OSE Immunotherapeutics (OSE.PA)

OSE Reported First Half 2018 Financial Results and Provided a Corporate Update

Yesterday, OSE Immunotherapeutics (EPA: OSE.PA) reported first half 2018 financial results, and provided a clinical and business update. Major highlights of the half included: **1)** A global license agreement with Boehringer Ingelheim (private) for the development of OSE-172, a monoclonal antibody targeting signal regulatory peptide alpha (SIRPa), worth up to $1.35 billion, and **2)**The Company's sponsored Atalante-1 Phase III study evaluating *Tedopi* in patients with non-small cell lung cancer (NSCLC) received approval from the independent data safety monitoring committee to continue in patients with advanced NSCLC that fail immune checkpoint inhibitor therapy. OSE ended the first half of 2018 with cash and financial assets of €21.5 million ($24.5 million), which is expected to fund operations until H2 2019.

- **Clinical Study with OSE-172 is Expected by Year End.** OSE is developing OSE-172, a first in class humanized IgG4 monoclonal antibody targeting SIRPa, a component of the CD-47 pathway, which we recently reviewed. The Company signed a global partnership with Boehringer Ingelheim in April 2018, to develop OSE-172 in multiple cancer indications. The deal is worth up to $1.35 billion, assuming OSE reaches pre-specified development, commercialization, and sales milestones. OSE plans to initiate a Phase I study evaluating OSE-172 in various cancer indications by the end of 2018, which will trigger a milestone payment of up to €15 million ($18.45 million).
- **Update of Clinical Programs.** OSE is developing several candidates in the immuno-oncology and auto-immune space in addition to OSE-172. **Figure 1** outlines key advancements during H1 2018 and upcoming catalysts for each program.

Expected Upcoming Milestones

- 2018 – Phase II clinical trial evaluating *Tedopi* plus anti-PD-1 inhibition in pancreatic cancer.
- 2018 – Publications regarding OSE-172.
- 2018 – Proof of concept preclinical data with OSE-703 in various cancers.
- End of 2018 – Phase I/II clinical trial evaluating OSE-172 in various cancer indications.
- End of 2018 – Phase I clinical trial evaluating OSE-127in ulcerative colitis or other auto-immune diseases.
- End of 2018 – Phase II study evaluating FR104 in immune mediated diseases.

Analysts

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Market Data

Price	$4.54
Market Cap (M)	$66
EV (M)	$52
Shares Outstanding (M)	14.5
Fully Diluted Shares (M)	15.0
Avg Daily Vol	9,384
52-week Range:	$3.23 - $5.64
Cash (M)	$18.9
Net Cash/Share	$0.96
Annualized Cash Burn (M)	$15.1
Years of Cash Left	1.3
Debt (M)	$5.0

All relevant values covered at 1 Euro to 1.16 USD

Financials

FY Dec		2015A	2016A	2017A	2018A
EPS	H1	(0.34)	2.44	(0.53)	0.38
	H2	NA	NA	NA	NA
	FY	(0.63)	1.77	(0.89)	NA

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Figure 1. Updates and Upcoming Catalysts for Select Candidates in OSE's Pipeline

Candidate	Update	Upcoming catalyst
Tedopi (noepitope vaccine)	○ Pivotal Atalante-1 study resumed in the US, EU, and Israel. As a reminder, the study was amended to include patients with advanced NSCLC that have failed prior immune checkpoint inhibitor treatment. ○ Received a €435,000 ($508,950) grant from Bpifance to evaluate *Tedopi*'s target profile.	○ Initiate a Phase II study of *Tedopi* in combination with a PD-1 inhibitor in pancreatic cancer in 2018.
FR104 (anti-CD28 antibody)	○ Announced preclinical data with FR104 showing synergy between CD28 blockade and mTOR inhibition in a nonhuman primate model of graft-versus host disease.	○ Initiate a Phase II study of FR104 in rheumatoid arthritis (RA) in conjunction with Janssen Biotech (NYSE: JNJ).
OSE-127 (anti-IL7R antibody)	○ Presented data the American Association of Immunologists (AAI) annual meeting in May, showing that OSE-127 significantly decreased inflammation in colon biopsies of patients with inflammatory bowel disease. The study also found that non-responsiveness to anti-TNF therapy is due in part to the deregulation of IL-7 receptor signaling, suggesting a role of IL-7R as a therapeutic target and biomarker (abstract).	○ Expected to initiate a Phase I study of OSE-127 in ulcerative colitis by the end of 2018.

Source: LifeSci Capital

Risk to Investment

We consider an investment in OSE Immunotherapeutics to be a high-risk investment. OSE Immunotherapeutics is a development stage company with no history of taking a treatment to market and currently has no FDA or EMA approved drugs in its portfolio. Furthermore, early indications of efficacy do not necessarily translate into positive late-stage results. Ongoing clinical trials will result in significant additional expenses to the Company and may require additional rounds of dilutive financing. As with any company, OSE Immunotherapeutics may be unable to obtain sufficient capital to fund planned development programs. There are regulatory risks associated with the development of any drug and OSE Immunotherapeutics may not receive FDA or EMA approval for its candidate despite significant time and financial investments. Regulatory approval to market and sell a drug does not guarantee that the drug will penetrate the market, and sales may not meet expectations.

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