

# OSE Immunotherapeutics

Company update

Transforming into R&amp;D powerhouse

Pharma &amp; biotech

Despite the ongoing pandemic and difficult times for most of the industry, OSE has managed to progress its R&D activities, which most recently culminated in an out-licensing deal. All this helped the share price to triple since the beginning of 2020. OSE carried out a successful private placement of €18.6m in November 2020 followed by a substantial loan from the European Investment Bank in February 2021, which gives OSE access to up to €25m. The funding provides visibility to Q222, which could be supplemented by potential milestone payments from its partners. Upcoming newsflow from the clinical and preclinical pipeline should provide continued catalysts and hence continue to support the share price. Our updated valuation is €291m or €16.2 per share.

30 April 2021

**Price** €11.62

**Market cap** €209m

Gross cash (€m) at end-FY20 (government debt not included) 22.9

Shares in issue 18.0m

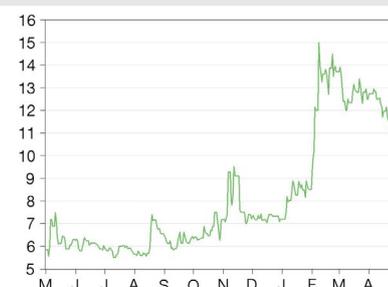
Free float 25%

Code OSE

Primary exchange Euronext Paris

Secondary exchange N/A

## Share price performance



%	1m	3m	12m
Abs	(10.3)	36.7	119.2
Rel (local)	(14.2)	18.4	63.1
52-week high/low		€15.0	€5.5

## Business description

OSE Immunotherapeutics is an immunotherapy company based in Nantes and Paris, France, and listed on the Euronext Paris exchange. OSE is developing immunotherapies for the treatment of solid tumours and autoimmune diseases and has established several partnerships with large pharma companies.

## Next events

Additional NSCLC patient data from the Phase III Tedopi trial	Q221
Initiation of Phase II trial with OSE-127 by Servier	Q2/Q321
Start of CoVepiT Phase I trial	H121
First clinical data from Phase I with BI 765063	H121

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Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/19	26.0	(1.2)	(0.30)	0.0	N/A	N/A
12/20	10.4	(18.5)	(1.02)	0.0	N/A	N/A
12/21e	16.0	(14.1)	(0.85)	0.0	N/A	N/A
12/22e	0.0	(30.4)	(1.69)	0.0	N/A	N/A

Note: \*PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

## FR104 out-licensed, third partner on board

On 26 April 2021, OSE announced that it had out-licensed rights to FR104 in the organ transplantation market to Veloxis Pharmaceuticals. Veloxis plans to develop FR104 as a novel drug to prevent organ rejection after transplantation, while OSE retains the rights to develop FR104 in autoimmune diseases. According to the terms of the deal, OSE could receive up to €315m in milestone payments, which includes a €7m upfront payment and tiered royalties. We view the deal terms as attractive, as they are much better than those OSE had agreed with Janssen several years ago (which has since returned the rights) and Veloxis received rights only to a specific therapy area.

## Upcoming newsflow

OSE is now focusing on regulatory interactions and partnering discussions regarding its most advanced Phase III asset, Tedopi, a cancer vaccine for NSCLC. A Phase I study in partnership with Boehringer Ingelheim (BI) is evaluating BI 765063, antagonist of SIRP $\alpha$ , in solid tumours is ongoing and the first results are expected in H121. Two Phase II trials with OSE-127, an anti-IL-7R $\alpha$  antibody, are underway in ulcerative colitis (sponsored by OSE, ongoing) and Sjögren's syndrome (sponsored by Servier, start in Q2/Q321). The new project CoVepiT, a potentially prophylactic vaccine against the SARS-CoV-2 virus, is progressing as well, with the Phase I study expected to start shortly.

## Valuation: €291m or €16.2 per share

Our updated valuation of OSE is €291m or €16.2 per share, compared to €240m or €16.0 per share previously. The main change to our model is the addition of milestone payments (risk-adjusted and discounted; royalties are not reflected for now) related to the Veloxis deal. The valuation per share is virtually unchanged as the uplift resulting from the deal was offset by the private placement in November.

## Veloxis deal terms are attractive

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Veloxis Pharmaceuticals is a Danish biotech that was acquired for \$1.3bn in 2019 by Japanese Asahi Kasei Group (market capitalisation of c \$14.8bn). Since Veloxis is owned by a large group, we do not expect a granular development plan for FR104, but the chief scientific officer of the company indicated that as the first step it will aim to develop FR104 as novel alternative to calcineurin inhibitors (CNIs) for immunosuppression in kidney transplantation. CNIs (cyclosporine A and tacrolimus) are the cornerstone in this setting and have been used in renal transplant recipients for more than 20 years, which indicates a lack of treatment changing novel therapeutics.

FR104 is a CD28 antagonist. CD28 acts as co-receptor in the T-cell receptor (TCR) and delivers stimulatory signals from antigen-presenting cells to T-cells. An antagonist of CD28 has potential clinical applications in multiple autoimmune diseases and transplantation where T-cells are involved.

It is worth remembering that FR104 was previously out-licensed to Janssen which, after portfolio reprioritisation, returned the rights to OSE in 2018. The terms of that deal stipulated milestone payments of up to €155m plus royalties, including €10m as an upfront payment (this and the upfront payment from Veloxis mean that OSE has already received €17m from this asset). However, Janssen had rights to develop the drug candidate in autoimmune diseases and transplantation, while Veloxis gained rights in transplantation only. So, all in all, we view the deal terms as attractive. To reflect the value of the Veloxis deal, we have included risk-adjusted and discounted milestone payments to OSE's valuation in our model.

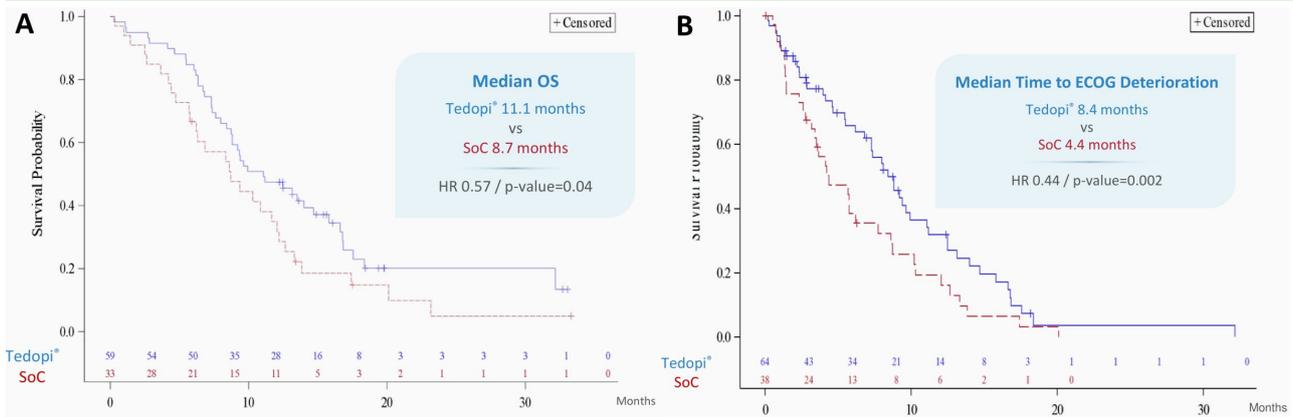
## Evaluating strategic options for Tedopi

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As a reminder, on 21 September 2020, OSE presented additional data from step one of the Phase III Atalante 1 trial at the virtual ESMO conference. The totality of data points to a favourable benefit/risk ratio of Tedopi treatment in patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) after failed checkpoint inhibitor treatment. One of the most interesting details was that median overall survival (mOS) reached statistical significance in the Tedopi vs chemotherapy arm of the per-protocol (mPP) analysis (Exhibit 1A). This is particularly encouraging as, due to the early end of the trial, the cross-arm comparison is limited. The time to ECOG deterioration (general health status of a patient) was also significantly longer in the Tedopi group, indicating better quality of life (Exhibit 1B). Our detailed analysis is in our previously [published report](#).

The Phase III trial evaluated Tedopi as second- or third-line treatment versus standard of care (docetaxel or pemetrexed) in HLA-A2-positive patients (c 45% of the total population) with locally advanced (stage IIIB), or metastatic (stage IV) NSCLC. Patients who have failed post-checkpoint inhibitor treatment represent an area where no novel treatment has been approved yet.

**Exhibit 1: Selected data from step one of Phase III trial with Tedopi – overall survival and quality of life benefit**



Source: OSE, ESMO 2020

Due to the COVID-19 pandemic, OSE has decided to terminate enrolment into step two of the trial, as NSCLC patients are vulnerable to coronavirus infections and there was therefore a substantial risk of data loss. However, the company expects to collect data from those patients who were randomised into step two before the termination, which is around 100 subjects. This means that data from a total of c 200 patients should be available by end-Q321.

OSE is now focusing on regulatory interactions and partnering discussions. As is typical in these situations, the timelines for any partnership deals are uncertain. The company expects regulatory filing to be achievable by the end of 2021.

## Tedopi beyond lung cancer: Investigator-led TEDOPaM and TEDOVA trials

Outside of its own Phase III trial, OSE collaborates with other investigators to collect as much data on Tedopi as possible. OSE was approached by GERCOR, an association of physicians, to carry out an exploratory Phase II TEDOPaM study with Tedopi in combination with nivolumab (Opdivo) in pancreatic cancer. The recruitment of new patients to this trial was interrupted by the COVID-19 pandemic and temporarily suspended in March 2020. The study is set to resume recruiting patients in Q221, but after the evaluation of interim data by the independent data monitoring committee, patients will no longer be treated with Opdivo. Going forward, the trial will focus on the combination of Tedopi plus chemotherapy (FOLFIRI) vs standalone chemotherapy. As this is an investigator-led trial, OSE has little influence on decisions. However, it is still a cost-effective opportunity to accumulate data with Tedopi. The primary endpoint remains a one-year survival rate and a preliminary readout is expected by end-2022.

The newest [addition](#) to Tedopi's R&D programme is an investigator-led trial with Tedopi alone or in combination with pembrolizumab (Keytruda, Merck & Co) as maintenance treatment in ovarian cancer patients after chemotherapy versus standard of care (so a three-arm trial). This trial is also sponsored by an investigator, ARCAGY-GINECO, while Merck & Co will provide Keytruda. As with the study in pancreatic cancer, the new TEDOVA trial is a cost-effective way for OSE to evaluate Tedopi in another cancer indication. Moreover, Merck & Co is providing Keytruda for free, so there is at least one large pharma with significant interest in the study.

## Exhibit 2: OSE's R&D pipeline



Source: OSE. Note: \*Affected by COVID-19 pandemic.

## BI 765063: First clinical data expected in H121

BI 765063 (OSE-172) is a SIRP- $\alpha$  antagonist for solid tumours. The CD47/SIRP- $\alpha$  space continues to [attract](#) significant interest from large pharma and biotech companies. BI 765063 is expected to work in a similar way to T-cell immune checkpoint inhibitors in the tumour microenvironment, but instead of T-cells, it inhibits the checkpoints between tumour cells and myeloid cells: myeloid-derived suppressor cells (MDSCs) and tumour-associated macrophages (TAMs). It binds to signal regulatory peptide alpha (SIRP $\alpha$ ) on myeloid cells, which inhibits SIRP $\alpha$ /CD47 interaction (CD47 on the surface of cancer cells). CD47 acts as a 'don't eat me' signal to macrophages of the immune system, so when blocked this increases the likelihood that the myeloid cell recognises the cancer cell as foreign, then attacks and digests the cancer cell. Phagocytosis leads to presentation of cancer antigens on the surface, which stimulates the immune system.

The most recent fundamental discovery was that in addition to being inhibited in the tumour microenvironment, the macrophages no longer secrete chemokines, small protein mediators which attract immune cells ([Gauttier et al, October 2020](#)). So, by expressing CD47, tumours not only induce a 'don't eat me' signal to macrophages, but also send a 'don't find me' signal. As a result, T-cells are no longer attracted to the tumour microenvironment (so called T-cell exclusion). BI 765063 was able to reverse this mechanism, which led to T-cell migration into the tumour.

A Phase I study in solid tumours is ongoing in partnership with BI, where BI 765063 is combined with BI's own T-cell checkpoint inhibitor PD-1 antagonist. The first results are expected in H121. OSE has received a total of €30m in licence payments from BI. Up to €1.1bn is still potentially due plus royalties on sales.

## CoVepiT: Prophylactic COVID-19 vaccine ready to enter clinical development

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CoVepiT is a new project announced in May 2020, which is focused on a vaccine against the pandemic virus SARS-CoV-2. OSE is using its expertise in the selection and optimisation of peptides and their formulation. After scanning thousands of potential neo-epitopes, OSE selected 11 proteins of coronaviruses with a very low level of mutation, but high potential for immunogenicity and broad coverage including all initial and novel SARS-CoV-2 variants identified globally to date. In preclinical and human ex vivo studies, the vaccine candidate [showed](#) the ability to induce T-cells against the SARS-CoV-2 virus. OSE has received authorisation to start the Phase I/II trial (n=48), which will begin enrolling patients shortly. This project is supported by a grant of up to €200k from Nantes Metropole and a [funding budget](#) of up to €5.2m from Bpifrance.

## OSE-127/S95011: Two Phase II trials and a milestone payment

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Following a positive Phase I in Q419 and a slight delay caused by the pandemic, OSE-127, an IL-7R $\alpha$  antagonist, is moving into Phase II development, which consists of two Phase II trials, one in ulcerative colitis (sponsored by OSE) and one in Sjögren's syndrome (sponsored by OSE's partner Servier). OSE [started](#) to enrol ulcerative colitis patients who had not responding to other treatments in December 2020. Meanwhile, Servier has indicated that regulatory authorisations have been received and the trial in Sjögren's syndrome should start by end-Q221 or early Q321.

OSE is developing OSE-127 in partnership with Servier, which has a two-step option to in-license it after completion of the Phase II trials. A €5m milestone payment from Servier is expected as soon as the first patient is recruited to the Phase II trial in Sjögren's syndrome. So far, OSE has received a total of €20.3m. Up to €252m in milestone payments is still potentially due plus royalties.

OSE-127 is a humanised monoclonal antibody against IL-7R $\alpha$ , specifically CD127, a cytokine that controls the proliferation, apoptosis and activation of CD4 and CD8 T-cells in humans. It is a novel and differentiated mechanism of action as OSE-127/S95011 is the only full antagonist of IL-7R.

## Expanding preclinical R&D pipeline

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In addition to making progress with a fairly diversified clinical R&D pipeline, OSE continues to innovate and grow its preclinical pipeline. In a [previous report](#), we introduced two projects: one focusing on **C-type lectin receptor (or CLEC-1) inhibition** and another involving OSE's **Bispecific Antibody Checkpoint Inhibitor (BiCKI) platform**. At this year's AACR conference (10–15 April), the company presented more preclinical data on these projects and introduced a new project, OSE-230, which is an **anti-ChemR23 antibody** aimed at modulating inflammation. This target is known as chemerin chemokine-like receptor 1 (CMKLR1), a G-protein coupled receptor (GPCR) expressed on myeloid immune cells. The new OSE-230 is a first-in-class therapeutic drug candidate that has potential to resolve chronic inflammation. The drug candidate can be developed in various chronic inflammation indications, which includes both autoimmune diseases and tumour-associated inflammation. It can therefore be developed as an anti-cancer drug as well, which was in fact the focus of the AACR poster presentation. Although all these projects are preclinical, they represent cutting-edge science and indicate OSE's striking internal capability to innovate. The company will likely explore multiple paths to obtain the best return from these assets, which could range from early licensing to moving into clinical development.

## Significant EIB loan indicates external validation

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The most recent positive news was the [loan facility](#) of up to €25m from the European Investment Bank announced in February 2021. The loan is divided into three tranches (two tranches of €10m each and a third tranche of €5m). The first tranche is unconditional and OSE indicated that it will request it before the end May 2021. According to OSE, this extends funding visibility until Q222. The remaining two tranches are conditional on specific clinical milestones being achieved.

The loan carries fixed annual interest of 5% and each drawdown matures in five years. OSE has also committed to issue warrants to the EIB after the first (850,000) and the second (550,000) drawdowns, which give the right to subscribe to one share of OSE. However, they will become exercisable only after the end of the tranche's maturity period. The loan also has an anti-dilution clause.

### Use of proceeds

The first tranche will be used to expand the development of Tedopi in additional cancer indications in combination with a checkpoint inhibitor; and the initiation of a Phase I/II trial with OSE-279 in a niche oncology indication. OSE-279 is OSE's proprietary checkpoint inhibitor and the benefits of investing in its development go beyond this single project. For example, OSE-279 could be combined with OSE's other anticancer drugs instead of third-party CPIs. OSE plans to use subsequent tranches to accelerate the development of other projects, in particular FR104 and the new asset OSE-230.

## Financials and valuation

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Total FY20 operating expenses were €29.4m (of which €22.4m related to R&D) versus €27.4m in FY19. R&D spending was somewhat ahead of our estimates, and we have therefore increased our 2021 operating loss estimate to €20.7m from €14.1m previously.

As of end-2020, OSE had cash, cash equivalents and financial assets of €29.4m, which is sufficient to fund operations until Q222, according to the company. This included the proceeds from a private placement of €18.6m in November 2020. The balance sheet also includes debt of €16.6m, which is mainly government loans or debt guaranteed by the government. As described above, the cash position will be further strengthened by the expected first drawdown of the EIB loan, which we include in our model and €5.1m in 2020 research tax credits.

Our updated valuation of OSE is €291m or €16.2 per share, compared to €240m or €16.0 per share previously. The valuation per share is virtually unchanged as the uplift resulting from the inclusion of milestones arising from the Veloxis deal was offset by the private placement in November 2020. We do not include royalties at this stage as there is no development visibility at present. We aim to update our model when we get more information.

To reflect the value of the Veloxis deal, we have included the potential milestone payments in our rNPV model, so they are spread out over a number of years in line with standard drug development timelines. We adjusted these milestones with standard success probabilities (15%) and discounted to the present time. Because this was a full out-licensing deal and Veloxis is owned by a large corporation, the granularity of the development details is not yet known, and we therefore do not have enough visibility for a bottom-up approach to calculate potential peak sales. So, our approach is conservative as it does not capture the expected royalties, which will be based on the sales achieved by the drug candidate.

**Exhibit 2: Sum-of-the-parts OSE valuation**

Product	Launch	Peak sales (\$m)	Unrisked NPV (€m)	Unrisked NPV/share (€)	Probability (%)	rNPV (€m)	rNPV/share (€)
Tedopi – NSCLC	2023	657	340.0	18.9	25%	85.0	4.7
OSE-127 – ulcerative colitis	2027	843	208.0	11.6	15%	41.0	2.3
OSE-172 – multiple cancer indications (TNBC)	2027	1,801	311.3	17.3	10%	44.1	2.5
FR104 – rheumatoid arthritis	2026	1,056	256.2	14.2	15%	48.5	2.7
FR104 - Veloxis deal milestones			112.7	6.3	15%	35.5	2.0
Cash, last reported*			36.4	2.0	100%	36.4	2.0
<b>Valuation</b>			<b>1,264.5</b>	<b>70.3</b>		<b>290.5</b>	<b>16.2</b>

Source: Edison Investment Research. Note: WACC = 12.5% for product valuations. Note: \*OSE's debt, not shown above, consists of government loans, which are typically repayable on commercial success only.

**Exhibit 3: Financial summary**

	€'000s	2019	2020	2021e	2022e
December		IFRS	IFRS	IFRS	IFRS
<b>PROFIT &amp; LOSS</b>					
Revenue		25,952	10,431	16,000	0
Cost of Sales		0	0	0	0
Gross Profit		25,952	10,431	16,000	0
Research and development		(21,655)	(22,355)	(22,400)	(22,400)
EBITDA		(897)	(18,109)	(13,583)	(29,811)
Operating Profit (before amort. and except.)		(1,220)	(18,533)	(13,678)	(29,896)
Intangible Amortisation		(251)	(457)	0	0
Exceptionals		0	0	0	0
Other		0	0	0	0
Operating Profit		(1,471)	(18,990)	(13,678)	(29,896)
Net Interest		8	0	(375)	(500)
Profit Before Tax (norm)		(1,212)	(18,533)	(14,053)	(30,396)
Profit Before Tax (reported)		(1,463)	(18,990)	(14,053)	(30,396)
Tax		(3,188)	2,692	0	0
Profit After Tax (norm)		(4,400)	(15,841)	(14,053)	(30,396)
Profit After Tax (reported)		(4,651)	(16,298)	(14,053)	(30,396)
Average Number of Shares Outstanding (m)		14.9	15.6	16.5	18.0
EPS - normalised (€)		(0.30)	(1.02)	(0.85)	(1.69)
EPS - normalised fully diluted (€)		(0.31)	(1.05)	(0.85)	(1.69)
EPS - reported (€)		0.38	(0.31)	0.0	0.0
Dividend per share (€)		0.0	0.0		
Gross Margin (%)		100.0	100.0	100.0	N/A
EBITDA Margin (%)		N/A	N/A	N/A	N/A
Operating Margin (before GW and except.) (%)		N/A	N/A	N/A	N/A
<b>BALANCE SHEET</b>					
Fixed Assets		55,871	57,141	57,046	56,961
Intangible Assets		52,600	52,600	52,600	52,600
Tangible Assets		1,009	947	852	767
Investments		2,262	3,594	3,594	3,594
Current Assets		26,589	30,442	31,662	3,138
Stocks		0	0	0	0
Debtors		747	1,074	1,074	1,074
Cash		25,842	29,368	30,588	2,064
Other		0	0	0	0
Current Liabilities		(14,330)	(14,128)	(14,128)	(14,128)
Creditors		(13,782)	(14,078)	(14,078)	(14,078)
Short term borrowings		(548)	(50)	(50)	(50)
Long Term Liabilities		(16,067)	(21,481)	(31,481)	(31,481)
Long term borrowings		(9,211)	(16,552)	(26,552)	(26,552)
Other long-term liabilities		(6,856)	(4,929)	(4,929)	(4,929)
Net Assets		52,063	51,974	43,099	14,490
<b>CASH FLOW</b>					
Operating Cash Flow		5,989	(16,807)	(15,406)	(28,024)
Net Interest		0	273	(375)	(500)
Tax		3,148	(2,742)	0	0
Capex		(336)	(210)	0	0
Acquisitions/disposals		0	0	0	0
Financing		0	17,427	0	0
Other		2,624	(1,258)	0	0
Dividends		0	0	0	0
Net Cash Flow		11,425	(3,317)	(8,780)	(28,524)
Opening net debt/(cash)		(5,113)	(16,083)	(12,766)	(3,986)
HP finance leases initiated		0	0	0	0
Other		(455)	0	0	0
Closing net debt/(cash)		(16,083)	(12,766)	(3,986)	24,538

Source: OSE Immunotherapeutics, Edison Investment Research

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