is €1,033 thousand split between a subvention of €355 thousand and a refundable advance of €677 thousand. The amounts will be granted based on the incurred costs which are eligible for the development of the product candidate. The refundable advance has a fix part (30%) which is booked as a financial liability, initially measured at fair value, and a variable part (70%) which is booked as deferred income in Trade and Other Liabilities. The Group has to reimburse the refundable advance to the Walloon region if the product candidate is commercialized. Only if the development of the product candidate is not successful and the IP rights are transferred to the Walloon region, the Group may keep the advance (see note 13.2). The reimbursement of the advance will start in 2027 for a period of 10 years. There is a fix and a variable part to be reimbursed. The fix part of the annual reimbursement is 30% of the total refundable advance. The variable part of 70% is depending on the product related sales (see note 20).

- a Settlement agreement with a partner of €394 thousand resulting from long lasting discussion on disputed costs incurred in the past

- the increase of the R&D tax credit compared with last year

18. SHARE-BASED PAYMENTS

The Company has a stock option scheme for the employees, consultants and directors of the Company and its subsidiaries for rendered services. In accordance with the terms of the plan, as approved by shareholders, employees may be granted options to purchase ordinary shares at an exercise price as mentioned below per ordinary share.

Each employee share option converts into one ordinary share of the Company on exercise. No amounts are paid or payable by the recipient on receipt of the option. The options carry neither rights to dividends nor voting rights. Options may be exercised at any time from the date of vesting to the date of their expiry.

The following share-based payment arrangements were in existence during the current and prior periods, there are no changes compared to the end of December 2022:

	Expiry Date	Exercise Price per warrant (€)	Fair value at grant date (€)	Warrants per 31 December 2022	Warrants per 30 June 2023
PLAN 2019					
Warrants	31 December 2024	5.34	2.47	306,125	306,125
PLAN 2020					
Warrants	27 November 2031	9.88	4.44	69,500	69,500
Warrants	27 November 2031	12.04	5.68	55,000	55,000
Warrants	27 November 2031	13.92	6.20	60,000	60,000
Warrants	27 November 2031	16.64	7.39	2,000	2,000
PLAN 2022					
Warrants	30 June 2029	14.07	5.31	142,000	142,000
TOTAL					**634,625**

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

	PLAN 2019	PLAN 2020	PLAN 2022
Average Share price (€)	5.34	11.73	14.84
Average Exercise Price (€)	5.34	11.89	15.2
Expected volatility of the shares (%)	55%	40%	35%
Expected dividends yield (%)	0%	0%	0%
Risk free interest rate (%)	0.10%	0.00%	2.66%

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

	Average Exercise Price (€)	Numbers of Warrants
Closing balance at 31 December 2018	**2.36**	**1,200,000**
Warrants accepted in December 2019	5.34	118,000
Closing balance at 31 December 2019	**2.63**	**1,318,000**
Warrants accepted in 2020	5.34	235,000
Warrants lapsed in 2020	5.34	-20,000
Closing balance at 31 December 2020	**3.01**	**1,533,000**
Warrants accepted in 2021	11.89	186,500
Warrants lapsed in 2021	5.34	-20,000
Closing balance at 31 December 2021	**3.68**	**1,699,500**
Warrants accepted in 2022	15.2	142,000
Warrants lapsed in 2022	5.34	-6.875
Warrants exercised in 2022	2.36	-1,200,000
Closing balance at 31 December 2022	**8.74**	**634,625**
Closing balance at 30 June 2023	**8.74**	**634,625**

19. CONTINGENCIES

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

At the end of June 2023, all parties have agreed to consolidate all litigation before the American Arbitration Association ("AAA") in New York. Hearings are scheduled in Q2, 2024 and Hyloris expects a final decision by the end of H1 2024.

20. COMMITMENTS AND CONTINGENT LIABILITIES

Hyloris has contractual commitments related to asset purchase, licenses and development agreements. The amounts are due upon reaching certain milestones dependent on successful completion of development stages of the different product candidates (including FDA approval) or on meeting specified sales targets. The Company disclosed as commitments the maximum that would be paid if all milestones and sales targets are achieved. The amounts are not risk-adjusted or discounted

As at 30 June 2023, there are no major changes compared to end of December 2022. Hyloris has contractual commitments and contingent liabilities for a maximum amount of €32,425 thousand on related to asset purchase, licenses and development agreements recorded under intangible assets. The slight decrease compared to last year is linked to R&D costs incurred during the period reducing the commitment of certain product-candidates.

The accounting treatment of the contractual commitments and contingent liabilities will vary per nature of triggering event. Development milestones until commercialization will be expensed or capitalized. Sales related commitments such as royalties, profit sharing and sales milestones will be expensed when incurred.

The following table details the total maximum contractual commitments (milestone payments only) at 30 June 2023 per product candidates if such products are successfully marketed (in € thousand):

As mentioned in note 13.2 the Group received an refundable advance from the Wallon region. The advance (€118 thousand) needs to be reimbursed if the relevant product candidate will be commercialised in the future.

The reimbursement of the advance will start in 2027 for a period of 10 years. There is a fix and a variable part to be reimbursed. The fix part of the annual reimbursement is 30% of the total advance. The variable part of the annual reimbursement is a fix percentage (below 1%) of the future annual turnover related to the product.

Product Candidate	In $ thousand	In € thousand	Converted in € (in € thousand)
HY-004 Tranexamic Acid MR	225		207
HY-029		300	300
Atomoxetine oral liquid	150		138
Metolazone IV	1,650		1,518
Dofetilide IV	350		322
HY-073	28,457		26,189
HY-074	175		161
Alenura (note 21.1)	3,900		3,589
TOTAL	**34,907**	**300**	**32,425**

As of June 30 2023, out of the total value of €32,425 thousand, €28,053 thousand should be considered as contingent liabilities as they are not triggered by a performance obligation from the counterparty, but triggered by (future) sales milestones.

Contingent liabilities attached to profit split and royalties which percentage varies based on achieved profit and/or sales are not considered in the above table as no maximum amount can be determined.

21. RELATED PARTY TRANSACTIONS

The reference shareholder is current CEO Stijn Van Rompay.

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

The related parties presented below are identified as:

- Vaneltix Inc and its affiliates, in which non-executive and independent member of the Board of directors, Carolyn Myers her partner, Dr. Dan Vickery is CEO and shareholder.
- The shareholders; Mr Stijn Van Rompay, an executive member of the board of the Company, CEO and reference shareholder of the Company; GRNR Invest BVBA, an entity controlled by Thomas Jacobsen, an Executive member of the Board of the Company;
- The Executive Management Team; and
- The Board of Directors (Non-Executive Directors)

21.1 TRANSACTIONS WITH VANELTIX, INC.

In 2021 the Group entered into a strategic collaboration with Vaneltix Pharma Inc. for the development and commercialisation of Alenura as first-line drug treatment for acute pain in interstitial cystitis /bladder pain syndrome (IC/BPS).

Under the terms of the agreement, Vaneltix will be responsible for the further development, manufacturing, regulatory affairs and commercialisation of Alenura in collaboration with Hyloris. In return, Hyloris will provide staged investments of in total maximum $6,700 thousand for Phase 2, manufacturing and regulatory related activities related activities and a 6% interest bearing (potential convertible) loan of $500 thousand (see note 9). Hyloris will be eligible to receive a tiered and incremental percentage of the product margin generated by Vaneltix.

The table below provides an overview as per 30 June 2023:

(in € thousand)	Financial Position	Transactions for the period	
		Profit Loss	Commitments
Other investments (see note 9)	460		
Prepayments	-		
Research and Development expenses		(1,410)	
Interest income		12	
Commitments and Contingent Liabilities			3,589
Total	**460**	**(1,398)**	**3,589**

- Jacobsen Management BV, an entity controlled by Thomas Jacobsen, an executive member of the Board of the Company and CBDO
- Finsys Management BA, an entity controlled by Jean-Luc Vandebroek, Chief Financial Officer
- Dr Dietmar Aichhorn, Chief Operating Officer
- Herault BVBA, an entity controlled by Koenraad Vanderelst, Chief Legal Officer

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

(in € thousand)	June 30, 2023	June 30, 2022
Short-term compensation (incl. management fees)	598	467
Share-based payments	39	95
Total	**637**	**562**

21.2 TRANSACTIONS WITH THE EXECUTIVE MANAGEMENT TEAM

Executive management team personnel include those persons having authority and responsibility for planning, directing and controlling the activities of the Group. As of 30 June 2023, members of the Executive Management Team are:

- SVR Management BVBA, an entity controlled by Stijn Van Rompay, an executive member of the Board of the Company, CEO and reference shareholder of the Company

As of 30 June 2023, members of the Executive Management Team owned the following securities of the Company:

	Shares		Warrants	
	Number (#)	Pct. (%)	Number (#)	Pct. (%)
Mr. Stijn Van Rompay	7,743,067	27.65	68,000	10.71
Mr. Thomas Jacobsen	3,857,838	13.78	-	0.00
Mr. Jean-Luc Vandebroek	9,000	0.03	40,000	6.30
Mr. Dietmar Aichhorn	32,500	0.12	40,000	6.30
Mr. Koenraad Vanderelst	17,443	0.06	50,000	7.88
TOTAL	**11,659,848**	**41.64**	**198,000**	**31.20**

Total outstanding shares and warrants existing as of 30 June 2023 are respectively 28,000,374 and 634,625.

21.3 TRANSACTIONS WITH THE BOARD OF DIRECTORS (NON-EXECUTIVE DIRECTORS)

As of 30 June 2023, non-executive members of the Board of directors are:

- Stefan Yee, Chairman
- Leon Van Rompay
- Marc Foidart
- Carolyn Myers
- James Gale
- Chris Buyse

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

(in € thousand)	June 30, 2023	June 30, 2022
Board fees	55	55
Share-based payments	5	15
Total	**60**	**70**

As of 30 June 2023, non-executive members of the Board of directors owned the following securities of the Company:

	Shares		Warrants	
	Number (#)	Pct. (%)	Number (#)	Pct. (%)
Stefan Yee	-	-	100,000	15.76%
Leon Van Rompay	-	-	-	-
Marc Foidart	-	-	-	-
Carolyn Myers	-	-	-	-
James Gale	-	-	-	-
Chris Buyse	-	-	-	-
TOTAL	**-**	**-**	**100,000**	**15.76%**

22. EVENTS AFTER THE END OF THE REPORTING PERIOD

None.

Statutory auditor's report to the board of directors of Hyloris Pharmaceuticals SA on the review of the condensed consolidated interim financial information as at 30 June 2023 and for the 6-month period then ended

Introduction

We have reviewed the accompanying condensed consolidated statement of financial position of Hyloris Pharmaceuticals SA as at 30 June 2023, the condensed consolidated statements of profit or loss and other comprehensive income, changes in equity and cash flows for the 6-month period then ended, and notes to the interim financial information ("the condensed consolidated interim financial information"). The board of directors is responsible for the preparation and presentation of this condensed consolidated interim financial information in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union. Our responsibility is to express a conclusion on this condensed consolidated interim financial information based on our review.

Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the accompanying condensed consolidated interim financial information as at 30 June 2023 and for the 6-month period then ended is not prepared, in all material respects, in accordance with IAS 34, "Interim Financial Reporting" as adopted by the European Union.

Zaventem, September 6, 2023

KPMG Bedrijfsrevisoren - Réviseurs d'Entreprises
Statutory Auditor
represented by

Olivier Declercq
Bedrijfsrevisor / Réviseur d'Entreprises

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