

**HALF-YEAR FINANCIAL REPORT  
AT JUNE 30, 2022**

**OSE IMMUNOTHERAPEUTICS**

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**STATEMENT BY THE PERSON RESPONSIBLE FOR THE HALF-  
YEAR FINANCIAL REPORT**

**OSE IMMUNOTHERAPEUTICS**

## **STATEMENT BY THE PERSON RESPONSIBLE FOR THE HALF-YEAR FINANCIAL REPORT**

Mr. Alexis Vandier, Chief Executive Officer of OSE Immunotherapeutics

Sworn statement:

“I hereby certify that, to the best of my knowledge, the financial statements have been prepared in accordance with applicable accounting standards and give a true and fair picture of the assets and liabilities, financial position and net income of the Company and of all the companies included in its scope of consolidation, and that the half-year activity report faithfully reflects the significant developments in the first six months of the fiscal year, their impact on the half-year financial statements and main related-party transactions as well as providing a description of the main risks and uncertainties for the remaining six months of the fiscal year.”

Paris, September 22, 2022

Mr. Alexis Vandier  
Chief Executive Officer of OSE Immunotherapeutics

### **OSE Immunotherapeutics in summary:**

OSE Immunotherapeutics, announced in mid-July 2022, the arrival of Alexis Vandier as new Chief Executive Officer of the Company, with a wealth of international managerial experience in the pharmaceutical industry.

OSE is a clinical-stage biotechnology company specializing in therapeutic innovations in Immuno-Oncology and Immuno-Inflammation. Its Research and Development platforms are based on its recognized expertise in T lymphocytic cell immunity and myeloid cell immunity. A wealth of experience established in these two fields has enabled the development of leading “First in class” products that the Company develops directly or through partnerships with the pharmaceutical industry actively seeking new therapies.

Tedopi<sup>®</sup>, a T-specific immunotherapy based on highly selected neoepitopes, is being developed in a Phase 3 clinical trial. The product activates T lymphocytes capable of killing tumor cells that they have learned to recognize. This product has obtained significant results versus chemotherapy in “Non-Small Cell Lung Cancer” in patients with secondary resistance after failure of checkpoint inhibitors [Anti PD-(L) 1] where therapeutic need is very important, and in other Phase 2 clinical trials in combination are underway with international clinical research groups. The Company will capitalize on these clinical results to meet with registration agencies and actively prepare for further development.

FR 104 (Vel 101), a “First in Class” anti-CD28 monoclonal antibody capable of blocking T lymphocytes, this time pathogenic in transplants and autoimmune diseases. A Phase 1/2 clinical trial is underway in renal transplant (sponsored by the Centre Hospitalier Universitaire de Nantes). A transplantation license agreement with Veloxis Pharmaceuticals, Inc., makes it possible to study a new subcutaneous formulation in Phase 1 in the United States and to prepare for further development in transplantation with this pharmaceutical player specializing in this field.

BI 765063 (OSE-172) an anti-SIRP $\alpha$  monoclonal antibody, a target expressed on myeloid cells on the SIRP $\alpha$ /CD-47 axis, was developed in partnership with Boehringer Ingelheim in advanced solid tumors. The positive results of the Phase 1 dose escalation clinical trial as a single agent and then in combination with ezabemlimab (Boehringer’s PD1 antagonist) have enabled the initiation of two ongoing Phase 1 cohort expansion trials.

OSE-127/S95011, an interleukin-7 receptor antagonist monoclonal antibody involved in the survival of pathogenic T lymphocytes, is being developed in partnership with Servier. Two Phase 2 clinical trials are underway in autoimmune diseases where T lymphocytes are involved, ulcerative colitis (OSE as sponsor) and Sjögren’s Syndrome (Servier as sponsor). In addition, preclinical results in certain leukemias, such as acute lymphoblastic leukemias (ALL) were published in December 2021 at the annual meeting of the ASH (American Society of Hematology).

OSE-279 is an anti-PD1 antibody that blocks a T lymphocyte brake enabling activation of non-specific T cells in oncology. It is currently in the advanced preclinical stage. It should progress to a Phase 1 clinical trial at the end of the year. It is also the “backbone” component of a platform called BiCKI<sup>®</sup> for new original bispecific or bifunctional therapies.

BiCKI® platform, anti-PD-1 platform merged with innovative immunotherapy targets. Preclinical efficacy studies were presented at a conference for BiCKI®-IL-7, a first bifunctional therapy that targets PD-1 and simultaneously delivers the cytokine IL-7. This product is able to restore the function of exhausted T lymphocytic cells, a frequent cause of clinical escape of anti-PD1. It increases T stem cells capable of reconstituting memory and effector T cells to increase antitumor efficacy.

A platform for resolving inflammation, a first agonist antibody to the ChemR23 target, expressed on myeloid cells, has been developed with the ability to resolve chronic inflammation by driving affected tissues to complete the inflammation program and restore tissue integrity. These results, published preclinically for several chronic inflammatory pathologies, make it a first clinical candidate for a new therapeutic class.

The Company's registered office is based in Nantes, the Company has been listed on Euronext Paris since 2015 and has continued its develop mainly through its industrial agreements. The future activities and financing of the Company depend on a combination of factors, OSE should be able to continue to be financed, in particular through existing or future industrial agreements or other financing, if the work in progress proves positive, also taking into account the development of competitive therapies and the regulatory approval of innovations developed at different stages of development.

**CONDENSED CONSOLIDATED HALF-YEAR FINANCIAL  
STATEMENTS  
JUNE 30, 2022**

**OSE IMMUNOTHERAPEUTICS**

**FINANCIAL STATEMENTS**

**In euros**

**OSE IMMUNOTHERAPEUTICS SA**

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Period from 1/1/2022-6/30/2022

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# CONSOLIDATED BALANCE SHEET

(Amount in €K)

ASSETS	Note	6/30/2022	12/31/2021
<b>NON-CURRENT ASSETS</b>			
Intangible assets	1.1	49 957	51 122
Property, plant and equipment		860	926
Rights of use	1.2	4 609	4 513
Financial assets		731	936
Deferred tax assets	10.1	180	173
<b>TOTAL NON-CURRENT ASSETS</b>		<b>56 337</b>	<b>57 670</b>
<b>CURRENT ASSETS</b>			
Trade receivables		406	772
Other current assets	2.1	14 329	9 854
Cash and cash equivalents		31 193	33 579
<b>TOTAL CURRENT ASSETS</b>		<b>45 928</b>	<b>44 206</b>
<b>TOTAL ASSETS</b>		<b>102 266</b>	<b>101 876</b>
<b>EQUITY AND LIABILITIES</b>			
		<b>6/30/2022</b>	<b>12/31/2021</b>
<b>SHAREHOLDERS' EQUITY</b>			
Share capital	4.1	3 705	3 705
Share premium	4.1	65 605	65 605
Treasury stock	4.4	(447)	(160)
Reserves and retained earnings		(20 086)	(4 411)
Consolidated result		(1 979)	(16 850)
<b>TOTAL CONSOLIDATED EQUITY</b>		<b>46 798</b>	<b>47 890</b>
<b>NON-CURRENT LIABILITIES</b>			
Non-current financial liabilities	5	28 098	30 801
Lease non-current liabilities	5	3 984	3 965
Non-current deferred tax liabilities	10.2	1 630	1 748
Non-current provisions	7	571	710
<b>TOTAL NON-CURRENT LIABILITIES</b>		<b>34 283</b>	<b>37 224</b>
<b>CURRENT LIABILITIES</b>			
Current financial liabilities	5	2 824	1 611
Lease current liabilities	5	866	756
Trade payables		13 625	9 607
Tax due liabilities		28	14
Current tax liability		2 141	3 724
Other debts and accruals	6.1	1 700	1 050
<b>TOTAL CURRENT LIABILITIES</b>		<b>21 184</b>	<b>16 761</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>102 266</b>	<b>101 876</b>

# STATEMENT OF COMPREHENSIVE INCOME

IN €K	Note	First half 2022	First half 2021
Revenue	8.1	16 047	8 975
Other operating income	8.1	0	0
<b>TOTAL REVENUES</b>		<b>16 047</b>	<b>8 975</b>
R&D expenses (1)	8.2	(14 395)	(14 419)
Overhead expenses	8.3	(3 813)	(3 413)
Expenses related to share-based payments	8.4	(1 182)	(2 724)
<b>OPERATING INCOME - CURRENT</b>		<b>(3 341)</b>	<b>(11 580)</b>
Other operating expenses		(84)	0
<b>OPERATING INCOME</b>		<b>(3 425)</b>	<b>(11 580)</b>
Financial products	9	2 023	9
Financial expenses	9	(708)	(190)
<b>PROFIT/LOSS BEFORE TAX</b>		<b>(2 110)</b>	<b>(11 761)</b>
<b>INCOME TAX</b>	10.3	<b>132</b>	<b>273</b>
<b>CONSOLIDATED NET INCOME</b>		<b>(1 979)</b>	<b>(11 488)</b>
<i>Of which consolidated net result attributable to shareholders</i>		<i>(1 979)</i>	<i>(11 488)</i>
<b>Net earnings attributable to shareholders</b>			
Weighted average number of shares outstanding	12	18 527 401	18 006 502
- Basic earnings per share (€/share)		(0,11)	(0,64)
- Diluted earnings per share (€/share)		(0,11)	(0,64)

IN €K	First half 2022	First half 2021
<b>NET INCOME</b>	<b>(1 979)</b>	<b>(11 488)</b>
<i>Amounts to be recycled in the income statement:</i>		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(46)	19
<i>Amounts not to be recycled in the income statement:</i>		
Actuarial gains and losses on post-employment benefits (net of tax)	34	17
<b>Other comprehensive income in the period</b>	<b>(13)</b>	<b>36</b>
<b>COMPREHENSIVE INCOME</b>	<b>(1 992)</b>	<b>(11 452)</b>

(1) the allocations mentioned in H1 2021 in current operating income were entirely transferred to R&D expenses, i.e. €439 thousand for consistency reasons.

## STATEMENT OF CHANGES IN CONSOLIDATED EQUITY

IN €K	Share capital	Share premium	Currency translation transactions	Own shares	Reserves and consolidated result	Total consolidated equity
<b>CONSOLIDATED EQUITY AS OF DECEMBER 31, 2020</b>	3 597	65 449	(104)	(93)	(7 485)	61 364
<b>Consolidated result</b>					(16 850)	(16 850)
<i>Actuarial difference</i>					25	25
<i>Foreign exchange gains and losses</i>			(55)			(55)
<b>Global consolidated result</b>	0	0	(55)	0	(16 825)	(16 879)
Capital variation - share subscription warrants	8	187				195
Capital variation - founders' share warrants	2	59				61
Capital variation - free shares	98	(98)				0
Retrospective impact - Change in accounting method (net of tax)					144	144
ID impact on OPI patent conversion difference				9		9
Subscription of share subscription warrants		9				9
Payment in shares					2 944	2 944
Transactions on treasury shares				(67)	110	43
<b>CONSOLIDATED EQUITY AS OF DECEMBER 31, 2021</b>	3 705	65 605	(150)	(160)	(21 111)	47 890
<b>Consolidated result</b>					(1 979)	(1 979)
<i>Actuarial difference</i>					34	34
<i>Foreign exchange gains and losses</i>			(46)			(46)
<b>Global consolidated result</b>	0	0	(46)	0	(1 946)	(1 992)
ID impact on OPI patent conversion difference				(6)		(6)
Payment in shares					1 062	1 062
Transactions on treasury shares				(287)	132	(155)
<b>CONSOLIDATED EQUITY AS OF JUNE 30, 2022</b>	3 705	65 605	(203)	(447)	(21 863)	46 798

# CONSOLIDATED CASH FLOW STATEMENT

IN €K	Note	First half 2022	First half 2021
<b>Consolidated net income</b>		<b>-1 979</b>	<b>-11 488</b>
+/- Depreciation, amortization and provision expenses	1.2	1 385	586
+/- Provision for pensions and retirement	7	1	66
+/- Provision for litigations		-103	0
+/- Amortization on "right-of-use"	1.3	370	258
+/- Share-based payments (1)	8.4	1 062	2 060
<b>Cash flow after net borrowing cost and taxes</b>		<b>735</b>	<b>-8 518</b>
+ Net borrowing cost	5	-1 309	210
+/- Income tax expenses	10.3	-132	-273
<b>Cash flow from operations before net borrowing cost and taxes (A)</b>		<b>-706</b>	<b>-8 581</b>
- Tax paid		0	0
- Change in tax receivables / liabilities		-110	0
+/- Working capital variation (2)		-1 105	1 984
<b>CASH FLOW FROM OPERATING ACTIVITIES (D)</b>		<b>-1 921</b>	<b>-6 597</b>
- Acquisition of property, plant and equipment and intangible assets	1.2	-154	-127
+ Receipts related to the sale of rights of use		0	792
+/- Change in non-current financial assets		204	-361
<b>CASH FLOW FROM INVESTING ACTIVITIES (E)</b>		<b>50</b>	<b>304</b>
+ Capital increase (including share premium)	4.1	0	257
+/- Capital increase costs	4.1	0	0
+ Loan subscription	5	0	5 232
- Loan repayment	5	-144	-37
- Lease debt repayment (3)	5	-371	-1 098
- Net interest paid	5	0	-165
+/- Net cash (used in) generated by financing activities		0	0
<b>CASH FLOW FROM FINANCING ACTIVITIES (F)</b>		<b>-515</b>	<b>4 189</b>
+/- Currency translation transactions (G)		0	0
<b>CASH VARIATION H = (D + E + F + G)</b>		<b>-2 386</b>	<b>-2 104</b>
<b>CASH OPENING BALANCE (I)</b>	2.1	<b>33 579</b>	<b>29 368</b>
<b>CASH CLOSING BALANCE (J)</b> (4)	2.1	<b>31 193</b>	<b>27 264</b>

IN €K	First half 2022	First half 2021
Cash and cash equivalents according to IAS 7	31 193	27 264
<b>AVAILABLE CASH</b>	<b>31 193</b>	<b>27 264</b>

(1) €1,062 thousand in valuation costs for free shares and founders' share warrants awarded as of June 30, 2022.

(2) Mainly explained by:

- decrease of trade receivables for €366 thousand
- increase of other current assets for €4,475 thousand
- increase in trade payables for €4,018 thousand
- decrease of social and tax payables for €1,583 thousand
- increase in other debts for €650 thousand

(3) Explained by IFRS 16 application, which corresponds to reimbursement of lease liabilities for €371 thousand.

# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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## 1. INFORMATION ON THE COMPANY PRESENTING THE FINANCIAL STATEMENTS

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OSE Immunotherapeutics (the “Group” or the “Company”) is a biotechnology company focused on developing innovative immunotherapies acting on activator or suppressor cells to stimulate or inhibit the immune response for immuno-oncology and autoimmune diseases and transplantation. It has a portfolio of innovative clinical and preclinical products and agreements with international pharmaceutical groups. The registered office of OSE Immunotherapeutics is in Nantes. Teams are based in Nantes and Paris.

OPI, a wholly-owned subsidiary of OSE Immunotherapeutics, is a company governed by Swiss law, founded in February 2012, which owns the rights to Tedopi® (OSE-2101), which it acquired from Biotech Synergy (US) in April 2012. OPI grants OSE Immunotherapeutics the license to Tedopi® (OSE-2101).

OSE Immunotherapeutics Inc. is a company governed by US law, founded in April 2017, in order to serve as a point of support for international scientific collaboration.

## 2. HIGHLIGHTS

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### 2.1. Creation of an International Scientific Council

In June 2022, the Company convened a Scientific Advisory Board combining the expertise of renowned scientists and international opinion leaders in the fields of immunology, immuno-oncology, inflammation and immunotherapy.

The Scientific Council will work in collaboration with the Company’s Management Team and will advise its Board of Directors on the scientific, medical, translational and development strategy to be pursued.

The Scientific Board is composed of the following members: Prof. Wolf-Hervé Fridman (University of Paris), Dr. Sophie Brouard (CRTI, Nantes), Dr. Bernard Malissen (CIML, Marseille), Prof. Miriam Merad (Mount Sinai, New-York), Prof. Charles Serhan (Harvard, Boston), Dr. Jennifer Wargo (MT Anderson Cancer Center, Houston).

### 2.2. Presentation of four posters at the 2022 ASCO Annual Meeting

In June 2022, OSE presented four posters at the ASCO Annual Meeting on the following topics:

- Phase 3 Atalante 1 clinical trial in non-small cell lung cancer post checkpoint inhibitor treatment failure: Tedopi<sup>®</sup>, a specific immunotherapy based on neo-epitopes, shows significant patient-reported results versus chemotherapy
- Positive interim results of Tedopi<sup>®</sup> versus FOLFIRINOX maintenance strategy in the Phase 2 TEDOPaM clinical trial in pancreatic cancer (GERCOR)

### 2.3. COVEPIT: Positive analysis of the long-term immune T response of CoVepiT, a prophylactic vaccine candidate against COVID-19

In March 2022, the Company announced positive long-term immunological results at six months in healthy volunteers with strong memory T responses against the virus proteins. At the same time, the resolution of local indurations related to the T cells' mechanism of action and a good tolerability profile were confirmed. The vaccine remains independent of the mutations identified in current and emerging variants. Faced with existing therapeutic offers, a simpler industrial scale-up is being prepared in order to be ready in the future to face a possible new pandemic wave linked to a new variant of concern.

### 2.4. Clec 1 Presentation of advances in Immunology research at the London Immuno-Oncology Summit Europe and Boston: Tumor Myeloid-Directed Therapies Summit

In May and June 2022, the Company was invited to present the progress of its research programs on myeloid cells, in particular on the CLEC-1 target, a new myeloid checkpoint inhibitor target in cancer immunotherapy. The highly attractive field of myeloid cells and macrophages has been identified as a poor prognostic factor in oncology.

### 2.5. BI765063/OSE172: OSE Immunotherapeutics and its partner Boehringer Ingelheim announced the first patient treated in the Phase 1 expansion of the clinical trial of BI 765063, a SIRP $\alpha$ antagonist monoclonal antibody targeting myeloid cells in immuno-oncology

In early May 2022, the Company announced a new expansion of the Phase 1 clinical trial triggering a milestone payment of €10 million from Boehringer Ingelheim to OSE Immunotherapeutics with BI76503, a first-in-class SIRP $\alpha$  inhibitor on the SIRP $\alpha$ /CD47 myeloid axis. The expansion trial is being conducted in combination with Boehringer's anti-PD-1 antibody ezabenlimab in advanced hepatocellular carcinoma and head and neck cancer, two new indications in oncology. In parallel, BI 765063 is being evaluated in Europe in an expanded cohort Phase 1 clinical trial in patients with advanced colorectal cancer and endometrial cancer.

## 2.6. Acceptance of the Investigational New Drug (IND) application in the United States for VEL-101/FR104, a CD28 antagonist, obtained by Veloxis Pharmaceuticals, Inc., partner of OSE Immunotherapeutics in transplantation

In January 2022, the Company announced the approval of the Investigational New Drug (IND) application by the Food & Drug Administration (FDA) obtained by Veloxis Pharmaceuticals, Inc. for a clinical trial with VEL-101/FR104, a CD28 antagonist monoclonal antibody fragment. This trial will be sponsored and conducted by Veloxis Pharmaceuticals in the United States. As part of the global licensing agreement signed in April 2021, this first step triggered a payment of €5 million from Veloxis Pharmaceuticals, Inc. This payment was received in the first quarter of 2022.

## 2.7. Appointment of Dominique Costantini as Interim Chief Executive Officer following the departure of Alexis Peyroles

In January 2022, the Company announced the departure of Alexis Peyroles as Chief Executive Officer of the Company. Dominique Costantini, Chairwoman of the Board of Directors of OSE Immunotherapeutics and Chief Executive Officer from 2012 to 2018, was appointed Interim Chief Executive Officer, which ended with the appointment of Alexis Vandier as Chief Executive Officer of the Company in July 2022.

### 3. ACCOUNTING POLICIES AND PRINCIPLES

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#### 3.1. Basis of preparation of the consolidated financial statements

The condensed consolidated half-year financial statements of OSE IMMUNOTHERAPEUTICS, the consolidating entity, and its subsidiaries OPI and OSE Immunotherapeutics Inc. (the “Group”), approved by the Board of Directors on September 22, 2022, are presented in thousands of euros and are prepared in compliance with IFRS (International Financial Reporting Standard) as adopted by the European Union on June 30, 2022.

In terms of the condensed financial statements, the consolidated half-year financial statements do not include all of the financial information required for full annual financial statements and must be read in conjunction with the Group’s financial statements for the fiscal year ended December 31, 2021, subject to the specific procedures for preparing interim financial statements, as described below.

The Board of Directors adopted the going concern assumption, in view of the following:

- Cash and cash equivalents available at June 30, 2022, amounting to €31,193 thousand.

Consequently, this cash enables the Company to finance its development costs over the next 12 months, in particular the following clinical and preclinical studies:

- Tedopi®
- FR104

- OSE-127 whose development is partly supported through Phase 2 under the licensing option agreement with Servier and the EFFIMab consortium
- OSE-230
- BiCKI®-IL-7

Lastly, as a listed company, and as authorized by the last General Shareholders' Meeting, the Company has the option to use, if necessary, the financial instruments to which listed companies have access, as well as to draw down the second EIB tranche in the event of need.

### 3.2. Reporting date

Consolidated entities' reporting date is December 31 which is the Group's reporting date.

### 3.3. Standards and interpretations applicable from January 1, 2022

The Group applied the following standards and interpretations adopted by the European Union:

- Amendments to IFRS 3 (Reference to the conceptual framework)
- Amendments to IAS 16 (Proceeds before intended use)
- Amendments to IAS 37 (Onerous contracts - Cost of fulfilling contracts)

### 3.4. Standards, amendments and interpretations adopted by the European Union and applicable to fiscal years beginning on or after January 1, 2023, and not adopted in advance by the Company

The Company did not adopt in advance other standards, amendments, revisions and interpretations of published standards effective for annual periods beginning on or after January 1, 2023. Management does not expect these standards to have a material impact on the Company's financial statements.

### 3.5. Key accounting estimates and judgments

The preparation of financial statements in accordance with IFRS requires judgments, estimates and assumptions to be made which affect the amounts and disclosures that appear in the financial statements. Actual results may prove to be very different from these estimates depending on the various assumptions or conditions and, where applicable, a sensitivity analysis may be carried out if the difference is significant.

#### *Estimates and assumptions*

- **Valuation of free share allocation plans (AGA), share subscription warrants (BSA) and founders' share warrants (BSPCE)**

The fair value of the free share allocation plans, share subscription warrants and founders' share warrants allocated is measured on the basis of a valuation model that takes into consideration the probability of the plans' vesting requirements being met.

The fair value of the share subscription warrants and founders' share warrants granted is measured on the basis of actuarial valuation models. These models require the Company to use certain calculation assumptions such as the expected volatility of the share price (see Note 4.3).

- **Recognition of corporate tax**

The Company is liable to pay income tax in France for its business activities. Deferred tax assets mainly relate to tax loss carryforwards which are only recognized to the extent that it is probable that future taxable profits will be available. The Group must use its judgment to determine the probability of the existence of future taxable profits.

These deferred tax assets are recognized within the limit of tax liabilities recognized in the form of deferred tax liabilities, payment of which may be avoided by the Company, and the thresholds provided for by tax legislation (see Note 10).

- **Revenue recognition**

Within the context of a sale or licensing agreement, the Company may defer recognition of a portion of revenue, irrespective of the payments received (see Note 8.1). Determining the duration of this deferral requires the use of estimates.

- **Intangible assets arising from the acquisition of Effimune**

The fair value of intangible assets associated with the FR104 and OSE-127 molecules was estimated on the basis of business plans reflecting management's best estimate (see Note 1.1).

- **Estimation and recognition of R&D expenses provisioned under trade payables**

R&D expenses are systematically recognized as expenses as the research programs progress. Based on the information supplied by service providers or by work schedules provided for in contracts, on the reporting date, Management determines the progress of each of the research services on a pro rata basis and, where necessary, settles the expenses for the fiscal year.

#### 4. NOTES TO THE FINANCIAL STATEMENTS

##### NOTE 1: NON-CURRENT ASSETS

###### 1.1 Intangible assets

In €K	12/31/2021	Increase	Decrease	Amortization	06/30/2022
R&D expenses acquired put into service	35,273	-	-	- 1,168	34,105
R&D expenses acquired (ongoing)	15,700	-	-		15,700
Other intangible assets	149	12	-	- 8	153
	<b>51,122</b>	<b>12</b>	<b>-</b>	<b>- 1,177</b>	<b>49,957</b>

In 2016, following the acquisition of Effimune, the Company valued two molecules, FR104 and OSE-127. These molecules were valued on the basis of future cash flow estimates.

Impairment tests are carried out once a year on non-current assets with an indefinite useful life or which cannot be amortized.

As part of the signature of a worldwide licensing agreement with Veloxis Pharmaceuticals, the Company sold the worldwide rights to develop, manufacture, register and market the FR104 molecule in all transplantation indications. In accordance with IAS 38.97, which specifies that an asset must begin to be amortized when it can be used in the manner intended by management, the transfer of rights entails the start of the amortization of this molecule.

The amortization period used corresponds to the end of the product's term of protection (product, process, administration methods, etc.) by intellectual property rights, in particular patents. This protection is provided until December 2036, excluding any extensions related to obtaining marketing authorizations.

As of June 30, 2022, the cumulative amortization recorded in the financial statements amounted to €2,804 thousand.

###### 1.2 Rights of use

OSE Immunotherapeutics identified one new lease (covered by the standard) in the first half of 2022 with the following characteristics:

- A lease for real estate in France. The incremental borrowing rate used was 1.15%.

Rights of use break down as follows:

IN €K	12/31/2021	Increase	Decrease	6/30/2022
<b><u>Gross values (real estate assets)</u></b>				
Lease agreement (Nantes Lot 1)	537	0	0	537
Lease agreement (Nantes Lot 2)	208	0	0	208
Lease agreement (Nantes Lot 3)	127	0	0	127
Lease agreement (Paris Suffren Lot 1) *	406	0	406	0
Lease agreement (Paris Suffren Lot 2) **	296	0	296	0
Leasing (Cytek Cytometre)	281	0	0	281
Lease agreement (Paris Catalogne)	4 052	0	0	4 052
Lease agreement (La Chapelle Sur Erdre) ***	0	466	0	466
	<b>5 908</b>	<b>466</b>	<b>702</b>	<b>5 672</b>
<b><u>Amortization</u></b>				
Lease agreement (Nantes Lot 1)	310	51	0	361
Lease agreement (Nantes Lot 2)	96	17	0	113
Lease agreement (Nantes Lot 3)	30	15	0	45
Lease agreement (Paris Suffren Lot 1) *	395	0	395	0
Lease agreement (Paris Suffren Lot 2) **	296	0	296	0
Leasing (Cytek Cytometre)	107	35	0	142
Lease agreement (Paris Catalogne)	150	223	0	374
Lease agreement (La Chapelle Sur Erdre) ***	0	28	0	28
	<b>1 384</b>	<b>370</b>	<b>691</b>	<b>1 063</b>
<b><u>Impairment</u></b>				
Lease agreement (Paris Suffren Lot 1) *	11	0	11	0
Lease agreement (Paris Suffren Lot 2) **	0	0	0	0
	<b>11</b>	<b>0</b>	<b>11</b>	<b>0</b>
<b><u>Net Values</u></b>				
Lease agreement (Nantes Lot 1)	227	0	51	176
Lease agreement (Nantes Lot 2)	112	0	17	95
Lease agreement (Nantes Lot 3)	97	0	15	82
Lease agreement (Paris Suffren Lot 1) *	(0)	0	(0)	0
Lease agreement (Paris Suffren Lot 2) **	0	0	0	0
Leasing (Cytek Cytometre)	174	0	35	139
Lease agreement (Paris Catalogne)	3 902	0	223	3 678
Lease agreement (La Chapelle Sur Erdre) ***	0	466	28	438
	<b>4 513</b>	<b>466</b>	<b>370</b>	<b>4 609</b>

\* End of contract at 1/31/2022

\*\* End of contract at 1/31/2022

\*\*\* Effective lease date 12/15/2021 (1/1/2022)

## NOTE 2: CURRENT ASSETS

### 2.1 Other current assets

Other current assets break down as follows:

IN €K	6/30/2022	12/31/2021
Value added tax (1)	2 189	1 715
Trade debtors (2)	42	151
Prepaid expenses (3)	4 005	2 964
Prepaid income (4)	682	671
Government - tax receivable	10	9
Research tax credit (5)	7 403	4 344
<b>Total</b>	<b>14 329</b>	<b>9 854</b>

- (1) Value-added Tax includes VAT refund claims of €199 thousand, for FNP VAT of €399 thousand and €1,474 thousand for deductible VAT on services.
- (2) "Trade debtors" mainly comprises €41 thousand of trade discounts and rebates receivable.
- (3) Prepaid expenses are mainly composed of R&D expenses, including €454 thousand on Tedopi® progress, €440 thousand on COV19 progress, €314 thousand on the OSE-127 progress, €169 thousand on OSE-230 progress, €152 thousand on OSE-172 progress and €30 thousand on OSE-279 progress.
- (4) "Prepaid income" mainly comprises grants receivable amounting to €557 thousand.
- (5) The Research Tax Credit item comprises the tax receivable relating to the 2021 CIR and the H1 2022 CIR provision.

**NOTE 3: FINANCIAL ASSETS AND LIABILITIES AND IMPACT ON INCOME**

The Company's financial assets were measured as follows as of June 30, 2022:

IN €K	6/30/2022		Fair value through the income statement	Loans and receivables	Liabilities at amortized cost
	Balance sheet	Fair value			
Non-current financial assets	731	731		731	
Rights of use	4 609	4 609		4 609	
Trade receivables	406	406		406	
Other current assets (excl trade receivables)	10 325	10 325		10 325	
Cash and cash equivalents	31 193	31 193		31 193	
<b>Total financial assets</b>	<b>47 264</b>	<b>47 264</b>	-	<b>47 264</b>	-
Non-current financial liabilities	28 098	28 098	2 053		26 045
Non-current lease liabilities	3 984	3 984			3 984
Current financial liabilities	2 824	2 824			2 824
Current lease liabilities	866	866			866
Trade payables	13 625	13 625			13 625
<b>Total financial liabilities</b>	<b>49 398</b>	<b>49 398</b>	<b>2 053</b>	-	<b>47 345</b>

IN €K	Impacts on the income statement at June 30, 2022	
	Interest	Change in fair value
Assets at fair value through the income statement	0	0
Loans and receivables		
Assets at amortized cost		0
Cash and cash equivalents	3	
<b>Total</b>	<b>3</b>	<b>0</b>
Lease liabilities at amortized cost	35	
Liabilities at fair value through profit or loss	0	
Liabilities measured at amortized cost	626	(1 935)
<b>Total</b>	<b>661</b>	<b>(1 935)</b>

## NOTE 4: CAPITAL

### 4.1 Issued capital

Date	Nature of transactions	Capital in €	Issue premium in €	Number of shares created	Number of shares making up the capital	Nominal value in €	Stated capital in €
<b>At December 31, 2020</b>		<b>3 596 607</b>	<b>65 448 952</b>	<b>7 934 097</b>	<b>17 983 038</b>	<b>0,20</b>	<b>3 596 607</b>
June	Capital increase - Share subscription warrants (1)	400	8 900	2 000	17 985 038	0,20	3 597 007
June	Capital increase - Share subscription warrants (2)	6 000	133 500	30 000	18 015 038	0,20	3 603 007
June	Capital increase - Share subscription warrants (3)	1 000	22 250	5 000	18 020 038	0,20	3 604 007
June	Capital increase - Founders' share warrants (4)	2 000	59 400	10 000	18 030 038	0,20	3 606 007
June	Capital increase - Free Share Allocation (5)	30 000	(30 000)	150 000	18 180 038	0,20	3 636 007
June	Capital increase - Free Share Allocation (6)	20 000	(20 000)	100 000	18 280 038	0,20	3 656 007
June	Capital increase - Share subscription warrants (7)	1 000	22 250	5 000	18 285 038	0,20	3 657 007
July	Share subscription warrants - EIB share subscription warrants (8)		8 500	0	18 285 038	0,20	3 657 007
December	Capital increase - Free Share Allocation (9)	46 200	(46 200)	231 000	18 516 038	0,20	3 703 207
December	Capital increase - Free Share Allocation (10)	2 273	(2 273)	11 363	18 527 401	0,20	3 705 480
<b>At December 31, 2021</b>		<b>3 705 480</b>	<b>65 605 279</b>	<b>8 478 460</b>	<b>18 527 401</b>	<b>0,20</b>	<b>3 705 480</b>
<b>At June 30, 2022</b>		<b>3 705 480</b>	<b>65 605 279</b>	<b>8 478 460</b>	<b>18 527 401</b>	<b>0,20</b>	<b>3 705 480</b>

On June 30, 2022, the share capital stood at €3,705,480. It is divided into 18,527,401 fully subscribed and paid up ordinary shares with a par value of €0.20.

### 4.2 Equity instruments authorized but not issued

The Combined General Shareholders' Meeting of June 16, 2020, gave the Board of Directors full authority to increase the capital, on one or more occasions, by a maximum of 500,000 new shares:

At December 31, 2020, the Board of Directors had not yet allocated 500,000 of the 500,000 equity instruments.

The Combined General Shareholders' Meeting of June 24, 2021, gave the Board of Directors full authority to increase the capital, on one or more occasions, by a maximum of 500,000 new shares:

On June 24, 2021, the Board of Directors (under the delegation of June 16, 2020) decided to issue 80,000 founders' share warrants (2021) to non-salaried, non-executive directors (i.e. 10,000 founders' share warrants per director).

On March 28, 2022, the Chief Executive Officer's decision following the Board of Directors' meeting of December 7, 2021 (under the delegation of June 24, 2021), issued and allocated 150,000 free shares to Nicolas Poirier as a director representing employee shareholders and 228,700 free shares to non-corporate officer employees.

The Combined General Shareholders' Meeting of June 23, 2022, gave the Board of Directors full authority to increase the capital, on one or more occasions, by a maximum of 500,000 new shares:

On June 23, 2022, the Board of Directors (under the delegation of June 23, 2022) decided to issue 80,000 founders' share warrants (2021) to non-salaried, non-executive directors (i.e. 10,000 founders' share warrants per director).

As of June 30, 2022, there remain:

- 420,000 equity instruments under the authority of the Combined General Shareholders' Meeting of June 16, 2020;
- 121,300 equity instruments under the authority of the Combined General Shareholders' Meeting of June 24, 2021;
- 420,000 equity instruments under the authority of the Combined General Shareholders' Meeting of June 23, 2022.

### 4.3 Share subscription warrants, founders' share warrants and free shares

#### 4.3.1 - Share subscription warrants/Founders' share warrants

The Company issued the following share subscription warrant and founders' share warrant plans:

Type	Creation date	Exercise price	Subscription period	Total created	Subscriptions during the fiscal year							Total subscribed and/or exercised at 6/30/2022	
					2015 and before	2016	2017	2018	2019	2020	2021		2022
<b>Share subscription warrants and founders' share warrants</b>													
Share subscription warrants 2012	11/29/2013	1 €	11/29/2013-2/28/2014	40 000	40 000								40 000
Share subscription warrants 2014 1	6/2/2014	8 €	6/2/2014-6/30/2014	118 649	118 649								118 649
Share subscription warrants 2014 2	7/1/2014	8 €	7/1/2014-7/16/2014	33 333	33 333								33 333
Share subscription warrants 2014 3	3/27/2015	8 €	3/27/2015-9/30/2016	120 000	100 000	10 000							110 000
Share subscription warrants 2014 4	3/27/2015	8 €	Undetermined	125 000	36 744	88 256							125 000
Share subscription warrants 2014 5	3/27/2015	8 €	4/1/2016-10/1/2016	25 000	-	25 000							25 000
Share subscription warrants 2014 7	12/1/2015	8 €	12/1/2015-9/30/2016	50 000	-	39 000							39 000
EFFIMUNE share subscription warrants 2010-2	10/29/2010	5,8 €	12/8/2011-12/7/2016	23 620	23 620								23 620
EFFIMUNE share subscription warrants 2014-2	7/1/2014	7 €	7/1/2014-6/30/2019	30 700		30 700							30 700
EFFIMUNE share subscription warrants 2014-1	11/25/2014	7 €	11/25/2014-11/24/2019	3 500		3 500							3 500
Share subscription warrants 2015	3/27/2015	10,8 €	3/27/2015-5/30/2015	136 222	136 222								136 222
Share subscription warrants 2017	7/18/2017	4,65 €	7/18/2017-7/17/2021	52 000			30 000	12 000					42 000
Founders' share warrants 2018	6/13/2018	4,17 €	6/13/2018-6/13/2023	25 900				25 900					25 900
Share subscription warrants 2018	6/13/2018	4,17 €	6/13/2018-6/13/2023	42 850									-
Founders' share warrants 2019	6/26/2019	3,58 €	6/26/2019-6/26/2024	60 000				60 000					60 000
Founders' share warrants 2020	6/17/2020	6,14 €	6/17/2020-6/17/2025	70 000						70 000			70 000
Founders' share warrants 2021	6/24/2021	11,05 €	6/24/2021-6/24/2026	80 000							80 000		80 000
EIB share subscription warrants 2021 *	7/8/2021	10,59 €	7/8/2021-7/8/2033	850 000							850 000		850 000
Founders' share warrants 2022	6/23/2022	6,63 €	6/23/2022-6/23/2027	80 000								80 000	80 000
<b>Total share subscription warrants and founders' share warrants</b>				<b>2 083 034</b>	<b>488 568</b>	<b>196 456</b>	<b>30 000</b>	<b>37 900</b>	<b>60 000</b>	<b>70 000</b>	<b>930 000</b>	<b>80 000</b>	<b>1 892 924</b>

The table below specifies the assumptions used for the valuation of the share subscription warrant and founders' share warrant plans set up for previous years:

	Share subscription warrants 2017	Share subscription warrants 2018	Founders' share warrants 2018	Founders' share warrants 2019	Founders' share warrants 2020	Founders' share warrants 2021
Date of GM establishing plan	5/31/2016	6/14/2017	6/14/2017	6/13/2018	6/26/2019	6/24/2021
Number of authorized shares	52 000	42 850	25 900	60 000	70 000	80 000
Subscription price	0,60 €	0,70 €	0,00 €	0,00 €	0,00 €	0,00 €
Date of subscription	7/18/2017	6/13/2018	6/13/2018	6/26/2019	6/17/2020	6/24/2021
Vesting of share subscription warrants	on subscription	on subscription	on subscription	on subscription	on subscription	on subscription
Exercise price	€4.65/share	€4.17/share	€4.17/share	€3.58/share	€6.14/share	€11.05/share
Option type	American	American	American	American	American	American
Spot rate	4,05 €	4,09 €	4,09 €	3,52 €	6,16 €	11,32 €
Maturity	4 years	5 years	5 years	5 years	5 years	5 years
Volatility	46,98%	47,08%	47,08%	44,67%	50,05%	53,94%
EUR interest rate	0,1494%	0,3812%	0,3812%	-0,2062%	-0,3107%	-0,2509%
Dividend yield	0%	0%	0%	0%	0%	0%
Estimated fair value per share subscription warrant	1,30	1,64	1,64	1,32	2,59	5,17
Number of options subscribed	42 000	0	25 900	60 000	70 000	80 000
Subscription price	0,60	0,70	0,00	0,00	0,00	0,00
<b>Number of options exercised</b>	42 000	-	-	-	10 000,0	
Contractual expiry date	7/17/2021	6/13/2023	6/13/2023	6/26/2024	6/17/2025	6/24/2026
Vesting period	none	none	none	none	none	none

During the first half of 2022, the Group implemented the plan described below:

- The Board of Directors decided to issue a total of 80,000 founders' share warrants (2022), i.e. 10,000 founders' share warrants for each non-salaried non-executive director in office on June 23, 2022.

	Founders' share warrants 2022
Date of GM establishing plan	6/23/2022
Number of authorized shares	80 000
Subscription price	0,00 €
Date of subscription	6/23/2022
Vesting of share subscription warrants/founders' w	on subscription
Exercise price	€6.63/share
Option type	American
Spot rate	6,64 €
Maturity	5 years
Volatility	58,87%
EUR interest rate	1,9422%
Dividend yield	0%
Estimated fair value per share subscription warrant	3,42
Number of options subscribed	80 000
Subscription price	0,00
<b>Number of options exercised</b>	
Contractual expiry date	6/23/2027
Vesting period	none

- Issuance dated July 8, 2021 of 850,000 share subscription warrants to the European Investment Bank for the payment of the first tranche for €10 million of the loan granted.

EIB share warrants	(1) Features
Date of attribution	08/07/2021
Numer of share subscription warrant issued	850 000
Subscription price	0.01 € / share
Subscription date	2021-07-08
Parity	1 share warrant = 1 "AO"
Share nominal value	0.20 € / share
Share premium	10.39 € / share
Exercise price	10.59€ / share
Period of exercise	2021/07/08 - 2033/07/08

#### 4.3.2 - Free shares

The Company issued the following free share plans:

Date of attribution	Exercise period	Total allocated	Total acquired in 1H2022	Total non-exercised and expired
<b>Free Share Allocation</b>				
3/28/2022	3/28/2022-3/28/2023	228 700		
3/28/2022	3/28/2022-3/28/2023	150 000		
<b>Total Free share allocation</b>		<b>378 700</b>	-	-

On March 28, 2022, the Board of Directors allocated free shares with the following characteristics:

Allocation to Nicolas Poirier:

- Number of shares allocated (existing or to be issued): 150,000,
- Value of the share on the allocation date (according to the market price): €8.00,
- Vesting period and employment requirement: 1 year,
- Lock-up period: 1 year.

Employee allocation:

- Number of shares allocated (existing or to be issued): 228,700,
- Value of the share on the allocation date (according to the market price): €8.00,
- Vesting period and employment requirement: 1 year,
- Lock-up period: 1 year.

#### 4.3.3 - Corporate officers, employees and consultants

The expense recognized on June 30, 2022, for share-based payments to corporate officers, employees and consultants stood at €1,062 thousand exclusively associated with the 2022 free share allocation plans and the 2022 founders' share warrant plan.

The employer's contribution in relation to free shares stood at €120 thousand. Thus, expenses associated with share-based payments totaled €1,182 thousand.

All these benefits were granted to corporate officers, employees and consultants.

Share subscription warrants/founders' share warrants measured at the fair value of the options determined using the Bjerksund & Stensland model.

Free share allocations were measured using a model that considers the probability of achieving related vesting conditions.

The valuation of the conditions of the plans was measured by an external service provider.

## NOTE 5: FINANCIAL LIABILITIES

Financial liabilities are presented in the table below which distinguishes between non-current and current liabilities:

IN €K	12/31/2021	Increase	Decrease	Other transactions *	6/30/2022	Interest at 6/30/2022
BPI EFFIMAB Advance	4 688	37			4 726	(37)
BPI EFFICLIN Advance	6 464	20			6 484	(20)
Guaranteed loan	5 932			(835)	5 097	
BPI COVEPIT Advance	911	3			913	(3)
BPI CAPACITY / COVEPIT 2 Advance	3 008	8			3 015	(8)
EIB LOAN	5 810				5 810	
EIB LOAN - Share subscription warrant compo	3 989		(1 935)		2 053	
<b>Non-current financial liabilities</b>	<b>30 801</b>	<b>68</b>	<b>(1 935)</b>	<b>(835)</b>	<b>28 098</b>	<b>(68)</b>
Nantes Lot 1 Lease	124			(52)	73	
Nantes Lot 2 Lease	78			(18)	61	
Nantes Lot 3 Lease	69			(16)	53	
Paris Suffren Lot 1 Lease	(0)				(0)	
Place de Catalogne Lease	3 595			(247)	3 349	
Leasing Cytometre	98			(34)	64	
La Chapelle Sur Erdre		466		(81)	385	
<b>Non-current lease liabilities</b>	<b>3 965</b>	<b>466</b>		<b>(446)</b>	<b>3 984</b>	
BPI EFFIMAB Advance						
BPI EFFICLIN Advance						
Guaranteed loan	1 093		(156)	835	1 772	(23)
BPI COVEPIT Advance						
BPI CAPACITY / COVEPIT 2 Advance						
EIB LOAN	517	535			1 052	(535)
Current financial liabilities (bank accounts)	1		(1)			
<b>Current financial liabilities</b>	<b>1 611</b>	<b>535</b>	<b>(157)</b>	<b>835</b>	<b>2 824</b>	<b>(558)</b>
Nantes Lot 1 Lease	117		(53)	52	116	(2)
Nantes Lot 2 Lease	42		(18)	18	42	(1)
Nantes Lot 3 Lease	32		(14)	16	33	(1)
Paris Suffren Lot 1 Lease	10		(10)		0	
Place de Catalogne Lease	476		(180)	247	542	(28)
Leasing Cytometre	79		(34)	34	79	(2)
La Chapelle Sur Erdre			(26)	81	55	(1)
<b>Current lease liabilities</b>	<b>756</b>		<b>(336)</b>	<b>446</b>	<b>866</b>	<b>(35)</b>
<b>Total financial liabilities</b>	<b>37 133</b>	<b>1 068</b>	<b>(2 428)</b>		<b>35 773</b>	<b>(661)</b>

\*This column includes the current/non-current breakdown of the year.

The table below shows the schedule of financial liabilities:

IN €K	Less than 1 year	June 2024	June 2025	June 2026	June 2027 and after	Total
BPI EFFIMAB Advance	-			255	4 471	4 726
BPI EFFICLIN Advance	-		233	1 072	5 179	6 484
Guaranteed loan	1 772	1 798	1 798	1 502		6 869
BPI COVEPIT Advance	-		175	227	511	914
BPI CAPACITY / COVEPIT 2 Advance	-	766	1 000	1 000	250	3 015
EIB LOAN	1 052				7 863	8 915
Current financial liabilities (bank accounts)	-					-
<b>Financial liabilities</b>	<b>2 824</b>	<b>2 564</b>	<b>3 206</b>	<b>4 055</b>	<b>18 273</b>	<b>30 922</b>
Nantes Lot 1 Lease	116	73	-	-		188
Nantes Lot 2 Lease	42	35	26			102
Nantes Lot 3 Lease	33	31	22	-		86
Place de Catalogne Lease	542	488	481	474	1 906	3 891
Leasing Cytometre	79	64	-	-	-	143
La Chapelle Sur Erdre	55	53	53	52	227	440
<b>Lease liabilities</b>	<b>866</b>	<b>744</b>	<b>582</b>	<b>526</b>	<b>2 133</b>	<b>4 851</b>
<b>Total financial liabilities</b>	<b>3 690</b>	<b>3 308</b>	<b>3 787</b>	<b>4 581</b>	<b>20 407</b>	<b>35 773</b>

**Lease liabilities (see Note 1.2)**

## Financial liabilities

### Repayable advances

The amount of repayable advances indicated corresponds to the amounts received by the Company. However, their repayment is subject to the success of the product developed in each of the aid programs.

### French Government-guaranteed loan

To address the financial consequences of the COVID-19 pandemic, on May 5, 2020, a French Government-guaranteed loan of €6,960,000 was granted, split between three banks (CIC, CM and BNP).

These loans meet the conditions of the Rectifying Finance Law for 2020, no. 2020-289, of March 23, 2020, and the specifications defined in the decree dated March 23, 2020, providing the French Government guarantee to credit and financial institutions under that law.

This funding is one-year cash loan immediately made available to the borrower for the full amount on the date that the funds are transferred into their current account. Capital will be repaid and interest and ancillary costs paid in a single installment on the annual repayment date, with the option for the borrower to apply to spread the outstanding amount due on the repayment date over a further four years. Management exercised the option allowing it to repay this loan at a maturity of five years.

The optional amortization amendments to French Government-guaranteed loans enabling the repayment to be spread over five years were signed at the end of March 2021.

The funds received and conditions are as follows:

- Crédit Mutuel = €2,300,000 received on May 6, 2020. 48 monthly payments with a first payment on June 5, 2022 and a final payment on May 5, 2026. (Fixed rate: 0.70% / APR: 1.39% per year).

- BNP = €2,300,000 received on May 6, 2020. 48 monthly payments with a first payment on June 5, 2022 and a final payment on May 5, 2026. (Fixed rate: 0.75% / APR: 1.44% per year). An additional commission was recognized on July 30, 2021 for €48,489. The total amount due at the reporting date is therefore €2,348,489.
- CIC = €2,360,000 received on May 18, 2020. 48 monthly payments with a first due on June 15, 2022 and a final payment on May 15, 2026. (Fixed rate: 0.70% / APR: 1.39% per year).

In the first half of 2022, repayments began as follows:

- Crédit Mutuel = Payment of the first installment of €47 thousand, bringing the balance due to €2,253 thousand.
- CIC = Payment of the first installment of €48 thousand, bringing the balance due to €2,312 thousand.
- BNP = Payment of the first installment of €48 thousand, bringing the balance due to €2,300 thousand.

### **EIB loan**

In early July 2021, the Company received the payment of €10 million for the first tranche of the loan granted by the European Investment Bank (EIB) on February 12, 2021.

This type of financing, granted by the EIB, and benefiting from a guarantee from the European Commission under the European Fund for Strategic Investments (known as the “Juncker Plan”), aims to support developed research and innovation projects by companies with high growth potential.

This first tranche bears a fixed annual interest rate of 5% paid annually, with a maturity of five years.

The first tranche is accompanied by the issue of share subscription warrants (BSA) entitling EIB in the event of exercise, to subscribe to 850,000 shares of the Company (i.e. 4.44% of the share capital on an undiluted basis). The share subscription warrants are not subject to a request for admission to trading on any market.

The subscription price is €0.01 per share subscription warrant, i.e. €8,500.

The EIB has a put option on these share subscription warrants. The terms of this option are as follows:

EIB share put warrants	
Option type	Put option
Underlying	share subscription warrants
Quantity	850 000
Warrant selling price	Spot share OSE – Exercise price
Date of attribution	7/8/2021
Exercise period	7/8/2021-7/8/2026
<b>Option capped to a €15 million payment (this option will be exercised, when appropriate, for the quantity of warrants allowing to obtain a €15 million payment, the remaining warrant being kept by the EIB)</b>	
Option condition of exercise	<ul style="list-style-type: none"> <li>- Change of control of the issuer</li> <li>- Reached maturity</li> <li>- Reimbursement of the loan</li> <li>- Nonpayment of the issuer</li> </ul>

The Company also has a call option on these share subscription warrants. The terms of this option are as follows:

EIB share subscription warrants	
Option type	Call option
Underlying	Share subscription warrants
Quantity	850 000
Warrant purchase price	Spot share OSE – Exercise price
Date of attribution	7/8/2021
Exercise period	7/8/2021-7/9/2033
Option condition of exercise	<ul style="list-style-type: none"> <li>- Exit i.e. Transfer of all shares from key shareholders to a third party</li> <li>- Warrants have to be exercisable and not exercised</li> </ul>

The valuation of the share subscription warrants on the issue date (July 8, 2021) breaks down as follows:

- Share subscription warrants issued, excluding additional options - part (1): +€5.89/share
- EIB put option - part (2) : +€0.00/share
- Company call option - part (3) : -€0.96/share

A total of **€4.93/share**. For all the 850,000 share subscription warrants issued, the valuation is therefore €4.19 million.

The valuation of share subscription warrants at December 31, 2021 breaks down as follows:

- Share subscription warrants issued, excluding additional options - part (1): +€5.71/share

- EIB put option - part (2): +€0.00/share
- Company call option - part (3): -€1.02/share

A total of **€4.69/share**. For all of the 850,000 share subscription warrants issued, the valuation at December 31 was €3.99 million.

The valuation of share subscription warrants at June 30, 2022 breaks down as follows:

- Share subscription warrants issued, excluding additional options - part (1): +€3.05/share
- EIB put option - part (2): +€0.00/share
- Company call option - part (3): -€0.63/share

A total of **€2.42/share**. For all the 850,000 share subscription warrants issued, the valuation was €2.05 million.

Given the characteristics of the loan contract, this financial instrument is considered as a hybrid instrument consisting of a host (debt) and embedded derivatives (call and put share subscription warrants).

- The debt is measured using the amortized cost method including issue costs corresponding to the fair value of the share subscription warrants (on the issue date) for €4.19 million and taking into account an effective interest rate of 18.56%.
- The share subscription warrants are derivative liabilities to be measured at fair value through profit or loss at each reporting date (i.e. €2,137.13 thousand at June 30, 2022).

## **NOTE 6: CURRENT LIABILITIES**

### **6.1. Other current liabilities**

<b>IN €K</b>	<b>6/30/2022</b>	<b>12/31/2021</b>
Deferred income	1 698	1 046
Other	2	4
<b>Total other debts and accruals</b>	<b>1 700</b>	<b>1 050</b>

The deferred income item increased compared to the previous reporting date. This item is mainly composed of:

- €1,148 thousand under the collaboration and licensing agreement signed with Boehringer Ingelheim (OSE-172), corresponding to the estimated costs remaining to be incurred by the Group in 2022.
- €550 thousand related to the CAPA Building grant (linked to the progress of costs incurred).

## NOTE 7: CURRENT AND NON-CURRENT PROVISIONS

Provisions break down as follows:

IN €K	12/31/2021	Increase through the income statement	Decrease through the income statement	Conso restatement	6/30/2022
Provision for pension commitments (1)	421	-	36		385
Provision for risks and litigation	289	965	- 310	- 758	186
	710	965	- 346	- 758	571

(1) of which the effect of actuarial gains and losses of €37 thousand

### Provision for pension commitments

The pension commitment provision is measured in accordance with the applicable collective agreement, i.e. the pharmaceutical industry collective agreement, and according to the new IFRIC method. The assumptions made were as follows:

- Mortality table: regulatory table TH (men)/TF (women) 00-02,
- Estimated retirement age: 62,
- Ratio of wage increases: 2%,
- Staff turnover: low turnover,
- Discount rate: 3.07%,
- Social security contribution rates: between 39% and 45% depending on the category.

On June 30, 2022, the average monthly headcount stood at 60 compared with 53 on December 31, 2021.

## NOTE 8: OPERATING INCOME

### 8.1. Revenue from collaboration agreements

As of June 30, 2022, the breakdown of operating income is as follows:

IN €K	First half 2022		First half 2021	
	Revenue	Deferred income	Revenue	Deferred income
<b>BI Agreement</b>				
Milestone	8 980			
Re-invoicing of direct costs	1 360	1 149	1 931	341
<b>Servier agreement</b>				
Milestone				
Re-invoicing for chemical batch production	684		412	
<b>Veloxis agreement</b>				
Upfront	5 000		6 632	368
Reagent sales	20			1 840
<b>Labexchange Die / Laborgerateborse GmbH contract</b>				
Sales of finished products	4			
<b>Total</b>	<b>16 048</b>	<b>1 149</b>	<b>8 975</b>	<b>2 549</b>

Revenue amounted to €16,047 thousand and consisted of income from agreements with our industrial partners:

#### **Boehringer Ingelheim (BI):**

The IFRS 15 analysis of the BI contract revealed two performance obligations:

- A license on OSE's technology related to OSE-172 for development and marketing,
- A development service.

The transaction price is composed of:

- An upfront,
- Development milestones,
- Royalties,
- The re-invoicing of a portion of development costs.

The transaction price is allocated to the two performance obligations identified using the residual method.

Revenues allocated to the license are recognized at the date of transfer of the license, corresponding to the date of signature of the contract. Nevertheless, the assessment of the revenue attributed to the license is variable due to the uncertainty related to the achievement of milestones and royalties.

At each milestone, when it becomes highly probable, it can be added back to the transaction price and thus recognized in revenue.

In addition, as long as OSE participates in the development, a portion of the transaction price must be allocated to development services.

Consequently, in respect of the first half of 2022 and following the payment of Milestone 4 (following the inclusion of the first patient in the Phase 1 clinical trial expansion), recognized in revenue was:

- €1,360 thousand related to the re-invoicing of development costs including a double-digit margin and recognized in proportion to the costs incurred.
- €8,980 thousand allocated to intellectual property using the residual method

### ***Servier***

The Servier agreement, signed in December 2016, is a contract covering collaboration, options and a license on the OSE-127 product. This contract involved three phases:

- Before exercising option 1, OSE is required to complete Phase 1 clinical trials common to all OSE-127 applications but does not transfer any rights to its intellectual property (“IP”).
- Following the exercise of option 1, OSE sells a partial development license for the completion of Phase 2 clinical trials on Sjögren’s Syndrome. This Phase 2 clinical trial is carried out by Servier only. But OSE is required to complete the “Option 2 plan” corresponding in particular to Phase 2 clinical trials on ulcerative colitis (“UC”).
- Upon exercise of option 2, OSE will sell an exclusive development and marketing license for the entire IP relating to OSE 127.

The financial terms of this contract were as follows:

- Upfront fee: €10.25 million,
- Exercise of option 1: €10 million,
- Exercise of option 2: €20 million,
- Development milestones,
- Royalties,
- Re-invoicing of a portion of the IP costs.

Even if OSE retained the legal ownership of the IP and the decision-making power over the development activities it conducts, it effectively transferred control of the IP to Servier as soon as the contract was signed by granting options to Servier:

- Exercisable at any time and
- The second of which leads to the transfer to Servier of all rights to OSE’s IP on OSE-127.

Therefore, development activities were conducted on an underlying IP controlled by Servier and were to be considered as services rendered by OSE to Servier.

There were therefore two performance obligations in the contract:

- Right of use of intellectual property,
- A development service.

An amendment was signed in March 2020 with the following main changes:

- Option 2 of €20 million was broken down:
  - o A first milestone of €5 million paid to OSE on the inclusion of the first patient in Phase 2 clinical trials of Sjögren's Syndrome.
  - o Option 2, for €15 million, which may be exercised by Servier depending on the results of one of the two Phase 2 clinical trials.
- The Phase 2 clinical trial in UC conducted by OSE may be resized at OSE's discretion.

Thus, since signing the amendment with Servier in March 2020, OSE is no longer required to provide development services. As of this date, the amounts received from Servier will be allocated in full to the license.

Thus, for 2021 and following the inclusion of the first patient treated in the Phase 2 clinical trial in Sjogren's Syndrome, the Company received the €5 million payment of the second milestone. In accordance with the accounting treatment described below, this amount was allocated in full to the license and recognized as revenue for the 2021 fiscal year.

In addition, during the first half of 2022, the Company re-invoiced €684 thousand for production costs for clinical batches and a portion of intellectual property costs.

### ***Veloxis***

The IFRS 15 analysis of the Veloxis contract revealed two performance obligations:

- Transfer of intellectual property (FR104 molecule),
- Sales of products related to the molecule FR104.

The transaction price is allocated to the two performance obligations identified in proportion to the specific sale prices of each of these obligations. A double-digit margin is applied to product sales.

Revenues allocated to the license are recognized at the date of transfer of the license, corresponding to the date of signature of the contract.

Revenue allocated to the sale of products is recognized at the time of delivery.

Consequently, in respect of the first half of 2022, recognized in revenue was:

- €20 thousand related to the sale of reagents including a margin and recognized on delivery,
- €5,000 thousand allocated to the transfer of intellectual property by applying the residual method.

For deferred income, see Note 6.1. Other current liabilities

## **8.2. Research and development expenses**

IN €K	6/30/2022	6/30/2021
Subcontractor	10 188	10 512
Fees	1 478	1 364
Small equipment	815	564
Advertising and press relation	32	67
Employee benefits expense	2 509	2 833
Depreciation and provisions	1 341	588
Provision for Risks/Litigation	(9)	0
Taxes	36	34
Royalties	1 250	1 683
Others	197	88
<b>R&amp;D expenses</b>	<b>17 837</b>	<b>17 732</b>
CIR	(3 058)	(2 734)
Subsidy income	(384)	(580)
<b>Total R&amp;D expenses adjusted</b>	<b>14 395</b>	<b>14 419</b>

Subcontracting expenses increased compared to 2021, in line with the product development phases, and in particular the Phase 2 clinical trial for OSE-127, the Phase 1 clinical trial for OSE-172, costs of CMC for OSE-230 and OSE-279.

Activity at the Nantes laboratory is accelerating as indicated by the increase in consumables in 2022 compared to 2021.

The increase in fees is correlated with the change in the patent portfolio, mainly on OSE-127 and Tedopi®.

As in 2021, the royalty item corresponds to the recognition of a provision for the INSERM royalty for FR104 triggered by the milestone invoiced to Veloxis in 2022.

The increase in the provision item is mainly due to the amortization of the FR104 molecule following the signing of the VELOXIS contract that began on April 23, 2021 (see Note 1.1). The allocations mentioned in H1 2021 in current operating income were entirely transferred to R&D expenses, i.e. €439 thousand for consistency reasons.

Thus, after deduction of the research tax credit and subsidies, the total amount of R&D expenses was stable at €14,395 thousand.

### 8.3. Overhead expenses

IN €K	6/30/2022	6/30/2021
Fees	1 338	1 609
Small equipment	23	10
Advertising and press relation	32	33
Employee benefits expense	1 283	1 116
Depreciation and provisions	329	256
Provision for Risks/Litigation	26	0
Taxes	49	47
Directors' fees	187	158
Others	546	185
<b>Total overhead expenses</b>	<b>3 813</b>	<b>3 413</b>

Fees include legal, financial (financial communication, accounting, etc.) and human resources services. The increase compared to 2021 is mainly due to an increase in recruitment services, outsourcing of functions and legal fees relating to the EIB loan.

The increase in the provisions item is mainly due to the new leases for Paris place de Catalogne (started on September 1, 2021) and La Chapelle sur Erdre (started on January 1, 2022) restated in accordance with IFRS 16 (see Note 1.3).

The "Other" item includes rental expenses, up following the signing of two new leases.

### 8.4. Employee benefits expenses

The employee benefits expenses allocated to R&D expenses for €2,509 thousand and to overhead for €1,283 thousand, as well as directors' fees paid for €187 thousand, break down as follows:

IN €K	6/30/2022	6/30/2021
Salary and wage benefits	3 792	3 882
Directors' fees	187	158
Pension commitments	1	66
	<b>3 980</b>	<b>4 106</b>
Expenses related to employee share-based payments	908	2 414
	<b>908</b>	<b>2 414</b>

On June 30, 2022, the average monthly headcount stood at 60 compared with 53 on December 31, 2021.

## NOTE 9: NET FINANCIAL INCOME

IN €K	H1 2022	H1 2021
Foreign exchange gain	84	2
Revenue on cash equivalents	3	6
Change in fair value of derivative liabilities (share subscription warrant)	1 935	0
Change in fair value of marketable securities	0	0
<b>Total financial income</b>	<b>2 023</b>	<b>9</b>
Foreign exchange loss	47	7
Interest expense	626	181
Interest on lease liabilities	35	1
Provision for impairment of marketable securities	1	0
<b>Total financial expenses</b>	<b>708</b>	<b>190</b>
<b>Total financial income and expenses</b>	<b>1 315</b>	<b>(181)</b>

The change in net financial income is mainly due to:

- The increase in interest on the EFFIMAB AND EFFICLIN repayable advances, the French Government-guaranteed loan and on the EIB loan
- Change in fair value of the derivative share subscription warrant liability under the EIB contract.

## NOTE 10: CORPORATE TAX

### 10.1. Deferred tax assets

The Company recognized a deferred tax asset for OPI (Swiss subsidiary) valued at €1.18 million calculated on the basis of a 13.99% tax rate (Swiss rates under ordinary law applied since January 1, 2020).

At June 30, 2022, deferred tax assets stood at €180 thousand.

### 10.2. Net deferred tax liabilities

Given its level of development, the Company only recognizes deferred tax assets in the amount of its tax liabilities recognized as deferred tax liabilities, payment of which may be avoided by the Company, even in the absence of any profit forecast. As of June 30, 2022, tax loss carryforwards amounted to €79 million.

In 2016, the Company recognized a deferred tax liability for the FR104 and OSE-127 molecules, valued at €52.6 million. Consequently, the Company recognized its deferred tax assets at the level of its deferred tax liabilities. As at December 31, 2018, the net deferred tax liability amounted to €2,010 thousand.

Since January 1, 2019, under the 2019 finance act modifying the tax regime for income from the sale or licensing of patents, the Company applied a deferred tax rate of 10% when calculating deferred tax liabilities and assets generated in France.

In light of the administrative clarifications of April 22, 2020, profits eligible for the preferential regime may be offset against tax loss carryforwards as of December 31, 2019. As a result, deferred tax assets on tax loss carryforwards were recognized in the amount of deferred tax liabilities (with the application of the cap on tax loss carryforwards). Deferred tax assets on tax loss carryforwards recognized at June 30, 2022 amounted to €3,630 thousand.

As a result, as of June 30, 2022, the net deferred tax liability amounted to €1,630 thousand.

### 10.3. Income tax expense

At June 30, 2022, the Group generated income (net of tax) of €132 thousand which breaks down as follows:

- Net deferred tax income of €133 thousand, mainly corresponding to:
  - A decrease in the deferred tax liabilities of €116 thousand between December 31, 2021 and June 30, 2022 (including a €2 thousand increase in the deferred tax liability on cancellation of Euronext fees and €118 thousand of additional losses carried forward after taking into account the VELOXIS contract).
  - An increase in deferred tax assets of €13 thousand between December 31, 2021 and June 30, 2022 related to OPI patents.
  - A decrease in the deferred tax liabilities related to the OCI impacts of actuarial gains and losses of €4 thousand.
- Current tax expense for €1 thousand.

The tax proof breaks down as follows:

CONSOLIDATED RESULT (IFRS)		6/30/2022
<b>Net income before tax</b>		<i>(2 111)</i>
<b>Tax rate</b>		<b>10%</b>
<b>Theoretical tax</b>		<b>211</b>
Permanent differences		<i>1 501</i>
Swiss tax rate		<i>13</i>
Other tax or tax credit		<i>(1)</i>
Deferred tax on recognized deficit		<i>0</i>
Deferred tax on non-recognized deficit		<i>(1 603)</i>
Other		<i>11</i>
<b>Income tax</b>		<b>132</b>
<b>Income tax accounted</b>		<b>(132)</b>
Net effective tax rate		6,25%

## NOTE 11: COMMITMENTS

### 11.1. Other off-balance sheet commitments

As part of the initial transaction for the acquisition of Memopi® (including Tedopi®) assets from the pharmaceutical company Takeda, the Company agreed to pay an earn-out when its product was registered, then no more than single-digit royalties on future sales. The following commitments are transferred to the Company by way of merger-absorption.

#### Collateral pledged

Interest-bearing bank account pledged to Crédit Mutuel as collateral, amounting to €10 thousand.

Interest-bearing bank account pledged to CIC as collateral, amounting to €146 thousand.

Interest-bearing bank account pledged to CIC as collateral, amounting to €161 thousand.

#### Guarantees given

€18 thousand lease payment guarantee to CIC.

#### Guarantees received

The Company received a guarantee from Bpifrance covering 70% of the original amount of its loans from BNP, Crédit Mutuel and CIC, for €375 thousand each. The outstanding principal at June 30, 2020, amounted to €70 thousand.

The Company does not have any other off-balance sheet commitments.

The outstanding principal at June 30, 2022, amounted to €6,865 thousand.

## NOTE 12: EARNINGS PER SHARE

Earnings per share are calculated by dividing consolidated net income by the weighted average number of shares outstanding in the fiscal year.

Result per share	H1 2022	H1 2021
Net Result in €K	- 1 979	- 11 488
Weighted average number of shares outstanding	18 527 401	18 006 502
Basic earnings per share (€/share)	- 0,11	- 0,64

The allocations of subscription share warrants, founders' share warrants and free shares have no dilutive effect on earnings per share.

## NOTE 13: FINANCIAL RISK MANAGEMENT

The Group's main financial instruments are in cash. These instruments are managed for the purpose of funding the Company's activities. The Group's policy is not to subscribe for financial instruments for speculative purposes. The Group does not use any financial derivatives.

The main risks to which the Company is exposed are liquidity risk, foreign exchange risk and interest rate and credit risk. No change was recorded between December 31, 2021 and June 30, 2022.

## NOTE 14: RELATED PARTIES

### 14.1. Compensation of management and members of the Board of Directors

No post-employment benefits were granted to members of the Board of Directors.

Compensation paid to management and members of the Board of Directors breaks down as follows:

IN €K	6/30/2022	6/30/2021
Salaries and other short-term benefits *	1 418	751
Directors' fees	187	158
Share-based payments **	586	1 163
Fees	16	6
<b>Total</b>	<b>2 207</b>	<b>2 078</b>

\* Excluding social charges

\*\* Relating to the allocation of free shares and share subscription and founders' share warrants

Methods used to measure the benefit of share-based payments are shown in Note 4.3.

## NOTE 15: EVENTS AFTER THE REPORTING PERIOD

### 15. 1 Appointment of Alexis Vandier as Chief Executive Officer

In July 2022, the Company was pleased to announce the appointment of Alexis Vandier as Chief Executive Officer, with immediate effect. Alexis Vandier brings to the Company his experience of remarkable successes in the pharmaceutical industry, through a range of international responsibilities and in various therapeutic areas, including oncology.

Alexis Vandier was previously Vice Chairman - Global Asset Lead at Ipsen, playing a driving role in the construction of a leading oncology platform in its market, notably with the Company's flagship product, a tyrosine kinase inhibitor (Cabometyx®, cabozantinib). Alexis collaborated on the launch of this product and developed its full commercial potential in various cancer indications 2.

Across 40 countries. He also managed partnerships with Exelixis in the United States, with Roche and BMS (co-developments with nivolumab and atezolizumab).

Alexis has gained more than 20 years of international and leadership experience in various pharma business lines. First at Sanofi, for 11 years in Corporate Strategy and Business Development, Finance and Marketing, then at Ipsen, for 12 years in direct collaboration with Marc de Garidel in several positions in Strategy, Business Development, Alliance Management and Innovation / Marketing. in different regions of the world (Europe, Asia and the United States). Alexis also became Chief Executive Officer of Ipsen France where he accelerated the development of the Company in the fields of Medical, Market Access and External Affairs, leading successful launches in oncology and rare diseases.

Alexis is a graduate of École Centrale de Lyon, with a Master's degree in engineering, and the University of Economics of Lyon II.

### 15. 2 New data on Tedopi® in the Phase 3 clinical trial in advanced non-small cell lung cancer at European Society for Medical Oncology (ESMO) Conference 2022

In September 2022, the Company presented new data on Tedopi® in the Phase 3 clinical trial in patients with advanced non-small cell lung cancer after immune checkpoint inhibitor treatment failure, at the European Society for Medical Oncology (ESMO) 2022 conference.

## **HALF-YEAR ACTIVITY REPORT**

## **OSE IMMUNOTHERAPEUTICS**

## I. COMPANY ACTIVITY IN THE FIRST HALF OF 2022

### 1.1 Position and development of the Company's business over the fiscal year

#### 1.1.1 *Capital structure at June 30, 2022*

As of June 30, 2022, the Company's share capital was €3,705,480.20, divided into 18,527,401 shares with a nominal value of €0.20, fully paid up.

As of June 30, 2022, the breakdown of the Company's share capital and voting rights was as follows:

Shareholders	6/30/2022		
	Number of shares	% of capital	% Voting rights
Dominique Costantini	2 007 163	10,8%	16,3%
Alexis Peyroles *	929 862	5,0%	6,8%
Maryvonne Hiance **	424 084	2,3%	3,5%
Nicolas Poirier	92 802	1,0%	1,2%
Corporate officers and other employees	500 359	2,7%	3,2%
Public	14 473 131	78,1%	69,1%
<b>TOTAL as of 6/30/2022</b>	<b>18 527 401</b>	<b>100%</b>	<b>100%</b>

\* *Directly and indirectly through the intermediary of his asset management company Aperana Consulting.*

\*\* *Directly and indirectly through her asset management company HIANCE MD2A.*

#### 1.1.2 *Development of the Company's business*

Despite the COVID-19 health crisis and the war in Ukraine, the Company continued its research and development work in the first half of 2022.

### **JUNE 2022**

OSE Immunotherapeutics and its clinical partners GERCOR, ARCAGY-GINECO and the FoRT Foundation (Fondazione Ricerca Traslazionale) presented four posters on the combination of Tedopi® neo-epitopes in several cancer indications at the 2022 ASCO (American Society of Clinical Oncology) annual meeting held from June 4 to 7:

- Phase 3 Atalante 1 clinical trial in non-small cell lung cancer post checkpoint inhibitor treatment failure: Tedopi®, a specific immunotherapy based on neo-epitopes, shows significant patient-reported results versus chemotherapy;
- Positive interim results of Tedopi® versus FOLFIRINOX maintenance strategy in the Phase 2 TEDOPaM clinical trial in pancreatic cancer (GERCOR)

OSE Immunotherapeutics announces the appointment of six leading international experts to its new Scientific Board to support the Company in its new phase of growth and its scientific orientations. The Scientific Council is composed of the following members:

Prof. Wolf-Hervé Fridman (University of Paris), Dr. Sophie Brouard (CRTI, Nantes), Dr. Bernard Malissen (CIML, Marseille), Prof. Miriam Merad (Mount Sinai, New-York), Prof. Charles Serhan (Harvard, Boston), Dr. Jennifer Wargo (MT Anderson Cancer Center, Houston).

OSE Immunotherapeutics announces a collaboration with Microsoft, enabling it to further develop its digital tools and infrastructure, in particular in terms of Artificial Intelligence and algorithmic approaches applied to the development of innovative first-in-class immunotherapies.

## **MAY 2022**

OSE Immunotherapeutics announces that the European Patent Office (EPO) has granted a new patent that strengthens the protection of CLEC-1 (among the CLR receptors - C-type lectin receptors), its new myeloid checkpoint inhibitor target, and its use in the treatment of cancer. This patent provides protection until 2037.

Boehringer Ingelheim and OSE Immunotherapeutics announce a new milestone in their licensing and collaboration agreement under which Boehringer Ingelheim has acquired the exclusive rights to BI 765063, a first-in-class SIRP $\alpha$  inhibitor on the SIRP $\alpha$ /myeloid axis CD47. The first patient was treated in the Phase 1 expansion clinical trial led by Boehringer Ingelheim in advanced cancers that are difficult to treat. The start of the Phase 1 clinical expansion trial triggers a milestone payment of €10 million from Boehringer Ingelheim to OSE Immunotherapeutics.

## **APRIL 2022**

OSE Immunotherapeutics announces that the Company is invited to present the latest advances on its platform of bispecific checkpoint inhibitors BiCKI<sup>®</sup>, and in particular on BiCKI<sup>®</sup>-IL-7, a bispecific therapy targeting PD-1 and interleukin-7 (IL-7), in a plenary oral presentation in an “educational session” dedicated to immunocytokines at the annual meeting of the American Association for Cancer Research (AACR) (New Orleans, Louisiana, April 8 - 13, 2022).

## **MARCH 2022**

OSE Immunotherapeutics announces that the results of early biomarker analyses from the ongoing Phase 1 clinical trial with the SIRP $\alpha$  inhibitor, BI 765063, in patients with advanced solid tumors, have been selected for a poster presentation at the annual meeting of the American Association for Cancer Research (AACR) to be held in New Orleans (Louisiana) from April 8 to 13, 2022.

OSE Immunotherapeutics announced a positive long-term memory response with CoVepiT, its multi-target anti-COVID T vaccine:

- Positive long-term immunological results at six months in healthy volunteers with strong memory T responses against the virus proteins.

- CoVepiT, based on 13 peptides, induces long-lasting immunity against a wide variety of structural and non-structural viral proteins.
- The vaccine remains independent of the mutations identified in current and emerging variants.

## **FEBRUARY 2022**

Transfer of shares from compartment C to compartment B of Euronext Paris as of January 31, 2022.

OSE Immunotherapeutics announced the “Fast Track” designation from the FDA for VEL-101/FR104, a CD28 antagonist, obtained by Veloxis Pharmaceuticals, Inc., its transplant partner.

Appointment of Alexandre Lebeaut by co-option as an independent director of the Company (to replace Alexis Peyroles who resigned from his position as director).

## **JANUARY 2022**

Appointment of Dominique Costantini as Interim Chief Executive Officer following the departure of Alexis Peyroles.

Dominique Costantini, currently Chairwoman of the Board of Directors of OSE Immunotherapeutics and Chief Executive Officer from 2012 to 2018, was appointed Interim Chief Executive Officer, with immediate effect.

Alexis Peyroles resigned for health reasons, he will remain involved in the progress of OSE Immunotherapeutics. He will continue to support the Company during the coming months through a consulting assignment to ensure a smooth handover.

OSE Immunotherapeutics received approval from the Japanese Patent Office for a new patent protecting the use of Tedopi®, a combination of neo-epitopes, after failure of an immune checkpoint inhibitor treatment in HLA-A2 positive patients with cancer. This patent will strengthen the international intellectual property of Tedopi® and will ensure new protection of the product until 2037.

OSE Immunotherapeutics announced the acceptance of the IND application in the United States for VEL-101/FR104, a CD28 antagonist, obtained by Veloxis Pharmaceuticals, Inc., its transplant partner. As part of the worldwide licensing agreement signed in April 2021, this first step triggers a payment of €5 million from Veloxis Pharmaceuticals, Inc. to OSE Immunotherapeutics.

### ***1.1.3 Issuance of share warrants (BSA), founders’ warrants (BSPCE) and free shares (AGA)***

In the first half of 2022, the following financial instruments were issued or allocated:

#### ***Issuance of 80,000 founders’ share warrants***

Under Article L. 225-44 of the French Commercial Code, as amended by the PACTE law of May 22, 2019, it is now possible to compensate independent directors with founders’ share warrants.

As such, on June 23, 2022, the Board of Directors, using the delegation granted by the Combined General Shareholders' Meeting of June 23, 2022, allocated 80,000 founders' share warrants, i.e. 10,000 founders' share warrants for the benefit of each non-salaried non-executive director in office on June 23, 2022, in accordance with Article 163 bis G II of the French General Tax Code.

These free founders' share warrants may be exercised between June 24, 2022 and June 23, 2027 and give the right to subscribe to 80,000 new shares at a price of €6.63 per share.

## 1.2 Progress made and difficulties encountered

### IN IMMUNO-ONCOLOGY

#### - **T-SPECIFIC IMMUNOTHERAPY: TEDOPI<sup>®</sup>, POSITIVE RESULTS FROM PHASE 3 CLINICAL TRIAL IN NON-SMALL CELL CANCER (NSCLC) IN SECONDARY RESISTANCE TO A TREATMENT WITH A CHECKPOINT INHIBITOR**

The Atalante 1 clinical trial evaluated the benefit of Tedopi<sup>®</sup>, a T-specific immunotherapy in HLA-A2 positive patients, as a second or third-line treatment in non-small cell lung cancer, stage IIIB invasive or stage IV metastatic, after failure of a checkpoint inhibitor. Treatment with Tedopi<sup>®</sup> was compared with chemotherapy with docetaxel or pemetrexed and the primary endpoint of the trial was overall survival.

Tedopi<sup>®</sup> has shown a favorable benefit/risk ratio compared to standard therapy (docetaxel or pemetrexed) in HLA-A2 positive NSCLC patients with secondary resistance to immune checkpoint inhibitors.

In the first half of 2022, capitalizing on these positive data in a Phase III clinical trial, the Company worked on the preparation of future discussions with the agencies on the best development / regulatory strategy options to register Tedopi<sup>®</sup> in non-small cell lung cancer in secondary resistance after checkpoint inhibitors.

#### - **TEDOPI<sup>®</sup>, IN PHASE 2 CLINICAL TRIAL IN PANCREATIC CANCER: CONTINUATION OF INCLUSIONS IN THE TRIAL ACCORDING TO AN AMENDED TRIAL PROTOCOL**

**Tedopi<sup>®</sup>'s** TEDOPaM trial as a treatment for pancreatic cancer as a monotherapy and in combination with BMS' nivolumab Opdivo<sup>®</sup> has been suspended due to COVID-19. The GERCOR indicated that the IDMC, after analyzing the data on the first 29 patients, recommended stopping treatment with Opdivo and proposed adding chemotherapy to Tedopi<sup>®</sup>. The GERCOR made modifications to the protocol and the first patients were randomized with two arms in the trial of Tedopi<sup>®</sup> plus FOLFIRI vs. FOLFIRI. The main endpoint of the trial remains the one-year survival rate.

An interim analysis on the first 29 patients gave interesting results for Tedopi<sup>®</sup> in monotherapy versus Folfiri, presented at ASCO by Gercor in June 2022.

Recruitment has continued since its resumption in 2021.

- **TEDOPI®: CONTINUATION OF TWO PHASE 2 CLINICAL TRIALS WITH TEDOPI® IN COMBINATION WITH A CHECKPOINT INHIBITOR IN NON-SMALL CELL LUNG CANCER AND IN OVARIAN CANCER, IN COLLABORATION WITH EXPERT ONCOLOGY GROUPS**

A Phase 2 clinical trial has started in non-small cell lung cancer, sponsored and conducted by FoRT, an Italian oncology foundation. The purpose of this trial is to evaluate Tedopi® in combination with a checkpoint inhibitor, Opdivo® (nivolumab), versus Tedopi® in combination with chemotherapy, versus chemotherapy alone as a second-line treatment in patients with non-small cell lung cancer after a first-line treatment with chemoimmunotherapy. The first patient was randomized in November 2021 and recruitment has continued since then.

A second Phase 2 clinical trial, 'TEDOVA', was initiated in ovarian cancer, promoted and conducted by ARCAGY-GINECO. The purpose of this trial is to evaluate Tedopi® as maintenance therapy, alone or in combination with an anti-PD-1 immune checkpoint inhibitor, Keytruda® (pembrolizumab), versus standard of care in patients with platinum-sensitive ovarian cancer in a first or second relapse setting whose disease is controlled after platinum-based chemotherapy and who have received prior treatment with bevacizumab and a PARP inhibitor. The first patient was randomized in August 2021 and recruitment has continued since then.

The design of the two trials was presented at the ASCO conference in June 2022.

Clinical trial momentum on this product was created via the results of Atalante Phase 1 in lung cancer, with three additional Phase 2 trials ongoing.

- **COVEPIT, PROPHYLACTIC VVACCINE AGAINST COVID-19: POSITIVE EX-VIVO PRECLINICAL RESULTS - CLINICALLY POSITIVE LONG-TERM IMMUNOLOGICAL RESULTS AT SIX MONTHS IN HEALTHY VOLUNTEERS WITH STRONG MEMORY T RESPONSES AGAINST THE VIRUS PROTEINS**

In May 2020, OSE Immunotherapeutics committed to the fight against COVID-19 and announced the launch of a research program on a vaccine called CoVepiT.

The Phase 1 clinical trial began in April 2021 to assess the tolerability, reactogenicity and immunogenicity of CoVepiT in healthy adult volunteers.

In July 2021, the Company voluntarily suspended enrollment and administration of CoVepiT in the Phase 1 clinical trial initiated in April 2021, as a precautionary measure due to a limited number of grade 1 adverse events (nodule-like indurations at the injection site) and one grade 2 adverse event in one participant. The data were then analyzed regularly with the independent Safety Monitoring Committee and the investigating center in Ghent, Belgium. Indurations resolved within a few weeks for most participants (no systemic reaction, no fever, no inflammation, no local ulceration), with continued follow-up showing a good tolerability profile. This profile with frequent indurations is close to that of vaccines that induce a T cell response (1, 2, 3) and is regularly linked to this T mechanism of action.

In March 2022, the Company announced the positive analysis of the long-term immune T response of CoVepiT with positive immunological results at six months on the memory T response in vaccinated subjects. At the same time, the resolution of local indurations related to the T cells' mechanism of action and a good tolerability profile were confirmed.

OSE Immunotherapeutics has thus validated the concept and paradigm that long-term immunity against coronavirus could be achieved in human with its T cell vaccine platform inducing durable memory T lymphocytes, with additional properties as T cells resident in the lung already described in preclinical studies.

For immunocompromised patients, new treatments such as monoclonal antibodies or antiviral treatments are available. It is also recommended to carry out regular booster injections of the vaccines registered in this fragile population whose antibody response is deficient.

With these new treatments available and multiple vaccine boosters recommended for these patients, further clinical development of CoVepiT is currently difficult. Based on the positive long-term T-response results, the Company's strategy is now to select the most relevant peptides to enable simpler industrial scale-up to be ready for another pandemic wave linked to a new variant of concern.

## **IN IMMUNO-ONCOLOGY: CLINICAL AND PRECLINICAL ADVANCES**

- **BI 765063 (OSE-172), IN PHASE 1 CLINICAL TRIAL IN ADVANCED SOLID TUMORS: PROMISING DATA FOR THE DOSE ESCALATION PHASE AND START-UP OF THE EXPANSION PHASE**

Following significant preclinical results obtained in a number of cancer models, a full pharmacotoxicology report and production of GMP-compliant batches, the National Agency for the Safety of Health Products (ANSM) in France and the Federal Agency for Medicines and Health Products (AFMPS) in Belgium authorized the Phase 1 clinical trial of the OSE-172 checkpoint inhibitor, renamed BI 765063, a monoclonal antibody that selectively targets SIRP $\alpha$ . The dose-escalation Phase 1 clinical trial of the SIRP $\alpha$  monoclonal antibody, BI 765063, a myeloid checkpoint inhibitor, has been positively completed, administered alone and in combination with a monoclonal antibody and PD-1 antagonist of Boehringer Ingelheim, BI 754091, a checkpoint inhibitor, without limiting toxicity, the results of clinical efficacy signals were presented at ASCO 2021 and at ESMO 2021 in combination with the anti PD1. Clinical development continued in a Phase 1 cohort expansion trial in colorectal cancer and endometrial cancer.

A new Phase 1 expansion clinical trial was set up by Boehringer Ingelheim, in combination with their anti PD-1 in patients with metastatic or recurrent hepatocellular carcinoma (HCC), or squamous cell carcinoma of the head and neck (CCSTC).

The start of the Phase 1 expansion clinical trial triggered a milestone payment of €10 million from Boehringer Ingelheim to OSE.

- **CLEC-1, FIRST PRECLINICAL EFFICACY DATA FOR CLEC-1, A NEW CHECKPOINT FOR MYELOID IMMUNE CELLS IN IMMUNO-ONCOLOGY**

OSE Immunotherapeutics teams have characterized a new myeloid checkpoint target, CLEC-1 (among CLR-C-type lectin receptors), and have identified antagonistic monoclonal antibodies that block this new signal, also expressed on myeloid cells (presentation at the 2020 conference of the AACR “American Association for Cancer Research”).

The identification of CLEC-1 and its antagonists constitute an exciting innovative step in cancer immunotherapy.

First preclinical data were presented at the 36th SITC (Society for Immunotherapy of Cancer) annual conference in November 2021.

In May and June 2022, the Company was invited to a conference in London, the “Immuno-Oncology Summit Europe” and then in Boston “Tumor Myeloid-Directed Therapies Summit”, to present the progress of the CLEC-1 program, a new myeloid checkpoint inhibitor target in immuno-oncology. This domain of myeloid cells have been identified as a factor of poor prognosis in oncology.

In 2022, OSE Immunotherapeutics teams are continuing their research and strategy to protect inventions, as also shown by the new European patent granted on CLEC-1 in May 2022.

- **BICKI®, PRECLINICAL ADVANCES**

BiCKI® is a platform of bispecific or bifunctional antibodies, innovative therapies that can combine an anti-PD-1 with several other immunological actors to obtain a bivalent therapy. The first candidate paired with the anti-PD1 in the same product is an IL-7 cytokine, BiCKI®-IL-7. This potential new tool for combating resistance mechanisms to anti-PD(L)-1 treatments is intended for a population of patients immune to checkpoint inhibitor treatments.

In 2022, the Company was invited to present preclinical data on BiCKI®-IL-7, its bifunctional program targeting PD-1 and IL-7 in cancer immunotherapy at the 2022 annual conference of the American Association for Cancer Research (AACR).

In 2022, OSE Immunotherapeutics teams are actively pursuing their research on this asset and the BiCKI® platform.

- **OSE-279, A HUMANIZED ANTI-PD MONOCLONAL ANTIBODY.**

OSE-279 is a humanized anti-PD1 monoclonal antibody that blocks PD-L1 and PD-L2, the PD1 ligands overexpressed by tumor cells. PD-L1 and PD-L2 are used by tumor cells to evade the immune system. Stimulation of PD-L1 and PD-L2 on cancerous tumors and on other types of cells in the tumor microenvironment represents a mechanism of tumor escape from the immune response.

OSE-279 is the key anti-PD1 backbone of BiCKI®-IL-7\*, an innovative bifunctional therapy combining an anti-PD1 with the cytokine IL-7 and targeting PD1 to stimulate the function of exhausted T cells and disarm the suppressive activity of regulatory T cells.

This anti-PD-1 is intended to enter a Phase 1 clinical trial at the end of 2022. This will enable the

Company to hold its own patented anti-PD-1 that it may subsequently, depending on the results observed, develop in niche indications where patient needs remain high and/or in combination with other products in its portfolio.

The Company has therefore continued to work on the production of clinical batches for a future clinical phase. In March 2022, it received a first notice of allowance in the United States for OSE-279 and its use in the treatment of cancer.

## **IN THE FIELD OF AUTOIMMUNITY AND INFLAMMATION**

### **OSE-127/S95011, CONTINUING THE PHASE 2 CLINICAL TRIAL IN ULCERATIVE COLITIS AFTER REVIEW OF THE RESULTS OF THE FUTILITY ANALYSIS**

OSE-127/S95011, an immunomodulatory monoclonal antibody targeting the CD127 receptor, the alpha chain of the Interleukin 7 receptor, is being developed under a two-step licensing option agreement granted to Servier for its development and marketing in autoimmune diseases.

The Phase 2 trial in ulcerative colitis, an autoimmune bowel disease started in December 2020, sponsored by OSE Immunotherapeutics.

The futility analysis has been conducted in December 2021, according to the protocol, on the first 50 patients (i.e. 33% of the total patient enrollment planned for the trial) having completed the Induction Phase of the trial. The primary endpoint of the futility analysis was the efficacy of OSE-127/S95011 versus placebo assessed according to the reduction in the modified Mayo Score (an index used to assess the activity of ulcerative colitis).

Based on the efficacy and tolerability results of this analysis, the Independent Data Monitoring Committee (IDMC) of the trial recommended the continuation of the trial evaluating OSE-127/S95011 in patients with ulcerative colitis.

Moreover OSE-127/S95011 has shown a good safety and tolerability profile in the whole patient population as already demonstrated in healthy volunteers in the Phase 1 study.

Following the recommendation of the Independent Data Monitoring Committee of the trial, OSE Immunotherapeutics is therefore continuing the ongoing clinical trial in parallel. The Company is also continuing preclinical studies in immuno hematology following the first results presented at the end of 2021.

### **- CONTINUATION OF A PHASE 2 CLINICAL TRIAL OF OSE-127/S95011 IN SJÖGREN'S SYNDROME**

In parallel, another Phase 2 in Sjögren's Syndrome, a systemic autoimmune disease characterized by damage to the exocrine glands, in particular the lacrimal and salivary glands, has started in August 2021 sponsored by Servier. As stipulated in the licensing option agreement, Servier has made a €5 million milestone payment to OSE Immunotherapeutics upon inclusion of the first patient in this Phase 2 trial in Sjögren's Syndrome at the end of August 2021. A second payment of €15 million is expected if Servier exercises the option at the end of the two Phase 2 clinical trials.

The trial continued in the first half of 2022.

- **FR104, CONTINUATION OF THE GLOBAL LICENSE AGREEMENT WITH VELOXIS PHARMACEUTICALS INC. IN ALL TRANSPLANT INDICATIONS**

FR104 is an immunomodulator consisting of an optimized monoclonal antibody fragment targeting the CD28 receptor, a key component of the destruction function of effector T lymphocytes which are deleterious in autoimmune diseases and transplantation.

In April 2021, a global licensing agreement was signed with Veloxis Pharmaceuticals Inc., according to which OSE Immunotherapeutics grants it the worldwide rights to develop, manufacture, register and market FR104 in all transplantation indications. At the same time, OSE Immunotherapeutics retains all rights to develop FR104 in autoimmune diseases. Through this agreement, Veloxis plans to develop FR104 to provide a potential therapeutic alternative for the prophylaxis of organ rejection in solid organ transplant patients.

Under this agreement, OSE Immunotherapeutics will be able to receive up to €315 million in potential milestone payments, including a payment of €7 million paid at signature and royalties on sales.

At the end of January 2022, Veloxis Pharmaceuticals, Inc. received acceptance of the New Investigational Drug (IND) application in the United States for VEL-101/FR104. As part of the worldwide licensing agreement signed in April 2021, this first step triggered a €5 million payment from Veloxis Pharmaceuticals, Inc. to OSE Immunotherapeutics.

A Phase 1/2 clinical trial evaluating FR104, administered for the first time in patients who have received a renal transplant, is also underway as part of a clinical collaboration agreement between OSE Immunotherapeutics and the Centre Hospitalier Universitaire de Nantes as sponsor. This Phase 1/2 clinical trial aims to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and efficacy of FR104 in patients who have received a renal transplant.

In May 2022, Veloxis set up a new trial evaluating the safety, tolerability, pharmacokinetics and pharmacodynamics of single increasing doses of VEL-101 or of the placebo administered subcutaneously (SC) or intravenously (IV). Approximately 56 participants will be included and monitored for 50 days.

- **OSE-230, FIRST PRODUCT IN THE FIELD OF INFLAMMATION RESOLUTION, SCIENTIFIC PUBLICATION IN “SCIENCE ADVANCES 2021”**

OSE-230 is an agonist antibody against ChemR23, also known as chemerin chemokine-like receptor 1 (CMKLR1), a G-protein coupled receptor (GPCR) expressed on myeloid immune cells known to modulate inflammation.

Most anti-inflammatory agents act using a mechanism that blocks pro-inflammation pathways. In contrast, OSE Immunotherapeutics is developing OSE-230 as a first-in-class therapeutic agent with the potential to resolve chronic inflammation by driving affected tissues to complete the inflammation

program and restore tissue integrity.

OSE-230 was first published in the scientific journal “Science Advances 2021”, confirming the breakthrough innovation of the OSE-230 research program. This discovery opens up development avenues for OSE-230 in several chronic inflammation indications such as inflammatory bowel disease, inflammatory lung or kidney disease, arthritis or type 1 diabetes.

In 2022, OSE Immunotherapeutics teams are actively pursuing their preclinical research.

### 1.3 Foreseeable changes and future outlook

Progress of the portfolio is based on its current products:

#### **T-SPECIFIC IMMUNOTHERAPY BASED ON MODIFIED EPITOPES STIMULATING T CELLS**

##### **- TEDOPI®: STRATEGY AND NEXT STEPS**

The international Phase 3 clinical trial of Tedopi®, Atalante 1, was designed to evaluate the benefits of the product in HLA-A2 positive patients in second- or third-line therapy versus second- or third-line chemotherapy (docetaxel or pemetrexed) in invasive stage IIIB or metastatic stage IV non-small cell lung cancer after failure of treatment with anti-PD-1 and anti-PD-L1 checkpoint inhibitors. The main assessment endpoint is overall survival.

The results of the Phase 3 Tedopi® trial have shown significant survival benefits with Tedopi® versus a standard chemotherapy treatment (docetaxel or pemetrexed) in positive HLA-A2 positive patients with NSCLC and in secondary resistance after immune checkpoint inhibitors. Importantly, the non-NSCLC patients included in this trial had failed second-line checkpoint inhibitor treatments and represent a hard-to-treat patient population with high medical need. On the basis of these results, OSE Immunotherapeutics is preparing an early access dossier which will be proposed to the regulatory agencies at the end of 2022, and will also present an additional proposed Phase 3 clinical trial in second line treatment, in secondary resistance after failure of a checkpoint inhibitor, used as a first-line treatment, an indication that has become the most frequent for this class, and still with high therapeutic need in the event of escape.

At the same time, given that the positive Phase 3 results significantly strengthened the value of Tedopi®, the Company is continuing to explore potential partnering opportunities for the product.

The Company will also continue the Phase 2 clinical trials previously presented at ASCO in 2022, namely:

- The TEDOPaM trial in pancreatic cancer;
- The trial conducted with Arcagy Gineco in ovarian cancer;
- The trial with ForT in lung cancer in combination.

##### **- COVEPIT, POSITIVE LONG-TERM IMMUNOLOGICAL RESULTS AT SIX MONTHS IN HEALTHY VOLUNTEERS WITH STRONG MEMORY T RESPONSES AGAINST THE VIRUS PROTEINS; A STRATEGY FOCUSED ON INDUSTRIAL**

## **SCALE-UP IN THE EVENT OF ANOTHER PANDEMIC WAVE LINKED TO A NEW VARIANT OF CONCERN**

The positive analysis of the long-term immune T response of CoVepiT showed positive immunological results at six months on the memory T response in vaccinated subjects (results announced on March 16, 2022).

OSE Immunotherapeutics has thus validated the concept and paradigm that long-term immunity against coronavirus could be achieved in human with its T cell vaccine platform inducing long-term memory T lymphocytes, with additional properties as T cells resident in the lung, already described in preclinical trials.

For immunocompromised patients, new treatments such as monoclonal antibodies or antiviral treatments are available. It is also recommended to carry out regular booster injections of the vaccines registered in this fragile population whose antibody response is deficient.

With these new treatments available and multiple vaccine boosters recommended for these patients, further clinical development of CoVepiT is currently difficult.

Based on the positive long-term T-response results, the Company's strategy is now to select the most relevant peptides to enable simpler industrial scale-up to be ready for another pandemic wave linked to a new variant of concern.

## **IN IMMUNO-ONCOLOGY: CLINICAL AND PRECLINICAL ADVANCES**

- **BI 765063 (OSE-172), IN PHASE 1 CLINICAL TRIAL IN ADVANCED SOLID TUMORS: THE INNOVATIVE APPROACH OF A COMBINATION OF PD-1 ANTAGONIST TREATMENTS**

Based on the first promising results of BI 765063 (OSE-172), a SIRP $\alpha$  antagonist, in Phase 1 clinical trial as a monotherapy and in combination, the Company is moving forward in 2022 on the expansion of the Phase 1 clinical trial in cohorts of different types of cancers: colorectal cancer and endometrial cancer and also in a new cohort of liver cancer and head and neck cancer to explore the potential of the approach of a combination of these two products as a relevant therapeutic strategy in solid tumors.

The Company will continue the preclinical development of its other preclinical products in immuno-oncology: CLEC-1, a new immune myeloid checkpoint that regulates the anti-tumor response, BiCKI<sup>®</sup>, the anti-PD-1 bispecific checkpoint inhibitor antibody platform and OSE-279, an anti-PD-1.

The entry of OSE-279 in Phase 1 clinical trial in immuno-oncology is expected for the end of 2022. This would allow the Company to own a patented anti-PD-1 that it could subsequently develop in niche indications where patient needs remain high and/or in combination with other products in its portfolio.

## **IN AUTOIMMUNE DISEASES AND TRANSPLANTATION**

- **FR104, TWO ONGOING CLINICAL TRIALS**

At the end of January 2022, Veloxis Pharmaceuticals, Inc. received acceptance of the New Investigational Drug (IND) application in the United States for VEL-101/FR104. As part of the worldwide licensing agreement signed in April 2021, this first step triggered a €5 million payment from Veloxis Pharmaceuticals, Inc. to OSE Immunotherapeutics. This Phase 1 clinical trial will continue in 2022.

#### - **OSE-127/S95011, TWO ONGOING PHASE 2 CLINICAL TRIALS**

OSE-127/S95011 is subject to a two-step licensing option granted to Servier for its development and marketing in autoimmune diseases. This licensing option will allow the product to be developed until the completion of a Phase 2 clinical trial.

After positive Phase 1 clinical results of OSE-127/S95011 and the exercise of option 1 in February 2019, a Phase 2 trial has been underway in ulcerative colitis since December 2020 sponsored by OSE Immunotherapeutics.

Another Phase 2 in Sjögren's Syndrome started in August 2021 sponsored by Servier. The inclusion of the first patient in this Phase 2 study triggered a milestone payment of €5 million to OSE.

Option 2 is expected to be exercised upon completion of these two Phase 2 clinical trials. Continued development after these trials, if step 2 of this licensing option is validated, will be carried out by Servier.

Product development will also continue until the Phase 2 clinical trial as part of the EFFIMab consortium (with public and private partners and with OSE Immunotherapeutics as leader).

#### - **OSE-230, UNDER PRECLINICAL DEVELOPMENT**

The Company will continue the preclinical development of OSE-230, a ChemR23 agonist antibody, in chronic inflammation. This first-in-class therapeutic agent has the potential to activate the physiological pathways of chronic inflammation and restore the integrity of the pathological tissue.

#### **PARTNERSHIPS - VALUE CREATION:**

The Company continues to seek new collaboration or license agreements that could be initiated at various stages of product development, with industry players involved in the field of activation and regulation immunology and in therapeutic combinations of high clinical interest.

The Company has in-depth knowledge of the development of immunology products with applications in oncology or for other autoimmune diseases. It benefits from additional expertise and complementary skills in terms of development and international registration. It is a specialist organization, headed by an experienced management team with a cutting-edge research team with expertise in clinical and pharmaceutical development for the development, industrialization of programs and product registration.

**Three international strategic partnerships were signed in 2016, 2018 and 2021 and are in place with three pharmaceutical groups for three different products.**

These objectives create value for Company shareholders in the short, medium and long term. By advancing its programs, the Company intends to benefit from medium/long term revenue which will go a long way to covering its cash requirements with royalties and milestone payments under partnership agreements.

- As part of the two-step license option agreement signed with SERVIER in December 2016 for OSE-127, the development of the product will be continued by OSE until the completion of a Phase 2 clinical trial in ulcerative colitis, an autoimmune bowel disease and/or Sjögren's Syndrome by SERVIER laboratories. Continued development after this Phase 2 trial will be carried out by SERVIER, as part of the license option.
- Under the collaboration and exclusive licensing agreement (signed in April 2018) with Boehringer Ingelheim to jointly develop OSE-172, Boehringer Ingelheim will fund the product candidate's development in various types of cancer, its registration and international marketing.
- Worldwide licensing agreement with **Veloxis**, for the development, manufacture and marketing of **FR104** in the organ transplant market (OSE Immunotherapeutics retains all rights to develop FR104 in autoimmune diseases).

An agreement restricted to a single country per agreement was signed for a fourth product: Tedopi®:

- In 2015, an agreement was signed for **Tedopi®** with **RAFA laboratories** and covers Israel only where there is extensive immunological knowledge and expertise.
- At the end of 2019 a second country-level agreement for **Tedopi®** was signed with CKD (Chong Kun Dang Pharmaceutical Corporation), one of the pharmaceutical leaders in Korea covering only Korea where medical demand accounts for about 1% of the global market.

#### 1.4 Research and development activities

- See 1.2

#### 1.5 Main risks and uncertainties to which the Company is exposed

The main risks and uncertainties to which OSE Immunotherapeutics may be exposed in the second half of 2022 are of the same nature as those described in paragraph 3 "Risk factors" of the Registration Document dated April 15, 2022, available to download on the Company's website under the section "Investors/Documentation/Registration Document" and on the AMF website.

Concerning the health crisis linked to COVID-19 and the war in Ukraine, we refer you to the highlights of the fiscal year described in the financial notes.

#### 1.6 Use of financial instruments by the Company

The Company used financial instruments in the reporting period (see Note 3 of the financial statements above).

## 1.7 Transactions with related parties

In the first half of 2022, the following transactions were recorded:

### **Dominique Costantini**

The Board of Directors approved the combination of an employment contract with the position of Chairman of the Board of Directors on March 28, 2018. In the first half of 2022, she received €235,176 gross from the Company in respect of her employment agreement.

It should be noted that a bonus of €71,843 gross was paid to Dominique Costantini at the beginning of fiscal year 2022 in respect of fiscal year 2021.

### **Nicolas Poirier**

In the first half of 2022, Nicolas Poirier received €199,885 gross from the Company under his employment agreement as Scientific Director of the Company.

It should be noted that a bonus of €62,500 gross was paid to Nicolas Poirier at the beginning of the 2022 fiscal year in respect of the 2021 fiscal year.

### **Board of Directors**

Members of the Board of Directors received a total of €187,246 net in directors' fees from the Company for the first half of 2022.

## HALF-YEAR FINANCIAL STATEMENTS AS OF JUNE 30, 2022

### 2.1 Presentation of the Company's half-year consolidated financial statements

The consolidated financial statements of OSE Immunotherapeutics and its subsidiaries (the "Group"), are presented in euros and are prepared in accordance with IFRS standards (International Financial Reporting Standard) as adopted by the European Union and those published by the IASB (International Accounting Standards Board) as of June 30, 2022.

### 2.2 Consolidated balance sheet

The consolidated balance sheet for the first half of 2022 stood at €102,266 thousand compared with €101,876 thousand as of December 31, 2021.

### 2.3 Consolidated income statement

As of June 30, 2022, the Group's revenue totaled €16,047 thousand compared with €8,975 thousand as of June 30, 2021.

Operating expenses by function - €K	06/30/2022	06/30/2021	Change	% change
R&D expenses	14,395	14,419	-23	-0.16%
Overhead expenses	3,813	3,413	400	11.71%
Expenses related to share-based payments	1,182	2,724	-1,543	-56.62%
Total	19,390	20,556	-1,166	-5.67%

The breakdown of R&D expenses in the first half of 2022 is as follows:

- €11,666 thousand in subcontracting and fees, before recording the research tax credit of €3,058 thousand and subsidies received in the amount of €384 thousand;
- €2,509 thousand in employee benefits expense allocated to research and development;
- €1,332 thousand in additions to/reversals of depreciation, amortization and provisions allocated to research and development;
- €1,250 thousand in royalties (Provision for INSERM royalty in respect of FR104);
- €1,079 thousand: small consumables dedicated to R&D, taxes, miscellaneous expenses.

The breakdown of overhead expenses for the first half of 2022 is as follows:

- €1,338 thousand in fees and sub-contracting;
- €1,283 thousand in employee benefits expense allocated to the operational management team;
- €187 thousand in directors' fees;
- €329 thousand in additions to/reversals of depreciation, amortization and provisions;
- €675 thousand: cost of premises, conference expenses, travel expenses, banking fees, charges and other taxes.

Operating income for the first half of 2022 was -€3,425 thousand. Net income for the first half of 2021 was -€1,979 thousand.

#### 2.4 Indebtedness (consolidated financial statements)

Financial liabilities totaled €35,773 thousand (including €4,851 thousand in lease liabilities related to the application of IFRS 16). These financial liabilities consist of €15,139 thousand in repayable advances, whose repayment is subject to the success of the various programs under development, €6,869 thousand of the French Government-guaranteed loan and €8,915 thousand of the EIB loan.

The Group's cash totaled €31,193 thousand as of June 30, 2022.

Net financial debt thus totaled €4,580 thousand as of June 30, 2022.

## II. SUBSIDIARIES AND EQUITY INTERESTS – INVESTMENT SECURITIES

### 3.1 Activity of subsidiaries

The activity of the subsidiary OPI is limited to managing the industrial property of our Tedopi® technology.

The activity of the US subsidiary OSE Immunotherapeutics Inc. is limited to supporting international scientific collaborations, given the current and future developments of Tedopi® in the United States (recruitment, partnership, licensing, etc.).

### 3.2 Equity holdings or takeovers

The Company did not acquire any equity holdings in any other company in the first half of 2022.

### 3.3 Controlled companies

Since March 25, 2014, the Company has held all of the share capital and voting rights of OPI.

Since April 18, 2017, the Company has held all of the share capital and voting rights of OSE Immunotherapeutics Inc.

**STATUTORY AUDITORS' REPORT ON THE CONDENSED HALF-  
YEAR FINANCIAL STATEMENTS**

**OSE IMMUNOTHERAPEUTICS**