2014 Onxeo Review and 2015 Perspectives

2014 Consolidated Financial Results

- **Successful strategic merger and acquisition of Danish company Topotarget giving birth to Onxeo**
- **Products' major achievements:**
  - **Beleodaq® approval in the US for PTCL 2nd line treatment and launch by US partner**
  - **Validive® phase II positive data**
- **FY 2014: proforma net profit of €7.3m (excluding one-time cost) and cash reserves increased to €57.2m**

Paris (France), Copenhagen (Denmark), March 4, 2015 – Onxeo S.A. (Euronext Paris, NASDAQ OMX Copenhagen: ONXEO), an innovative company specializing in the development of orphan oncology drugs, today published its 2014 consolidated accounts and provided a review of its 2014 achievements and a preview of the 2015 perspectives.

"2014 will remain a pivotal year in the Company's history. As first major step of our corporate growth strategy implementation, we merged with Topotarget mid-2014 acquiring Beleodaq®, a promising asset with large potential indications, enlarged the team with seasoned Danish professionals and on top of that, received siginificant milestones from Spectum following Beleodaq® first approval in July.

Besides, our pipeline has also significantly progressed. Notably Validive®,has obtained positive phase II results in the prevention of severe oral mucositis, in which it showed a reduction of incidence of this highly burdening condition

At last, from a financial standpoint, the company has significantly increased it cash reserves ensuring a stronger position and allowing to reach full speed in the development of our promising coumpounds.

Overall, 2014 will remain as the year when the company has become the Orphan Oncology Innovator, symbolically marking its transformation with the new name Onxeo.

I would like to specially thank my team for achieving these ambitious goals, going through this transformation to build the new Onxeo. I also thank all our shareholders, institutional and individual, for their support and confidence throughout this unique year and express to them all our utmost commitment to success", said Judith Greciet, CEO of Onxeo.

2014 Highlights and perspectives

Expansion of key orphan oncology programs

Company's key orphan oncology programs Validive®, Livatag® and Beleodaq® are high added-value programs focusing on significant and unmet medical needs, showing strong sales potential. In 2014, the team has reached important development milestones, which contributed to increase the overall company value:

Beleodaq® (belinostat)

- In July 2014, the Food and Drug Administration (FDA) granted conditional marketing authorization in the USA for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL) in 2nd line treatment after failure of standardized chemotherapy used in first line (CHOP protocol). As per contract, this approval has triggered a $25 million milestone payment from Spectrum Pharmaceuticals which was received in November. The commercialization of Beleodaq® by the Spectrum Pharmaceuticals' oncology sales team has started in late July 2014 with positive level of sales estimated to around 5M USD, resulting in first royalties for Onxeo.
- Following this conditional marketing authorization in 2nd-line PTCL, a Beleodaq® Phase III trial is planned to be initiated H1 2016 for the same PTCL patients but in first line of treatment, combined with CHOP, expanding therefore the indication from 2nd to 1st line of treatment.
- Prior to this Phase III initiation, a phase I study with the combined treatment Beleodaq® + CHOP (BelCHOP) is ongoing to determine the optimal dose of the combination and its safety profile. This study is expected to recruit up to 28 patients by Q3 2015 and is the preliminary step of the phase III trial. .
- Beyond PTCL, Beleodaq® profile and first data advocate for the development of new promising orphan oncology indications. The company is currently discussing with its partner to finalize future product development plans.

Validive® (clonidine Lauriad®)

- End of October 2014, Onxeo reported positive preliminary top-line results of the large international Phase II trial comparing the efficacy and safety of Validive® versus placebo in the prevention of oral severe mucositis in 183 head and neck cancer patients. Validive® has shown to reduce of 16% (absolute value) the incidence of severe oral mucositis in treated patients versus placebo, to delay the occurrence of the mucositis and allow a higher intensity of radiation before appearing. The safety profile of Validive® was very good with no major safety issue.
- The study's advisory committee, made up of internationally recognised experts, has confirmed that these data were supportive to further pursue Validive® development plan and recommended advancing its development program through a Phase III study on the same patient population. This Phase III trial evaluating Validive®'s efficacy is being prepared and the Company plans to initiate it in 2015.
- Validive®'s development will benefit from the "fast track" status obtained from the Food and Drug Administration in January 2014. This status is granted for drugs developed for life-threatening diseases for which the medical need is strong. It facilitates interactions with the FDA and optimizes review duration during development and registration.
- Oral mucositis is a very severe adverse effect of chemoradiation therapy which, at a severe stage, is highly painful and debilitating. There is no current preventing option for such disease and the need for such treatment is particularly high.

Livatag® (doxorubicin Transdrug™)

- Active recruitment in the Phase III trial ReLive in primary liver cancer, with 40 % of planned patients already randomized. In 2015, the international expansion of ReLive will be supported by broadening the ReLive trial into new regions such as MENA (Middle East North Africa) countriesto optimize recruitment rate.
- The product safety profile has been so far confirmed, twice again in 2014, by the trial's Data Safety Monitoring Board who meets twice a year to review all the safety data of the treated patients.
- Livatag® also obtained FDA "fast track" status for treating hepatocellular carcinoma as a second-line treatment after sorafenib In addition, the product's patent protection was reinforced in February 2014 with a new family of patents protecting its specific dosing regimen, and issued by the European Patent Office. This second patent family significantly strengthens and extends the product's patent protection in Europe until 2032 against the marketing of generics.

Major development for the Company, the creation of Onxeo, resulting from the merger of BioAlliance Pharma and Topotarget

2014 was a cornerstone year for the Company which became Onxeo in August, through the merger between BioAlliance Pharma SA and Topotarget A/S. This was a major first step in the company growth strategy implementation .

This operation has enabled the company to gain critical mass in orphan oncology, its strategic field, as a European player with competitive advantages:

- An enlarged and advanced clinical pipeline,
- A reinforced team with strong scientific skills,
- A US based co- development and commercial partner on Beleodaq®,

Onxeo is listed on both Euronext and Nasdaq OMX in Copenhagen. The market capitalization has reached the 250 M€ threshold, which positions the company among the leading biotechs in Europe.

2014 consolidated financial information

2014 consolidated accounts reflect the successful implementation of Onxeo growth strategy through the merger with Topotarget. The strategic partnership attached to lead product Beleodaq® has indeed brought to the company significant revenues consisting of cash milestone payments from Spectrum Pharmaceuticals as well as 1 million Spectrum shares, sold by Onxeo during the Summer. These revenues, together with the new financing organized end 2014 have significantly strengthened the overall cash position.

The accounting of the merger has the following consequences in the consolidated accounts:

- The operation itself is booked as an acquisition, for the total consideration of €83.4m. After deduction of the book value of contributed assets and liabilities, the preliminary goodwill of €44.3m has been entirely allocated to intangible assets, representing acquired IP R&D and synergies.

	31/12/2014	31/12/2013

Intangible assets	87 932	23
Other non-current assets	1 120	1 277
Current assets	5 720	5 104
Cash and cash equivalents	57 227	11 328
TOTAL ASSETS	**151 999**	**17 732**
Shareholder's equity	121 971	7 888
Differed tax losses	13 805	0
Liabilities	16 223	9 843
TOTAL LIABILITIES	**151 999**	**17 732**

- The merger accounting effective date being June 30, 2014, the consolidated P&L account does not include the activity of Topotarget over H1. In order to facilitate the reading of the accounts, a proforma consolidated P&L account is presented below to reflect the merger as if it had occurred on January 1, 2014. Consolidated P&L is also presented below.

€ '000	**31/12/2014 proforma**	**31/12/2014**	**31/12/2013**
Recurring revenues from licensing agreements	1 625	1 625	755
Non recurring revenues from licensing agreements	33 674	20 455	530
Other revenues	1	1	181
Total revenues	**35 300**	**22 081**	**1 467**
Purchases	(249)	(249)	(264)
Personnel expenses	(8 266)	(7 116)	(5 347)
External charges	(14 646)	(13 563)	(10 687)
Taxes other than on income	(311)	(311)	(298)
Depreciation and amortization, net	(1 025)	(972)	(233)
Allowances to provisions, net	(63)	(63)	60
Other operating income		0	5
Other operating expenses	(424)	(424)	(125)
Total operating expenses	**(24 983)**	**(22 697)**	**(16 888)**
Current operating income / (loss)	**10 317**	**(616)**	**(15 422)**
Share of results of associates	(77)	(77)	(29)
Other non-current operating income and expense	(9 734)	(4 861)	0
Operating income / (loss)	**505**	**(5 554)**	**(15 450)**
Financial income	**55**	**5**	**126**
Income tax	(2 966)	(2 150)	0
Net income/(loss)	**(2 406)**	**(7 699)**	**(15 325)**

Net income/ (loss) excluding non-current expenses (one-time costs)	**7 328**	**(2 838)**	**(15 325)**

Revenues on a proforma basis are mostly driven by non-recurring items linked with license agreements. Beyond the milestones and the 1 million shares received from Spectrum upon registration of Beleodaq® for a total of $43m (out of which $25m over H2), Onxeo also booked a $2m upfront payment from new partner Innocutis (Sitavig®). Recurring revenues grow as well as a result of the simultaneous launch in the Summer 2014 of Beleodaq® and Sitavig® in the United States.

Operating expenses are naturally impacted by the new perimeter of the company, with additional workforce from former Topotarget, based in Onxeo Danish branch in Copenhagen, and the new R&D program with Beleodaq®. As a whole, R&D expenses in the consolidated accounts on a proforma basis

increase by 48%, from €10m to €14.8m, due to Beleodaq® developments in first indication PTCL and also the deployment of Livatag® international phase III in HCC and relating clinical manufacturing program.

Consolidated accounts are significantly impacted by two non-recurring items:

- Merger-related costs of €4.8m (proforma €9.7m)
- An income tax due by the Danish branch on Beleodaq® revenues of €2.2m (proforma €3m)

Excluding these non-recurring costs, Onxeo consolidated annual result is a loss of €2.4m and on a proforma basis a profit of €7.3m.

From a cash standpoint, 2014 has been a year of considerable change : cash reserves have soared from €15.5m to €57.2m, due to the Spectrum milestones as well as the capital increase completed in December 2014. This financing, together with Financière de la Montagne shareholder's loan brought total net proceeds of €37.5m at year-end.

"The successful implementation of our merger is clearly shown by the quality of acquired assets, source of immediate and significant revenues and cash additions", said Nicolas Fellmann, Chief Financial Officer of Onxeo. *"The strengthened cash position provides a visibility of over two years and enables us to pursue an optimized and efficient development of our R&D programs, while at the same time monitoring closely other operating expenses".*

Onxeo will comment on major current issues and its annual financial statements during its SFAF meeting which will be held on March 5, 2015 at 9:30am at the Company's headquarters (49 boulevard Martial Valin, Paris 15°, France), and during the audio/web conference the same day at 5:30 pm:

Tel: +33 (0)1 70 77 09 43
Webconference:
http://anywhereconference.com?UserAudioMode=DATA&Name=&Conference=135292673&PIN=473081
Audio Playback Numbers : +33(0)1 72 00 15 00
Audio Playback Reference : 292673

About PTCL

Lymphoma is the most common blood cancer. Hodgkin's and non-Hodgkin's lymphoma are the main two forms of lymphoma. The lymphoma survives when the lymphocytes, a type of white blood cell, increase abnormally and accumulate in one or more lymphatic ganglions or in lymphatic tissue. Two types of lymphocytes may develop: B lymphocytes (B cells) and T lymphocytes (T cells). Peripheral T-Cell Lymphoma (PTCL) is a sub-type of non-Hodgkin's lymphoma. In the United States, PTCL accounts for around 10 to 15% of non-Hodgkin's lymphoma and its global incidence is estimated at 12,000 cases each year.

About oral mucositis

Severe oral mucositis is a particularly invalidating pathology induced by radio/chemotherapy treatments and very frequent in patients with head and neck cancer. It may induce intense oral pain and eating disability requiring enteral or parenteral nutritional support. Thirty per cent of patients need to be hospitalized as a result and

symptoms can force patients to stop treatment for an undefined period thus reducing treatment efficacy. Oral mucositis has currently no validated curative or preventive treatment.

About primary liver cancer, or HepatoCellular Carcinoma

Hepatocellular carcinoma (HCC) or hepatocarcinoma is the most common of the primary liver cancers (85% to 90%). It is an aggressive cancer which is resistant to chemotherapy. It is the second highest cause of death from cancer worldwide. It is commonly diagnosed at an advanced stage at which time few therapeutic alternatives exist, presenting a strong therapeutic need. The risk factors are well known: infection by hepatitis viruses (B and C), overconsumption of alcohol (another major cause of cirrhosis) and metabolic diseases, especially obesity, a growing cause of cirrhosis and HCC.

About Onxeo

Onxeo has the vision to become a global leader and pioneer in oncology, with a focus on orphan or rare cancers, through developing innovative therapeutic alternatives to "make the difference". The Onxeo teams are determined to develop innovative medicines to provide patients with hope and significantly improve their lives.

Key products at advanced development stage are:

Livatag® (Doxorubicin Transdrug™): Phase III in hepatocellular carcinoma
Validive® (Clonidine Lauriad®): Phase II in severe oral mucositis: Positive preliminary top-line results
Beleodaq® (belinostat): registered in the US in peripheral T-cell lymphoma
For more information, visit the website www.onxeo.com

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