Morning Update

BRYAN, GARNIER & CO

23rd September 2021

OSE IMMUNO

Healthcare
Biotech

BUY

TARGET PRICE	EUR17 (+48%)
SHARE PRICE	EUR11.50
EPS 3Y CAGR	NM

Shaping up the pipeline of novel therapies in oncologic and autoimmune indications

Financial visibility until Q3 2022

The company reported H1 2021 financial results and provided corporate update. At the end of H1 2021, OSE reported revenues of nearly EUR9m, which included an upfront payment of EUR7m from Veloxis for FR104, and operating expenses of EUR20.6m, mainly comprised of R&D spent. OSE ended 1H 2021 with EUR27.3m in cash and cash equivalents, adding the loan agreement of EUR25m with EIB, we believe that OSE has sufficient funds to maintain its operations until Q3 2022. We adjust our financial model to reflect 1H21 results.

On track to execute on the strategy

OSE is building a diverse clinical pipeline in oncology and autoimmune indications based on in-depth understanding of immune regulation. During the corporate update the management reminded that OSE's strategy is based on early-stage development of promising therapeutic candidates with the aim to successfully secure attractive partnership agreements. As a testimony to that, in H1 2021 OSE secured yet another licensing deal for FR104 - with Veloxis Pharmaceuticals (a subsidiary of Asahi Kasei), for up to EUR315m in potential milestones, as well as royalties on sales. According to agreement, Veloxis will be responsible for all development, production and commercialization costs for FR104 in transplant indications, while OSE retains the rights for the asset in autoimmune diseases.

During the conference call, OSE revealed target autoimmune indication for FR104 – Grave's disease, for which the phase II study could be initiated by the end of 2021/beginning 2022. Graves' hyperthyroidism is caused by autoantibodies that induce excessive thyroid hormone secretion, which in severe from could lead to life-threatening 'thyroid storm' associated with tachycardia, increased blood pressure, high fever, delirium and a high mortality, as well as severe ophthalmic complication (GO). Considering the role of CD28 in autoimmune processes (see our note from January, 2020) and high unmet medical need for safer therapies in GD, we believe that FR104, could provide novel therapeutic option in this indication. Moreover, the market for GD therapy could also be quite sizable: Tepezza (from Horizon Therapeutics), an only approved treatment for moderate-severe GO is expected to generate sales revenues over USD1.5bn in 2021. We believe that more details on the upcoming phase II study could be provided during OSE's R&D day on October 12.

ESMO presentation provides additional angle for Tedopi

During the 1H21 conference call, the management also discussed recent presentation at ESMO 2021, featuring the final results of the phase III Atalante-1 study of its cancer vaccine Tedopi. The final Atalante-1 data showed positive outcome in the 'population of interest' (PoI). We note that as per ESMO presentation, PoI and statistical plan for this subgroup were discussed with FDA in July 2021 (prior to data lock). PoI was defined as NSCLC patients with who progressed on CT and IO, but after at least 12-week treatment with IO (secondary resistance to IO).

(continued on next page)

Market Data	
Bloomberg / Reuters	OSE FP/OSE.PA
Market Cap.	EUR210m
E.V.	EUR200m
Free Float	0%
Avg. Daily volume (6m)	82.00
12m high / low	EUR15.0 / EUR6.1
Ytd Perf.	59.7%

EURM	12/20	* 12/21e	* 12/22e	* 12/23e
Sales	10.4	18.9	18.1	35.8
% Change		*81.4%*	*-4.3%*	*97.9%*
EBITDA	-19.0	-18.1	-10.8	1.8
% Change		*4.7%*	*40.2%*	*NS*
EBIT	-19.0	-18.1	-10.8	1.8
% Change		*4.7%*	*40.2%*	*NS*
Net Income	-16.6	-11.5	-6.2	5.3
% Change		*30.6%*	*45.8%*	*NS*
ROE	NM	NM	NM	NM

**Data have been modified by at least +/- 5% from last publication*

	12/20	* 12/21e	* 12/22e	* 12/23e
EV/Sales	19.2x	11.1x	11.9x	5.9x
EV/EBITDA	NS	NS	NS	115.3x
EV/EBIT	NS	NS	NS	115.3x
EPS	-1.06	-0.64	-0.35	0.29
% change		*40.0%*	*45.8%*	*NS*
P/E	NM	NM	NM	39.4x
Div Yield	NM	NM	NM	NM

Next Catalyst :

R&D day – October 12th

Last rating Change:

2020-1-13, Winning by DEALing with early-stage programs

Last FV Change:

2021-4-6, Positive 2021 outlook with anticipated advancements of the lead clinical programmes

Last Reports:

2021-9-20, OSE IMMUNO (CORPORATE, TP EUR17) | Tedopi improved mOS for in NSCLC with secondary resistance to IO

RESEARCH AS A SERVICE

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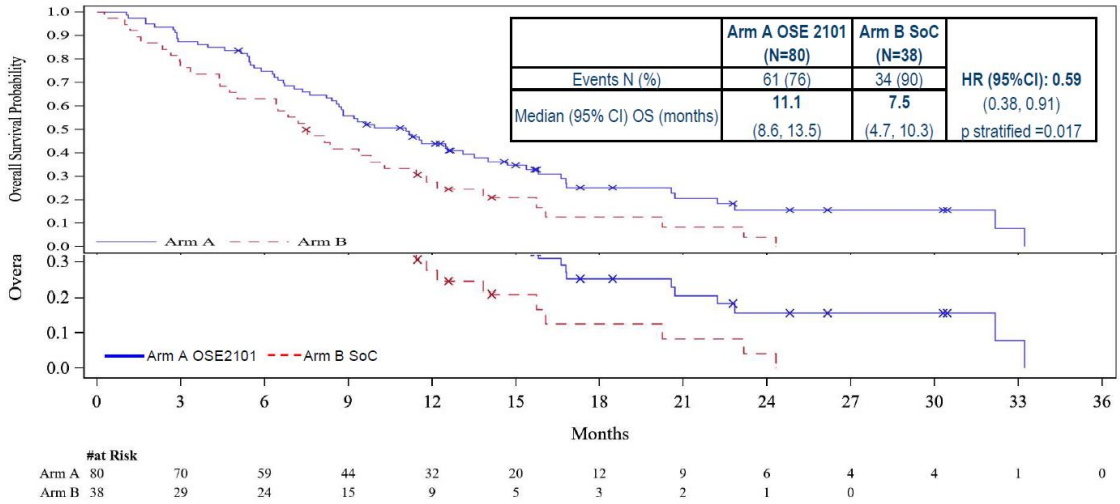
In Pol, Tedopi significantly improved mOS to 11.1 months compared to 7.5 months for SoC (HR=0.59, p=0.02) (Fig. 1), whereas in the total population OS was trending positively, but did not reach statistical significance (HR=0.86, p=0.36). Moreover, there were only 38% of SAEs in Tedopi arm, compared to 68% in SoC and QoL Global Health Status was maintained in Tedopi arm (p<0.05).
On another hand, there was no statistical difference between Tedopi vs SoC arms on 6 months DCR (25% vs 24%), mPFS (2.7mo vs 3.4mo) or ORR (8% vs 18%). During the conference call management pointed out that this is expectable from cancer vaccine due to the mechanism of action. We note that cancer vaccines usually do not show sufficient efficacy as monotherapy and OS improvement in Tedopi's case is quite encouraging. We also remind that patients were allowed to switch to CT post progression on Tedopi. Additionally, the primary endpoint of the Atalante-1 study was mOS, which was successfully met for PoI.

Figure 1: Tedopi improved survival in NSCLC with secondary resistance to IO



Source: Company's ESMO 2021 presentation

Regulatory path forward for Tedopi could soon become more clear

Overall, Tedopi showed positive benefit/risk ratio, with statistically significant benefit on OS in specific subset of NSCLC patients. The company expects to discuss these data with the FDA and define the regulatory path forward. In our view the approval in r/r NSCLC with secondary resistance to IO could require additional clinical study, but overall the results look encouraging. We also note that in Atalante-1 study nearly 50% of initially selected patients had secondary resistance, which represents a significant slice of IO-refractory population. Considering that NSCLC is still a leading cause of cancer death and there are very limited options for these patients post progression on IO, we believe that Tedopi as a monotherapy could enter the segment of NSCLC market with an attractive size.

We also believe that with such clean safety profile and clear signs of clinical activity, Tedopi is a promising combination partner as well. We remind that several combination studies are underway: the phase II TEDOVA study in ovarian cancer in combination with Keytruda, the phase II in NSCLC in combination with Opdivo, and the phase II TEDOPaM study in pancreatic cancer in combination with chemotherapy. In our view, the updates from these studies could further strengthen Tepodi's case and attract sizable partnership agreements.

Changes to our financial model, reiterate TP of EUR17 and assume BUY rating

Following ESMO presentation and positive results in NSCLC with secondary resistance to IO, we update our projection for Tedopi to include this target population, for which we assume the launch in 2025. We assume the PoS of 50%, in-line with the phase III assets in oncology. Additionally, on the back of ESMO data from the phase I study of BI 765063 (see our note from September 17th) we raise PoS for this programme to 15%, from 10% previously. We also now add Grave's disease to our FR104 estimates, for which we expect the company to secure partnership agreement in 2023, with potential launch in 2026. For FR104 in GD we assume PoS of 15%, lower than for similar-stage assets in autoimmune indications as the study yet to be initiated. Following recent pause of the COVID-19 vaccine study and considering the fast pace among the competition, we remove this programme from our financial projections in order to stay conservative in our estimates. The positive effect from changes to Tedopi, BI765063, and FR104 projections was fully offset by removal of CoVepiT. As the result, we reiterate our TP of EUR17 and BUY rating.

Morning Update

BRYAN, GARNIER & CO

OSE IMMUNO

RATING	
Target price	EUR17 (+48%)
Share price	EUR11.50
Market Cap.	EUR210m
EPS 3Y CAGR	NM

Fiscal year end 31/12	2019	2020	* 2021e	* 2022e	* 2023e
Financial Summary					
EPS (EUR)	-0.31	-1.06	-0.64	-0.35	0.29
Restated EPS (EUR)	-0.31	-1.06	-0.64	-0.35	0.29
% change	-184.5%	-239.9%	-40.0%	-45.8%	-
Net dividend (EUR)	0.00	0.00	0.00	0.00	0.00
Average yearly Price	3.7	-	-	-	-
Avg. Number of shares, diluted (m)	14.8	15.6	18.0	18.0	18.0
Historical Entreprise value (EURm)	8.61	-	-	-	-
Valuation (x)					
EV/Sales	0.3x	-	11.13x	11.92x	5.85x
EV/EBITDA	-5.9x	-	NM	NM	NS
EV/EBIT	-5.9x	-	NM	NM	NS
P/E	-11.9x	-	NM	NM	39.35x
Net dividend yield (%)	0.0%	-	NM	NM	NM
Profit & Loss Account (EURm)					
Revenues	26.0	10.4	18.9	18.1	35.8
Change (%)	6%	-60%	81%	-4%	98%
R&D	-21.6	-22.4	-27.0	-22.0	-27.0
Adjusted EBITDA	-1.4	-19.0	-18.1	-10.8	1.8
EBIT	-1.4	-19.0	-18.1	-10.8	1.8
Change (%)	-1.3	-12.1	0.0	-0.4	-
Financial results	0.0	-0.3	-0.2	-0.4	-0.4
Pre-Tax profits	-1.5	-19.2	-18.3	-11.2	1.4
Exceptionals	0.0	0.0	0.0	0.0	0.0
Tax	-3.2	2.7	6.8	5.0	3.8
Profits from associates	0.0	0.0	0.0	0.0	0.0
Minority interests	0.0	0.0	0.0	0.0	0.0
Net profit	-4.6	-16.6	-11.5	-6.2	5.3
Restated net profit	-4.6	-16.6	-11.5	-6.2	5.3
Change (%)	-185%	-257%	-31%	-46%	-
Cash Flow Statement (EURm)					
Operating cash flows	-5	-17	-11	-6	5
Change in working capital	9	-3	0	0	0
Capex, net	5.27	-0.02	0.88	0.88	0.88
Free Cash flow	9	-19	-11	-5	6
Financial investments, net	2.4	-0.5	0.0	0.0	0.0
Dividends	0	0	0	0	0
Capital increase	6	24	10	10	0
Other	-1	-1	0	0	0
Net debt (+)/cash (-)	-15	-11	0	5	-1
Balance Sheet (EURm)					
Tangible fixed assets	1.0	0.9	0.9	0.9	0.9
Intangibles assets	52.6	52.6	51.7	50.8	50.0
Cash & equivalents	25.8	29.4	28.5	32.9	38.8
current assets	7.2	10.5	10.5	10.5	10.5
Other assets	2.3	3.6	3.6	3.6	3.6
Total assets	88.9	97.0	95.2	98.7	103.8
L & ST Debt	11.2	18.9	28.7	38.4	38.2
Provisions	0.4	0.5	0.5	0.5	0.5
Others liabilities	16.8	13.5	13.5	13.5	13.5
Minority interests	0.0	0.0	0.0	0.0	0.0
Shareholders' funds	58.5	61.4	49.9	43.6	48.9
Total Liabilities	30.4	35.6	44.8	54.5	54.3
Ratios					
Gross margin	100.0%	100.0%	100.0%	100.0%	100.0%
EBITDA margin	-5.6%	-182.3%	-95.7%	-59.8%	5.1%
Operating margin	-5.6%	-182.3%	-95.7%	-59.8%	5.1%
Tax rate	-	-	-	-	-
Net margin	-17.9%	-158.9%	-60.8%	-34.5%	14.7%
Dividend payout	0.0%	0.0%	0.0%	0.0%	0.0%

Source: Company Data; Bryan, Garnier & Co ests.

BRYAN, GARNIER & CO

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CONVICTION BUY	The highest possible rating, based on a very strong conviction in the mid/long-term outlook and strategic choices made by a company, and should therefore be reflected in the extent of upside in the associated target price. There is no reason to limit the number of CONVICTION BUY ratings, however they must also reflect some kind of preference in relative terms within a sector.
BUY	This rating should traditionally be applied to companies for which we expect a positive absolute share price performance over a 6 to 12 month period. The opinion is based not only on the TP (which represents theoretical upside relative to the current share price over a 12-month period) but also takes into consideration a number of other factors that may include a SWOT analysis, momentum, technical aspects or the sector backdrop.
NEUTRAL	This rating is the equivalent of a recommendation not to trade in a stock in the short term, either as a buyer or a seller, for many potential reasons. The view is intended to be temporary since it has been proven that few stocks actually remain within a narrow -5%/+5% range over a long period of time. The rating is particularly valid in exceptional market conditions. Our intention is to limit the total number of NEUTRAL ratings to 20%.
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ESG

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	RED	This is a red flag. The rating says that there is at least one topic identified that is simply not acceptable at present state.
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