

## Onxeo Reports Half-Year 2018 Financial Results and Provides Business Outlook

- **Clinical development of Onxeo's lead product candidate AsiDNA™ progressing to plan**
  - Preliminary safety and activity results of DRIIV-1 study are expected in Q4 2018
  - Two combination clinical trials with AsiDNA™ planned for early 2019
- **New optimized candidate from platON™ proprietary platform ready to enter preclinical stage by end 2018**
- **Cash position of €11m at June 30, 2018 enables an expanded clinical development plan of AsiDNA™ into 2020**

Paris, July 27, 2018 – 6:00 pm CEST - Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO FRO010095596), a clinical-stage biotechnology company specializing in the development of innovative drugs in oncology, in particular against rare or resistant cancers, today reported its consolidated half-year financial results<sup>1</sup>, as of June 30, 2018 and provided a business update.

**Judith Greciet, Chief Executive Officer of Onxeo, said:** *"The first half of 2018 was marked by an important step in the development of our lead product candidate AsiDNA™ as it entered a phase I clinical trial DRIIV-1 in patients with advanced solid tumors. We expect preliminary data in Q4 2018 which will confirm both the safety and systemic activity of this first-in-class DNA repair inhibitor. In parallel, we have conducted substantial preclinical work with AsiDNA™ in combination with other anticancer agents to assess its full potential. In that context, we have already obtained very compelling data regarding the synergistic effects and reversion of tumor resistance by AsiDNA™ when combined with a PARP inhibitor. Additional results on the interest of combining AsiDNA™ with belinostat have also been acquired and other experiments are ongoing to show the value of combining AsiDNA™ with carboplatin, a standard-of-care in chemotherapy. Together with the expected outcomes from the DRIIV-1 clinical study, this solid body of preclinical data opens a range of new clinical development opportunities to harvest the full potential of AsiDNA™ and we have planned already to broaden its development in combination as soon as 2019.*

*Furthermore, the extensive screening and optimization work on new molecules sourced from our PlatON™ platform is bearing fruit and we expect to advance the next optimized candidate into preclinical development by the end of the year, thereby enlarging Onxeo's pipeline.*

*At this time and considering our available preclinical data, it appears that AsiDNA™ in combination with PARPi and/or carboplatin is the most promising option while belinostat could be best combined with a new candidate sourced from platON™, due to the respective pharmacokinetic properties of these assets.*

*During this half-year, we also strengthened our cash position with an equity line and the monetization of Beleodaq® royalties, to support the momentum of our development programs with this highly attractive technology in DNA targeting."*

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<sup>1</sup> Half-year financial statements have been the subject of a limited review. The limited review report will be issued after the procedures required for the publication of the half-yearly financial report have been finalized.



## HALF-YEAR 2018 FINANCIAL RESULTS

**Revenues** for the first half of 2018 stood at €2.1 million and consisted of:

- €1.2 million in recurring revenues, corresponding to product sales from the European named patient program (NPP) and sales-based royalties related to the license agreements with Spectrum Pharmaceuticals. The decrease compared to 2017 mainly comes from the sale of the Loramyc® and Sitavig products to Vectans Pharma at the end of July 2017.
- €0.9 million in non-recurring revenues including mainly milestone payments from a licensing agreement. The implementation of the new IFRS15 standards on revenue recognition as of January 1, 2018, negatively impacted Onxeo's non-recurring revenue by approximately €0.5 million in the first half of 2018.

**Operating expenses** amounted to €7.6 million in H1 2018, which represented a decrease of 48% compared to H1 2017 which was essentially due to cost reduction following the interruption of the Livatag® program.

The Company also booked a €4 million operational income corresponding to the write-off of a cash advance from Bpifrance relating to the Livatag® program, for which the objective of commercial success was not achieved.

On July 27, 2018, the board of directors reviewed the Company's consolidated accounts for the first-half of 2018 and recorded an impairment charge of €8.6 million pursuant to value tests performed in accordance with IFRS accounting standards. This accounting adjustment results from a potential better synergy between belinostat and a future compound from platON™ versus a development with AsiDNA™, thereby postponing cumulative future cash flows on this product. This does not impact in any way the Company's current or future cash balance or its ability to advance its strategic value creation strategy as planned. The impairment triggered a reduction of the Company's deferred tax liability by €1.7 million, recognized as a profit.

H1 2018 **total net loss** was of €8.8 million, compared to €11.6 million in H1 2017.

<b>Consolidated income statement (IFRS)</b> <i>In thousands of euros</i>	<b>30/06/2018</b> <b>(6 months)</b>	<b>30/06/2017</b> <b>(6 months)</b>
<b>Revenues, of which:</b>	<b>2,102</b>	<b>3,367</b>
<i>Recurring revenues</i>	1,040	1,893
<i>Non-recurring revenues</i>	1 062	1,474
<b>Operating expenses, of which</b>	<b>(7,578)</b>	<b>(14,674)</b>
<i>R&amp;D expenses (net of R&amp;D tax credit)</i>	(3,187)	(10,481)
<b>Operating income/(loss) before non-recurring items</b>	<b>(5,476)</b>	<b>(11,307)</b>
<b>Non-recurring operating income/(loss), of which</b>	<b>(4,627)</b>	(17)
<i>impairment of R&amp;D assets related to Beleodaq®</i>	(8,549)	-
<b>Financial income/(loss)</b>	<b>(444)</b>	<b>(338)</b>
<b>Income tax</b>	<b>1,711</b>	<b>35</b>
<b>Net profit/(loss)</b>	<b>(8,836)</b>	<b>(11,627)</b>

## CASH POSITION AT JUNE 30, 2018

At June 30, 2018, the Company had a consolidated cash position of €11 million compared with €14.3 million at December 31, 2017, providing visibility until Q1 2020, based on the current financing plan that includes an expanded development for AsiDNA™.

Cash variation takes into account the \$7.5 million (net proceed of €6.1m) of non-dilutive capital from SWK Holdings Corporation through the sale of rights related to future Beleodaq® royalties on June 7, 2018. In order to actively pursue its R&D programs, Onxeo also implemented, on June 15, 2018, an equity financing line including an incentive program through the issuance of new shares over a 10-month period representing a maximum amount of €5.4 million with Nice & Green SA, included in the financing plan.



## HALF-YEAR 2018 CORPORATE HIGHLIGHTS, RECENT EVENTS & OUTLOOK

- **AsiDNA™**

- Onxeo obtained a new 'composition of matter' patent in Europe in January 2018 covering multiple compounds, including AsiDNA™, and providing protection until 2031 with a potential extension to 2036. Together with previously granted patents, Onxeo's intellectual property for its DNA-targeting technologies, products and combinations is now protected by 10 patent families worldwide.
- The Company also initiated, end of April 2018, a dose-escalation phase I study (DRIIV-1) with AsiDNA™ to assess the compound's safety profile and identify its optimal clinical dose, as well as determine its active dose at tumor level, in patients with advanced solid cancer. Preliminary results are expected in Q4 2018.
- New preclinical results of AsiDNA™ in combination with PARP inhibitors, announced in July 2018, showed a strong synergistic effect and a reversion of tumor resistance, thereby confirming the relevance of combining AsiDNA™ with PARP inhibitors. These positive *in vitro* and *in vivo* data, together with the expected activity results of the DRIIV-1 study, will support further clinical development of AsiDNA™ in combination with PARP inhibitors, which should start from end 2018. Results from preclinical studies of other combinations will be available after the summer.

These results comfort AsiDNA™ as the Company's priority development program.

- **platON™**

- Onxeo's patented chemistry platform enables the Company to generate additional innovative DNA-targeting drug candidates.
- Several compounds are currently in the selection and optimization phase and Onxeo expects to initiate the preclinical evaluation of a new drug candidate by the end of 2018.

- **Belinostat**

- Preclinical data obtained in combination with AsiDNA™ were presented to the scientific community during one of the two poster presentations at AACR 2018.

- **Corporate governance**

- On May 16, 2018, the shareholders' Ordinary General Meeting renewed for three years the terms of office as director of Mr. Thomas Hofstaetter, President of Onxeo's Compensation and Scientific & Business Development committees.

## UPCOMING FINANCIAL PUBLICATIONS & EVENTS

- **Q3 2018 financial information:** Thursday, October 25, 2018, after market

### About Onxeo

Onxeo (Euronext Paris, NASDAQ Copenhagen: ONXEO) is a French biotechnology company developing innovative oncology drugs based on DNA-targeting and epigenetics, two of the most sought-after mechanisms of action in cancer treatment today. 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 DNA break repair inhibitor based on a unique decoy mechanism. AsiDNA™ has already successfully completed a Phase I trial in metastatic melanoma via local administration and is currently being evaluated for systemic (IV) administration in solid tumors in the DRIIV-1 phase I study (DNA Repair Inhibitor administered IntraVenously).

AsiDNA™ is the first compound generated from **platON™**, the Company's proprietary chemistry platform of decoy oligonucleotides based on three components, a sequence of double strand oligonucleotides, a linker and a cellular uptake facilitator. PlatON™ will continue to generate innovative compounds targeting tumor DNA functions and broaden Onxeo's pipeline.

Onxeo's R&D pipeline also includes **belinostat**, an HDAC inhibitor (epigenetics), of which an oral form could be used in combination with other anti-cancer agents for liquid or solid tumors. Belinostat is already conditionally FDA-approved in the US as a 2<sup>nd</sup> line treatment for patients with peripheral T cell lymphoma and marketed in the US by Onxeo's partner, Spectrum Pharmaceuticals, under the name Beleodaq® (belinostat IV form).



For further information, please visit [www.onxeo.com](http://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](http://www.amf-france.org)) or on the Company's website ([www.onxeo.com](http://www.onxeo.com)).

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## APPENDICES - HALF-YEARLY CONSOLIDATED ACCOUNTS AT JUNE 30, 2018

The 2018 half-yearly financial report will be available on the Company's website within the prescribed deadlines.

### CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS in K€	30/06/2018	31/12/2017
<b>Non-current assets</b>		
Intangible assets	38,734	47,535
Tangible assets	275	344
Financial assets	244	232
<b>Total non-current assets</b>	<b>39,253</b>	<b>48,111</b>
<b>Current assets</b>		
Stock and work-in-progress	33	30
Trade receivables	1,483	552
Other receivables	6,519	15,103
Cash	11,014	14,277
<b>Total current assets</b>	<b>19,049</b>	<b>29,962</b>
<b>TOTAL ASSETS</b>	<b>58,302</b>	<b>78,073</b>

LIABILITIES AND SHAREHOLDERS' EQUITY K€	30/06/2018	31/12/2017
<b>Shareholders' equity</b>		
Share capital	12,684	12,674
Less: treasury shares	-96	-89
Premium	39,892	269,060
Reserves	-1,395	-172,700
Earnings	-8,836	-59,071
<b>Total shareholders' equity</b>	<b>42,248</b>	<b>49,873</b>
<b>Non-current liabilities</b>		
Deferred tax liabilities	2,366	4,094
Provisions	546	550
Other financial liabilities	7,067	4,714
<b>Total non-current liabilities</b>	<b>9,979</b>	<b>9,358</b>
<b>Current liabilities</b>		
Short-term financial debt	101	130
Trade payables and related accounts	4,330	5,956
Other liabilities	1,644	12,755
<b>Total current liabilities</b>	<b>6,075</b>	<b>18,842</b>
<b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>	<b>58,302</b>	<b>78,073</b>

**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME**

In K€	30/06/2018	30/06/2017
Recurrent sales from licensing agreement	1,040	1,893
Non-current sales from licensing agreement	1,062	1,474
<b>Total sales</b>	<b>2,102</b>	<b>3,367</b>
Purchases	-211	-415
Personnel costs	-2,682	-3,716
External expenses	-4,228	-9,672
Duties and taxes	-196	-179
Depreciation and amortization, net	-311	-900
Allowances to provisions, net	163	969
Other operating income		3
Other operating expenses	-114	-765
<b>Operating expenses</b>	<b>-7,578</b>	<b>-14,674</b>
<b>Current operating income</b>	<b>-5,476</b>	<b>-11,307</b>
Share of income under the equity method		-17
Other operational income	4,036	
Other operational expenses	-8,663	
<b>Operating income after share of income under the equity method</b>	<b>-10,103</b>	<b>-11,324</b>
Income from cash and cash equivalents		530
Other financial income	87	16
Financial expenses	-532	-884
<b>Financial income</b>	<b>-444</b>	<b>-338</b>
<b>Pre-tax income</b>	<b>-10,547</b>	<b>-11,663</b>
Income tax	1,711	35
-of which deferred tax	1,728	0
<b>Net profit/loss</b>	<b>-8,836</b>	<b>-11,627</b>
Earnings per share	-0,17	-0,23
Diluted earnings per share	-0,17	-0,23

**OTHER ELEMENTS OF THE STATEMENT OF COMPREHENSIVE INCOME**

In K€	30/06/2018	30/06/2017
<b>Income for the period</b>	<b>-8,836</b>	<b>-11,627</b>
Other comprehensive income		
Translation adjustments	2,201	955
Losses and gains on derecognition of assets available for sale		
Cash flow hedges		
Tax related to elements of the comprehensive income		
<b>Other items recycled as income</b>	<b>2 201</b>	<b>955</b>
Actuarial gains and losses	0	-21
<b>Other non-recyclable items classified as income</b>	<b>0</b>	<b>-21</b>
Other elements of the comprehensive income for the period net of taxes	2,201	934
<b>Total comprehensive income for the period</b>	<b>-6,635</b>	<b>-10,693</b>
Total comprehensive income attributable to :	-6,635	-10,593
- Owners of the parent company		
- Minority interests		



## CONSOLIDATED NET CASH FLOW STATEMENT

In K€	30/06/2018	31/12/2017	30/06/2017
Consolidated net loss	<b>-8,836</b>	<b>-59,071</b>	<b>-11,627</b>
+/- Depreciation, impairment and provisions, net (excluding provisions against working capital)	8,888	40,253	949
-/+ Unrealized gains and losses associated with changes in fair value	432		
+/- Non-cash income and expenses on stock options and similar items	311	980	249
-/+ Other calculated income and expenses	-67	-137	-92
-/+ Capital gains and losses on disposal			
-/+ Dilution gains and losses			
+/- Share of earning associates	0	0	17
- Dividends (non-consolidated equity)			
<b>Gross operating cash flow after net cost of debt and tax</b>	<b>728</b>	<b>-17,973</b>	<b>-10,504</b>
+ Cost of financial debt, net	12	492	338
+/- Tax liabilities (including deferred tax)	-1,728	-7,801	35
<b>Gross operating cash flow before net cost of debt and tax</b>	<b>-988</b>	<b>-25,282</b>	<b>-10,130</b>
- Taxes paid			
+/- Changes in operating WCR (including debt related to employee benefits)	-8,631	-2,999	-5,547
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>	<b>-9,620</b>	<b>-28,281</b>	<b>-15,677</b>
- Expenditures on acquisition of tangible and intangible assets	-17	-65	-25
+ Proceeds of disposals of tangible and intangible assets			2
- Expenditures on acquisition of financial assets (non-consolidated equity)	12	-2	-2
+ Proceeds of disposals of financial assets (non-consolidated equity)			2
+/- Impact of perimeter variations			
+ Dividends received (non-consolidated equity, associated companies)			
+/- Changes in agreed upon loans and advances			
+ Investment grants received			
+/- Other cash flow from investment activities			
<b>NET CASH FLOW FROM OPERATING ACTIVITIES</b>	<b>-5</b>	<b>-67</b>	<b>-23</b>
Cash flow from merger			
+ Amounts received from shareholders at capital increases			
. From parent company shareholders	48	14,012	14,702
. From minority interest of merged entity			
+ Amounts received from stock options			
-/+ Buy-back and resale of treasury shares	-1	-68	-1
- Dividends paid during period			
. To shareholders of parent company			
. To minority interests of merged entity			
+ Proceeds of new loans	6,375		
- Reimbursement of loans (including finance leases)	-77	-154	-320
- Net interests paid (including finance leases)			
+/- Other flows related to financing activities	-12	-354	-229
<b>NET CASH FLOW FROM FINANCING ACTIVITIES</b>	<b>6,333</b>	<b>13,437</b>	<b>14,155</b>
+/- Impact of fluctuations in foreign exchange rates	29	-55	-44
<b>CHANGES IN CAHS AND CASH EQUIVALENTS</b>	<b>-3,263</b>	<b>-14,966</b>	<b>-1,590</b>
<b>CASH AND CASH EQUIVALENTS at start of period</b>	<b>14,277</b>	<b>27,654</b>	<b>29,243</b>
<b>CASH AND CASH EQUIVALENTS at end of period</b>	<b>11,014</b>	<b>14,277</b>	<b>27,654</b>