# OSE Immunotherapeutics Announces Corporate Update and H1 2022 Results

**Corporate**

- **Alexis Vandier appointed new Chief Executive Officer to guide the Company through its next phase of growth**
- **Strategy focused on leveraging both the Company's clinical portfolio of first-in-class assets in immuno-oncology and immuno-inflammation along with its two unique pioneering pre-clinical platforms**
- **Newly formed international Scientific Advisory Board**

**Pipeline**

- **Tedopi® (T-cell specific immunotherapy) - New clinical advances and analyses presented at ASCO and ESMO 2022**
- **€10 million milestone payment received from Boehringer Ingelheim for the initiation of the Phase 1 clinical expansion trial of BI 765063, SIRPα antagonist monoclonal antibody, in advanced hepatocellular carcinoma and head and neck cancer patients**
- **€5 million milestone payment received from Veloxis Pharmaceuticals, Inc., for CD28 antagonist VEL-101/FR104 following acceptance of the US Investigational New Drug (IND) Application**

**Financials**

- **€16 million turnover and €31 million available cash as of June 30, 2022, providing financial visibility until Q3 2023**

**Conference call with live webcast on September 23rd at 2:00 p.m. CET / 8:00 a.m. ET.**

**Nantes, France – September 22nd, 2022, 6:00 p.m. CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE), an integrated biotech company focused on developing first-in-class assets targeting cancer and inflammatory diseases,** today provides updates on key milestones achieved during H1 2022 and reports its consolidated half-year financial results as of June 30, 2022.

**Alexis Vandier, Chief Executive Officer of OSE Immunotherapeutics**, comments: "*It is a great honor to have joined OSE Immunotherapeutics as Chief Executive Officer. OSE is at the forefront of the science needed to develop first-in-class assets to break the efficacy ceiling of immunotherapeutics targeting immuno-oncology (IO) and immuno-inflammation (I&I) indications. In the first half of 2022, we have continued to make important progress, including with our most advanced product Tedopi®, which had demonstrated positive results in a Phase 3 trial in Non-Small Cell Lung Cancer (NSCLC) patients in secondary resistance after checkpoint inhibitor failure. We intend*

*to further leverage this lead asset Tedopi® in NSCLC and in other cancer indications explored in partnership with clinical oncology groups, both as a monotherapy and in combination.*

*We continue to focus our research efforts on developing next-generation first-in-class therapies from our unique proprietary drug discovery platforms to generate significant value: the BiCKI® platform focused on immuno-oncology, and its most advanced BiCKI® candidate targeting anti-PD1xIL-7; and the Myeloid platform, focused on optimizing the therapeutic potential of myeloid cells in IO and I&I where our most advanced preclinical product, OSE-230, has the potential to resolve chronic inflammation.*

*We have also seen important progress in the first half of 2022 with our partnered products. This has resulted in OSE Immunotherapeutics receiving a €10 million milestone payment from Boehringer Ingelheim for the initiation of the Phase 1 clinical expansion trial of BI 765063 in advanced hepatocellular carcinoma and head and neck cancer patients and a further €5 million milestone payment from Veloxis Pharmaceuticals, Inc., for FR104, a CD28 antagonist, following US Investigational New Drug (IND) acceptance for kidney transplant immunosuppression.*

*I am very confident that the globally advanced clinical pipeline that we have today addressing high medical unmet needs, as well as our pioneering platforms, will allow us to deliver on our ambitious goals, and ultimately to improve the lives of patients with cancer and inflammatory diseases.*"

**CORPORATE GOVERNANCE - NEW CHIEF EXECUTIVE OFFICER (CEO) AND SCIENTIFIC ADVISORY BOARD (SAB)**

**Appointment of Alexis Vandier as CEO**

Alexis Vandier was appointed CEO of OSE Immunotherapeutics, effective July 13, 2022. Mr. Vandier brings more than 20 years of experience with extensive international management and leadership experience in the pharmaceutical industry. He joins OSE Immunotherapeutics from Ipsen, where he latest served as Vice-President – Global Asset Lead, heading their efforts to build a leading oncology platform.

As CEO, Mr. Vandier will lead OSE's corporate, business and development strategy focused on maximizing the value potential of the Company's lead clinical assets, including its ongoing partnered clinical programs and its two proprietary drug discovery platforms BiCKI® and Myeloid.

**A newly formed SAB combining the expertise of renowned scientific and international key-opinion leaders in the fields of immunology, immuno-oncology, inflammation and immunotherapy**

- The SAB, appointed in June 2022, will work with the Company's leadership team and advise its Board of Directors on its scientific, medical, translational and developmental strategy.
- The SAB includes Pr. Wolf-Hervé Fridman (Université de Paris), Dr. Sophie Brouard (CRTI, Nantes), Dr. Bernard Malissen (CIML, Marseille), Pr. Miriam Merad (Mount Sinai, New-York), Pr. Charles Serhan (Harvard, Boston) and Dr. Jennifer Wargo (MD Anderson Cancer Center, Houston).

**STRATEGY UPDATE**

The Company pursues the ambition "to become a fast-growing biotech company combining a clinical portfolio of first-in-class assets in immuno-oncology and immuno-inflammation with a unique pioneering, highly productive pre-clinical platform engine."

OSE Immunotherapeutics is in a unique position to achieve this ambitious goal based on its:

- Ability to master complex biology, particularly with regards to T-cells and myeloid cells and their ability to improve the treatment of IO and I&I indications,

- Strong clinical development expertise and
- Well-balanced clinical portfolio of wholly owned and partnered assets.

The Company is continuing to focus significant resources on Tedopi®, its most advanced asset and is working diligently to ensure it can start an additional Phase 3 study, in NSCLC patients with secondary resistance after failure with a first line immune checkpoint inhibitor treatment. The Company is further preparing a submission for early access to make this treatment available for patients with a high unmet medical need as soon as possible. Beyond use in monotherapy, Tedopi® is being developed in combination in several phase 2 trials led by clinical oncology groups.

OSE Immunotherapeutics will also continue to support its partners, Boehringer Ingelheim, Servier and Veloxis, to ensure their assets can progress into late-stage clinical trials.

In parallel, OSE Immunotherapeutics expects to be able to generate further significant value from its two proprietary drug discovery platforms:

- **BiCKI® platform** focused on immuno-oncology (IO) is a bispecific fusion protein platform relying on the proprietary anti-PD1 backbone (OSE-279) to increase anti-tumor efficacy. The most advanced BiCKI® candidate is targeting anti-PD1xIL-7.
- **Myeloid platform**, which is focused on optimizing the therapeutic potential of myeloid cells in IO and immuno-inflammation (I&I). **OSE-230** (ChemR23 agonist mAb) is the most advanced candidate generated by the platform, with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

**MAJOR CLINICAL PROGRESS IN IMMUNO-ONCOLOGY AND IMMUNO-INFLAMMATION**

**TEDOPI®, a T-cell specific immunotherapy: Positive clinical results and analyses shared at the American Society of Clinical Oncology (ASCO) and at the European Society for Medical Oncology (ESMO) annual meetings**

***ASCO (June 2022)***

- In advanced HLA-A2+ non-small cell lung cancer (NSCLC) patients after failure to immune checkpoint inhibitors, final data of Phase 3 Atalante-1 randomized trial were presented by Prof. Benjamin Besse (Gustave Roussy Institute, Villejuif, France). This presentation featured final positive Patient Reported Outcomes (PROs) significantly better with Tedopi® than with chemotherapy in the primary analysis for the population of interest (n=118 patients), defined as NSCLC patients in secondary resistance after checkpoint inhibitor failure. These PROs results and secondary endpoints were also confirmed as significant in the global population as sensitivity analysis (n=219 patients).
- In advanced pancreatic ductal adenocarcinoma, a randomized non-comparative Phase II study of maintenance with Tedopi®, in monotherapy or in combination with nivolumab, or FOLFIRI after induction with FOLFIRINOX was presented by Dr. Anthony Turpin (Lille University Hospital, Lille, France). This presentation featured the first interim results from this Phase 2 clinical trial of Tedopi® in advanced or metastatic pancreatic cancer. The primary endpoint of the trial is the one-year survival rate (Fleming- futility analysis; null hypothesis <25%), and the key secondary endpoint was the Time to maintenance Strategy Failure (TSF= time maintenance + FOLFIRI reintroduction). The GERCOR oncology clinician group and the PRODIGE Intergroup, are sponsors of this study named TEDOPaM.

***ESMO (September 2022)***

- A first analysis compared Tedopi® to the Standard of Care (SoC) in patients with advanced NSCLC after secondary resistance to sequential use of chemotherapy followed by immunotherapy (CT-IO).

The results have shown that in advanced HLA-A2+ NSCLC patients with IO secondary resistance after sequential CT-IO (n=118), overall survival (OS) was longer with Tedopi® versus SoC regardless of the use (or not) of post progression anticancer treatment (with 13.5 months versus 10.6, HR=0.71; without 6.3 months versus 4.5, HR=0.76).

- A second analysis assessed the overall benefit/risk of Tedopi® versus SoC chemotherapy in patients with NSCLC who failed therapy with immune checkpoint inhibitors. The Net Treatment Benefit (NTB), a new statistical method combining efficacy, safety and quality of life, was assessed in the overall population (n=219). NTB of Tedopi® was of 19% and reached statistical significance (p=0.035).

**BI 765063, a myeloid checkpoint inhibitor being developed in partnership with Boehringer Ingelheim**

- In May 2022, the initiation of the Phase 1 clinical expansion trial with BI 765063 sponsored and conducted by Boehringer Ingelheim triggered a €10 million milestone payment from Boehringer Ingelheim to OSE Immunotherapeutics. The trial is being conducted in advanced hepatocellular carcinoma and head and neck cancer patients in combination, in particular with anti-PD-1 antibody ezabenlimab.

**VEL-101/FR104, a monoclonal antibody antagonist of CD28 developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation**

- In January 2022, Veloxis obtained acceptance of the IND from the Food & Drug Administration (FDA) for a clinical trial with VEL-101/FR104 sponsored and conducted by Veloxis in the US. Based on the global license agreement signed in April 2021, this first milestone triggered a €5 million payment from Veloxis to OSE Immunotherapeutics.
- In February 2022, Veloxis obtained Fast Track Designation from the FDA for VEL-101/FR104 being developed for prophylaxis of renal allograft rejection in recipients of kidney transplants.
- In May 2022, dosing of the first participant in the Phase 1 occurred.

**CoVepiT, a prophylactic vaccine candidate against COVID-19: Positive long-term immune T cell memory responses**

- In March 2022, positive long term immunological results at 6 months induced by CoVepiT in healthy volunteers with strong T cell memory responses against virus proteins were announced. In parallel, the resolution of local indurations related to T cell mechanism of action and the good safety profile were confirmed.
- However, new treatments like monoclonal antibodies or anti-viral treatments and new vaccines covering emerging variants are already available for targeted immunocompromised patients. Given these new therapeutic alternatives and multiple boosters recommended for these patients, additional clinical development of CoVepiT is made difficult. The Company's strategy is now to select the most relevant peptides allowing for an easier industrial scale-up to be ready at the request of Health Authorities for any new pandemic crisis with a novel variant.

**R&D PROGRAMS IN IMMUNOTHERAPY**

**BiCKI®-IL-7, a novel bispecific therapy combining anti-PD-1 and the cytokine IL-7**

- Presentation at the American Association for Cancer Research (AACR) in April 2022: Update on the advancements made with BiCKI®-IL-7 in an oral session dedicated to an overview of the novel trends in cytokine immunotherapy. This presentation highlighted the differentiation of the novel bispecific therapy

combining anti-PD1 and IL-7 cytokine and positioned it as a high potential asset for cancer patients suffering from immune escape following checkpoint inhibitor treatments.

**New myeloid checkpoint target CLEC-1* (a C type lectin receptor) and first monoclonal antibody antagonists of CLEC-1 blocking the "Don't Eat Me" signal**

- Presentations at the Immuno-Oncology Summit Europe in May 2022 and Tumor Myeloid-Directed Therapies Summit in June 2022:
  - CLEC-1, a novel checkpoint to regulate the antigen cross-presentation properties of dendritic cells.
  - The identification and validation of novel immune checkpoint targets and development of their antagonists as an innovation in cancer immunotherapy to enhance myeloid cells and promote antigen presentation to bridge the innate and adaptative immune system.
  - How the SIRPα-CD47 axis stimulates macrophages to recruit the adaptive immune arm via chemoattraction, and inhibition of this pathway may avoid T cell exclusion in synergy with T cell immune checkpoint and clinical translation.

**Collaborative program between OSE Immunotherapeutics and Dr Elise Chiffoleau's (https://cr2ti.univ-nantes.fr/research/team-1) research teams (Center for Research in Transplantation and Translational Immunology (CR2TI), UMR1064, INSERM, Nantes University at Nantes University Hospital).*

**A strong intellectual property (IP) with a broad scope to strengthen candidates' position in our portfolio**

- Three new patents granted: in January 2022, a Japanese patent for use of Tedopi® after failure with PD-1 or PD-L1 immune checkpoint inhibitor treatment in HLA-A2 positive cancer patients, until 2037; in March 2022, a US patent for OSE-279 and its use in cancer treatment, until 2039; in May 2022, a European patent covering CLEC-1, novel myeloid immune checkpoint target for cancer immunotherapy, until 2037.

**H1 2022 RESULTS**

The key figures of the 2022 consolidated half-year results are reported below:

| *In k€* | June 30, 2022 | June 30, 2021 |
|---|---|---|
| Operating result | (3,425) | (11,580) |
| Net result | (1,979) | (11,488) |
| *In k€* | June 30, 2022 | December 31, 2021 |
| Available cash | 31,193 | 33,579 |
| Consolidated balance sheet | 102,266 | 101,876 |

As of June 30, 2022, available cash amounted to €31 million, giving a financial visibility until Q3 2023.

During the first half of 2022, OSE Immunotherapeutics secured:

- €10 million milestone payment as part of the global collaboration and license agreement with Boehringer Ingelheim for BI 765063, a SIRPα inhibitor on the SIRPα/ CD47 myeloid pathway.
- €5 million milestone payment as part of the license agreement with Veloxis Pharmaceuticals Inc. for VEL-101/FR104, anti-CD28, in transplant indications.

This available cash will enable the Company to finance its clinical development and R&D costs for earlier stage products.

The turnover amounted to €16 million due to the milestones achieved with Boehringer Ingelheim for BI 765063 and with Veloxis for VEL-101/FR104.

During the first half of 2022, the Company recorded a consolidated net result of €-2 million.

Current operating expenses were €19.4 million (versus €20.6 million for the same period in 2021) of which 78% are related to R&D. Without the R&D tax credit product, operating expenses are quite stable compared to H1 2021.

The Board of Directors of September 22, 2022, has approved the Company's semester accounts as of June 30, 2022. The full "Half-year financial report" (Regulated information) is available on : https://ose-immuno.com/en/investors/ . The limited review procedures on the consolidated accounts have been performed. The report on this limited review is being issued.

*OSE Immunotherapeutics will hold a conference call on September 23 at 2:00 p.m. CET / 8:00 a.m. ET for analysts to give an update on business progress during the first half of 2022.*

*The live webcast will be available at the following link:*

*https://channel.royalcast.com/landingpage/oseimmunotherapeutics-en/20220923_1/*

*A replay of the webcast following the event will be available on the Company's website:*
https://ose-immuno.com/en/

**ABOUT OSE Immunotherapeutics**

OSE Immunotherapeutics is an integrated biotech company focused on developing first-in-class assets targeting cancer and inflammatory diseases.

The Company's current well-balanced first-in-class clinical pipeline includes:

- **Tedopi®** (T-cell specific immunotherapy, off-the-shelf neoepitope-based): the Company's most advanced product; positive results for Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure. Other sponsored combination Phase 2 trials in solid tumors are ongoing.
- **OSE-279** (anti-PD1 - advanced preclinical stage).
- **OSE-127/S95011** (humanized monoclonal antibody antagonist of IL-7 receptor) developed in partnership with Servier; ongoing Phase 2 in ulcerative colitis (sponsor OSE Immunotherapeutics) and ongoing Phase 2a in Sjögren's syndrome (sponsor Servier).
- **VEL-101/FR104** (anti-CD28 monoclonal antibody) developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsor Nantes University Hospital); Phase 1 ongoing in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **BI 765063** (anti-SIRPα mAb on CD47/SIRPα pathway) developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results of BI 765063 in monotherapy and in combination, in particular with anti-PD-1 antibody ezabenlimab; BI sponsored international Phase 1b clinical trial ongoing in combination with ezabenlimab alone or with other drugs in patients with recurrent/metastatic head and neck squamous cell carcinoma (HNSCC) and hepatocellular carcinoma (HCC).

OSE Immunotherapeutics expects to generate further significant value from its two proprietary drug discovery platforms, which are central to its ambitious goal to deliver next-generation first-in-class immunotherapeutics:

- **BiCKI® platform** focused on immuno-oncology (IO) is a bispecific fusion protein platform built on the key backbone component of anti-PD1 combined with a new immunotherapy target to increase anti-tumor efficacy. The most advanced BiCKI® candidate is targeting anti-PD1xIL-7.
- **Myeloid platform**, which is focused on optimizing the therapeutic potential of myeloid cells in IO and immuno-inflammation (I&I). **OSE-230** (ChemR23 agonist mAb) is the most advanced candidate generated by the platform, with the potential to resolve chronic inflammation by driving affected tissues to tissue integrity.

Additional information about OSE Immunotherapeutics assets is available on the Company's website: www.ose-immuno.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 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 Universal Registration Document filed with the AMF on 15 April 2022, including the annual financial report for the fiscal year 2021, 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.

## *CONSOLIDATED PROFIT & LOSS*

| In K€ | H1 2022 | H1 2021 |
|---|---|---|
| Turnover | 16,047 | 8,975 |
| **OPERATING INCOME - RECURRING** | **16,047** | **8,975** |
| Research & Development expenses | (14,395) | (14,419) |
| Overhead expenses | (3,813) | (3,413) |
| Expenses related to share-based payments | (1,182) | (2,724) |
| **OPERATING PROFIT/LOSS - RECURRING** | **(3,341)** | **(11,580)** |
| Other operating income and expenses | (84) | 0 |
| **OPERATING RESULT** | **(3,425)** | **(11,580)** |
| Financial income | 2,023 | 9 |
| Financial expenses | (708) | (190) |
| **PROFIT/LOSS BEFORE TAX** | **(2,110)** | **(11,761)** |
| **INCOME TAX** | **132** | **273** |
| **CONSOLIDATED NET RESULT** | **(1,979)** | **(11,488)** |
| ***Of which consolidated net result attributable to shareholders*** | ***(1,979)*** | ***(11,488)*** |
| Net earnings attributable to shareholders | | |
| Weighted average number of shares outstanding | 18,527,401 | 18,006,502 |
| • The basic and diluted result per common share (€/share) | (0,11) | (0,64) |
| • Diluted result per share | (0,11) | (0,64) |

| In K€ | H1 2022 | H1 2021 |
|---|---|---|
| **NET RESULT** | **(1,979)** | **(11,488)** |
| *Amounts to be recycled in the income statement:* | | |
| Unrealized gains on securities available for sale, net of tax | | |
| Currency conversion difference | 46 | 19 |
| *Amounts not to be recycled in the income statement:* | | |
| Actuarial gains and losses on post-employment benefits | 34 | 17 |
| Other comprehensive income in the period | **(13)** | **36** |
| **GLOBAL PROFIT/LOSS** | **(1,992)** | **(11,452)** |

## *CONSOLIDATED BALANCE SHEET*

| ASSETS in K€ | June 30, 2022 | December 31, 2021 |
|---|---|---|
| **NON-CURRENT ASSETS** | | |
| Intangible assets | 49,957 | 51,122 |
| Other intangible assets | 860 | 0 |
| Tangible assets | | 926 |
| Rights of use | 4,609 | 4,513 |
| Financial assets | 731 | 936 |
| Deferred tax assets | 180 | 173 |
| ***TOTAL NON-CURRENT ASSETS*** | ***56,337*** | ***57,670*** |
| **CURRENT ASSETS** | | |
| Trade receivables | 406 | 772 |
| Other current assets | 14,329 | 9,854 |
| Cash and cash equivalents | 31,193 | 33,579 |
| ***TOTAL CURRENT ASSETS*** | ***45,928*** | ***44,206*** |
| **TOTAL ASSETS** | **102,266** | **101,876** |

| EQUITY & LIABILITIES in K€ | June 30, 2022 | December 31, 2021 |
|---|---|---|
| **SHAREHOLDERS' EQUITY** | | |
| Stated capital | 3,705 | 3,705 |
| Share premium | 38,778 | 38,778 |
| Merger premium | 26,827 | 26,827 |
| Treasury stock | (447) | (160) |
| Reserves and retained earnings | (20,086) | (4,411) |
| Consolidated result | (1,979) | (16,850) |
| ***TOTAL SHAREHOLDERS' EQUITY*** | ***46 798*** | ***47,890*** |
| **NON-CURRENT DEBTS** | | |
| Non-current financial liabilities | 28,098 | 30,801 |
| Non-current lease liabilities | 3,984 | 3,965 |
| Non-current deferred tax liabilities | 1,630 | 1,748 |
| Non-current provisions | 571 | 710 |
| ***TOTAL NON-CURRENT DEBTS*** | ***34,283*** | ***37,224*** |
| **CURRENT DEBTS** | | |
| Current financial liabilities | 2,824 | 1,611 |
| Current lease liabilities | 866 | 756 |
| Trade payables | 13,625 | 9,607 |
| Corporate income tax liabilities | 28 | 14 |
| Social and tax payables | 2,141 | 3,724 |
| Other debts and accruals | 1,700 | 1,050 |
| ***TOTAL CURRENT DEBTS*** | ***21,184*** | ***16,761*** |
| **TOTAL LIABILITIES** | **102,266** | **101,876** |