

Onxeo reports its financial results for the first half of 2020 and provides an update on its activities

- **The cash position of €19.6 million, which was strengthened in the first half of the year by two strategic transactions, provides financial visibility into Q1 2022**
- **Patient inclusion process has started in the Phase 1b/2 REVOCAN study evaluating the effect of AsiDNA™ on resistance to niraparib and preliminary results are expected in early 2021**
- **Topline results of the AsiDNA™ DRIIV-1b study in combination with chemotherapy are expected in late 2020/early 2021**
- **Invus, new reference shareholder, has been coopted as a director of the Company.**

Paris (France), September 17, 2020 – 5:45 pm CEST - Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), (“Onxeo” or “the Company”), a clinical-stage biotechnology company specializing in the development of innovative drugs targeting tumor DNA Damage response (DDR), in particular against rare or resistant cancers, today reported its consolidated financial results for the six months ended June 30, 2020, and provided an update on its activities.

Judith Greciet, CEO of Onxeo, said: *“The first half of 2020 has truly been extraordinary, with a pandemic that has directly or indirectly impacted the lives of every one of us. I would like to take this opportunity to thank all of our employees who have been able to adapt to this unprecedented context and whose mobilization and team spirit have made it possible to achieve an exceptional first half of the year in terms of preclinical and clinical development as well as financial performance. We are delighted that AsiDNA™’s development is gaining momentum and that we are progressively moving closer to our strategic objectives: to finalize the DRIIV-1b study to confirm AsiDNA™’s interest in combination with DNA breakers and to demonstrate AsiDNA™’s ability to abrogate the acquired resistance of tumors to certain targeted therapies. Indeed, while the efficacy of cancer treatments is increasingly improving, resistance is a real problem in the short and medium term and delaying or even preventing its emergence represents one of the major challenges in oncology today. This is the objective of Revocan, a phase 1b/2 study set up with Gustave Roussy, in which AsiDNA™ is being tested in patients with relapsed ovarian cancer showing signs of acquired resistance to niraparib treatment. The patient inclusion process in this study has started and, in accordance with our road map, we expect preliminary results as early as the first quarter of 2021.*

It is also important to note that, despite the highly uncertain environment in the financial markets, we have considerably strengthened Onxeo’s financial position with two major strategic transactions. In April, we received €6 million from our US partner Acrotech in consideration for the grant of additional exclusive rights to belinostat, and in early June, we completed a €7.3 million private placement with Financière de la Montagne, our historical shareholder, and Invus, a strategic international investor. In addition to reinforcing the financial visibility until the first quarter of 2022, well beyond the expected key clinical results, this operation has brought into the capital, with a seat on the Board of Directors, a second reference investor who is able to support the company’s growth strategy over the long term.

Thus, the impact of Covid-19 on our activities remains limited to date and we remain fully mobilized to deliver tangible results and confirm the value of our assets”.

**FINANCIAL RESULTS¹ OF THE 1st HALF-YEAR 2020**

Revenues for the first half of 2020 amounted to 1.1 million euros and consisted mainly of direct sales of Beleodaq® under the European Controlled Access Program (NPP), transferred to the partner Acrotech Biopharma as part of the agreement signed in early April, and to royalties on sales of Beleodaq® in the United States by Acrotech, used in full to repay the bond loan from SWK Holdings. These revenues have been recognized up to the date of the agreement signed with Acrotech, which explains the decrease compared to the recurring revenues of EUR 1.4 million recorded in H1 2019.

Operating expenses amounted to EUR 5.5 million in H1 2020, a significant decrease compared to the expenses recognized in H1 2019. This change is mainly due to completion in 2019 of industrial activities for clinical trial purposes relating to AsidNA™.

The agreement concluded with Acrotech Biopharma on April 6, 2020 was analyzed under IFRS as a disposal of belinostat-related assets. This led to the recognition of the following items in **other operating income and expenses (non-current)**:

- A net income of 5,686 thousand euros corresponding to the transaction price of 6,116 thousand euro less the amount of future belinostat development costs to be borne by Onxeo estimated at 430 thousand euros.
- An expense of 2,769 thousand euros corresponding to the net carrying amount of Beleodaq®/belinostat-related R&D assets.
- In the context of the bond loan from SWK, an income of 7,171 thousand euros corresponding to the estimated royalties still to be received from the initial license² as of the date of signature of the new agreement with Acrotech. These royalties will be entirely allocated to the repayment of the balance of the bond loan. Although this future income is booked upfront in accordance with IFRS, the interest expense relating to the bond loan from SWK will continue to be booked on an annual basis.

After taking into account the financial result and a tax related to the transaction with Acrotech, Onxeo reported a **net profit of €5 million** for the first half of 2020, compared to a loss of €8.5 million in 2019.

Consolidated income statement (IFRS) <i>In thousands of euros</i>	06/30/2020	06/30/2019
Revenues, including:	1,082	1,703
<i>Recurring revenues</i>	1,076	1,425
<i>Non-recurring revenues</i>	6	278
Operating expenses	(5,067)	(8,637)
Other current operating income	34	-
Current operating income	(3,951)	(6,934)
Other non-current operating income and expenses	10,040	-
Share of profit (loss) of companies accounted for by the equity method	-	(28)
Operating profit after equity method income (loss)	6,089	(6,962)
Financial result	(224)	(1 550)
Pre-tax income	5,065	(8,512)
Income tax	(823)	2
Net income	5,042	(8,510)

¹ Limited review procedures have been performed on the interim financial statements. The review report was issued after the completion of the procedures required for the publication of the interim financial report.

² In March 2019, Acrotech acquired from Spectrum Pharmaceuticals (SPPI) the license to belinostat for certain territories, including the United States, Canada, Mexico, and India. The new agreement grants Acrotech a royalty-free license to belinostat in all other territories.



CASH AND CASH EQUIVALENTS AS OF JUNE 30, 2020

At June 30, 2020, the Company had consolidated cash and cash equivalents of 19.6 million euros, compared to 5.7 million euros at December 31, 2019.

This strong increase is mainly due to the financing implemented during the six-month period through private placement and equity line, which provided Onxeo with net proceeds of EUR 10.5 million, as well as the agreement with Acrotech Biopharma for a net amount of EUR 5.1 million after payment of the share to SpePharm. These cash inflows added to the receipt of the 2019 research tax credit for an amount of 1.4 million euros and to license revenues and direct sales under the NPP program for 3 million euros have allowed the absorption of operating expenses.

On the basis of its development plan, Onxeo has sufficient financial visibility to carry out its projects beyond the next key milestones until the first quarter of 2022.

HIGHLIGHTS OF THE 1ST HALF-YEAR 2020, RECENT DEVELOPMENTS AND OUTLOOK

AsiDNA™

- In January 2020, Onxeo entered into a clinical research agreement with Gustave Roussy to conduct REVOCAN, a Phase 1b/2 clinical trial of AsiDNA™ in the treatment of relapsing ovarian cancer. This study, which is sponsored by Gustave Roussy, is designed to evaluate the effect of AsiDNA™ on acquired resistance to the PARP inhibitor niraparib (PARPi) in the maintenance treatment of relapsing second-line ovarian cancer.
- In May 2020, the REVOCAN Phase 1b/2 study evaluating the effect of AsiDNA™ on resistance to niraparib, a PARP inhibitor, in relapsed ovarian cancer received approval from the French National Agency for the Safety of Medicines and Health Products (ANSM) and the Committee for the Protection of Persons (CPP).
- At the AACR (American Association for Cancer Research) Annual Meeting held virtually from June 22-24, 2020, Onxeo presented the results of pre-clinical studies supporting the ability of AsiDNA™ to reverse PARPi resistance by preventing the regrowth of persistent cells. These results are extremely encouraging for the progress of the REVOCAN study and clearly reinforce AsiDNA™'s interest in the fight against resistance.
- On August 25, 2020, the final results of DRIIV, dose-escalation study of AsiDNA™ via intravenous (IV) route, were published in the British Journal of Cancer. This study demonstrated the activity and optimal dose for AsiDNA™ IV in combination. Enrollment of the last two patients in the DRIIV-1b extension study, which is analyzing the combination of AsiDNA™ with chemotherapy in patients with advanced solid tumors, is ongoing and topline results are expected in late 2020/early 2021.
- On September 3, 2020, Onxeo received a Notice of Intent from the U.S. Patent and Trademark Office for a new patent strengthening the protection of AsiDNA™ and its related compounds by systemic administration in the treatment of triple negative breast cancer and chemoresistant lung cancer, alone or in combination with chemotherapy, radiotherapy or other agents that damage tumor DNA. It will be valid in the United States until 2037.

OX401

- In late January 2020, Onxeo presented to the scientific community OX401, a next-generation PARP agonist sourced from its proprietary decoy agonist platform, platON™, at the PARP & DDR Inhibitors Summit 2020 in Boston, USA.
- In February 2020, Onxeo announced the acceptance of a poster presentation of OX401 at the ESMO-TAT 2020 congress, which is dedicated to research on targeted cancer therapies.
- In June 2020, Onxeo preclinically confirmed the profile of OX401. Through its action on PARP and the activation of an anti-tumor immune response via the cGAS-STING pathway, OX401 demonstrated in vivo a higher potency of activity than current PARP inhibitors, as evidenced by complete control of tumor growth.
- The next key preclinical milestone will be the study combining OX401 with immune checkpoint inhibitors. For this phase, Onxeo benefits from the expertise accumulated during the development of AsiDNA™ and has thus obtained in a few months an optimized compound, which is ready to enter the final stages of pre-clinical validation. These translational studies will allow Onxeo to best prepare the compound for entry into the clinic, which could take place within 18 to 24 months.



FINANCING & CORPORATE

- 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 sold its shares in SpeBio to SpePharm at their nominal value, thereby transferring its share of the joint venture's cash to SpePharm for an amount of approximately 3.5 million euros. In addition, Onxeo is required to pay 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 4 years.
- On April 6, 2020, Onxeo entered into exclusive agreements with Acrotech Biopharma LLC to extend Acrotech's rights to belinostat to all countries not covered by the previous agreement between Onxeo and Acrotech. In consideration, Onxeo received a payment of \$6.6 million (6 million euros) from Acrotech, of which \$0.9 million is allocated to the aforementioned settlement agreement. Onxeo will continue to receive from Acrotech the royalties and milestone payments relating to belinostat in the United States for an amount equivalent to the outstanding loan and interest due to SWK Holding. Beyond that, belinostat will no longer generate additional revenues and is therefore no longer considered a strategic product for the Company.
- On May 27, 2020, the investment bank Bryan Garnier & Co initiated Onxeo's coverage with a "buy" recommendation.
- On June 9, 2020, Onxeo completed a private placement for a total amount of approximately €7.3 million with a new investor, Invus Public Equities LP, and its historical shareholder, Financière de la Montagne.
- On July 29, 2020, the Company announced the transfer of the listing of Onxeo shares from the regulated market Euronext Paris (compartment C) to the multilateral trading facility Euronext Growth Paris. This transfer is intended to enable Onxeo to be listed on a market which is more appropriate to the Company's size and its market capitalization and will be effective at the earliest on October 31, 2020 .

GOVERNANCE

- At its meeting on September 17, 2020, the Board of Directors of Onxeo co-opted Mr. Julien Miara, representing Invus Public Equities LP, as a director of the Company, to replace Mr. Jean-Pierre Kinet who resigned. The Board warmly thanks Mr. Kinet for his significant contribution to its work since 2016.

This cooptation of Mr. Miara follows his appointment as observer to the Board of Directors on June 2, 2020 and will be submitted to the shareholders for approval at the Company's next ordinary general meeting. The Board of Directors is currently composed of 7 members, 4 men and 3 women, including 4 independent members.

COVID-19 PANDEMIC CONTEXT

- As of March 12, 2020, the Company has implemented appropriate measures to ensure the safety of its employees and the continuity of its operations within the framework of the rules imposed by French health and government authorities. At the date of publication of this press release, the impact of the pandemic is limited on the Company's planned or ongoing activities. The situation is being closely monitored by Onxeo's management and will be reassessed and adjusted as the health situation evolves.

The 2020 half-yearly financial report will be available to the public 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 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. Preliminary results from the first cohort with carboplatin alone showed good tolerability, stabilization of the disease and an increase in the duration of treatment compared to previous 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 chapter 3 "Risk Factors" ("*Facteurs de Risque*") of the Company's universal registration document filed with the *Autorité des marchés financiers* on April 27, 2020 under number D.20-0362, which is available on the websites of the *Autorité des marchés financiers* (www.amf-france.org) and the Company (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