

Onxeo Reports First-Half 2017 Results and Business Update

- Sound cash position of €27.7m as at June 30, 2017 and cash runway till Q1 2019
- Development of the core assets on track with multiple short-term milestones
 - Livatag® Phase III results expected before the end of September 2017
 - Preclinical results of Beleodaq® in other indications / combinations expected by the end of September 2017
 - AsiDNA™ (systemic administration) Phase I trial submission planned by the end of 2017

Paris, July 28, 2017 – 7:00 pm CEST. Onxeo S.A. (Euronext Paris, NASDAQ Copenhagen: ONXEO), a clinical-stage biotechnology company specializing in the development of innovative drugs for the treatment of orphan diseases, in particular in oncology, today reported its consolidated half-year financials to June 30, 2017, and provided an update on the key achievements over the first six months of the year as well as its recent developments.

“The first half of 2017 was marked by a strong momentum in all areas of Onxeo’s activity. First of all, we completed, on schedule, the enrollment for our ReLive trial in the treatment of primary liver cancer with Livatag®, our most-advanced drug candidate. The DSMB¹ of ReLive delivered its 10th unanimous positive recommendation to continue the trial, thus confirming the compound’s acceptable tolerance profile, and we’re now expecting the preliminary efficacy results before the end of September. Over the half year, we continued the exploratory preclinical program with Beleodaq® in other indications or combinations, with first results expected at the end of the third quarter of 2017. Our most significant scientific achievement so far this year was the preclinical proof of concept of AsiDNA™ activity via intravenous administration, thereby considerably expanding its potential. These robust preclinical data provide a solid foundation from which to advance this first-in-class DNA repair inhibitor towards clinical development. Last but not least, from a financial perspective, we successfully completed a €15m private placement with prominent US and European investors who showed a keen interest in supporting the ramp-up in our strategic programs.” said Judith Greciet, CEO of Onxeo.

H1 2017 CONSOLIDATED FINANCIAL STATEMENT

Financial statements have been subject to a limited review by the Company’s statutory auditors.

Consolidated financial statements (IFRS) <i>In thousands of euros</i>	30/06/2017 (6 months)	30/06/2016 (6 months)
Revenues, of which :	3,367	1,878
<i>Recurring revenues</i>	1,893	1,824
<i>Non-recurring revenues</i>	1,474	54
Operating expenses, of which	(14,674)	(13,043)
<i>R&D expenses (net of R&D tax credit)</i>	(10,481)	(8,534)
Operating profit/loss	(11,324)	(11,185)
Financial income	(338)	(210)
Income tax	35	167
Net profit/loss	(11,627)	(11,227)

¹ The Data Safety Monitoring Board is a Committee of independent European experts in charge of the blind review of the trial tolerance data.



Revenues for the first half of 2017 increased by 79% to €3.4 million and consisted of:

- €1.9m in recurring revenue resulting from the sale of products to Onxeo's commercial partners and royalties on sales.
- €1.5 in non-recurring revenue, the significant increase compared to the first half of 2016 corresponding essentially to the phased IFRS recognition of the initial payment associated with the exclusive license agreement signed with Pint Pharma in 2016.

Operating expenses stood at €14.7 million for H1 2017, a 12.5% increase compared to the same period in 2016, due to the deployment of R&D activities. This included notably the launch of the AsiDNA™ industrial and preclinical programs, acquired in March 2016, for which the Company has set up an ambition development plan. In addition, the Company has continued its phase III clinical trial with Livatag®, and has also continued its preclinical development program for Beleodaq®. In parallel, a tight control has been maintained over other operating expenses in order to optimize the company's cash burn.

Financial income was mainly impacted by exchange rate variances resulting from the company's operations as well as its assets denominated in foreign currency.

All in all, the net loss for the semester was comparable to last year.

SOUND CASH POSITION OF €27.7 MILLION

At June 30, 2017, the Company had a sound consolidated cash position of €27.7 million, including gross proceeds of €15 million from the capital increase resulting from the late June 2017 private placement with US and European investors. Taking into account the €3.9 million reimbursement of 2016 Research Tax Credit expected in 2017, Onxeo's cash runway extends up to Q1 2019.

H1 2017 HIGHLIGHTS AND RECENT DEVELOPMENTS

- **Livatag®**
 - Completion in January 2017 of the enrollment and randomization of 390 patients for the phase III study (ReLive) to assess the efficacy of Livatag®, a nanoformulation of doxorubicine (doxorubicine Transdrug™), in treating advanced hepatocellular carcinoma (HCC).
 - Notice of Allowance received in May 2017 from the U.S. Patent and Trademark Office for a patent application covering the specific route of administration for Livatag®.
 - 10th unanimous positive DSMB recommendation to continue the ReLive trial received in late May 2017.
 - First readout of the ReLive trial expected before the end of September 2017.
- **Beleodaq®**
 - Preparatory work ongoing at Spectrum Pharmaceuticals to prepare a phase III trial assessing Beleodaq as a first-line treatment for Peripheral T-Cell Lymphoma (PTCL).
 - Managed access program for patients with PTCL in several European countries launched at the end of April 2017 with Clinigen.
 - Ongoing exploratory preclinical program in other indications/combinations with first results expected end of September 2017.
- **AsiDNA™**
 - Partnership signed with the Institut Curie in January 2017 to investigate the benefits of combining the Company's first-in-class DNA repair inhibitor with radiotherapy and immunotherapy in the treatment of drug-resistant cancers.
 - Additional patent granted in February 2017, extending protection of AsiDNA™ in the USA.
 - Positive in vivo proof-of-concept results released early July 2017 confirming the activity via systemic (intravenous) administration of AsiDNA™; Company on track to file a phase I trial submission dossier to regulatory authorities by the end of 2017.



• Corporate Governance

- At the beginning of 2017, Onxeo appointed two seasoned executives to accelerate preclinical and clinical development of its orphan oncology programs:
 - Françoise Bono, PhD, was named Chief Scientific Officer to lead preclinical activities;
 - Olivier de Beaumont, MD, MBA, was appointed Chief Medical Officer to lead clinical development and operations, medical and regulatory affairs.
- The Annual General Meeting of April 26, 2017, approved the appointment of two new independent directors, Mrs. Christine Garnier and Mrs. Elvira Sanz Urgoiti, both acknowledged experts from the pharmaceutical industry. Onxeo's Board of Directors has 9 members, out of which 7 independent Directors and over 40% of women.

About Onxeo

Onxeo is a biotechnology company developing innovative drugs for the treatment of orphan diseases in oncology, driven by high therapeutic demand in one of the fastest growing segments of the pharmaceutical industry.

Onxeo's objective is to become a major international player in the field of rare cancers. Its growth strategy is founded on the development of innovative, effective and safe drugs based on breakthrough technologies that can make a real difference in the treatment of orphan oncology diseases and considerably improve the quality of life of patients affected by rare or resistant cancers.

Onxeo's comprehensive portfolio features a broad orphan oncology pipeline, with 3 major products in several on-going preclinical and clinical programs, alone or in combination for various cancer indications:

- **Livatag[®]** (Doxorubicin Transdrug[™]): Currently evaluated in the treatment of Hepatocellular carcinoma (HCC, also called primary liver cancer) in a phase III trial, ReLive. ReLive is a randomized, international trial designed to demonstrate the efficacy and the safety of Livatag[®] compared to the best available treatment chosen by the physician in 390 patients with advanced HCC after failure or intolerance to sorafenib.
- **Beleodaq[®]** (belinostat): FDA conditional approved in the US in 2014 under the agency's accelerated approval program as a second-line treatment for patients with peripheral T-cell lymphoma (PTCL) and currently marketed by Onxeo's partner in the US, Spectrum Pharmaceuticals; belinostat in combination with other anti-cancer agents is currently in development in first-line treatment for patients with PTCL (BeLCHOP) and in solid tumors.
- **AsiDNA[™]**: The first-in-class siDNA (signal-interfering DNA) which has successfully undergone a proof-of-concept Phase I trial with a local administration in metastatic melanoma. The recent positive preclinical proof-of-concept results confirmed AsiDNA[™] activity via systemic administration in a murine model of triple negative breast cancer (TNBC).

The Company is headquartered in Paris, France with offices in Copenhagen and in New York, and has approximately 60 employees. Onxeo is listed on Euronext in Paris, France and Nasdaq Copenhagen, Denmark (Ticker: ONXEO, ISIN Code: FR0010095596).

Learn more by visiting 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).



Onxeo

Valerie Leroy,
Investor Relations
investors@onxeo.com
+33 1 45 58 76 00

Media Relations

Caroline Carmagnol / Laetitia Abbar
Alize RP
alize-onxeo@alizerp.com
+33 6 64 18 99 59 / +33 6 47 38 90 04

**Investor Relations / Strategic
Communications**

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 - HALF YEAR CONSOLIDATED ACCOUNTS AS AT 30 JUNE 2017

The full 2017 half-yearly financial report will be available on the [Company's website](#).

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

ASSETS in K€	30/06/2017	31/12/2016
Non-current assets		
Intangible assets	86,442	87,213
Tangible assets	644	713
Financial assets	337	306
Deferred tax assets	0	0
Total non-current assets	87,423	88,232
Current assets		
Stock and work-in-progress	18	184
Trade receivables	2,071	1,548
Other receivables	8,332	5,893
Financial investments	3,202	5,302
Cash	24,452	23,941
Total current assets	38,075	36,868
TOTAL ASSETS	125,498	125,100

LIABILITIES AND SHAREHOLDERS' EQUITY K€	30/06/2017	31/12/2016
Shareholders' equity		
Share capital	12,643	11,761
Less: treasury shares	-96	-97
Premium	269,195	255,960
Reserves	-173,301	-150,864
Earnings	-11,627	-22,671
Total shareholders' equity	96,814	94,089
Non-current liabilities		
Deferred tax liabilities	11,860	11,895
Provisions	558	637
Other financial liabilities	4,715	4,723
Other liabilities	574	1,339
Total non-current liabilities	17,706	18,594
Current liabilities		
Short-term financial debt	155	106
Trade payables and related accounts	7,835	9,246
Other liabilities	2,987	3,065
Total current liabilities	10,977	12,417
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	125 498	125 100



CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

In K€	30/06/2017	30/06/2016
Recurrent sales from licensing agreement	1,893	1,824
Non-current sales from licensing agreement	1,474	54
Total sales	3,367	1,878
Purchases	-415	-298
Personnel costs	-3,716	-3,455
External expenses	-9,672	-8,484
Duties and taxes	-179	-155
Depreciation and amortization, net	-900	-912
Allowances to provisions, net	969	327
Other operating income	3	30
Other operating expenses	-765	-95
Operating expenses	-14,674	-13,043
Current operating income	-11,307	-11,165
Share of income under the equity method	-17	-20
Other operational income and expenses	0	0
Operating income after share of income under the equity method	-11,324	-11,185
Income from cash and cash equivalents	530	188
Other financial income	16	39
Financial expenses	-884	-436
Financial income	-338	-210
Pre-tax income	-11,663	-11,395
Income tax	0	0
-of which deferred tax	35	167
Net profit/loss	-11,627	-11,227
Earnings per share	(0,23)	(0,27)
Diluted earnings per share	(0,23)	(0,27)

OTHER ELEMENTS OF THE STATEMENT OF COMPREHENSIVE INCOME

In K€	30/06/2017	30/06/2016
Income for the period	-11,627	-11,227
Other comprehensive income	0	0
Translation adjustments	955	-203
Losses and gains on derecognition of assets available for sale	0	0
Cash flow hedges	0	0
Tax related to elements of the comprehensive income	0	0
Other items recycled as income	955	-203
Actuarial gains and losses	-21	-80
Other non-recyclable items classified as income	-21	-80
Other elements of the comprehensive income for the period net of taxes	934	-283
Total comprehensive income for the period	-10,693	-11 510
Total comprehensive income attributable to :		
- Owners of the parent company	-10,693	-11,510
- Minority interests		



CONSOLIDATED NET CASH FLOW STATEMENT

In K€	30/06/2017	31/12/2016	30/06/2016
Consolidated net loss	-11,627	-22,671	-11,227
+/- Depreciation, impairment and provisions, net (excluding provisions against working capital)	949	1,606	386
-/+ Unrealized gains and losses associated with changes in fair value		0	0
+/- Non-cash income and expenses on stock options and similar items	249	482	113
-/+ Other calculated income and expenses	-92	109	140
-/+ Capital gains and losses on disposal	0	0	0
-/+ Dilution gains and losses			0
+/- Share of earning associates	17	43	20
- Dividends (non-consolidated equity)			0
Gross operating cash flow after net cost of debt and tax	-10,504	-20,432	-10,568
+ Cost of financial debt, net	338	-923	218
+/- Tax liabilities (including deferred tax)	35	538	-167
Gross operating cash flow before net cost of debt and tax	-10,130	-20,817	-10,517
- Taxes paid			0
+/- Changes in operating WCR (including debt related to employee benefits)	-5,547	3,208	-4,122
NET CASH FLOW FROM OPERATING ACTIVITIES	-15,677	-17,609	-14,639
- Expenditures on acquisition of tangible and intangible assets	-25	-316	-97
+ Proceeds of disposals of tangible and intangible assets	2	-229	0
- Expenditures on acquisition of financial assets (non-consolidated equity)	-2	-7	0
+ Proceeds of disposals of financial assets (non-consolidated equity)	2	-5	-111
+/- Impact of perimeter variations			0
+ Dividends received (non-consolidated equity, associated companies)			0
+/- Changes in agreed upon loans and advances			0
+ Investment grants received			0
+/- Other cash flow from investment activities		2,406	0
NET CASH FLOW FROM OPERATING ACTIVITIES	-23	1,849	-208
Cash flow from merger	0	0	0
+ Amounts received from shareholders at capital increases			0
. From parent company shareholders	14,702	12,122	1,000
. From minority interest of merged entity			
+ Amounts received from stock options			0
-/+ Buy-back and resale of treasury shares	1	60	36
- Dividends paid during period			0
. To shareholders of parent company			0
. To minority interests of merged entity			0
+ Proceeds of new loans		0	0
- Reimbursement of loans (including finance leases)	-320	-213	143
- Net interests paid (including finance leases)	0	0	0
+/- Other flows related to financing activities	-229	0	-243
NET CASH FLOW FROM FINANCING ACTIVITIES	14,155	11,968	936
+/- Impact of fluctuations in foreign exchange rates	-44	-758	-283
CHANGES IN CAHS AND CASH EQUIVALENTS	-1,590	-4,549	-14,194
CASH AND CASH EQUIVALENTS at start of period	29,243	33,793	33,793
CASH AND CASH EQUIVALENTS at end of period	27,654	29,243	19,598