

Onxeo Reports its 2021 Half-Yearly Financial Results and Provides an Update on its Activities

- Cash position of €24.5 million as of June 30, 2021, providing financial visibility until the end of 2022 and enabling the Company to accelerate its development and its portfolio
- Preparing an ambitious clinical plan for AsiDNA™, with implementation to be initiated in the fall of 2021

Paris (France), July 29, 2021 – 6 pm CEST - Onxeo S.A. (Euronext Growth Paris: ALONX, Nasdaq First North: ONXEO), « Onxeo », a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage response (DDR) in oncology, today announced its consolidated half-yearly financial results to June 30, 2021 and provides an update on its activities.

Judith Greciet, Chief Executive Officer of Onxeo, said: “Building upon the advances achieved in 2020, the first half of 2021 was marked by the strengthening of our financial resources and the furtherance of several preclinical and clinical programs, in particular those aimed at AsiDNA™.

With regard to AsiDNA™, the data obtained during the first half of the year confirm the exceptional properties of this drug candidate and will give rise to a wider range of clinical prospects.

AsiDNA™’s highly novel mechanism of action hijacking DNA repair functions is the basis of its novel antitumor properties, such as the ability to fight tumor resistance to several important classes of targeted therapies¹, to induce a deficiency of the HR repair pathway, necessary for PARPi to be fully effective², to increase the efficacy of reference treatments such as chemotherapy³. Other properties such as action on tumor metabolism and antitumor immune response are also under investigation.

Over the past few weeks, we have assembled a Scientific Advisory Committee composed of eminent members of the international medical and scientific community in the fields of DDR, resistance to treatment and, more generally, drug development in oncology. The appointment of Dr. Shefali Agarwal, a global clinical development expert, as Chairwoman of our Board of Directors, is also a strong signal of a new strategic focus in the Company’s development.

With their support and expert advice, we are currently revisiting the opportunities and priorities for the development of AsiDNA™, with the aim of implementing, starting this fall, an ambitious global clinical plan that will aim to maximize its worth by targeting the indications and combinations creating the most value.

In the meantime, the REVOCAN study of AsiDNA™ in combination with PARP inhibitors is continuing under the guidance of its sponsor, Gustave Roussy, and the AsiDNA™ Children study, sponsored by the Institut Curie to evaluate AsiDNA™ in combination with radiotherapy in recurrent high-grade glioma (HGG) in children, is also expected to begin this year.

In addition, we have secured Onxeo’s financial visibility until the end of 2022, notably through a rights issue widely supported by our shareholders, and in particular by our core shareholders, Invus and Financière de la Montagne.

Lastly, the first half of 2021 has still been largely subject to the uncertainties of the global pandemic, and I would like to warmly thank the Onxeo teams, our partners and our shareholders for their involvement and unfailing support, which will enable us to approach the major strategic steps that will be taken in the next 18 months with confidence and self-assurance. “

¹ Data presented at AACR [2020](#) et [2021](#)

² [Press release on June 9, 2021](#)

³ [Long Stabilization and Disease Control with AsiDNA™, a first-in-class DNA Repair Inhibitor in Combination with Carboplatin](#) Oncology & Cancer Case Reports 2021, Vol.07, Issue 2, 001-007 – Dr Nuria Kotecki – March 2021

FINANCIAL RESULTS FOR THE FIRST HALF OF 2021

Consolidated income statement (IFRS) <i>In thousands of euros</i>	30/06/2021	30/06/2020
Revenues, including:	589	1,082
<i>Recurring revenues</i>	0	1,076
<i>Non-recurring revenues</i>	589	6
Operating expenses	(5,367)	(5,067)
	(2,390)	(1,916)
Other current operating income	33	34
Current operating income	(4,745)	(3,951)
Other non-current operating income and expenses	198	10,040
Share of profit (loss) of companies accounted for by the equity method	-	-
Operating profit after equity method income (loss)	(4,547)	6,089
Financial result	(238)	(224)
Pre-tax income	(4,785)	5,065
Income tax	15	(823)
Net income	(4,770)	5,042

Consolidated revenues for the period ended June 30, 2021, amounted to 0.6 million euros and consisted exclusively of contractual licensing fees for a non-strategic product, whereas revenues for the first half of 2020, amounting to 1.1 million euros, corresponded to revenues from the commercialization of Beleodaq, which have been recognized in the Group's accounts until the date of signature of the licensing agreement with Acrotech Biopharma in April 2020.

Operating expenses increased slightly as a result of the evolution of R&D expenses, which went from 1.9 million euros at June 30, 2020 to 2.4 million euros at June 30, 2021, in line with the progress of AsiDNA™ and OX401 programs.

The strong variation in **other non-current operating income and expenses**, which went from a net amount of 10 million euros in the first half of 2020 to a net amount of 0.2 million, is due to the recognition in 2020 of the effects of the license agreement with Acrotech Biopharma, and notably

- an income of 5,7 million euros in net proceeds from the transaction,
- an expense of 2,8 million euros corresponding to the net book value of the R&D assets related to Beleodaq,
- an income of 7,1 million euros corresponding to the amount of royalties, evaluated by management, that the group expected to receive after the date of signature of the agreement and through which it will repay the balance of the SWK loan.

The **financial result** at June 30, 2021, is a loss of 0.2 million euro, mainly due to the cost of the bond loan with SWK Holdings.

As a result of the changes in business activity reflected by the income and expense items described above, the **net result** for the six months ended June 30, 2021, is a loss of 4.8 million euros, compared with a profit of 5 million euros for the first half of 2020.

CASH AND CASH EQUIVALENTS AT JUNE 30, 2021

The Group's cash position on June 30, 2021, was 24.5 million euros, compared with 14.5 million euros at December 31, 2020. The change in cash and cash equivalents is mainly due to the financing implemented during the first half of the year, State-backed loans and a capital increase, which provided Onxeo with net proceeds of 14.4 million euros and enabled it to meet operating expenses of 5.4 million euros.

The cash available on June 30, 2021, provides Onxeo with visibility until at least the end of 2022.

HIGHLIGHTS OF THE 1ST HALF-YEAR 2021, RECENT DEVELOPMENTS AND OUTLOOK

CORPORATE & GOVERNANCE

- On January 28, 2021, the Company announced that it had obtained non-dilutive financing of 5 million euros in the form of State Guaranteed Loans.
- On March 10, 2021, the Company announced the launch of a capital increase with preferential subscription rights for shareholders in France and Denmark, based on the seventeenth and twentieth resolutions adopted by the extraordinary shareholders' meeting of June 19, 2020.
- On April 12, 2021, the Company announced the success of this capital increase, with a subscription rate of approximately 104.8%, corresponding to 13,677,125 New Shares, of which 7,565,328 were requested on an unrestricted basis, fully allocated through the exercise of the extension clause. The gross amount of the capital increase, including issue premium, amounts to 9,710,758.75 euros. At the end of the capital increase, the Company's share capital amounted to 22,998,733.75 euros, divided into 91,994,935 shares with a nominal value of 0.25 euro each.
- On May 27, 2021, Onxeo announced the formation of a Scientific Advisory Committee composed of leading scientific and clinical experts in the fields of DNA Damage Response, immunology and oncology drug development. This committee will advise and guide the Company in advancing its PlatON™ platform and developing innovative therapies that address unmet medical needs and improve the outlook for cancer patients.
- On June 10, 2021, the General Meeting of Shareholders renewed the term of office of Walter Thomas Hofstaetter as Director for three years and ratified the appointment of two new Directors: Mr. Julien Miara, representing Invus, and Dr. Shefali Agarwal, an independent Director. Jean-Pierre Bizzari, an independent member of the Board of Directors, has resigned from his position for personal reasons at the end of June 2021.
- On July 29, 2021, the Company announced the appointment of Dr. Shefali Agarwal as Chairperson of the Board of Directors, replacing Ms. Danièle Guyot-Caparros, who remains an independent member of the Board and Chairperson of the Audit committee (*please refer to the press release published today*).

To date, the Board of Directors is thus composed of 7 members, 3 men and 4 women, including 4 independent members.

AsiDNA™

- In February 2021, Onxeo entered into a clinical research agreement with Institut Curie, France's leading cancer center, to conduct a Phase 1b/2 study to evaluate the effect of AsiDNA™ in combination with radiotherapy in children with recurrent high-grade glioma (HGG) eligible for re-irradiation. This study is supported by a grant from the European Fight Kids Cancer program and is being conducted as part of the European Innovative Therapies for Children with Cancer (ITCC) consortium. The Institut Curie, as sponsor of the study, will submit the request for authorization to the health authorities and ethics committees, with the aim of initiating this study in 2021.
- Onxeo completed the DRIIV-1b study of AsiDNA™ in combination with reference chemotherapies (carboplatin and paclitaxel) in patients with advanced solid tumors during the first half of 2021. The very favorable safety profile of AsiDNA™ was confirmed and significantly longer control times were observed than with previous treatment lines. These results were published in the scientific journal *Oncology & Cancer Case Reports* in March 2021.

- The Company presented new preclinical data at the American Association for Cancer Research (AACR) meeting in April 2021 showing that acquired resistance to KRASG12C inhibitors (a new class of targeted therapies), evolves from persistent drug-tolerant cells vulnerable to AsiDNA™.
- The REVOCAN study evaluating the combination of AsiDNA™ with PARP inhibitors (PARPi) in relapsed ovarian cancer also continued in the first half of 2021. Results from Part 1b of the study, which will focus on the safety of this combination, are now expected from Gustave Roussy, the sponsor, in the second half of 2021.
- In addition, Onxeo has continued its active policy of industrial protection of its compounds and their applications and announced in June 2021 the authorization of a new patent in the United States that extends the protection of AsiDNA™ associated with PARP inhibitors. This new patent protects both AsiDNA™ in combination with any PARP inhibitor, and a method of treating cancers with a so-called "HR proficient" genetic profile with this combination. This patent is based on preclinical data showing that AsiDNA™ is able, through its novel mechanism of action, to interfere with DNA repair pathways, including the homologous recombination (HR) pathway. AsiDNA™ thus produces a "HR-deficient" background, which is necessary for PARPi to be fully effective, regardless of the initial genetic background of the tumor.

The work undertaken with our experts, especially those of our newly formed Scientific Advisory Committee, to establish an ambitious and robust clinical plan for AsiDNA™ will of course rely on these programs to determine the new directions of its development, which will be implemented from the fall of 2021.

As part of the acceleration of the development of AsiDNA™, the Company could also file an IND application to extend its clinical program to the United States.

OX400

Based on Onxeo's decoy agonist technology, OX400 compounds are positioned as potent PARP agonists, acting on both the DNA damage response and the activation of the immune response.

New preclinical results presented at the American Association for Cancer Research (AACR) meeting in April 2021 showed that by specifically trapping and hyper-activating PARP, OX400 compounds have the potential to modulate the immune response and deplete tumor cell metabolism. Ongoing in-vitro and in-vivo studies of OX400 compounds aim to validate their action, alone and in combination with immunotherapies, and to optimize their efficacy profile. These translational studies will help optimize the entry into the clinic, which could occur within 12 to 18 months.

COVID-19 PANDEMIC CONTEXT

To date, the Company considers that it has experienced only a limited impact from the health crisis and has limited exposure to risks on its operations due to the Covid-19 epidemic. The impact has mainly been a slowdown in the pace of recruitment for the REVOCAN study, leading to a delay in obtaining the first results.

However, Onxeo does not exclude that a resumption of containment measures could affect the smooth running of its subcontracted activities, in particular the conduct of clinical trials, and thus lead to delays in the development of its products and a greater consumption of cash. In addition, the effect of this epidemic on the global economy and financial markets could impact the Company's ability to obtain financing in the capital markets and, consequently, the conduct of its business. The Company has put in place appropriate measures to protect its employees and to ensure the continuity of its operations and will adapt these measures as circumstances require.

The 2021 half-year financial report is available on the [Company's website](#).

About Onxeo

Onxeo (Euronext Paris, NASDAQ 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 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 first-in-class, highly differentiated clinical stage candidate in the field of DNA Damage Response (DDR). Its decoy and agonist mechanism acting upstream of multiple DDR pathways results in distinctive antitumoral properties, notably the ability to prevent or abrogate tumor resistance to targeted therapies such as PARP inhibitors and a strong synergy with tumor DNA-damaging agents such as radio/chemotherapy. AsiDNA™ is currently in combination clinical studies in hard-to-treat solid tumors.

OX401 is a new drug candidate from platON™, optimized to be a potent PARP agonist acting on both the DNA Damage Response and the activation of immune response, without inducing resistance. OX401 is undergoing preclinical proof-of-concept studies, alone and in combination with immunotherapies.

For more 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).

Contacts

Onxeo

Valerie Leroy,
Investor Relations
investors@onxeo.com
+33 1 45 58 76 00

Media Relations

Nicolas Merigeau
NewCap
onxeo@newcap.eu
+33 1 44 71 94 98

Investor Relations / Strategic Communication

Dušan Orešanský / Emmanuel Huynh
NewCap
onxeo@newcap.eu
+33 1 44 71 94 92

Certified Adviser for Nasdaq First North

Kapital Partner
www.kapitalpartner.dk
info@kapitalpartner.dk
+45 89 88 78 46

APPENDIX

INTERIM CONSOLIDATED FINANCIAL STATEMENTS AT JUNE 30, 2021

CONSOLIDATED BALANCE SHEET

ASSETS (in thousands €)	6/30/2021	12/31/2020
Non-current assets		
Intangible assets	20,532	20,534
Tangible assets	58	83
Rights of use	2,334	2,479
Other financial fixed assets	224	233
Total non-current assets	23,148	23,329
Current assets		
Trade receivables and related accounts	5,959	6,654
Other receivables	2,501	2,000
Cash and cash equivalents	24,462	14,523
Total current assets	32,922	23,177
TOTAL ASSETS	56,070	46,506

LIABILITIES AND SHAREHOLDERS' EQUITY (in thousands of €)	6/30/2021	12/31/2020
Shareholders' equity		
Capital	22,999	19,579
Less: treasury shares	-188	-182
Share premium	24,588	18,577
Reserves	-8,792	-10,027
Earnings	-4,770	1,089
Total shareholders' equity	33,837	29,036
Non-current liabilities		
Provisions	1,719	1,640
Deferred tax liability	393	415
Non-current financial debts	6,727	4,278
Other non-current liabilities	4,831	5,089
Total non-current liabilities	13,670	11,423
Current liabilities		
Short-term borrowings and financial debts	3,812	1,979
Trade payables and related accounts	3,220	2,762
Other current liabilities	1,531	1,306
Total current liabilities	8,563	6,047
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	56,070	46,506

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In thousands of €	6/30/2021	6/30/2020
Recurring revenues from licensing agreements		1,076
Non-recurring revenues from licensing agreements	589	6
Total revenues	589	1,082
Purchases	-194	-188
Personnel expenses	-2,128	-2,026
External expenses	-2,298	-2,228
Taxes and duties	-75	-95
Net depreciation, amortization and provisions	-421	-327
Other current operating expenses	-251	-202
Operating expenses	-5,367	-5,067
Other current operating income	33	34
Current operating income	-4,745	-3,951
Other non-current operating income	332	12,857
Other non-current operating expenses	-134	-2,817
Share of income from equity affiliates		
Operating result after share of income from equity affiliates	-4,547	6,089
Net cost of financial debt	-381	-515
Other financial income	291	316
Other financial expenses	-148	-25
Financial income/loss	-238	-224
Income before tax	-4,785	1,560
Income tax expense	15	-823
- of which deferred tax		-565
Consolidated net income/loss	-4,770	5,042
Earnings per share	-0.06	0.08
Diluted earnings per share	-0.06	0.08

In thousands of €	6/30/2021	6/30/2020
Result for the period	-4,770	5,042
Currency translation adjustments	23	-8
Other items recyclable as a result	23	-8
Actuarial gains and losses	50	17
Other items not recyclable as a result	50	17
Other comprehensive income for the period, net of tax	73	9
Total comprehensive income for the period	-4,697	5,051
Total comprehensive income attributable to:		
- owners of the parent company	-4,697	5,051
- minority interests		

STATEMENT OF CHANGES IN CONSOLIDATED SHAREHOLDERS' EQUITY

In thousands of €	Change in reserves and earnings							
	Capital	Treasury shares	Share premium	Translation reserves	Gains and losses recognized in equity	Consolidated reserves and earnings	Total Differences	TOTAL
Shareholders' equity as of 1/1/2019	13,344	-97	41,824	-109	-97	-9,462	-9,669	45,402
Total comprehensive income for the period				75	-54	-33,728	-33,707	-33,707
Capital increase	1,986		3,100				0	5,086
Treasury shares		-92				-71	-71	-163
Other movements						138	138	138
Share-based payments						441	441	441
Shareholders' equity as of 12/31/2019	15,329	-189	44,924	-34	-151	-42,682	-42,868	17,197
Total comprehensive income for the period				-8	17	5,042	5,051	5,051
Capital increase	4,250		6,186					10,436
Treasury shares		39						39
Other movements			-32,577			32,772	32,772	195
Share-based payments						18	18	18
Shareholders' equity as of 6/30/2020	19,579	-150	18,533	-42	-134	-4,850	-5,026	32,936
Total comprehensive income for the period				-63	-39	-3953	-4055	-4055
Capital increase			44			188	188	232
Treasury shares		-32				89	89	56
Other movements				14		-210	-195	-195
Share-based payments						61	61	61
Shareholders' equity at 12/31/2020	19,579	-182	18,577	-91	-173	-8,674	-8,938	29,036
Total comprehensive income for the period				23	50	-4,770	-4,697	-4,697
Capital increase	3,419		6,011					9,430
Treasury shares		-6				-2	-2	-8
Other movements								
Share-based payments						75	75	75
Shareholders' equity as of 6/30/2021	22,999	-188	24,588	-68	-123	-13,371	-13,562	33,837

CONSOLIDATED STATEMENT OF NET CASH FLOWS

In thousands of €	Note	6/30/2021	12/31/2020	6/30/2020
Consolidated net result		-4,770	1,089	5,042
+/- Net depreciation, amortization and provisions (excluding those related to current assets)	4, 5, 9.1	438	-8,215	-9,149
-/+ Unrealized gains and losses related to changes in fair value		-148	-290	9
+/- Calculated income and expenses related to stock options and similar instruments	8.4	75	79	18
-/+ Other calculated income and expenses				
-/+ Capital gains and losses on disposals			57	57
-/+ Dilution gains and losses				
+/- Share of profit/(loss) of equity affiliates				
+/- Other items with no impact on cash		114		
Cash flow from operations after cost of net financial debt and taxes		4,291	-7,280	-4,023
+ Cost of gross financial debt	12	385	959	515
+/- Tax expense (including deferred taxes)		-15	757	823
Cash flow from operations before cost of net financial debt and tax		-3,921	-5,564	-2,685
- Taxes paid				
+/- Change in operating working capital requirements (including employee benefit liabilities)		634	886	1,459
NET CASH FLOW FROM OPERATING ACTIVITIES		-3,289	-4,678	-1,226
- Disbursements related to acquisitions of property, plant and equipment and intangible assets		-8	-119	-109
+ Proceeds from disposals of property, plant and equipment and intangible assets			6,116	6,116
- Disbursements related to acquisitions of financial assets (non-consolidated investments)				
+ Proceeds from disposals of financial assets (non-consolidated investments)		9	4	4
+/- Impact of changes in perimeter			14	14
+ Dividends received (equity affiliates, non-consolidated investments)				
+/- Change in loans and advances granted				
+ Investment grants received				
+/- Other cash flows from investment activities				
NET CASH FLOW FROM INVESTMENT ACTIVITIES		1	6,015	6,025
+ Amounts received from shareholders in connection with capital increases				
. Paid by the shareholders of the parent company	8.1	9,428	10,568	10,436
. Paid by minority shareholders of consolidated companies				
+ Amounts received upon exercise of stock options				
-/+ Net purchases and resales of treasury shares	8.2	-6	8	97
+ Proceeds from new borrowings		5,000		
- Repayment of loans (including finance leases)	9.3, 10.1	-1,199	-3,094	-1,422
Of which repayment of rights of use (IFRS16)		-244	-475	-226
+/- Other cash flows from financing activities		3	-1	2
NET CASH FLOW FROM FINANCING ACTIVITIES		13,226	7,481	9,113
+/- Impact of changes in foreign exchange rates		1	-3	-1
CHANGE IN NET CASH AND CASH EQUIVALENTS		9,939	8,815	13,911
INITIAL CASH POSITION		14,523	5,708	5,708
FINAL CASH POSITION		24,462	14,523	19,619