

## Oxurion NV announces 2021 Full Year Results and 2022 Outlook

- **THR-149** – Positive results from Part A of the Phase 2 clinical trial assessing THR-149 for the treatment of Diabetic Macular Edema (DME) (“KALAHARI”), and first patient dosed in Part B evaluating THR-149 versus aflibercept for the second line treatment of DME for the 40-50% of patients that suboptimally respond to standard of care anti-VEGF therapy.
- **THR-687** – First patient dosed in Part A of Phase 2 clinical trial evaluating THR-687 for the treatment of DME in treatment naïve subjects (“INTEGRAL”), and enrollment completed post-closing.
- **Financing** – Capital commitment entered into with Negma Group (Negma) pursuant to which Negma has committed to subscribe to up to EUR 30 million in mandatory convertible bonds to be issued in tranches and subject to certain conditions, and EUR 10 million convertible bond financing secured from Kreos Capital and Pontifax Ventures.
- **Cash position** – Available cash of EUR 10 million (including investments) at the end of December 2021.

**Leuven, BE, Boston, MA, US – February 22, 2022 – 08.00**

**AM CET** – [Oxurion NV](#) (Euronext Brussels: OXUR) (the “**Company**” or “**Oxurion**”), a biopharmaceutical company developing next generation standard of care ophthalmic therapies, with a clinical stage portfolio in vascular retinal

disorders today announces its unaudited full year results for the twelve-month period ending December 31, 2021, and provides an operational update and an outlook for the remainder of 2022.

The Company has two novel therapeutics in clinical development. THR-149 is a potent plasma kallikrein inhibitor being developed as a potential new standard of care for the 40-50% of DME patients showing suboptimal response to anti-VEGF therapy. THR-687 is a highly selective pan-RGD integrin antagonist that is being developed as a potential first line therapy for DME patients as well as potentially wet age-related macular degeneration (wet AMD) and macular edema following retinal vein occlusion (ME-RVO).

**Tom Graney, CFA, CEO of Oxurion, commented:**

*“During*

*2021, Oxurion made excellent progress by focusing our resources on the clinical development of THR-149 and THR-687, which if successfully developed together would serve a market exceeding USD 12 billion. In addition, we secured sources of capital to enable us to further invest behind both of our exciting programs.*

*Earlier this month*

*we were pleased to report positive results from Part A of our Phase 2 trial of THR-149 in patients with DME. The Part A results included post-hoc analysis by a masked reading center revealing that by excluding two patients with certain abnormalities at baseline, a >9 letter gain in mean BCVA was achieved during Part A. This >9 letter gain was maintained for the remaining four months of the trial after the last THR-149 injection with no rescue treatment required. As a result, patients with these abnormalities will be excluded from Part B of the trial, which compares THR-*

149 to current standard of care aflibercept for the 40-50% of patients that suboptimally respond to anti-VEGF therapy and currently have limited treatment options. Part B of the KALAHARI trial is recruiting with these protocol amendments in place with topline data expected mid-2023.

We are also delighted that Part A of our Phase 2 DME trial of THR-687 is fully enrolled with results expected in the second quarter of this year. THR-687 has the potential to become a first line treatment for DME, and we are also planning to develop THR-687 for wet AMD and potentially ME-RVO assuming Part A of the DME trial is successful.

We look forward to reporting on our progress as we continue to deliver further value inflection points for both THR-149 and THR-687, including very important THR-687 Part A data in the near future.”

## 2021 Highlights

### Operational

- [Positive results from Part A of Phase 2 KALAHARI trial](#) evaluating THR-149 for treatment of DME. THR-149 acts through inhibition of the plasma kallikrein-kinin (PKal-Kinin) system, a validated VEGF-independent target for DME treatment. Three IVT injections of THR-149 (0.13mg) delivered a clinically meaningful improvement in Best Corrected Visual Acuity (BCVA), the primary endpoint for registration in DME, and also stabilized Central Subfield Thickness (CST), a promising result in a population which, if left untreated, CST would be expected to deteriorate. Based on these data, Oxurion decided to move THR-149 (0.13mg) into Part B of the trial. Further characterization of the BCVA data was shared at the [American Society for Retinal Specialists \(ASRS\)](#) Annual Scientific Meeting.
- [First patient dosed in Part B of Phase 2 KALAHARI trial](#) evaluating multiple administrations of THR-149 versus aflibercept for treatment of DME. The primary objective of Part B of the trial is to assess the difference in treatment effect between THR-149 (0.13mg) and aflibercept from baseline to Month 3, in terms of increase in BCVA, the primary endpoint, in the 40-50% of patients that suboptimally respond to standard of care anti-VEGF therapy.
- [Institutional Review Board \(IRB\) approval](#) received to initiate a Phase 2 clinical trial of THR-687 in patients with DME. Together with its earlier submission to the U.S. Food and Drug Administration (FDA) of the final protocol to the Investigational New Drug (IND) application, the approval was an important step forward for the Phase 2 INTEGRAL trial.
- [The first patient has been dosed](#) in Oxurion’s Phase 2 INTEGRAL trial evaluating THR-687 in patients with DME. Enrollment was completed post-closing.
- The [Journal of Pharmacokinetics and Pharmacodynamics](#) published two papers describing the pharmacokinetic properties of THR-149 and THR-687 following intravitreal (IVT) injection in animals utilizing novel pharmacokinetic models developed by Oxurion.

- The '[Progress in Retinal and Eye Research](#)' journal published an article highlighting the cutting-edge science and rationale for the design and development of THR-687 and described the potential of pan-RGD integrin antagonists to improve the treatment of diabetic retinopathy and wet AMD.
- [Positive Phase 1 clinical data](#) evaluating THR-687 for treatment of DME were published in Ophthalmology Science, the American Academy of Ophthalmology Journal.
- Appointment of Tom Graney, CFA as Oxurion's Chief Executive Officer and Dr. [Patrik De Haes](#), M.D. as non-executive Chairman.
- Appointment of Hanne Callewaert as Chief Operating Officer and Professor Alan Stitt as Chief Scientific Officer.
- [Refined focus and resources](#) towards executing Oxurion's clinical development strategy, including advancing the THR-687 and THR-149 programs. The Company reduced its head count by approximately one-third and will no longer make direct investments in non-core activities, including research in dry AMD and oncology (Oncurious NV).

## Financial

- Entered into a [capital commitment with Negma](#) pursuant to which Negma has committed to subscribe to up to EUR 30 million in mandatory convertible bonds to be issued in tranches and subject to certain conditions.
- 1,210 convertible bonds issued to Negma (representing an aggregate amount of EUR 3,025,000) of which 540 convertible bonds were converted into 775,334 shares at the end of December 2021.
- [Secured a EUR 10 million convertible bond financing](#) from Kreos Capital and Pontifax Ventures.
- Cash position (including investments) of EUR 10 million at the end of December 2021.

## Post-closing events

- Announcement at the [Angiogenesis, Exudation, and Degeneration 2022 Conference](#) that post-hoc analysis by the masked reading center from Part A of the KALAHARI trial revealed that by excluding two patients with certain abnormalities at baseline from Part A, a >9 letter gain in mean BCVA was achieved and maintained for the remaining four months of the trial after the last THR-149 injection with no rescue treatment required.
- Protocol amendment approved to reflect the post-hoc analysis of the Part A data by excluding patients with these abnormalities at baseline from Part B of the KALAHARI trial.
- Enrollment completed in Part A of the INTEGRAL trial for THR-687.

## 2022 outlook

- **THR-149.** Part B of the KALAHARI trial is ongoing, assessing three monthly injections of THR-149, compared to three monthly injections of aflibercept, up to Month 3. As from Month 3, the safety and efficacy of a switched fourth injection (THR-149 to aflibercept or aflibercept to THR-149) will be evaluated in about half of the subjects whereas in the other half of the subjects the durability of three monthly injections (THR-149 or aflibercept) will be assessed through a single sham injection until Month 6. Enrollment of approximately 108 patients in Part B in over 50 sites in several European countries and the U.S. will continue during 2022, with topline results expected in mid-2023.
- **THR-687.** Topline data is expected from Part A of the INTEGRAL trial in the second quarter of this year. Assuming Part A is successful, the Company plans to immediately start Part B of the INTEGRAL trial with topline data expected in the second half of 2023. The Company is also planning to start an additional Phase 2 trial of THR-687 in wet AMD during 2022 if Part A is successful.

### **Details 2021 Full Year Financial Results (unaudited)**

Total income amounted to EUR 1.1 million in 2021, compared to EUR 2.1 million in 2020.

Gross profit of EUR 0.5 million in 2021, compared to EUR 1.5 million in 2020.

R&D expenses in 2021 were EUR 20.7 million compared to EUR 22.1 million in 2020. R&D expenses were mainly related to clinical activities in THR-687 and THR-149. The 2020 figure included a milestone payment of EUR 2.0 million related to the development of THR-149. Government grants and income from recharge of costs are deducted from the research and development expenses.

Selling and marketing expenses of EUR 1.3 million in 2021, compared to EUR 3.3 million in 2020.

General and administrative expenses of EUR 7.2 million in 2021, compared to EUR 5.5 million in 2020.

In 2021, Oxurion made a loss for the year of EUR 29.6 million, compared to a loss for the year in 2020 of EUR 28.6 million resulting in negative diluted earnings per share of EUR 0.77 in 2021 versus EUR 0.75 in 2020.

The financial results included in this press release were prepared on the basis of continuation. On December 31, 2021, the Company had cash and cash equivalents of EUR 10 million (including investments), compared with EUR 24.8 million (including investments) at December 31, 2020. In addition to available cash, the Company expects to meet its working capital requirements through a combination of debt and equity, including drawing future tranches from the Negma funding program described above, accessing the debt markets through Kreos/Pontifax and/or other debt providers, raising additional equity capital, and/or attracting potential non-dilutive funding, all of which is uncertain. Under the funding program with Negma described above, the Company will have access to up to EUR 27.5 million in the twelve-month period starting from this press release provided the Company can and does draw the maximum tranche on a monthly basis, which is subject to certain conditions that may not be met.

Considering the current available cash position, the budgets for 2022 and 2023, the funding possibilities potentially available to the Company from Negma and others, and the possibility the Company has to reduce its working capital requirements if necessary, the board of directors considers that it is appropriate for the Company to continue to account on the basis of continuation based on the information available on the date of this press release.

When approving the Company's 2020 annual report and its 2021 HY report, the board of directors considered that there was a material uncertainty with respect to the Company's ability to continue as a going concern. In the opinion of the board of directors, there continues to be a material uncertainty with respect to the Company's ability to continue as a going concern on the date of this press release. A more complete description of the Company's risks can be found in the latest PDF-version of the Company's presentation, which can be found [here](#).

The financial results contained in this press release are unaudited. Audited financial results and the 2021 annual report for the period ending December 31, 2021, will be published on the Company's website by March 25, 2022.

### **Unaudited consolidated statement of profit and loss**

In '000 euro (for the year ended 31 December)	2021	2020
<b>Income</b>	<b>1.128</b>	<b>2.078</b>
Sales	967	2.000
Income from royalties	161	78
<b>Cost of sales</b>	<b>-612</b>	<b>-550</b>
<b>Gross profit</b>	<b>516</b>	<b>1.528</b>
Research and development expenses	-20.696	-22.053
General and administrative expenses	-7.150	-5.489
Selling expenses	-1.274	-3.252
Other operating income	1.245	777
Other operating expense	-9	-6
Impairment losses	-1.127	-125
<b>Operating result</b>	<b>-28.495</b>	<b>-28.620</b>
Finance income	171	468
Finance expense	-1.268	-408
<b>Result before income tax</b>	<b>-29.592</b>	<b>-28.560</b>
Taxes	-3	0
<b>Result of the year</b>	<b>-29.595</b>	<b>-28.560</b>
Attributable to:		
Equity holders of the company	-29.158	-28.012
Non-controlling interest	-437	-548
<b>Result per share</b>		
Basic earnings / loss (-) per share (euro)	-0,77	-0,75
Diluted earnings / loss (-) per share (euro)	-0,77	-0,75

In '000 euro (as at 31 December)	2021	2020
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<b>Result of the year</b>	<b>-29.595</b>	<b>-28.560</b>
<b>Other comprehensive income:</b>		
Remeasurement of defined benefit pension schemes	566	-297
Fair value gain/(loss) on investments designated as at FVTOCI	-5	0
<i>Other comprehensive income that will not be reclassified to profit or loss</i>	561	-297
Exchange differences arising on translation of foreign operations	122	-127
<i>Other comprehensive income that will or may be reclassified to profit or loss</i>	122	-127
<b>Other comprehensive income, net of income tax</b>	<b>683</b>	<b>-424</b>
<b>Total comprehensive loss (-) / income for the year</b>	<b>-28.912</b>	<b>-28.984</b>
Attributable to:		
Equity holders of the company	<b>-28.475</b>	<b>-28.436</b>
Non-controlling interest	<b>-437</b>	<b>-548</b>

### **Unaudited consolidated statement of financial position**

In '000 euro (as at 31 December)	2021	2020
<b>ASSETS</b>		
Property, plant and equipment	120	230
Right-of-use assets	252	1.069
Intangible assets	1.000	2.127
Other non-current assets	95	96
Non-current tax credit	4.000	3.708
<b>Non-current assets</b>	<b>5.467</b>	<b>7.230</b>
Inventories	60	85
Trade and other receivables	2.517	1.451
Current tax receivables	845	719
Investments	247	288
Cash and cash equivalents	9.740	24.511
<b>Current assets</b>	<b>13.409</b>	<b>27.054</b>
<b>Total assets</b>	<b>18.876</b>	<b>34.284</b>
<b>EQUITY AND LIABILITIES</b>		
Share capital	46.029	44.913
Share premium	234	0
Other comprehensive income	-356	-1.039
Other reserves	-5.266	-6.133
Retained earnings	-41.719	-12.561
<b>Equity attributable to equity holders of the company</b>	<b>-1.078</b>	<b>25.180</b>
<b>Non-controlling interest</b>	<b>-30</b>	<b>-132</b>
<b>Total equity</b>	<b>-1.108</b>	<b>25.048</b>
Lease liabilities	44	447
Employee benefit liabilities	594	1.096
Convertible loans	8.433	0
<b>Non-current liabilities</b>	<b>9.071</b>	<b>1.543</b>
Trade payables	4.979	4.377
Lease liabilities	221	649
Convertible loans	3.401	0
Other short-term liabilities	2.312	2.667
<b>Current liabilities</b>	<b>10.913</b>	<b>7.693</b>

Total equity and liabilities	18.876	34.284
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## Unaudited consolidated statement of cash flows

In '000 euro (for the year ended 31 December)	2021	2020
<b>Cash flows from operating activities</b>		
Loss for the period	-29.595	-28.560
Finance expense	896	408
Finance income	-171	-468
Depreciation of property, plant and equipment	77	194
Amortization and impairment of intangible assets	1.127	125
Amortization of right-of-use assets	600	916
Gain on sale of property, plant and equipment	-344	-7
Fair value adjustments of financial instruments	372	0
(Reversal of) impairment losses on current assets	629	801
Increase / Decrease (-) in provisions	64	0
Equity settled share-based payment transactions	1.107	458
Increase (-) / Decrease in trade and other receivables and inventories	-2.037	700
Increase / Decrease (-) in short-term liabilities	297	-1.646
<b>Net cash flows generated / used (-) in operating activities</b>	<b>-26.978</b>	<b>-27.079</b>
<b>Cash flows from investing activities</b>		
Disposal of property, plant and equipment (following a sale)	394	35
Decrease / Increase (-) in investments	36	10.154
Interest received and similar income	9	-6
Purchase of property, plant and equipment	-32	-119
<b>Net cash flows generated / used (-) in investing activities</b>	<b>407</b>	<b>10.064</b>
<b>Cash flows from financing activities</b>		
Principal paid on lease liabilities	-599	-903
Proceeds from loans and borrowings	11.150	0
Other financial income / expense (-)	-20	0
Interest paid on lease liabilities	-3	-16
Proceeds from capital increases in subsidiaries from non-controlling interest	86	0
Proceeds from capital and share premium increases, gross amount	1.350	0
Paid interests and other bank charges	-186	-12
<b>Net cash flows used (-) / generated in financing activities</b>	<b>11.778</b>	<b>-931</b>
<b>Net change in cash and cash equivalents</b>	<b>-14.793</b>	<b>-17.946</b>
Net cash and cash equivalents at the beginning of the period	24.511	42.492
Effect of exchange rate fluctuations	22	-35
<b>Net cash and cash equivalents at the end of the period</b>	<b>9.740</b>	<b>24.511</b>

## Unaudited consolidated statement of changes in equity

Share capital	Share premium	Other comprehensive income reserve	Other reserves	Retained earnings	Attributable to equity holders of the company	Non-controlling interest	Total
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<b>Balance as at 1 January 2020</b>	<b>100.644</b>	<b>0</b>	<b>-615</b>	<b>-12.122</b>	<b>-34.747</b>	<b>53.160</b>	<b>146</b>	<b>53.306</b>
<b>Total comprehensive income of the year</b>								
Result of the year	0	0	0	0	-28.012	-28.012	-548	-28.560
Change to foreign currency translation difference	0	0	-127	0	0	-127	0	-127
Remeasurement of DBO	0	0	-297	0	0	-297	0	-297
Net change in fair value of investments	0	0	0	-2	0	-2	0	-2
<b>Contributions by and distributions to owners</b>								
Issue of ordinary shares	0	0	0	0	0	0	270	270
Capital decrease	-55.731	0	0	5.533	50.198	0	0	0
Share-based payment transactions	0	0	0	458	0	458	0	458
<b>Balance as at 31 December 2020</b>	<b>44.913</b>	<b>0</b>	<b>-1.039</b>	<b>-6.133</b>	<b>-12.561</b>	<b>25.180</b>	<b>-132</b>	<b>25.048</b>

	Share capital	Share premium	Other comprehensive income reserve	Other reserves	Retained earnings	Attributable to equity holders of the company	Non-controlling interest	Total
<b>Balance as at 1 January 2021</b>	<b>44.913</b>	<b>0</b>	<b>-1.039</b>	<b>-6.133</b>	<b>-12.561</b>	<b>25.180</b>	<b>-132</b>	<b>25.048</b>
<b>Total comprehensive income of the year</b>								
Result of the year	0	0	0	0	-29.158	-29.158	-437	-29.595
Change to foreign currency translation difference	0	0	122	0	0	122	0	122
Remeasurement of DBO	0	0	566	0	0	566	0	566
Net change in fair value of investments	0	0	-5	0	0	-5	0	-5
<b>Total comprehensive income for the year</b>	<b>0</b>	<b>0</b>	<b>683</b>	<b>0</b>	<b>-29.158</b>	<b>-28.475</b>	<b>-437</b>	<b>-28.912</b>
<b>Contributions by and distributions to owners</b>								
Issue of ordinary shares	1.116	234	0	213	0	1.563	0	1.563
Share-based payment transactions	0	0	0	1.107	0	1.107	0	1.107
<b>Total contributions by and distributions to owners</b>	<b>1.116</b>	<b>234</b>	<b>0</b>	<b>1.320</b>	<b>0</b>	<b>2.670</b>	<b>0</b>	<b>2.670</b>
Transactions with non-controlling interests	0	0	0	-453	0	-453	539	86
<b>Balance as at 31 December 2021</b>	<b>46.029</b>	<b>234</b>	<b>-356</b>	<b>-5.266</b>	<b>-41.719</b>	<b>-1.078</b>	<b>-30</b>	<b>-1.108</b>

**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 retinal vascular disorders including diabetic macular edema (DME), the leading cause of vision loss in diabetic patients worldwide as well as other conditions, including wet age-related macular degeneration (wet AMD) and macular edema following retinal vein occlusion (ME-RVO).

Oxurion is aiming to build a leading global franchise in the treatment of retinal vascular disorders based on the successful development of its two novel therapeutics. THR-149 is a potent plasma kallikrein inhibitor being developed as a potential new standard of care for the 40-50% of DME patients showing suboptimal response to anti-VEGF therapy. THR-687 is a highly selective pan-RGD integrin antagonist that is being developed as a potential first line therapy for DME patients as well as wet AMD and potentially ME-RVO. Oxurion is headquartered in Leuven, Belgium, with corporate operations in Boston, MA. More information is available at [www.oxurion.com](http://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 any 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 and in the latest PDF-version of the Company’s presentation; which can be found [here](#). 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.*

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