# 2016 Results: Significant Milestones, First Profit, More Growth to Come

- **Two global license and license option agreements signed with Janssen Biotech in July and with Servier in December for maximum cumulated amounts of worth > €400 million* plus royalties**
- **An international phase 3 clinical trial launched in the first semester in immuno-oncology with Tedopi®, a combination of neo-epitopes**
- **A new checkpoint inhibitor on suppressor myeloid cells with significant preclinical results in several cancers presented at immuno-oncology congresses**
- **First net annual profit of €21 million** due to the license option agreement with Janssen Biotech and to the merger completed at the end of May**
- **Available cash of €17.8 million as of December 31, due to the license agreement with Janssen Biotech plus €10.25 million received from Servier in payment of the license option early 2017**
- **Cash for operations until second half of 2018**

**Nantes, March 28, 2017, 6:00 p.m. - OSE Immunotherapeutics SA** (ISIN: FR0012127173; Mnémo: OSE) today reports it annual financial results as of December 31, 2016, and provides an update on the key achievements as well as the company's outlook for its agonist and antagonist immunotherapies.

*"We achieved significant progress in 2016, including securing two partnerships with world renowned pharmaceutical groups that ensure the focused development of our disruptive immunotherapies for auto-immune disorders."* said Dominique Costantini, CEO of OSE Immunotherapeutics. *"In addition, we met key preclinical and clinical development goals for our immuno-oncology franchise specifically for our lead product Tedopi®, as well as OSE-172 (Effi-DEM). We intend to broaden our pipeline in immuno-oncology over the next few months, including for our most advanced clinical product, Tedopi®, which will be evaluated in combination with checkpoints inhibitors and in new cancer indications. Moreover, with financial results which, for the first time, show an annual net profit of 21 million euros and a financial visibility until the second half of 2018, the company is in a solid financial position to take the next steps of its growth."*

## 2016 KEY MILESTONES

**MERGER-ABSORPTION** of Effimune by OSE Pharma completed on May 31, 2016, to create OSE Immunotherapeutics, a new international player, leader in innovative immunotherapies of activation and regulation.

### IN IMMUNO-ONCOLOGY: CLINICAL AND PRECLINICAL ACHIEVEMENTS

**Tedopi®**, an innovative proprietary combination of neoepitopes, began in early 2016 a pivotal clinical phase 3 registration study in advanced lung cancer in Europe and in the United States. Tedopi® is the Company's most advanced product, with the phase 3 study expected to be completed by the end of 2018.

** €155 M (Janssen Biotech) + €272 M (Servier)*
*** Including a badwill of €24.4 M due to the merger operation*

**OSE-172 (Effi-DEM)**, a new generation checkpoint inhibitor targeting SIRP-α receptor (i.e. to block suppressive myeloid and macrophage cells), has demonstrated compelling preclinical results in various cancer models, presented at multiple scientific international conferences in 2016.

A non-interventional study in patients with hepatocellular carcinoma (HCC, primary liver cancer) was initiated in May 2016. This study is a private-public research program supported by the French National Cancer Institute (INCa, Institut National du Cancer) and the Direction Générale de l'Offre de Soins (DGOS, the French access to healthcare services). This collaborative research program aims to evaluate SIRP-alpha in several types of tumor.

## IN AUTO-IMMUNE DISEASES: STRATEGIC PARTNERSHIP AGREEMENTS

**FR104,** CD28-antagonist, was licensed to Janssen Biotech (Group Johnson & Johnson) in July 2016 to pursue clinical development in auto-immune diseases at the conclusion of the phase 1 trial.

OSE Immunotherapeutics is eligible to receive up to a potential total of €155 million which includes an option exercise fee of €10 million which was paid in August 2016 and potential development, regulatory and commercial milestone payments as well as royalties on sales.

The positive phase 1 clinical results of FR104 conducted in healthy subjects demonstrated the product's good tolerance and first signal of its immunosuppressive activity.

**OSE-127** (Effi-7), an antagonist of the interleukin-7 receptor (IL-7), was the subject of a license option agreement with Servier, announced in December 2016 for the development and commercialization of the product in auto-immune diseases.

OSE Immunotherapeutics is eligible to receive up to €272 million including an upfront payment of €10.25 million which was paid in January 2017 and additional payments totaling €30 million upon the exercise of a two-steps license option. These steps will finance the development of OSE-127 (Effi-7) up to the completion of a phase 2 clinical trial planned in ulcerative colitis, an autoimmune bowel disease. Further payments will be linked to the achievement of clinical development and registration in multiple indications, as well as sales milestones with double-digit royalties on sales.

Preclinical studies have demonstrated the product's efficacy in *in vivo* models of ulcerative colitis, a T-cell mediated disease. These results were presented at the annual international congress of immunology, « Federation of Clinical Immunology Societies », in June 2016.

## 2017 OUTLOOK

### IN IMMUNO-ONCOLOGY: EXTENSION OF THE FRANCHISE AND DEVELOPMENT OF TEDOPI® THERAPEUTIC POTENTIAL

In addition to the ongoing pivotal registration study with Tedopi® in advanced lung cancer, OSE Immunotherapeutics is considering a phase 2 clinical trial with Tedopi® in combination with a checkpoint inhibitor in the same indication, in collaboration with a European research institution.

The Company is also evaluating potentially extending the development of Tedopi® into new cancer indications (pancreas, bladder cancers) with exploratory phase 2 studies, in partnership with collaborative oncology groups.

### IN AUTO-IMMUNE DISEASES: TO PURSUE THE PRODUCT'S CLINICAL DEVELOPMENT THROUGH PARTNERSHIPS

Following the positive phase 1 results with FR104, and the license agreement with Janssen Biotech in July 2016, the product's clinical development will be pursued in auto-immune diseases.

Currently in preclinical stage for ulcerative colitis, further development of OSE-127 (Effi-7) through phase 2 will be pursued as part of the EFFIMab consortium, led by OSE Immunotherapeutics and including private and public partners. Per the license option agreement signed at the end of 2016, Servier will be responsible for further development of the product following phase 2.

The Company will pursue the research of new collaborative or license agreements, which can be initiated at different stages of product development, with players involved in the field of activation and regulation immunology and in therapeutic combinations of high clinical interest.

## 2016 ANNUAL RESULTS

Meeting of Board of Directors of OSE Immunotherapeutics was held on March 28, 2017. Following the opinion of the Audit Committee, the Board approved the annual and consolidated financial statements prepared under IFRS at 31 December 2016. These accounts have been audited by the Statutory Auditors.

The key figures of the 2016 consolidated annual results are reported below (and presented in the attached tables):

| In k€ | 12/31/2016 | 12/31/2015 |
|---|---|---|
| Operating result | 17 499 | (5 420) |
| Net result | 20 666 | (5 584) |
| Available cash* | 17 766 | 15 133 |
| Consolidated balance sheet | 89 547 | 16 995 |

As of December 31, 2016, available cash* amounted to €17.8 million following the license agreement for FR104 signed with Janssen Biotech in July 2016.

During the first quarter 2017, OSE Immunotherapeutics' cash position was reinforced by a €10.25 million payment triggered by the license option agreement for OSE-127 (Effi-7) signed with Servier at the end of December 2016.

For the first time, as of December 2016, the Company recorded a net annual profit of €21 million as a result of the license agreement for FR104 with Janssen Biotech in July 2016 which triggered a payment of €10 million, and of the merger of Effimune and OSE Pharma to create OSE Immunotherapeutics in May 2016.

Current operating expenses represented €8.2 million, including €5.2 million of R&D expenses, versus €5.4 million for the same period of 2015, in line with the acceleration of R&D portfolio development, and in particular the pivotal phase 3 study of Tedopi® launched in Europe and in the United States.

The total consolidated balance sheet amounted to €90 million against €17 million as of December 31, 2016.

As of today, the Company has funds for operations until the second half of 2018.

These results are in line with expectations with all stated clinical targets delivered on schedule in 2016.

** Cash and cash equivalents and Current financial assets*

## RISK FACTORS

The risk factors affecting the Company are set out in paragraph 4 of the reference document filed with the French financial market authority ("AMF") on June 8, 2016.

## REFERENCE DOCUMENT AND ANNUAL FINANCIAL REPORT

The Company intends to file with the AMF a reference document and an annual financial report for 2016. These documents should be made available to the public in the second quarter of 2017.

**OSE Immunotherapeutics will comment on major current issues and on its annual financial statements during an Analyst meeting which will be held on March 30, 2017 at 10:00am CET at the "SFAF" - 135, boulevard Hausmann - 75008 Paris and during an audio/web conference the same day at 6:00pm CET:**

**Audio connection numbers: FR :** +33 170 770 943 ; **UK :** +44 2033679461 ; **US :** +1 8554027761

**Webconference:**
http://www.anywhereconference.com?UserAudioMode=DATA&Name=&Conference=135306981&PIN=32341749

**Audio playback numbers and reference: FR** : +33 172 001 500; **UK** : +44 2033679460; **US** : +1 877 64 230 18
**REF : 306981#**

### ABOUT OSE IMMUNOTHERAPEUTICS

***Our ambition is to become a world leader in activation and regulation immunotherapies***

OSE Immunotherapeutics is a biotechnology company focused on the development of innovative immunotherapies for immune activation and regulation in the fields of immuno-oncology, auto-immune diseases and transplantation. The company has a balanced portfolio of first-in-class products with a diversified risk profile ranging from clinical phase 3 registration trials to R&D:

**In immuno-oncology**:

- **Tedopi® (OSE-2101), a combination of 10 optimized neo-epitopes** to induce specific T activation in immuno-oncology - **Currently in registration Phase 3 trial advanced NSCLC HLA A2+ patients EU /US -** Orphan Status in the US **- Registration expected in 2019 - A Phase 2 with Tedopi® in combination with a checkpoint inhibitor** in NSCLC is considered in 2017**.**
- **OSE-172 (Effi-DEM), new generation checkpoint inhibitor** targeting the **SIRP-α receptor - In preclinical development** for several cancer models.

**In auto-immune diseases and transplantation**:

- **FR104,** CD28-antagonist in immunotherapy - **Phase 1 trial completed** – For the treatment of autoimmune diseases and for use with transplantation - **Licensed to Janssen Biotech Inc.** to pursue clinical development.
- **OSE-127 (Effi-7),** interleukin receptor-7 antagonist - **In preclinical development** for inflammatory bowel diseases and other autoimmune diseases. **License option agreement with Servier** for the development and commercialization.

The portfolio's blockbuster potential gives OSE Immunotherapeutics the ability to enter global agreements at different stages of development with major pharmaceutical players.

Immunotherapy is a highly promising and growing market. By 2023 Immunotherapy of cancer could represent nearly 60% of treatments against less than 3% at present * and the projected market is estimated at $67 billion in 2018 **.

There are more than 80 autoimmune diseases that represent a significant market including major players in the pharmaceutical industry with sales towards $10 billion for the main products. The medical need is largely unmet and requires the provision of new innovative products involved in the regulation of the immune system.

**Citi Research Equity*
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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 Immunotherapeutics. They do not constitute historical facts. These information and statements include financial projections that are based upon certain assumptions and assessments made by OSE Immunotherapeutics' 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.
These 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 Immunotherapeutics management believes that the forward-looking statements and information are reasonable, the OSE Immunotherapeutics' 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 Immunotherapeutics. 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 Immunotherapeutics 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 Immunotherapeutics Reference Document filed with the AMF on 8 June 2016 under the number R.16-052, the consolidated financial statements and the management report for the fiscal year 2015, as well as the Merger Document registered with the AMF on 26 April 2016 under number E.16-026, all available on the OSE Immunotherapeutics' website.
Other than as required by applicable law, OSE Immunotherapeutics issues this press release at the date hereof and does not undertake any obligation to update or revise the forward-looking information or statements.

# APPENDICES

## Consolidated Profit & Loss

| P&L in kEuros | 12/31/2016 | 12/31/2015 |
|---|---|---|
| Turnover | 383 | 4 |
| **Total Revenues** | **383** | **4** |
| Research and development expenses | (5 149) | (2 245) |
| Overhead expenses | (2 792) | (1 322) |
| Expenses related to shares payments | (679) | (1 857) |
| **Operating Profit/Loss - current** | **(8 236)** | **(5 420)** |
| Other operating products (Janssen) | 10 000 | 0 |
| Other operating expenses (INSERM) | (2 325) | 0 |
| Other operating products (badwill) | 24 360 | 0 |
| Other operating expenses | (6 300) | 0 |
| **Operating Profit/Loss** | **17 499** | **(5 420)** |
| Financial products | 146 | 71 |
| Financial expenses | (53) | (225) |
| **Profit/Loss Before Tax** | **17 592** | **(5 573)** |
| Income Tax | 3 074 | (11) |
| **Net Profit/Loss** | **20 666** | **(5 584)** |
| *Conversions gains and losses* | (29) | (95) |
| **Global Profit/Loss** | **20 637** | **(5 679)** |
| **Basic and diluted earnings per share** | **1,65** | **(0,59)** |

# Consolidated Balance Sheet

| Assets in kEuros | 12/31/2016 | 12/31/2015 |
|---|---|---|
| Intangible assets | 52 600 | 0 |
| Tangible assets | 110 | 65 |
| Financial assets | 142 | 54 |
| Deffered tax assets | 157 | 0 |
| ***Total non current assets*** | **53 009** | **119** |
| Trade receivables | 12 318 | 0 |
| Other accounts receivables | 6 454 | 1 742 |
| Current financial assets | 2 881 | 5 801 |
| Cash and cash equivalents | 14 885 | 9 332 |
| ***Total current assets*** | **36 538** | **16 876** |
| **Total assets** | **89 547** | **16 995** |

| Equity & Liabilities in kEuros | 12/31/2016 | 12/31/2015 |
|---|---|---|
| Stated capital | 2 858 | 2 010 |
| ***Total shareholders' equity*** | **64 525** | **14 476** |
| Non current financial liabilities | 1 197 | 204 |
| Non current deferred tax liabilities | 5 003 | 0 |
| Non current provisions | 158 | 10 |
| ***Total non current debts*** | **6 358** | **214** |
| Current financial liabilities | 587 | 776 |
| Trade payables | 4 256 | 1 129 |
| Other payables | 3 148 | 302 |
| Other debts and accruals | 10 672 | 98 |
| ***Total current debts*** | **18 663** | **2 304** |
| **Total liabilities** | **89 547** | **16 995** |

# Consolidated Statement of Changes in Equity

| In kEuros | Share capital | Share premium | Currency translation transactions | Own shares | Retained earnings and result | Total consolidated equity |
|---|---|---|---|---|---|---|
| | | | | | | |
| **Consolidated equity as at December 31st, 2014** | **1 605** | **1 700** | **(4)** | **0** | **(4 104)** | **(803)** |
| | | | | | | |
| **Consolidated result** | | | | | (5 584) | (5 584) |
| *Currency translation transactions* | | | (95) | | | (95) |
| **Global consolidated result** | **-** | **-** | **(95)** | **0** | **(5 584)** | **(5 679)** |
| Capital variation | 397 | 20 967 | | | | 21 364 |
| Warrant subscription | | 157 | | | | 157 |
| Capital increase expenses | | (2 146) | | | | (2 146) |
| Shares based payments | 7 | 291 | | | 1 559 | 1 857 |
| Own shares transactions | | | | (279) | 5 | (274) |
| | | | | | | |
| **Consolidated equity as at December 31st, 2015** | **2 010** | **20 969** | **(98)** | **(279)** | **(8 125)** | **14 476** |
| | | | | | | |
| **Consolidated result** | | | | | 20 666 | 20 666 |
| *Actuarial difference* | | | | | (20) | (20) |
| *Currency translation transactions* | | | (9) | | | (9) |
| **Global consolidated result** | **-** | **-** | **(9)** | **0** | **20 646** | **20 637** |
| Capital variation | 27 | 825 | | | | 852 |
| Merger | 821 | 27 334 | | | | 28 155 |
| Merger costs | | (479) | | | | (479) |
| Revenue recognition - Effimune impact | | | | | 864 | 864 |
| Orion warrants - cancellation of shares based payment accounted as of 12/31/2015 | | | | | (339) | (339) |
| Warrant subscription | | 7 | | | | 7 |
| Deffered tax | | | | | 3 | 3 |
| Capital increase expenses - Effimune | | (53) | | | 53 | 0 |
| Share based payments | | | | | 305 | 305 |
| Own shares transactions | | | | 111 | (68) | 43 |
| | | | | | | |
| **Consolidated equity as at December 31st, 2016** | **2 858** | **48 603** | **(107)** | **(168)** | **13 341** | **64 527** |

# Consolidated Cash Flow Statement

| | In kEuros | 12/31/2016 | 12/31/2015 |
|---|---|---|---|
| | **Consolidated result** | **20 666** | **(5 584)** |
| +/- | Depreciation, amortization and provision expenses | 107 | 99 |
| - | Badwill | (24 365) | |
| + | Derecognition of asset | 6 300 | |
| +/- | Shares based payments | 680 | 1 857 |
| +/- | Other calculated income and expenses | 7 | (4) |
| | **Cash flow before tax** | **3 395** | **(3 632)** |
| + | Financial charges | (8) | 43 |
| - | Income tax expenses | (3 074) | |
| +/- | Working capital variation | 370 | (1 025) |
| | **CASH FLOW FROM OPERATING ACTIVITIES (A)** | **684** | **(4 614)** |
| - | Tangible assets increase | (30) | (43) |
| +/- | Financial assets variation | 141 | (279) |
| +/- | Mutual finds units accounted in current financial assets | 2 920 | (5 888) |
| +/- | Change in scope of consolidation | 3 163 | |
| +/- | Loans and advances variation | (89) | (26) |
| | **CASH FLOW FROM INVESTING ACTIVITIES (B)** | **6 105** | **-6 236** |
| + | Capital increase (including share premium) | 137 | 20 188 |
| +/- | Own shares transactions | (98) | 5 |
| - | Capital increase and merger expenses | (479) | (2 146) |
| + | Warrant subscription | 7 | 157 |
| + | Loans subscription | 11 | 1 263 |
| - | Loans repayment | (821) | (345) |
| - | Financial charges | 8 | (43) |
| +/- | Other flows from financing activities | 0 | 4 |
| | **CASH FLOW FROM FINANCING ACTIVITIES ©** | **(1 234)** | **19 083** |
| +/- | Currency translation transactions (D) | 0 | 1 |
| | **CASH VARIATION E = (A + B + C + D)** | **5 555** | **8 234** |
| | **CASH OPENING BALANCE (F)** | 9 330 | 1 096 |
| | **CASH CLOSING BALANCE (G)** | 14 885 | 9 330 |
| | **DIFFERENCE : E (G-F)** | 0 | 0 |

As of December 31, 2016 the available cash is as follows:

| In kEuros | 31/12/2016 | 31/12/2015 |
|---|---|---|
| Cash & equivalents according to IAS 7 | 14 885 | 9 330 |
| Current financial assets | 2 881 | 5 801 |
| **Available Cash** | **17 766** | **15 131** |