

Onxeo Reports Full Year 2022 Financial Results and Provides Clinical Development Updates

- Phase 1b/2 trial of AsiDNA™ in combination with olaparib in the United States in recurrent ovarian, breast and metastatic castration-resistant prostate cancer continues to enroll patients
- Advancing Second Product, OX425, a pan-DDR decoy targeting multiple proteins & repair pathways towards submission of US IND in the second half of 2023
 - Preclinical update at AACR 2023 provided a comprehensive preclinical rationale for the potential use of OX425 in patients bearing HRD/HRP tumors or acquired PARPi-resistance
- Cash position of €14.6 million as of December 31, 2022
- Financial visibility until the 2nd quarter of 2024

Paris (France), April 24, 2023 – 8:00 pm CEST – Onxeo S.A. (Euronext Growth Paris: **ALONX**), a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage Response (DDR) and driver oncogenes, today reported its consolidated results for the fiscal year ending December 31, 2022.

Dr. Shefali Agarwal, Chairwoman of the Board of Directors and CEO, stated: *“2022 was a pivotal year for our Company, with renewed governance. Thanks to the support of our two main and historical shareholders, Invus and Financière de la Montagne, we were able to refocus our R&D efforts to the United States. A first major step in this direction was the FDA clearance of the initial Investigational New Drug (IND) application for AsiDNA™, our first-in-class drug candidate, last June 30. Since then, we have initiated, in December 2022, a Phase 1b/2 trial for AsiDNA™ in combination with Olaparib in recurrent ovarian, breast and metastatic castration-resistant prostate cancer. At the same time, REVOCAN study, Phase 1b/2 study is ongoing, and we observed encouraging activity from the preliminary data highlighting the potential of AsiDNA™ for patients with recurrent ovarian cancer who are progressing on an initial treatment with a PARP inhibitor. This study sponsored by Gustave Roussy Cancer Campus continues to enroll patients and we look forward to obtaining additional data. Last but not least, we are finalizing the preclinical development of OX425, our new compound sourced from the PlatON™ platform, in order to file an IND application in the United States in the second half of 2023.*

As the company is actively moving forward its R&D portfolio, the Company has received the necessary financial support, which will allow the extension of the Company’s runway to the second quarter of 2024.”



FY 2022 FINANCIAL RESULTS*

Consolidated income statement (IFRS) In thousands of euros	31/12/2022	31/12/2021
Revenues	1,443	4,062
Operating expenses, of which:	(19,008)	(9,722)
<i>R&D expenses</i>	(11,054)	(4,904)
Other recurring operating income	450	78
Recurring operating income/loss	(17,115)	(5,582)
Other non-recurring operating income and expenses	389	439
Operating income/loss after income from equity affiliates	(16,727)	(5,143)
Financial result	(2,549)	(693)
tax	(285)	(100)
Loss	(19,562)	(5,937)

*Audit procedures on the consolidated accounts have been carried out. The certification report will be issued once the management report has been verified.

Revenues for full-year 2022 totaled €1.4 million and consisted of flat-rate royalties due from Biogen under a licensing agreement for a non-strategic product.

Operating expenses rose sharply from €9.7 million in 2021 to €19.0 million in 2022, mainly due to:

- Personnel expenses, which increase from €4.0 million to €8.6 million, as a result of the recruitment of Onxeo's American team during the second quarter of 2022 and the changes in management and staff in 2022.
- External expenses increased from €4.1 million to €9.4 million, due to the growth of R&D expenses related to the industrial development of AsiDNA and the preclinical development of OX425. These R&D expenses thus increase from 4.9 million in 2021 to €11.1 million in 2022.

The **financial result** was a loss of €2.6 million in 2022, and primarily consisted of interest on the bond loan with SWK, which has been fully repaid during the year.

After taking into account a corporate tax expense of €0.3 million, the Group recorded a **net loss** of €19.5 million in 2022 compared to a loss of €5.9 million in 2021.

FINANCIAL STRUCTURE

As of December 31, 2022, the Group had a cash position of €14.6 million, compared with €17.9 million at December 31, 2021. The outstanding financial debt at the end of 2022 amounted to €9.1 million, which includes state-backed loans obtained in February 2021 as well as the €4 million convertible bond debt issued in April 2022.

The financial statements have been prepared on a going concern basis. This principle has been adopted by the Board of Directors on the basis of a consolidated net cash position of 14.6 million euros at December 31, 2022 and the financing commitments received from its main shareholders Invus and Financière de la Montagne, as well as from a new investor, in the amount of 14.3 million euros. The Group will thus be able to finance its activities at least until the second quarter of 2024 on the basis of its financing plan.

2022 HIGHLIGHTS AND RECENT DEVELOPMENTS

Preclinical development

Onxeo presented new preclinical data on March 9, 2022, confirming the relevance of combining AsiDNA™ with PARP inhibitors (PARPi) in tumor models with an active homologous recombination repair (HRP) pathway at the ESMO Targeted Anticancer Therapies Congress. Although PARP inhibitors have shown significant benefits in cancer patients with deficient homologous recombination repair (HRD), they show no or very limited



efficacy in tumors with active or proficient homologous recombination repair (HRP). The data presented by Onxeo highlight the therapeutic opportunity of combining AsiDNA™ and PARPi in HRP tumors to overcome intrinsic or acquired resistance in clinical situation.

At the American Association for Cancer Research (AACR) Annual Meeting held from April 8 to 13, 2022, the Company presented new preclinical data confirming the capabilities of AsiDNA™ to protect against cancer therapy toxicity and to combat tumor resistance:

- In the collaboration with Prof. Gilles Favre (Toulouse Cancer Research Center), AsiDNA™ was shown to prevent the emergence of resistance to tyrosine kinase inhibitors in several oncogenic addiction models, highlighting the therapeutic opportunity of combining AsiDNA™ with tyrosine kinase inhibitors (TKI) to overcome resistance in a clinical setting.
- In addition, within the framework of the collaboration with Prof. Marie Dutreix (Institut Curie), experiments in *in vivo* and *in vitro* models have shown the potential of AsiDNA™ to protect healthy cells from the toxicity of several cancer treatments. Indeed, when combined with different anticancer treatments (carboplatin +/- Paclitaxel in long-term treatment, Radiotherapy, Doxorubicin, PARP inhibitors), AsiDNA™ induces its nuclear target engagement only in dividing cells, while preserving healthy non dividing cells. Furthermore, in some proliferating healthy cells, AsiDNA™ induces division arrest or boosts their DNA repair activity, protecting them from the toxic effects of anti-cancer treatments.

Clinical development

On June 30, 2022, the Company announced that the Food and Drug Administration (FDA) issued “Safe to Proceed” to our first Investigational New Drug (IND) application for AsiDNA™.

This decision allowed the Company to initiate a multi-center 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 after initial treatment with PARP inhibitors. This clinical trial started in December 2022, with the activation of the first clinical study site in the United States, Next Oncology in San Antonio and enrolled first patient in March 2023.

In addition, during 2022, Onxeo continued its two trials conducted in collaboration with two academic research centers of excellence in oncology:

- The REVOCAN study, a phase 1b/2 trial evaluating the combination of AsiDNA™ with PARP inhibitors in the 2nd line maintenance treatment of relapsed ovarian cancer. Gustave Roussy is the sponsor of this study. The first interim analysis in 10 patients in January 2023 did not show any dose-limiting toxicity and demonstrated that the combination is generally well tolerated. The interim analysis demonstrated encouraging clinical activity with six patients showing stable disease and one patient showing a complete response with a disease control rate of approximately 70%. The study has enrolled 17 patients so far, a detailed results of the interim analysis will be published by the investigator.
- The Phase 1b/2 trial evaluating AsiDNA in combination with radiotherapy in the treatment of recurrent high-grade glioma in children, an indication with a particularly poor prognosis. Institut Curie is the sponsor of this study, which is supported by a grant from the European Fight Kids Cancer program. Onxeo has announced the treatment of a first patient in early September 2022. Five patients have been enrolled so far, and the combination has been well tolerated.

Governance

- On January 3, 2022, Onxeo announced the appointment of Julien Miara as interim Chief Executive Officer, replacing Judith Greciet. Ms. Greciet left the Company during the first half of 2022.
- On April 7, 2022, Dr. Shefali Agarwal, M.D succeeded Julien Miara and was appointed Chairwoman and Chief Executive Officer of Onxeo.
- The Annual 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 mandate of GammaX Corporate



Advisory, represented by Jacques Mallet, as Director for a further three years. Danielle Guyot-Caparros, whose third mandate expired at this General Meeting, did not wish to renew her mandate.

Following these changes, the Board of Directors is composed of seven members, three of whom are independent.

2023 OUTLOOK

In 2023, the Company will continue to pursue its value creation strategy based on the development of its therapeutic innovations until proof of concept in humans, with the following main milestones:

AsiDNA™

- Enrollment to continue in the U.S. phase 1b/2 trial in combination with Olaparib in ovarian, breast and prostate cancers to identify the RP2D in combination with Olaparib.
- Clinical updates expected in the second half of 2023 from phase 1b/2 trials conducted in France and European Union under the sponsorship of academic centers:
 - o REVOCAN trial with Gustave Roussy
 - o Pediatric trial in High-Grade Glioma with Institut Curie
- Submissions for publications in international scientific journals of the results of preclinical or clinical studies as part of the development plan to demonstrate the potential of AsiDNA.

OX425

- Finalization of the IND-enabling preclinical studies.
- Preparation of an IND application with the FDA in S2 2023.

PlatON

- Continued evaluation and optimization of PlatON platform and potential new drug candidates.

About Onxeo

Onxeo (Euronext Growth Paris: ALONX) 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 DNA decoy therapeutics, 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 DNA decoy therapeutic 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 and the US in combination with other treatment modalities in difficult-to-treat solid tumors.

OX425, the second compound from platON, is a novel pan-DDR Decoy with high antitumor activity. It also mediates multiple immunostimulatory effects by activating the STING pathway. OX425 is currently undergoing IND-enabling preclinical development.

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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APPENDICE

CONSOLIDATED FINANCIAL STATEMENTS AT 31/12/2022

The 2022 Financial Report will be available on the [Company's website](#) as of April 28, 2023.

CONSOLIDATED BALANCE SHEET

ASSETS in €K	12/31/2022	12/31/2021
Non-current assets		
Intangible fixed assets	20,531	20,531
Tangible assets	794	180
Rights of use	1,093	2,057
Other financial fixed assets	90	162
Total non-current assets	22,507	22,930
Current assets		
Trade receivables and related accounts	1,473	8,526
Other receivables	4,521	3,721
Cash and cash equivalents	14,856	17,887
Total current assets	20,579	30,133
TOTAL ASSETS	43,086	53,063

LIABILITIES AND SHAREHOLDERS' EQUITY K€	12/31/2022	12/31/2021
Shareholders' equity		
Capital	27,877	22,999
Less: Treasury shares	-81	-181
Share premium	27,705	24,583
Reserves	-13,669	-8,522
Earnings	-19,562	-5,937
Total shareholders' equity	22,270	32,942
Non-current liabilities		
Provisions	869	1,508
Deferred tax liability	0	204
Non-current financial debts	8,104	5,082
Non-current lease liabilities	646	1,428
Other non-current liabilities	4,048	4,835
Total non-current liabilities	13,667	13,057
Current liabilities		
Current provisions	20	
Short-term borrowings and financial liabilities	1,003	2,953
Current lease liabilities	335	471
Trade payables and related accounts	3,449	2,832
Other current liabilities	2,342	807
Total current liabilities	7,149	7,063
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	43,086	53,063



CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In K€	12/31/2022	12/31/2021
Revenues	1,443	4,062
Purchases	-514	-368
Personnel expenses	-8,624	-3,984
External expenses	-9,392	-4,131
Taxes and duties	-52	-99
Net depreciation, amortization and provisions	-1	-468
Other current operating expenses	-423	-672
Operating expenses	-19,008	-9,722
Other current operating income and expenses	450	78
Current operating income	-17,115	-5,582
Other non-current operating income	395	439
Other non-current operating expenses	-6	
Share of income from equity affiliates		
Operating result after share of income from equity affiliates	-16,727	-5,143
Net cost of financial debt	-2,173	-840
Other financial income	124	513
Other financial expenses	-500	-366
Financial income	-2,549	-693
Tax expenses	-285	-100
- of which deferred taxes	204	211
Consolidated net income	-19,562	-5,937
Earnings per share	-0.18	-0.07
Diluted earnings per share	-0.18	-0.07

In K€	12/31/2022	12/31/2021
Result for the period	-19,562	-5,937
Currency translation adjustments	105	218
Other items recyclable as a result	105	218
Actuarial gains and losses	86	49
Other items non-recyclable as a result	86	49
Other comprehensive income for the period, net of tax	191	267
Total comprehensive income for the period	-19,371	-5,670
Total comprehensive income attributable to the parent company owners	-19,371	-5,670
Minority interests		



CONSOLIDATED STATEMENT OF NET CASH FLOWS

K€	31/12/2022	31/12/2021
Consolidated net loss	-19,562	-5,937
+/- Depreciation, amortization and provisions, net (excluding provisions against working capital)	-167	511
+/- Unrealized gain and losses associated with changes in fair value	213	-182
+/- Non-cash income and expenses on stock options and similar items	724	224
+/- Other calculated income and expenses		
+/- Capital gains and losses on disposal		
+/- Dilution gains and losses		
+/- Share of equity affiliates		
Gross operating cash flow after cost of net debt and taxes	-18,792	-5,384
+ Cost of net debt	2,189	848
+/- Tax expenses (including deferred taxes)	285	100
Gross Operating cash flow before cost of net debt and taxes	-16,318	-4,436
- Taxes paid		
+/- Changes in operating WCR (including debt related to employee benefits)	6,875	-4,136
NET CASH FLOW FROM OPERATING ACTIVITIES	-9,443	-8,572
- Expenditures on acquisition of tangible and intangible assets	-488	-139
+ Proceeds of disposal of tangible and intangible assets		
- Expenditures on acquisition of financial assets		
+ Proceeds of disposal of financial assets	80	73
+/- Effect on changes in scope of consolidation		
+ Dividends received (equity affiliates, unconsolidated investments)		
+/- Change in loans and advances granted		
+ Capital grants received		
+/- Other changes from investment transactions		
NET CASH FLOW FROM INVESTING ACTIVITIES	-409	-66
+ Net amount received from shareholders on capital increase		
. Paid by shareholders of the parent company	7,875	9,351
. Paid by minority interest in consolidated companies		
+ Amount received on exercise of stock options		
-/+ Purchase and Sale of treasury shares	99	1
+ Amounts received on issuances of new loans		
- Reimbursements of loans (including lease debts)	-1,513	2,620
o/w repayment of lease debts (IFRS16)	-405	-487
+/- Others flows related to financing activities	1	4
NET CASH FLOW FROM FINANCING ACTIVITIES	6,463	11,976
+/- Effects of fluctuations in foreign exchange rates	87	25
CHANGE IN CASH AND CASH EQUIVALENTS	-3,301	3,363
CASH AND CASH EQUIVALENTS AT START OF YEAR	17,886	14,523
CASH AND CASH EQUIVALENTS AT YEAR END	14,585	17,886