# OSE Immunotherapeutics: 2017 Annual Results and Clinical Advances of its Proprietary and Partnered Products
# Key Clinical Portfolio Development Progress Planned for 2018

- **Tedopi® (neoepitopes): Phase 3 clinical trial in NSCLC – Redeployment in the U.S., Europe and Israel, based on a revised protocol focused on patients who have failed a previous treatment with PD-1/PD-L1 immune checkpoint inhibitors.**
- **OSE-172 (SIRPa-antagonist, myeloid checkpoint inhibitor): Initiation of clinical phase expected in 2018 in immuno-oncology; €9.2 million in new funding received in July 2017 from Bpifrance.**
- **OSE-127 (IL-7R antagonist): Initiation of clinical phase expected in 2018 in autoimmune diseases; €2.6 million milestone payment received from Bpifrance.**
- **FR104 (CD28-antagonist): Phase 2 clinical initiation expected in 2018 in rheumatoid arthritis by licensee Janssen Biotech.**

- **€6.7 million turnover recorded due to the spread of the €10.25 million Servier upfront fees for OSE-127 option license.**
- **Cash available as of December 31, 2017 of €12.5 million (included current financial assets), not including the 2016 & 2017 research tax credits of €5.5 million planned S1 2018.**

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

*"Throughout 2017, in close collaboration with Janssen Biotech and Servier, we have continued the development of our breakthrough immunotherapies in autoimmune diseases, including preparation for the start of clinical phase of OSE-127 in ulcerative colitis by the end of 2018,"* said Dominique Costantini, CEO of OSE Immunotherapeutics. *"We have also advanced our programs in immuno-oncology and within the next few months expect to start clinical phase with OSE-172, as well as an exploratory Phase 2 clinical trial in pancreatic cancer with Tedopi® in combination with checkpoint inhibitors. Finally, after redefining the recruitment strategy in our Phase 3 trial of Tedopi® in advanced lung cancer, we are very happy to be able to redeploy the trial internationally in early 2018. Clinical advances of four of our products, two of which being partnered with leading pharmaceutical partners, are the next steps of the Company's growth, supported by our partnerships with international pharmaceutical groups and by the grants obtained from Bpifrance.*

## 2017 KEY MILESTONES AND 2018 OUTLOOK

### IMMUNO-ONCOLOGY : FOLLOWING CLINICAL AND PRECLINICAL ADVANCES IN 2017
### TEDOPI®: REDEPLOYMENT OF THE PHASE 3 CLINICAL PHASE AND A NEW CANCER INDICATION IN PHASE 2 – OSE-172: ENTRY INTO CLINICAL PHASE PLANNED IN 2018

***Tedopi®, an innovative proprietary combination of neoepitopes***

***International Phase 3 in advanced Non-Small Cell Lung Cancer: Trial redeployed in the U.S., seven European countries and Israel, based on a revised protocol in patients who have failed previous treatment with PD-1/PD-L1 checkpoint inhibitors***

- After temporary pause of new patient accrual end of June 2017, following the recommendation of the trial's Independent Data Monitoring Committee, a new recruitment strategy was defined, based on a review of mature clinical data assessing the treated patients' profiles in relation to the potential benefit of Tedopi®. The revised protocol focuses on a subgroup of patients who have failed previous treatment with PD-1/PD-L1 immune checkpoint inhibitors.
- Based on this revised protocol, in Q1 2018, competents authorities in the U.S. and Europe approved resume of patient accrual. In addition, the approval from Israeli competent authorities to initiate the trial adds Israel to the U.S. and to seven European countries for the redeployment of the international Phase 3 Tedopi® trial.

***Phase 2 trial in pancreatic cancer, in clinical collaboration with the GERCOR group, an independent French non-profit network of cancer specialists***

- In September 2017, a collaboration was concluded with the GERCOR oncology cooperative group involved in digestive cancer to evaluate Tedopi® in locally advanced or metastatic pancreatic cancer. This is a Phase 2 trial of maintenance therapy with Tedopi® alone or in combination with a PD-1 checkpoint inhibitor versus Folfiri*, in patients with stable disease after four months of standard chemotherapy with Folforinox**.
- Initiation of this Phase 2 is expected in 2018.

** Folfiri: combination chemotherapy with folinic acid, fluorouracil and irinotecan*

*** Folfirinox: combination chemotherapy with folinic acid, fluorouracil, irinotecan and oxaliplatin*

***OSE-172, a new generation checkpoint inhibitor targeting myeloid cells via the SIRPa receptor – A focus on clinical development in tumor microenvironment : Clinical program planned end of 2018***

- New preclinical data were presented at international immuno-oncology and immunology conferences that show the strong impact of OSE-172 on the tumor micro-environment by targeting suppressive myeloid cells through a specific blockade of SIRPa. OSE-172 has a unique and beneficial pharmacologic profile, and is highly selective for promoting T-lymphocytes that destroy cancer cells.

- In July, the company received a €9.2 million grant from Bpifrance as part of a collaborative program (EFFI-CLIN) to support the development of OSE-172, planned to enter clinical Phase in 2018. This program will include product manufacturing, translational studies and a clinical program planned through Phase 2.

***OSE-703, a cytotoxic monoclonal antibody targeting the alpha-chain of the receptor for interleukin-7***

- In June 2017, the company entered into a research collaboration with Memorial Sloan Kettering Cancer Center (MSKCC) in New York. The goal of this collaboration is to explore the efficacy profile and the development potential of immunotherapy with OSE-703 in solid tumors. The research is being conducted by Prasad S. Adusumilli, M.D., an expert in tumor immunology and in the development of chimeric antigen receptor T-cell (CAR T-cell) immunotherapy.

## AUTOIMMUNE DISEASES: PROGRAMS DEVELOPED THROUGH STRATEGIC PARTNERSHIPS AND CLINICAL MILESTONES EXPECTED IN 2018

***OSE-127, a humanized monoclonal antibody targeting the CD127 receptor, the alpha chain of the interleukin-7 receptor (IL-7R) – License option with Servier (December 2016) to develop and commercialize the product in autoimmune diseases***

- New positive clinical results and translational data, presented in June at the Federation of Clinical Immunology Societies conference, have shown a differentiated mechanism of action for OSE-127 able to fight pathologic local homing of inflammatory T lymphocytes, key players in the chronicity of inflammatory bowel disease.
- In June 2017, the company received a €2.597 million payment from Bpifrance, after achieving a milestone in the collaborative EFFIMab project developing OSE-127 in ulcerative colitis.

***FR104, CD28-antagonist: Phase 1 completed – License agreement with Janssen Biotech (July 2016) to pursue the product's clinical development in autoimmune diseases***

- Following positive Phase 1 results, the product's development is being pursued in partnership with Janssen Biotech to prepare its entry into Phase 2 trial in rheumatoid arthritis planned for the end of 2018.

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.

## 2017 ANNUAL RESULTS

Meeting of Board of Directors of OSE Immunotherapeutics was held on March 28, 2018. Following the opinion of the Audit Committee, the Board approved the annual and consolidated financial statements prepared under IFRS at 31 December 2017.

The key figures of the 2017 consolidated annual results are reported below (and presented in the attached tables):

| In k€ | 12/31/2017 | 12/31/2016 |
|---|---|---|
| Current operating result | -12 626 | -8 236 |
| Operating result | -12 626 | 17 499 |
| Net result | -10 503 | 20 666 |
| Available cash* | 12 528 | 17 766 |
| Consolidated balance sheet | 77 353 | 89 547 |

As of December 31, 2017, available cash* amounted to €12.528 million, excluded 2016 and 2017 research tax credits totalling €5.585 million.

This available cash will enable the Company to finance its 2018 development costs including the Phase 3 clinical trial with Tedopi®, the preclinical and Phase 1 clinical development of OSE-127 and of OSE-172, and R&D costs on earlier stage products. In addition, the company should reach a new milestone this year in the development of OSE-127 as part of its contract with Servier, that could generate a cash inflow of €12 million.

Moreover, completion of the next key milestone related to the company's collaborative program on OSE-172 (EFFI-CLIN), if validated, will trigger a payment of €5.5 million from Bpifrance in 2018.

As of today, the Company has funds to pursue its activities during the next 12 months following the publication of the accounts closed on December 31, 2017.

As a reminder, the 2016 operating result was positively impacted, both due to the license option exercise by Janssen Biotech for FR104 and to a badwill due to the merger operation of May 2016.

Moreover, due to the merger between OSE Pharma and Effimune, 2016 annual results include only 7 months of Effimune operational expenses.

* *Cash and cash equivalents and Current financial assets*

## 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, autoimmune diseases and transplantation. The company has several scientific and technological platforms: neoepitopes, agonist or antagonist monoclonal antibodies, ideally positioned to fight cancer and autoimmune diseases. Its first-in-class clinical portfolio offers a diversified risk profile.

**In immuno-oncology:**

- **Tedopi®**, 10 combined neo-epitopes to induce a specific T lymphocyte activation. Phase III trial in advanced NSCLC: after temporary pause of new patient accrual end of June 2017, new recruitment strategy in December 2017, following the recommendation of the trial's Independent Data Monitoring Committee, to focus the trial on patients who failed a previous treatment with a PD-1/PD-L1 immune checkpoint inhibitor. In Q1 2018, after approvals from the competent authorities, resume of patient accrual in the US, in Europe, and initiation of the trial in Israel.
  **Phase II with Tedopi®** in combination with an immune checkpoint inhibitor planned in advanced pancreatic cancer, in collaboration with GERCOR, a cooperative group of clinical research.
- **OSE-172**, new generation checkpoint inhibitor targeting myeloid cells via the SIRP-α receptor - In preclinical development for several cancer models. Clinical program planned end of 2018.
- **OSE-703**, cytotoxic monoclonal antibody against the alpha chain of IL-7R - Under a research collaboration with Memorial Sloan Kettering Cancer Center, New York.

**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**, interleukin receptor-7 antagonist - In preclinical development for inflammatory bowel diseases and other autoimmune diseases. Clinical Phase planned end of 2018. 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*
***BCC Research*

**Click and follow us on Twitter and LinkedIn**


**Contacts**

**OSE Immunotherapeutics**
Sylvie Détry
**Sylvie.detry@ose-immuno.com**
+33 143 297 857

**U.S. Media: LifeSci Public Relations**
Matt Middleman, M.D.
**matt@lifescipublicrelations.com**
+1 646 627 8384

**French Media: FP2COM**
Florence Portejoie
**fportejoie@fp2com.fr**
+33 607 768 283

**U.S. and European Investors**
Chris Maggos
**chris@lifesciadvisors.com**
+41 79 367 6254

***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 28 April 2017 under the number R.17-038, including the annual financial report for the fiscal year 2016, 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 | 12/31/2017 | 12/31/2016 |
|---|---|---|
| Turnover | 6 682 | 383 |
| Other operating income | 0 | 0 |
| **Total Revenues** | **6 682** | **383** |
| Research and development expenses | (14 641) | (5 149) |
| Overhead expenses | (3 161) | (2 792) |
| Expenses related to shares payments | (1 505) | (679) |
| **OPERATING PROFIT/LOSS - CURRENT** | **(12 626)** | **(8 236)** |
| Other operating products (badwill) | 0 | 34 360 |
| Other operating expenses | 0 | (8 625) |
| **OPERATING PROFIT/LOSS** | **(12 626)** | **17 499** |
| Financial products | 70 | 146 |
| Financial expenses | (185) | (53) |
| **PROFIT/LOSS BEFORE TAX** | **(12 741)** | **17 592** |
| Income Tax | 2 238 | 3 074 |
| **NET PROFIT/LOSS** | **(10 503)** | **20 666** |
| *Conversions gains and losses* | 93 | (29) |
| **GLOBAL PROFIT/LOSS** | **(10 410)** | **20 637** |
| ***Of which consolidated net result attributable to shareholders*** | ***(10 503)*** | ***20 666*** |
| **Net earnings attributable to shareholders** | | |
| Weighted average number of shares outstanding | **14 360 869** | **12 508 121** |
| **Basic and diluted earnings per share** | **(0,73)** | **1,65** |

| IN K€ | 2017 | 2016 |
|---|---|---|
| **NET RESULT** | **(10 503)** | **20 666** |
| *Amounts to be recycled in the income statement:* | | |
| Unrealized gains on securities available for sale, net of tax | | |
| Currency conversion difference | 92 | (9) |
| *Amounts not to be recycled in the income statement:* | | |
| Actuarial gains and losses on post-employment benefits | 0 | (20) |
| Other comprehensive income in the period | **93** | **(29)** |
| **GLOBAL PROFIT/LOSS** | **(10 410)** | **20 637** |

# CONSOLIDATED BALANCE SHEET

| ASSETS IN KEUROS | 12/31/2017 | 12/31/2016 |
|---|---|---|
| Intangible assets | 52 600 | 52 600 |
| Tangible assets | 429 | 110 |
| Financial assets | 77 | 142 |
| Deffered tax assets | 261 | 157 |
| ***TOTAL NON CURRENT ASSETS*** | ***53 367*** | ***53 009*** |
| Trade receivables | 127 | 12 318 |
| Other current assets | 5 715 | 2 529 |
| Tax accounts receivables | 5 615 | 3 925 |
| Current financial assets | 2 882 | 2 881 |
| Cash and cash equivalents | 9 646 | 14 885 |
| ***Total current assets*** | ***23 986*** | ***36 538*** |
| **TOTAL ASSETS** | **77 353** | **89 547** |

| EQUITY & LIABILITIES in K€ | 12/31/2017 | 12/31/2016 |
|---|---|---|
| **SHAREHOLDERS' EQUITY** | | |
| Stated capital | 2 898 | 2 858 |
| Share premium | 21 743 | 21 748 |
| Merger premium | 26 855 | 26 855 |
| Treasury stock | (191) | (168) |
| Reserves and retained earnings | 14 644 | (7 434) |
| Consolidated result | (10 503) | 20 666 |
| ***TOTAL SHAREHOLDERS' EQUITY*** | ***55 446*** | ***64 525*** |
| **NON-CURRENT DEBTS** | | |
| Non-current financial liabilities | 4 296 | 1 197 |
| Non-current deferred tax liabilities | 2 866 | 5 003 |
| Non-current provisions | 247 | 158 |
| ***TOTAL NON-CURRENT DEBTS*** | ***7 410*** | ***6 358*** |
| **CURRENT DEBTS** | | |
| Current financial liabilities | 589 | 587 |
| Trade payables | 8 776 | 4 256 |
| Corporate income tax liabilities | 1 | 8 |
| Social and tax payables | 1 060 | 3 148 |
| Other debts and accruals | 4 071 | 10 664 |
| ***TOTAL CURRENT DEBTS*** | ***14 497*** | ***18 663*** |
| **TOTAL LIABILITIES** | **77 353** | **89 547** |

## Consolidated Cash Flow Statement

| | In kEuros | 2017 | 2016 |
|---|---|---|---|
| | **Consolidated result** | **(10 503)** | **20 666** |
| +/- | Depreciation, amortization and provision expenses | 123 | 107 |
| - | Badwill | 0 | (24 365) |
| + | Derecognition of asset | 0 | 6 300 |
| +/- | Shares based payments (1) | 1 373 | 680 |
| +/- | Other calculated income and expenses | 0 | 7 |
| | **Cash flow before tax** | **(9 007)** | **3 395** |
| + | Financial charges | 0 | (8) |
| - | Income tax expenses (included deferred tax) | (2 238) | (3 074) |
| | **CASH FLOW FROM OPERATING ACTIVITIES (A)** | **(11 245)** | **313** |
| - | Paid taxes | | |
| +/- | Working capital variation (2) | 3 249 | 370 |
| | **CASH FLOW FROM INVESTING ACTIVITIES (D)** | (7 996) | 684 |
| - | Tangible assets increase | (353) | (30) |
| +/ | Current financial assets variation | (2) | 2 920 |
| +/- | Non-current financial assets variation | (10) | 141 |
| +/- | Change in scope of consolidation | 0 | 3 163 |
| +/- | Loans and advances variation | 66 | (89) |
| | **CASH FLOW FROM INVESTING ACTIVITIES (E)** | **(299)** | **6 105** |
| + | Capital increase (including share premium) | 17 | 137 |
| +/- | Own shares transactions | (67) | (98) |
| - | Capital increase and merger expenses | 0 | (479) |
| + | Warrant subscription (3) | 18 | 7 |
| + | Loans subscription | 3 564 | 11 |
| - | Loans repayment | (465) | (821) |
| - | Financial charges | (11) | 8 |
| +/- | Other flows from financing activities | 0 | 0 |
| | **CASH FLOW FROM FINANCING ACTIVITIES (F)** | **3 056** | **(1 234)** |
| +/- | Currency translation transactions (G) | 0 | 0 |
| | **CASH VARIATION H = (D E + F + G)** | **(5 239)** | **5 555** |
| | **CASH OPENING BALANCE (I)** | 14 885 | 9 330 |
| | **CASH CLOSING BALANCE (J)** | 9 646 | 14 885 |
| | **DIFFERENCE : H (J-I)** | 0 | 0 |

*(1) Warrants and free shares awards granted in 2017 and valuated for 1373 K€*

*(2) Mainly explained by :*

- *Decrease of trade receivable for 12 191 k€*
- *Increase of other current assets for 3 186 k€*
- *Increase of tax accounts receivable for 1 690 k€*
- *Decrease of other non-current liabilities for 2 147 k€*
- *Increase of trade accounts payable for 4 521 k€*
- *Decrease of social and tax payable for 2 089 k€*
- *Decrease of other debts for 6 593 k€*
- *Diferred tax income for 2 238 k€*

*(3) 30 000 warrants subscripted with an unit value of 0.60€*

As of December 31, 2017 the available cash is as follows:

| **In kEuros** | 31/12/2017 | 31/12/2016 |
|---|---|---|
| Cash & equivalents according to IAS 7 | 9 646 | 14 885 |
| Current financial assets | 2 882 | 2 881 |
| **Available Cash** | **12 528** | **17 766** |