

Biotechnology

OSE.PA - NXT PA September 22, 2021

Intraday Price 9/22/21	\$13.56
Rating:	Buy
12-Month Target Price:	\$22.00
52-Week Range:	\$7.13 - \$19.18
Market Cap (M):	247.9
Shares O/S (M):	18.3
Float:	59.6%
Avg. Daily Volume (000):	86.6
Debt (M):	\$19.6
Dividend:	\$0.00
Dividend Yield:	0.0%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Expenses ('000)

	2020A	2021E	2022E
H1	€12,935	€20,556A	€21,023
H2	€16,486	€20,000	€22,775
CY	€29,421	€40,556	€43,798
<i>Prior</i>	—	€30,892	€33,730



OSE Immunotherapeutics SA is listed on the Euronext Paris Exchange under the symbol "OSE". The stock does not trade on a US Exchange or OTC. Modeling and historical financials are recorded in euros while the price target, current price, and market data are translated into USD.

EVENT INFORMATION

Immuno-oncology R&D Day

Tuesday, October 12, 2021

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OSE Immunotherapeutics SA

Buy

Reports 1H21; ESMO Highlights; R&D Day Up Next (Oct. 12) – Maintain Buy

Summary

- **OSE Immunotherapeutics reported 1H2021 results yesterday, post-close, with a net loss of (~\$13.6M or €11.6M). The company ended the period with ~\$32M (€27.3M) in cash and cash equivalents on the balance sheet, which should provide runway into CY3Q22.**
- **Two programs in focus at ESMO. OSE presented data from two programs at the recently concluded ESMO Congress (held on Sept. 16-21); both of which generated positive results (more details on page 2):**
 - **P3 Atalante-1 results. Tedopi (off-the-shelf cancer vaccine), in HLA-A2+ non-small cell lung cancer patients after immune checkpoint inhibitor (ICI) failure, demonstrated a clinically meaningful gain in overall survival (OS) of 3.6 months over standard of care (SoC), 11.6 mos vs. 7.5 mos SoC, p=0.017; HR=0.59.**
 - **P1 study: BI 765063 (SIRPα inhibitor)/PD-1 combination cohort. In n=16 evaluable solid tumor patients, preliminary antitumor activity was observed in three patients with advanced colorectal or endometrial cancer, which were confirmed partial responses (PRs). Safety profile was also consistent with prior readout, with no dose-limiting toxicity or on-target, class-related AEs observed, except for one case of anemia (Grade 2).**
- **Conclusion. The ESMO updates provide us with greater confidence in the two drug candidates. However, while positive, the OSE story is not only about Tedopi and BI 765063 ('don't eat me signal,' myeloid checkpoint inhibitor). OSE also has a deep pipeline of earlier-stage programs. With a history of securing non-dilutive funding via partnerships to advance its programs (having received €72M in the last five years from collaborations), we expect OSE to continue this strategy, to mobilize some of its unencumbered assets via partnerships to further unlock value for investors. R&D Day is next (October 12).**

Details

Model update. We are adjusting our operating expense estimates for 2021 to €40.6M, from €30.9M, and for 2022 to €43.8M, from €33.4M, as the company invests additional capital primarily into R&D to reflect increased clinical development efforts. No change to PT.

Tedopi program – ESMO update

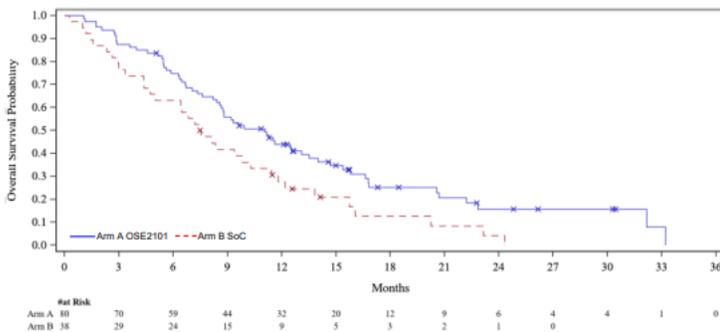
Phase 3 Atalante-1 study. OSE's Tedopi, is an off-the-shelf neoepitope-based cancer vaccine designed to help boost the immune system to recognize and kill the cancer. The open-label, randomized, multi-center Phase 3 Atalante-1 study evaluated Tedopi as a monotherapy as 2L/3L treatment in metastatic, non-small cell lung cancer (NSCLC) HLA-A2+ patients vs. SoC chemotherapy (docetaxel or pemetrexed). The primary endpoint was OS. When the study was initiated in 2016, it was investigating Tedopi in patients that progressed after chemotherapy. However, given the shifting NSCLC landscape with chemo/checkpoints doublet as standard 1L treatment, the study was paused and redesigned in 2018 to evaluate only a subgroup of patients (specifically, chemotherapy-checkpoint {CT-IO} failures that have progressed or Population of Interest {PoI}). A total of 219 patients were enrolled in Atalante 1. 183 (84%) of these patients received sequential CT-IO, of which 118 patients (54%) met the PoI criteria.

(continued on page 2)

Atalante-1 study results (Pol). Final results from the Phase 3 study (n=118, Pol) were announced in a late-breaking presentation at this year's ESMO by Professor B. Besse. Overall, Tedopi demonstrated a favorable benefit/risk ratio profile vs. standard of care (SoC) chemo in advanced HLA-A2+ NSCLC patients with secondary resistance to ICI.

- **Clinical efficacy.** On the primary endpoint, Tedopi demonstrated clinical benefit: an OS of 11.1 mos vs. 7.5 for SoC (p=0.017; HR=0.59). On the secondary endpoint of 6-month progression-free survival (PFS) and overall response rate (ORR), the data did not trend in the same direction. PFS was: 2.7 Tedopi vs.3.2 SoC; ORR was 8% vs.18%, respectively. 6-month disease control rate was 25% Tedopi vs. 24% SoC. Does it matter? The key thing to keep in mind is that cytotoxic therapies like chemo will yield a stronger response or tumor shrinkage in a shorter timeframe, which is reflected in the ORR, for example, whereas cancer vaccines may have a delayed effect as a consequence of their immunological mechanisms of action (MOA). The FDA recognizes this ([Guidance Document for Therapeutic Cancer Vaccines](#)). As such, the gold standard for any late-stage cancer treatment is OS. Accordingly, Tedopi, which acts by reactivating T cells, has a latent effect, as observed in the OS readout. Post-progression survival was also significantly longer on the Tedopi arm (8.6 months versus 3.3 months; p=0.0005).
- **Safety.** Fewer severe adverse events (SAEs) were observed with Tedopi (Tedopi 38% vs. SoC 68%, p<0.001).
- **Quality of life:** ECOG deterioration took significantly longer in the Tedopi arm (8.6 months vs. 3.3 months; p=0.0005)

Exhibit 1. Atalante-1 P3 Final Results – Overall Survival. Tedopi demonstrated a clinical benefit of 3.6 months in OS over standard of care chemo (an OS of 11.1 mos vs. 7.5 for SoC {p=0.017; HR=0.59}), as seen by the clear separation of the curves in the Pol population.



	Arm A OSE 2101 (N=80)	Arm B SoC (N=38)	HR (95%CI): 0.59 (0.38, 0.91) p stratified =0.017
Events N (%)	61 (76)	34 (90)	
Median (95% CI) OS (months)	11.1 (8.6, 13.5)	7.5 (4.7, 10.3)	

Source: Company Reports, Besse B. et al., ESMO 2021.

Next steps. OSE is expected to engage with regulatory agencies (EMA and FDA) within the next 6 months to determine the best path forward for Tedopi. Although the Atalante-1 results are compelling, given the start and stop in the study, OSE may have to run an additional trial to add to the 118 patient numbers to fortify the results further, in order to gain regulatory approval.

Exhibit 2. Tedopi combination studies underway. Tedopi is also being explored in additional indications by several cooperative groups: **(1)** the Italian oncology foundation, FoRT (Fondazione Ricerca Traslazionale), will explore Tedopi in combination with Bristol's (BMY–NR) anti-PD-1 Opdivo as 2L treatment in HLA-A2+ NSCLC after first-line chemo-IO; **(2)** GERCOR, a not-for-profit oncology cooperative group based in France (with a network of 200 centers), will carry out a study in pancreatic cancer (TEDOPI/ FOLFIRI vs. FOFIRI); and **(3)** the Association de Recherche sur les Cancers dont GYNécologiques (ARCAGY-GINECO) will investigate Tedopi as maintenance therapy, following platinum-based chemotherapy and Avastin and a PARP inhibitor, (Tedopi as monotherapy or in combination with Keytruda vs. best supportive care) in recurrent ovarian cancer.



Source: Company Reports.

BI 765063 program – ESMO update

BI 765063 blocks the ‘don’t eat me signal’ by targeting SIRP α of the CD47:SIRP α axis. As a reminder, the gene encoding human SIRP α is polymorphic; that is, it comes in several different forms. The two most prevalent variants are SIRP α V1 and SIRP α V2. BI 765063 is a SIRP α inhibitor that binds to the V1 SIRP α allele with high affinity, but it also binds to the V2 SIRP α allele with low affinity. Since BI 765063 targets SIRP α , which is more narrowly expressed than CD47, it is expected to exhibit a superior safety profile (i.e., lower target sink and limited, or reduced, rates of anemia and cytopenia) to other product candidates directly targeting CD47 with similar efficacy. CD47 is expressed on red blood cells and platelets whereas SIRP α is not. In addition, BI 765063 lacks SIRP γ binding. As such, T-cell activation is preserved.

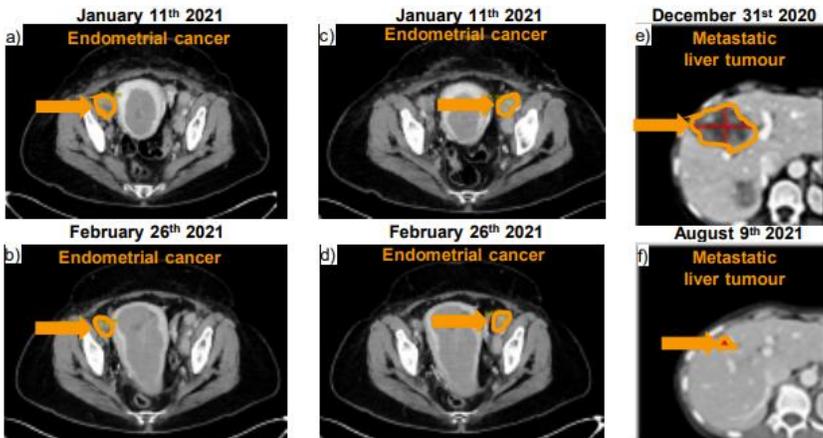
BI 765063 Study design. The Phase 1 clinical trial is a two-step, open-label, multi-center study, evaluating the safety and efficacy of BI 765063 as monotherapy and in combination with ezabenlimab (BI 754091, an anti-PD-1) in SIRP α V1/V1 or V1/V2 heterozygous patients with advanced solid tumors. In the completed Step 1 monotherapy portion (n=50), nine doses of BI 765063 were evaluated (reported at ASCO 2021). This was followed by the combination portion (n=18) where two doses of BI 765063 (18 and 24 mg/kg IV every 3 weeks) were assessed in combination with BI 754091 (240mg IV every 3 weeks) (reported at ESMO 2021). Primary endpoints were dose-limiting toxicities (DLTs), maximum tolerated dose (MTD), and recommended Phase 2 dose (RP2D). Step 2 is the dose confirmation/expansion portion, which will begin recruiting patients shortly.

BI 765063 (myeloid checkpoint) data is starting to build. At this year’s ESMO, combination data from the Step 1 portion of the study was reported. Eighteen patients received one or more doses of BI 765063 (18/24mg/kg q3w) and anti-PD-1 ezabenlimab (240mg q3w): nine V1/V1 patients and nine V1/V2 patients. Eight patients (44.4%) had prior PD-1 therapy, while the remaining were PD-1 naïve. All had failed standard therapies. Sixteen patients (up from 12 in the abstract) were evaluable for efficacy. The most frequent tumor types were CRC (n=4), endometrial (n=3), liver cancer (n=2), and cervical cancer (n=2).

Data highlights:

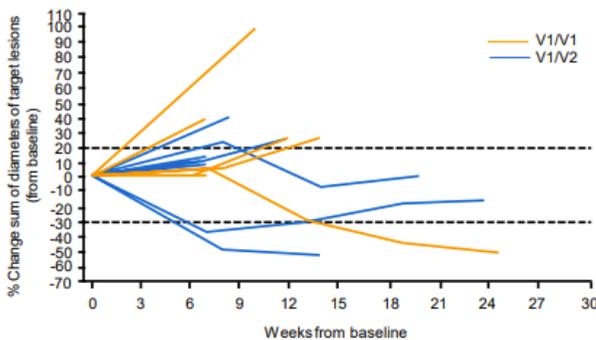
- **Efficacy:** three confirmed partial responses (PR) in patients with microsatellite stable (MSS) advanced endometrium or colorectal cancer (increased from two PRs described in ESMO abstract); in addition, one patient with hepatocellular carcinoma (HCC) had a partial response with BI 765063 monotherapy, which is still ongoing (>9 months reported at ASCO 2021).
- **Safety:** anti-SIRP α BI 765063 with BI745091 was well-tolerated with no dose-limiting toxicities (DLTs); MTD was also not reached. Important to note, no thrombocytopenia, lymphopenia, nor neutropenia was observed (which is typical of the class) and only one case of anemia (Grade 2) was seen.
- **Dosing:** RP2D and dosing schedule of BI 765063 was determined as 24mg/kg; full receptor occupancy (RO) occurred with a once-every three-week dosing schedule.

Exhibit 3. Activity in patients with microsatellite stable (MSS) tumors. Shown are CT scans of two patients: a V1/V2 heterozygous 72-year-old female patient with endometrial cancer (a,b,c,d); V1/V1 homozygous 44-year-old female patient with MSS CRC (e,f). Before treatment (a,c, e) and after combo treatment (b, d, f). Both patients had confirmed PRs; one with target lesion shrinkage of 37% (e) and another was 50% (f).



Source: Kotecki N et al., ESMO 2021.

Exhibit 4. BI 765063 has activity in both SIRP α V1/V1 and V1/V2 patients. Spider plot of percentage change in sum of diameters of target lesions from baseline. While BI 765063 is known to bind the V2 SIRP α less tightly, both alleles appeared to respond to the drug combination, which increases the expected patient pool for OSE's / Boehringer's BI 765063 (from the initial anticipated V1/V1 population).



Source: Kotecki N et al., ESMO 2021.

Patient characteristics of those that achieved a PR: Patient 1 had MSS endometrial cancer (PD-L1 CPS 46%, three prior lines of therapy) and achieved a maximum target shrinkage of 37%. Patient 2 had endometrial cancer (microsatellite and PD-L1 status unknown, two prior lines of therapy), and a maximum tumor lesion shrinkage of 53%. Patient 3 had MSS colorectal cancer (PD-L1 CPS 6.3%, five prior lines of therapy), and a 50% maximum target lesion shrinkage.

The takeaway? MSS cancers are FDA-validated biomarkers. However, currently approved checkpoints (such as PD-1s/PD-L1s) to date have demonstrated modest activity in tumors expressing MSS. For reference, in a recent study (GARNET trial) reported at this year's ESMO on GlaxoSmithkline's (GSK-NR) anti-PD1, dostarlimab evaluated in patients with endometrial cancer (Abstract #76P), achieved an ORR of 13.4% in MSS vs. 44.7% in microsatellite instability high/hypermethylated (MSI-H) patients. Thus far, in endometrial cancer, for instance, checkpoints are only approved in MSI-H tumors or mismatch repair deficient (dMMR) tumors. Here, while the sample size is very small, an overall response rate (ORR) of at least 66% (2/3, given that one MSS status was unknown) was seen. Importantly, MSI-H tumors comprise only 30% of endometrial cancer. The majority of colorectal as well as endometrial cancers are MSS.

The BI 765063 program is less advanced in the clinic, relative to some of its 'CD47:SIRP α peers. However, with superior safety to date (in at least 68 patients), BI 765063 could potentially emerge as best-in-class, if the efficacy data can be replicated in a larger setting.

Next steps. The expansion portion of the Phase 1b (Step 2) will begin recruiting patients with MSS colorectal (n=30) and endometrial cancer (n=10) soon. While partner Boehringer is expected to also explore the combination in the V1/V2 population in addition to V1/V1, this expansion study that OSE is conducting will only recruit SIRP α V1/V1 homozygous patients. Note, the makeup of the SIRP α allele patient population in the US/EU is as follows: V1/V1 is ~45%, V1/V2 is ~45%, and V2/V2 is ~10%. While OSE moves on to the expansion phase of the Phase 1 study, BI is already working on clinical trials that the company will want to pursue. Although there may be additional translational data presented at a medical conference, we expect initial proof of concept (PoC) clinical data from the expansion cohort potentially sometime in 2022.

Exhibit 5. Catalysts in the next 6 months. Multiple operational updates are expected in the coming six months as the clinical programs advance. Near-term, we are watching for the US IND for FR104 in kidney transplant patients to be accepted by the FDA, which is expected to trigger a milestone payment from partner Veloxis Pharmaceuticals (details unknown); additional details from the Phase 3 Atalante-1 study results at the upcoming R&D Day (Oct. 12); as well as the futility analysis report on the OSE-127 program in ulcerative colitis. In addition, there may be an update by YE21 on the status of the CoVePiT program, which was paused earlier in the year (whether it will be re-initiated or discontinued).

Disease area	Program	Partner	Catalyst	Timing
NSCLC	Tedopi®		Results presentation	Q4' 21
Transplantation	FR104		IND US	Q4' 21
Ulcerative Colitis	OSE-127 / S95011		Futility analysis	Q1' 22
Graves' disease	FR104		Ph 1 start	Q1' 22
Niche tumour indication	OSE-279		Ph 1 start	H1' 22

Immuno-oncology R&D update on 12th October

Source: Company Reports.

OSE Immunotherapeutics SA (OSE.PA)

OSE Immunotherapeutics (OSE.PA) Income Statement (€000) YE December 31	FY 2018A	FY 2019A	FY 2020A	1H21A	2H21E	FY 2021E	FY 2022E	FY 2023E	FY 2024E	FY 2025E	FY 2026E	FY 2027E	FY 2028E	FY 2029E	FY 2030E
Product Revenue:															
Tedopi - NSCLC								60,446	74,811	109,021	124,330	133,832	137,355	141,001	159,253
BI 765063 (OSE-172: SIRPa) - solid tumors								-	-	4,465	10,059	47,546	111,908	138,227	171,462
FR104 (CD28) - RA								-	-	-	-	20,061	60,242	79,595	90,884
FR104 (CD28) - transplant (kidney)								-	-	-	262	2,592	5,168	11,772	18,357
OSE-127 (IL-7R) - UC								-	-	-	-	3,467	46,637	58,966	106,140
OSE-127 (IL-7R) - SS								-	-	-	3,097	4,774	22,897	36,976	51,815
Turnover	24,456	25,952	10,418	8,975	5,000	13,975	20,000	12,000	10,000	12,000	12,000	10,000			
Other operating revenue			13												
Net revenue	24,456	25,952	10,431	8,975	5,000	13,975	20,000	72,446	84,811	125,486	149,749	222,272	384,207	466,536	597,911
Collaborative revenue:															
Total Revenue	24,456	25,952	10,431	8,975	5,000	13,975	20,000	72,446	84,811	125,486	149,749	222,272	384,207	466,536	597,911
Gross Margins:															
Cost of Goods Sold											44,925	66,682	115,262	116,634	149,478
Gross Profit	24,456	25,952	10,431	8,975	5,000	13,975	20,000	72,446	84,811	125,486	104,824	155,591	268,945	349,902	448,433
Operating Expenses:															
Research and development expenses	15,057	21,655	22,355	13,980	14,000	27,980	30,778	32,317	33,933	35,629	37,411	39,281	41,245	43,308	45,473
Overhead expenses	3,448	3,898	4,783	3,413	3,200	6,613	6,944	7,291	7,655	8,038	8,440	8,862	9,305	9,770	10,259
Expenses related to shares payments	977	1,868	2,283	2,724	2,800	5,524	6,076	6,380	6,699	7,034	7,386	7,755	8,143	8,550	8,978
Other operating products	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other operating expenses	127	2	-	-	-	-	-	-	-	-	-	-	-	-	-
Depreciation				439		439									
Total Expenses	19,609	27,423	29,421	20,556	20,000	40,556	43,798	45,988	48,287	50,702	98,161	122,580	173,956	178,262	214,187
Operating Income (Loss)	4,847	(1,472)	(18,990)	(11,581)	(15,000)	(26,581)	(23,798)	26,458	36,524	74,785	51,587	99,692	210,251	288,274	383,724
Financial products	86	221	31	9		9									
Financial expenses	(227)	(213)	(288)	(189)		(189)									
Interest and other income	-	-	-	-		-									
Total Other Income	(141)	8	(257)	(180)	-	(180)	-	-	-	-	-	-	-	-	-
Pretax Income	4,707	(1,464)	(19,247)	(11,761)	(15,000)	(26,761)	(23,798)	26,458	36,524	74,785	51,587	99,692	210,251	288,274	383,724
Income tax benefit (expense)	783	3,188	(2,692)	(273)	-	(273)	-	-	-	-	-	-	10,513	14,414	30,698
Tax Rate													5%	5%	8%
GAAP Net Income (Loss)	5,490	(4,652)	(16,555)	(11,488)	(15,000)	(26,488)	(23,798)	26,458	36,524	74,785	51,587	99,692	199,739	273,860	353,026
Foreign currency translation loss				36		36									
Total comprehensive loss	5,490	(4,652)	(16,555)	(11,452)	(15,000)	(26,452)	(23,798)	26,458	36,524	74,785	51,587	99,692	199,739	273,860	353,026
GAAP-EPS	0.38	(0.31)	(1.06)	(0.64)	(0.83)	(1.47)	(1.19)	1.32	1.82	3.71	2.56	4.93	9.85	13.48	17.35
GAAP-EPS (Dil)	0.35	(0.31)	(1.06)	(0.64)	(0.83)	(1.47)	(1.19)	1.32	1.82	3.71	2.56	4.93	9.85	13.48	17.35
Wgtd Avg Shrs (Bas) - '000s	14,635	14,892	15,556	17,983	18,001	17,992	20,029	20,069	20,109	20,150	20,190	20,230	20,271	20,311	20,352
Wgtd Avg Shrs (Dil) - '000s	15,070	14,892	15,556	17,983	18,001	17,992	20,029	20,069	20,109	20,150	20,190	20,230	20,271	20,311	20,352

Source: Company reports and Maxim

DISCLOSURES

OSE Immunotherapeutics SA Rating History as of 09/21/2021

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution		As of: 09/21/21	
		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	87%	53%
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither outperform nor underperform its relevant index over the next 12 months.	13%	44%
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	0%	0%

**See valuation section for company specific relevant indices*

I, Naureen Quibria, Ph.D., attest that the views expressed in this research report accurately reflect my personal views about the subject security and issuer. Furthermore, no part of my compensation was, is, or will be directly or indirectly related to the specific recommendation or views expressed in this research report.

The research analyst(s) primarily responsible for the preparation of this research report have received compensation based upon various factors, including the firm's total revenues, a portion of which is generated by investment banking activities.

Maxim Group makes a market in OSE Immunotherapeutics SA

Maxim Group expects to receive or intends to seek compensation for investment banking services from OSE Immunotherapeutics SA in the next 3 months.

OSE.PA: For OSE Immunotherapeutics SA, we use the BTK (NYSE Biotechnology Index) as the relevant index.

Valuation Methods

OSE.PA: We model commercialization of Tedopi in 2L+ non-small cell lung cancer in 2023 (EU & US), with a 50% risk adjustment. We model the remaining launches with a 30% risk adjustment: BI 765063 in 2025 (EU & US); FR104 in kidney transplantation in 2026 (US) and 2027 (EU), in rheumatoid arthritis in 2027(EU) and 2028 (US); OSE-127 in ulcerative colitis in 2027 (EU) and 2028 (US), in Sjögren's Syndrome in 2026 (EU). A 30% discount is applied to the free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive a 12-month price target.

Price Target and Investment Risks

OSE.PA: Aside from general market and other economic risks, risks particular to our price target and rating for OSE Immunotherapeutics SA. include: (1) the regulatory and clinical risk associated with product development; (2) the rate and degree of progress of product development; (3) the rate of regulatory approval and timelines to potential commercialization of products; (4) the level of success achieved in clinical trials; (5) the requirements for marketing authorization from regulatory bodies in the United States and other countries; (6) the liquidity and market volatility of the company's equity securities; (7) regulatory and manufacturing requirements and uncertainties; (8) product and technology developments by competitors, potentially with more resources and commercial infrastructure; (9) inability, of product(s), if approved, to gain adequate market share; (10) impact of comprehensive tax reform in the US and Ex-US tax policy; (11) delays related to COVID-19 could impact the company's ability to operate and conduct clinical trials; (12) failure of third-parties to meet contractual obligations, potentially impacting drug development; (13) inability to satisfy existing and/or future debt obligations; (14) the ability to access capital, via equity financing or convertible debt securities, as well as currently outstanding and possible future warrants and convertible preferred shares, will likely have a dilutive effect on shareholders; (15) OSE relies on partnership revenues to advance some of its pipeline, and if that capital is not available, it may need to cease some of its operations; (16) the shares are listed on the Euronext Paris Exchange; the shares are not listed in the US.

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Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. Price Volatility: Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

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Medium – Fundamental Criteria: This is a risk rating assigned to companies that may have average revenue and earnings visibility, positive cash flow, and is fairly liquid. Accordingly, both price volatility and fundamental risk are expected to approximate the industry average.

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Corporate Headquarters

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Institutional Sales Trading: 212-895-3873

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