

Onxeo Reports Full-Year 2019 Financial Results and Provides Business Update

- Cash position of €5.7 million at December 31, 2019, combined with \$6.6 million from new agreement with Acrotech, provide extended financial visibility into Q2 2021
- AsiDNA™ to advance to phase 1b/2 study REVOCAN in combination with niraparib in patients with relapsed ovarian cancer to evaluate effect on acquired resistance with preliminary data possibly by end 2020/early 2021
- Topline results from DRIIV-1b study of AsiDNA™ in combination with reference chemotherapy in multi-treated advanced solid tumors expected by end 2020
- Impact of Covid-19 on Company's operations are limited, assuming the situation improves in Q3 2020

Paris (France), April 17, 2020 – 5.45 pm CEST - Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO - FRO010095596), (“Onxeo”, “the Company” or “the Group”), a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage response (DDR) in oncology, in particular against rare or resistant cancers, today reported its consolidated financial results for the fiscal ending December 31, 2019, and provided a business update.

Judith Greciet, Chief Executive Officer of Onxeo, said: “During 2019, Onxeo concentrated its operational efforts on its high-potential DDR-related development programs. As a result, AsiDNA™, our lead drug candidate, reached several major clinical milestones during the year. First of all, we demonstrated in the DRIIV-1 study that our differentiated DDR inhibitor was active in man by IV route, while being well tolerated. Based on this promising data and given its mode of action particularly well suited for use in combination, we initiated in mid-2019 DRIIV-1b, the first combination study of AsiDNA™ with a reference chemotherapy in patients with advanced multi-treated cancers. The first part of DRIIV-1b demonstrated that AsiDNA™ in combination with carboplatin is well-tolerated and two out of the first three patients had their disease “controlled”, with a tumor progression that stopped for a period longer than that of previous treatments. Topline results of the second part of the study, combining AsiDNA™ with carboplatin and paclitaxel, should be available by end 2020.

Importantly, our R&D teams focused on the much differentiated ability of AsiDNA™ to overcome the acquired resistance of tumors to PARP inhibitors (PARPi), a major class of targeted therapies with, unfortunately, a decreasing efficacy over time due to tumors cells ability to resist treatment. In January 2020, we announced having entered into a Clinical Research Agreement with Gustave Roussy to conduct the REVOCAN phase 1b/2 study designed to evaluate the effect of AsiDNA™ on the acquired resistance to niraparib used in the 2nd line maintenance treatment of relapsed ovarian cancer. Our plan is to obtain preliminary results by year-end or early next year. If positive, this first study would represent a very significant value catalyst, positioning AsiDNA™ as an essential treatment option to stop acquired resistance to PARPi.

In parallel, we advanced the preclinical development of OX401, our new drug candidate designed as a next-generation PARPi that places Onxeo at the crossroads of DNA Damage Response and immuno oncology, the two most attractive domains in cancer treatment. We expect preclinical proof of concept of this exciting drug candidate this year.

Besides, we are pleased to have reached an exclusive agreement with Acrotech Biopharma in the form of a \$6.6 million payment in exchange for exclusive rights on belinostat, in addition to the ones Acrotech already had. This transaction extends our cash runway into Q2 2021 and consolidates our strategic transition to a company focused in the domain of tumor DNA Damage Response, with compelling assets, especially to address the major challenge in oncology which is the tumor resistance to treatments.

Lastly, we are all facing the exceptional situation resulting from the Covid-19 pandemic. We had business continuation measures in place and, since day 1 of confinement, were able to maintain all teams' activity, mostly working from home. To date, the impact on our activities and timelines has been kept quite minimal. Of course, we are managing the situation closely and continuously but the final impact will only be known once we have more visibility on how and when the situation returns to normal. “



FINANCIAL HIGHLIGHTS FOR 2019

Consolidated income statement (IFRS) <i>In thousands of euros</i>	12/31/2019	12/31/2018
Revenues, of which:	4,289	6,127
<i>Recurring revenues</i>	3,455	2,310
<i>Non-recurring revenues</i>	833	3,817
Operating expenses, of which	(14,178)	(14,200)
<i>R&D expenses</i>	(7,718)	(7,539)
Other current operating income	95	4,546
Current operating income / (loss)	(9,794)	(3,527)
Other operating income and expenses	(24,543)	(12,117)
Share of profit from equity affiliates	(39)	5,176
Operating income/(loss) after share of profit from equity affiliates	(34,376)	(10,468)
Financial income/(loss)	(1,677)	(691)
Income tax	2,324	1,760
Net profit/loss	(33,728)	(9,399)

The audit procedures on the consolidated accounts have been performed. The certification report will be issued after verification of the management report.

Revenues for the full-year 2019 stood at €4.3 million and consisted of:

- €3.5 million in recurring revenues, compared with €2.3 million in 2018, corresponding to both sales of Beleodaq® within the European named patient program (NPP) and royalties on sales of Beleodaq® from partner Acrotech Biopharma in the United States.
- €0.8 million in non-recurring revenues, mainly constituted of contractual payments from license agreement divested to Vectans Pharma in 2017, from which Onxeo continued to benefit in 2019.

Operating expenses stood at €14.2 million in 2019, in line with 2018, resulting mainly from active preclinical and clinical development of AsiDNA™ and the new OX401 program.

The variation of **other current operating income** compared to the previous year is linked to a public grant in the form of a cash advance definitely acquired by the Company in 2018, in the amount of €4.1 million.

Non-current operating income & expenses amounted to -€24.5 million and include:

- a €6 million provision relating to future payments due by Onxeo within the framework of the settlement agreement signed with SpePharm and SpeBio on February 11, 2020;
- a €3.7 million provision for impairment of SpeBio shares sold by Onxeo to SpePharm at their nominal value, according to the terms of the aforementioned settlement;
- a €12.9 million provision for impairment of Beleodaq®-related assets pursuant to the impairment test performed in accordance with IFRS accounting standards, mainly due to the granting of the worldwide rights to belinostat to Acrotech Biopharma in April 2020;
- a €2 million provision for impairment of goodwill pursuant to the impairment test performed in accordance with IFRS accounting standards, reflecting increased financial market risks.

Financial income stood at (€1.7) million, mainly explained by interests repaid on the bond financing put in place in 2018 with SWK Holding. The higher level compared to 2018 is due to higher royalties received from Acrotech Biopharma, used to repay the loan.

The positive income tax in the amount of €2.3 million represents a reduction of deferred tax liabilities resulting from the impairment of intangible assets, both Beleodaq®-related assets and goodwill.

As a result, the Group recorded a **total net loss** of €33.7 million in 2019, mostly driven by non-cash items.



CASH POSITION AT DECEMBER 31, 2019

At December 31, 2019, the Company had a consolidated cash position of €5.7 million, compared with €11.3 million at December 31, 2018. This variation relates mainly to the operational expenditure of the Company, in particular to research and development expenses, partly offset by a financing of €4.9 million from the equity line set up with Nice & Green and by revenues from product sales and licensing agreements. The cash position of €7.3 million at March 31, 2020, together with the \$6.6 million (equivalent to €6 million) recently received from Acrotech and the balance of the equity line today provides Onxeo with sufficient visibility to advance its projects, particularly the clinical development programs of AsiDNA™ in combination, into the second quarter of 2021.

FULL-YEAR 2019 HIGHLIGHTS, RECENT DEVELOPMENTS AND OUTLOOK FOR 2020

AsiDNA™

- In April 2019, presentation of 5 posters at 2019 American Association for Cancer Research (AACR) Annual Meeting (Atlanta, USA) with supportive data on AsiDNA™ as a therapy with strong potential for cancer treatment.
- In May 2019, release of final positive data from DRIIV-1, a phase 1 study of AsiDNA™ via intravenous administration in in patients with advanced solid tumors.
- In May 2019, Onxeo also started DRIIV-1b, a phase 1b clinical study of AsiDNA™ in combination with a reference chemotherapy (carboplatin and paclitaxel) in patients with solid tumors.
- In September 2019, release of the positive intermediate results from the first part of the DRIIV-1b study (AsiDNA™ + carboplatin) showing a stabilized disease without tumor progression for two out of the three treated patients. The 2nd part of the study (AsiDNA™ + carboplatin and paclitaxel) is ongoing with top line results expected in 2020.
- In the fourth quarter of 2019, Onxeo was granted two new patents: one in Europe, reinforcing the protection of AsiDNA™ and all compounds from the platON™ platform and their application in the treatment of cancer alone or in combination with other treatments; a second in the United States, protecting the combination of AsiDNA™ with any PARP inhibitor in the treatment of cancer. Onxeo's assets are now protected by more than 10 patent families until at least 2036.
- Late-2019, Onxeo had sustained scientific activity with the presentation of the DRIIV-1 study results at ACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics (Boston, USA) and the publication of a preclinical study combining AsiDNA™ to a PARP inhibitor (olaparib) in the peer-reviewed journal *Frontiers in Oncology*.
- In January 2020, Onxeo announced a clinical research agreement with Gustave Roussy to conduct REVOCAN, a phase 1b/2 clinical trial of AsiDNA™ for treatment of relapsed ovarian cancer. The study, sponsored by Gustave Roussy, will evaluate the effect of AsiDNA™ on the acquired resistance to PARP inhibitor niraparib in 2nd line maintenance treatment of relapsed ovarian is currently under review by the French agency (ANSM) and Ethics Committee. Assuming the recruitment can start from mid-year, the Company aims to obtain preliminary results by year-end 2020 or early in 2021.

OX401

- At the end of June 2019, Onxeo announced its pipeline expansion with a new optimized compound, OX401, the second candidate sourced from Onxeo's proprietary platform of decoy agonists, platON™. OX401 was optimized to maintain the unique decoy mechanism of action of AsiDNA™, while specifically targeting PARP and immune response. Its properties position OX401 as a next-generation PARPi, at the crossroads of two of the most active areas in oncology, DNA Damage Response and immunotherapy.
- In March 2020, Onxeo presented OX401 at the European ESMO-TAT Congress 2020 in Paris.
- Proof-of-concept preclinical studies of OX401 are ongoing with results expected this year.

Corporate & Financing

- Following the Ordinary General Meeting of May 22, 2019, Ms. Danièle Guyot-Caparras, independent director of Onxeo since June 2013, was appointed as the new Chair of the Board of Directors, taking over Mr. Joseph Zakrzewski whose term of office ended at the date of the General Meeting.
- In early June 2019, Onxeo renewed the equity line with Nice & Green by issuing 12 million share subscription warrants giving access to 12 million new shares over a period of 12 months.



- At the end of June 2019, the equity research company Kepler Cheuvreux initiated coverage of ONXEO with a “Buy” recommendation.
- In October 2019, Onxeo announced a collaboration agreement with the French State and the Île-de-France Region as part of the Innov'up Leader PIA program (Program of Investments for the Future) with funding of €495,000. The winning project of Onxeo involves the development of a drug candidate sourced from PlatON™ for new therapeutic targets in immuno-oncology.
- In February 2020, Onxeo announced an agreement to settle the remaining actions in the litigation with SpePharm and SpeBio. Within the framework of this agreement, Onxeo sold its shares in SpeBio to SpePharm at their nominal value, thereby transferring its share of the cash of the joint venture amounting to approximately €3.5 million. Furthermore, Onxeo will pay 15 to 20% of net cash received on future commercial agreements concerning Onxeo’s R&D assets for a total cumulative amount of €6 million within the next 4 years.
- On April 6, 2020, Onxeo entered into an exclusive agreement with Acrotech Biopharma LLC which extends Acrotech’s rights to belinostat to all territories not previously covered under Onxeo’s prior agreement with Acrotech. Within the framework of this transaction, Onxeo received a one-time payment of \$6.6 million from Acrotech, of which €0.9 million are allocated to the above mentioned settlement agreement. This transaction completes the strategic shift of Onxeo towards DDR-related drug development and expands its cash runway into Q2 2021. Onxeo will continue to receive from Acrotech royalties and payments related to milestones on belinostat in the US, up to an amount equivalent to the outstanding loan plus interests owed to SWK Holding. Beyond this, belinostat will not generate additional revenues and is therefore no longer considered to be a strategic product for the Group. Accordingly, any meaningful news regarding belinostat would only be reported in annual and semi-annual financial reports.

Context of the Covid-19 pandemic

- The Company implemented from March 12, 2020 the appropriate measures to ensure its employees’ safety and the continuity of its operations in accordance with the rules imposed by health and governmental authorities in France. At the date of this release, it is not yet possible to estimate the final delays, if any, on the planned and ongoing activities of the Company. However, the company has limited exposure currently as its strategic Revocan clinical study is under review and not yet in active phase and a large part of its preclinical program is performed internally and mostly maintained, under strict sanitary conditions. Should containment measures and Covid-19 impact be extended beyond Q3 2020, this assessment might be reviewed and adjusted.

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 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 assessing the safety and efficacy of a 600 mg dose of AsiDNA™ in combination with carboplatin and then with carboplatin and paclitaxel, in patients with solid tumors who are eligible for such treatments.

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 section 5.7.1.4 "Risk Factors" ("*Facteurs de Risque*") of the 2018 registration document filed with the *Autorité des marchés financiers* on April 25, 2019 under number D.19-0282, which is available on the *Autorité des marchés financiers* website (www.amf-france.org) or on the Company's website (www.onxeo.com).

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

Investor Relations US

Brian Ritchie
LifeSci Advisors
britchie@lifesciadvisors.com
+1 212 915 2578



APPENDIX

FULL YEAR CONSOLIDATED ACCOUNTS AS AT DECEMBER 31, 2019

The 2019 full-year financial report will be made available on the Company's website within the statutory deadlines.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS in K€	12/31/2019	12/31/2018
Non-current assets		
Intangible assets	23,358	38,573
Tangible assets	109	296
Right-of-use assets	2,718	
Investments in equity-accounted companies	20	3,701
Other financial fixed assets	141	304
Total non-current assets	26,345	42,874
Current assets		
Stocks and work in progress	64	47
Accounts receivable and related accounts	991	1,479
Other receivables	4,520	7,597
Cash and cash equivalent	5,708	11,253
Total current assets	11,284	20,376
TOTAL ASSETS	37,629	63,250

LIABILITIES AND SHAREHOLDERS' EQUITY in K€	12/31/2019	12/31/2018
Shareholders' equity		
Share capital	15,329	13,344
Minus: treasury shares	-189	-97
Share premium	44,924	41,824
Reserves	-9,139	-270
Earnings	-33,728	-9,399
Total equity	17,197	45,402
Non-current liabilities		
Deferred tax liabilities		2,330
Provisions	6,821	531
Other financial liabilities	7,412	6,593
Total non-current liabilities	14,233	9,455
Current liabilities		
Short-term borrowings and financial debts	1,170	450
Trade payables and related accounts	3,672	4,145
Other liabilities	1,358	3,798
Total current liabilities	6,199	8,393
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	37,629	63,250



CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In K€	12/31/2019	12/31/2018
Recurring revenue from licensing agreements	3,455	2,310
Non-recurring revenue from licensing agreements	833	3,817
Total revenues	4,289	6,127
Purchases	-350	-215
Personnel expenses	-4,808	-5,438
External expenses	-7,857	-8,731
Taxes and duties	-127	-346
Net depreciation, amortization and provisions	-671	-92
Other current operating expenses	-365	622
Operating expenses	-14,178	-14,200
Other current operating income	95	4,546
Current operating income (loss)	-9,794	-3,527
Other operating income and expenses	-24,543	-12,117
Share of profit from equity affiliates	-39	5,176
Operating loss after share of profit from equity affiliates	-34,376	-10,468
Income from cash and cash equivalents	19	15
Gross cost of financial debt	-1,037	-601
Other financial income and expenses	-659	-104
Financial Income (loss)	-1,677	-691
Income tax expense	2,324	1,760
- of which deferred taxes	2,330	1,764
Consolidated net income (loss)	-33,728	-9,399
Earnings per share	(0.55)	(0.18)
Diluted earnings per share	(0.55)	(0.18)

In K€	12/31/2019	12/31/2018
Result for the period	-33,728	-9,399
Currency translation differences	75	43
Other items recyclable as a result	75	43
Actuarial gains and losses	-54	-11
Other items non-recyclable as a result	-54	-11
Other comprehensive income for the period, net of tax	21	32
Total comprehensive income for the period	-33,707	-9,367
Total comprehensive income attributable to parent company owners	-33,707	-9,367
Minority interests		



CONSOLIDATED NET CASH FLOW STATEMENT

K€	12/31/2019	12/31/2018
Consolidated net loss	-33,728	-9,399
+/- Depreciation, impairment and provisions, net (1) (excluding provisions against working capital)	25,394	9,175
+/- Unrealized gain and losses associated with changes in fair value	484	
+/- Non cash income and expenses on stock options and similar items	441	927
+/- Other calculated income and expenses		-173
+/- Capital gains and losses on disposal		
+/- dilution gains and losses		
+/- Share of earning associates	39	-5,176
Gross operating cash flow after cost of net debt and taxes	-7,371	-4,646
+ Cost of net debt	1,037	691
+/- Tax expenses (including deferred taxes)	-2,324	-1,764
Gross Operating cash flow before cost of net debt and taxes	-8,658	-5,719
- Taxes paid		
+/- Changes in operating WCR (including debt related to employee benefits)	959	-5,546
NET CASH FLOW FROM OPERATING ACTIVITIES	-7,699	-11,265
- Expenditures on acquisition of tangible and intangible assets	-26	-45
+ Proceeds of disposal of tangible and intangible assets		
- Expenditures on acquisition of financial assets		0
+ Proceeds of disposal of financial assets	163	
+/- Effect on changes in scope of consolidation		
+/- Change in loans and advance granted		
+ Capital grants received		
+/- Other changes from investment transactions		45
NET CASH FLOW FROM INVESTING ACTIVITIES	137	0
+ Net amount received from shareholders on capital increase		
. Paid by shareholders of the parent company	4,743	2,747
. Paid by minority interest in consolidated companies		
+ Amount received on exercise of stock options		
-/+ Purchase and Sale of treasury shares		-150
+ Amounts received on issuances of new loans		5,926
- Reimbursements of loans (including lease debts)	-2,729	-193
o/w repayment of lease debts (IFRS16)	-452	
+/- Others flows related to financing activities	-1	-81
NET CASH FLOW FROM FINANCING ACTIVITIES	2,014	8,249
+/- Effects of fluctuations in foreign exchange rates	3	-8
CHANGE IN CASH AND CASH EQUIVALENTS	-5,545	-3,024
CASH AND CASH EQUIVALENTS at start of year	11,253	14,277
CASH AND CASH EQUIVALENTS at year end	5,708	11,253