

# Onxeo Reports its Half-Year 2022 Financial Results and Provides an Update on its Activities

- > Refocusing R&D efforts as well as accelerating preclinical and clinical programs globally
- Cash position of €26.9 million as of June 30, 2022
- > Financial visibility assured until Q2 2023

Paris (France), September 13, 2022 - 7:30 p.m. CEST - Onxeo S.A. (Euronext Growth Paris: ALONX, Nasdaq First North Copenhagen<sup>1</sup>: ONXEO), hereafter "Onxeo" or the "Company", a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage Response (DDR), today reports its consolidated half-year financial results to June 30, 2022 and provides an update on its activities.

Dr. Shefali Agarwal, President and CEO of Onxeo, said: "This first half of the year has been an opportunity for Onxeo to undergo profound transformations, both in its organization and governance, with the aim of refocusing our clinical research efforts and strengthening our presence globally. This new focus has been made possible due to the support of our long-term shareholders Invus and Financière de la Montagne, who participated in our latest capital increase, which secures our operations until the second quarter of 2023.

One of the important achievements of our thoughtful development plan was the very first approval by the Food and Drug Administration (FDA) of the initial Investigational New Drug (IND) application for AsiDNA, an encouraging progress since the formation of our U.S. team this April. We expect to initiate a clinical trial based on the safe to proceed letter from FDA in the second half of 2022 at multiple U.S. clinical sites.

We also continue our two Phase 1b/2 clinical trials, Revocan and the clinical trial targeting recurrent highgrade glioma in children, sponsored respectively by our partners Gustave Roussy and the Institut Curie.

Finally, we have continued our efforts to optimize our OX400 family of compounds and other preclinical assets, with the objective of entering clinical trials for a first drug candidate in 2023 and thereafter."

#### FINANCIAL RESULTS FOR THE FIRST HALF OF 2022

Consolidated income statement (IFRS) In thousands of euros	30/06/2022	30/06/2021
Revenues, of which:	0	589
Recurring revenues	0	0
Non-recurring revenues	0	589
Operating expenses, including:	(9,631)	(5,367)
R&D expenditure	(4,107)	(1,389)
Other current operating income	282	33
Current operating income	(9,348)	(4,745)
Other non-recurring operating income and expenses	385	198
Income from companies accounted for by the equity method		
Operating profit after share of profit of associates	(8,963)	(4,547)
Financial result	(2,448)	(238)

<sup>&</sup>lt;sup>1</sup> The company reminds shareholders that the delisting of Onxeo shares from the First North Growth market in Copenhagen has been approved and the last day of trading on this market will be November 8, 2022. The company will keep its primary listing on Euronext Growth Paris.



Income tax expense	(55)	15
Net income	(11,471)	(4,770)

The half-year accounts as of June 30, 2022, drawn up according to IFRS standards and approved by the Board of Directors on September 13,22, have not been audited.

The Group has not recorded any consolidated revenues for the period ended June 30, 2022.

Operating expenses amounted to €9.6 million. The increase compared to €5.4 million in 2021 is mainly due to the evolution of the Company's headcount in France and the United States and to the growth in R&D expenses. The latter increased by €1.4 million in the first half of 2022 to reach €4.1 million, mainly due to industrial development and manufacturing of clinical batches for AsiDNA. This increase was partially offset by a decrease in general and administrative expenses.

**Financial result** was a loss of €2.4 million and consisted mainly of the interest expense on the bond loan with SWK Holdings.

The Group's total **net loss** was thus €11.5 million in the first half of 2022, compared with a loss of €4.8 million for the same period in 2021.

#### **CASH POSITION AT JUNE 30, 2022**

At June 30, 2022, the Group's cash position was €26.9 million, compared to €17.9 million euros at December 31, 2021. This increase comes mainly from the issue of new shares (€8 million) and the convertible bond issue (€4 million), carried out during the first half of the year. These resources provide the Company with sufficient visibility to carry out its projects, including the expansion of the clinical development of AsiDNA and the continuation of the preclinical development of the OX400 compounds, until Q2 2023.

#### HIGHLIGHTS OF THE FIRST HALF OF 2022 AND RECENT DEVELOPMENTS

#### **AsiDNA**

- The Food and Drug Administration (FDA) approved the initial Investigational New Drug (IND) application for AsiDNA at the end of June, allowing Onxeo to initiate a multicenter Phase 1b/2 trial to evaluate the safety and efficacy of AsiDNA in combination with the PARP inhibitor Olaparib in patients with epithelial ovarian cancer, breast cancer and metastatic castration-resistant prostate cancer who have progressed despite initial treatment with PARP inhibitors. This is the first IND filed by Onxeo since the arrival of the U.S. team in April 2022. The Company plans to launch this clinical trial in the second half of 2022 at 3 to 5 potential clinical sites in the United States.
- Two trials conducted in collaboration with two academic research centers of excellence in oncology continued during the semester:
  - The phase 1b/2 Revocan trial evaluating the addition of AsiDNA to combat resistance to PARP inhibitors in the 2<sup>nd</sup> line maintenance treatment of recurrent ovarian cancer for which Gustave Roussy is the study sponsor. Due to a slower than expected patient recruitment rate, first results are now expected in the second half of 2022.
  - o The Phase 1b/2 trial evaluating AsiDNA in combination with radiotherapy in the treatment of recurrent high-grade glioma in children ("Children" study), an indication with a particularly poor prognosis. The Institut Curie is the sponsor of this study, which is being conducted by the European ITCC consortium², and is funded by the European Fight Kids Cancer program. Treatment of a first patient has been announced for August 2022.

<sup>&</sup>lt;sup>2</sup> The <u>Innovative Therapeutics for Children with Cancer Consortium</u> (ITCC) is a non-profit organization of 63 European pediatric oncology departments with expertise in conducting early phase trials in children and adolescents, and 25 European research laboratories.



- Onxeo presented innovative new data at the ESMO Targeted Anticancer Therapies 2022 Congress on March 7-8, 2022, confirming the relevance of combining AsiDNA™ with PARP inhibitors (PARPi) in the treatment of tumors with an active homologous recombination pathway to overcome intrinsic or acquired resistance in the clinical setting.
- The Company also presented new data at the American Association for Cancer Research (AACR) Annual Meeting, held on April 8-13, 2022, demonstrating AsiDNA's ability to overcome tumor resistance and protect against the toxicity of cancer treatments. Specifically, these data support AsiDNA's ability to overcome resistance to tyrosine kinase inhibitors in lung cancer models and to protect healthy cells when combined with conventional anti-tumor treatments.

#### OX400

 During the first half of 2022, Onxeo continued the optimization of OX401, the first compound of the OX400 family from its PlatON platform, to improve its action on the PARP protein, involved in tumor DNA repair pathways, and its activation of the anti-tumor immune response via the cGAS-STING pathway. The Group expects to select the optimized compound and enter preclinical development in 2022.

#### Governance

- On January 3, 2022, Onxeo announced the appointment of Julien Miara as interim Chief Executive Officer, replacing Judith Greciet. Mrs Greciet left the Company during the first half of 2022.
- On April 7, 2022, Dr. Shefali Agarwal succeeded Julien Miara and was appointed President and CEO of Onxeo.
- The Combined General Meeting of June 15, 2022 appointed Khalil Barrage, Managing Director at Invus, as a new director for three years. The shareholders also renewed the term of office of GammaX Corporate Advisory, represented by Jacques Mallet, for an additional 3-year term. Danielle Guyot-Caparros, whose third term of office expired at this General Meeting, did not wish to renew her mandate.

As a result of these changes, the Board of Directors has now eight members, out of which four are independent.

#### **Delisting from Copenhagen's First North Market**

- The Company has applied for and received, by letter dated August 29, approval from Nasdaq in Copenhagen for the Onxeo shares to be withdrawn from trading on the Nasdaq First North Growth market. In accordance with Nasdaq regulations, the Danish Onxeo shares will remain tradable on the Nasdaq First North Growth market, subject to the availability of counterparties, for a period until November 8, 2022. The company maintains its primary listing on Euronext Growth Paris.

#### **OUTLOOK**

The Company continues to pursue its strategy based on the development of its therapeutic innovations up to proof of concept in humans, with the following projected activities:

#### **AsiDNA**

- Initiation of patient enrolment in a U.S. Phase 1b/2 clinical trial;
- First results (part 1b) of the REVOCAN study expected from the study sponsor, Gustave Roussy;
- Continuation of the Children study (phase 1b/2) conducted by the European ITCC consortium, with the support of the Institut Curie.

#### OX400

- Optimization of the most promising OX400 compound;
- Preclinical proof of concept in vitro and in vivo in combination with immunotherapies;
- Development of the translational and regulatory plan for entry into the clinic in 2023.

#### platON



Continued evaluation and optimization of new compounds.

The 2022 half-year financial report is available on the Company's website.

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#### **About Onxeo**

Onxeo (Euronext Growth Paris, NASDAQ First North Growth Copenhagen: ONXEO) is a clinical-stage biotechnology company developing innovative oncology drugs targeting tumor DNA-binding functions through unique mechanisms of action in the sought-after field of DNA Damage Response (DDR). The Company is focused on bringing early-stage first-in-class or disruptive compounds from translational research to clinical proof-of-concept, a value-creating inflection point appealing to potential partners.

**platON** is Onxeo's proprietary chemistry platform of oligonucleotides acting as decoy agonists, which generates new innovative compounds and broaden the Company's product pipeline.

AsiDNA, the first compound from platON, is a highly differentiated, clinical-stage first-in-class candidate in the field of DNA damage response (DDR) applied to oncology. Its decoy and agonist mechanism acting upstream of multiple DDR pathways results in distinctive antitumor properties, including the ability to prevent or abrogate tumor resistance to targeted therapies such as PARP inhibitors and strong synergy with tumor DNA-damaging agents such as radio-chemotherapy. AsiDNA is currently being studied in Europe in combination with other treatment modalities in difficult-to-treat solid tumors.

**OX400** is a series of new drug candidates from platON, designed to be a next-generation PARP inhibitor acting on both the DNA Damage Response and the activation of immune response, without inducing resistance. The lead OX400 candidate is currently being optimized and is undergoing preclinical proof-of-concept studies, alone and in combination with immunotherapies.

For further information, please visit www.onxeo.com.

#### **Forward looking statements**

This communication expressly or implicitly contains certain forward-looking statements concerning Onxeo and its business. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Onxeo to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Onxeo is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise. For a discussion of risks and uncertainties which could cause actual results, financial condition, performance or achievements of Onxeo to differ from those contained in the forward-looking statements, please refer to the risk factors described in the most recent Company's registration document or in any other periodic financial report and in any other press release, which are available free of charge on the websites of the Company Group (www.onxeo.com) and/or the AMF (www.amf-france.org).

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### **APPENDIX**

## CONSOLIDATED FINANCIAL STATEMENTS AT JUNE 30, 2022

### CONSOLIDATED BALANCE SHEET

ASSETS (in thousands €)	June 30, 2022	December 31, 2021
No.		
Non-current assets		
Intangible assets	20,531	20,531
Property, plant and equipment	232	180
Rights of use	1,792	2,057
Other financial assets	160	162
Total non-current assets	22,715	22,930
Current assets		
Trade receivables and related accounts	4,109	8,526
Other current receivables	3,016	3,721
Cash and cash equivalents	26,861	17,887
Total current assets	33,986	30,133
TOTAL ASSETS	56,701	53,063

LIABILITIES AND SHAREHOLDERS' EQUITY (in thousands of €)	June 30, 2022	December 31, 2021
Shareholders' equity		
Capital	27,877	22,999
Less: Treasury shares	-144	-181
Additional paid-in capital	27,705	24,583
Retained earnings	-14,072	-8,522
Result	-11,471	-5,937
Total shareholders' equity	29,895	32,942
Non-current liabilities		
Non-current provisions	926	1,508
Deferred tax liability		204
Non-current financial debts	8,743	5,082
Non-current lease liabilities	1,192	1,428
Other non-current liabilities	4,122	4,835
Total non-current liabilities	14,983	13,057
Current liabilities		
Current provisions	247	
Short-term borrowings and financial liabilities	4,422	2,953
Current lease liabilities	470	471
Trade payables and related accounts	4,166	2,832
Other current liabilities	2,518	807
Total current liabilities	11,823	7,063
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	56,701	53,063



### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In thousands of €	June 30, 2022	June 30, 2021
December 11 and 12 and		
Recurring revenue from license agreements  Non-recurring revenue from license agreements		589
Total revenues	0	589
Purchases consumed	-242	-194
Personnel expenses	-4,258	-2,128
External expenses	-4,652	-2,298
Taxes	-25	-75
Net depreciation and provisions	-237	-421
Other current operating expenses	-217	-251
Operating expenses	-9,631	-5,367
Other current operating income	282	33
Recurring operating income	-9,348	-4,745
Other operating income	385	332
Other operating expenses	0	-134
Share of profit from equity affiliates		
Operating income after share of profit from equity affiliates	-8,963	-4,547
Cost of net financial debt	-2,154	-381
Other financial income	122	291
Other financial expenses	-416	-148
Financial income	-2,448	-238
Income before tax	-11,412	-4,785
Income tax expense - of which deferred tax	-59	15
Net income of all consolidated accounts	-11,471	-4,770
Earnings per share	-0.11	-0.06
Diluted earnings per share	-0.11	-0.06

In thousands of €	June 30, 2022	June 30, 2021
Earnings for the period	-11,471	-4,770
Translation differences	113	23
Other items that can be reclassified to profit or loss	113	23
Actuarial gains and losses	93	50
Other items that cannot be reclassified to profit or loss	93	50
Other comprehensive income for the period, net of tax	207	73
Total comprehensive income for the period	-11,264	-4,697
Total comprehensive income attributable to:		
- owners of parent	-11,264	-4,697
- non-controlling interests		



### CONSOLIDATED STATEMENT OF NET CASH FLOWS

In thousands of €	June 30, 2022	December 31, 2021	June 30, 2021
Consolidated net income	-11,471	-5,937	-4,770
+/- Net depreciation and provisions (excluding those related to current	48	511	438
assets)	40	311	
-/+ Unrealized gains and losses related to changes in fair value	174		-148
+/- Income and expenses calculated in relation to stock options and	219	-182	75
similar instruments		22.4	
-/+ Other calculated income and expenses		224	
-/+ Capital gains and losses on disposals			
-/+ Dilution gains and losses			
+/- Share of profit from equity affiliates			111
+/- Other items with no impact on cash			114
Cash flow from operations after cost of net financial debt and	-11,029	-5,384	4,291
tax			
+ Cost of gross financial debt	2,157	848	385
+/- Tax expense (including deferred taxes)	59	100	-15
Cash flow from operations before cost of net financial debt and	-8,813	-4,436	-3,921
tax		·	·
- Tax paid			
+/- Change in operating working capital requirements (including employee benefit liabilities)	7,368	-4,136	634
NET CASH FLOW PROVIDED BY OPERATING ACTIVITIES	-1,446	-8,572	2 200
- Disbursements related to acquisitions of property, plant and	-1,440	-0,572	-3,289
equipment and intangible assets	-71	-139	-8
+ Cash receipts related to disposals of property, plant and equipment			
and intangible assets			
- Disbursements related to acquisitions of financial assets (non-			
consolidated shares)			
+ Cash receipts related to disposals of financial assets (non-consolidated	3	73	9
shares)	3	,3	3
+/- Impact of changes in the scope of consolidation			
+ Dividends received (equity affiliates, non-consolidated shares)			
+/- Change in loans and advances granted			
+ Investment grants received			
+/- Other flows related to investment operations			
NET CASH FLOW USED IN INVESTING ACTIVITIES	-68	-66	1
+ Sums received from shareholders on capital increases			
. Paid by the shareholders of the parent company	7,961	9,351	9,428
. Paid by minority shareholders of consolidated companies			
+ Amounts received on exercise of stock options			
-/+ Net repurchases and resales of own shares	37	1	-6
+ Cash inflow from new loans			5,000
- Loan repayments (including finance leases)	2,343	2,620	-1,199
Of which reimbursement of rights of use (IFRS16)	-238	-487	-244
+/- Other flows related to financing operations	3	4	3
NET CASH FLOW USED IN FINANCING ACTIVITIES	10,343	11,976	13,226
+/- Impact of foreign exchange rate changes	144	25	1
CHANGE IN NET CASH FLOW	8,974	3,363	9,939
INITIAL CASH FLOW	17,886	14,523	14,523
FINAL CASH FLOW	26,861	17,886	24,462