

# HALF-YEAR FINANCIAL REPORT AS OF JUNE 30, 2020

#### **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

Alexis Peyroles, 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 17, 2020

Alexis Peyroles
Chief Executive Officer of OSE Immunotherapeutics

# CONDENSED CONSOLIDATED HALF-YEAR FINANCIAL STATEMENTS 6/30/2020

#### **OSE IMMUNOTHERAPEUTICS**

FINANCIAL STATEMENTS
In euros

#### **OSE IMMUNOTHERAPEUTICS SA**

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For the first half ending 06/30/2020

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## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(Amount in €K)

ASSETS	Note	June 30, 2020	December 31, 2019
NON-CURRENT ASSETS			
R&D expenses acquired	1.1	52 600	52 600
Property, plant and equipment	1.2	993	1 009
Rights of use	1.3	3 095	1 692
Financial assets	1.4	607	287
Deferred tax assets	10.1	167	283
TOTAL NON-CURRENT ASSETS		57 463	55 871
CURRENT ASSETS			
Trade receivables	2.2	3 318	747
Other current assets	2.3	7 045	6 474
Cash and cash equivalents	2.1	22 920	25 842
TOTAL CURRENT ASSETS		33 283	33 062
TOTAL ASSETS EQUITY & LIABILITIES		90 745	88 933

EQUITY & LIABILITIES		June 30, 2020	December 31, 2019
SHAREHOLDERS' EQUITY			
Stated capital	4.1	3 089	3 001
Share premium	4.1	21 583	21 670
Merger premium	4.1	26 827	26 827
Treasury stock	4.4	(143)	(148)
Reserves and retained earnings		8 181	11 838
Consolidated result		(3 114)	(4 652)
TOTAL SHAREHOLDERS' EQUITY		56 423	58 536
NON-CURRENT DEBTS			
Non-current financial liabilities	3.5	16 152	9 211
Long-term lease liabilities	3.5	2 570	1 413
Deferred tax liabilities	10.2	802	5 066
Non-current provisions	7	460	377
TOTAL NON-CURRENT DEBTS		19 984	16 067
CURRENT DEBTS			
Current financial liabilities	3.5	532	548
Short-term lease liabilities	3.5	575	309
Trade payables	3.6.1	7 810	6 918
Current tax liabilities	3.6.2	3	20
Tax and social security liabilities	6.2	2 465	1 723
Other debts and accruals	6.3	2 955	4 812
TOTAL CURRENT DEBTS		14 339	14 330
TOTAL SHAREHOLDER'S EQUITY AND LIABILITIES		90 745	88 933

## STATEMENT OF COMPREHENSIVE INCOME

In €k	Note	First half 2020	First half 2019
Revenue	8.1	5 849	15 979
Other operating revenues	8.1	0	0
OPERATING INCOME - RECURRING		5 849	15 979
R&D expenses	8.2	(9 087)	(9 189)
Overhead expenses	8.3	(2 672)	(2 199)
Expenses related to share-based payments	8.4	(1 176)	(673)
OPERATING PROFIT/LOSS - RECURRING		(7 085)	3 919
Other operating revenues and expenses		0	0
OPERATING PROFIT/LOSS		(7 085)	3 918
Financial income	9	28	143
Financial expenses	9	(150)	(74)
PROFIT/(LOSS) BEFORE TAX		(7 208)	3 987
INCOME TAX	10.3	4 094	(3 472)
CONSOLIDATED NET RESULT		(3 114)	514
of which consolidated net result attributable to shareholders		(3 114)	514
N			
Net earnings attributable to shareholders		15.005.010	440000:-
Weighted average number of shares outstanding	12	15 087 010	14 820 345
		(0,21)	0,03
<ul> <li>Basic earnings per share (€/share)</li> <li>Diluted earnings per share (€/share)</li> </ul>		(0,21)	0,03

In €k	First half 2020	First half 2019
NET RESULT	(3 114)	514
	(0 == 1)	
Amounts to be recycled in the income statement:		
Unrealized gains on securities available for sale, net of tax		
Currency conversion difference	(16)	(17)
Amounts not to be recycled in the income statement:		
Actuarial gains and losses on post-employment benefits	1	(24)
Other comprehensive income in the period	(15)	(41)
CONSOLIDATED COMPREHENSIVE PROFIT/(LOSS)	(3 129)	473

# Statement of changes in consolidated equity

In €k	Capital of consolidated entities	Additional paid-in capital	Additional paid-in capital EFFIMUNE	Cumulative impact of exchange rate fluctuations	Treasury shares	Reserves and consolidated profit/(loss)	Total consolidated shareholder's equity
CONSOLIDATED SHAREHOLDERS' EQUITY AS OF 12/31/2018	2 963	21 708	26 827	(57)	(168)	10 481	61 755
Consolidated profit/(loss) for the period						2 829	2 829
Actuarial gains and losses						(24)	(24)
Foreign exchange gains and losses				(17)		(=1)	(17)
Consolidated comprehensive profit/(loss)	0	0	0	(17)	0	2 805	2 788
Changes in capital - Free Share Allocation	30	(30)		. ,			0
Deferred taxes on actuarial gains and losses (IAS 19)		, ,				2	2
Share-based payments						534	534
Transaction on Treasury shares					19	(14)	5
CONSOLIDATED SHAREHOLDERS' EQUITY AS OF 06/30/2019	2 993	21 678	26 827	(74)	(149)	13 809	65 084
Consolidated profit/(loss) for the period						(4 652)	(4 652)
Actuarial gain or loss (net of tax)						(37)	(37)
Foreign exchange gains and losses				(43)			(43)
Consolidated comprehensive profit/(loss)	0	0	0	(43)	0	(4 689)	(4 732)
Changes in capital - Free Share Allocation	38	(38)					0
Share-based payments						1 511	1 511
Transaction on Treasury shares					20	(17)	3
CONSOLIDATED SHAREHOLDERS' EQUITY AS OF 12/31/2019	3 001	21 670	26 827	(100)	(148)	7 286	58 536
Consolidated profit/(loss) for the period						(3 114)	(3 114)
Actuarial gain or loss (net of tax)						1	1
Foreign exchange gains and losses				(16)			(16)
Consolidated comprehensive profit/(loss)	0	0	0	(16)	0	(3 114)	(3 129)
Changes in capital - Free Share Allocation	87	(87)					0
Share-based payments						905	905
Transaction on Treasury shares					5	105	110
CONSOLIDATED SHAREHOLDERS' EQUITY AS OF 06/30/2020	3 089	21 583	26 827	(116)	(143)	5 182	56 423

# STATEMENT OF CASH FLOWS

I	In €k	Note	First half 2020	First half 20
1	Net result		-3 114	5.
/-	Net depreciation, amortization and provisions	1.2, 7	215	1
/	Amortization of rights of use	1.3	210	1
/-	Calculated revenues and expenses linked to stock options (1)	8.4	905	5
	Other calculated revenues and expenses		0	
	Cash flow after net borrowing cost and taxes		-1 784	13
+ :	Net borrowing cost	5	137	
	Income tax expense (including deferred taxes)	10.3	-4 094	3.4
	Cash flow from operations before net borrowing cost and taxes (A)		-5 742	4 7
	Taxes paid		-50	
	Change in W.C.R. (2)		-3 442	89
	NET CASH FLOW FROM OPERATING ACTIVITIES ((D)		-9 233	13 7
- :	Purchases of property, plant & equipment and intangible assets	1.2	-117	-
/-	Change in UCITS classified as current financial assets	2.1	0	-
F :	Proceeds from disposal of non-current financial assets (non-consolidated shares)	1.4	12	
/-	Changes in loans and advances	1.4	-320	
ľ	NET CASH FLOWS FROM INVESTMENT ACTIVITIES (E)		-425	-3
-	Capital increase (including issue premium)	4.1	0	
	Acquisition and disposal of Treasury shares	4.4	0	
<b>-</b> :	Proceeds from new borrowings	5	6 960	
- :	Loan repayments	5	-141	-
	Lease liability repayments (3)	5	-220	-
- :	Net interest paid	5	137	
ľ	NET CASH FLOWS FROM FINANCING ACTIVITIES (F)		6 736	5
/- I	Impact of changes in foreign exchange rates (G)		0	
(	CHANGE IN NET CASH POSITION H = (D + E + F + G)		-2 922	13 9
(	OPENING CASH BALANCE (I)	2.1	25 842	9:
(	CLOSING CASHBALANCE(J)	2.1	22 920	23:
	CLOSING CASH BALANCE (J)  DIFFERENCE: H-(J-I)	2.1	22 920	Ī

In €k	First half 2020	First half 2019
Cash and cash equivalents according to IAS7 Current financial assets not meeting IAS 7 criteria	22 920 0	23 562 2 965
AVAILABLE CASH	22 920	26 527

- (1) €905,000 in valuation costs for free shares and founders' warrants awarded at June 30, 2020.
- (2) The change in working capital requirement was primarily due to the following:
  - increase in trade receivables amounting to €2,571,000
  - increase in other current assets amounting to €571,000
  - increase in trade payables amounting to €892,000
  - increase in tax and employee-related payables amounting to €741,000
  - decrease in other payables amounting to €1,857,000
- (3) This line relates to the application of IFRS 16 and corresponds to the repayment of lease liabilities amounting to €220,000.

### **N**OTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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

OSE Immunotherapeutics 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.

#### 2.1. COVID-19

The emergence and spread of the Coronavirus in early 2020 have impacted the global economic environment.

At this point, Management cannot reliably assess the impacts that this crisis may have on the Group's business should it continue. However, Management considers that the medium-term impact should be moderate and should not hinder its ability to continue as a going concern.

The initial impacts in the first half of 2020 were as follows:

- Following the lockdown imposed by the Government on March 17, 2020, the Company's laboratory operations slowed down due to the slowdown in the supply of consumables and limited access to animal facilities. Over a four-week period the Company introduced limited operations only for a skeleton laboratory staff;
- The rate of recruitment onto clinical trials was reduced, given the measures taken in hospitals which are focused on fighting COVID-19;
- Recruitment halted for step 2 of the Atalante study (see next paragraph).

Should the crisis intensify, the impacts may be as follows:

- The rate of recruitment of patients onto clinical trials may be reduced, given the measures taken in hospitals which are focused on fighting COVID-19.
- The Company may also be subject to subcontractor prioritization policies, particularly for clinical batch production of its products.

# 2.2. Phase 3 Tedopi® clinical trial: positive outcome of Step 1 of the Atalante 1 trial in non-small cell lung cancer

In April 2020, the Company announced that the analysis of data from Step 1 under the protocol of the Phase 3 of Tedopi®, Atalante 1 clinical trial, showed that the primary endpoint for this step had been achieved. This study is conducted in HLA-A2 positive patients with non-small cell lung cancer (NSCLC), post checkpoint inhibitor treatment failure (PD-1/PD-L1).

However, in the context of the COVID-19 epidemic, a decision was taken to voluntarily and permanently suspend recruitment due to the risks that may arise for patients and the direct consequences on data from Step 2 of the trial that will thus not be conducted.

#### 2.3. Amendment to the OSE-127 contract with Servier

On March 17, 2020, the Company and Servier signed an amendment of the worldwide licensing option for OSE-127, an IL-7 receptor antagonist developed in autoimmune diseases.

This amendment covers the terms and conditions for exercising the licensing option by modifying Step 2 of the option. OSE Immunotherapeutics will thus receive a milestone payment of €5 million from Servier on enrollment of the first patient in Phase 2a clinical study scheduled to start in Sjögren's Syndrome and an additional payment of €15 million on exercise of the option 2 at the end of the two scheduled Phase 2 studies, with priority being given to the study in Sjögren's Syndrome. The initial agreement provided for a total payment of €20 million at the end of Phase 2 in ulcerative colitis.

#### 2.4. French Government-Guaranteed loan (PGE)

In May 2020, the Company obtained €7 million of funding through a French government-guaranteed loan (Prêt Garanti par l'Etat - "PGE") introduced in the context of the COVID-19 pandemic, with a group of French banks, enabling the Company to strengthen its cash position. The loan has a one-year term with an option to extend for a further 4 years, the overall effective rate is 0.25% corresponding to the guarantee fee. If the loan is extended beyond the first year, the interest rate will be set through an amendment.

#### 2.5. Launch of a prophylactic vaccine program against COVID-19

In May 2020, the Company announced that it had joined the fight against COVID-19 by working to develop a prophylactic vaccine against the SARS-CoV-2 pandemic virus.

It is drawing on the expertise gained through its epitope optimization technology (neoepitopes) Memopi®, recently validated in step 1 of the Phase 3 Tedopi® clinical trial, a combination of antitumor epitopes, to enhance the memory T lymphocyte immune response against specific antigens.

#### 2.6. Capital increase

Following the issue of free shares in 2019, presented in the appendices below, in the first half the Company carried out the following capital increases:

- on March 26, 2020: €28,360 capital increase through the issue of 141,800 new shares;
- on June 27, 2020: €59,060 capital increase through the issue of 295,300 new shares.

Following this transaction, the share capital stood at €3,088,564.80.

#### 2.7. Allocation and Issuance

In the first half of 2020 the Company allocated 250,000 free shares and 70,000 founders' warrants (see paragraph 4-2 of the consolidated financial statements). On June 17, the Board of Directors also discussed the issuance of a maximum of 250,000 additional free shares, not allocated to date.

#### 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 17, 2020, are presented in thousands of euro and were prepared in accordance with the International Financial Reporting Standards IAS 34 "Interim financial reporting" as adopted by the European Union (regulation 1606/2002 of July 19, 2002) as of June 30, 2020.

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 ending December 31, 2019, 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:

Available cash as of June 30, 2020, which totaled €22,920,000 will enable the Company to fund its development costs over the next twelve months, particularly the following clinical and pre-clinical studies:

- Tedopi®
- FR104
- OSE-127 whose development is partially funded by Servier up to Phase 2 under the licensing and license option agreement, as well as by the EFFIMAB consortium
- OSE-172, whose development is funded by Boehringer Ingelheim under a collaboration and licensing agreement, and by the consortium EFFI-CLIN, supporting several development stages and a clinical program planned up to phase 2

Lastly, as a listed company, and as authorized by the last General Shareholders' Meeting, the Company has the option, if needed, to use the financial instruments to which listed companies have access.

#### 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, 2020

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

- Amendments to IAS 1 Presentation of financial statements
- Amendments to IFRS 3 Business combinations
- Amendments to IAS 8 Accounting policies, changes in accounting estimates and errors
- Amendments to IFRS 9, IAS 39 and IFRS 7 Reform of interest rate benchmarks

# 3.4. Standards, amendments and interpretations adopted by the European Union and applicable to annual periods beginning on or after January 1, 2021, and 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, 2021. Management does not expect these standards to have a material impact on the Company's financial statements.

This involves the following standards, amendments, revisions and interpretations:

- Amendments to IFRS 4 on insurance contracts (Apply IFRS 9 Financial instruments with IFRS 4).

#### 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

The main items in question related to share-based payments, deferred tax, intangible assets arising from the merger, revenue and R&D expenses.

 Valuation of free share allocation plans (AGA) share subscription warrant plans (BSA) and founders' warrant allocation plans (BSPCE).

The fair value of the AGA, BSA and BSPCE awarded 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 Company founders' 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 the best management 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. N**OTES TO THE FINANCIAL STATEMENTS

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

#### 1.1 Intangible assets

As of June 30, 2020, no indications of impairment were identified in respect of the molecules acquired, despite the context of COVID-19.

#### 1.2 Rights of use

OSE Immunotherapeutics identified two new leases (covered by the standard) in the first half of 2020 with the following characteristics:

- A lease for real estate in France. The incremental borrowing rate used was 2%.
- A sale-leaseback agreement under property, plant and equipment ("Cytometry" research equipment) initially acquired on May 28, 2020 and sold on June 24, 2020. This is considered a sale under IFRS 15 and a right of use was measured applying an interest rate implicit in the lease of 2.11%.

Rights of use break down as follows:

In €k	12/31/2019	Increase	Decrease	6/30/2020
Gross values (non-current assets)				
Loggo agreement (Nantos Let 1)	537	0	0	537
Lease agreement (Nantes Lot 1)		-	-	
Lease agreement (Nantes Lot 2)	208	0	0	208
Lease agreement (Paris Lot 1)	1 198	0	0	1 198
Lease agreement (Paris Lot 2) *	0	1 332	0	1 332
Lease (Cytek Cytometre) **	0	281	0	281
	1 943	1 613	0	3 556
Amortization				0.000
Lease agreement (Nantes Lot 1)	103	51	0	155
Lease agreement (Nantes Lot 2)	26	17	0	44
Lease agreement (Paris Lot 1)	122	66	0	188
Lease agreement (Paris Lot 2) *	0	74	0	74
Lease (Cytek Cytometre) **	0	1	0	1
	251	210	0	462
<u>Net values</u>				
Lease agreement (Nantes Lot 1)	434	(51)	0	383
Lease agreement (Nantes Lot 2)	182	(17)	0	165
Lease agreement (Paris Lot 1)	1 076	(66)	0	1 009
Lease agreement (Paris Lot 2) *	0	1 258	0	1 258
Lease (Cytek Cytometre) **	0	280	0	280
	1 692	1 403	0	3 095

<sup>\*</sup> effective lease date January 1, 2020

<sup>\*\*</sup> effective lease date June 24, 2020

#### 2.1 Other current assets

Other current assets break down as follows:

In €k	6/30/2020	12/31/2019
Value Added Tax (1)	937	978
Trade debtors (2)	129	77
Prepaid expenses (3)	2 673	1 787
Prepaid income (4)	543	546
Government - tax receivable (5)	27	28
Other current assets	4 309	3 415
Research tax credit (5)	2 737	3 059
Total	7 045	6 474

- (1) "Value Added Tax" includes applications for VAT refunds amounting to €238,000 and VAT on FNP amounting to €282,000.
- (2) "Trade debtors" mainly comprises €117,000 of trade discounts and rebates receivable.
- (3) "Prepaid expenses" mainly comprise R&D expenses.
- (4) "Prepaid income" mainly comprises grants receivable amounting to €394,000 and a holdback of €149,000 for the prefinancing of the 2017 Research Tax Credit (CIR).
- (5) "Government tax receivable" and Research Tax Credit comprises a tax credit of €2,737,000 under the 2020 Research Tax Credit (CIR) and a tax credit of €27,000 under company value-added contribution (CVAE).

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

The Company's financial assets were measured as follows as at June 30, 2020:

	6/30/2020				
In €k	Statement of Financial Position Value	FV	FV per income statement	Loans and receivables	Liabilities at amortized cost
Non-current financial assets	607	607		607	
Rights of use	3 095	3 095		3 095	
Trade receivables	3 318	3 318		3 318	
Other current assets	7 045	7 045		7 045	
Current financial assets	-	-	-		
Cash and cash equivalents	22 920	22 920		22 920	
Total Financial Assets	36 985	36 985	-	36 985	-
Non-current financial liabilities	16 152	16 152			16 152
Non-current lease liabilities	2 570	2 570			2 570
Current financial liabilities	532	532			532
Current lease liabilities	575	575			575
Trade payables	7 810	7 810			7 810
Other current debts	2 955	2 955			2 955
Total Financial Liabilities	30 594	30 594	-	-	30 594

	Impacts o	Impacts on the income		
	statement a	t June 30, 2020		
In €k	Interest	Change in fair value		
Assets in JV through income statement Loans and receivables Assets at amortized cost Cash and cash equivalents	8	0		
Total	8			
Lease liabilities at amortized cost  JV liabilities through income statement Liabilities measured at amortized cost	29 0 21			
Total	50	89		

#### **NOTE 4: CAPITAL**

#### 4.1 Issued capital

Dates	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 €
	At December 31, 2018	2 963 402	48 535 112	4 768 071	14 817 012	0,20	2 963 402
June	Capital increase - Free Share Allocation	30 000	(30 000)	150 000	14 967 012	0,20	2 993 402
December	Issue of 38,712 free shares	7 742	(7 742)	38 712	15 005 724	0,20	3 001 144
	At December 31, 2019	3 001 144	48 497 370	4 956 783	15 005 724	0,20	3 001 144
March	Capital increase - Free Share Allocation (1)	28 360	(28 360)	141 800	15 147 524	0,20	3 029 504
June	Capital Increase - Free Share Allocation (2)	30 000	(30 000)	150 000	15 297 524	0,20	3 059 504
June	Capital Increase - Free Share Allocation (3)	29 060	(29 060)	145 300	15 442 824	0,20	3 088 564
	As of June 30, 2020	3 088 564	48 409 950	5 393 883	15 442 824	0,20	3 088 564

- (1) Capital increase through the acquisition and issuance of 141,800 free shares.
- (2) Capital increase through the acquisition and issuance of 150,000 free shares.
- (3) Capital increase through the acquisition and issuance of 143,300 free shares.

On June 30, 2020, the share capital stood at  $\le$ 3,088,564. It is divided into 15,442,824 fully subscribed and paid up common shares with a par value of  $\le$ 0.20.

#### 4.2 Equity instruments authorized but not issued

The Combined General Shareholders' Meeting of June 14, 2017, 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 December 31, 2019, the Board of Directors had not yet allocated 69,913 of the 500,000 equity instruments.

The Combined General Shareholders' Meeting of June 13, 2018, 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 December 31, 2019, the Board of Directors had not yet allocated 140,000 of the 500,000 equity instruments.

The Combined General Shareholders' Meeting of June 26, 2019, 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 December 31, 2019, the Board of Directors had not yet allocated 500,000 of the 500,000 equity instruments.

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:

- On June 17, 2020, the Board of Directors decided to:
  - 100,000 free shares issued to Nicolas Poirier (under the authority granted on June 13, 2018).
  - 150,000 free shares allocated to Alexis Peyroles (under the authority granted on June 26, 2019)
  - 70,000 (2020) founders' warrants issued to non-salaried, non-executive directors (i.e. 10,000 founders' warrants per director) (under the authority granted on June 26, 2019)

As such, as of June 30, 2020, there remain:

- 69,913 equity instruments under the authority of the Combined Shareholders' Meeting on June 14, 2017;
- 40,000 equity instruments under the authority of the Combined Shareholders' Meeting on June 13, 2018;
- 280,000 equity instruments under the authority of the Combined Shareholders' Meeting on June 26, 2019;
- 500,000 equity instruments under the authority of the Combined Shareholders' Meeting on June 16, 2020.

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

The Company issued the following free share plans:

Allocation date	Exercise period	Total allocated	Exercised during the fiscal year 6/30/2020	Total exercised at 6/30/2020
Free Share Allocation				
03/12/2019	3/12/2019-3/11/2020	149 200	141 800	141 800
6/26/2019	6/26/2019-6/25/2020	150 000	150 000	150 000
6/26/2019	6/26/2019-6/25/2020	148 400	145 300	145 300
12/10/2019	12/10/2019-12/09/2020	22 625		-
6/17/2020	6/17/2020-6/17/2021	150 000		-
6/17/2020	6/17/2020-6/17/2021	100 000		-
Total Free Share		720 225	437 100	437 100

Allocation on March 12, 2019, the Board of Directors allocated free shares with the following characteristics:

#### Allocation to employees:

- Number of shares allocated (existing or to be issued): 149,200,
- Value of the share on the allocation date (according to the market price): €4.09,
- Vesting period and employment requirement: 1 year,
- Lock-up period: 1 year.

On June 26, 2019, the Board of Directors allocated free shares with the following characteristics:

#### Allocation to Alexis Peyroles:

- Number of shares allocated (existing or to be issued): 150,000,
- Value of the share on the allocation date (according to the market price): €3.52,
- Vesting period and employment requirement: 1 year,
- Lock-up period: 1 year.

#### Allocation to employees:

- Number of shares allocated (existing or to be issued): 148,400,
- Value of the share on the allocation date (according to the market price): €3.52,
- Vesting period and employment requirement: 1 year,
- Lock-up period: 1 year.

On December 10, 2019, the Board of Directors allocated free shares with the following characteristics:

#### Allocation to Alexis Peyroles:

- Number of shares allocated (existing or to be issued): 22,625,

- Value of the share on the allocation date (according to the market price): €3.59,
- Vesting period and employment requirement: 1 year,
- Lock-up period: 1 year.

On June 17, 2020, the Board of Directors allocated free shares with the following characteristics:

#### Allocation to Nicolas Poirier:

- Number of shares allocated (existing or to be issued): 100,000,
- Value of the share on the allocation date (according to the market price): €6.16,
- Vesting period and employment requirement: 1 year,
- Lock-up period: 1 year.

#### Allocation to Alexis Peyroles:

- Number of shares allocated (existing or to be issued): 150,000,
- Value of the share on the allocation date (according to the market price): €6.16,
- Vesting period and employment requirement: 1 year,
- Lock-up period: 1 year.

As shares were subscribed and warrants exercised, tables of plans introduced in previous fiscal years were updated as follows:

	2014 3 share subscription warrants	2014 5 share subscription warrants	2014 6 share subscription warrants	2014 7 share subscription warrants	2015 share subscription warrants	2015 3 founders' share warrants
Date of GM establishing plan	3/27/2015	3/27/2015	3/27/2015	12/01/2015	3/27/2015	3/27/2015
Number of authorized shares	120 000	25 000	10 000	50 000	136 222	25 000
Subscription price	0,10€	0,10 €	0,10 €	0,10 €	1,08 €	1,08 €
Subscription date	3/27/2015	04/01/2016	04/01/2017	12/01/2015	5/30/2015	04/01/2019
Vesting of share subscription warrants	on subscription	on subscription	on subscription	on subscription	on subscription	on subscription
Exercise price	€8/share	€8/share	€8/share	€8/share	€10.80/share	€10.80/share
Option type	American	American	Ame ri ca n	American	American	Ame ri ca n
Spot rate	10,12 €	10,12 €	10,12 €	8,56 €	10,12 €	10,12 €
Maturity	5 years	5 years	5 years	3.5 years	5 years	5 years
Volatility	52,94%	54,70%	54,70%	55,88%	51,26%	49,71%
EUR interest rate	-0,0375%	0,3543%	0,3543%	-0,0318%	0,4690%	0,6241%
Dividend yield	0%	0%	0%	0%	0%	0%
Estimated fair value per share subscription warrant	4,95	4,95	4,95	3,59	4,14	4,46
Number of options subscribed	110 000	25 000	0	39 000	136 222	0
Subscription price	0,10	0,10	0,10	0,10	1,08	1,08
Number of options exercised	-	-	-	0	0	-
Contractual expiration date	6/30/2019	6/30/2019	6/30/2019	6/30/2019	3/30/2020	10/01/2019
Vesting period	none	none	none	none	none	none

During 2020, the Group introduced the plan described below:

- The Board of Directors decided to issue a total of 70,000 (2020) founders' warrants, i.e. 10,000 founders' warrants for each non-salaried non-executive director in office on June 17, 2020.

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

#### Corporate officers and employees

The expense recognized on June 30, 2020, for share-based payments to corporate officers, employees and consultants stood at €904,000 exclusively associated with the 2020 free share allocation plans and the 2020 founders' warrant plan.

The employer's contribution in relation to free shares stood at €272,000. Thus, expenses associated with share-based payments totaled €1,176,000.

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

Share subscription warrants/founders' 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	12/31/2019	Increase	Decrease	Other transactions *	6/30/2020	Interest at 6/30/2020
	2.1.0				2.440	
BPI EFFIMAB Advance	3 148				3 148	
BPI EFFICLIN Advance	6 044				6 044	
P2RI Loan	0			(10)	0	
BPI EFFIDEM Advance	19			(19)	0	
State-backed loan	0	6 960	_		6 960	_
Non-current financial liabilities	9 211	6 960	0	(19)	16 152	0
Nantes Lot 1 Lease	332			(52)	280	
Nantes Lot 2 Lease	149			(17)	132	
Paris Suffren Lease Lot 1	932			(69)	862	0
Paris Suffren Lease Lot 2	0	1 172		(79)	1 093	
Leasing Cytometre		209		(6)	203	
Non-current lease liabilities	1 413	1 381	0	(224)	2 570	0
BPI EFFIMAB Advance	92			23	115	(23)
BPI EFFICLIN Advance	95			81	176	(81)
P2RI Loan	321		(141)	1	181	(3)
BPI EFFIDEM Advance	39		` ,	19	58	(0)
State-backed Ioan		17		(15)	2	(2)
Bank overdrafts	3		(3)		(0)	, ,
Current financial liabilities	549	17	(143)	109	532	(110)
Nantes Lot 1 Lease	112		(49)	52	116	(4)
Nantes Lot 2 Lease	37		(16)	17	39	(2)
Paris Suffren Lease Lot 1	160		(60)	69	169	(10)
Paris Suffren Lease Lot 2	0	160	(66)	79	173	(13)
Leasing Cytometre		72	0	6	78	0
Current lease liabilities	309	232	(191)	224	575	(29)
Total financial liabilities	17 714	8 591	(334)	90	19 829	(139)

<sup>\*</sup>This column includes the recurring and non-recurring breakdown as well as IFRS 9, IAS 20 and IFRS 16 restatements for the year.

The table below shows the schedule of financial liabilities:

In €k	Less than 1 year	June 2022	June 2023	June 2024	June 2025 and after	Total
	yeui				and arter	
BPI EFFIMAB Advances	115				3 148	3 263
BPI EFFICLIN Advance	176			204	5 840	6 220
P2RI Loan	181					181
BPI EFFIDEM Advance	58					58
State-backed Ioan	2				6 960	6 962
Financial liabilities	532	-	-	204	15 948	16 684
Nantes Lot 1 Lease	116	104	103	73		396
Nantes Lot 2 Lease	39	35	35	35	26	170
Paris Suffren Lease Lot 1	169	138	136	133	456	1 031
Paris Suffren Lease Lot 2	173	155	152	149	636	1 266
Leasing Cytometre	78	70	69	64	-	281
Leasing liabilities	575	503	495	454	1 118	3 145
Total financial liabilities	1 107	503	495	658	17 066	19 829

#### Lease liabilities (see Note 1.2)

#### 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, n°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 has already decided to exercise the option and repay this loan at the end of 5 years. This is a French Government-guaranteed loan under article 6 of the aforementioned law. The annual percentage rate is 0.25% corresponding to the guarantee fee and, should the loan be extended beyond the first year, the interest rate will be set through an amendment.

The funds received and conditions are as follows:

- Crédit Mutuel = €2,300,000 received May 6, 2020 repayable on May 6, 2025.
- BNP = €2,300,000 received on May 6, 2020 repayable on May 6, 2025.
- CIC = €2,360,000 received on May 18, 2020 repayable on May 18, 2025.

#### **NOTE 6: CURRENT DEBTS**

#### 6.1. Other current debts

In €k	6/30/2020	12/31/2019
Deferred income Miscellaneous	2 955	4811
Total other debts and accruals	2 955	4 812

The €1.85 million decrease in deferred income was mainly due to:

- The deferment of the €10 million milestone received on March 5, 2019, as a result of the exercise of Servier's option for OSE 127, generating deferred income of €3,356,000 as of December 31, 2019. €1,812,000 in deferred income is outstanding as of June 30, 2020.
- The deferment of the €15 million milestone received in the first half of 2019 under a collaboration

and licensing agreement signed with Boehringer Ingelheim (OSE 172), generating deferred income of €572,000 as of December 31, 2019. €166,000 in deferred income is outstanding as of June 30, 2020.

Other deferred income breaks down as follows:

- Boehringer Ingelheim: €959,000 within the context of re-invoicing of development expenses;
- DC TARGET and IMMUNOMONITOR grant of €20,000.

#### **NOTE 7: CURRENT AND NON-CURRENT PROVISIONS**

Provisions break down as follows:

In €k	12/31/2019	Increase	Decrease	Changes in scope	6/30/2020
Provision for pension commitments	377	83			460
	377	83	-	-	460

#### **Provision for pension commitments**

The provision for pension commitments was measured in accordance with the applicable collective agreement, i.e. the pharmaceutical industry collective agreement. The assumptions made were as follows:

- Mortality table: regulatory table TH (men)/TF (women) 00-02,
- Estimated retirement age: 65,
- Ratio of wage increases: 2%,
- Staff turnover: low turnover,
- Discount rate: 0.74%,
- Social security contribution rates: between 35% and 45% depending on the category.

On June 30, 2020, the average monthly headcount stood at 43 compared with 35 on December 31, 2019.

#### **NOTE 8: OPERATING INCOME**

#### 8.1. Revenue from collaboration agreements

As of June 30, 2020, the breakdown of operating income is as follows:

In €k	First hal	f 2020	First ha	alf 2019
	Revenue	Deferred income	Revenue	Deferred income
BI agreement				
Disposal of IP			13 094	
Re-invoicing of co-development costs	406	166	491	1 415
Re-invoicing of direct costs	1 511	959	2 326	
Servier agreement				
Milestones	1 543	1 812	2 777	7 223
Sale of OSE-127 vials	1 876		64	
Supplementary development service				
RAFA Agreement				
Distribution license	0	-	3	74
CKD Agreement				
Distribution license	500			
Créapharm				
Re-invoicing of expenses	13			
Total	5 849	2 937	18 755	8 712

Revenue stood at €5,849,000 and comprised:

- €406,000 in co-development costs related to milestone payments received and deferred to include development services to be provided by OSE on behalf of Boehringer Ingelheim (BI).
   €166,000 in deferred income is outstanding.
- €1,511,000 for re-invoicing of expenses as provided in the agreement signed with Boehringer Ingelheim.
- €1,543,000 for a portion of milestone payments amounting to €10,000,000 received upon exercise of the option by SERVIER.
- €1,876,000 related to the sale of OSE-127 vials under a supply contract signed with SERVIER and for the re-invoicing of a portion of intellectual property-related fees.
- 500,000 for meeting the first milestone in the contract with CKD signed in 2019.
- €13,000 in re-invoicing following a dispute with Créapharm.

For deferred income, see Note 6.1. Other current debts.

#### 8.2. R&D expenses

In €k	6/30/2020	6/30/2019
Sub-contracting	8 459	8 825
Fees	952	521
Employee benefits expense	2 024	1 675
Allocation/reversal of depreciation, amortization and provisions	107	73
Charges	3	0
Taxes and duties	22	18
Other	487	561
R&D expenses	12 054	11 672
CIR	(2 737)	(2 255)
Subsidy received	(231)	(229)
Total R&D expenses	9 087	9 189

Sub-contracting expenses are unchanged in relation to the first half of 2019. They mainly comprise costs for Tedopi® Phase 3, OSE-127's CMC and OSE-172 Phase 1.

The increase in fees is directly correlated with an increase in consultancy costs linked to the number and complexity of research and development projects. Intellectual property fees have also increased in line with the changing patent portfolio.

Other overheads mainly comprise consumables and travel expenses for conferences. The decrease in costs is due to the impact of COVID-19 (cancellation of conferences and travel, reduction in laboratory activity) and the end of the agreement giving access to Inserm's premises.

After deducting the Research Tax Credit (CIR), total R&D costs remain unchanged despite the increased headcount.

#### 8.3. Overhead expenses

In €k	6/30/2020	6/30/2019
Storage sub-contracting	18	0
Fees	810	656
Employee benefits expense	1 283	987
Allocation to depreciation, amortization and provisions	237	32
Charges	4	4
Taxes and duties	37	58
Directors' fees	88	77
Other	194	385
Total overhead expenses	2 672	2 199

Fees comprised miscellaneous expenses (legal, accounting, financial communication, listing, etc.) and increased compared to the first half of 2019. This increase is due to significant efforts by the company in communications with investors/shareholders.

Other overheads amounting to €195,000 mainly comprised travel costs.

#### 8.4. Employee benefits expense

R&D expenses of €2,024,000 and overheads of €1,283,000 recognized as employee benefits expense break down as follows:

In €k	6/30/2020	6/30/2019
Salary and wage benefits	3 225	2 627
Directors' fees	88	77
Pension commitments	82	34
	3 395	2 738
Expenses related to employee share-based payments	995	673
	995	673

On June 30, 2020, the average monthly headcount stood at 43 compared with 35 on December 31, 2019.

**NOTE 9: NET FINANCIAL INCOME** 

In €k	H1 2020	H1 2019
Foreign exchange gain	19	24
Revenue on cash equivalents	8	13
Other financial income	0	2
Change in fair value of marketable securities	0	104
Total financial income	28	143
Foreign exchange loss	9	15
Interest expense	110	43
Interest on lease liabilities	29	15
Provision for liabilities and charges	2	0
Total financial expenses	150	74
Total financial income	(121)	69

The decrease in net financial income was mainly due to:

- An increase in interest expenses to €110,000, mainly due to interest on the EFFIMAB and EFFICLIN repayable advances.
- An increase in lease liabilities to €29,000, mainly as a result of IFRS 16 (new lease agreements).
- Absence of material investment securities as of June 30, 2020.

#### 10.1. Deferred tax assets

The Company recognized a deferred tax asset for OPI (Swiss subsidiary) valued at €1.19 million calculated on the basis of a 13.99% tax rate (Swiss rates under ordinary law applied since January 1, 2020).

At June 30, 2020, deferred tax assets stood at €167,000.

#### 10.2. Net deferred tax liabilities

In 2016, the Company recognized a deferred tax liability for the FR104 and OSE-127 molecules, valued at €52.6 million.

In accordance with IAS 12, until December 31, 2018, this deferred tax liability was offset by the deferred tax assets on tax loss carryforwards of the French company: the net deferred tax liability stood at €2,010,000 at December 31, 2018.

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.

As of December 31, 2019, pending administrative clarifications, the tax loss carryforwards were not considered to be chargeable to the profits eligible for the preferential regime. Given these factors, an impairment of €3,370,000 was applied to these deferred tax assets.

In light of the administrative clarifications of April 22, 2020, profits eligible for the preferential regime may be offset against tax loss carryforwards. Consequently, €3,370,000 in deferred tax assets on tax loss carryforwards were recognized.

As of June 30, 2020, net deferred tax liabilities fell by €4,264,000 to £802,000 (compared with £5,066,000 as of December 31, 2019).

#### 10.3. Income tax expense

At June 30, 2020, the Group generated income (net of tax) of €4,094,000, which breaks down as follows:

- Deferred tax income of €4,146,000 mainly relating to:
  - A decrease in deferred tax liabilities of €4,264,000 between December 31, 2018, and December 31, 2019 (including €3,370,000 relating to the reversal of deferred tax assets on tax loss carryforwards at June 30, 2020).
  - A decrease in deferred tax liabilities of €116,000 between December 31, 2019 and June 30, 2020 related to the OPI patents following a change in the tax rate under Swiss common law from January 1, 2020 (from 24.16% to 13.99%).

- Tax expense payable of €51,000 (including €50,000 in withholding tax).

#### **NOTE 11: COMMITMENTS**

#### 11.1. Other off-statement of financial position 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 were transferred to the Company through merger.

#### Collateral pledged

Interest-bearing bank account pledged to Crédit Mutuel as collateral, amounting to €10,000

Interest-bearing bank account pledged to CIC as collateral, amounting to €146,000

Interest-bearing bank account pledged to CIC as collateral, amounting to €161,000

#### Guarantees given

€18,000 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 €375,000 each. The outstanding principal at June 30, 2020, amounted to €70,000.

The Company does not have any other off-statement of financial position commitments.

#### **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.

Basic earnings	H1 2020	H1 2019
Profit (loss) for the period (€K)	- 3 114	514
Weighted average number of shares outstanding	15 087 010	14 820 345
Basic earnings per share (€/share)	- 0,21	0,03

The weighted average number of shares at June 30, 2020 takes into account the capital increases

during the fiscal year.

#### **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, 2019 and June 30, 2020.

#### **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	6/30/2020	6/30/2019
Salaries and other short-term benefits *	675	434
Directors' fees	88	77
Share-based payments **	533	312
Fees	6	5
Total	1 302	828

<sup>\*</sup> Excluding social charges

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

#### **NOTE 15: EVENTS AFTER THE REPORTING PERIOD**

In July 2020, the Company announced that it had been awarded a grant of €200,000 from Nantes Métropole to develop CoVepiT, its prophylactic COVID-19 vaccine.

In August 2020, the Company announced positive preclinical results for CoVepiT, its multi-target COVID-19 vaccine.

These initial data support CoVepiT's potential as a novel and differentiated vaccine against COVID-19, using technology known to induce memory T lymphocytes against multiple SARS-CoV-2 virus targets.

They show that CoVepiT provides tissue-resident memory sentinel T cell response with long-term protective immunity in barrier tissues such as the respiratory tract and the lung, associated with long-term protective immunity.

<sup>\*\*</sup> Relating to the allocation of free shares and share subscription and founders' warrants

**HALF-YEAR ACTIVITY REPORT** 

**OSE IMMUNOTHERAPEUTICS** 

#### I. COMPANY ACTIVITY IN THE FIRST HALF OF 2020

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

#### 1.1.1 Capital structure at June 30, 2020

As of June 30, 2020, the Company's share capital was €3,088,564.80, divided into 15,442,824 shares with a nominal value of €0.20, fully paid up.

As of June 30, 2020, the breakdown of the Company's share capital and voting rights was as follows:

Name	June 30, 2020		
	Number of shares	% of capital	% of voting rights
Groupe Emile Loria	3,411,557	22.09%	16.71%
Guy Chatelain	195,490	1.27%	1.00%
Dominique Costantini	1,978,663	12.81%	18.12%
Alexis Peyroles (1)	748,288	4.85%	5.52%
Maryvonne Hiance (2)	424,084	2.75%	3.85%
Nicolas Poirier	92,802	0.60%	0.50%
Public	8,591,940	55.64%	54.29%
Total	15,442,824	100%	100%

<sup>(1)</sup> Directly and indirectly through the intermediary of his asset management company Aperana Consulting.

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

Despite the COVID-19 health crisis, the Company continued its research and development work in the first half of 2020.

#### January 2020

New family of patents awarded by Japanese Patent Office related to TEDOPI® and the induction of early T lymphocyte memory response for use in the treatment of cancer in HLA-A2 positive patients. This patent protects the product until 2035.

#### February 2020

<sup>(2)</sup> Directly and indirectly through her asset management company HIANCE MD2A.

Collaboration agreement signed with MabSilico, on artificial intelligence applied to the development of therapeutic antibodies to build on artificial intelligence to develop monoclonal antibodies, including innovative bispecific antibodies (BiCKI® platform).

#### **March 2020**

Amendment signed to the worldwide licensing option with SERVIER for OSE-127, an IL-7 receptor antagonist developed in autoimmune diseases.

This amendment covers the terms and conditions for exercising the licensing option by modifying Step 2 of the option. OSE Immunotherapeutics will thus receive a milestone payment of €5 million from SERVIER on enrollment of the first patient in Phase 2a clinical study scheduled to start in Sjögren's Syndrome and an additional payment of €15 million on exercise of the option at the end of the two scheduled Phase 2 studies, with priority being given to the study in Sjögren's Syndrome. The initial agreement provided for a total payment of €20 million at the end of Phase 2 in ulcerative colitis.

#### April 2020

Announcement of the initial results of step 1 of the Atalante study: analysis of data from step 1 under the protocol of the Phase 3 Tedopi®, Atalante 1 clinical trial, showed that the primary endpoint for this step had been achieved. This study is conducted in HLA-A2 positive patients with non-small cell lung cancer (NSCLC), post checkpoint inhibitor treatment failure (PD-1/PD-L1).

However, in the context of the COVID-19 epidemic, a decision was taken to voluntarily and permanently suspend recruitment due to the risks that may arise for patients and the direct consequences on data from Step 2 of the trial that will thus not be conducted.

#### May 2020

- Launch of a program of prophalycitc vaccine against COVID-19: the Company announced that it had joined the fight against COVID-19 by working actively to develop a prophylactic vaccine against the SARS-CoV-2 pandemic virus.
  - It is drawing on the expertise gained through its epitope optimization technology (neoepitopes) Memopi®, recently validated in step 1 of the Phase 3 Tedopi® clinical trial, a combination of antitumor epitopes, to enhance the memory T lymphocyte immune response against specific antigens.
- Funding of €7 million obtained through a French government-guaranteed loan (Prêt Garanti par l'Etat - "PGE") introduced in the context of the COVID-19 pandemic, with a group of French banks, enabling the Company to strengthen its cash position.

#### June 2020

- Oral presentation to the AACR on the CLEC-1 project: the Company identified monoclonal antibody antagonists targeting CLEC-1 as new myeloid checkpoint inhibitors for immunooncology.
- Presentation to the AACR of a poster for the BiCKI®-IL7 project: the Company presented new data on its BiCKI® bispecific checkpoint inhibitor platform, and BiCKI®-IL-7, a bifunctional anti-PD-1/IL-7 in cancer immunotherapy.
- 1.1.3 Issuance of share warrants (BSA), founders' warrants (BSPCE) and free share allocation (AGA)

In the first half of 2020, the following financial instruments were issued or allocated:

#### Vesting of 437,100 free shares allocated

Vesting of the free share allocation of 141,800 to non-corporate officer employees (March 2020)

At its meeting on December 5, 2018, the Board of Directors, using the delegation granted by the Combined Shareholders' Meeting on June 14, 2017, allocated 150,000 free shares to non-corporate officer employees. On March 12, 2019, the Chief Executive Officer, using the delegation granted by the Board of Directors on December 5, 2018, allocated 149,200 free shares to non-corporate officer employees.

On March 26, 2020, having assessed the share vesting criteria for each of the beneficiaries still present at the Company, the Board of Directors issued 141,800 shares.

Vesting of 150,000 free shares allocated to the Chief Executive Officer (June 2020)

At its meeting on June 26, 2019, the Board of Directors, using the delegation granted by the Combined Shareholders' Meeting on June 13, 2018, allocated 150,000 free shares to Alexis Peyroles (Chief Executive Officer).

On June 17, 2020, the Board of Directors granted the Chief Executive Officer full authority to assess the share vesting criteria in order to issue 150,000 shares.

On June 26, 2020, having assessed the share vesting criteria, the Chief Executive Officer issued 150,000 shares.

Vesting of 145,300 free shares allocated to non-corporate officer employees (June 2020)

At its meeting on June 26, 2019, the Board of Directors, using the delegation granted by the Combined Shareholders' Meeting on June 13, 2018, allocated 150,000 free shares to non-corporate officer employees. The Chief Executive Officer, using the delegation granted by the Board of Directors on June 26, 2019, allocated 148,400 free shares to non-corporate officer employees.

On June 17, 2020, the Board of Directors granted the Chief Executive Officer full authority to assess the share vesting criteria for each of the beneficiaries still present at the Company in order to issue 145,300 shares.

On June 26, 2020, having assessed the share vesting criteria, the Chief Executive Officer issued 145,300 shares.

#### Issuance of 500,000 free shares

150,000 free shares issued to the Chief Executive Officer (June 2020) and 100,000 to the Chief Scientific Officer

At its meeting on June 17, 2020, the Board of Directors made use of the delegation granted by the Combined Shareholders' Meeting on June 26, 2019, to allocate 150,000 free shares to Alexis Peyroles (Chief Executive Officer) and 100,000 free shares to Nicolas Poirier (Chief Scientific Officer).

Free shares subject to a share allocation plan will only vest one year after the Allocation Date ("Vesting Period"), provided that, at the end of the Vesting Period, the beneficiaries remain employed by OSE Immunotherapeutics, any of its subsidiaries, or any affiliated companies within the meaning of article L. 233-16 of the French Commercial Code.

Issuance of a maximum of 250,000 free shares to non-corporate officer employees (June 2020)

At its meeting on June 17, 2020, the Board of Directors, using the delegation granted by the Combined Shareholders' Meeting on June 26, 2019, allocated 250,000 free shares to non-corporate officer employees. As of June 30, 2020, the Chief Executive Officer has not used the delegation granted by the Board of Directors on June 17, 2020.

#### Issuance of 70,000 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 17, 2020, the Board of Directors, using the delegation granted by the Combined General Shareholders' Meeting of June 26, 2019, allocated 70,000 founders' share warrants, i.e. 10,000 founders' share warrants for the benefit of each non-salaried non-executive director in office on June 17, 2020, in accordance with article 163 bis G II of the French General Tax Code.

These free founders' share warrants may be exercised between June 17, 2020 and June 17, 2025 and entitle the holder to subscribe to 70,000 new shares at a price of €3.58 per share.

#### 1.2 Progress made and difficulties encountered

#### **TEDOPI®**

The IDMC (Independent Data Monitoring Committee) related to the study's Steering Committee met on March 25, 2020. In light of the COVID-19 crisis and its impact on the integrity of the study's data, the impact of COVID-19 on cancer patients and, in particular, those with lung cancer and undergoing chemotherapy (control arm of the Atalante-1 trial), the IDMC recommended the permanent suspension of inclusions in step 2 of the study. The Company has reviewed the positive results of step 1 of the study, with the principal endpoint of the study in terms of the 12-month survival rate of patients treated in the Tedopi arm having been achieved. The Company is now in the process of analyzing all the results from step 1 and assessing the best regulatory strategy for the continued development of the product and the possibility of industrial partnerships.

**Phase 2 TEDOPaM trial**: the recruitment of new patients under Tedopi's Tedopam trial as a treatment for pancreatic cancer as a monotherapy and in combination with BMS' nivolumab Opdivo® has been suspended due to COVID-19. GERCOR indicated that it would proceed with the analysis of data for the first 29 patients before deciding whether to resume recruitment.

Moreover, plans for new phase 2 studies, in combination with a PD-1 checkpoint inhibitor, are under discussion and under study.

**BI 765063/OSE-172** 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 SIRPα.

The Phase 1 clinical trial is a dosage study of the monoclonal antibody targeting SIRP $\alpha$ , BI 765063, a myeloid checkpoint inhibitor administered as a single agent and in combination with Boehringer Ingelheim's monoclonal antibody PD-1 antagonist BI 754091, a T-lymphocyte checkpoint inhibitor.

This study is underway in France and Belgium and is continuing as a monotherapy. There are plans to combine it with Boehringer Ingelheim anti PD-1 in the coming months. The specific timing of the next stages of the study is under review based on discussions with investigators in the context of the COVID-19 epidemic.

#### **OSE-127**

The phase 1 study involved 63 healthy volunteers and ended on November 29, 2019.

The positive results in terms of product safety mean that the phase 2 ulcerative colitis study and, in the case of SERVIER, a phase 2 Sjögren's Syndrome study, can be scheduled and launched.

On March 17, 2020, the Company and Servier signed an amendment of the worldwide licensing option for OSE-127, an IL-7 receptor antagonist developed in autoimmune diseases.

Both companies have been able to make progress in preparing these two phase 2 studies in the second quarter of 2020 and, despite the difficulty in accessing hospitals, the Company expects to file an application for clinical study authorization in summer. It remains too early to give a precise date for the first patient to be treated in these studies but the aim is to have these first patients by the end of the year subject to the authorization of all the relevant authorities.

#### FR104

On November 2, 2018, the Company acquired all the worldwide rights to FR104 from Janssen Biotech Inc., effective December 31, 2018. Janssen Biotech's decision to return the FR104 program to OSE was motivated by an internal strategy review and prioritization of its own product portfolio.

The Company is exploring the positioning of FR104 and its future clinical progress, in particular a possible partnership to develop it for use in transplants or other autoimmune disease indications.

#### **Preclinical development:**

BiCKI®: the bispecific BiCKI® platform with backbone component anti-PD-1 is under development with two targets identified.

This bi-specific platform should be a means of overcoming the current limitations of anti-PD-1/PD-L1 monoclonal antibodies in Immuno-Oncology. This platform is at the early pre-clinical stage and will require a significant proportion of investment and research team time in 2020/21.

Pharmaceutical companies have expressed an interest in this type of product which should make it

possible to enter into preliminary discussions with certain companies in 2020. Initial pre-clinical studies, in particular in relation to CMC, continued in the first quarter of 2020 for a number of these BiCKI® projects and the anti PD-1 backbone antibody (OSE-279).

Two new targets and antibodies were announced at conferences acting on myeloids, CLEC-1 antagonists in immuno-oncology, and antagonist in the area of resolvins affecting chronic inflammatory diseases and cancerology.

CoVepiT: a COVID-19 vaccine project was launched, using the same epitope selection / optimization technology as that used for Tedopi® with a selection of epitopes relevant for these SARS-CoV virus infections. The initial encouraging pre-clinical results were received during the summer. Depending on the pre-clinical results, the priority will be to identify a partner at an early stage, if a clinical development can be defined.

#### 1.3 <u>Foreseeable changes and future outlook</u>

Progress of the portfolio is based on its current products:

#### Immuno-oncology

**TEDOPI**<sup>®</sup>: as a single agent or in combination with a checkpoint inhibitor in immuno-oncology

The Phase 3 trial of Atalante 1 for lung cancer, aimed at evaluating the product's benefits for HLA-A2 positive patients in second and third line treatment after the failure of a checkpoint inhibitor for stage IIIB invasive or IV metastatic non-small cell lung cancer, compared with current therapeutic standards in this population of patients was halted. The primary endpoint for the first step was achieved with 46% of patients in this first step treated with Tedopi having survived for at least 12 months. This international trial was conducted in the United States, Europe and Israel.

The Company will present the full results of this step 1 at an international medical conference in the fall of 2020. The Company is also working on identifying an industrial partner to potentially market Tedopi® outside Israel and Korea where partnership agreements have already been signed.

In fact, the class of immune checkpoint inhibitors is becoming the new standard treatment for advanced non-small cell lung cancer (NSCLC), showing greater efficacy than chemotherapy in first and second line treatment. The population of "post-checkpoint inhibitor" patients, a specific population experiencing immune escape in this kind of treatment, represents a specific population for which no approved treatment is currently available and for which there is a strong medical need.

**Recruitment to the phase 2 clinical trial for pancreatic cancer** sponsored by GERCOR has been suspended due to COVID-19:

This study aims to evaluate Tedopi® as a maintenance treatment, in monotherapy or in combination with a PD-1 checkpoint inhibitor, or versus Folfiri,\* in locally advanced or metastatic pancreatic cancer in HLA-A2 positive patients with stable disease after four months of standard chemotherapy with Folfirinox.\*\* The main objective of the study is overall survival. This trial is being conducted in collaboration with the cooperative group for digestive cancers of GERCOR, the sponsor.

- \* Folfiri: a chemotherapy regimen combining folinic acid, fluorouracil and irinotecan
- \*\* Folfirinox: a chemotherapy regimen combining folinic acid, fluorouracil, irinotecan and oxaliplatin

**BI 765063/OSE-172**: currently in the clinical phase, the first results are expected in the first half of 2021. This product has been developed in collaboration with Boehringer Ingelheim, following the collaboration and license agreement signed in April 2018.

#### **Autoimmune diseases**

**FR-104**: The Company is continuing to explore the positioning of FR104 and its future clinical advances, in particular a possible partnership to develop it for rheumatoid arthritis, and possibly other autoimmune disease indications or transplants.

**OSE-127**: Phase 2 planned for ulcerative colitis, an autoimmune bowel disease, should begin by the end of 2020 if not delayed by the COVID-19 epidemic. Servier will sponsor a phase 2 study for Sjögren's Syndrome.

Continued development after phase 2 will be ensured by Servier, provided that this partner exercises the second part of the option under the agreement signed in December 2016.

#### R&D

The Company will continue to develop its BiCKI® platform as well as other checkpoint inhibitors or immunomodulators, which may also be selected and optimized for development based on the proofs of concept developed in R&D.

#### Partnerships - value creation:

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.

## Two international strategic partnerships were signed in 2016 - 2018 and are in place with two pharmaceutical groups for two 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.

- Under the 2-step license option agreement entered into with SERVIER In December 2016 relating to OSE-127, the development of the product is to be continued by OSE until the completion of a phase 2 clinical trial for ulcerative colitis, an autoimmune bowel disease and/or Sjögren's disease by the Servier laboratories. Servier will continue development after this phase 2 trial under the license option agreement.
- 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.

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 <u>Main risks and uncertainties to which the Company is exposed</u>

The main risks and uncertainties to which OSE Immunotherapeutics may be exposed in the second half of 2020 are of the same nature as those described in paragraph 3 "Risk factors" of the registration document dated April 15, 2020, available to download on the Company's website under the section "Investors/documentation/registration document" and on the AMF website.

Regarding the COVID-19 health crisis, please refer to the highlights of the fiscal year described in the financial appendices.

#### 1.6 <u>Use of financial instruments by the Company</u>

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

#### 1.7 <u>Transactions with related parties</u>

In the first half of 2020, the following transactions were recorded:

#### **Alexis Peyroles**

In the first half of 2020, Alexis Peyroles, Chief Executive Officer, received €263,687 gross from the Company in respect of his employment contract as Chief Operating Officer. The Board of Directors approved the combination of an employment contract with the position of Chief Executive Officer on March 28, 2018.

At the beginning of the 2020 fiscal year Alexis Peyroles was paid a bonus of €83,125 gross for the 2019 fiscal year.

#### **Dominique Costantini**

On March 28, 2018, the employment contract of Ms Costantini, Chairman of the Board of Directors, was amended to clarify the realignment of her position to focus on early development with the same terms and conditions, particularly in terms of compensation. From January 1, 2020, her contract was extended to include all development. 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 2020, she received €211,819 gross from the Company in respect of her employment contract.

At the beginning of the 2020 fiscal year, Dominique Costantini was paid a bonus of €68,750 gross for the 2019 fiscal year.

#### **Maryvonne Hiance**

In the first half of 2020, Maryvonne Hiance, Vice Chairman of OSE IMMUNOTHERAPEUTICS, received €103,030 gross from the Company in respect of her employment contract as Director of Strategy, signed with the Company on May 31, 2016.

At the beginning of the 2020 fiscal year, Maryvonne Hiance was paid a bonus of €30,000 gross for the 2019 fiscal year.

#### **Board of Directors**

Members of the Board of Directors received a total of €58,500 net in directors' fees from the Company for the first half of 2020.

#### HALF-YEAR FINANCIAL STATEMENTS AS OF JUNE 30, 2020

#### 2.1 <u>Presentation of the Company's half-year consolidated financial statements</u>

The consolidated financial statements of OSE Immunotherapeutics and its subsidiaries (the Group), are presented in euros and are drawn up 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, 2020.

#### 2.2 <u>Consolidated statement of financial position</u>

The consolidated statement of financial position for the first half of 2020 stood at €90,745,000 compared with €88,933,000 as of December 31, 2019.

#### 2.3 Consolidated income statement

As of June 30, 2020, the Group's revenue totaled €5,849,000 compared with €15,979,000 as of June 30, 2019.

Operating expenses by function - €K	6/30/2020	6/30/2019	Change	% var
R&D expenses	9,087	9,189	30	0.3%
Overhead expenses	2,672	2,199	342	15.5%
Expenses related to share-based payments	1,176	673	503	74.8%
Total	12,935	12,061	875	7.25%

The breakdown of research and development expenses in the first half of 2020 is as follows:

- €9,411,000 in sub-contracting and fees, before recording the research tax credit of €2,737,000 and subsidies received in the amount of €231,000
- €2,024,000 in employee benefits expense allocated to research and development
- €107,000 in allocation/reversal of depreciation, amortization and provisions
- €513,000: taxes and duties, miscellaneous expenses

The breakdown of overhead expenses for the first half of 2020 is as follows:

- €828,000 in fees and sub-contracting
- €1,283,000 in employee benefits expenses allocated to the operational management team
- €88,000 in Directors' fees
- €237,000 in allocation/reversal of depreciation, amortization and provisions
- €236,000: cost of premises, conference expenses, travel expenses, banking fees, charges and other taxes

Operating income for the first half of 2020 was -€7,085,000. Net income for the first half of 2020 was -€3,114,000.

#### 2.4 <u>Indebtedness (consolidated financial statements)</u>

Financial liabilities totaled €19,829,000 (including €3,144,000 in lease liabilities related to the application of IFRS 16).

The Group's cash totaled €22,920,000 as of June 30, 2020.

As such, net financial debt totaled -€3,091,000 as of June 30, 2020.

#### II. <u>SUBSIDIARIES AND EQUITY INTERESTS – INVESTMENT SECURITIES</u>

#### 3.1 Subsidiary activities

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 2019.

#### 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**