

## 2015 Annual Results in Line with Forecasts, and Significant Clinical Advances

## 2016 Outlook: Further Development and Merger Project with Effimune

- Successful IPO on Euronext with €21.1m raised in late March 2015
- First pharmaceutical licensing agreement signed in Israel in May 2015
- International Phase 3 pivotal study of Tedopi® for advanced lung cancer: initiation in Europe and in the US in January 2016 and inclusion of the first patients in February 2016
- Merger project with Effimune to create a leading group in the field of activation and regulation immunotherapy announced in February 2016
- Available cash and cash equivalents as of 31 December 2015: € 15.1m funding the next key steps

Paris 21 March 2016, 17:45 – OSE Pharma SA (ISIN: FR0012127173; Mnemo: OSE), an immunology company developing a T-specific immunotherapy, currently in a registration Phase 3 study, today announces financial annual results for 2015 as well as key achievements and the company's outlook for 2016.

*“2015 was a transformational year for OSE Pharma, beginning with a successful IPO supported by our shareholders and investors which funded the Phase 3 clinical trial of Tedopi® in lung cancer. Through the year we completed, on schedule, all of the preparatory steps for the study, which, today, is open in Europe and in the USA, with first patients having been recruited and treated,”* commented Dominique Costantini, Chief Executive Officer of OSE Pharma. *“Looking ahead, we are confident that in the coming year we will continue to deliver transformative steps and open additional growth prospects, in particular as a result of our merger project with Effimune which was announced at the end of February 2016. The combination of the two companies will create a reference group in activation and regulation immunotherapies, with a deeper clinical pipeline, teams with a strong common ambition, and technologies which act on the immune system to offer more efficient treatments to patients with severe pathologies.”*

### 2015 KEY ACHIEVEMENTS

#### **IPO ON EURONEXT AND STRENGTHENING FINANCIAL POSITION**

The IPO successfully completed at the end of March 2015 and raised € 21.1 million. The net proceeds of the IPO have been directed to the financing of the Phase 3 study of Tedopi® in Non-Small Cell Lung Cancer (NSCLC), and have provided OSE Pharma with the financial means to take the study to completion.

## **REGISTRATION CLINICAL TRIAL OF TEDOPI<sup>®</sup>, ATALANTE 1, IN NON-SMALL CELL LUNG CANCER: PREPARATION OF THE STUDY IN EUROPE AND IN THE USA, FIRST PATIENTS TREATED IN EARLY 2016**

All the preparatory steps for the implementation of the Phase 3 trial, including industrial scaling up, were carried out in 2015, which allowed the start of the trial on schedule in Europe and in the USA in early 2016. The first patients were included and treated in early February. The results of this pivotal trial, the last step before registration, are expected in 2018.

## **SIGNATURE OF A FIRST PARTNERSHIP AGREEMENT WITH RAFA LABORATORIES**

From a commercial point of view, a first licensing and distribution agreement for Israel was signed in May 2015 with Rafa Laboratories, a pharmaceutical company specializing in oncology and rare pulmonary diseases. The agreement includes a payment of €100,000 at signature and milestones at registration of Tedopi<sup>®</sup>, with profit sharing depending on product sales in Israel.

## **OUTLOOK**

### **DEVELOPMENT OF THE THERAPEUTIC POTENTIAL OF TEDOPI<sup>®</sup>**

While Tedopi<sup>®</sup> is being evaluated in a registration pivotal trial, OSE Pharma is also exploring development of the product as a combination therapy to provide lung cancer patients with a new treatment option. A Phase 2 clinical trial of Tedopi<sup>®</sup> combined with a checkpoint inhibitor (a product that leverages the brake on T-cytotoxic lymphocytes) is being considered for 2017 in partnership with a European research organization.

### **MERGER PROJECT OF OSE PHARMA AND EFFIMUNE TO CREATE OSE IMMUNOTHERAPEUTICS, A LEADING GROUP IN ACTIVATION AND REGULATION IMMUNOTHERAPY**

The proposed merger of OSE Pharma and Effimune will create a new leader in immunotherapy which benefits from a balanced portfolio that would open major avenues to growth and have financial visibility of about two years to advance its projects.

Located in Nantes, France, Effimune is a biotech company specializing in immune regulation for applications in transplantation, autoimmunity and immuno-oncology. The originality of Effimune's therapeutic strategy, compared to conventional immunosuppression, is the modification in the balance between effector and regulatory immune cells by targeting key receptors. It is complementary with OSE Pharma's approach based on activation of effector cells (activation of T-lymphocytes by neo-epitopes).

Effimune portfolio:

- FR104, currently in Phase 1 trial, targets indications for autoimmune diseases and transplantation. It is a CD28-antagonist, a key receptor blocking the destructive function of effector T lymphocytes.

At the end of 2013, while in a preclinical stage, a global option and license agreement was signed with Janssen Biotech (J&J group, a leading pharmaceutical company). This option could be exercised in the second half of 2016 to continue Phase 2 clinical development, with expected payments of milestones and royalties.

- Effi-7, in preclinical development for autoimmune diseases and transplantation. The compound is an antagonist of the Interleukin 7 receptor. This monoclonal immunomodulatory antibody has achieved in vivo proof of concept for several autoimmune models. Effi-7 is partially financed by a consortium named Effimab and led by Effimune.

- Effi-dem, in preclinical development for immuno-oncology, is a 2<sup>nd</sup> generation checkpoint inhibitor.
- R&D: the company develops additional drug candidates targeting new receptors of interest in immuno-oncology, autoimmune and inflammatory diseases, and transplantation.

Upon completion of the merger, the combined company, OSE Immunotherapeutics, will have expertise in research and development in the fields of immunoregulation and immunoactivation, with complementary teams and expertise from start-up to advanced clinical projects. It will have a balanced portfolio, from R&D through to the last clinical stage before registration.

The Boards of Directors of both OSE Pharma and Effimune have approved the proposed terms of the merger, which will be submitted for approval to the shareholders of the two companies during Extraordinary General Meetings that are expected to take place at the end of the second quarter of 2016. The merger will result in the shareholders of OSE Pharma owning approximately 71% of the capital of the merged entity and the shareholders of Effimune, 29%.

## 2015 ANNUAL RESULTS

The Board of Directors of OSE Pharma held on March 16, 2016. Following the opinion of the Audit Committee, the Board approved the annual and consolidated financial statements prepared under IFRS as at 31 December 2015. These accounts have been audited by the Statutory Auditors.

*As of today, March 21, 2016, the full “annual financial report” is available on the investor section of the company’s website, [www.osepharma.com](http://www.osepharma.com).*

**The key figures of the 2015 consolidated results are reported below:**

<i>In k€</i>	<b>12/31/2015</b>	<b>12/31/2014</b>
<b>Available cash and cash equivalents</b>	<b>15,131</b>	<b>1,096</b>
<b>Consolidated Assets</b>	<b>16,995</b>	<b>1,980</b>
<b>Operating result</b>	<b>(5,420)</b>	<b>(2,815)</b>
<b>Net result</b>	<b>(5,584)</b>	<b>(2,835)</b>

Available cash and cash equivalents as of 31 December 2015 amounted to € 15.1 million.

The operating result for the fiscal year 2015 was a loss of € 5.42 million against a loss of € 2.8 million for financial year 2014.

R&D expenditure grew to € 2.25 million in 2015, from € 2.02 million in 2014, primarily due to the preparation of the pivotal study of Tedopi®. This included € 0.671 million deducted from this expenditure as research tax credits. G&A expenses are subject to a constant cost control and stood at € 1.32 million, mainly due to listing related expenses and strengthening of the teams.

These results are in line with expectations with all stated clinical targets delivered on schedule in 2015.

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## **ABOUT OSE PHARMA**

OSE Pharma is a biotechnology company that designs and develops cancer immunotherapy treatments aimed at re-educating the immune system to fight cancer while preserving patients' quality of life. The Company is conducting a Phase 3 registration trial, named Atalante 1, in Europe and the USA for its lead product, Tedopi®, in the treatment of NSCLC. *For more information on Atalante 1 and its eligibility criteria, please visit the website: <https://clinicaltrials.gov/ct2/show/NCT02654587>*

Tedopi® (OSE-2101) is a new “off-the-shelf” cancer immunotherapy approach based on OSE Pharma’s proprietary Memopi® technology. This technology is based on “neo-epitopes” (small synthetic peptides chemically modified to increase the binding the HLA A2 or TCR receptors) which activate a cytotoxic T-cell response and leads the immune system to destroy cancer cells. More than 10,000 epitopes were selected to obtain a therapeutic universal T vaccine.

Tedopi® combines 10 optimized “neo-epitopes” simultaneously acting against 5 tumor-associated antigens (TAAs). These 5 antigens have been selected because they are a factor of poor prognosis in several types of cancers. The 10 “neo-epitopes” have been selected and modified to enhance their binding to HLA-A2 and TCR receptors, and trigger a stronger cytotoxic T-cell response and lead the immune system to destroy cancer cells expressing the HLA-A2 antigen or one of the targeted cancer antigens.

The Phase 3 trial is based on Phase 2 results showing an immune T-cell response significantly correlated with a survival increase, as well as on the long term survival benefit observed in highly pretreated patients with a poor prognosis.

Tedopi® can also be developed in Phase 2 in combination with other immunotherapeutic products or targeted therapies. It is also considered for other oncology indications (ovary, colon, breast) for HLA-A2 positive patients. OSE Pharma is listed on Euronext Paris (ISIN: FR0012127173; Mnemo: OSE).

For more information, please visit [www.osepharma.com](http://www.osepharma.com)



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### **Forward-looking statements**

This press release contains express or implied information and statements that might be deemed forward-looking information and statements in respect of OSE PHARMA. They do not constitute historical facts. These information and statements include financial projections that are based upon certain assumptions and assessments made by OSE PHARMA's management in light of its experience and its perception of historical trends, current economic and industry conditions, expected future developments and other factors they believe to be appropriate.

Forward-looking statements include statements typically using conditional and containing verbs such as "expect", "anticipate", "believe", "target", "plan", or "estimate", their declensions and conjugations and words of similar import.

Although the OSE PHARMA's management believes that the forward-looking statements and information are reasonable, the OSE PHARMA's shareholders and other investors are cautioned that the completion of such expectations is by nature subject to various risks, known or not, and uncertainties which are difficult to predict and generally beyond the control of OSE PHARMA. These risks could cause actual results and developments to differ materially from those expressed in or implied or projected by the forward-looking statements. These risks include those discussed or identified in the public filings made by OSE PHARMA with the AMF. Such forward-looking statements are not guarantees of future performance.

This press release includes only summary information and should be read with the OSE PHARMA Reference Document filed with the AMF on 12 June 2015 under the number R.15-051 as well as the consolidated financial statements and the management report for the fiscal year 2015, available on the OSE PHARMA website.

OSE PHARMA undertakes no obligation to update any forward-looking statements except what would be required by applicable laws and regulations

## APPENDICES

### Consolidated balance sheet

(in thousands of Euros)

Assets in kEuros	31/12/2015	31/12/2014
Intangible assets		
Tangible assets	65	25
Financial assets	54	28
<b>Total non current assets</b>	<b>119</b>	<b>53</b>
Trade receivables		
Other accounts receivables	1,742	816
Current financial assets	5,801	-
Cash and cash equivalents	9,332	1,111
<b>Total current assets</b>	<b>16,876</b>	<b>1,927</b>
<b>Total assets</b>	<b>16,995</b>	<b>1,980</b>

Liabilities in kEuros	31/12/2015	31/12/2014
Stated capital	2,010	1,605
<b>Total shareholders' equity</b>	<b>14,476</b>	<b>(803)</b>
Non current financial liabilities	204	894
Non current provisions	10	-
<b>Total non current debts</b>	<b>214</b>	<b>894</b>
Current financial liabilities	776	284
Trade payables	1,129	1,518
Other payables and accruals	302	87
Other debts	98	-
<b>Total current debts</b>	<b>2,304</b>	<b>1,889</b>
<b>Total liabilities</b>	<b>16,995</b>	<b>1,980</b>

## Consolidated profit and loss account

<b>P&amp;L in kEuros</b>	<b>31/12/2015</b>	<b>31/12/2014</b>
Turnover	4	-
Other operating revenues	-	-
<b>Total Revenues</b>	<b>4</b>	<b>-</b>
Research and development expenses	(2,245)	(2,015)
Overhead expenses	(1,322)	(665)
Expenses related to shares payment	(1,857)	(135)
<b>Operating Loss</b>	<b>(5,420)</b>	<b>(2,815)</b>
Financial products	71	8
Financial expenses	(225)	(26)
<b>Loss Before Tax</b>	<b>(5,573)</b>	<b>(2,833)</b>
Tax incurred	(11)	(2)
<b>Net Loss</b>	<b>(5,584)</b>	<b>(2,835)</b>
<i>Conversions gains and losses</i>	(95)	(17)
<b>Global Loss</b>	<b>(5,679)</b>	<b>(2,852)</b>
<b>Basic and diluted earnings per share</b>	<b>(0.59)</b>	<b>(0.36)</b>

## Consolidated cash flow statement

In kEuros	31/12/2015	31/12/2014
<b>Consolidated result</b>	<b>-5,584</b>	<b>-2,835</b>
+/- Depreciation, amortization and provision expenses	99	0
+/- Shares based payment (1)	1,857	135
+/- Other calculated income and expense	-4	0
<b>Cash flow before tax</b>	<b>-3,632</b>	<b>-2,700</b>
+ Financial charges	43	0
+/- Working capital variation	-1,025	763
<b>CASH FLOW FROM OPERATING ACTIVITIES (A)</b>	<b>-4,614</b>	<b>-1,937</b>
- Tangible assets increase	-43	-25
- Financial assets increase	-279	0
+/- Increase of mutual funds classified in current financial assets	-5,888	0
- Loans and advances increase	-26	0
<b>CASH FLOW FROM INVESTING ACTIVITIES (B)</b>	<b>-6,235</b>	<b>-25</b>
+ Capital increase (including share premium) (2)	20,188	2,763
+/- Own shares transactions	5	0
- Capital increase expenses	-2,146	0
+ Warrant subscription (3)	157	15
+ Loans subscription (4)	1,263	0
- Loans repayment	-345	0
- Financial charges	-43	0
+/- Other flows from financing activities	4	0
<b>CASH FLOW FROM FINANCING ACTIVITIES (C)</b>	<b>19,083</b>	<b>2,778</b>
+/- Currency translation transactions (D)	0	0
<b>CASH VARIATION E = (A + B + C + D)</b>	<b>8,234</b>	<b>816</b>
<b>CASH OPENING BALANCE (F)</b>	<b>1,096</b>	<b>280</b>
<b>CASH CLOSING BALANCE (G)</b>	<b>9,330</b>	<b>1,096</b>
<b>DIFFERENCE : E (G-F)</b>	<b>0</b>	<b>0</b>

(1) Including 298 thousand Euros that have been used to subscribe warrants (BSA) (4 thousand Euros) and to exercise them (294 thousand Euros)

(2) Excluding the conversion increase of 1,177 thousand Euros fixed income loan and linked interests (cf 4) and increase of 294 thousand Euros linked to the transactions deemed to be paid in equity (cf 1)

(3) Excluding 4 thousand Euros linked to the transactions deemed to be paid in equity (cf 1)

(4) Including the fixed income loan subscription and linked interests for 1,177 thousand Euros converted in equity

End of 2015, available cash and cash equivalents were:

In kEuros	31/12/2015
Cash and cash equivalents according to IAS 7	9,330
Current financial assets which do not meet IAS 7 criteria	5,801
<b>CASH AVAILABLE</b>	<b>15,131</b>