ONXEO

THE ORPHAN ONCOLOGY INNOVATOR

A post holiday period marked by turbulent stock markets since the beginning of summer

Dear Onxeo Shareholders,

Over the summer, due to a complex international situation, the financial markets have experienced high volatility, causing stock prices worldwide to fall sharply. Onxeo's stock has been impacted, probably more than some other Biotechs. With this in mind, I want to share with you my conviction that our company has significant, strong assets with many catalysts in the short and medium terms that I believe will enable us to deliver solid, sustained growth.

Onxeo has reached several milestones over the first six months of 2015, and we taken critical steps in our R&D programs. The second half of the year will remain very active and will allow us to demonstrate our capabilities to deliver consistent results in the clinical, scientific and business arenas, as detailed on the following pages.

Our strategy is clear: to develop drugs with high potential, focused on rare cancers, based on innovative technological approaches to address unmet medical needs. Our target market - orphan oncology drugs - is highly dynamic and our pipeline in this area is well advanced, with vast potential. Onxeo's teams are committed to advancing our R&D programs and have the necessary expertise to do so successfully.

We have what it takes to succeed, and I am convinced that while pursuing our growth plan with determination, these fundamentals will be our future growth catalysts. **I truly hope that you, as our shareholders, remain conscious of the company's solid fundamentals and capacity to deliver the expected growth.**

This autumn, we will participate in two events dedicated to retail investors, InvestorDagen in Copenhagen in September and Actionaria conference in Paris in November. We sincerely hope to have the opportunity to meet as many of our shareholders as possible during these meetings.

On the behalf of Onxeo's entire team, I would like to thank you for your continued support and your loyalty, especially in these complex and challenging period.

Judith Greciet, CEO

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September 2015

Orphan Oncology: a highly attractive market

A strong medical need

Orphan status is granted to drugs developed for the treatment of very severe diseases, affecting a small proportion of the population, up to 250,000 cases in the U.S. and 200,000 in Europe, which have a strong need for efficient therapeutic options. Today, 7,000 diseases are considered rare or orphan, and less than 5% currently have available treatments *(Source: EvaluatePharma®)*.

A fast-growing market

The orphan drug market represents a high potential in terms of value creation. It comprises products considered to be the most dynamic in the pharmaceutical sector. **Its expected global sales should reach 176 billion dollars in 2020, with an expected 10%+ growth per year.**

In this market, oncology drugs represent the majority of treatments. It is estimated that among the top 20 selling orphan drugs worldwide in 2020, 15 of them will be for oncology indications.
(Source: EvaluatePharma®).

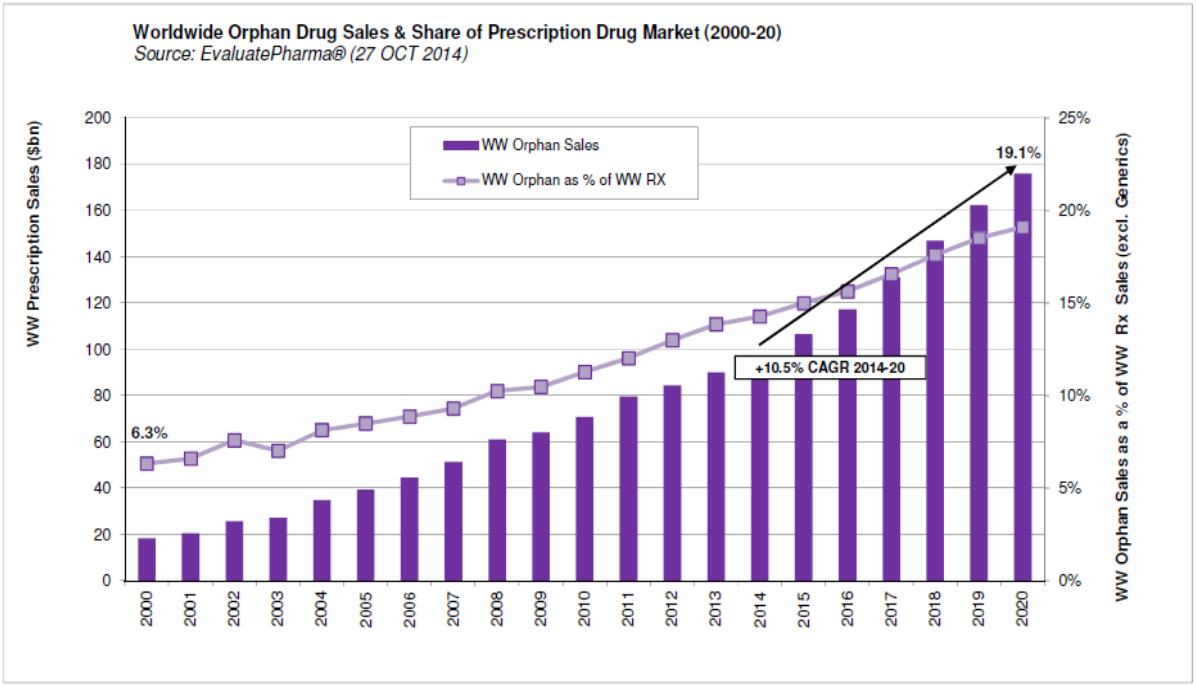
Incentive measures

The growth of orphan drugs results in part from attractive measures put in place by health authorities to foster the development of new drugs in this area and facilitate market access. These incentives include: optimizing clinical development both in terms of time and cost, enabling faster market access, more favorable price and reimbursement environment for differentiated products, and reinforced protection with a commercial exclusivity following the market authorization of 7 years in the US and 10 years in Europe.

These advantages suit Onxeo's business model particularly well, based on our focus on products with cost- and time-optimized development plans while targeting premium, high-value markets.

This confirms the strength of our business model. **All of our programs in this sector have significant sales potential.** Thanks to their « orphan status », already granted by the health authorities, they will benefit from **optimized clinical development and accelerated review and approval from agencies.**

Orphan drugs market is a fast-growing market estimated to reach $176Bn by 2020



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Significant achievements in the first half of 2015 & short and mid term catalysts

Livatag®: Progression of "ReLive" Phase III trial

- **HepatoCellular Carcinoma: (HCC)** a very severe cancer, the 6th most prevalent cancer in the world and the 2nd leading cause of cancer-related death; only one drug is currently approved (sorafenib in advanced HCC) and HCC represents a significant unmet medical need.
- **Livatag®, a novel therapeutic approach for HCC,** based on the innovative «Transdrug™» technology designed to formulate a chemotherapy (doxorubicin) with nanoparticles.
- By specifically accumulating in the liver cells and overcoming resistance to doxorubicin, Livatag® represents a potential significant breakthrough in the treatment of HCC.
- **ReLive:** an international clinical trial based on Phase II results that showed a doubling of the median survival duration in treated patients.
  - 50% of patients randomized (total of 400 planned patients) and more than 100 patients already treated with Livatag®.
  - In April, the 6th Data Safety Monitoring Board (DSMB) has delivered a positive assessment and confirmed Livatag®'s safety profile.
  - Trial implemented in 11 countries (Europe + U.S.) including four new ones opened in regions with a high prevalence of HCC, enabling us to increase the recruitment rate.
  - Expected preliminary outcomes of the Phase III by 1H 2017.

- **October 2015: 7th DSMB reviewing Livatag®'s safety profile.**

- **1H 2017: Preliminary outcomes of Phase III trial.**

Complete press releases on www.onxeo.com.

Beleodaq®: Phase I data in a new indication expected by year-end 2015 (PTCL 1st line)

- Already registered and commercialized in the U.S. as a **2nd line treatment for PTCL** (Peripheral T-Cell Lymphoma, a type of rare non hodgkin lymphoma) by our partner Spectrum Pharmaceuticals.
- **A pan-HDAC inhibitor** with a mechanism of action that provides broad clinical potential, alone or in association with other anticancer treatments. As a result, Beleodaq® has interesting clinical potential in **multiple orphan indications.**
- **Strong scientific recognition**
  - Publication of the pivotal Phase II BELIEF trial data in the *Journal of Clinical Oncology* showing positive results in patients as a 2nd line treatment for PTCL .
  - Three preclinical and clinical studies supporting the potential of Beleodaq® in multiple orphan oncology indications presented at the 2015 ASCO Annual Meeting.
- A development plan including expansion of PTCL indication to 1st line treatment.
- **4Q 2015: Publication of Phase I results and safety profile of Beleodaq® + CHOP combination allowing finalization of the Phase III protocol in 1st line treatment of PTCL.**

Validive®: Phase III preparation following positive Phase II trial

- **Prevention of Severe Oral Mucositis** (SOM), a severe inflammation of oral mucosa induced by radiochemotherapy in patients with H&N cancer.
- Appropriate and easy to administer formulation: mucoadhesive tablet (Lauriad®) delivering locally high concentrations of clonidine, directly into the oral cavity.
- A significant medical need: no approved SOM treatment in solid cancer.
- Phase II final results confirmed positive efficacy and safety profiles, presented at 2015 ASCO Annual Meeting and MASCC/ISOO International Symposium on Supportive Care in Cancer.
- **1H 2016: Initiation of the Validive® Phase III trial.**

ONXEO IN THE PRESS

Le Revenu has interviewed Judith Greciet, CEO of Onxeo on the occasion of French Life Science Days – 01/07/2015

Watch the video

Onxeo: Good financial visibility – Oddo Nextcap 03/08/2015

Onxeo has published on July 30, 2015, its consolidated interim results. Given the cash position of €42.9 million posted at the end of June, the company is financed until the first half of 2017. Onxeo is one of the rare biotech companies which generate recurring revenues directly derived from royalties earned on its products sales.
Broker's analyst note available here

STRONG SCIENTIFIC RECOGNITION

Onxeo presented the final data from its global Phase II clinical trial of Validive® (clonidine Lauriad®) during a poster session at the 2015 American Society of Clinical Oncology (ASCO) Annual Meeting, in May in Chicago.
The same results were presented in an oral presentation at the 2015 MASCC/ISOO International Symposium, in June in Copenhagen. On this occasion, Onxeo held a meeting of its Advisory Board to discuss design of the Phase III clinical trial.

The ASCO annual meeting is a major event in the field of oncology that brings together 30,000 health professionals and updates on the major latest steps and results achieved in oncology worldwide.
The annual MASCC/ISOO meeting is dedicated to supportive care in cancer and particularly to therapeutic options to minimize symptoms and complications associated with cancer as well as therapy-induced side effects.

Onxeo announced the publication of results from the pivotal BELIEF study which was selected as a Rapid Communication in the *Journal of Clinical Oncology* (JCO), the journal of the American Society of Clinical Oncology. This is a highly distinguished category that the JCO reserves for papers judged to have great impact to their broad clinical readership

The JCO is peer-reviewed and is one of the most recognized, selective, and specialized journals within oncology.

2015 H2 FINANCIAL CALENDAR

ANALYST MEEETING
16 September 2015

INVESTORDAGEN, COPENHAGEN
22 September 2015

LARGE & MID CAP EVENT
7 – 8 October 2015

QUATERLY INFORMATION AS OF SEPTEMBER 30 2015
5 November 2015

ACTIONARIA CONGRESS FOR SHAREHOLDERS
20 – 21 November 2015

Register

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