OSE Immunotherapeutics

FY25 results

Set for a strategically important year

Healthcare

8 June 2026

OSE Immunotherapeutics (OSE) has published its FY25 results, reaffirming its strategy of streamlining its clinical pipeline to focus on its core assets, Tedopi and Iusvertikimab. Both assets are anticipated to hit multiple milestones across FY26–28, creating a potentially catalyst-rich period ahead. OSE reported gross cash of €17.0m as at 31 March 2026 and recently announced a flexible bridging equity financing facility worth up to c €19m over a 24-month period. Including initial proceeds, management has guided a cash runway to end-2026. We estimate that OSE will need to raise a total of up to €90m between FY26 and FY29 to fund its plans over the next three years, which we believe is likely to include a mix of equity, debt and potential milestone payments from partners. We value the company at €386.7m or €16.6 per share (€371.3m or €16.5 per share previously).

Year end	Revenue (€m)	PBT (€m)	EPS (€)	DPS (€)	P/E (x)	Yield (%)
12/24	83.4	39.8	1.46	0.00	2.5	N/A
12/25	2.7	(41.8)	(1.69)	0.00	N/A	N/A
12/26e	2.5	(25.4)	(1.13)	0.00	N/A	N/A
12/27e	7.5	(21.0)	(0.93)	0.00	N/A	N/A

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

Streamlined approach in play for core assets

Cancer vaccine Tedopi continues to advance through the registrational Phase III ARTEMIA programme in non-small cell lung cancer (NSCLC). Following its second successful independent data monitoring committee (IDMC) review, where it was advised the trial should continue without modification, ARTEMIA is on track for a futility analysis in Q326, before a top-line readout in Q128. For Iusvertikimab, OSE is seeking partners to continue development in ulcerative colitis (UC), an indication backed by encouraging Phase II data. In January 2026, OSE announced that internal development efforts will now focus on chronic pouchitis and hidradenitis suppurativa, for which OSE plans to run a new Phase II study from H226, although we note that this is subject to securing appropriate financing.

Refreshed management steering the ship

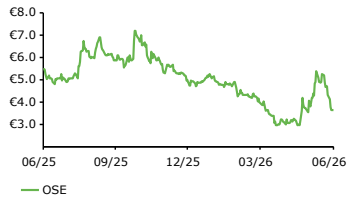
In March 2026, OSE confirmed the transition of Marc Le Bozec from interim to permanent CEO. Le Bozec had been in the role since shortly after OSE's September 2025 AGM, when a new board of directors was announced. In addition, OSE's CFO, Thomas Gidoin, was appointed deputy CEO in addition to CFO and Aurore Morello was confirmed as CSO (from head of research and director of R&D programmes). The refreshed leadership team is committed to executing OSE's core goal of developing life-changing therapies for patients facing high unmet medical needs, according to the 2026–28 strategic plan.

Valuation: €386.7m or €16.6 per share

As we updated our investment case in January 2026 , our valuation adjusts only slightly with the FY25 results. We value OSE at €386.7m or €16.6/share (from €371.3m or €16.5/share previously). Based on our estimates, we expect OSE will need to drawdown c €8–10m from the bridging facility in FY26 (of which the initial €2m has been received) to support operations to year-end.

Price	**€3.69**
Market cap	**€84m**
	€0.86/$
Gross cash and equivalents at 31 March 2026	€17.0m
Shares in issue	22.7m
Free float	65.0%
Code	OSE
Primary exchange	NXT PA
Secondary exchange	N/A

Share price performance



%	1m	3m	12m
Abs	2.2	(9.0)	(38.9)
52-week high/low		€7.7	€2.9

Business description

OSE Immunotherapeutics 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 new Phase II study	H226 (subject to funding)
ARTEMIA futility analysis	Q326
ARTEMIA results	Q128

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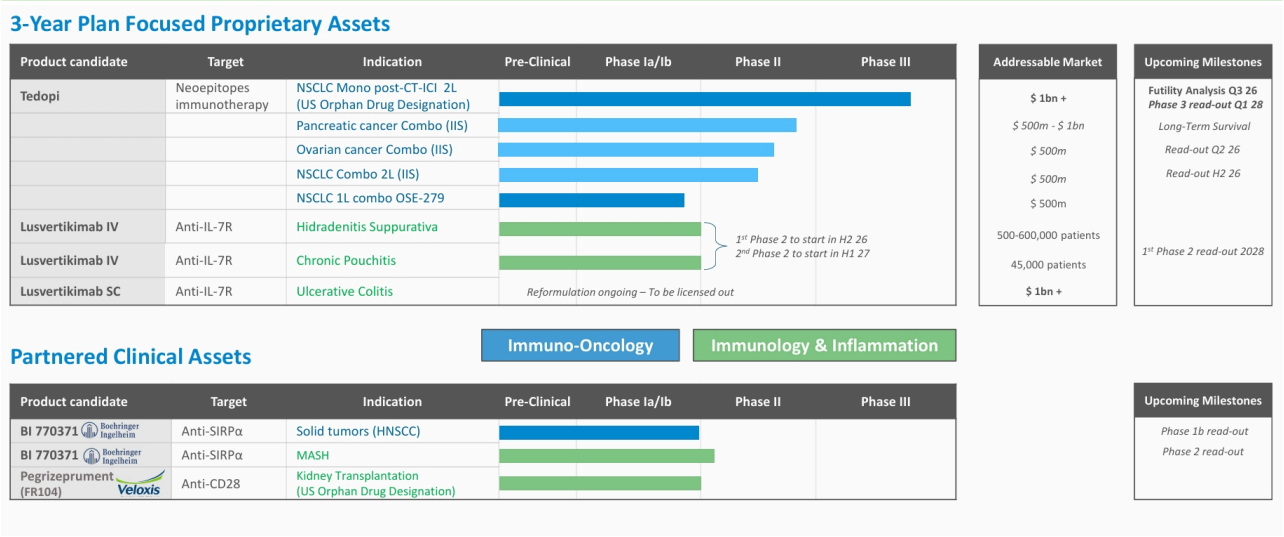
Focused pipeline offers multiple upcoming potential catalysts

OSE's clinical development pipeline spans a range of disease areas (Exhibit 1). The company's renewed strategy is intended to accelerate its most promising clinical-stage candidates. These include:

- Lead immuno-oncology asset, off-the-shelf neoepitope-based cancer vaccine Tedopi in NSCLC, though there are several collaborative programmes ongoing that may support a broader application of the candidate to additional settings.
- Lead immuno-inflammation candidate, monoclonal antibody therapy lusvertikimab, for which the company plans to explore its potential in chronic pouchitis (as the initial top focus) and hidradenitis suppurativa with the existing intravenous (IV) formulation. OSE is also developing a subcutaneous (SC) formulation of the candidate, which management believes will improve its partnering prospects in UC, an indication in which encouraging clinical data have already been reported.

We discuss plans for these two lead candidates in further detail below.

Exhibit 1: OSE's clinical development pipeline



Source: OSE Immunotherapeutics Q126 corporate presentation

Beyond its proprietary programmes, OSE has a strong history of establishing partnerships with large pharmacuetical companies. However, we note that with the renewed strategy, the company has made the decision to concentrate on its core, self-owned programmes. While OSE had previously been engaged in a global licence and collaboration agreement with AbbVie for OSE-230 (also known as ABBV-230) in chronic inflammation, it announced in March 2026 that development would be paused. Previously, OSE had planned to conduct incremental preclinical and Phase I research to support the programme with AbbVie, but the decision to pause these efforts was made to allow the company to focus its resources on Tedopi and lusvertikimab. As part of this same announcement, OSE confirmed that Boehringer Ingelheim (BI) had opted to halt development of the partnered asset BI 770371 specifically in metabolic dysfunction-associated steatohepatitis (MASH) after some Phase II data showed a lack of efficacy in this indication; the candidate showed favourable safety and will continue to be explored in oncology under the partnership.

We acknowledge the potential upside from the partnered programmes that remain ongoing, including BI 770371 in head and neck squamous cell carcinoma (HNSCC) where the data have been more encouraging. We highlight that these partnered programmes no longer have any bearing on OSE's cash runway, as no milestone payments are expected with these programmes within the 2026–28 strategic plan. Separately, OSE remains in an ongoing partnership with Veloxis Pharmaceuticals for pegrizeprument (also known as FR104 and VEL-101) as a maintenance therapy for patients following kidney transplantation. Again, OSE does not rely on this programme for near-term value creation, although we note the potential for it to provide long-term upside, should the programme be successful with subsequent clinical development efforts.

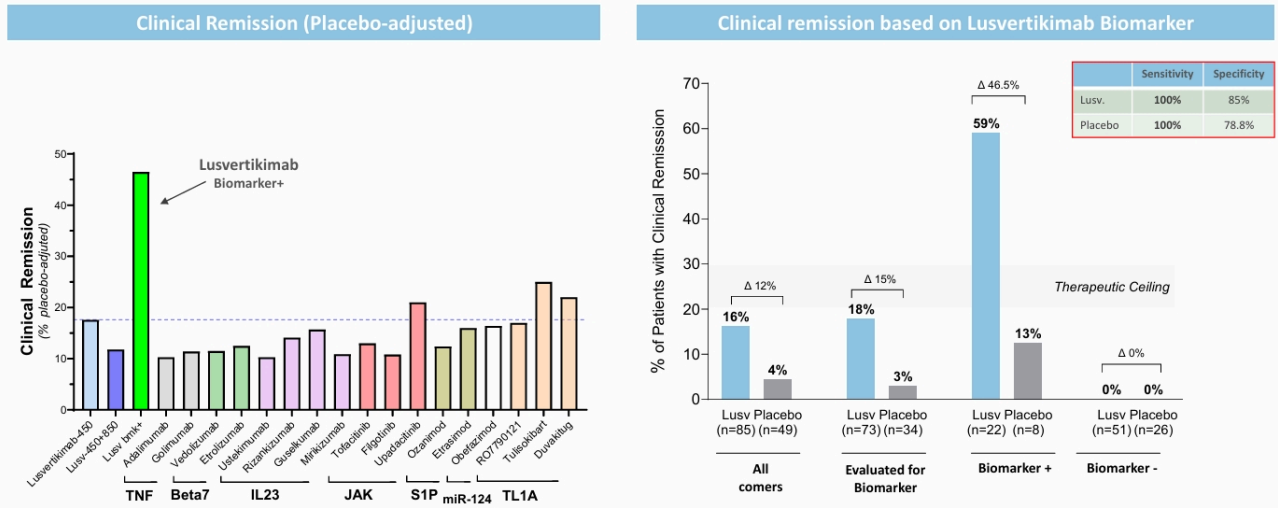
Lusvertikimab to take a pragmatic development path

Lusvertikimab is a monoclonal antibody therapy, designed as an antagonist of the interleukin-7 receptor (IL-7R). More specifically, the drug candidate targets CD127, a cytokine that modulates the proliferation, apoptosis and activation of CD4 and CD8 T cells. To our knowledge, this represents a unique and differentiated mechanism of action in immuno-inflammation. While lusvertikimab's mechanism of action is applicable to a range of chronic inflammatory conditions, most recently it has shown promise in the Phase II CoTikiS trial in UC.

The latest from lusvertikimab in the clinic

CoTikiS (n=136) was a multicentre, randomised, double-blind, placebo-controlled Phase II study assessing lusvertikimab at 450mg and 850mg doses. The week 10 primary endpoint was the Modified Mayo Score (a global disease activity index measure for UC), which was met with statistical significance. For a more detailed discussion of these trial results, we direct readers to our prior update note. Clinical remission was measured as a secondary endpoint at week 10. OSE identified a niche following a detailed retrospective analysis of CoTikiS. This biomarker-driven approach was developed by utilising artificial intelligence and transfer learning, whereby the model was trained on multimodal data from millions of chronic inflammatory disease patients and refined with data from CoTikiS. This led to the identification of a new predictive biomarker (a composite IL7R axis biomarker), offering the potential to improve clinical remission rates through a precision medicine approach with lusvertikimab. The data demonstrated that the biomarker-positive population (pooled 450mg and 850mg doses) showed a placebo-adjusted clinical remission rate of 46.5%, offering potential to overcome the therapeutic ceiling. Management estimates that 30–40% of UC patients could benefit from this precision medicine approach, offering the potential to maximise placebo-adjusted clinical remission rates (Exhibit 2).

Exhibit 2: Potential for lusvertikimab to overcome the UC therapeutic ceiling



Source: OSE Immunotherapeutics Q1 2026 corporate presentation

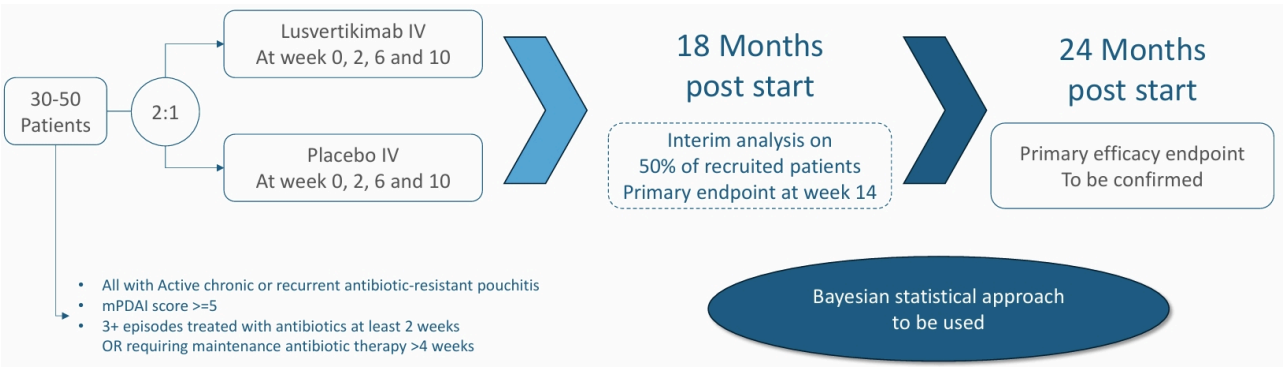
Looking ahead in UC, OSE plans to develop an SC formulation of the candidate, which the UC market considers to be a more desirable administration approach (compared to the existing IV formulation). In parallel, OSE will continue to generate non-clinical (ex-vivo) data in UC to support a potential precision medicine approach. Management is currently seeking partnership opportunities to progress the candidate in UC, and should the early findings of this precision-medicine approach be confirmed, it could make lusvertikimab a more attractive prospect for partnering, incremental to the favourable results from Phase II, in our view. We also highlight that Abivax, another key player in the UC field, recently reported mixed Phase III data, potentially creating a gap that OSE could be well positioned to fill. According to a report by Future Market Insights, the global UC treatment market was valued at $8.3bn in 2025, and projected to reach $14.9bn by 2035, growing at a CAGR of 6.0% across this period, reflecting the growing prevalence of the disease. We therefore believe that the opportunity in this space could be sizeable, should OSE be successful in securing an appropriate partner to continue the development of lusvertikimab in this indication.

New indications: chronic pouchitis and hidradenitis suppurativa

As part of OSE's renewed strategy, the existing intravenous (IV) formulation of lusvertikimab will be repositioned, to focus on chronic pouchitis (as the initial top focus) and hidradenitis suppurativa. Management believes that these plans will require modest financial investment, compared to continuing the clinical development of the candidate in UC, as part of its commitment to maintaining financial discipline. This also has the potential to expand lusvertikimab's value offering, potentially with a faster route to market.

Chronic antibiotic-refractory pouchitis stems from severe inflammation of the ileal pouch, a surgically created pouch formed following colectomy in patients with conditions such as UC. Chronic pouchitis is the most common long-term complication of this type of surgery, and it is estimated that 30% of UC patients are refractory to available therapies, reflecting a meaningful though relatively niche patient population within the inflammatory bowel disease space. Chronic antibiotic-refractory pouchitis is increasingly understood as an immune-mediated condition, sharing mechanistic overlap with UC and broader inflammatory pathways. First-line treatment for chronic pouchitis relies on antibiotics, though patients who fail to respond are managed with corticosteroids and advanced immunosuppressive or biologic therapies, but clinical research is somewhat limited, and we highlight that there are currently no FDA-approved biologic treatments in the antibody-refractory setting. We therefore see a clear unmet need for targeted therapies that can more effectively address the underlying immune dysregulation and provide durable disease control. Again, subject to securing appropriate financing, OSE plans to initiate a Phase IIa study in chronic antibiotic-refractory pouchitis from H226 (Exhibit 3).

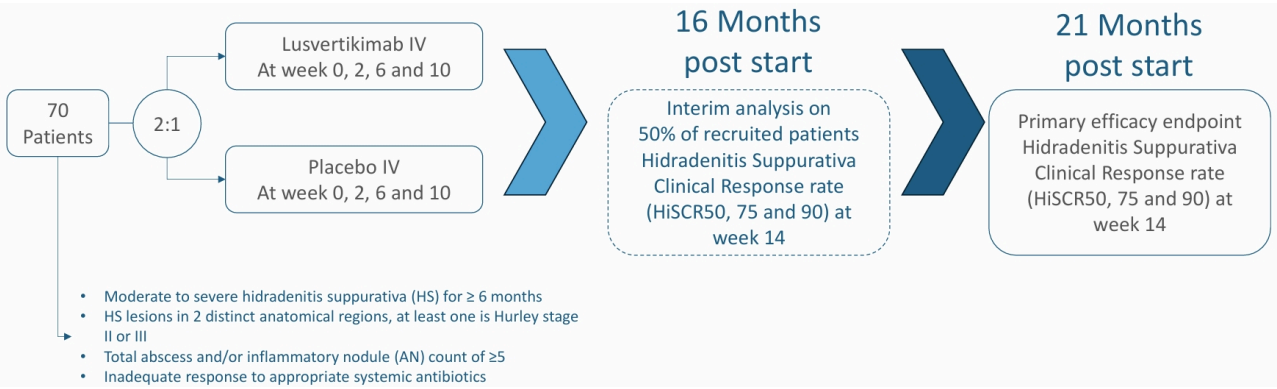
Exhibit 3: Expected design and timelines for a Phase IIa study in chronic antibiotic-refractory pouchitis



Source: OSE Immunotherapeutics Q! 2026 corporate presentation

Hidradenitis suppurativa is a chronic, recurrent inflammatory condition characterised by painful nodules, abscesses and drinking sinus tracts in areas such as the underarms and groin, driven by dysregulated immune activity (over-activation of inflammatory signalling pathways). It is estimated to afflict c 1% of the global population, although underdiagnosis is common. Hidradenitis suppurativa is increasingly recognised as part of a broader, systemic inflammatory profile, with a well-documented association with inflammatory bowel diseases such as UC, reflecting shared immune pathways and cytokine drivers. Current treatment options are limited, typically involving prolonged courses of antibiotics, hormonal therapies, surgical intervention in advanced cases and biologic agents, with Humira (generic name: adalimumab) the only widely approved targeted therapy for moderate-to-severe disease. Despite these approaches, many patients experience inadequate disease control, frequent relapses and significant impairment in quality of life, highlighting a clear unmet need for more effective and durable therapies that address the underlying condition. Subject to securing appropriate financing, OSE plans to initiate a Phase II proof-of-concept trial (Exhibit 4).

Exhibit 4: Expected design and timelines for a Phase II study in hidradenitis suppurativa



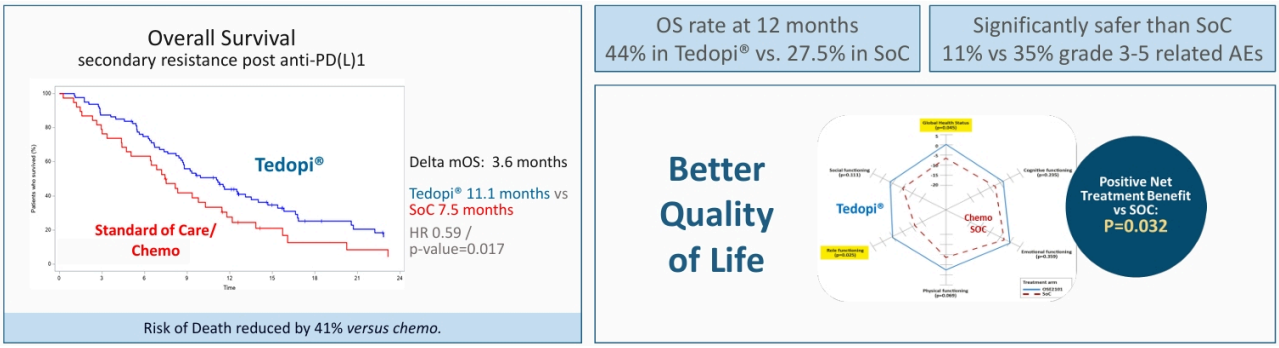
Source: OSE Immunotherapeutics Q1 2026 corporate presentation

Tedopi offers 'pipeline in a product' potential

The latest from Tedopi in the clinic

The main opportunity for Tedopi is in NSCLC (targeting the second-line setting), specifically looking at patients with secondary resistance to standard-of-care immune checkpoints inhibitors (ICIs), that is, where disease progression is experienced after 12 weeks of ICI treatment. Tedopi has been designed to directly activate tumour-specific T-cells that then bind tumour-associated antigens presented on the surface of cancer cells by the HLA A2 receptor; c 45% of NSCLC patients are HLA-A2 positive. The candidate has already shown its potential as a monotherapy in the ATALANTE-1 trial, which was a randomised Phase III study evaluating the candidate in the second- or third-line treatment setting after ICI failure in HLA A2 positive NSCLC patients. Recruitment for ATALANTE-1 was adversely affected by the COVID-19 pandemic, though outcomes for patients that completed treatment were promising, in our view. The primary endpoint was met (in the subgroup showing secondary resistance to ICIs, the population of interest), with significantly improved overall survival (OS) rates, and the results showed positive patient-reported outcomes, quality of life and safety (Exhibit 5).

Exhibit 5: Key outcomes from the ATALANTE-1 trial

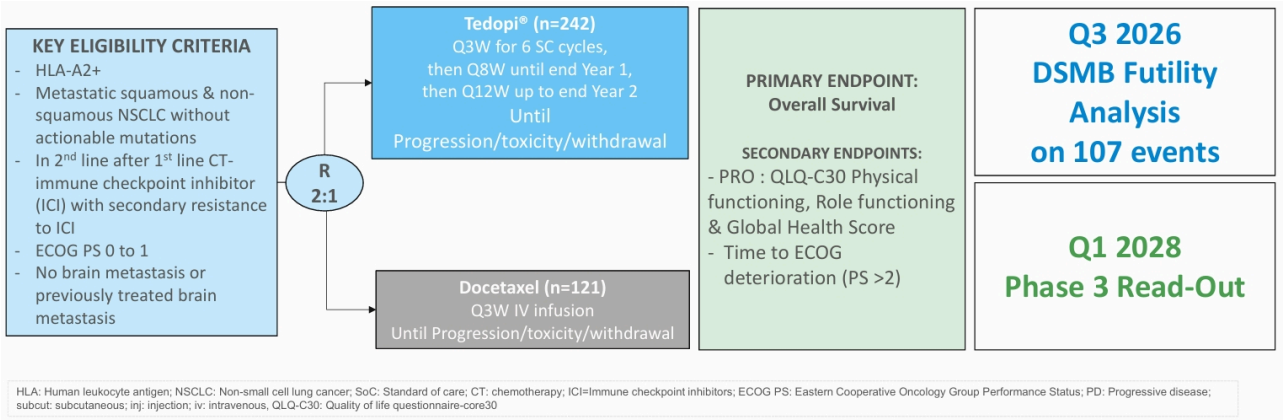


Source: OSE Immunotherapeutics Q1 2026 corporate presentation

In focus: Registrational Phase III ARTEMIA trial

Tedopi is currently being evaluated in the international registrational Phase III ARTEMIA trial. ARTEMIA is assessing Tedopi as a second-line monotherapy in NSCLC patients, after first-line ICI treatment. The trial is randomising participants (expected n=363) 2:1 to receive either Tedopi or docetaxel. The programme is being facilitated by a companion diagnostic screening test to identify HLA-A2 positive NSCLC patients, who are expected to be more likely to respond to the Tedopi epitopes. The primary endpoint for the trial will be OS, while secondary endpoints will be based on patient-reported outcomes and quality of life (Exhibit 6).

Exhibit 6: Design of the registrational Phase III ARTEMIA programme



Source: OSE Immunotherapeutics Q1 2026 corporate presentation

In February 2026, OSE received a second positive recommendation from the IDMC to continue the Phase III ARTEMIA trial without any modifications, serving as an encouraging sign that the trial is progressing as planned. Looking ahead, a futility analysis is expected in Q326, and patient recruitment remains on track to be complete by end-2026. After this, there will be a primary endpoint readout in Q128, representing a significant inflection point.

Expansion potential with combination approaches in additional settings

Tedopi offers 'pipeline in a product' potential, through its possible application in additional settings. Notably, and as discussed in our recently published thematic report on immuno-oncology, we see various opportunities to bolster the efficacy of the cancer vaccine through combination treatment regimens. OSE is involved in three distinct Phase II collaborative programmes with external oncology groups, aiming to expand the clinical utility of Tedopi, including:

- in combination with chemotherapy for pancreatic cancer (TEDOPaM, sponsored by GERCOR Group, an independent French multidisciplinary cooperative group);
- alone or with Keytruda for ovarian cancer (TEDOVA, led by ARCAGY-GINECO, another French cooperative group specialised in women's cancers); and
- with Opdivo or docetaxel for NSCLC (CombiTED, led by FoRT, an Italian non-profit foundation).

Positive topline results were previously presented in pancreatic cancer in June 2025. The TEDOPaM trial met its primary endpoint of one-year OS and showed favourable safety outcomes; it is currently in the long-term follow-up phase. For the TEDOVA trial in ovarian cancer, topline results were reported in May 2026. The primary endpoint of progression-free survival (PFS) was met with statistical significance (median PFS of 4.1 months with Tedopi plus pembrolizumab, compared to 2.8 months with best available care). For the CombiTED trial in NSCLC trial, topline results are expected in H226. In our view, these studies in additional settings complement the lead programme and, with the TEDOPaM results, provide further clinical validation for Tedopi. Ultimately, these programmes serve as cost-efficient opportunities to bolster Tedopi's value proposition.

Financials

R&D ramps up with Tedopi Phase III trial

OSE has reported its full FY25 financial results, marking a year of significant strategic repositioning for the company. As a clinical-stage biotechnology company, OSE does not generate product sales revenues; reported revenues primarily comprise licensing, upfront, milestone and service-related payments from partners.

In FY25, OSE reported revenue of €2.7m, ahead of our €1.8m estimate. Revenue was primarily derived from outstanding payments related to the AbbVie and BI partnerships, alongside Tedopi sales generated through compassionate-use and early-access programmes. This compares with FY24 revenue of €83.4m, which was largely driven by upfront payments from AbbVie and BI of approximately €42m and €39m, respectively.

Operating expenses increased 12.3% year-on-year to €44.6m. The increase was driven by an 11.5% rise in R&D expenditure to €33.9m (FY24: €30.4m), reflecting costs associated with the ongoing Phase III ARTEMIA trial of Tedopi, development of the subcutaneous formulation of lusvertikimab and other research activities. R&D represented 76.1% of total operating expenses in FY25, broadly consistent with FY24 (76.7%).

General and administrative (G&A) expenses increased 34.0% year-on-year to €8.8m (FY24: €6.5m), primarily reflecting legal and advisory costs associated with the corporate restructuring announced during 2025. As a result, OSE reported an adjusted operating loss of €41.9m, compared with our estimate of €32.9m, versus an operating profit of €43.7m in FY24, which benefited from substantial partnership-related upfront revenues.

Estimate revisions

Following the FY25 results and management's updated guidance on clinical development priorities, we have revised our FY26 forecasts. Most notably, we have reduced our FY26 R&D expense estimate to €20.2m from €22.8m previously. Our forecasts continue to assume ongoing development activities for Tedopi and the subcutaneous formulation of lusvertikimab but exclude the planned clinical study in chronic pouchitis, the newly selected rare disease indication for lusvertikimab. We intend to incorporate this programme into our forecasts once clinical development is initiated.

We have also made modest adjustments to our revenue and G&A assumptions. Overall, we now forecast an FY26 operating loss of €24.3m, compared with our previous estimate of €28.4m. We additionally introduce FY27 forecasts, projecting an operating loss of €19.6m.

Funded through FY26 based on management guidance

OSE ended FY25 with gross cash and cash equivalents of €22.7m (including €17.6m cash and a further €5.1m held in short-term deposits). The company reported debt of €31.8m, including c €16m owed to the European Investment Bank (EIB), of which around €7m is scheduled for repayment in July 2026. The gross cash figure at the end of March 2026 was €17m.

In May 2026, OSE announced a bridge financing agreement with IRIS Capital Investment, providing potential proceeds of approximately €19.3m (based on the closing share price on 27 May 2026) through the issuance of up to 4m warrants over a 24-month period. The agreement includes an expected upfront payment of €2m, which we understand was received in early June.

Management has indicated that initial proceeds from the facility should extend the company's cash runway through the end of 2026, including the scheduled EIB repayment. Based on our current forecasts, we estimate that OSE will need to draw approximately €8–10m from the facility over the coming months, assuming no alternative financing sources become available, to support planned clinical development activities and operational requirements throughout FY26.

Valuation

Following the release of the full FY25 results, we roll forward our model and incorporate the FY26 estimated net cash position while keeping our underlying assumptions on the clinical programmes unchanged. Our valuation shifts modestly to €386.7m or €16.6 per share, from €371.3m or €16.5 per share previously.

Exhibit 7: OSE risk-adjusted net present value

Product	Launch	Peak sales (€m)	NPV (€m)	NPV/share (€)	Probability	rNPV (€m)	rNPV/share (€)
Tedopi - NSCLC (second-line)	2029	690	518.5	22.2	67%	344.2	14.7
Lusvertikimab/OSE-127 - ulcerative colitis	2032	2,360	332.1	14.2	21%	68.1	2.9
Estimated net Cash/(Debt) at 31 December 2026 (including lease liabilities)			(25.5)	(1.1)	100%	(25.5)	(1.1)
Valuation			**825.0**	**35.3**		**386.7**	**16.6**

Source: Edison Investment Research

Exhibit 8: Financial Summary

€000s	2023	2024	2025	2026e	2027e
December	**IFRS**	**IFRS**	**IFRS**	**IFRS**	**IFRS**
PROFIT & LOSS					
Revenue	2,227	83,434	2,691	2,489	7,513
Cost of Sales	0	0	0	0	0
Gross Profit	2,227	83,434	2,691	2,489	7,513
Research and development	(17,158)	(30,444)	(33,932)	(20,180)	(20,364)
Overhead expenses	(6,015)	(6,530)	(8,751)	(6,563)	(6,760)
EBITDA	**(19,566)**	**47,045**	**(34,237)**	**(23,702)**	**(19,055)**
Operating Profit (before amort. and excepts.)	**(22,986)**	**43,735**	**(41,904)**	**(24,255)**	**(19,611)**
Net Interest	(235)	(3,903)	72	(1,117)	(1,390)
Profit Before Tax (norm)	**(23,221)**	**39,832**	**(41,832)**	**(25,372)**	**(21,001)**
Profit Before Tax (reported)	**(23,221)**	**39,832**	**(37,413)**	**(25,372)**	**(21,001)**
Tax	218	(2,387)	(275)	0	0
Profit After Tax (norm)	**(23,003)**	**37,445**	**(42,107)**	**(25,372)**	**(21,001)**
Profit After Tax (reported)	**(23,003)**	**37,445**	**(37,688)**	**(25,372)**	**(21,001)**
Average Number of Shares Outstanding (m)	19.6	21.8	22.3	22.5	22.5
EPS - basic (€)	(1.2)	1.7	(1.9)	(1.1)	(0.9)
EPS - diluted (€)	(1.2)	1.5	(1.7)	(1.1)	(0.9)
BALANCE SHEET					
Fixed Assets	**51,576**	**54,026**	**46,870**	**46,367**	**45,861**
Intangible Assets	46,401	44,010	41,544	41,127	40,710
Tangible Assets	464	355	311	225	136
Short-term deposits/financial assets	910	6,400	1,456	1,456	1,456
Investments	3,801	3,261	5,015	5,015	5,015
Current Assets	**30,478**	**69,935**	**31,986**	**11,114**	**9,694**
Stocks	0	0	0	0	0
Debtors	982	4,138	311	0	0
Short-term deposits/financial assets	0	41,000	5,095	0	0
Cash and cash equivalents	18,672	16,745	17,554	2,088	668
Other	10,824	8,052	9,026	9,026	9,026
Current Liabilities	**18,799**	**20,222**	**24,895**	**28,146**	**19,095**
Trade payables	9,299	7,724	8,823	10,588	11,117
Short term borrowings	6,403	7,199	9,968	11,454	1,874
Other	3,097	5,299	6,104	6,104	6,104
Long Term Liabilities	**40,280**	**39,927**	**26,203**	**16,949**	**15,075**
Long term borrowings	35,508	35,659	21,833	13,347	11,473
Deferred tax liabilities	1,311	1,074	1,215	1,215	1,215
Other long term liabilities	3,461	3,194	3,155	2,387	2,387
Net Assets	**22,975**	**63,812**	**27,758**	**12,386**	**21,385**
CASH FLOW					
Net income	(23,003)	37,445	(37,688)	(25,372)	(21,001)
Movements in working capital	(835)	1,980	2,300	2,076	529
Depreciation and other	3,420	3,310	3,248	553	556
Net Interest	(657)	3,903	(72)	0	0
Tax	(435)	(233)	137	0	0
Others	1,746	2,088	1,522	0	0
Net Cash Flows from Operations	**(19,764)**	**48,440**	**(34,034)**	**(22,743)**	**(19,916)**
Capex	(232)	(77)	(98)	(50)	(50)
Acquisitions/disposals	0	0	1	0	0
Others	(275)	(265)	(22)	0	0
Net Cash Flow from Investing Activities	**(507)**	**(46,909)**	**41,355**	**5,045**	**(50)**
Equity Financing	11,357	1,157	71	10,000	30,000
Debt financing	2,304	(3,336)	(6,402)	(7,000)	(11,454)
Other	(337)	(1,279)	(181)	(768)	0
Dividends	0	0	0	0	0
Net Cash Flow from Financing Activities	**13,324**	**(3,458)**	**(6,512)**	**2,232**	**18,546**
Effect of FX	0	0	0	0	0
Net Cash Flow	(6,947)	(1,927)	809	(15,466)	(1,420)
Opening cash	25,619	18,672	16,745	17,554	2,088
Forex adjustments	0	0	0	0	0
Closing cash	**18,672**	**16,745**	**17,554**	**2,088**	**668**
Closing (net debt)/cash	**(27,129)**	**(29,387)**	**(17,822)**	**(25,520)**	**(15,486)**

Source: Company documents, Edison Investment Research

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