

OSE Immunotherapeutics Reports Full Year 2023 Financial Results and Provides Business Strategy Update

Financial highlights

- €18.7 million available cash as of December 31st, 2023, not including the upcoming \$48 million payment as part of the recent collaboration and license partnership (February 2024) with AbbVie¹, nor the €5.8 million of R&D Tax credit, providing reinforced financial visibility until 2026.

Proprietary clinical pipeline highlights

- Tedopi[®], optimized epitope-based cancer vaccine: dossier and protocol approved by the Food and Drug Administration (FDA) to launch a new confirmatory Phase 3 clinical trial in second-line lung cancer in patients with acquired/secondary resistance to anti-PD(L)1. Completion of patient enrollment in the Phase 2 in pancreatic cancer; ongoing Phase 2 in combination in ovarian cancer and lung cancer.
- OSE-127/Lusvertikimab, anti-IL-7 receptor monoclonal antibody: completion of patient enrollment in Phase 2 clinical trial in ulcerative colitis; top-line results expected mid-2024. Positive opinion from the European Medicines Agency (EMA) on Orphan Drug Designation for Lusvertikimab in Acute Lymphoblastic Leukemia.
- OSE-279, proprietary anti-PD1: positive efficacy and safety results from Phase 1/2 study in advanced solid tumors.

Partnered Programs

- OSE-230, anti-ChemR23 agonist monoclonal antibody, in IND-enabling studies: new partnership with AbbVie (\$48 million upfront, up to \$665 million additional milestones) for severe and chronic inflammatory diseases.
- BI 765063 and BI 770371, two selective SIRP α antagonist programs in clinical development in solid tumors in partnership with Boehringer Ingelheim.
- FR104/VEL-101, anti-CD28 selective monoclonal antibody, developed in partnership with Veloxis Pharmaceuticals, Inc.: two clinical trials, a Phase 1/2 and a Phase 1, completed in 2023; results expected in 2024.

Nantes, France – March 27, 2024, 6:00pm CET – OSE Immunotherapeutics SA (ISIN: FR0012127173; Mnemo: OSE) today reported its consolidated annual financial results for 2023 and provided an update on key proprietary clinical and preclinical achievements, on ongoing collaboration and licensing agreements, as well as on the 2024 Company's outlook.

¹ The transaction is subject to the satisfaction of customary closing conditions, including the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act.

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, commented: *“The Company has built today a broad and independent portfolio of five clinical assets, three pharmaceutical partnerships and three research platforms, all with potential key milestones expected in 2024. We have achieved significant steps in 2023 and all of which put in place during this year will help advance our key priorities on our clinical and preclinical stage products in immuno-oncology and inflammation in the coming months. We started 2024 with a major achievement for the Company’s growth as we also reinforced our financial resources with a new license and collaboration agreement with AbbVie valued up to \$713 million, including a \$48 million upfront payment, in line with our business-model of recurrent and strategic pharmaceutical partnerships. We will advance the Company’s clinical programs and continue investing in our R&D drug discovery engine to identify novel therapeutics for patients with high medical need in inflammation, autoimmune diseases and immuno-oncology.*

The conduct of our Tedopi® new pivotal Phase 3 clinical program in second-line non-small cell lung cancer, in patients with secondary/acquired resistance, is on track. Two dossiers were filed to the Food & Drug Administration (FDA) end of 2023: a companion test to identify HLA-A2 positive cancer patients eligible (collaboration with the company GenDx) and a clinical protocol. Both dossiers were approved mid-January 2024 and will be filed in Europe in the coming weeks.

Completion of patient enrollment in the Phase 2 trial evaluating Lusvertikimab in ulcerative colitis was recently announced, and we are now eagerly looking forward to the top-line efficacy results after the induction phase and first early assessment after 6 months of therapy expected mid-2024.

The ongoing Phase 1/2 trial with proprietary anti-PD1 OSE-279 in solid tumors has confirmed positive clinical efficacy results with a high anti-tumor response rate in difficult-to-treat patients. These results encourage further clinical development in the future, used in monotherapy in already identified cancer niche indications and to explore combinations with OSE drug candidates, in particular with our neo-epitope cancer vaccine.

The positive interim data analysis from the FIRsT Phase 1/2 study evaluation of anti-CD28 FR104/VEL-101 in renal transplant marks a key advancement in the clinical development towards a Phase 2 trial under preparation by our partner Veloxis Pharmaceuticals.

Two clinical drug-candidates, BI 765063 and BI 770371, from our selective SIRPa myeloid checkpoint technology are being evaluated by Boehringer Ingelheim in combination in cancer patients, in particular in metastatic or recurrent head and neck squamous cell carcinoma (HNSCC) and hepatocellular carcinoma (HCC). Promising results from the first Phase 1 study, with early clinical efficacy data and biomarkers predictive of response and survival, were presented at the 2023 AACR and ESMO conferences.

We also look forward to generating additive value in immunology with our novel ‘pro-resolutive monoclonal antibody’ platform with additional identified GPCR targets, as well as our ‘myeloid checkpoint’ and ‘cytokine’ drug discovery platforms of which the latest updates are steadily selected for presentation at international scientific congresses. In parallel, at early research level, we keep strengthening our first-in-kind platform built at the intersection of Antibody Engineering, Data Science, Artificial Intelligence (AI) and novel RNA Therapeutics technologies to develop next-generation

immunotherapy medicines modulating immune cell responses in the field of immuno-inflammation and immuno-oncology.

Looking ahead to 2024, we are excited by several key clinical, preclinical and partnership milestones to advance the Company's growth path with the involvement of our teams, experts and partners, all fully committed to innovation in service of patients".

Anne-Laure Autret-Cornet, Chief Financial Officer of OSE Immunotherapeutics, adds: *"Our business-model is mostly based on recurrent and strategic partnerships with pharmaceutical companies. Thanks to the collaboration and license agreement signed with AbbVie, we strongly reinforced our financial visibility, which will allow us to pursue our investments in our proprietary clinical programs and our innovative R&D engine to increase their intrinsic value and to prepare the next wave of Company's growth".*

2023 FINANCIAL RESULTS

A meeting of the Board of Directors of OSE Immunotherapeutics was held on March 27, 2024. Following the Audit Committee opinion, the Board approved the annual and consolidated financial statements prepared under IFRS on 31 December 2023.

The key figures of the 2023 consolidated annual results are reported below (and presented in the attached tables):

In K€	December 31, 2023	December 31, 2022
Current operating result	(22,980)	(18,392)
Operating result	(22,986)	(18,476)
Net result	(23,221)	(17,760)
Available cash*	18,672	25,620
Consolidated balance sheet	82,054	91,781

As of December 31, 2023, the Company's available cash totaled €18.7 million, versus €25.6 million as of December 31, 2022.

In 2024, the Company will reinforce its financial position with a \$48 million upfront payment as part of the global and exclusive license and collaboration on OSE-230 signed with AbbVie in February 2024 giving a financial visibility until 2026.

In 2023, OSE Immunotherapeutics secured:

- **An equity financing line** with Vester Finance, set up on April 27, 2023. This financing has triggered at the end of September a capital increase of €11.6 million (without any discount on the share price at the date of signature). To supplement its financial resources and in order to extend its financial

visibility until the fourth quarter of 2024, OSE Immunotherapeutics signed on 27 September 2023, an extension to this equity financing line agreement with Vester Finance, at the same conditions².

This extension, approved by the Board of Directors of September 27, 2023, acting on delegation from the general assembly meeting of shareholders of June 22, 2023³, relates to a maximum of 900,000 shares of the Company, representing a maximum of 4,16% of the share capital, that Vester committed to subscribe on its own initiative, over a maximum period of 24 months, subject to certain usual contractual conditions.

Assuming that the totality of this additional line of financing is used in full, a shareholder holding 1.00% of the capital of OSE Immunotherapeutics before its establishment, would see his stake increase to 0.96% of the capital on an undiluted basis⁴ and 0.96% of the share capital on a diluted basis⁵.

This transaction does not give rise to the preparation of a prospectus subject to the approval of the "Autorité des Marchés Financiers", based on Article 1 of the Prospectus Regulation granting an exemption when a transaction relates to a dilution less than 20% of the Company's share capital.

The number of shares issued under this agreement and admitted to trading are communicated monthly on the Company's website.

- **Loans and "PGE Resilience"**

The Company obtained the formal agreement on loans for a total amount of €5.3 million with the collective support of "La Région Pays de la Loire", Bpifrance and its banking pool composed by banks CIC, Crédit Mutuel and BNP to finance its strategic R&D programs. Favorable conditions were granted for these loans, with an interest range of 2-4% and reimbursement timelines within 3 to 5 years. Part of these loans is composed by a "PGE Resilience" ("Prêt Garanti par l'État") loan guaranteed by the French State, implemented in the context of the Ukrainian crisis.

2023 Financial results

The audit procedures on the consolidated accounts have been performed. The certification report will be issued after finalization of the procedures required for the purposes of filing the registration document.

The Company recorded a consolidated operating loss of €-23.0 million. Current operating expenses were €25.2 million (versus €36.6 million in 2022) of which 74% related to R&D. R&D expenses amounted to €17.1 million versus €26.9 million in 2022.

² These conditions are described in the Company's press release dated April 27, 2023. The shares will therefore be issued on the basis of the lowest average daily price weighted by volumes over the period of the two trading sessions preceding each issue, reduced a maximum discount of 6%, in compliance with the price rule and the ceiling set by the general meeting. Under the terms of the delegation granted by the general meeting, the issue price of the shares must be "at least equal to the weighted average of the prices of the last three trading sessions preceding the fixing of the issue price, possibly reduced by a maximum discount of 20%".

³ 21st resolution: delegation of capital increase with elimination of shareholders' preferential subscription rights for the benefit of categories of people meeting specific characteristics. Vester Finance falls well into the targeted category as a regular investor in so-called "small cap" growth companies, particularly in the health or biotechnology sector.

⁴ Based on the 21,651,401 shares issuable upon exercise of the dilutive instruments issued by the Company to date.

⁵ Based on the 1,830,000 shares that may be issued upon exercise of the dilutive instruments issued by the Company to date.

APPENDICES

CONSOLIDATED PROFIT & LOSS

P&L IN K€	December 31, 2023	December 31, 2022
Turnover	2,227	18,302
Total Revenues	2,227	18,302
Research and development expenses	(17,158)	(26,893)
Overhead expenses	(6,015)	(6,672)
Expenses related to shares payments	(2,034)	(3,130)
OPERATING PROFIT/LOSS - CURRENT	(22,980)	(18,392)
Other operating expenses	(6)	(84)
OPERATING PROFIT/LOSS	(22,986)	(18,476)
Financial products	2,177	2,079
Financial expenses	(2,412)	(1,624)
PROFIT/LOSS BEFORE TAX	(23,221)	(18,022)
Income Tax	219	263
NET PROFIT/LOSS	(23,003)	(17,760)
<i>Of which consolidated net result attributable to shareholders</i>	<i>(23,003)</i>	<i>(17,760)</i>
Net earnings attributable to shareholders		
Weighted average number of shares outstanding	19,562,147	18,527,401
Basic earnings per share	(1.18)	(0.96)
Diluted earnings per share	(1.18)	(0.96)

IN K€	2023	2022
NET RESULT	(23,003)	(17,760)
<i>Amounts to be recycled in the income statement:</i>		
Currency conversion difference	(77)	(61)
<i>Amounts not to be recycled in the income statement:</i>	(9)	122
Other comprehensive income in the period	(86)	(61)
GLOBAL PROFIT/LOSS	(23,089)	(17,699)

CONSOLIDATED BALANCE SHEET

ASSETS IN K€	December 31, 2023	December 31, 2022
Acquired R&D costs	46,401	48,784
Tangible assets	464	743
Right-of-use assets	3,606	4,236
Financial assets	910	635
Differed tax assets	195	182
TOTAL NON-CURRENT ASSETS	51,576	54,581
Trade receivables	982	403
Other current assets	10,824	11,177
Cash and cash equivalents	18,672	25,620
TOTAL CURRENT ASSETS	30,478	37,200
TOTAL ASSETS	82,054	91,781

EQUITY & LIABILITIES IN K€	December 31, 2023	December 31, 2022
SHAREHOLDERS' EQUITY		
Stated capital	4,330	3,705
Share premium	49,816	38,784
Merger premium	26,827	26,827
Treasury stock	(408)	(549)
Reserves and retained earnings	(34,587)	(18,349)
Consolidated result	(23,003)	(17,760)
TOTAL SHAREHOLDERS' EQUITY	22,975	32,658
NON-CURRENT DEBTS		
Non-current financial liabilities	35,508	37,231
Non-current lease liabilities	3,032	3,586
Non-current deferred tax liabilities	1,311	1,514
Non-current provisions	429	524
TOTAL NON-CURRENT DEBTS	40,280	42,856
CURRENT DEBTS		
Current financial liabilities	6,403	3,093
Current lease liabilities	858	883
Trade payables	9,299	8,539
Corporate income tax liabilities	20	21
Social and tax payables	1,867	2,916
Other debts and accruals	351	816
TOTAL CURRENT DEBTS	18,799	16,268
TOTAL LIABILITIES	82,054	91,781

CONSOLIDATED CASH FLOW STATEMENTS

In K€	December 31, 2023	December 31, 2022
CONSOLIDATED RESULT	(23,003)	(17,760)
+/- Depreciation, amortization and provision expenses	2,574	2,744
+ Amortization on "right-of-use"	846	742
+/- Shares based payments (1)	1,746	2,728
CASH FLOW BEFORE TAX	(17,838)	(11,545)
+ Financial charges	(657)	(3,066)
- Income tax expenses	(219)	(263)
- Tax paid	(216)	(236)
+/- Working capital variation (2)	(835)	(3,142)
CASH FLOW FROM OPERATING ACTIVITIES (A)	(19,764)	(18,252)
- Tangible assets increase	(16)	(274)
+/- Financial assets variation	0	0
+/- Net variation in rights-of-use	(216)	0
+/- Loans and advances variation	(275)	300
CASH FLOW FROM INVESTING ACTIVITIES (B)	(507)	26
+ Capital increase (including share premium)	11,357	
+/- Own shares transactions	0	
+ Warrant subscription	300	
+ Loan subscription	5,023	12,056
- Loan repayment	(2,719)	(1,010)
- Lease debt repayment (3)	(637)	(785)
- Financial charges		
CASH FLOW FROM FINANCING ACTIVITIES (C)	13,324	10,267
+/- Currency translation transactions (D)		
CASH VARIATION E = (A + B + C + D)	(6,948)	(7,959)
CASH OPENING BALANCE (F)	25,620	33,579
CASH CLOSING BALANCE (G)	18,672	25,620
DIFFERENCE: E (G-F)		0

(1) Warrants and free shares awards granted in 2023 and valued for 1,746 K€

(2) Mainly explained by:

- Increase in trade receivable for 578 K€
- Decrease in other current assets for 353 K€
- Increase in trade accounts payable for 759K€
- Decrease in social and tax payable for 1,048 K€
- Decrease in other debts for 464 K€

(3) Explained by IFRS16 application, which corresponds to reimbursement of lease debt for 637 K€

ABOUT OSE IMMUNOTHERAPEUTICS

OSE Immunotherapeutics is a biotech company dedicated to developing first-in-class assets in immuno-oncology (IO) and immuno-inflammation (I&I).

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

- **Tedopi[®]** (immunotherapy activating tumor specific T-cells, off-the-shelf, neoepitope-based): this cancer vaccine is the Company's most advanced product; positive results from the Phase 3 trial (Atalante 1) in Non-Small Cell Lung Cancer patients in secondary resistance after checkpoint inhibitor failure. Other Phase 2 trials, sponsored by clinical oncology groups, of Tedopi[®] in combination are ongoing in solid tumors.
- **OSE-279** (anti-PD1): first positive results in the ongoing Phase 1/2 in solid tumors.
- **OSE-127 - lusvertikimab** (humanized monoclonal antibody antagonist of IL-7 receptor); ongoing Phase 2 in Ulcerative Colitis (sponsor OSE Immunotherapeutics); ongoing preclinical research in leukemia (OSE Immunotherapeutics).
- **FR-104/VEL-101** (anti-CD28 monoclonal antibody): developed in partnership with Veloxis Pharmaceuticals, Inc. in transplantation; ongoing Phase 1/2 in renal transplant (sponsor Nantes University Hospital); successful Phase 1 in the US (sponsor Veloxis Pharmaceuticals, Inc.).
- **BI 765063** and **BI 770371** (anti-SIRP α monoclonal antibody on CD47/SIRP α pathway) developed in partnership with Boehringer Ingelheim in advanced solid tumors; positive Phase 1 dose escalation results in monotherapy and in combination, in particular with anti-PD-1 antibody ezabenlimab; international Phase 1b ongoing clinical trial 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-230** (ChemR23 agonist mAb) developed in partnership with AbbVie in chronic inflammation.

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

- **Pro-resolutive mAb platform** focused on targeting and advancing inflammation resolution and optimizing the therapeutic potential of targeting Neutrophils and Macrophages in I&I. **OSE-230** (licensed to AbbVie) is the first candidate generated by the platform, additional discovery programs ongoing on new pro-resolutive GPCRs.
- **Myeloid Checkpoint platform** focused on optimizing the therapeutic potential of myeloid cells in IO by targeting immune regulatory receptors expressed by Macrophages and Dendritic cells. **BI 765063** and **BI 770371** (licensed to Boehringer Ingelheim) are the most advanced candidates generated by the platform. Ongoing additional discovery programs, in particular with positive preclinical results obtained in monotherapy with new anti-CLEC-1 mAbs.
- **Cytokine platform** focused on leveraging the Cis-Delivery of cytokine in IO and I&I. BiCKI[®] 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. **BiCKI[®]-IL-7v** is the most advanced BiCKI[®] candidate targeting anti-PD1xIL-7. Ongoing additional discovery programs on Cis-Demasking technologies.

Contacts

OSE Immunotherapeutics

Sylvie Détry
sylvie.detry@ose-immuno.com

Nicolas Poirier
Chief Executive Officer

nicolas.poirier@ose-immuno.com

French Media: FP2COM

Florence Portejoie
fportejoie@fp2com.fr
+33 6 07 768 283

U.S. Media Contact

RooneyPartners LLC
Kate Barrette
kbarrette@rooneypartners.com
+1 212 223 0561

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 May 2, 2023, including the annual financial report for the fiscal year 2022, 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.