



THE ORPHAN ONCOLOGY INNOVATOR

PRESS RELEASE

Onxeo Reports Full-Year 2017 Financial Results and Provides Business Update

- **Advancement of core pipeline assets on track with key development catalysts expected in 2018**
- **First new molecule generated from platON™, Onxeo's proprietary development platform, to enter preclinical studies by end of 2018**
- **Cash position of €14.3m at December 31, 2017, to support current operating plan through mid-2019**

Paris, March 29, 2018 – 6:10 pm CEST - Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO FR0010095596), a biotechnology company specializing in the development of innovative drugs in oncology, in particular against rare or resistant cancers, today reported its consolidated full-year financials, as of December 31, 2017 and provided a business update.

“2017 was a pivotal year for Onxeo that demonstrated the depth of our development pipeline and the strength of our translational expertise. Shortly following our decision to conclude the development of Livatag® in liver cancer, we quickly and successfully shifted our focus towards innovative and high-value mechanisms of action in oncology, DNA-targeting and epigenetics. This strategic shift is supported by two key development assets, AsiDNA™ and belinostat, as well as our unique proprietary chemistry platform of decoy oligonucleotides, platON™. AsiDNA™, our first-in-class DNA repair inhibitor generated from this platform, is currently the subject of an extensive development program aimed at demonstrating the breadth of its potential applications in oncology. Importantly, our robust AsiDNA™ preclinical program has already generated compelling outcomes as a single therapy, as well as significant synergy in combination with other treatments, including belinostat or PARP inhibitors. AsiDNA™ will shortly enter its second phase I clinical trial, DRIIV, as a systemic monotherapy in solid tumors, with initial results expected before the end of 2018. These results will be crucial to confirming the potency of AsiDNA™ via systemic administration. Furthermore, we intend to expand our development pipeline in the near-term with new innovative molecules screened from the platON™ platform. Specifically, a new compound generated from platON™ is expected to enter pre-clinical development by the end of 2018. Finally, based on the divestment of multiple non-core products, our cost-reduction plan and a successful international private placement, the Company's cash position of €14.3 million at the end of 2017 is expected to support the continued planned advancement of our development programs well beyond the key value-creating milestones anticipated this year,” said Judith Greciet, CEO of Onxeo.



FY 2017 FINANCIAL RESULTS

Revenues for full-year 2017 stood at €9.5 million and consisted of:

- €3.0 million in recurring revenues, comprised of royalties paid by the Group's partners on sales of products, primarily Beleodaq®, and of sales of products directly to these partners. The 12% decrease compared to 2016 was a result of the sale of Onxeo's non-core legacy products, Loramyc® and Sitavig®, to Vectans Pharma in July, 2017.
- €6.5 million in non-recurring revenues, primarily due to the sale of Loramyc® and Sitavig® for €4 million to Vectans Pharma, and the signing of a worldwide license agreement for Validive® with Monopar Therapeutics for an upfront fee of €0.8 million. Non-recurring revenues for full-year 2017 also included the phased IFRS recognition of the initial payment associated with the exclusive license agreement signed with Pint Pharma in 2016.

Operating expenses were €28.7 million in 2017, which represented a slight increase (+4%) compared to 2016, and were driven by the increase in R&D expenses, particularly costs associated with the Relive phase III trial of Livatag® and AsiDNA™ programs.

Non-current operating expenses were €47.2 million and consisted primarily of up to €38.1 million impairment of R&D assets related to Beleodaq®¹. This accounting adjustment does not impact in any way the Company's cash balance or its ability to advance its strategic value creation strategy as planned. As a result of the depreciation, the Group reduced the amount of its deferred tax liability, leading to the recording of a tax income of €7.8 million. Non-current operating expenses also reflected the sum of the €9.2 million that the Commercial Court of Paris ordered the Company to pay in its dispute with SpeBio and SpePharm, a decision that the Group has appealed.

2017 **total net loss** was €59.1 million, compared to €22.7 million in 2016.

Consolidated income statement (IFRS) <i>In thousands of euros</i>	31/12/2017	31/12/2016
Revenues, of which:	9,505	4,423
<i>Recurring revenues</i>	3,042	3,454
<i>Non-recurring revenues</i>	6,463	969
Operating expenses, of which	(28,694)	(27,591)
<i>R&D expenses (net of R&D tax credit)</i>	(18,857)	(18,075)
Operating income/(loss) before non-recurring items	(19,189)	(23,168)
Non-recurring operating income, of which	(47,188)	(43)
<i>impairment of R&D assets related to Beleodaq®</i>	<i>(38,111)</i>	-
Financial income	(491)	1,106
Income tax	7,797	(566)
Net profit/loss	(59,071)	(22,671)

CASH POSITION AT DECEMBER 31, 2017

At December 31, 2017, the Company had a consolidated cash position of €14.3 million compared with €29.2 million at December 31, 2016.

Excluding the net proceeds of €14 million from the successful international private placement completed in June 2017 and the €9.2 million owed to SpeBio and SpePharm, cash burn amounted to €19.7 million over the period, which is related to the Company's operating costs, including research and development expenses.

The reduction in operating expenses as of 2018, including the cost reduction measures implemented following the conclusion of the Livatag® program, combined with the resources currently available, enable Onxeo to extend its cash runway until mid-2019 and thus to cover planned activities until the next value-creating inflexion points.

¹ Refer to March 14, 2018 press release published by the company and available on the Company's website



Annual and consolidated 2017 accounts were approved by the Board of Directors on March 29, 2018 and will be submitted to shareholders approval on May 16th, 2018.

RECENT CORPORATE HIGHLIGHTS AND EXPECTED 2018 MILESTONES

- **AsiDNA™**

- Presented in-vivo study results at AACR in April 2017, demonstrating the therapeutic potential of combining AsiDNA™ with PARP (Poly ADP-Ribose Polymerase) inhibitors
- Generated positive in-vivo proof-of-concept results in July 2017 that confirmed the activity of AsiDNA™ by systemic administration (intravenously)
- Reported compelling in-vitro pre-clinical results in September 2017 demonstrating the association of AsiDNA™ with histone deacetylase inhibitors (HDACi), including belinostat, on various tumor lines
- Obtained a composition of matter patent in Europe in January 2018 covering multiple products, including AsiDNA™, providing protection until 2031, with a potential extension to 2036. Together with previously granted patents, Onxeo's intellectual property for DNA-targeting technologies, products and combinations is now protected by 10 patent families worldwide.
- Announced that the results of two pre-clinical studies highlighting the potential of AsiDNA™ as an anti-cancer treatment were accepted for poster presentations at the 2018 AACR Annual Meeting in April 2018.

Onxeo has filed submission dossier of a dose-escalation phase I study (DRIIV) with AsiDNA™ as a systemic single therapy in solid tumors to regulatory authorities in France and Belgium at the end of 2017. This study is expected to start shortly and aims to confirm the potency of AsiDNA™ via systemic administration, its safety profile and optimal clinical dose. First results are expected before the end of 2018.

Based on these phase I DRIIV preliminary data and the in vivo results of the various combinations which are currently explored, notably with belinostat, the Company intends to initiate a clinical trial with the most relevant association by the end of 2018.

- **platON™**

- Onxeo intends to leverage platON™ to expand its pipeline with additional innovative DNA-targeting drug candidates and expects to initiate the preclinical evaluation of a new drug candidate before the end of 2018.

- **Belinostat**

- Onxeo conducted extensive preclinical studies to evaluate the association of belinostat, which creates double-strand tumor DNA breaks, and AsiDNA™, which interferes with their repair. These studies yielded promising results that will be presented to the scientific community during one of the two poster presentations at AACR 2018. The Company is further undergoing in vivo experiment to confirm these data and if relevant, could initiate a clinical trial on the use of these two key compounds in combination in 2018.
- The Company also develops an oral formulation of belinostat, which is currently only available intravenously. Beyond significant benefits for patients and physicians in terms of ease of administration, oral belinostat would also provide Onxeo with the opportunity to potentially extend its patent protection around belinostat until 2038 and support the rationale of developing belinostat in combination with other drugs for new indications.
- Beleodaq® (IV form of belinostat), already conditionally approved by the U.S. Food and Drug Administration as 2nd-line treatment for patients with peripheral T-cell lymphoma (PTCL) and currently marketed in the US by Spectrum Pharmaceuticals, is expected to begin a phase III trial, conducted by Spectrum, to assess Beleodaq® in 1st-line treatment of PTCL.

- **Monetization of non-strategic products**

- Monetized multiple non-core assets by:
 - Divesting two products in oral pathologies, Sitavig® and Loramyc®, for a total upfront payment of €4 million. Onxeo is also eligible to receive potential earn-out payments based on the cumulative worldwide commercial performance of the products.



- Granting a global exclusive license of Validive®, Onxeo's phase III-ready product for the treatment of severe oral mucositis induced by radiotherapy or chemotherapy in patients suffering from head and neck cancer, to Monopar Therapeutics for an immediate \$1.0 million license fee and potential future milestone payments.

UPCOMING FINANCIAL PUBLICATIONS & EVENTS

- **Q1 2018 financial information:** Friday, May 4, 2018, after market
- **Shareholder's general meeting on the first call:** Wednesday, May 16, 2018
- **Shareholder's general meeting on the second call** (if the required quorum was not reached at the first AGM): Tuesday, June 19, 2018

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's R&D pipeline includes **belinostat**, an HDAC inhibitor (epigenetics) currently being developed in oral form to 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 2nd 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).

Onxeo is also 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 developed for systemic (IV) administration in solid tumors.

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 new compounds that will broaden Onxeo's pipeline.

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 5.5.1.4 "Risk Factors" ("*Facteurs de Risque*") of the 2016 reference document filed with the *Autorité des marchés financiers* on April 24, 2017 under number D.17-0423, 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 31 DECEMBER 2017

The complete 2017 full-year financial report will be available within the legal deadlines on the Company's website.

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS (€k)	31/12/2017	31/12/2016
Non-current assets		
Intangible assets	47,535	87,213
Property, plant and equipment	344	713
Long-term investments	232	306
Deferred tax assets	0	0
Total non-current assets	48,111	88,232
Current assets		
Inventories and work in progress	30	184
Trade accounts receivable and related accounts	740	1,548
Other accounts receivable	15,810	5,893
Financial investments	0	5,302
Cash and cash equivalents	14,277	23,941
Total current assets	30,857	36,868
TOTAL ASSETS	78,073	78 073

LIABILITIES AND SHAREHOLDERS' EQUITY (€k)	31/12/2017	31/12/2016
Shareholders' equity		
Share capital	12,674	11,761
Less: treasury shares	-89	-97
Share premium	269,060	255,960
Reserves	(172,700)	(150,864)
Earnings	(59,071)	(22,671)
Total shareholders' equity	49,873	94,089
Non-current liabilities		
Deferred tax liabilities	4,094	11,895
Provisions	550	637
Other liabilities	4,714	6,062
Total non-current liabilities	9,358	18,594
Current liabilities		
Short-term debt	130	106
Trade payables and related accounts	5,956	9,246
Other liabilities	12,755	3,065
Total current liabilities	18,842	12,417
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	78,073	125,100



CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

in thousands of €	31/12/2017	31/12/2016
Recurring revenue	3,042	3,455
Non-recurring revenue	6,463	969
Total revenue	9,505	4,423
Purchases	(634)	(655)
Personnel costs	(8,217)	(6,984)
External expenses	(17,555)	(17,129)
Taxes and duties	(367)	(223)
Net decrease in depreciation and amortisation	(1,796)	(1,864)
Net allocations to provisions	74	(628)
Other operating income	4	122
Other operating expenses	(203)	(229)
Operating expenses	(28,694)	(27,591)
Loss from recurring operating	(19,189)	(23,168)
Share of loss of associates	0)	(43)
Other operating income and expenses	47,188	0
Operating loss after share of loss of associates	(66,376)	(23,212)
Income from cash and cash equivalents	13	680
Other financial income	615	1,076
Financial expenses	(1,119)	(649)
Net financial income (expense)	(491)	1,106
Pre-tax loss	(66,867)	(22,106)
Tax expense	7 797	(566)
- Of which deferred tax	7,801	538
Net loss	(59,071)	(22,671)
Earnings per share	(1.17)	(0.48)
Diluted earnings per share	(1.17)	(0.48)

in thousands of €	31/12/2017	31/12/2016
Loss for the year	(59,071)	(22,671)
Other comprehensive income	0	0
Translation adjustments	(2,528)	(701)
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	(2,528)	(701)
Actuarial gains and losses	7	(57)
Other items that may not be classified to profit or loss	78	(57)
Other comprehensive income for the year, net of tax	(2,522)	(758)
Total comprehensive income for the year	(61,592)	(23,429)
Total comprehensive income attributable to the owners of the parent company	(61,592)	(23,429)
Minority interests		



CONSOLIDATED NET CASH FLOW STATEMENT

K€	31/12/2017	31/12/2016
Consolidated net loss	(59,071)	(22,671)
+/- Depreciation, impairment and provisions, net (1) (excluding provisions against working capital)	40,253 0	1,606 0
+/- Unrealized gain and losses associated with changes in fair value	0	0
+/- Non cash income and expenses on stock options and similar items	980	482
+/- Other calculated income and expenses	(137)	109
+/- Capital gains and losses on disposal	0	-141
+/- dilution gains and losses	0	
+/- Share of earning associates	0	43
- Dividends (non-consolidated investments)	0	
Gross operating cash flow after cost of net debt and taxes	(17,973)	(20,432)
+ Cost of net debt	492	(923)
+/- Tax expenses (including deferred taxes)	(7,801)	538
Gross Operating cash flow before cost of net debt and taxes	(25,282)	(20,817)
- Taxes paid	0	
+/- Changes in operating WCR (including debt related to employee benefits)	(2,999)	3,208
NET CASH FLOW FROM OPERATING ACTIVITIES	(28,281)	(17,609)
- Expenditures on acquisition of tangible and intangible assets	(65)	(316)
+ Proceeds of disposal of tangible and intangible assets	0	(229)
- Expenditures on acquisition of financial assets	(2)	(7)
+ Proceeds of disposal of financial assets	-0	(5)
+/- Effect on changes in scope of consolidation	0	
+ Dividends received (equity accounted investment)	0	
+/- Change in loans and advance granted	0	
+ Capital grants received	0	
+/- Other changes from investment transactions	0	2,406
NET CASH FLOW FROM INVESTING ACTIVITIES	(67)	1,849
Cash flow resulting from the merger	0	0
+ Net amount received from shareholders on capital increase		
. Paid by shareholders of the parent company	14,012	12,122
. Paid by minority interest in consolidated companies		
+ Amount received on exercise of stock options		
+/- Purchase and Sale of treasury shares	(68)	60
- Dividends paid in the year		
- Dividends paid to minority shareholders in consolidated companies		
'- Dividends paid to minority shareholders		
+ Amounts received on issuances of new loans		
- Reimbursements of loans (including finance leases)	(154)	(213)
- Net interest received		
+/- Others flows related to financing activities	(354)	
NET CASH FLOW FROM FINANCING ACTIVITIES	13,437	11,968
+/- Effects of fluctuations in foreign exchange rates	(55)	(758)
CHANGE IN CASH AND CASH EQUIVALENTS	(14,966)	(4,549)
CASH AND CASH EQUIVALENTS at start of year	29,243	33,793
CASH AND CASH EQUIVALENTS at year end	14,277	29,243