

OSE Immunotherapeutics

Primed for value appreciation

OSE Immunotherapeutics is a clinical-stage immuno-oncology and immuno-inflammation company, with a pipeline spanning all stages of development. The company recently reported its **FY24 results**, reflecting a successful clinical period. OSE's two lead programmes made notable progress throughout 2024, with the launch of the Phase III ARTEMIA trial for Tedopi in non-small cell lung cancer (NSCLC) and lusvertikimab presenting favourable Phase II results in ulcerative colitis (UC). The company also continued to execute on its multi-partnership strategy by signing new agreements, including agreements with AbbVie and Boehringer Ingelheim. As we update our assumptions, our valuation for OSE adjusts to €560.8m or €25.6/share (from €541.2m or €24.8/share previously).

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/23	2.2	(23.2)	(1.18)	0.00	N/A	N/A
12/24e	83.4	39.8	1.48	0.00	3.9	N/A
12/25e	63.5	27.0	1.23	0.00	4.7	N/A
12/26e	101.5	63.3	2.89	0.00	2.0	N/A

Note: PBT shown is normalised PBT. EPS shown is diluted EPS.

Tedopi and lusvertikimab remain the value drivers

We expect Tedopi to remain a key focus for investors as it progresses through the final stages of clinical development. ARTEMIA commenced in September 2024, and interim updates are expected from 2026, followed by a conclusion in 2027. As the most clinically advanced off-the-shelf neoepitope-based cancer vaccine (to our knowledge), strategically targeting the second-line setting, we believe Tedopi could represent a sizeable commercial opportunity. Lusvertikimab, OSE's leading immuno-inflammation candidate, has successfully completed the Phase II CoTikiS trial in UC. Further supportive data were presented at the European Crohn's and Colitis Organisation (ECCO) 2025 congress, laying a foundation for further development efforts. With a recently strengthened [leadership team](#), we believe OSE is well positioned to advance each of its programmes through the clinic.

Cash runway: Funded into 2027

We expect OSE's year-end gross cash position (€64.2m, including non-current term deposits) to be further supported by the €17.5m in anticipated milestones from Boehringer Ingelheim and €6.3m pending from the €8.4m in public funding. Based on our cash burn projections, we estimate these combined funds to be sufficient to support operations into 2027 (in line with management guidance), accounting for debt repayments and assuming no further licensing income.

Valuation: €560.8m or €25.6 per share

We adjust our near-term forecasts for the FY24 results and latest updates on OSE's pipeline. While we keep our long-term assumptions unchanged for Tedopi and lusvertikimab, we have adjusted our model for the third in-house asset, OSE-279, which we understand will now be evaluated as a combination treatment with Tedopi in NSCLC in the first-line setting. This, along with the model roll forward and latest net cash position, results in our valuation adjusting to €560.8m or €25.6 per share (from €541.2 or €24.8 per share previously).

FY24 results and outlook

Healthcare

3 April 2025

Price €5.78
Market cap €127m

€0.92/US\$

Net cash (including current and non-current term deposits and lease liabilities) as at 31 December 2024 €18.0m

Shares in issue 21.9m

Free float 65.0%

Code OSE

Primary exchange NXT PA

Secondary exchange N/A

Share price performance



%	1m	3m	12m
Abs	(11.8)	(22.8)	19.3
52-week high/low		€11.6	€4.5

Business description

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

Next events

Lusvertikimab: extension UC data	May 2025
Tedopi: Phase II PDAC results presentation	Q225
ARTEMIA interim updates	2026

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OSE Immunotherapeutics is a research client of Edison Investment Research Limited

Investment summary

Company description: Broad pipeline with established partnerships

OSE is a biotechnology company based in Nantes and Paris in France, and is listed on the Euronext Paris exchange. It is focused on developing novel and efficacious new treatments in immuno-oncology, as well as in immuno-inflammation. The company's lead immuno-oncology asset is cancer vaccine Tedopi, which is being developed as a new therapy targeting the second-line setting in NSCLC. Tedopi showed promise in the prior ATALANTE-1 trial, and it is now being evaluated in the registrational ARTEMIA trial. Also in the company's immuno-oncology pipeline is OSE-279, a new immune checkpoint inhibitor (ICI) that may show promise in combination treatment approaches. Its leading immuno-inflammation programme is lusvertikimab (formerly OSE-127) in UC. The candidate recently successfully completed a Phase II trial, meeting primary and secondary endpoints. Beyond its proprietary programmes, OSE also has several established partnered programmes, bolstering the company's value proposition. These include BI 770371 (in partnership with Boehringer Ingelheim) for both solid tumours and metabolic diseases; FR104/VEL-101 (in partnership with Veloxis Pharmaceuticals) as a maintenance therapy for patients following kidney transplantations; and ABBV-230 (in partnership with AbbVie) for chronic inflammation.

Valuation: €560.8m or €25.6 per share

We value OSE at €560.8m or €25.6 per share, based on a risk-adjusted net present value (rNPV) calculation for its three in-house and three partnered programmes. While we keep our market assumptions for the two lead in-house programmes (Tedopi and lusvertikimab) unchanged, we have updated our estimates for OSE-279 following clarity from management on the planned clinical pathway for the candidate (c 5% of our per-share valuation). We assume peak sales potential of c €477m for the asset, based on 20% market penetration and drug pricing in line with other approved ICIs. Given the early-stage development (Phase I/II) we have used a conservative probability of success (PoS) of 14% for the programme. For the partnered compounds, pending further updates from management, we keep our launch and commercial potential estimates unchanged, although we acknowledge that, given the nature of the agreements, there can be some variability in planned timelines and targets.

Financials: Cash runway into 2027

OSE's business model, which includes a mix of in-house and partnered programmes, allows it to manage risk and balance sheet strength, while maximising its pipeline potential. FY24 was a particularly successful year for the company, with c €85m in non-dilutive funding from milestone payments and grants, supporting a healthy year-end gross cash balance of €64.2m (including cash, cash equivalents and fixed-term deposits classified as current and non-current financial assets). While the company also has €46.1m of debt on its books (including lease liabilities), no major repayments are due before H226, which provides a cash runway into FY27, based on our burn projections. Potential milestone payments from out-licensing or partnering should help extend the runway further.

Sensitivities: The usual risks for a pure-play biotechnology company

OSE is subject to typical biotech risks, such as the unpredictability of trials, regulatory discussions, competitor successes, financing and commercial risks. However, OSE's pipeline is diverse, with active programmes in immuno-oncology and immuno-inflammation, somewhat mitigating its exposure to binary risk events. For the lead immuno-oncology candidate, Tedopi, OSE will fund the programme through to filing for regulatory approval. However, for OSE's other programmes, further capital may be required to fund subsequent trials, which, if realised through equity issuances, may result in shareholder dilution. New partnerships may be initiated to support further development efforts for OSE's programmes, but this remains uncertain. As such, for the lead immuno-inflammation lusvertikimab programme, our model assumes that a licensing deal will be secured within 2025, but we acknowledge underlying imprecisions and variability in anticipating the timing and terms of deals. For these two lead programmes, we believe the clinical data to date have established proof-of-concept, but ongoing and subsequent late-stage trials may still be considered near-term R&D sensitivities. The partnerships with Boehringer Ingelheim, Veloxis and AbbVie somewhat offset the impact of clinical trial expenditures. However, as is typical with such deals in the healthcare sector, the assets involved in these partnerships may be returned to OSE in the event of clinical trial failures or strategic changes from partners. This was the case with lusvertikimab (formerly OSE-127), which was previously out-licensed to Servier, but returned in 2023.

Active and diverse clinical development pipelines

OSE's clinical development programmes comprise a combination of proprietary and partnered programmes, broadly covering various disease areas within the immuno-oncology and immuno-inflammation space (Exhibit 1). We saw tangible progress across all of OSE's pipeline activities in FY24, and we anticipate the momentum will be sustained through FY25 and beyond. We discuss OSE's key programmes below.

Exhibit 1: OSE's clinical development pipeline in immuno-oncology and immuno-inflammation

	Product candidate	Target	Indication	Research	IND-enabling	Phase Ia/Ib	Phase II	Phase III	Upcoming Milestones
I&I	OSE-127 <i>Lusvertikimab</i>	Anti-IL-7R	Ulcerative Colitis					Positive Results	Extension data Strategic update
	BI 770371	Anti-SIRPα	MASH						Phase 2a update
	FR104/VEL-101	Anti-CD28	Kidney Transplantation						Phase 2 start
	ABBV-230	Anti-ChemR23	Chronic Inflammation						Phase 1 start
	OSE-220 <i>Pro-Resolutive mAbs</i>	Undisclosed GPCR Agonist	Chronic Inflammation						Preclinical update
I-O	Tedopi	Neopeptides immunotherapy	NSCLC Mono post-ICI 2L PDAC Combo (<i>exploratory eIIIS</i>) OC Mono or Combo (<i>eIIIS</i>) NSCLC Combo 2L post-ICI (<i>eIIIS</i>)					Pivotal Phase 3 EU + US	Phase 3 update Phase 2 readout H1-2025 Phase 2 readout H1-2026 Phase 2 readout H2-2026
	OSE-279	Anti-PD1	Solid tumors						Phase 1b combo data
	BI 770371	Anti-SIRPα	Solid tumors (HNSCC)						Phase 1b results
	IL-7R CAR-T	IL-7R CAR-T	IL-7R+ tumors						IND
	Anti-PD1/cytokine	Undisclosed	Solid tumors						Preclinical update

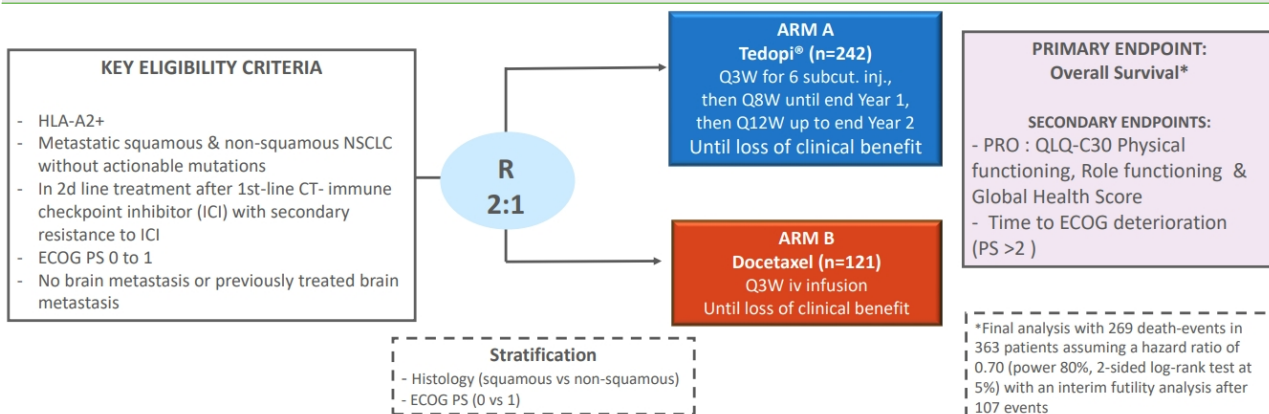
Source: OSE corporate presentation

Immuno-oncology pipeline remains robust

Tedopi: Nearing approval as a second-line treatment for NSCLC

Tedopi is, to our knowledge, the most advanced-stage neopeptide-based cancer vaccine in clinical development. Hence, we expect that investors will pay close attention to the Phase III [ARTEMIA](#) trial, which will assess the candidate as a monotherapy in the second-line setting for NSCLC, after the current use of ICIs as first-line treatments. ARTEMIA has been designed to randomise participants (expected n=363) 2:1 to receive either Tedopi or standard-of-care (SoC) docetaxel. This registrational programme is being facilitated by a companion diagnostic screening test to identify HLA-A2 positive NSCLC patients, who are more likely to respond to the Tedopi epitopes. The primary endpoint for the trial will be overall survival (OS), typical for such oncology trials, while secondary endpoints will be based on patient-reported outcomes and quality of life (Exhibit 2).

Exhibit 2: ARTEMIA trial design



Source: OSE corporate presentation

We highlight that the Tedopi programme is financially supported by the 'France 2030' innovation programme through

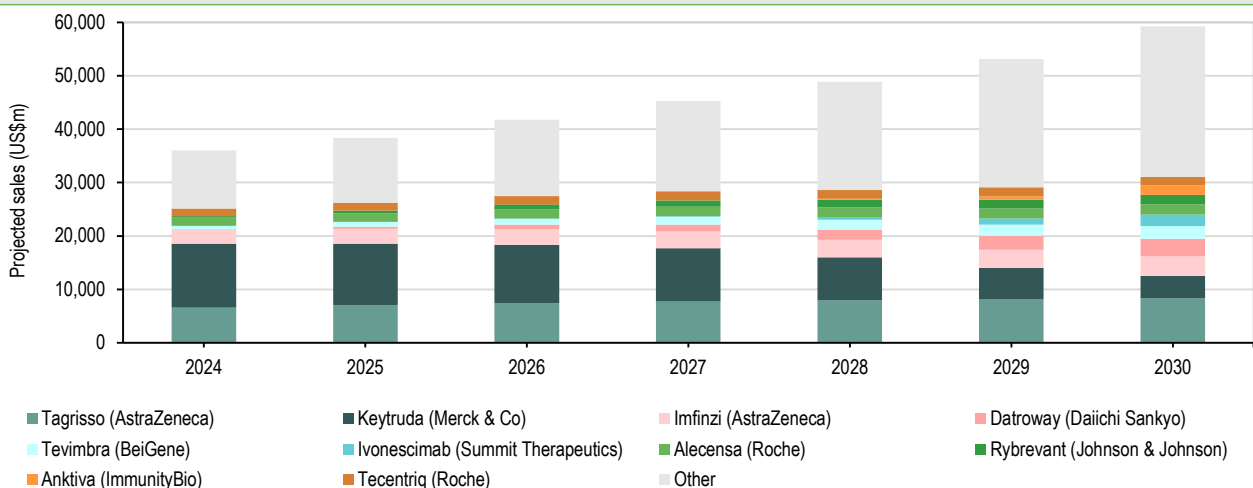
€8.4m in non-dilutive public funding. Throughout 2024, OSE utilised €2.1m, with the remaining amount to be spread over the life of the programme.

With lung cancer being the leading **cause** of cancer deaths across the globe, an array of treatments has been developed to address the condition. However, there is still a need for novel and effective treatment options. NSCLC is the most prevalent form of lung cancer, accounting for **80–85%** of cases, and is typically treated with platinum-based doublet chemotherapy (cisplatin or carboplatin in combination with gemcitabine, paclitaxel or docetaxel). In many cases this treatment regimen may only translate to **modest** responses. We highlight that the emergence of ICIs has had a profound effect on the NSCLC treatment landscape, offering improved durability of responses and more favourable safety outcomes compared to chemotherapy. ICIs are now used in the second-line treatment setting, as well as in the first-line treatment setting when used in combination with chemotherapeutic agents for late-stage NSCLC, termed chemo-immunotherapy. In spite of these developments in the field, long-term survival for NSCLC patients remains an ongoing medical challenge, most notably for metastatic NSCLC, where five-year survival rates are **c 10%**. The **SoC** in the second-line treatment setting for NSCLC has historically been docetaxel, though many randomised Phase III clinical trials have aimed to offer improvements:

- CANOPY-02 (n=237; canakinumab in combination with docetaxel versus docetaxel alone): median OS of 10.6 months versus 11.3 months; primary endpoint of OS was not met.
- CONTACT-01 (n=366; cabozantinib in combination with atezolizumab versus docetaxel alone): median OS of 10.7 months versus 10.5 months; primary endpoint of OS was not met.
- SAPPHIRE (n=577; sitravatinib in combination with nivolumab versus docetaxel alone): median OS of 12.2 months versus 10.6 months; primary endpoint of OS was not met.
- EVOKE-01 (n=603, sacituzumab govitecan versus docetaxel alone): median OS of 11.1 months versus 9.8 months; primary endpoint of OS was not met.

In our view, there is a potentially significant commercial opportunity for Tedopi, should it be successful with regulatory approval, as a novel off-the-shelf neoepitope-based cancer vaccine. We acknowledge that the NSCLC landscape is competitive, and is dominated by ICIs, such as Merck’s blockbuster Keytruda (pembrolizumab). However, OSE’s strategy of targeting the second-line setting may somewhat avoid direct competition with ICIs and other established or emerging therapies, enabling the company to garner a share of the growing NSCLC treatment market, which is projected to reach a sizeable c \$59.5bn by 2030, at a CAGR of 9.4% from 2023, according to EvaluatePharma (Exhibit 3). We highlight Summit Therapeutics’ bispecific antibody ivonescimab, which has emerged as a promising drug candidate in the field, having shown a potential **outperformance** compared to Keytruda. However, subsequent late-stage clinical data are still required to validate these claims. Should it be successful with regulatory approval, it is anticipated to be commercialised no sooner than 2026.

Exhibit 3: Projected sales for the NSCLC treatment market



Source: Edison Investment Research, EvaluatePharma

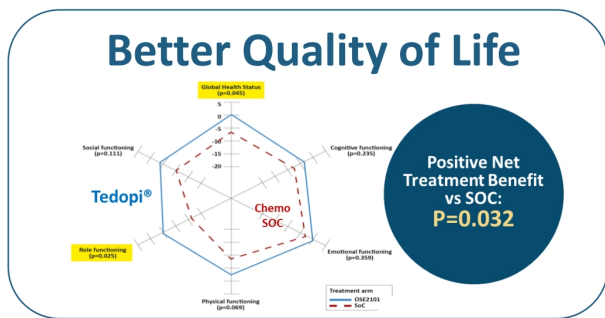
Clinical results for the candidate to date have been promising, with the most recent data coming from the Phase III ATALANTE-1 trial. This study focused on the second- or third-line setting following ICI failure in HLA-A2 positive NSCLC patients; results have been published in *Annals of Oncology*. Enrolment for ATALANTE-1 was halted early due to the COVID-19 pandemic, meaning that only 219 out of the planned 363 participants were enrolled. The 219 participants were randomised to receive either Tedopi (n=139) or SoC chemotherapy (n=80). Of these patients, 118 (54%) were classified as being the population of interest with secondary resistance, and these were included in the main analysis.

Importantly, the primary endpoint of OS was met, showing significantly improved survival rates versus the SoC. The results also showed desired patient-reported outcomes, quality of life and safety (Exhibit 4). Key takeaways included:

- Median OS of 11.1 months with Tedopi (versus 7.5 months with SoC treatment, corresponding to a reduced risk of death by 41% with Tedopi (Exhibit 5)).
- OS rate of 44.4% at 12 months with Tedopi (versus 27.5% with SoC treatment).
- Median post-progression survival of 7.7 months with Tedopi (versus 4.6 months with SoC treatment).
- Rate of severe adverse events of only 11% with Tedopi (versus 35% with SoC treatment).

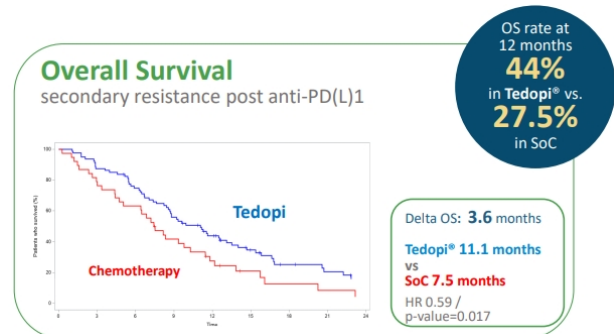
Following the conclusion of ATALANTE-1, OSE received positive recommendations from the Food and Drug Administration (FDA) and European Medicines Agency to launch the registrational ARTEMIA trial, which, as discussed above, commenced in September 2024. We expect interim updates from 2026, with top-line results in 2027 and, provided the data are positive, a commercial launch from 2028.

Exhibit 4: ATALANTE-1 quality of life outcomes



Source: OSE corporate presentation

Exhibit 5: ATALANTE-1 overall survival results



Source: OSE corporate presentation

Beyond the Phase III trial assessing Tedopi as a monotherapy in NSCLC, OSE is also engaged in three separate Phase II programmes with external oncology groups, seeking to expand the clinical utility of Tedopi in additional oncology indications through various combination approaches. These include: with chemotherapy for pancreatic cancer (TEDOPaM, sponsored by GERCOR Group); alone or with Keytruda for ovarian cancer (TEDOVA, led by ARCAGY-GINECO); and with Opdivo or docetaxel for NSCLC (CombiTED, led by Italian foundation FoRT). In March 2025, OSE announced [positive top-line results](#) in pancreatic cancer, which showed that Tedopi met the primary endpoint of the study. The remaining ovarian cancer trial completed enrolment in December 2024 and top-line results are due to be reported in Q226, while the remaining NSCLC trial is due to complete enrolment in Q225, followed by top-line results in H226. While we recognise these studies are important in providing further clinical validation for Tedopi, we note that investigator-sponsored trials may not necessarily align with OSE's future clinical development strategy for the cancer vaccine. Though, if Tedopi does demonstrate improved survival rates in these combinations, we believe this has the potential to increase its value proposition.

OSE-279: An emerging therapy in the ICI space

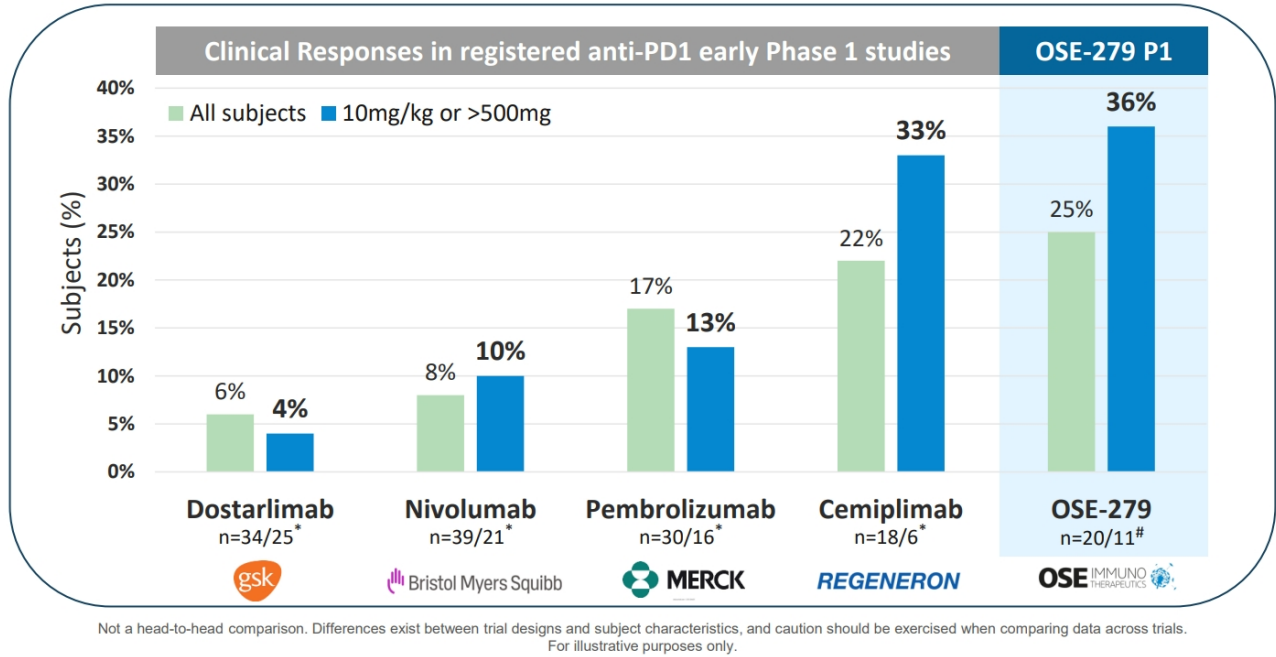
OSE is also focused on the clinical development of its proprietary ICI, OSE-279, which is currently being tested in [Phase I/II](#). This is a first-in-human, open-label trial primarily designed to determine the maximum tolerated dose and recommended Phase II dose in advanced solid tumours. Secondary objectives of the study focus on anti-tumour activity, safety, receptor occupancy, pharmacokinetics and pharmacodynamics (PK/PD).

The most recent update for the programme was in [February 2024](#), which corresponded to the first 20 participants involved in the trial, representing 13 different types of tumour. According to the update, there were four partial responses confirmed from patients receiving 600mg every six weeks, and a 36% response rate was observed in patients with anal squamous cell carcinoma, undifferentiated pleomorphic sarcoma, oncocytic thyroid cancer and alveolar soft part sarcoma, potentially showing a competitive edge over current approved anti-PD1 ICIs (though we caution that there may be limitations in comparing clinical trial data to historical data due to differences in trial designs and control) (Exhibit 6). Desirable PK/PD outcomes were also recorded, alongside a favourable safety profile.

OSE now aims to differentiate OSE-279 in the ICI market by evaluating it in combination with Tedopi, which may ultimately maximise the utility of the programme with potential to overcome some of the challenges associated with cancer resistance mechanisms. Management has communicated that the ongoing Phase I/II trial will continue by

assessing OSE-279 in combination with Tedopi in the first-line setting in HLA-A2 positive NSCLC patients with high expression of programmed death receptor ligand 1 (PD-L1).

Exhibit 6: Clinical responses in anti-PD1 ICIs in early Phase I trials



Source: OSE corporate presentation. Note: *Patnaik et al. Cancer Chem & Pharm 2021; Brahmer et al. JCO 2010; Patnaik et al. Clin Cancer Res 2015; Papadopoulos et al. Clin Cancer Res 2020. Robert et al. ESMO-TAT 2024.

We acknowledge that the ICI landscape is a highly competitive space, with multiple approved drugs already in the market. Most ICIs are monoclonal antibodies designed to inhibit receptors that are used by cancers to evade the body's immune responses. ICIs switch the tumour microenvironment from 'cold' (ie immunosuppressive) to 'hot' (ie vulnerable to the immune system). Merck's PD-1 checkpoint inhibitor, pembrolizumab (Keytruda), continues to dominate the ICI market, having received FDA approval for the treatment of 20 cancer types and currently marketed for 19. To date, the FDA has approved four different categories of ICIs, including inhibitors of PD-1; the ligand PD-L1; the cytotoxic T-lymphocyte associated protein 4 (CTLA-4); and lymphocyte-activation gene 3 (LAG-3) (Exhibit 7). A product called Opdualag (a combination of nivolumab and relatlimab) targets both PD-1 and LAG-3, and has been approved for the treatment of melanoma.

Exhibit 7: Approved ICIs

Drug	Company	Target	Launch year	Number of marketed indications	Patent expiry	Peak sales year*	Peak sales (US\$)*
Nivolumab (Opdivo)	Bristol Myers Squibb	PD-1	2014	12	2028	2025	9.5bn
Pembrolizumab (Keytruda)	Merck & Co	PD-1	2014	19	2028	2026	32.0bn
Cemiplimab (Libtayo)	Regeneron/Sanofi	PD-1	2018	6	2035	2030	2.1bn
Dostarlimab (Jemperli)	GSK	PD-1	2021	2	2034	2030	1.1bn
Tislelizumab (Tevimbra)	BeiGene	PD-1	2020	10	2033	2030	2.5bn
Retifanlimab (Zynyz)	Incyte	PD-1	2023	1	2036	2030	217m
Atezolizumab (Tecentriq)	Roche	PD-L1	2016	8	2032	2029	4.4bn
Avelumab (Bavencio)	EMD Serono/Merck	PD-L1	2017	3	2033	2026	830m
Durvalumab (Imfinzi)	AstraZeneca	PD-L1	2017	8	2031	2030	6.5bn
Ipilimumab (Yervoy)	Bristol Myers Squibb	CTLA-4	2011	7	2025	2024	2.5bn
Nivolumab/relatlimab (Opdualag)	Bristol Myers Squibb	PD-1/LAG-3	2022	1	2034	2030	2.0bn

Source: Edison Investment Research, EvaluatePharma. Note: *Either actual reported figures or projected up to 2030.

Partnered programmes in immuno-oncology

BI 770371, being developed through a partnership with Boehringer Ingelheim, is an anti-SIRPα antibody that operates through a similar mechanism to T cell ICIs in the tumour microenvironment, but is designed to block the checkpoints between tumour cells and myeloid cells, rather than T cells. OSE has already received €104m from Boehringer Ingelheim through this partnership, though it may be entitled to a total of €1.1bn plus tiered royalties on global sales from

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Boehringer Ingelheim, contingent on clinical development progress. A Phase Ib clinical trial readout in solid tumours is expected within 2025.

Following a considerable [expansion of partnership terms](#), we highlight that OSE's partnership with Boehringer Ingelheim now also covers the clinical development of BI 770371 in metabolic dysfunction-associated steatohepatitis (often referred to as MASH, formerly called non-alcoholic steatohepatitis or NASH). This was associated with a €25.3m one-off payment, and following a January 2025 launch, we note that a Phase IIa clinical trial readout in MASH is expected from 2026. The partnership now also includes a programme based on OSE's cis-targeting anti-PD1/cytokine platform. €13.5m was received upon signing this deal, and there is potential for an additional near-term milestone payment of €17.5m. This is a preclinical programme intended to bolster Boehringer Ingelheim's pipeline of novel immune-modulatory cancer candidates. Since this is not a proprietary programme for OSE, the company will have little control over its progression, but we view the external recognition as encouraging for OSE's R&D capabilities, with the potential to provide an additional revenue stream.

The **CAR-T (chimeric antigen receptor-T cell therapy) programme**, through a commercial and revenue sharing agreement with the Memorial Sloan Kettering Cancer Center (MSK), is also underway, as of [June 2024](#). While OSE and the MSK were already engaged in a research collaboration for a preclinical non-antagonist interleukin-7 receptor (IL-7R) monoclonal antibody to be used either as a therapeutic or for the design of CAR-Ts, the more recent agreement specifically covers patent rights for CAR-Ts targeting IL-7R expressing cancers. While precise details have not been disclosed, we understand that this is currently in the preclinical stages of development, and the MSK is taking full responsibility for research through to commercialisation of the programme. Any potential future revenues will be shared with OSE.

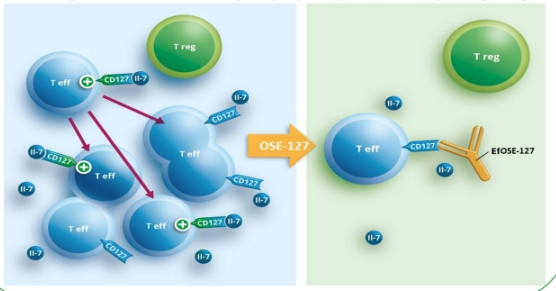
Immuno-inflammation pipeline presents growth opportunities

Lusvertikimab: Potential disruptor to the UC/IBD landscape

Lusvertikimab (formerly OSE-127) is the company's most advanced clinical candidate in the immuno-inflammation space. It is a monoclonal antibody therapy targeting the IL-7 receptor, which is implicated in UC and other forms of inflammatory bowel disease (IBD); it is also relevant in other immuno-inflammatory conditions such as in dermatology and rheumatology. More specifically, lusvertikimab targets CD127, a cytokine that modulates the proliferation, apoptosis and activation of CD4 and CD8 T cells. This represents, to our knowledge, a unique and differentiated mechanism of action in immuno-inflammation (Exhibit 8). Most recently, lusvertikimab successfully completed the Phase II CoTikiS clinical trial, laying a robust foundation for further clinical development efforts, in our view.

Exhibit 8: Lusvertikimab's unique mechanism of action

Tackling the fuel of memory T-lymphocytes while sparing Tregs



A differentiated and highly qualified candidate

- IL-7 produced by inflamed tissues sustain T-cell survival and chronicity, drives Th1 and Th17 T cell differentiation
- IL-7R pathway overexpression in anti-TNF IBD non-responders¹
- Lusvertikimab, first non-internalizing (fully antagonist) acting as pure antagonist anti-IL-7R mAb² – no antagonist activity on TSLP
- Good safety, PK/PD profile in Phase 1³, no cytokine release, confirmed target-engagement
- Positive Phase-2 study in UC; Full Phase 2 induction results in Feb. 2025⁴
- High preclinical activity in acute leukemia (T and B-ALL)⁵
ASH Merit Award 2024

Source: OSE corporate presentation.

1: Belarif et al. JCI 2019; 2: Belarif et al. Nature Communication (2018); 3: Poirier et al. Journal of Immunology 2023; 4: [Microsoft Word - EN_250224_ECCO Clinical presentation_vf2](#); 5: [EN_221103_ASH_OSE-127.pdf](#)

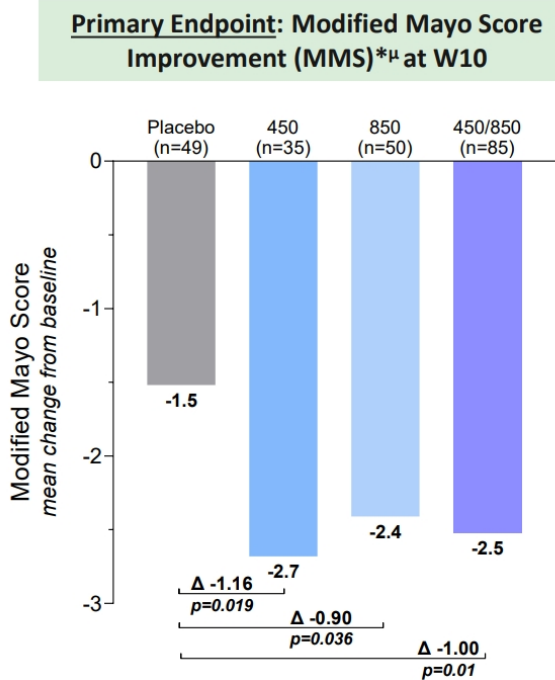
Top-line results for the CoTikiS trial were initially announced in [July 2024](#), followed by the reporting of more detailed results in [November 2024](#). More recently, in [February 2025](#), OSE presented up-to-date insights and additional data at the ECCO Congress.

Importantly, the primary endpoint (improvement of the modified Mayo Score (MMS) at week 10) was met with statistical significance at the two tested doses (450mg and 850mg). While the placebo group showed a 1.5-point improvement from baseline, the 850mg dose group saw a 2.4-point improvement and the 450mg dose group saw a 2.7-point

improvement. Overall, the pooled cohort recorded a 2.5-point improvement on the MMS from baseline. On a placebo-adjusted basis, these data translated to a 0.9-point difference compared to placebo ($p=0.036$) in the 850mg group, and a 1.16-point difference compared to placebo ($p=0.019$) in the 450mg cohort. For the pooled cohort ($n=85$), a 1.00-point difference versus placebo ($p=0.010$) was recorded at week 10 (Exhibit 9). We highlight that the greater responses observed in the lower of the two dose groups was a theme for most of the measures in the CoTikiS results. We understand that this may be due to a number of factors, such as individual patient differences and/or whether they were treatment naive, for example, and do not believe this trend should have an impact on how the overall results are interpreted.

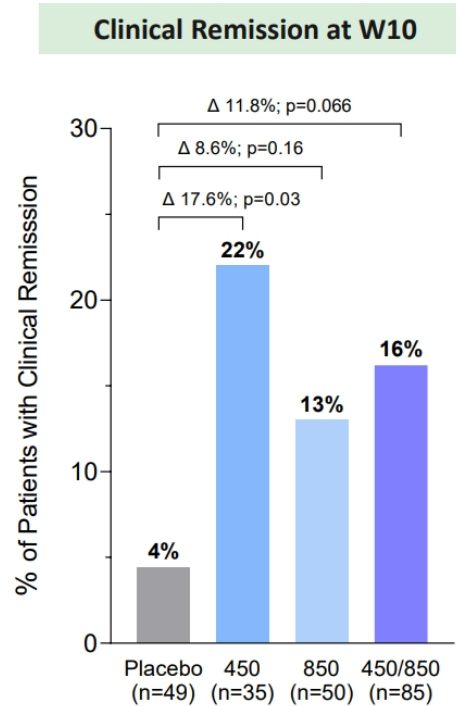
One of the key secondary efficacy measures was clinical remission (defined by an MMS of ≤ 2 points with no individual sub-score of >1 point; rectal bleeding at 0; stool frequency score of 0 or 1; endoscopic score of 0 or 1). Encouragingly, the data showed that 16% of the patients in the pooled group ($p=0.066$), 13% of patients in the 850mg dose group ($p=0.160$) and 22% of patients in the 450mg dose group ($p=0.030$) achieved clinical remission, compared to just 4% in the placebo group (Exhibit 10). We believe these results compare favourably to the data from the Phase III induction trial for AbbVie's Skyrizi, which [showed](#) a clinical remission rate of 20.3% for the candidate versus 6.2% for placebo following a 12-week treatment period. Skyrizi was [approved](#) by the FDA in June 2024, and according to Evaluate Pharma, is projected to achieve $> \$22$ bn by 2030. However, we caution against direct read-across when interpreting clinical trial data, and note that while this provides directional guidance, firm conclusions cannot be drawn given the possible differences in, for example, patient populations, trial design, treatment dosage and duration.

Exhibit 9: CoTikiS primary endpoint results – MMS improvement



Source: OSE corporate presentation. Note: *μ: Least square mean difference between luvetrikimab and placebo = difference between groups of the mean change in MMS between baseline and week 10.

Exhibit 10: CoTikiS clinical remission results



Source: OSE corporate presentation

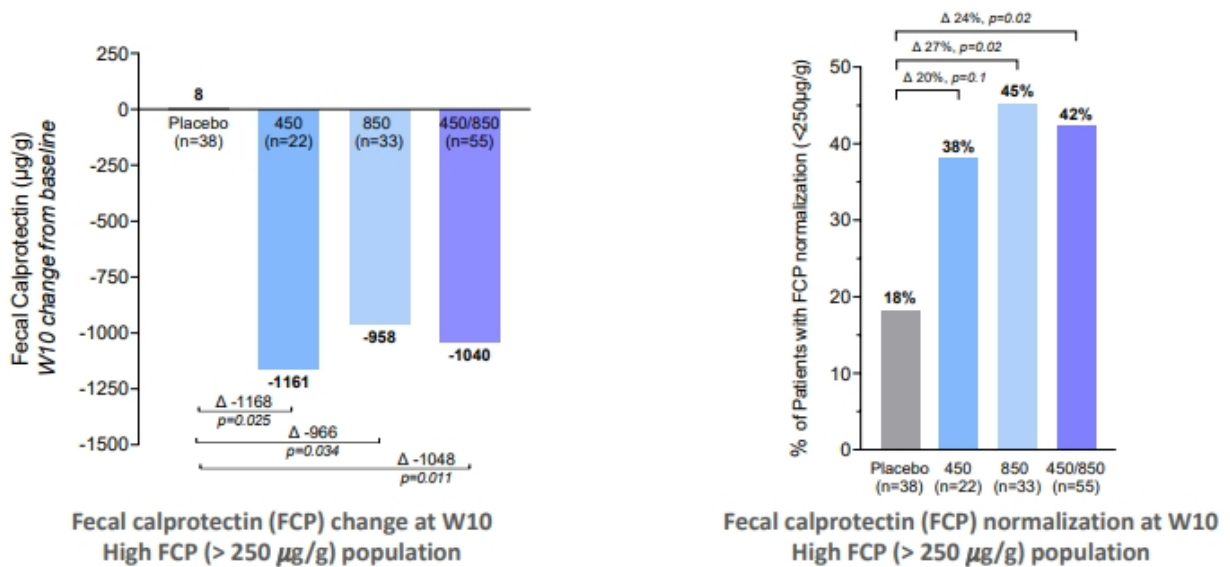
We note that an early interim futility analysis (including c 30% of patients) had proposed an interruption of the 450mg group, and as such, the 850mg group was initially considered for the primary analysis. However, in the final analysis the futility of the 450mg group was not confirmed, and the Statistical Analysis Plan Addendum confirmed the inclusion of the 450mg group in all final analyses. In addition to the results discussed above, other key secondary measure outcomes included:

- Endoscopic improvement rate: 32% for the pooled group compared to 13% for the placebo group ($p=0.027$).
- Endoscopic remission rate: 25% for the pooled group compared to 13% for the placebo group ($p=0.120$).
- UC Endoscopic Index of Severity (UCEIS) mean score change: 1.35-point benefit for the pooled group compared to a 0.32-point improvement for the placebo group ($p=0.007$).

- Fecal calprotectin (FCP): -716µg/g for the pooled group (p=0.004), -635µg/g for the 850mg group (p=0.018) and -830µg/g for the 450mg group (p=0.009), compared to +189µg/g for the placebo group.

As part of the ECCO update, particular focus was placed on patients classified as having 'active disease' at baseline, defined by FCP (a recognised biomarker of mucosal inflammation in UC) levels at baseline exceeding a threshold of 250µg/g. In terms of FCP change from baseline for this subpopulation, the pooled group showed a 1,048µg/g improvement compared to placebo (p=0.011). For the measures of normalisation (to FCP levels below 250µg/g), 42% of the pooled group with active disease showed normalisation at week 10, a 24% benefit compared to placebo (p=0.02) (Exhibit 11). Collectively, we believe these data show promise for the potential of lusvertikimab to address moderate to severe UC, particularly in patients characterised as having active disease.

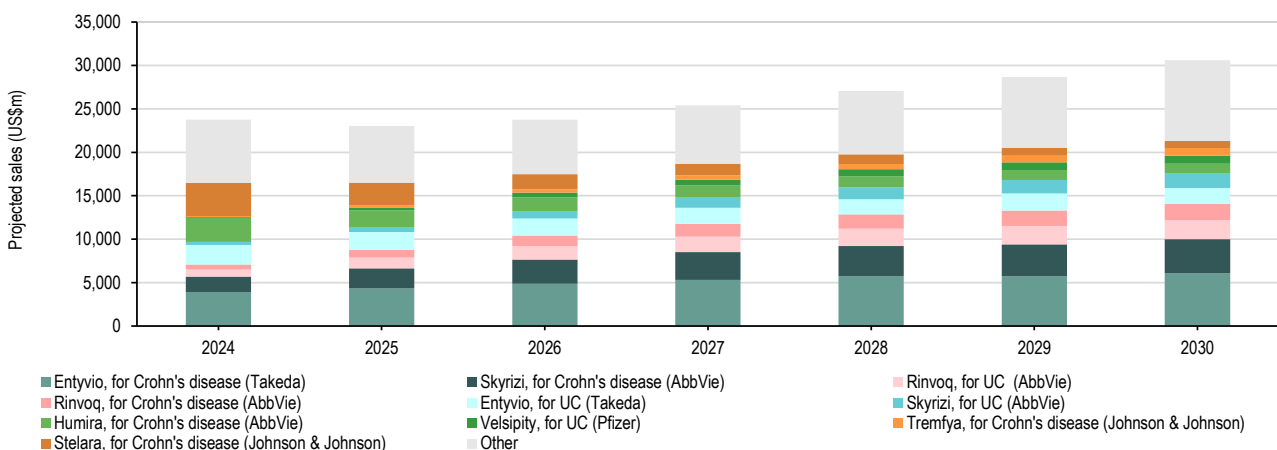
Exhibit 11: Additional CoTikiS results presented at the ECCO Congress showed that lusvertikimab significantly decreased/normalised FCP after 10 weeks of treatment in patients with active disease



Source: Company resources

At the ECCO Congress, OSE also presented new preclinical data focusing on the combination of lusvertikimab with anti-IL-12/23 antibody therapies in chronic colitis. These results showed that while IL-12/23 antagonists can be effective, monotherapy is insufficient to achieve complete remission. However, when combined with an IL-7 receptor antagonist such as lusvertikimab, the synergy can lead to a reduction of all colitis symptoms. While encouraging, we note that this is early-stage research and highlight that the main focus for OSE remains the lead post-Phase II programme. Nevertheless, it highlights a potential expandable opportunity for lusvertikimab in the broader IBD market, which is projected to reach c \$30.6bn by 2030, according to Evaluate Pharma (Exhibit 12).

Exhibit 12: Projected sales for the IBD treatment market



Source: Edison Investment Research, EvaluatePharma

OSE and Edison hosted a key opinion leader (KOL) webinar in March 2025, providing up-to-date insights into lusvertikimab following the ECCO congress. Below is a recording of the KOL event, which:

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- provides an overview of the candidate's mechanism of action, presented by Nicolas Poirier, CEO of OSE Immunotherapeutics;
- showcases the key clinical results from CoTikiS, presented by Professor Arnaud Bourreille, Institut des Maladies de l'Appareil Digestif;
- discusses the additional data that was shared at ECCO, which showed that lusvertikimab significantly decreased FCP after 10 weeks of treatment in UC patients with active disease, presented by Professor Vipul Jairath, Schulich School of Medicine and Dentistry; and
- discusses the current treatment landscape in UC and IBD, presented by Professor Laurent Peyrin-Biroulet, Nancy University Hospital.

KOL insights post-ECCO webinar recording



Presented by
OSE IMMUNO THERAPEUTICS

LUSVERTIKIMAB AND THE FUTURE OF IBD
 KOL Insights Post-ECCO

Wednesday, 5 March
 6pm CET / 12pm ET

EDISON
 WE LIGHT KNOWLEDGE

Key Opinion Leader
Prof. Laurent Peyrin-Biroulet
 Nancy University Hospital

Industry Leader
Nicolas Poirier, PhD
 CEO, OSE Immunotherapeutics

Key Opinion Leader
Prof. Arnaud Bourreille
 Institut des Maladies de l'Appareil Digestif

Key Opinion Leader
Prof. Vipul Jairath
 Schulich School of Medicine and Dentistry

Source: Edison Investment Research, OSE Immunotherapeutics

Partnered programmes in immuno-inflammation

FR104/VEL-101 (recently given the name [pegrizeprium](#)), being developed through a partnership with Veloxis Pharmaceuticals (an Asahi Kasei company), is an anti-CD28 monoclonal antibody. The candidate has a dual mechanism of action, working by directly blocking CD28-mediated T-cell activation and indirectly allowing for CTLA-4 mediated immunosuppressive functions. OSE has already received €13.9m from Veloxis, but may be entitled to €315m in total plus tiered royalties on any global sales. FR104/VEL-101 is currently being evaluated in the Phase I/II [FIRsT](#) trial as a potential maintenance therapy for patients following kidney transplantations. The last update was in [June 2024](#), when positive top-line data were showcased at the Annual American Transplant Congress. Ten kidney transplant patients at low risk of rejection were included, of which eight evaluable participants were treated with FR104/VEL-101 over one year post transplantation. Notably, Tacrolimus (a calcineurin inhibitor and the SoC immunosuppressant treatment to prevent organ rejection) was discontinued for these patients six months after their transplantations. The final results showed favourable safety outcomes, with no cases of acute rejection, even after the discontinuation of Tacrolimus. We note that calcineurin inhibitors, while effective immunosuppressants, are often associated with significant side effects, such as renal failure and neurotoxic effects. We therefore believe that a safer treatment alternative, such as FR104/VEL-101, may present a desirable treatment option. Management expects the results of the FIRsT trial to guide dose selection for a subsequent Phase II trial.

ABBV-230 (formerly OSE-230) is being developed with AbbVie through a global licence and collaboration agreement, which was first announced in [February 2024](#), an H124 highlight for OSE. This is a \$713m biobuck deal, involving an upfront payment of \$48m and up to \$665m in milestone payments, in addition to the potential for tiered royalties based

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on global net sales. The candidate originated from OSE's myeloid platform, and we believe the external recognition, especially at the preclinical stage, validates OSE's R&D capabilities. It is a monoclonal antibody therapy, intended to resolve, rather than inhibit, inflammation pathways. More specifically, it has been designed to activate ChemR23, a G-protein coupled receptor target. [Research](#) has shown that ChemR23 activation may offer an effective mechanism of action for the treatment of inflammation by modulating the function of macrophages and neutrophils. We believe the candidate holds promise as a novel treatment for chronic and severe inflammatory diseases. Previously (October 2020), OSE [presented](#) encouraging preclinical data showing that the candidate successfully targeted receptors associated with restoring tissue homeostasis, demonstrating inflammation resolution in models for acute inflammation, chronic colitis, type 1 diabetes and multiple sclerosis.

Management team

CEO: Nicolas Poirier, PhD. Nicolas Poirier holds a PhD in immunology (European Center for Transplantation and Immunotherapy Sciences, Nantes), a double master's degree in biotechnology from the University of Nantes and in pharmacology from the University of Louis Pasteur in Strasbourg and a certification in Global Management from INSEAD. He has been chief scientific director and member of the management team of OSE Immunotherapeutics since 2016. He started his career at Tcl Pharma in 2009 as a researcher, became project manager at Effimune in 2012, then director of R&D programmes in 2014. In addition, he is an active member of the Strategic and Scientific Advisory Committee (COSSF) of the French biomedical industry association (MabDesign). Over the past 15 years, he has authored more than 50 peer-reviewed international scientific publications and holds over 40 issued patents in the field of immunotherapy. Nicolas Poirier and his team have obtained more than €45m in French and European public funding to co-finance OSE Immunotherapeutics' research and development programmes.

CFO: Anne-Laure Autret-Cornet. Anne-Laure has acquired seven years of experience in finance and audit within Deloitte and 10 years of experience in finance/biotech. She joined Effimune in 2013 as administrative and financial manager and upon the merger with OSE Pharma in 2016, Anne-Laure was appointed chief financial officer of OSE Immunotherapeutics. Anne-Laure Autret-Cornet graduated from ESSCA Management school and has received the certificate 'Corporate Finance' from HEC Paris in 2020.

Chief development officer: Sonya Montgomery. Dr Montgomery started her career in Canada, later holding various global leadership positions, including director and clinical lead at Pfizer (Connecticut and Cambridge, US), executive director clinical development at Relypsa (California, US), vice president clinical development at ProQR (Netherlands), vice president and head of clinical development at Gyroscope Therapeutics (London, UK), and more recently chief medical officer at Evox Therapeutics (Oxford, UK). She has also been an advisor on development strategy for early-stage biotech companies and supported their financial strategy. Dr Montgomery's expertise extends to defining and executing development strategies across various therapeutic areas and modalities. She is skilled in designing innovative and efficient development plans for biologics, advanced therapies, and small molecules. She has successfully partnered various clinical assets to large pharma, secured financing for pipeline programmes, and led programmes from discovery through registration in Europe and the United States.

Chief clinical and medical research officer: Silvia Comis, MD. Silvia Comis brings 30 years of international experience and leadership in the pharmaceutical industry with a strong expertise in clinical research and development as well as in medical affairs and real-world evidence in oncology, haematology and immuno-oncology. She was recently senior medical director IQVIA, and European head of early products medical affairs in oncology at Novartis, involved in all the immuno-oncology programmes with clinical innovations. Silvia is a medical doctor, endocrinologist and pharmacologist (Pavie University, Italy).

Chief business officer: Jean-Jacques AP Mention, PhD. Jean-Jacques brings more than 12 years of research in immunology and in virology at INSERM Paris, King's College London and Institut Pasteur Paris, with a teaching experience in biochemistry and enzymology at the University of Versailles Saint-Quentin-en-Yvelines. After his career as a researcher, he started his business development career at AXENIS in 2015 (start-up and spin-off of Institut Pasteur) as a director of business development, on a new humanized mouse model as a tool for fundamental, clinical, therapeutic and pharmaceutical research for which he is the co-inventor. In 2019, he became head of business development & scientific consulting at GenOway. He joined OSE Immunotherapeutics as director of business development before becoming chief business officer. Jean-Jacques A. P. Mention holds a PhD in immunology (Necker-Enfants Malades Hospitals Faculty of Sciences, Paris).

Head of research and director of R&D programmes: Aurore Morello. Aurore joined the Company in 2016 as a Researcher and Project Leader. She was appointed Head of Research and Director of R&D Programs in 2022. Before joining OSE, Aurore worked at the Memorial Sloan Kettering Cancer Center in New York in the field of engineered CAR-

T cell therapy. Prior to that, Aurore was focused on designing and improving novel targeted immunotherapy that can specifically induce apoptosis of cancer cells at the French National Center for Scientific Research (CNRS). Aurore holds a bachelor's degree in Cellular Biology and Genetics, and a master's degree in molecular biology, with a specialization in Immunology and Cellular Communication, both from the University of Rennes. She earned her PhD in Immunology and Cancer from the University of Bordeaux.

Chief corporate affairs and investor relations officer: Fiona Olivier. Fiona joined OSE Immunotherapeutics in November 2024 from Sanofi, where she served as global head of corporate affairs for the General Medicines division since 2021. In this role, she oversaw communications for a major transformation and modernisation effort. She led corporate affairs activities for the acquisition and integration of two immunology-focused biotech companies and spearheaded efforts to shape the market for global product launches. Fiona has 30 years of international experience in communications, public affairs and patient engagement at leading global companies such as AbbVie, Abbott and GSK. Additionally, she has worked as a consultant at Ketchum, a global communications firm (Omnicom company), serving clients across multiple sectors and geographies. Fiona's career has taken her from Ireland to Poland and the UK before arriving in France in 1997. She holds a degree in communications from Dublin City University, and a master's in public affairs and public policy from Sciences Po Paris.

Sensitivities

OSE Immunotherapeutics is subject to the usual risks associated with biotechnology companies, such as the unpredictable outcome of clinical trials, regulatory discussions, the success of competitors, as well as financing and commercial risks. We note, however, that the diverse nature of OSE's pipeline, with active programmes in various disease areas within immuno-oncology and immuno-inflammation, somewhat mitigates the company's exposure to binary risk events. For the lead immuno-oncology Tedopi programme, OSE is funding the programme through to filing for regulatory approval. The registrational Phase III ARTEMIA trial is underway, and we expect top-line results in 2027. Should the results be supportive, this would likely be followed by a commercial launch from 2028. We note that the successful commercialisation of Tedopi will be dependent on OSE securing licensing deals with larger pharmaceutical partners. Any challenges in securing such a partner may adversely affect the economics of potential transactions, and/or delay product uptake. Beyond Tedopi, for OSE's other programmes, further capital may be required to fund subsequent clinical trials, and if such financing is realised through equity issuances, this may result in dilution to existing shareholders.

Alternatively, new partnerships may be initiated to support subsequent development efforts for OSE's internal programmes, but this remains uncertain. For example, the lead immuno-inflammation lusvertikimab programme showed promising results in Phase II, providing a robust foundation for further development efforts, in our view. As such, our model assumes that a licensing deal will be secured within 2025. However, we acknowledge that there is inevitably underlying imprecisions and variability in anticipating the timing and terms of potential deals. We believe that for the two leading programmes (Tedopi in immuno-oncology and lusvertikimab in immuno-inflammation), the clinical data to date have established proof-of-concept. However, ongoing and subsequent late-stage clinical trials still present near-term R&D risks. Most importantly, the Phase III ARTEMIA trial will have an interim readout in 2026, which may give some insight to whether the data will confirm the positive results seen in prior clinical studies. We note that the ongoing partnerships with Boehringer Ingelheim, Veloxis and AbbVie somewhat offset the impact of clinical trial expenditures as a risk for the company. However, as is typical with such deals in the healthcare sector, the assets involved in these partnerships may be returned to OSE in the event of clinical trial failures or strategic changes from partners. This was the case with lusvertikimab (formerly OSE-127), which was previously out-licensed to Servier, but returned in 2023.

The gross cash position (including cash, cash equivalents and fixed-term deposits classified as current and non-current financial assets) of €64.2m, as reported in the company's FY24 results, should provide operational headroom into 2027, beyond key milestones for the Tedopi and lusvertikimab programmes. We believe that the necessity for further funding will most likely be contingent on OSE's ambitions and plans to broaden its clinical development pipeline, as well as interest from potential partners, which may alleviate the requirement for dilutive funding.

Valuation

We continue to value OSE using an rNPV approach, valuing the different assets (both in-house and partnered) separately, adjusted for the associated risk (based on the phase of clinical development). We use a flat discount rate of 12.5% across all clinical programmes. For the two lead in-house, self-developed programmes, Tedopi in NSCLC and lusvertikimab in UC, we keep our underlying assumptions (target market, product pricing, trial timelines, licensing deals and PoS) unchanged. These two assets continue to account for the bulk (c 80%) of our valuation of OSE.

However, we update our assumption for the third in-house asset, OSE-279 (c 5% of our per-share valuation), based on the recent communication by management on the future development pathway for the asset, which would entail testing the PD-L1 ICI in combination with Tedopi as a first-line treatment for HLA-A2 positive patients with NSCLC. If successful, this may allow the company to move Tedopi up the treatment chain to first-line in combination with other checkpoint inhibitors, materially expanding the drug's commercial potential.

We assume that the company will initiate a Phase I/II trial for OSE-279 in combination with Tedopi within H125, with a potential market launch in 2030 in NSCLC. We estimate an effective annual price of US\$35k in the US and €24,500 in Europe, in line with other approved ICIs. Based on these assumptions, we calculate peak sales of €477m (US\$534m) to be achieved in 2039, at patent maturity. Using a risk-adjustment factor of 14%, we forecast the revised rNPV for OSE-279 to be €31.3m (€35.9m previously).

For the partnered assets (BI 770371, FR104/VEL-101 and ABBV-230), we keep the underlying assumptions unchanged for now but will reassess these as we get more clarity on the progress made by partners on the development plans.

Reflecting the aforementioned changes, model roll forward and the latest net cash position, our valuation for OSE adjusts to €560.8m or €25.6/share, from €541.2m or €24.8/share. Exhibit 13 presents our rNPV valuation across the various programmes under development.

Exhibit 13: OSE rNPV valuation

Product	Launch	Peak sales (€m)	NPV (€m)	NPV/share (€)	Probability	rNPV (€m)	rNPV/share (€)
Tedopi - NSCLC (second-line)	2028	541	479.8	21.9	67%	317.2	14.5
Lusvertikimab/OSE-127 - ulcerative colitis	2028	819	335.3	15.3	35%	134.5	6.1
BI 770371 - MASH/ Solid tumours (HNSCC)	2029	513	185.8	8.5	14%	29.8	1.4
FR104 - kidney transplantation	2029	95	162.1	7.4	17%	29.9	1.4
OSE-279 - NSCLC (first-line)	2030	477	190.6	8.7	14%	31.3	1.4
Net Cash/(Debt) at 31 December 2024 (including lease liabilities)			18.0	0.8	100%	18.0	0.8
Valuation			1,371.6	62.5		560.8	25.6

Source: Edison Investment Research.

The end-FY24 gross cash position (€64.2m) was supported by the €45m and €39m upfront payments from AbbVie and Boehringer Ingelheim as well as the €2.1m received as part of the €8.4m public funding and €5.3m in research tax credits. Based on our projections (which assume receipt of the €17.5m in expected near-term milestone payment from Boehringer Ingelheim in FY25), we estimate the company has operating headroom into 2027 (in line with management guidance), even in the absence of further licensing or milestone payments. Note that our model assumes that the company will continue to receive inflows across its various assets from existing/new partnership deals and therefore we do not foresee the need for a new fund-raise. However, as an added sensitivity, in case of no further non-dilutive funding in the form of licensing income, we estimate it would be required to raise another c €50m in Q127 before becoming self-sustaining in FY28, following the launch of Tedopi in the US. If this requirement is met through equity funding, we estimate the need to issue c 8.6m shares (at the current share price of €5.8), resulting in our per-share valuation coming down to €20.0 from €25.6 currently (shares outstanding would increase from 21.9m to 30.6m).

Financials

An operationally rewarding year

OSE's pipeline is currently in the clinical stages of development and therefore all reported revenues comprise either licensing, upfront, milestone or servicing-related revenues from partners. FY24 was a particularly successful year for the company, with reported revenues of €83.4m (albeit lower than our estimate of €98.5m), which we believe primarily comprised the upfront payments related to the AbbVie and Boehringer Ingelheim deals (c €42m and c €39m) received

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in H124. We calculate that another €0.8m from the AbbVie payment has been recognised as revenue in H224 (from the remaining €2.8m, which the company had reflected as deferred income) and accounted for most of the €0.9m reported revenues in H224. The income from Boehringer Ingelheim during the period includes €25.3m related to the partial monetisation of royalties under the revised deal terms with Boehringer Ingelheim announced in May 2024 and a €13.5m milestone payment related to the purchase of a novel, cis-targeting anti-PD-1/cytokine asset in the preclinical stage (reflected as revenue from other products in the FY24 report).

The FY24 operating expenses rose materially over the previous year (+57.5%) to €39.7m, driven by a 77.4% y-o-y increase in R&D expenses to €30.4m, which we attribute to the initiation of the Phase II ARTEMIA study for lead immune-oncology asset Tedopi in September 2024, partially offset by the completion of the Phase II CoTikiS trial for lead immuno-inflammation asset lusvertikimab in July 2024. For context, R&D expenses in H224 were €16.6m, versus €13.9m in H124. R&D expenses in FY24 made up 76.7% of the total operating expenses for the year (68.1% in FY23). Overhead expenses went up by 8.6% (€6.5m versus €6.0m in FY23). Overall, the company reported an operating profit of €43.7m (we had estimated €65.5m) versus an operating loss of €23.0m in FY23.

Estimate revisions

We have made adjustments to our FY25 estimates based on the FY24 results and near-term operational visibility. We also introduce FY26 estimates with the model roll forward. For FY25 we estimate revenue of €63.5m versus €86.3m previously. The primary reason for this change is the removal of a €20m milestone payment we had previously assumed from partner Boehringer Ingelheim following the initiation of the Phase II trial in MASH. Note that our revised FY25 top-line estimates continue to assume the company will receive the remaining €17.5m near-term milestone payment from Boehringer Ingelheim related to the purchase of a novel, cis-targeting anti-in PD-1/cytokine asset in FY25 (this will be triggered by the initiation of potential clinical development for the asset) as well as other potential milestone payments for its partnered programmes and the upfront payment for a licensing deal for lusvertikimab (we assume this happens in 2025, with the partner taking over further clinical development and subsequent commercialisation). Given that none of these is certain, our revenue estimates are subject to revision as we gain clarity on operations.

For our operating expense forecast, we raise our R&D expectations for FY25 reflecting the FY24 run-rate but temper our estimate for other overhead expenses. We now project R&D expenses of €28.2m (€26.7m previously) and other overheads of €6.7m (€7.4m previously), which translates to an operating profit of €28.6m in FY25. For FY26, we forecast revenue of €101.5m and operating profitability of €64.2m.

Strong balance sheet position

OSE ended FY24 with a net cash balance of €18m. This includes gross cash of €64.2m (including current and non-current fixed term-deposits of €47.4m) and €46.1m of debt (including long-term debt of €35.7m, short-term debt of €7.2m and €3.3m of financial leases). Outstanding debt liabilities include loans from government agencies as well as repayable advances. Of the total indebtedness around €20m is made up of loans from the European Investment Bank (EIB), which is repayable after June 2026 with only minor debt servicing required prior to that. The EIB loan bears an interest rate of 5% and required the company to issue 1.4m warrants (850k for tranche 1 and 550k against tranche 2) to be exercised after July 2026 and December 2027, respectively. If fully converted (assuming no further equity issues from the company), this would dilute existing shareholders by c 6%. We note that in April 2023, OSE had entered into an equity financing agreement with Vester Finance, which held the option to subscribe to a maximum of 2.8m shares of the company over a maximum period of 24 months. As of September 2023, 2.74m warrants had been exercised at a weighted average exercise price of €4.31, netting OSE €11.6m in equity financing. Subsequently, the company signed an extension to this facility, against issue of a maximum of 900k shares. In its FY24 release, management communicated that no additional warrants were exercised in 2024 and as of 26 March 2025, the companies have entered into another agreement, providing Vester with a further 12-month extension to exercise the remaining 880k warrants at the same terms as previously agreed. If exercised fully, this would lead to a further dilution of c 4%.

Exhibit 14: Financial Summary

€000s	2022	2023	2024	2025e	2026e
December	IFRS	IFRS	IFRS	IFRS	IFRS
PROFIT & LOSS					
Revenue	18,302	2,227	83,435	63,486	101,450
Cost of Sales	0	0	0	0	0
Gross Profit	18,302	2,227	83,435	63,486	101,450
Research and development	(26,893)	(17,158)	(30,445)	(28,196)	(30,320)
Overhead expenses	(6,673)	(6,015)	(6,534)	(6,730)	(6,932)
EBITDA	(14,992)	(19,566)	49,992	29,768	65,483
Operating Profit (before amort. and excepts.)	(18,478)	(22,986)	43,735	28,560	64,198
Net Interest	455	(235)	(3,903)	(1,517)	(882)
Profit Before Tax (norm)	(18,023)	(23,221)	39,832	27,042	63,316
Profit Before Tax (reported)	(18,023)	(23,221)	39,832	27,042	63,316
Tax	263	218	(2,387)	0	0
Profit After Tax (norm)	(17,760)	(23,003)	37,445	27,042	63,316
Profit After Tax (reported)	(17,760)	(23,003)	37,445	27,042	63,316
Average Number of Shares Outstanding (m)	18.5	19.6	21.8	21.9	21.9
EPS - basic (€)	(0.96)	(1.18)	1.72	1.23	2.89
EPS - diluted (€)	(0.96)	(1.18)	1.48	1.23	2.89
EBITDA Margin (%)	N/A	N/A	60	47	65
Operating Margin (before GW and except.) (%)	N/A	N/A	52	45	63
BALANCE SHEET					
Fixed Assets	54,580	51,576	54,026	53,268	52,433
Intangible Assets	48,784	46,401	44,010	43,203	42,396
Tangible Assets	743	464	355	404	375
Short-term deposits/financial assets	635	910	6,400	6,400	6,400
Investments	4,418	3,801	3,261	9,661	9,661
Current Assets	37,200	30,478	69,935	88,288	141,131
Stocks	0	0	0	0	0
Debtors	403	982	4,138	4,345	4,562
Short-term deposits/financial assets	0	0	41,000	41,000	41,000
Cash and cash equivalents	25,620	18,672	16,745	34,891	87,517
Other	11,177	10,824	8,052	8,052	8,052
Current Liabilities	16,268	18,799	20,222	22,541	23,901
Trade payables	8,539	9,299	7,724	8,110	8,516
Short term borrowings	3,093	6,403	7,199	11,171	12,125
Other	4,636	3,097	5,299	3,260	3,260
Long Term Liabilities	42,855	40,280	39,927	28,161	15,494
Long term borrowings	37,231	35,508	35,659	24,488	12,363
Deferred tax liabilities	1,514	1,311	1,074	1,074	1,074
Other long term liabilities	4,110	3,461	3,194	2,599	2,057
Net Assets	32,657	22,975	63,812	90,853	154,169
CASH FLOW					
Net income	(17,760)	(23,003)	37,445	27,042	63,316
Movements in working capital	(3,142)	(835)	1,980	(1,860)	188
Depreciation and other	3,486	3,420	6,257	1,208	1,285
Net Interest	(3,066)	(657)	3,903	0	0
Tax	(499)	(435)	(233)	0	0
Others	2,728	1,746	2,088	0	0
Net Cash Flows from Operations	(18,253)	(19,764)	48,440	26,391	64,789
Capex	(274)	(232)	(77)	(450)	(450)
Acquisitions/disposals	0	0	0	0	0
Others	300	(275)	(265)	0	0
Net Cash Flow from Investing Activities	26	(507)	(46,909)	(450)	(450)
Equity Financing	6	11,357	1,157	0	0
Debt financing	11,046	2,304	(3,336)	(7,199)	(11,171)
Other	(785)	(337)	(1,279)	(595)	(542)
Dividends	0	0	0	0	0
Net Cash Flow from Financing Activities	10,267	13,324	(3,458)	(7,794)	(11,713)
Effect of FX	0	0	0	0	0
Net Cash Flow	(7,960)	(6,947)	(1,927)	18,147	52,626
Opening cash	33,579	25,619	18,672	16,745	34,892
Forex adjustments	0	0	0	0	0
Closing cash	25,619	18,672	16,745	34,892	87,518
Closing (net debt)/cash	(14,705)	(23,239)	(26,113)	(767)	63,030

Source: Company accounts, Edison Investment Research

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Revenue by geography

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Management team

CEO: Nicolas Poirier, PhD

Nicolas Poirier holds a PhD in immunology (European Center for Transplantation and Immunotherapy Sciences, Nantes), a double master's degree in biotechnology from the University of Nantes and in pharmacology from the University of Louis Pasteur in Strasbourg and a certification in Global Management from INSEAD. He has been chief scientific director and member of the management team of OSE Immunotherapeutics since 2016. He started his career at Tcl Pharma in 2009 as a researcher, became project manager at Effimune in 2012, then director of R&D programmes in 2014. In addition, he is an active member of the Strategic and Scientific Advisory Committee (COSSF) of the French biomedical industry association (MabDesign). Over the past 15 years, he has authored more than 50 peer-reviewed international scientific publications and holds over 40 issued patents in the field of immunotherapy. Nicolas Poirier and his team have obtained more than €45m in French and European public funding to co-finance OSE Immunotherapeutics' research and development programmes.

CFO: Anne-Laure Autret-Cornet

Anne-Laure has acquired seven years of experience in finance and audit within Deloitte and 10 years of experience in finance/biotech. She joined Effimune in 2013 as administrative and financial manager and upon the merger with OSE Pharma in 2016, Anne-Laure was appointed chief financial officer of OSE Immunotherapeutics. Anne-Laure Autret-Cornet graduated from ESSCA Management school and has received the certificate 'Corporate Finance' from HEC Paris in 2020.

Principal shareholders

	%
Emile Loria	12.1%
Dominique	9.2%
OSE Immunotherapeutics manager and employees	2.4%
Maryvonne Hiance	1.9%
Nicolas Poirier	1.6%
Saint Olive Gestion	0.8%
Mandarine Gestion	0.6%
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