EDISON

OSE Immunotherapeutics

Funding update

New diagnostic test to support Tedopi trial

Pharma and biotech

OSE Immunotherapeutics (OSE) has received €1.5m in non-dilutive funding from Bpifrance (a French public sector investment bank) to develop a companion diagnostic test to support the upcoming Phase III clinical trial for Tedopi, its lead cancer vaccine candidate in non-small cell lung cancer (NSCLC) second-line treatment. Management believes the test will help accelerate the clinical development of Tedopi because it will screen the target HLA-A2-positive NSCLC patients for the Phase III trial. We expect this confirmatory and potentially pivotal Phase III study for Tedopi to be initiated by end-FY23/early-FY24, which will mark a significant clinical milestone in our view. If successful, the trial results could bring significant and potential deal value for future licensing opportunities.

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	15.0	(17.8)	(0.96)	0.0	N/A	N/A
12/24e	15.0	(21.9)	(1.18)	0.0	N/A	N/A

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

OSE intends to develop a diagnostic test that will be used as a predictive immunological biomarker to screen patients with the HLA-A2 genotype, a target population for Tedopi treatment in the upcoming Phase III clinical trial. The diagnostic test, based on blood samples, will be used to enrol eligible patients, which will likely accelerate the patient recruitment process. We would like to highlight that NSCLC accounts for c 85% of lung cancers and the HLA gene is polymorphic, with c 45% of patients expressing the HLA-A2 subtype. Post immune checkpoint inhibitor (ICI) failure, the target population for Tedopi in second-line treatment, data are often considered rare, hence the diagnostic test will likely speed up the patient identification process. We note that Tedopi has orphan drug status in the US and is denoted as a precision medicine in Europe for HLA-A2-positive patients.

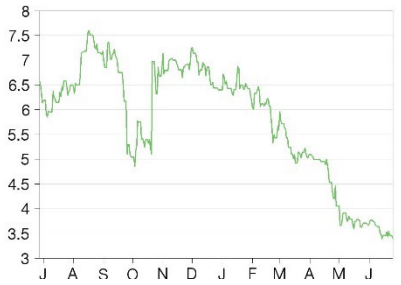
As a reminder, Tedopi, OSE's lead clinical asset, is being developed for treating patients with NSCLC with secondary resistance to ICIs. Tedopi reported positive top-line data from the Phase III ATALANTE-1 trial, demonstrating efficacy and safety in NSCLC patients. However, the data were not sufficient to satisfy the requirements for Tedopi's approval as the study did not achieve its full patient enrolment due to disruption during the COVID-19 pandemic. Following discussions with regulators (the FDA and EMA), a follow-on Phase III confirmatory and potentially pivotal trial is now planned in second-line NSCLC patients post ICI failure. We expect the new study to start by end-FY23/early-FY24, with readouts in FY25–26, and now estimate a launch date for Tedopi in 2028.

With an FY22 gross cash position of €25.6m, and assuming OSE fully exercises its debt and equity committed financing, management has guided for a cash runway into Q224.

26 June 2023

Price	**€3.4**
Market cap	**€63m**
	€0.94/US$
Net debt (€m) at 31 December 2022 (excluding lease liabilities)	14.7
Shares in issue	18.5m
Free float	65%
Code	OSE
Primary exchange	Euronext Paris
Secondary exchange	N/A

Share price performance



Business description

OSE Immunotherapeutics is an immunotherapy company based in Nantes and Paris, France, and 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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Edison profile page

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