Tiziana Life Sciences PLC (TLSA)
Rating: Buy

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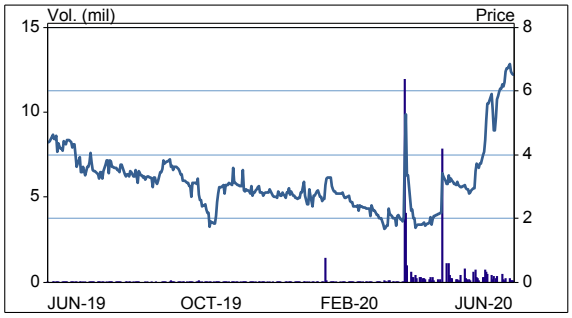
Grant Awarded in Alzheimer's Disease; StemPrintER Data; Reiterate Buy

Stock Data	06/04/2020
Price	$6.50
Exchange	NASDAQ
Price Target	$25.00
52-Week High	$7.70
52-Week Low	$1.54
Enterprise Value (M)	NA
Market Cap (M)	$209
Public Market Float (M)	8.8
Shares Outstanding (M)	30.7
3 Month Avg Volume	650,852
Short Interest (M)	0.07
Balance Sheet Metrics	
Cash (M)	£11.7
Total Debt (M)	£0.0
Total Cash/Share	£0.38
Book Value/Share	£(0.03)

General: Shares officially quoted in pence on London Exchange; American Depositary Shares trade on NASDAQ in dollars; HCW price target in dollars; estimates reflect pounds. Cash: pro forma.

EPS Diluted			
Full Year - Dec	2019E	2020E	2021E
1st Half	£(0.03)A	£(0.04)	£(0.05)
2nd Half	£(0.02)	£(0.04)	£(0.06)
FY	£(0.05)	£(0.08)	£(0.11)



Grant award to explore intranasal foralumab in Alzheimer's. In a press release yesterday, Tiziana announced that the Chairman of its Scientific Advisory Board (SAB), Dr. Howard Weiner, has received a competitive research grant from the National Institutes of Health (NIH) to investigate nasal anti-CD3 for the treatment of Alzheimer's disease (AD). The demonstration that nasally-administered anti-CD3 retards disease processes underlying the progression of AD in animal models further expands clinical development of nasally-administered foralumab, the only entirely human anti-CD3 monoclonal antibody, for the potential treatment of Alzheimer's and other neurodegerative diseases in humans. Intriguingly, Dr. Weiner unexpectedly found that nasal anti-CD3 modulates brain microglia in animal models. A landmark publication in the journal *Science* published in February of this year (Wang *et al*., *Science* 367: 688 - 694) clearly showed that activated microglia essentially 'erase' memories in mice. As a reminder, Tiziana has a worldwide exclusive license for nasal administration of anti-CD3 mAbs for treatment of neurodegenerative diseases, including AD, from Brigham and Women's Hospital, Harvard Medical School, Boston. Thus far, the company has successfully completed two Phase 1 trials and intends to initiate two Phase 2 trials with nasally and orally administered foralumab shortly for treatment of progressive multiple sclerosis and Crohn's disease, respectively. We reiterate our Buy rating and 12-month price target of $25 per ADS on TLSA.

Multiple foralumab formulations target lucrative indications. Tiziana has established three different routes of administration for its anti-CD3 fully-human monoclonal antibody, foralumab—an oral capsule for treatment of Crohn's disease (CD); an intranasal formulation for secondary progressive multiple sclerosis (SP-MS), along with AD as well; and an inhaled form to address lung inflammation and dysfunction in patients infected with the SARS-CoV-2 coronavirus, which is responsible for the COVID-19 pandemic. We anticipate that proof-of-concept studies could start within six to 12 months for oral foralumab in CD and intranasal foralumab in SP-MS. Conservatively, we do not currently include any contribution from future sales of foralumab in any indication beyond CD in our valuation assessment. Positive clinical data with foralumab for indications representing massive markets like AD and MS could thus constitute considerable upside to our assumptions.

StemPrintER and SPARE validation data presented at ASCO. In a poster presented at the virtual American Society for Clinical Oncology (ASCO) 2020 Annual Meeting (abstract #1057), scientists showcased data benchmarking the StemPrintER and SPARE (together referred to as StemPrintER) approaches against Oncotype DX, a well-known test used to predict the likelihood of breast cancer recurrence. This was a substantive data set comprising a 1,827-subject ER+/HER2- breast cancer patient cohort with 15-year follow-up from the European Institute of Oncology in Milan, Italy. StemPrintER delivered roughly 20% superiority to the Clinical Treatment Score (CTS) in providing prognostic information in all ER+/HER2- breast cancer patients. Crucially, in lymph node-negative (N0) and lymph node-positive (N1-3) patients, StemPrintER outperformed Oncotype DX by roughly 40 - 50%. StemPrintER adds prognostic value to CTS, but not vice versa.

Second cohort confirms StemPrintER superiority. A second poster (abstract #1020) presented at ASCO provided additional confirmation of the predictive edge for StemPrintER relative to the Oncotype DX approach. This comparison was made in an 818-patient data set known as the TransATAC cohort. StemPrintER significantly stratified high- vs. low-risk groups when adjusted for clinical parameters as expressed by the Clinical Treatment Score (CTS), identifying patients with a very low 10-year distant recurrence (DR) cumulative incidence across all subjects, as well as lymph node negative (N0) and lymph node positive (N1-3) patients. StemPrintER was shown to add prognostic information on top of CTS in the overall period as well as in both early (0-5 years) and late (5-10 years) intervals, among all patients, as well as in N0 but not N1-3 patients. Lastly, StemPrintER outperformed Oncotype DX in 10-year DR risk prediction in all patients, as well as in N0 and N1-3 patients, while showing superiority to Oncotype DX in adding prognostic information to CTS. StemPrintER significantly stratifies patients at high vs. low recurrence risk among low and intermediate, but not high, pre-specified Oncotype DX groups. We believe that despite the fact that the StemPrintER performance data were generated on retrospective data sets, the totality of the evidence appears compelling. This is driven by a) the size of the cohorts used and b) the fact that there was concordance between the cohorts, confirming the predictive power of StemPrintER and its superiority to Oncotype DX.

StemPrintER platform may disrupt breast cancer prediction. As a reminder, the genomics-based expression analysis underlying the original StemPrintER approach consists of a proprietary 20-gene stem cell signature derived from the transcriptional profile of normal mammary stem cells. This is capable of identifying breast cancers denoting poor prognoses via *in silico* analysis (i.e., using an algorithmic method). SPARE is an evolutionary iteration of this strategy, adding two well-established predictive clinicopathological parameters—lymph nodal status and tumor size—to the same 20-gene signature. A subset of five genes within this signature panel has been shown to retain similar predictive value, indicating that further optimization of the approach even beyond SPARE could be achieved.

Valuation methodology, risks and uncertainties. We use a discounted cash flow (DCF)-driven risk-adjusted net present value (rNPV) approach, which yields a ~$950M total firm value and price target of $25 per ADS, given 157M projected shares outstanding (roughly 31.4M ADSs based on five ordinary shares per ADS) as of mid-2021. Exchange rate: 1 US$ = £0.81. Investors should note that our valuation excludes all contribution from foralumab in areas beyond Crohn's disease; milciclib in cancers beyond HCC; TZLS-501 for any indication; and StemPrintER. Risks include: (1) delays in clinical studies with foralumab and milciclib; (2) adverse trial results with foralumab and milciclib; (3) negative regulatory decisions; (4) lower-than-anticipated market penetration rates; and (5) possible dilution risk.

Table 1: Tiziana Life Sciences PLC (TLSA)—Historical Income Statements, Financial Projections

FY end December 31
£ in thousands, except per share data

	2019E					2020E					
		1HA		2HE	2019E	1QE	2QE	3QE	4QE	2020E	2021E
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Service revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-
Expenses											
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-
Research & development	-	1,507	-	1,200	2,707	1,000	1,200	1,500	1,600	5,300	9,900
General and administrative	-	2,202	-	1,500	3,702	1,600	1,600	1,600	1,600	6,400	8,000
Total expenses	-	3,709	-	2,700	6,409	2,600	2,800	3,100	3,200	11,700	17,900
Gain (loss) from operations	-	(3,709)	-	(2,700)	(6,409)	(2,600)	(2,800)	(3,100)	(3,200)	(11,700)	(17,900)
Other income/expense											
Interest income/expense	-	(5)	-	(5)	(10)	-	-	-	-	-	-
Realized loss on marketable securities	-	-	-	-	-	-	-	-	-	-	-
Other income/expense	-	-	-	-	-	-	-	-	-	-	-
Total investment income and other	-	(5)	-	(5)	(10)	-	-	-	-	-	-
Loss before provision for income taxes	-	(3,714)	-	(2,705)	(6,419)	(2,600)	(2,800)	(3,100)	(3,200)	(11,700)	(17,900)
Provision for tax		27			27					-	-
Net loss/income	-	(3,687)	-	(2,705)	(6,392)	(2,600)	(2,800)	(3,100)	(3,200)	(11,700)	(17,900)
Net loss per share (basic)	-	(0.03)	-	(0.02)	(0.05)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	(0.11)
Net loss per share (diluted)	-	(0.03)	-	(0.02)	(0.05)	(0.02)	(0.02)	(0.02)	(0.02)	(0.08)	(0.11)
Weighted average number of shares outstanding (basic)	-	126,049	-	126,049	126,049	142,716	144,741	151,791	156,841	149,022	156,966
Weighted average number of shares outstanding (diluted)	-	126,049	-	126,049	126,049	142,716	144,741	151,791	156,841	149,022	156,966

Source: Company reports and H.C. Wainwright & Co. estimates.

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RETURN ASSESSMENT

Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

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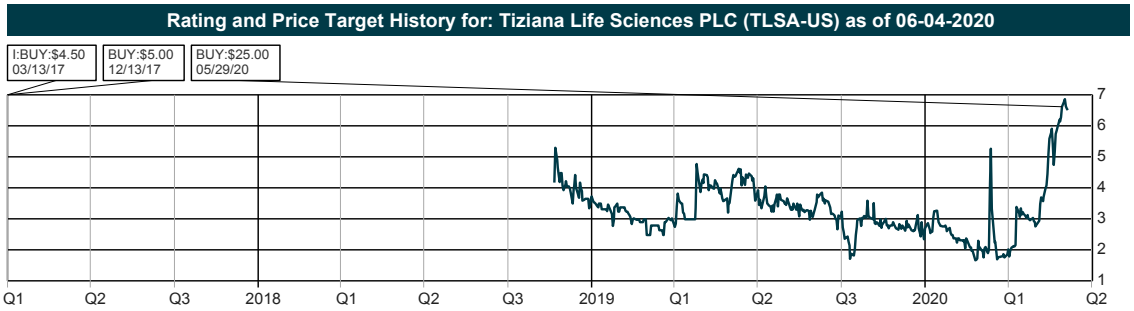

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Distribution of Ratings Table as of June 4, 2020				
			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	385	90.59%	135	35.06%
Neutral	37	8.71%	7	18.92%
Sell	0	0.00%	0	0.00%
Under Review	3	0.71%	3	100.00%

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