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PRESS RELEASE

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Oxurion NV Business Update - H1 2020

Progressing Clinical Development of Next Generation Diabetic Macular Edema (DME) Therapies – Beyond anti-VEGF

Positive data from Phase 1 study evaluating THR-687, a pan-RGD integrin antagonist, for the treatment of DME

First Patient dosed in Phase 2 ('KALAHARI') study evaluating THR-149, a potent plasma kallikrein inhibitor, for the treatment of DME

Total Cash & Investments at €37.9 million as of June 30, 2020

Highlights

- Focused on developing a diabetic macular edema (DME) franchise based on novel therapeutics with the potential to improve vision for all DME patients
- DME franchise based on two innovative drug candidates, THR-149 and THR-687 with different and complementary, non-VEGF modes of action
- First patient dosed in Phase 2 ('KALAHARI') study evaluating multiple injections of THR-149, a potent plasma kallikrein inhibitor, for the treatment of DME in September
- Positive data from Phase 1 study evaluating THR-687, a pan-RGD integrin antagonist, for the treatment of DME was announced in January
- Preparations for Phase 2 study with THR-687 in DME are progressing as planned. Study expected to start by mid-2021
- In August, Oxurion appointed Grace Chang, M.D., Ph.D. as Chief Medical Officer to lead the company's clinical programs for THR-149 and THR-687

Financial

- At the end of June 2020, Oxurion had cash, cash equivalents & investments of €37.9 million. This compares to €52.9 million at the end of December 2019.

Conference call scheduled on September 17 at 6.30 pm CET (details at the end of the release)

Leuven, Belgium, September 17, 2020 – 17.45 PM CET – Oxurion NV (Euronext Brussels: OXUR), a biopharmaceutical company developing next generation standard-of-care ophthalmic therapies, with a focus on diabetic macular edema (DME), today issues its business and financial update for the sixth-month period ending June 30, 2020.

Oxurion is focused on developing an industry leading DME franchise based on novel therapies designed to potentially provide improved visual outcomes for all DME patients.

The Company is progressing its pipeline of innovative clinical drug candidates for treating DME. DME is a significant global healthcare problem and the major cause of vision loss in diabetic patients worldwide.

Oxurion's clinical development pipeline consists of two novel products with different and complimentary, non-VEGF, modes of action:

- **THR-149** is a potent plasma kallikrein inhibitor with the potential to become the treatment of choice for DME patients who respond sub-optimally to anti-VEGF therapy.
- **THR-687** is a best in class small molecule pan-RGD integrin antagonist being developed to treat DME with the possibility to become the standard of care for all treatment-naïve DME patients.

Patrik De Haes, M.D., CEO of Oxurion, said:

"We have made significant progress in developing our DME franchise in the first half of 2020. Following the positive Phase 1 results for THR-149 in 2019, in January we announced positive and highly promising Phase 1 results with THR-687 showing that this novel pan-RGD integrin antagonist has the potential to deliver improved visual outcomes to a broad population of DME patients when compared to anti-VEGFs, the current standard of care.

We have recently started our Phase 2 study of THR-149 in patients with DME. This two-part study will first select the optimal dose of THR-149 and will then compare it with aflibercept in terms of improvements in best corrected visual acuity. This Phase 2 data is designed to support our plans to position THR-149 as the treatment of choice for the large number of DME patients who have a sub-optimal response to anti-VEGF therapy.

By successfully developing THR-149 and THR-687, two novel and complimentary drug candidates that could offer improved therapeutic options beyond anti-VGEFs, we believe we are positioned to build an industry leading DME franchise. We are confident that creating this franchise will deliver significant benefits to nearly all DME patients globally and will, in parallel, generate attractive returns for our shareholders."

Diabetic Macular Edema – Oxurion's key focus

Diabetic macular edema (DME) is a complication of diabetes caused by fluid accumulation in the macula (central part of the retina), due to leaking blood vessels, leading to swelling of the macular area due to the increased permeability of the vessels.

DME is a result of another complication of diabetes, called diabetic retinopathy (DR), in which blood vessels in the eye are damaged, allowing fluid to escape. DR is the presence and characteristic evolution of typical retinal microvascular lesions in an individual with diabetes. DR is a chronic, progressive, sight-threatening, and life-altering disease, and is the leading cause of vision loss in working-age adults (20-65 years).

DME, which is a consequence of DR, can occur at any stage in the development of DR. More than one in three people living with diabetes will develop some form of DR in their lifetime, and a third of those will have some vision-threatening form of the disease such as DME.

DR and DME are a growing public health concern due to the rapid growth in the number of people with diabetes globally.

An estimated 37.8 million people have been diagnosed with diabetes in the United States (US), European top five countries (EU5) (France, Germany, Italy, Spain, and the United Kingdom), and Japan. If the undiagnosed population is included, the estimated number of people with diabetes in these countries increases to 61.3 million people.

The prevalence of DME was estimated to be 2.8 million people in the US, EU5 and Japan in 2019. The market value for DME treatments in these markets was estimated to be between approximately $3.4 to $3.8 billion in 2019.

The market for DME therapies is dominated by anti-VEGFs, which are the current standard of care. However, anti-VEGFs have been shown to deliver sub-optimal results in a significant portion of the patient population. Around 40% of DME patients have an unsatisfactory early visual response with anti-VEGF therapy, and in many cases anti-VEGFs fail to achieve a clinically meaningful visual improvement.

Oxurion is focused on solving these unmet medical needs in DME.

Oxurion's Emerging DME Franchise

In general, treatment of DME is centered around anti-VEGF therapies. However, despite the significant success of anti-VEGFs, there will always be a need from both physicians and patients for improved therapies that have:

- Treatment capabilities for the 40% of DME patients who respond sub-optimally to anti-VGEFs
- Faster onset of action
- Better therapeutic effect in terms of visual function, best corrected visual acuity (BCVA), and response rate (proportion of patients)
- Longer duration of response allowing extended treatment intervals
- Improved convenience of treatment through a simpler dosing regimen

Those requirements are driving the development of THR-149 and THR-687 to meet specific unmet needs in the market so that both novel compounds could become the new standard of care for patients with DME.

Oxurion's emerging DME franchise will be based on the successful development of both THR-149 and THR-687, two novel therapeutics with different modes of action designed for specific complementary target patient groups. Oxurion is confident that with both THR-149 and THR-687 it will be able to provide new tailored therapeutic solutions that deliver improved clinical outcomes to most DME patients.

Oxurion's DME Pipeline

THR-149 – a plasma kallikrein inhibitor for treatment of DME

First patient treated in Phase 2 study evaluating THR-149 for treatment of DME.

THR-149 is a novel plasma kallikrein inhibitor being developed as a potential new standard of care for the 40% of DME patients who respond sub-optimally to anti-VEGF therapy.

THR-149 acts through inhibition of the Plasma Kallikrein-Kinin (PKaI-Kinin) system, a validated target for DME.

The Phase 1 study for THR-149 showed that it:

- is well-tolerated and safe. No dose-limiting toxicities nor drug-related serious adverse events were reported at any of the dosages evaluated in the study.

- delivered promising results in relation to efficacy, particularly improvements in the patient's BCVA. A rapid onset of action was observed from Day 1, with an increasing average improvement in BCVA of up to 7.5 letters at Day 14.

  Importantly, this activity was maintained with an average improvement in BCVA of 6.5 letters at Day 90 following a single injection of THR-149.

Data from this positive Phase 1 study with THR-149 was presented at several major retina conferences in Europe and the US in 2019, including the European Society of Retina Specialists (EURETINA) in Paris and the Retina Society Annual Meeting in London.

THR-149 is currently in a 2-part Phase 2 development program ('KALAHARI' study). The first part (Part A) will evaluate 3 dose levels of THR-149 in patients with DME to select the optimal dose which will then be compared against current anti-VEGF standard of care in the form of aflibercept (Eylea) in the second part of the study (Part B). Initial data (from Part A) is expected in mid-2021.

This novel drug candidate was generated using Bicycle Therapeutics' Bicycles® technology platform.

THR-687 - a small molecule pan-RGD integrin antagonist for the treatment of DME

Positive Phase 1 Results with THR-687 for the treatment of DME – Phase 2 program expected to start in mid-2021

Oxurion is developing THR-687, a best-in-class pan-RGD integrin antagonist, to preserve vision in a broad range of patients with DME.

Topline data from the Phase 1 trial showed that THR-687:

- Is well-tolerated and safe with no dose-limiting toxicities. No serious adverse events were reported at any of the doses evaluated in the study.
- The study also looked at efficacy including changes to the patient's BCVA. Across all doses, a rapid onset of action as measured by mean BCVA change was observed from Day 1 with an increase of 3.1 letters, which further improved to 9.2 letters at Month 1.
- This activity was maintained with a mean BCVA improvement of 8.3 letters at Month 3 following a single injection of THR-687.
- A clear dose response was seen in terms of BCVA with the highest dose of THR-687 delivering a mean BCVA Improvement of 11 letters at Day 14, with a peak improvement of 12.5 letters at Month 3.
- In addition, a peak mean central subfield thickness (CST) decrease of 106 µm was observed at Day 14 with the highest dose of THR-687.

Data from this positive Phase 1 study with THR-687 were presented by a leading retina expert at the Bascom Palmer Eye Institute Angiogenesis, Exudation, and Degeneration 2020 Meeting in February 2020 in Miami (US).

Oxurion is preparing a Phase 2 study with THR-687 that is expected to start in mid-2021.

Appointments

In August, Oxurion appointed Grace Chang, M.D., Ph.D. as its Chief Medical Officer (effective August 1, 2020). She will be responsible for leading the Company's clinical programs for both THR-687 and THR-149 as Oxurion looks to build a world-leading DME franchise that could provide much improved therapeutic solutions for all DME patients.

Dr Chang is a board-certified ophthalmologist and practicing vitreoretinal surgeon with deep expertise in ophthalmic drug research and development.

Dr Chang is currently an adjunct Clinical Associate Professor in the Department of Ophthalmology, Vitreoretinal Service at the University of Southern California in Los Angeles.

In March, Oxurion also appointed Kathleen Paisley as Chief Legal Officer and Michaël Dillen as Chief Corporate Development and Corporate Secretary.

Kathleen is an accomplished lawyer with more than 25 years' experience in major law firms practicing in Brussels, London and The Hague. She joins Oxurion from AMBOS NBGO where she was a Partner for nearly ten years. Kathleen has extensive experience with International business transactions, especially in the biotech and tech sector, regulatory compliance and EU competition law.

Kathleen has a degree from the Yale Law School as well as an MBA in Finance from Florida Atlantic University and has passed the Certified Public Accountancy exam.

Michaël was the Company Secretary and VP Corporate Development at Mithra Pharmaceuticals SA prior to joining Oxurion. He has 14 years of legal experience, including corporate development, corporate counsel, legal, regulatory, and company secretary activities, for pharmaceutical companies as well as at leading law firms. Previously, he was Chief Legal Officer at Terumo Corp.

Michaël received Law degrees from the University of Antwerp and Queen Mary University of London, and a Business degree from Solvay Brussels School.

JETREA® Marketing Authorization Being Transitioned to Inceptua Group

In March, Oxurion announced the signing of a JETREA® global commercial license agreement with Inceptua Group**.**

The Inceptua Group is a global pharmaceutical company and service partner spanning the product lifecycle – from clinical trials, through early access programs to licensing and commercialization of products. The Group has offices in Europe, the US and Asia.

On September 15, the Company received the final approval by the European Commission for the official transfer of the Marketing Authorization for JETREA® to Inceptua Group. This means that JETREA® is now being commercialized solely by Inceptua on a world-wide basis. This will allow Oxurion to fully focus on further developing its DME franchise.

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Pre-clinical and clinical activities are progressing as planned

Financial Update

During the first six months of 2020, Oxurion reported a gross profit of €0.9 million, compared to a gross profit of €0.6 million for the same period in 2019.

Oxurion's R&D expenses were €10 million during the first half year of 2020. In the same period of 2019, the R&D expenses were €12 million.

The incremental investments related to the start of the Phase 2 clinical study evaluating THR-149 and the work needed to prepare for the Phase 2 clinical study with THR-687 were largely offset by a €3.6 million decline in costs due to the halting of all THR-317 clinical developments, and an overall reduction of activities related to JETREA®.

Selling and marketing expenses amounted to €1.8 million compared to €3.4 million in the corresponding period of 2019. The decrease is directly related to the discontinuation of commercial support for JETREA®.

General and administrative expenses were €2.7 million. This compares to €3.3 million in the first half of 2019.

For the first half of 2020, Oxurion reported a net loss of €13.3 million (or -€0.35 per share), compared to a net loss of €33.3 million for the same period in 2019. The 2019 figure included the write-off of the €16.9 million remaining JETREA® intangible assets as well as an operating/current loss of €16.4 million.

As of June 30, 2020, Oxurion had €37.9 million in cash, cash equivalents and investments. This compared to €52.9 million as of the end of December 2019.

Conference call in English is scheduled on September 17, 2020, at 6:30 p.m. CET / 5.30 p.m BST

Webcast link to conference call:
https://www.investis-live.com/oxurion/5f5a449faf34541200228273/teys

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A replay of the call will be available on Oxurion's website (www.oxurion.com) following the live event.

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About Oxurion

Oxurion (Euronext Brussels: OXUR) is a biopharmaceutical company developing next generation standard of care ophthalmic therapies, which are designed to better preserve vision in patients with diabetic macular edema (DME), the leading cause of vision loss in diabetic patients worldwide.

Oxurion is building a leading global franchise in the treatment of DME, based on the successful development of its two novel therapeutics:

- THR-149, a plasma kallikrein inhibitor being developed as a potential new standard of care for DME patients who respond sub-optimally to anti-VEGF therapy.
  THR-149 has shown positive topline Phase 1 results for the treatment of DME. The Company is currently conducting a Phase 2 clinical trial evaluating THR-149 with DME-patients who previously responded sub-optimally to anti-VEGF therapy.
  THR-149 was developed in conjunction with Bicycle Therapeutics PLC (NASDAQ: BCYC)
- THR-687, is a pan-RGD integrin inhibitor, that is initially being developed as a potential new standard of care for all DME patients Positive topline results in a Phase 1 clinical study assessing it as a treatment for DME were announced in January 2020. THR-687 is expected to enter a Phase 2 clinical trial by mid 2021.
  THR-687 is an optimized compound derived from a broader library of integrin inhibitors in-licensed from Galapagos NV (Euronext & NASDAQ: GLPG).

Oxurion is headquartered in Leuven, Belgium, and is listed on the Euronext Brussels exchange under the symbol OXUR.

More information is available at www.oxurion.com.

Important information about forward-looking statements
Certain statements in this press release may be considered "forward-looking". Such forward-looking statements are based on current expectations, and, accordingly, entail and are influenced by various risks and uncertainties. The Company therefore cannot provide any assurance that such forward-looking statements will materialize and does not assume an obligation to update or revise any forward-looking statement, whether as a result of new information, future events or any other reason. Additional information concerning risks and uncertainties affecting the business and other factors that could cause actual results to differ materially from any forward-looking statement is contained in the Company's Annual Report. This press release does not constitute an offer or invitation for the sale or purchase of securities or assets of Oxurion in any jurisdiction. No securities of Oxurion may be offered or sold within the United States without registration under the U.S. Securities Act of 1933, as amended, or in compliance with an exemption therefrom, and in accordance with any applicable U.S. state securities laws.

Unaudited consolidated statement of profit and loss

In '000 euro (for the period ended on June 30)	**2020**	**2019**
Income	**1,259**	**1,807**
Sales	1,249	1,804
Income from royalties	10	3
Cost of sales	**-315**	**-1,224**
Gross profit	**944**	**583**
Research and development expenses	-9,005	-12,040
General and administrative expenses	-2,745	-3,329
Selling expenses	-1,774	-3,408
Other operating income	250	1,720
Impairment losses	0	-16,891
Operating result	**-13,230**	**-33,365**
Finance income	50	236
Finance expense	-139	-175
Result before income tax	**-13,319**	**-33,304**
Taxes	0	-7
Loss for the period	**-13,319**	**-33,311**
Attributable to:		
Equity holders of the company	-13,139	-33,317
Non-controlling interest	-180	6
Result per share		
Basic earnings/(loss) per share (euro)	-0.35	-0.87
Diluted earnings/(loss) per share (euro)	-0.35	-0.87

Unaudited consolidated statements of other comprehensive income

In '000 euro (for the period ended on June 30)	**2020**	**2019**
Loss for the period	**-13,319**	**-33,311**
Exchange differences on translation of foreign operations	48	29
Other comprehensive income, net of income tax	**48**	**29**
Other comprehensive income that will not be reclassified to profit or loss	48	29
Total comprehensive income for the period	**-13,271**	**-33,282**
Attributable to:		
Equity holders of the company	**-13,091**	**-33,288**
Non-controlling interest	**-180**	**6**

Unaudited consolidated statement of financial position

In '000 euro (as at)	**30-Jun-20**	**31-Dec-19**
ASSETS		
Property, plant and equipment	299	340
Right-of-use assets	1,783	2,212
Intangible assets	2,252	1,982
Other non-current assets	96	96
Non-current tax credit	3,602	3,385
Non-current assets	**8,032**	**8,015**
Inventories	20	20
Trade and other receivables	2,354	3,592
Current tax receivables	274	467
Investments	10,349	10,444
Cash and cash equivalents	27,509	42,492
Current assets	**40,506**	**57,015**
Total assets	**48,538**	**65,030**
EQUITY AND LIABILITIES		
Share capital	100,644	100,644
Share premium	0	0
Cumulative translation differences	-567	-615
Other reserves	-11,873	-12,122
Retained earnings	-47,886	-34,747
Equity attributable to equity holders of the company	**40,318**	**53,160**
Non-controlling interest	-34	146
Total equity	**40,284**	**53,306**
Lease liabilities	926	1,335
Non-current liabilities	**926**	**1,335**
Trade payables	2,581	4,725
Lease liabilities	883	898
Other short-term liabilities	3,864	4,766
Current liabilities	**7,328**	**10,389**
Total equity and liabilities	**48,538**	**65,030**

Unaudited consolidated statement of cash flows

In '000 euro (for the period ended on June 30)	**2020**	**2019**
Cash flows from operating activities		
Loss for the period	-13,319	-33,311
Finance expense	139	175
Finance income	-50	-236
Depreciation of property, plant and equipment	585	600
Amortization and impairment of intangible assets	0	18,468
Equity settled share-based payment transactions	249	257
Decrease in trade and other receivables including tax receivables and inventories	1,214	1,036
Decrease in short-term liabilities	-3,061	-4,140
Net cash flows used (-)/ generated in operating activities	***-14,243***	***-17,151***
Cash flows from investing activities		
Disposal of property, plant and equipment (following a sale)	22	14
Decrease / increase (-) in investments	95	0
Interest received and similar income	0	44
Purchase of property, plant and equipment	-92	-73
Net cash flows used (-) / generated in investing activities	***-245***	***-15***
Cash flows from financing activities		
Principal paid on lease liabilities	-454	-407
Interest paid on lease liabilities	-9	-13
Paid interests	-5	-4
Net cash flows used (-) / generated in financing activities	***-468***	***-424***
Net change in cash and cash equivalents	**-14,956**	**-17,590**
Net cash and cash equivalents at the beginning of the period	42,492	64,652
Effect of exchange rate fluctuations	-27	63
Net cash and cash equivalents at the end of the period	**27,509**	**47,125**

Unaudited consolidated statement of changes in equity

	Share capital	Share premium	Cumulative translation differences	Other reserves	Retained earnings	Attributable to equity holders of the company	Non-controlling interest	Total
As at January 1, 2019	**137,564**	**13**	**-273**	**-12,563**	**-19,853**	**104,888**	**422**	**105,310**
Loss for the period 2019	0	0	0	0	-33,317	**-33,317**	6	**-33,311**
Change to foreign currency translation difference and revaluation reserve	0	0	29	0	0	**29**	0	**29**
Share-based payment transactions	0	0	0	256	0	**256**	**0**	**256**
As at June 30, 2019	**137,564**	**13**	**-244**	**-12,307**	**-53,170**	**71,856**	**428**	**72,284**

As at January 1, 2020	**100,644**	**0**	**-615**	**-12,122**	**-34,747**	**53,160**	**146**	**53,306**
Loss for the period 2020		0	0	0	-13,139	**-13,139**	-180	**-13,319**
Change to foreign currency translation difference and revaluation reserve		0	48	0	0	**48**	0	**48**
Share-based payment transactions		0	0	249	0	**249**	0	**249**
As at June 30, 2020	**100,644**	**0**	**-567**	**-11,873**	**-47,886**	**40,318**	**-34**	**40,284**