EDISON

OSE Immunotherapeutics

Clinical update

Active year ahead for proprietary programmes

Pharma and biotech

OSE has refreshed its outlook for 2024, including the commencement of the confirmatory Phase III trial for lead asset Tedopi (an off-the-shelf, neoepitope-based cancer vaccine) in second-line non-small cell lung cancer (Q224 in the US and extension to European sites in H224), with the recent FDA review and slight timeline adjustment for its lead immuno-inflammation asset, OSE-127, currently in a Phase II trial for ulcerative colitis (UC). Across these proprietary programmes and alongside ongoing partnered programmes, we believe 2024 will be an active year for OSE, with several anticipated milestones and catalysts.

Year end	Revenue (€m)	PBT* (€m)	EPS* (€)	DPS (€)	P/E (x)	Yield (%)
12/21	26.3	(17.2)	(0.95)	0.0	N/A	N/A
12/22	18.3	(18.0)	(0.97)	0.0	N/A	N/A
12/23e	2.7	(26.2)	(1.34)	0.0	N/A	N/A
12/24e	15.0	(21.8)	(0.98)	0.0	N/A	N/A

Note: *PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

Following the positive FDA review for the confirmatory Phase III trial for Tedopi in the second-line setting (following secondary resistance to immune checkpoint inhibitors (ICIs)), OSE expects to launch clinical trials in the US in Q224 followed by Europe in H224. The trial will be supported by a companion diagnostic test to identify HLA-A2-positive patients eligible for Tedopi treatment. We expect the screening test will accelerate patient recruitment for this programme. We remind readers that Tedopi met its primary endpoint in the prior ATALANTE-1 Phase III trial in non-small cell lung cancer patients (third-line setting) but following approval of ICIs in the first-line setting, and based on positive feedback from the FDA and the European Medicines Agency, OSE decided to explore Tedopi as a second-line treatment, a materially larger commercial opportunity. OSE also continues to assess Tedopi in three partnered Phase II combination trials: pancreatic cancer (with chemotherapy; results in 2024), ovarian cancer (with pembrolizumab; results in 2025) and lung cancer (with nivolumab; results in 2025).

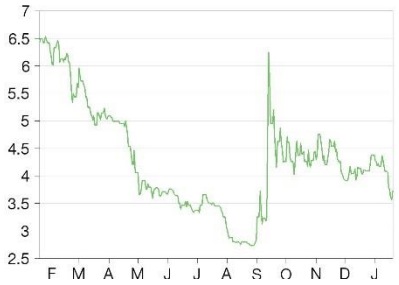
For OSE-127 (Lusvertikimab), patient recruitment is now expected to be complete in Q124, a slight delay over the prior guided timelines (Q323) due to a rebalancing of study sites; results are anticipated in mid-2024. Lusvertikimab (an anti-IL-7 receptor monoclonal antibody) is in the Phase II CoTikiS trial in moderate to severe UC patients. Following a recommendation to include patients naïve of biological treatments (in addition to those post failure of, or intolerant to, previous biological treatments), OSE has decided to redirect trial sites towards Eastern Europe, which has a greater population of such patients. OSE estimates recruitment will be complete in Q124, with results (from induction to week 10 and after six months of maintenance) now expected in mid-2024.

In immuno-oncology, OSE-279 (an anti-PD1 checkpoint inhibitor) is being investigated in a Phase I/II trial for advanced solid tumours and management plans to present updated data (following positive interim readouts) at the end of February 2024 (at the ESMO TAT conference). Management expects to have validated doses and regimens in Q124, which should guide the plans for further clinical studies.

22 January 2024

Price	**€3.73**
Market cap	**€81m**
	€0.92/US$
Pro-forma net debt (€m) at 30 June 2023 (including September equity raise)	8.2
Shares in issue	21.7m
Free float	65%
Code	OSE
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



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.

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