

Onxeo Reports Full-Year 2020 Financial Results and Provides Business Update

- Several major clinical milestones achieved in 2020 by AsiDNA™, including promising initial results in combination with chemotherapy and the launch of a new study to evaluate the abrogation of resistance to a targeted therapy
- Cash position of €14.5 million at December 31, 2020 supplemented by €14.7 million in new financing obtained in early 2021
- Extended financial visibility through the end of 2022, enabling the expansion of clinical and industrial development of AsiDNA™

Management live webcast today at 6.30 pm CEST - to participate:

https://us02web.zoom.us/webinar/register/WN_T6v8Hc8TRU67rKXPrz2nXw

Paris (France), April 21, 2021 – 5:45 pm CEST - Onxeo S.A. (Euronext Growth Paris: ALONX, Nasdaq First North Copenhagen: ONXEO), a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage response (DDR) in oncology, today reported its consolidated financial results for the fiscal ending December 31, 2020, and provided a business update.

Judith Greciet, Chief Executive Officer of Onxeo, declared: “2020 was marked for all by an unprecedented health crisis. Yet it will have allowed Onxeo to demonstrate the resilience of its teams and strategy. The clinical program for AsiDNA™, our lead candidate, made very significant progress in 2020 on its two development axes, synergy of efficacy with DNA breakers as radio or chemotherapy, and the fight against tumor resistance to targeted therapies.

On the first axis, the positive efficacy signals obtained in DR11V-1b, combining AsiDNA™ with reference chemotherapies, have enabled the preparation of a randomized phase 2 trial in lung cancer. Its adaptive design would allow it to be converted into a pivotal study based on initial positive results. Enrolment will start in the second half of 2021, as soon as regulatory approval is obtained. We have also initiated a Phase 1b/2 pediatric program with the Curie Institute in recurrent high-grade glioma, a brain cancer with a poor prognosis, against which the combination of AsiDNA™ with radiotherapy could offer an efficacy gain.

In the fight against resistance to targeted therapies, the Phase 1b/2 Revocan study, which is evaluating the effect of AsiDNA™ on resistance to a PARP inhibitor in ovarian cancer, began in late 2020 and patient enrollment is ongoing. This study is sponsored by Gustave Roussy who leads its management and we expect to receive preliminary results from the first group of patients during the second half of the year. In addition, recent results presented at AACR 2021 confirm the effect of AsiDNA™ on drug-tolerant cells, one of the causes of resistance to targeted therapies such as PARP, KRAS or tyrosine kinase inhibitors. These results provide a strong rationale to consider an expansion of the clinical development of AsiDNA™ in other very high potential combinations.

Finally, the OX400 candidates have confirmed in preclinical studies their action on tumor metabolism and the immune system, presaging promising clinical combinations with immunotherapies.

This extensive and ambitious R&D program reflects the significant potential of our candidates in multiple combinations and therapeutic areas.

Over the past twelve months, we have also significantly strengthened Onxeo's financial and shareholder structure. Invus, an international investor specializing in biotechnology, has joined Financière de la Montagne in the capital and on the Board of Directors of the Company. Their support has contributed to extend our financial horizon to the end of 2022 - well beyond the major clinical milestones expected in the next 18 months - and validates our strategy to expand the clinical and industrial development of our candidates."

FINANCIAL HIGHLIGHTS FOR 2020

Consolidated income statement (IFRS) In thousands of euros	12/31/2020	12/31/2019
Revenues, of which:	1,776	4,289
Recurring revenues	1,077	3,455
Non-recurring revenues	699	833
Operating expenses, of which:	(9,803)	(14,178)
R&D expenses	(3,946)	(7,718)
Other current operating income	213	95
Current operating income / (loss)	(7,814)	(9,794)
Other operating income and expenses	10,008	(24,543)
Share of profit from equity affiliates		(39)
Operating income/(loss) after share of profit from equity affiliates	2,194	(34,376)
Financial income/(loss)	(347)	(1,677)
Income tax	(757)	2,324
Net profit/loss	1,089	(33,728)

The 2020 consolidated accounts were approved by the board of directors on April 21, 2021. The audit procedures on the consolidated accounts have been carried out. The certification report is in the process of being issued.

Revenues for the year 2020 amounted to €1.8 million and include:

- €1.1 million in recurring revenue corresponding to sales of Beleodaq® under the European Named Patient Program (NPP) and royalties on sales of Beleodaq® in the United States by the partner Acrotech Biopharma. Its decrease from €3.5 million in 2019 is explained by the transfer of this activity to Acrotech as part of the licensing agreement signed in early April 2020.
- €0.7 million in non-recurring revenue, comprising contractual lump-sum royalties under the business transfer agreement signed in 2017 with Vectans Pharma.

Operating expenses amounted to €9.8 million, compared to €14.1 million in 2019. The 31% decrease is mainly related to lower R&D expenses, notably manufacturing operations of AsiDNA™ for clinical trials in 2019, as well as strict management of all the Company's expenses.

Other operating income (non-current) amounted to €10.0 million and included the impacts of the agreement with Acrotech Biopharma in April 2020, namely:

- a net income of 5.7 million euros corresponding to the transaction price of €6.1 million less payments to be made to Acrotech Biopharma for future product development costs estimated at €0.4 million;
- a charge of 2.8 million euros corresponding to the net book value of the R&D assets related to Beleodaq®/belinostat, reflecting the treatment of the contract with Acrotech under IFRS as a sale agreement;
- 7.1 million euros of proceeds, evaluated on the basis of the financing plan established by management, corresponding to the royalties that the Company expects to receive after the date of signature of the agreement and that are intended to repay the balance of the loan contracted with SWK Holdings Corporation. This amount includes 1.6 million euros of royalties recorded for 2020 after the transaction.

The **financial result** of €-0.3 million is mainly explained by the interest expense related to the bond debt with SWK.

The **tax charge** is €0.8 million and includes deferred taxes of €0.4 million, relating to the royalties the Company expects to receive after December 31, 2020, through which it will repay the balance of the SWK loan.

Net income for the year ended December 31, 2020 was a profit of €1.1 million, resulting mainly from the Acrotech transaction and its accounting treatment under IFRS, compared with a loss of €33.7 million for the year ended December 31, 2019 that was linked with a €12.9 million impairment of belinostat-related R&D assets as well as the impacts of the settlement agreement signed with SpePharm early 2020 (-€9.6 million).

STRENGTHENED FINANCIAL STRUCTURE

As of December 31, 2020, the Company had consolidated cash and cash equivalents of €14.5 million, compared to €5.7 million at the end of fiscal 2019. This sharp increase stems from financing obtained during the year; in particular, the Company completed a private placement in June 2020 with a new investor, Invus Public Equities LP, and Financière de la Montagne, the historical shareholder, for €7.3 million, and it also used the balance of its equity financing line for €3.2 million. The Company also received a payment of \$6.6 million in consideration for the granting of additional exclusive rights to belinostat to Acrotech Biopharma LLC in April 2020.

The Company's cash position has since been strengthened by obtaining, at the end of January 2021, a €5 million financing in the form of State Guaranteed Loans (SGL) and by the proceeds of the capital increase with shareholders' preferential subscription rights (PSR) finalized on April 12, for a gross amount of €9.7 million. The Company's financial visibility has thus been extended to the end of 2022.

FULL-YEAR 2020 HIGHLIGHTS, RECENT DEVELOPMENTS AND OUTLOOK FOR 2021

AsiDNA™

- Revocan study

At the beginning of 2020, Onxeo launched the Revocan study to evaluate the effect of AsiDNA™ on acquired resistance to a PARP inhibitor (PARPi), in 2nd line recurrent ovarian cancer. This Phase 1b/2 study is sponsored by Gustave Roussy. Enrollment in the study began at the end of 2020 and is continuing, albeit at a slower pace than anticipated, notably due to the epidemic situation. However, it should be noted that as study sponsor, GR is managing the project. Preliminary results of part 1b, initially expected in the first half of the year, are now expected from Gustave Roussy in the second half of the year. The study aims to confirm preclinical data presented at the American Association for Cancer Research (AACR) Annual Meeting in June 2020, which showed the ability of AsiDNA™ to reverse PARPi resistance, notably by preventing the regrowth of drug-tolerant cells.

- DRIIV1-b study - Upcoming phase 2 study

Onxeo published favorable interim results from the DRIIV-1b study of AsiDNA™ in combination with standard of care chemotherapies in patients with progressing metastatic tumors in November 2020. Exceptionally long disease control times were observed and are particularly encouraging signals of efficacy. As a result, the Company plans to continue development in this combination in 2021 with a randomized Phase 2 study of AsiDNA™ in non-small cell lung cancer. The adaptive design of this international multicenter study, currently under development, would allow its transformation into a pivotal study.

- New clinical developments

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.

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

INTELLECTUAL PROPERTY

In 2020, Onxeo pursued an active policy of industrial protection. The Company received a notice of allowance from the U.S. Patent and Trademark Office for a new patent enhancing the protection of AsiDNA™, which will be valid in the United States until 2037. A notice of intent to issue a new patent enhancing protection in Europe for AsiDNA™ combined with PARP inhibitors was also announced in late October 2020. Onxeo's portfolio of candidates is now protected by several patent families in all territories of interest until 2040.

OX400

Onxeo continued preclinical studies of new OX400 candidates, next-generation PARP agonists from its proprietary platON™ platform, in 2020. New results presented at AACR 2021 confirm that by specifically trapping and hyperactivating PARP, OX400 compounds have the potential to modulate the immune response and deplete tumor cell metabolism. The preclinical proof of concept of one or more OX400 compounds, expected in 2021, will be the starting point for the activities necessary for entry into the clinic, potentially in combination with immunotherapy, within 12 to 18 months.

CORPORATE & GOVERNANCE

- In February 2020, Onxeo announced that it had reached an out-of-court settlement agreement with SpePharm and SpeBio. As part of this agreement, Onxeo will pay SpePharm 15 to 20% of the net amounts to be received under future commercial agreements relating to Onxeo's R&D assets, for a total cumulative amount of 6 million euros within a period of 4 years, i.e. at the latest on January 31, 2024. The balance of this debt amounts to 5.1 million euros at December 31, 2020;
- At its meeting on September 17, 2020, the Board of Directors of Onxeo co-opted Invus Public Equities LP, represented by Mr. Julien Miara, as a director of the Company to replace Mr. Jean-Pierre Kinet, who resigned;
- In December 2020, Onxeo transferred the listing of its shares from the regulated market of Euronext Paris (compartment C) to the multilateral trading system Euronext Growth Paris. By coherence, Onxeo shares listed in Denmark on the Nasdaq Copenhagen regulated market have been transferred to the Nasdaq First North Growth multilateral trading facility.

CONTEXT OF THE COVID-19 PANDEMIC

The continuation of the global health crisis linked to the Covid-19 epidemic creates an uncertain situation. Even if Onxeo has been little impacted in 2020, it is difficult to measure the repercussions on the Company's activity and financial situation, which will depend on the intensity and duration of this crisis. The Company has put in place appropriate measures to protect its employees and to ensure the continuity of its operations. It will adapt these measures to the circumstances.

The 2020 Financial Report will be available on the [Company's website](#) as of April 23, 2021.

About Onxeo

Onxeo (Euronext Growth Paris: ALONX, Nasdaq First North 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 first-in-class, highly differentiated DNA Damage Response (DDR) inhibitor based on a decoy and agonist mechanism acting upstream of multiple DDR pathways. Translational research has highlighted the distinctive properties of AsiDNA™, notably its ability to abrogate tumor resistance to PARP inhibitors regardless of the genetic mutation status. AsiDNA™ has also shown a strong synergy with other tumor DNA-damaging agents such as chemotherapy and PARP inhibitors. The DRIIV-1 (DNA Repair Inhibitor-administered IntraVenously) phase I study has evaluated AsiDNA™ by systemic administration (IV) in advanced solid tumors and confirmed the active doses as well as a favorable human safety profile. The ongoing DRIIV-1b extension study is evaluating the safety and efficacy of AsiDNA™ at a dose of 600 mg in combination with the reference chemotherapy, carboplatin +/- paclitaxel, in advanced metastatic tumors. Preliminary results from both cohorts showed good tolerability, stabilization of the disease and an increase in treatment duration compared to previous treatments. The ongoing REVOCAN phase 1b/2 study evaluates the effect of AsiDNA™ on the acquired resistance to PARP inhibitor niraparib in relapsed ovarian cancer (sponsored by Gustave Roussy). A phase 1b/2 study, AsiDNA™ Children, will be initiated in 2021 to evaluate the association of AsiDNA™ with radiotherapy in children with relapsed high-grade glioma (sponsored by Institut Curie).

OX401 is a new drug candidate from platON™, optimized to be a next-generation PARP inhibitor 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 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

FULL YEAR CONSOLIDATED ACCOUNTS AT DECEMBER 31, 2020

CONSOLIDATED BALANCE SHEET

ASSETS in €K	12/31/2020	12/31/2019	Note
Non-current assets			
Intangible assets	20,534	23,358	6
Tangible assets	83	109	7.1
Rights of use	2,479	2,718	7.2
Investments in equity affiliates		20	
Other financial fixed assets	233	141	8
Total non-current assets	23,329	26,345	
Current assets			
Inventories and work in progress		64	
Trade receivables	6,654	3,353	9.1
Other receivables	2,000	2,159	9.2
Cash and cash equivalents	14,523	5,708	9.3
Total current assets	23,177	11,284	
TOTAL ASSETS	46,506	37,629	

LIABILITIES AND SHAREHOLDERS' EQUITY K€	12/31/2020	12/31/2019	Note
Shareholders' equity			
Capital	19,579	15,329	10.1
Less: Treasury shares	-182	-189	10.2
Share premium	18,577	44,924	10.3
Reserves	-10,024	-9,139	10.3
Earnings	1,089	-33,728	
Total shareholders' equity	29,036	17,197	
Non-current liabilities			
Provisions	1,640	6,821	11.1
Deferred tax liability	415		16
Non-current financial debts	4,278	7,412	11.2
Other non-current liabilities	5,089		11.3
Total non-current liabilities	11,423	14,233	
Current liabilities			
Short-term borrowings and financial debts	1,979	1,170	12.1
Trade payables	2,762	3,672	12.2
Other current liabilities	1,306	1,358	12.3
Total current liabilities	6,047	6,199	
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	46,506	37,629	

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In K€	12/31/2020	12/31/2019	Note
Recurring revenue from license agreements	1,077	3,455	
Non-recurring revenues from license agreements	699	833	
Total revenues	1,776	4,289	14.1
Purchases	-347	-350	
Personnel expenses	-4,265	-4,808	14.2
External expenses	-3,882	-7,857	14.3
Taxes and duties	-176	-127	
Net depreciation, amortization and provisions	-618	-671	
Other current operating expenses	-515	-365	
Operating expenses	-9,803	-14,178	
Other current operating income	213	95	
Current operating income	-7,814	-9,794	
Other non-current operating income	13,500		14.4
Other non-current operating expenses	-3,492	-24,543	14.4
Share of profit from equity affiliates		-39	
Operating income after share of profit of associates	2,194	-34,376	
Cost of net financial debt	-958	-1,018	
Other financial income	1,006		
Other financial expenses	-395	-659	
Financial income	-347	-1,677	15
Tax expenses	-757	2,324	16
- of which deferred taxes	-415	2,330	
Consolidated net income	1,089	-33,728	
Earnings per share	0.01	(0.55)	17
Diluted earnings per share	0.01	(0.55)	17

In K€	12/31/2020	12/31/2019	Note
Result for the period	1,089	-33,728	
Currency translation differences	-71	75	
Other items recyclable as a result	-71	75	
Actuarial gains and losses	-22	-54	
Other items not recyclable as a result	-22	-54	
Other comprehensive income for the period, net of tax	-93	21	
Total comprehensive income for the period	996	-33,707	
Total comprehensive income attributable to the the parent company owners	996	-33,707	
Minority interests			

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

In K€	Changes in reserves and results							TOTAL
	Capital	Treasury shares	Share premium	Translation reserves	Gains and losses recognized in equity	Reserves and consolidated results	Total Differences	
Shareholders' equity as of 1/01/2019	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				-71	-22	1,089	996	996
Capital increase	4,250		6,230			188	188	10,668
Treasury shares		7				89	89	95
Other movements			-32,577	14		32,562	32,577	
Share-based payments						79	79	79
Shareholders' equity as of 12/31/2020	19,579	-182	18,577	-91	-173	-8,674	-8,938	29,036

CONSOLIDATED STATEMENT OF NET CASH FLOWS

K€	12/31/2020	12/31/2019	Note
Consolidated net loss	1,089	-33,728	
+/- Depreciation, amortization and provisions, net (excluding provisions against working capital)	-8,215	25,394	6/7/11
+/- Unrealized gain and losses associated with changes in fair value	-290	484	
+/- Non-cash income and expenses on stock options and similar items	79	441	
+/- Other calculated income and expenses			
+/- Capital gains and losses on disposal	57		
+/- Dilution gains and losses			
+/- Share of equity affiliates		39	
Gross operating cash flow after cost of net debt and taxes	-7,280	-7,371	
+ Cost of net debt	959	1,037	15
+/- Tax expenses (including deferred taxes)	757	-2,324	16
Gross Operating cash flow before cost of net debt and taxes	-5,564	-8,658	
- Taxes paid			
+/- Changes in operating WCR (including debt related to employee benefits)	886	959	
NET CASH FLOW FROM OPERATING ACTIVITIES	-4,678	-7,699	
- Expenditures on acquisition of tangible and intangible assets	-119	-26	
+ Proceeds of disposal of tangible and intangible assets	6,116		
- Expenditures on acquisition of financial assets			
+ Proceeds of disposal of financial assets	4	163	
+/- Effect on changes in scope of consolidation	14		
+ 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	6,015	137	
+ Net amount received from shareholders on capital increase			
. Paid by shareholders of the parent company	10,568	4,743	10
. Paid by minority interest in consolidated companies			
+ Amount received on exercise of stock options			
-/+ Purchase and Sale of treasury shares	8		
+ Amounts received on issuances of new loans			
- Reimbursements of loans (including lease debts)	-3,094	-2,729	11/12/15
o/w repayment of lease debts (IFRS16)	-475	-452	
+/- Others flows related to financing activities	-1	-1	
NET CASH FLOW FROM FINANCING ACTIVITIES	7,481	2,014	
+/- Effects of fluctuations in foreign exchange rates	-3	3	
CHANGE IN CASH AND CASH EQUIVALENTS	8,815	-5,545	
CASH AND CASH EQUIVALENTS AT START OF YEAR	5,708	11,253	
CASH AND CASH EQUIVALENTS AT YEAR END	14,523	5,708	