

Onxeo Reports Full-Year 2018 Financial Results and Provides Business Update

- **Clinical development of AsiDNA™ continues in phase 1 study DRIIV-1**
 - Activity of AsiDNA™ demonstrated through the marked activation of its cellular targets enabling the determination of active doses and favorable tolerance profile
 - Impending initiation of a phase 1b study in combination with platinum-based chemotherapy and paclitaxel; preliminary results expected before year-end 2019
- **New lead compound sourced from platON™ ready to enter preclinical proof-of-concept studies**
- **Cash position of €11.3 million at December 31, 2018 and new equity financing negotiated to ensure cash runway into Q2 2020**

Paris (France), March 12, 2019 – 6.00 pm CET - Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO - FR0010095596), (“**Onxeo**” or “the **Company**”), 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 full-year financials, as of December 31, 2018, and provided a business update.

Judith Greciet, Chief Executive Officer of Onxeo, said: “2018 was marked by major achievements that confirmed the potential of our unique approach to DNA Damage response (DDR) with our first-in-class lead drug candidate AsiDNA™. In terms of development, we obtained remarkable data from several preclinical studies of AsiDNA™ in combination with other cancer treatments such as chemotherapy and PARP inhibitors, especially on tumor cell lines resistant to PARP inhibitors. We also identified predictive biomarkers of response to AsiDNA™, opening the way for its use in personalized medicine.

From a clinical standpoint, our phase 1 dose escalation study, DRIIV-1, of AsiDNA™ administered intravenously in advanced solid tumors continues at full speed and has already demonstrated the activity of AsiDNA™ through the activation of its tumor cell targets, with a good tolerance profile. We are now ready to start an extension Phase 1b study of AsiDNA™ in combination with chemotherapies, using the active doses determined in DRIIV-1. Preliminary results of this DRIIV-1b trial are expected before the end of the year and will be a major milestone for AsiDNA™.

In addition to our positive momentum with AsiDNA™, our first compound sourced from platON™ is ready to enter the preclinical proof-of-concept phase. This new candidate, which benefits from a differentiated set of features from AsiDNA™, will enlarge our pipeline and reinforce our unique positioning in the DDR field.”



2018 CORPORATE HIGHLIGHTS, RECENT DEVELOPMENTS AND OUTLOOK

AsiDNA™

- Extension of the AsiDNA™ intellectual property with two Intent-to-Grant notices from the European Patent Office (EPO) contributing to the worldwide protection of the compound and of its combinations with various anticancer agents until at least 2036. These new patents provide AsiDNA™ with extended protection and greater flexibility for its upcoming developments.
- Publication, in July 2018, of new preclinical results on AsiDNA™, revealing a strong synergy and the reversion of tumor resistance when combined to PARP inhibitors.
- Reporting, early November 2018, of positive interim results from the DRIIV-1 phase 1 clinical study with AsiDNA™ administered intravenously in advanced solid tumors: data confirmed a robust biological target engagement in patient tumor cells with no drug-related serious adverse event and no dose-limiting toxicity, opening the way to the next clinical step of testing AsiDNA™ in combination with chemotherapies. This study extension (DRIIV-1b) is expected to start in the coming weeks.
- In early January 2019, reporting of the identification of biomarkers predicting the response to AsiDNA™, which could optimize its clinical development by selecting the most responsive patients to AsiDNA™, as well as making it eligible to personalized medicine approaches.

platON™

- Optimization of a new lead compound throughout 2018.
- A new, innovative compound, with differentiated and complementary mechanisms of action to those of AsiDNA™, will enter regulatory preclinical evaluation in the 1st half of 2019.

Beleodaq®

- On March 1, 2019, Spectrum Pharmaceuticals (SPPI) announced the completion of the sale of its portfolio of seven FDA-approved hematology/oncology products, including Beleodaq®, to Acrotech Biopharma L.L.C. On the basis of the information provided to date by SPPI, the Company does not anticipate any significant impact of this transaction on activities and results from Beleodaq® for Onxeo.

Corporate & Financing

- In June 2018, the Company announced two financing operations:
 - Onxeo signed a royalty agreement with SWK Holdings Corporation, a US company specialized in financing in the life sciences sector. According to the terms of the agreement, Onxeo issued bonds in an amount of \$7.5 million, fully subscribed by SWK Holdings Corporation. The terms for repaying the bonds will allow the latter to directly receive the royalties and milestone payments on the sales stemming from the marketing of Beleodaq® (belinostat) by Spectrum Pharmaceuticals, Inc. for an amount of \$13.5 million.
 - The Company also set up an equity line of credit, including an incentive program, by issuing new shares over a period of 10 months, for a maximum amount of €5.4 million, with the company Nice & Green. At March 8, 2019, 3.9 million shares have been issued for an amount received by the Company of €3.9 million.
- In December 2018, the Paris Court of Appeal has rendered a decision in the litigation between Onxeo and SpePharm and SpeBio BV, condemning Onxeo to pay SpeBio, a 50%-owned subsidiary of Onxeo, the additional sum of approximately €2.8 million, actually paid early 2019. It is reminded that the first proceeding in front of the International Court of Arbitration of the International Chamber of Commerce (ICC) had been put on hold pending decision of the French Commercial Court and Court of Appeal. This proceeding will therefore resume and Onxeo will put all efforts in obtaining remedies from Spepharm.

In parallel, Onxeo sought to retrieve its 50% share of SpeBio cash (about €5 million including a €1.5 million intercompany loan). Following a negative decision early March from the other shareholder, SpePharm BV, during SpeBio 2019 general meeting as regards the cash distribution, the Company decided to negotiate an extension of its current equity line with Nice & Green, in order to secure sufficient financial resources to support the Company's operations beyond the critical milestones expected in the upcoming 12 months and to provide a cash runway into Q2 2020. The detailed terms of this financing will be announced when the operation is implemented.



FY 2018 FINANCIAL RESULTS

Revenues for the full-year 2018 stood at €6.1 million and consisted of:

- €2.3 million in recurring revenues, corresponding to sales of Beleodaq® within the European named patient program (NPP) and sales-based royalties related to the licensing agreements with Spectrum Pharmaceuticals. The decrease, compared to 2017, is mainly due to the sale of the Loramyc® and Sitavig products to Vectans Pharma at the end of July 2017.
- €3.8 million in non-recurring revenues, corresponding to contractual payments from license agreements in place or divested to Vectans Pharma, the latter being part of Vectans post-closing commitments. The implementation of the new IFRS15 standards on revenue recognition as of January 1, 2018, negatively impacted the non-recurring revenue of Onxeo by approximately €0.5 million in 2018.

Operating expenses stood at €9.7 million in 2018, which represented a decrease of 66% compared to 2017. This significant variation results from the termination in late 2017 of all Livatag®-related activities including a reduction of the workforce and a strict control of all expenses thereafter. R&D expenses for the year amounted to €7.5 million, i.e. 77% of operating expenses, and were fueled by the sustained development of AsidDNA™.

Non-current operating expenses amounted to €12.1 million, principally made of an impairment charge of €8.6 million pursuant to value tests performed in accordance with IFRS accounting standards already recognized at June 30, 2018. The impairment triggered a reduction of the deferred tax liability by €1.7 million, recognized as income tax credit. The Company also recorded a €2.8 million expense following the decision of the Paris Court of Appeal in the dispute with the companies SpeBio and SpePharm. Considering that SpeBio is 50% owned by Onxeo, a €5.2 million share of profit resulting from the penalties paid by Onxeo has been recorded in the group accounts as “Share of profit from equity affiliates”.

2018 total **net loss** amounted to €9.4 million, compared to €59.1 million in 2017.

Consolidated income statement (IFRS) <i>In thousands of euros</i>	31/12/2018	31/12/2017
Revenues, of which:	6,127	9,505
<i>Recurring revenues</i>	2,310	3,042
<i>Non-recurring revenues</i>	3,817	6,463
Operating expenses, of which	(9,654)	(28,694)
<i>R&D expenses (net of R&D tax credit)</i>	(7,539)	(18,857)
Operating income/(loss) before non-recurring items	(3,527)	(19,189)
Non-recurring operating income, of which	(12,117)	(47,188)
<i>impairment of R&D assets related to Beleodaq®</i>	(8,559)	(38,111)
Share of profit from equity affiliates	5,176	0
Financial income	(691)	(491)
Income tax	1,760	7,797
Net profit/loss	(9,399)	(59,071)

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

CASH POSITION AT DECEMBER 31, 2018

At December 31, 2018, the Company had a consolidated cash position of €11.3 million compared with €14.3 million at December 31, 2017.

The cash consumed in operation amounted to €11.3 million over the period, which is related to the operating costs of the Company, including research and development expenses net of R&D tax credit. This net payment was notably partly compensated by new financing schemes put in place during the year (royalty monetization and equity line), which have brought a total of €8.7 million.

Annual and consolidated 2018 accounts were approved by the Board of Directors on March 12, 2019 and will be submitted to shareholders' approval on April 26, 2019.



UPCOMING EVENTS & FINANCIAL PUBLICATIONS

- **Shareholder's general meeting on the first call:** Friday, April 26, 2019
- **Shareholder's general meeting on the second call** (if quorum is not reached at the first AGM): Wednesday, May 22, 2019
- **HY 2019 financial information:** Thursday, July 25, 2019, after market

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 (proprietary, acquired or in-licensed) from translational research to clinical proof-of-concept, a value-creating inflection point appealing to potential partners.

Onxeo is developing **AsiDNA™**, a first-in-class, highly differentiated DNA Damage Response (DDR) inhibitor based on a unique decoy & agonist mechanism acting upstream of multiple DDR pathways. Translational research has highlighted the unique properties of AsiDNA™, notably its ability to oppose and even reverse tumor resistance to PARP inhibitors regardless of the genetic mutation status, and its strong synergy with other tumor DNA-damaging agents such as chemotherapy and PARP inhibitors. The ongoing Phase I study DRIIV-1 (DNA Repair Inhibitor-administered IntraVenously) evaluates AsiDNA™ by systemic administration (IV) in solid tumors and has recently produced favorable tolerability and activity results.

AsiDNA™ is the first compound generated from **platON™**, the Company's proprietary chemistry platform of decoy oligonucleotides dedicated to generate new innovative compounds and broaden Onxeo's pipeline.

Onxeo's portfolio also includes **belinostat**, an HDAC inhibitor (epigenetics). Belinostat is already conditionally FDA-approved in the US as a 2nd line treatment for patients with peripheral T cell lymphoma and marketed in the US by Onxeo's partner, Acrotech Biopharma L.L.C., under the name Beleodaq® (belinostat IV form).

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 2017 registration document filed with the *Autorité des marchés financiers* on April 25, 2018 under number D.18-0389, which is available on the *Autorité des marchés financiers* website (www.amf-france.org) or on the Company's website (www.onxeo.com).

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APPENDIX

FULL YEAR CONSOLIDATED ACCOUNTS AS AT DECEMBER 31, 2018

The complete 2018 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	31/12/2018	31/12/2017
Non-current assets		
Intangible assets	38,573	47,535
Property, plant and equipment	296	344
Long-term investments	4,005	232
Deferred tax assets	0	0
Total non-current assets	42,874	48,111
Current assets		
Inventories and work in progress	47	30
Trade accounts receivable and related accounts	1,479	552
Other accounts receivable	7,597	15,103
Financial investments	0	0
Cash and cash equivalents	11,253	14,277
Total current assets	20,376	29,962
TOTAL ASSETS	63,250	78,073

LIABILITIES AND SHAREHOLDERS' EQUITY (€k)	31/12/2018	31/12/2017
Shareholders' equity		
Share capital	13,344	12,674
Less: treasury shares	-97	(89)
Share premium	41,824	269,060
Reserves	-270	(172,700)
Earnings	-9,399	(59,071)
Total shareholders' equity	45,402	49,873
Non-current liabilities		
Deferred tax liabilities	2,330	4,094
Provisions	531	550
Other financial liabilities	6,593	4,714
Total non-current liabilities	9,455	9,358
Current liabilities		
Short-term debt	450	130
Trade payables and related accounts	4,145	5,956
Other liabilities	3,798	12,755
Total current liabilities	8,394	18,842
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	63,250	78,073



CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In K€	31/12/2018	31/12/2017
Recurring revenue from licensing agreements	2,310	3,042
Non-recurring revenue from licensing agreements	3,817	6,463
Total revenue	6,127	9,505
Purchases	(215)	(634)
Personnel costs	(5,438)	(8,217)
External expenses	(8,731)	(17,555)
Taxes and duties	(346)	(367)
Net decrease in depreciation and amortisation	(540)	(1,796)
Net allocations to provisions	448	74
Other operating income	4,546	4
Other operating expenses	622	(203)
Operating expenses	(9,654)	(28,694)
Loss from recurring operating	(3,527)	(19,189)
Other operating income and expenses	(12,117)	-47,188
Operating result	(15,644)	-66,378
Share of profit from equity affiliates	5,176	0
Operating loss after share of profit from equity affiliates	(10,468)	-66,378
Income from cash and cash equivalents	15	13
Other financial income	331	615
Financial expenses	(1,037)	-1,119
Net financial income (expense)	(691)	-491
Pre-tax loss	(11,159)	-66,868
Tax expense	1,760	7,797
- Of which deferred tax	1,764	7,801
Net loss	(9,399)	-59,071
Earnings per share	(0.18)	(1.17)
Diluted earnings per share	(0.18)	(1.17)

In K€	31/12/2018	31/12/2017
Loss for the year	(9,399)	(59,071)
Other comprehensive income	0	0
Translation adjustments	(2,899)	(2,528)
Gains and losses on derecognition of assets available for sale	0	0
Cash flow hedges	0	0
Tax relating to comprehensive income items	0	0
Other items that may be reclassified to profit or loss	(2,899)	(2,528)
Actuarial gains and losses	11	7
Other items that may not be classified to profit or loss	11	78
Other comprehensive income for the year, net of tax	(2,888)	(2,522)
Total comprehensive income for the year	(12,287)	(61,592)
Total comprehensive income attributable to the owners of the parent company	(12,287)	(61,592)
Minority interests		



CONSOLIDATED NET CASH FLOW STATEMENT

K€	31/12/2018	31/12/2017
Consolidated net loss	(9,399)	(59,071)
+/- Depreciation, impairment and provisions, net (1) (excluding provisions against working capital)	9,175	40,253
+/- Unrealized gain and losses associated with changes in fair value		
+/- Non cash income and expenses on stock options and similar items	927	980
+/- Other calculated income and expenses	(173)	(137)
+/- Capital gains and losses on disposal		
+/- dilution gains and losses		
+/- Share of earning associates	(5,176)	
- Dividends (non-consolidated investments)		
Gross operating cash flow after cost of net debt and taxes	(4,646)	(17,973)
+ Cost of net debt	691	492
+/- Tax expenses (including deferred taxes)	(1,764)	(7,801)
Gross Operating cash flow before cost of net debt and taxes	(5,719)	(25,282)
- Taxes paid		
+/- Changes in operating WCR (including debt related to employee benefits)	(5,546)	(2,999)
NET CASH FLOW FROM OPERATING ACTIVITIES	(11,266)	(28,281)
- Expenditures on acquisition of tangible and intangible assets	(45)	(65)
+ Proceeds of disposal of tangible and intangible assets		
- Expenditures on acquisition of financial assets		(2)
+ Proceeds of disposal of financial assets		
+/- Effect on changes in scope of consolidation		
+ Dividends received (equity accounted investment)		
+/- Change in loans and advance granted		
+ Capital grants received		
+/- Other changes from investment transactions	45	
NET CASH FLOW FROM INVESTING ACTIVITIES	1	(67)
Cash flow resulting from the merger		
+ Net amount received from shareholders on capital increase		
. Paid by shareholders of the parent company	2,747	14,012
. Paid by minority interest in consolidated companies		
+ Amount received on exercise of stock options		
-/+ Purchase and Sale of treasury shares	(150)	(68)
- Dividends paid in the year		
- Dividends paid to minority shareholders in consolidated companies		
¹ - Dividends paid to minority shareholders		
+ Amounts received on issuances of new loans	5,926	
- Reimbursements of loans (including finance leases)	(193)	(154)
- Net interest received		
+/- Others flows related to financing activities	(81)	(354)
NET CASH FLOW FROM FINANCING ACTIVITIES	8,250	13,437
+/- Effects of fluctuations in foreign exchange rates	(8)	(55)
CHANGE IN CASH AND CASH EQUIVALENTS	(3,024)	(14,966)
CASH AND CASH EQUIVALENTS at start of year	14,277	29,243
CASH AND CASH EQUIVALENTS at year end	11,253	14,277