EDISON

# OSE Immunotherapeutics

## Renewed focus on advancing core assets

Strategy and valuation update

Healthcare

9 January 2026

**We revisit our investment case for OSE Immunotherapeutics following the recently presented strategic plans for 2026–28, reflecting a more streamlined focus on advancing its core clinical assets, Tedopi and Lusvertikimab. Tedopi remains on-track in the registrational Phase III ARTEMIA trial in non-small cell lung cancer (NSCLC), with a futility analysis planned in Q326, before a full readout in Q128. For Lusvertikimab, any Phase IIb development in ulcerative colitis (UC) would now be undertaken in partnership, with OSE targeting less capital-intensive indications internally (speciality or rare diseases). Management anticipates needing up to €90m over FY26–28 to support its plans, using a mix of equity, debt and potential milestone payments from partners. With several moving parts, we take a more conservative stance on OSE, with our valuation revising to €371.3m or €16.5 per share (from €560.8m or €25.6 per 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 |
| 12/24 | 83.4 | 39.8 | 1.46 | 0.00 | 3.5 | N/A |
| 12/25e | 1.8 | (32.5) | (1.27) | 0.00 | N/A | N/A |
| 12/26e | 1.5 | (29.4) | (1.31) | 0.00 | N/A | N/A |

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

## Registrational trial for Tedopi on-track

As a reminder, Tedopi is a neoepitope-based, off-the-shelf cancer vaccine. It has already demonstrated efficacy in the Phase III ATALANTE-1 trial, evaluating the candidate in the second- or third-line treatment setting, whereby risk of death was reduced by 41% in the Tedopi arm. It is now being evaluated in ARTEMIA, which commenced in September 2024. This is assessing Tedopi as a second-line monotherapy for NSCLC, after the use of ICIs as first-line treatments. The trial has been designed to randomise participants (expected n=363) 2:1 to receive either Tedopi or docetaxel. The primary endpoint for the trial will be overall survival, while secondary endpoints will be based on patient-reported outcomes and quality of life. Top-line results in Q128 will be a significant inflection point for investor attention.

## Recent management changes

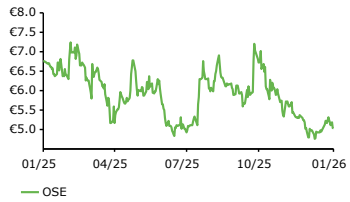
Following OSE's AGM in September 2025, a new board of directors has been announced, including the election of Markus Cappel as chairman and Marc Le Bozec as interim CEO (in place of Nicholas Poirier, who retains his position as CSO). Marc Le Bozec, alongside relatively new CFO Thomas Gidoin, have led a strategic evaluation of the business, focusing on maximising value across partnerships, finances and clinical development programmes.

## Valuation: €371.3m or €16.5 per share

With the new strategy, we reintroduce our estimates, adopting a more conservative stance, in line with management guidance. We now model Lusvertikimab being developed under a licensing agreement in UC and have removed partnered assets from our valuation. We await details on the new indications for Lusvertikimab before incorporating them in our estimates, but acknowledge potential upside from these. Our valuation resets to €371.3m or €16.5/share (from €560.8m or €25.6/share).

| | |
|---|---|
| **Price** | **€5.08** |
| **Market cap** | **€114m** |
| | €0.86/$ |
| Net cash and equivalents at 30 June 2025 | €2.9m |
| Shares in issue | 22.5m |
| Free float | 65.0% |
| Code | OSE |
| Primary exchange | NXT PA |
| Secondary exchange | N/A |

### Share price performance




| % | 1m | 3m | 12m |
|---|---|---|---|
| Abs | (16.4) | (14.7) | (34.5) |
| 52-week high/low | | €7.9 | €4.4 |

### 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 update | Early 2026 |
| ARTEMIA futility analysis | Q326 |
| ARTEMIA results | Q128 |

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## Strategic plan for 2026–28 outlines four value opportunities

OSE's strategic plan aims to accelerate its most promising proprietary clinical programmes (mainly Tedopi and Lusvertikimab) in a cost-efficient manner, creating multiple potential catalysts across the next three years while reaffirming the company's commitment to immunology. As part of this strategy, OSE has presented four key opportunities for value creation.

### 1: Tedopi in NSCLC

Importantly, Tedopi's registrational Phase III ARTEMIA programme continues as planned with the new strategy. OSE has communicated that recruitment is on track to be complete by end-2026. An interim futility analysis is planned in Q326, which will be followed by trial conclusion and a top-line readout of the results in Q128. According to management, limited further financial resources will be required to complete this clinical trial.

Beyond the lead programme for Tedopi, OSE is also engaged in three distinct Phase II programmes with external oncology groups, aiming to expand the clinical utility of Tedopi in additional oncology indications through various combination regimens. These include: with chemotherapy for pancreatic cancer (TEDOPaM, with GERCOR Group); alone or with Keytruda for ovarian cancer (TEDOVA, with ARCAGY-GINECO); and with Opdivo or docetaxel for NSCLC (CombiTED, with FoRT). In our view, these programmes represent cost-efficient opportunities to bolster the value proposition for Tedopi.

### 2: Lusvertikimab in speciality or rare diseases

As part of the strategy, OSE plans to reposition the existing intravenous (IV) formulation of Lusvertikimab, with a new focus on one or two speciality or rare diseases. Precise details, including specific indications and clinical development plans, are due to be revealed in early 2026. Management believes that these plans will require modest financial investment, compared to continuing the clinical development of Lusvertikimab in UC, as part of its commitment to maintaining financial discipline. This also has the potential to expand the value offering for the candidate in the immune-mediated condition space, with a potential faster route to market.

### 3: Enhancing partnering prospects for Lusvertikimab in UC

For Lusvertikimab, OSE plans to develop a subcutaneous 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 data in UC to support a potential precision medicine approach, but will not be conducting the previously planned Phase IIb clinical study. As a reminder, this was based on robust biomarker data indicating strong clinical responses in a subpopulation of UC patients from the Phase II CoTikiS trial, harbouring a specific biomarker (management estimates that this biomarker captures c 30% of the overall UC patient population, potentially offering remission rates in excess of 50% with Lusvertikimab).

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.

### 4: Continue leveraging OSE's differentiated research engine

Finally, OSE will continue to leverage its research engine to create promising new drug development programmes with the potential to address both rare and large indications. This is likely to include exploring potential combination strategies for Lusvertikimab, as well as generating new earlier-stage programmes as the company has done in the past, backed by its innovative discovery platforms. As part of this opportunity for value creation, OSE will optimise its intellectual property profile, seeking maximum value creation, which may enhance partnering prospects.

# Valuation

## In-house programmes

### Tedopi

We update our valuation of OSE to reflect the company's recent strategic repositioning. Tedopi remains the most advanced clinical candidate and a core value driver, underpinning the majority of our risk-adjusted net present value (rNPV). While our core commercial assumptions for Tedopi are largely unchanged, we now assume first market launch in 2029 (from 2028 previously), reflecting greater clarity on clinical timelines, with top-line Phase III ARTEMIA data expected in Q128.

We maintain our peak market penetration assumption of 25%, but increase annual treatment costs to $100k in the US (and $60k in Europe), from $70k previously. This is benchmarked against immune checkpoint inhibitors (ICIs), which typically command list prices of c $200k per annum, and assumes a 50% payer discount in the US. We retain a probability of success of 67% for Tedopi in NSCLC.

Tedopi is also being evaluated in several investigator-sponsored Phase II studies, including in NSCLC in combination with Opdivo, as well as in pancreatic cancer (in combination with chemotherapy) and ovarian cancer (in combination with Keytruda). These indications are not included in our current valuation and, hence, they represent potential upside, should clinical progress continue to be positive.

Consistent with prior assumptions, we model a post-Phase III global licensing agreement for Tedopi, with a total deal value of $715m and a flat royalty rate of 15%. This results in a rNPV of €305.7m, equivalent to €13.6 per share.

### Lusvertikimab

Lusvertikimab, OSE's second in-house clinical candidate, is now anticipated to progress in UC under an out-licensing partnership, using a subcutaneous formulation rather than the existing IV formulation evaluated in the Phase II CoTikiS trial. We assume completion of the subcutaneous formulation and generation of bioequivalence data versus the IV formulation by 2027, leading us to push our assumed partnering transaction to FY27 (from FY25 previously).

We see the strongest clinical and commercial potential in the biomarker-defined subpopulation of patients with moderate-to-severe UC, representing approximately 30% of the overall UC population. In this subgroup, Lusvertikimab achieved a clinical remission rate of 59% in the CoTikiS study (n=22), comparing favourably with the c 25–30% therapeutic ceiling observed with currently approved biologics and JAK inhibitors.

We assume the partner initiates a Phase IIb study in this selected population in 2027, followed by Phase III development and commercial launch in 2029 and 2032, respectively. Given the more targeted positioning, we model a peak penetration rate of 20% and annual treatment costs of $40k in the US and $24k in Europe, translating into peak sales potential of c $2.35bn in UC. However, reflecting the need for bioequivalence data and an additional Phase IIb study (versus a direct progression to Phase III in our prior model), we reduce our probability of success to 21%, from 35% previously.

For Lusvertikimab in UC, we assume a licensing transaction with a total deal value of $650m and a flat royalty rate of 10%. Given the earlier stage of development relative to Tedopi, we assume a more back-end-loaded structure, with c 70% of the value linked to commercial milestones. This results in an rNPV of €62.6m, or €2.4 per share, which we expect to increase as the programme advances clinically.

In addition, Pillar II of OSE's updated strategy is to explore Lusvertikimab's IV formulation in one or two speciality or rare disease indications. Management has guided that each Phase II study would require €10–15m of investment, with specific indications to be disclosed in early 2026. These potential programmes are not yet reflected in our valuation and could provide incremental upside once confirmed.

## Partnered programmes

Given limited visibility on development timelines and partner commitment across OSE's early-stage partnered programmes (AbbVie, Boehringer Ingelheim (BI) and Veloxis), we conservatively exclude these assets from our current

valuation, in line with management guidance. OSE recently announced an amendment to its collaboration with AbbVie, under which OSE will conduct preclinical and Phase I development of ABBV-230, with AbbVie retaining development and commercial rights following successful Phase I completion. In the context of OSE's focus on cash preservation and prioritisation of late-stage in-house assets, we expect this programme to be de-prioritised in the near term.

Similarly, visibility remains limited on BI's plans for BI 770371 and the cis-targeting anti-PD-1/cytokine platform asset, although management has indicated that the associated €17.5m milestone payment, linked to initiation of clinical activity, could be triggered between FY26 and FY28. We will revisit our treatment of partnered programmes as further clarity emerges.

Incorporating the above revisions and the updated net debt position, our rNPV-based valuation for OSE declines to €371.3m or €16.5 per share, from €560.8m or €25.6 per share previously. A detailed breakdown of our rNPV by programme is presented in Exhibit 1.

**Exhibit 1: 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 | 469.6 | 20.9 | 67% | 305.7 | 13.6 |
| Lusvertikimab/OSE-127 – ulcerative colitis | 2032 | 2,350 | 306.0 | 13.6 | 21% | 62.6 | 2.8 |
| Net cash/(debt) at 30 June 2025 (including lease liabilities) | | | 2.9 | 0.1 | 100% | 2.9 | 0.1 |
| **Valuation** | | | **778.5** | **34.7** | | **371.3** | **16.5** |

Source: Edison Investment Research

# Financials

## H125 results: Reflective of a transition period

OSE reported H125 results in October 2025, reflecting a transitional phase for the company following an exceptionally strong prior year period. Revenues/operating income declined sharply to €1.36m, compared with €82.6m in H124, which had benefited from significant non-recurring items, including a €42.2m payment from AbbVie and €40.1m from BI. H125 revenues comprised a €0.7m payment from AbbVie and €0.4m in Tedopi sales generated under the special access scheme.

Total operating expenses increased modestly to €21.5m (H124: €19.3m). R&D expenditure remained broadly stable at €14.8m (H124: €13.9m), primarily driven by the Phase III ARTEMIA study for Tedopi and the Phase II Lusvertikimab programme. R&D costs benefited from the recognition of €3.2m in R&D tax credits during the period. Other operating expenses were €4.5m (H124: €4.3m), with higher external fees largely offset by lower personnel costs. As a result, OSE reported an operating loss of €18.0m in H125, compared with an operating profit of €63.6m in H124, and operating cash outflows of €15.1m versus inflows of €66.4m in the prior year period.

## Estimate revisions: Milestone and partnering inflows pushed out

We have materially revised our revenue forecasts for FY25 and FY26 following the H125 results, the company's updated strategic priorities and improved visibility on near-term plans. We previously assumed receipt of a €17.5m milestone payment from BI and licensing income from a Lusvertikimab partnering transaction in FY25; these inflows are now pushed out to FY27. Consequently, our FY25 revenue estimate is reduced to €1.8m (from €63.5m previously), while our FY26 revenue estimate is revised down to €1.5m (from €101.5m).

On the cost side, we reduce our FY25 R&D expense forecast to €25.6m (from €28.2m) to reflect the H125 run rate and a more focused R&D programme in H225, centred primarily on the Phase III ARTEMIA trial. For FY26, we now model R&D expenditure of €22.8m (from €30.3m previously), reflecting the expectation that the Lusvertikimab Phase IIb UC study will be conducted under a partnership, likely commencing in 2027. Our FY26 estimates currently exclude potential R&D spend related to planned rare and speciality indications, for which further guidance is expected in early 2026. We also modestly adjust our overhead cost assumptions in line with the H125 run rate, to €6.9m in FY25 and €7.1m in FY26 (previously €7.2m and €7.4m, respectively). Overall, we now forecast operating losses of €32.9m in FY25 and €28.4m in FY26, versus operating profits of €28.6m and €64.2m in our prior estimates.

## Funding outlook: Equity raise likely in early FY26

OSE ended H125 with gross cash of €41.6m, comprising €25.4m in cash and €16.2m in term deposits. Total debt stood at €38.7m (including €3.9m in financial leases), consisting primarily of government-backed loans and repayable advances. This includes €15.7m in loans from the European Investment Bank (EIB), which are repayable after June 2027.

Based on current cash resources and our updated cash burn assumptions, we estimate that OSE is funded into H226. We model funding requirements of c €30m in FY26 and c €20m in FY27 to support operations and service debt through FY28, by which point we assume a licensing agreement for Tedopi, including an upfront payment, could be secured. Management has guided to an average funding requirement of around €30m per annum over FY26–29, to be met through a combination of equity issuance, renegotiation of EIB debt terms and partner milestone payments. Given plans to initiate one or two smaller Lusvertikimab studies in 2026, we expect OSE to raise equity capital in early FY26.

## Exhibit 2: Financial summary

| €000s | 2022 | 2023 | 2024 | 2025e | 2026e |
|---|---|---|---|---|---|
| Year end 31 December | IFRS | IFRS | IFRS | IFRS | IFRS |
| **PROFIT & LOSS** | | | | | |
| Revenue | 18,302 | 2,227 | 83,434 | 1,782 | 1,461 |
| Cost of Sales | 0 | 0 | 0 | 0 | 0 |
| Gross Profit | 18,302 | 2,227 | 83,434 | 1,782 | 1,461 |
| Research and development | (26,893) | (17,158) | (30,444) | (25,601) | (22,753) |
| Overhead expenses | (6,673) | (6,015) | (6,530) | (6,857) | (7,062) |
| EBITDA | (14,992) | (19,566) | 47,045 | (27,274) | (27,069) |
| Operating Profit (before amort. and exc | (18,478) | (22,986) | 43,735 | (32,901) | (28,354) |
| Net Interest | 455 | (235) | (3,903) | 382 | (996) |
| Profit Before Tax (norm) | (18,023) | (23,221) | 39,832 | (32,519) | (29,350) |
| Profit Before Tax (reported) | (18,023) | (23,221) | 39,832 | (28,100) | (29,350) |
| Tax | 263 | 218 | (2,387) | 0 | 0 |
| Profit After Tax (norm) | (17,760) | (23,003) | 37,445 | (32,519) | (29,350) |
| Profit After Tax (reported) | (17,760) | (23,003) | 37,445 | (28,100) | (29,350) |
| | | | | | |
| Average Number of Shares Outstandin | 19 | 20 | 22 | 22 | 22 |
| EPS - basic (€) | (1) | (1) | 2 | (1) | (1) |
| EPS - diluted (€) | (1) | (1) | 1 | (1) | (1) |
| | | | | | |
| EBITDA Margin (%) | N/A | N/A | 56 | N/A | N/A |
| Operating Margin (before GW and exce | N/A | N/A | 52 | N/A | N/A |
| | | | | | |
| **BALANCE SHEET** | | | | | |
| Fixed Assets | 54,580 | 51,576 | 54,026 | 48,361 | 47,526 |
| 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 | 1,493 | 1,493 |
| Investments | 4,418 | 3,801 | 3,261 | 4,754 | 4,754 |
| Current Assets | 37,200 | 30,478 | 69,935 | 35,859 | 25,231 |
| Stocks | 0 | 0 | 0 | 0 | 0 |
| Debtors | 403 | 982 | 4,138 | 0 | 0 |
| Short-term deposits/financial assets | 0 | 0 | 41,000 | 9,793 | 9,793 |
| Cash and cash equivalents | 25,620 | 18,672 | 16,745 | 18,014 | 7,386 |
| Other | 11,177 | 10,824 | 8,052 | 8,052 | 8,052 |
| Current Liabilities | 16,268 | 18,799 | 20,222 | 23,352 | 23,711 |
| Trade payables | 8,539 | 9,299 | 7,724 | 8,110 | 8,516 |
| Short term borrowings | 3,093 | 6,403 | 7,199 | 11,982 | 11,935 |
| Other | 4,636 | 3,097 | 5,299 | 3,260 | 3,260 |
| Long Term Liabilities | 42,855 | 40,280 | 39,927 | 27,350 | 14,879 |
| Long term borrowings | 37,231 | 35,508 | 35,659 | 23,677 | 11,742 |
| 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 | 2,063 |
| Net Assets | 32,657 | 22,975 | 63,812 | 33,518 | 34,168 |
| | | | | | |
| **CASH FLOW** | | | | | |
| Net income | (17,760) | (23,003) | 37,445 | (28,100) | (29,350) |
| Movements in working capital | (3,142) | (835) | 1,980 | 2,485 | 406 |
| Depreciation and other | 3,486 | 3,420 | 3,310 | 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 | 2,225 | 0 |
| Net Cash Flows from Operations | (18,253) | (19,764) | 48,440 | (26,601) | (27,660) |
| 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) | 35,664 | (450) |
| Equity Financing | 6 | 11,357 | 1,157 | 0 | 30,000 |
| Debt financing | 11,046 | 2,304 | (3,336) | (7,199) | (11,982) |
| Other | (785) | (337) | (1,279) | (595) | (536) |
| Dividends | 0 | 0 | 0 | 0 | 0 |
| Net Cash Flow from Financing Activitie | 10,267 | 13,324 | (3,458) | (7,794) | 17,482 |
| Effect of FX | 0 | 0 | 0 | 0 | 0 |
| Net Cash Flow | (7,960) | (6,947) | (1,927) | 1,269 | (10,628) |
| Opening cash | 33,579 | 25,619 | 18,672 | 16,745 | 18,014 |
| Forex adjustments | 0 | 0 | 0 | 0 | 0 |
| Closing cash | 25,619 | 18,672 | 16,745 | 18,014 | 7,386 |
| Closing (net debt)/cash | (14,705) | (23,239) | (26,113) | (17,645) | (16,291) |

Source: Company documents, Edison Investment Research

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