Tiziana Life Sciences PLC (TLSA)
Rating: Buy

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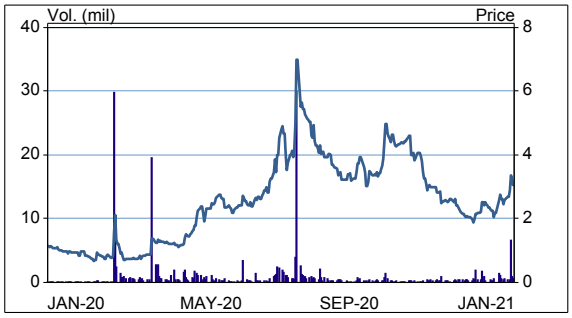
Foralumab Trial Complete; Chief Medical Officer Appointed; Reiterate Buy

Stock Data	01/15/2021
Price	$3.04
Exchange	NASDAQ
Price Target	$11.00
52-Week High	$12.17
52-Week Low	$0.62
Enterprise Value (M)	$353
Market Cap (M)	$404
Public Market Float (M)	25.1
Shares Outstanding (M)	177.8
3 Month Avg Volume	515,871
Short Interest (M)	0.41
Balance Sheet Metrics	
Cash (M)	$51.5
Total Debt (M)	$0.0
Total Cash/Share	$0.29
Book Value/Share	$(0.08)

General: American Depositary Shares trade on NASDAQ in dollars (one ADS = 2 ordinary shares); Cash estimated as of end-3Q20 following most recent equity offering.

EPS ($) Diluted			
Full Year - Dec	2019A	2020E	2021E
1st Half	(0.04)	(0.04)A	(0.06)
2nd Half	(0.03)	(0.04)	(0.07)
FY	(0.07)	(0.08)	(0.13)



Exploratory trial of foralumab in COVID-19 patients completed. In a press release earlier this month, Tiziana Life Sciences announced the completion of its clinical study in Brazil investigating nasally-administered foralumab, its proprietary human monoclonal antibody, either alone or in combination with orally administered dexamethasone in COVID-19 patients. The clinical study was completed in collaboration with scientific teams at the Harvard Medical School (Boston, USA), Santa Casa de Misericórdia de Santos Hospital (Santos, Brazil) and INTRIALS, a full-service Latin American contract research organization (CRO) based in São Paulo, Brazil. The last patients in the trial received their final dose on 21 December 2020. Top-line data from the trial is slated to be available later this month. Since COVID-19 enters through the nasal and respiratory passage, the proprietary nasal formulation and nasal delivery of foralumab may constitute an innovative approach to provide immediate relief to COVID-19 patients. Cytokine storm (also known as cytokine release syndrome, or CRS) and hyperinflammation, resulting in severe lung damage followed by respiratory failure, constitute the main underlying reasons for morbidity and mortality in COVID-19-infected patients. Recent clinical evidence suggests that levels of peripheral T regulatory cells (Tregs) is prominently reduced in severely ill COVID-19 patients, which could be one of the reasons for the hyperactivated immune system and damaged lungs seen in these patients. Tiziana scientists believe that stimulation of Tregs represents a highly innovative approach for the treatment of patients with COVID-19 and related viral respiratory diseases. We note that our current valuation does not include any contribution from the use of foralumab to treat COVID-19-infected patients. Thus, if the Brazilian trial proves successful, this could constitute meaningful upside to our estimates. Foralumab is also advancing in two Phase 2 programs, one in Crohn's Disease and the other in progressive multiple sclerosis (MS). We reiterate our Buy rating and 12-month price target of $11 per share.

Initial clinical feedback appears promising. Dr Thais Moreira, the lead scientist and coordinator of the clinical trial, stated that favorable feedback was received from patients enrolled in the study. Among the positive results that patients reported, the most common observation was that the treatment resulted in rapid improvement in smell sensation, which is frequently lost in COVID-19-infected patients (a condition known as anosmia). The clinical study enrolled a total of 39 patients with moderate-to-severe COVID-19 who did not require the use of a ventilator at the beginning of the study. This study had three cohorts: control (n=16), nasally-administered foralumab (n=12), and nasally administered foralumab with three days of priming with an orally-administered 6mg dose of dexamethasone (n=11). The primary endpoint of this study was safety of the treatment, while secondary endpoints were to evaluate the effect of treatment on disease severity symptoms, nasal tolerance, sense of smell, and biomarkers for disease progression. The pharmacokinetics (PK) of nasally administered foralumab will also be evaluated. Patient-reported outcome data to assess clinical responses related to COVID-19 symptoms, as per FDA guidelines, is also being collected.

Well-regarded biopharma expert with solid record in biotech drug development appointed Chief Medical Officer. In a press release last week, Tiziana also announced the appointment of Dr. Neil Graham MBBS, MD, MPH, as Chief Medical Officer (CMO). Dr. Graham is a medicines development expert and infectious diseases epidemiologist with global biotech and pharmaceuticals R&D experience in developing therapeutics through all stages of drug development (Phases 1 through 4), as well as *in vivo* and *in vitro* diagnostics, across many modalities. He has in-depth global development expertise (spanning the virology, respiratory, dermatology, allergy and rheumatology arenas) in early and late-stage clinical development as well as in medical affairs, with a strong track record of developing and accelerating clinical programs. He has supervised or worked on multiple Investigational New Drug (IND) filings; New Drug Application (NDA) and Biologics License Application (BLA) filings as well as defense; and has been involved in multiple successful launches. From 2010 to 2020, Dr Graham was VP of Strategic Program Direction, Immunology and Inflammation at Regeneron Pharmaceuticals (REGN; not rated), one of the world's best-known and most successful biotechnology firms, where he managed and oversaw a large portion of the Regeneron pipeline portfolio, including leading the immunology and inflammation antibody products across all stages of development from preclinical to post-launch. He was instrumental in the development of DUPIXENT (dupilumab), a blockbuster monoclonal antibody, from Phase 1 through its initial launch for atopic dermatitis, as well as expanding its development into asthma, sinusitis, and eight other indications. During his tenure at Regeneron, Dr. Graham also led the product development for KEVZARA (sarilumab), an IL-6R antibody for rheumatoid arthritis, and REGN3500, an anti-IL33 antibody for asthma and chronic obstructive pulmonary disease (COPD). As part of this role, he built innovative, high-performing development teams and managed Regeneron's regulatory filings, interactions with regulatory agencies, product launches, and business development and licensing activities across its product portfolio. Prior to Regeneron, Dr. Graham served as Senior Vice President, Program and Portfolio Management, at another high-profile biotech firm, where he oversaw the team of program leaders and managers across the portfolio from Phase 1 through launch, including the introduction of Incivek (telaprevir) for treatment of hepatitis C viral infection (HCV), and two innovative product candidates for cystic fibrosis—Kalydeco (ivacaftor) and Orkambi (lumacaftor/ivacaftor)—that are now on the market. Previously, he held roles as CMO at Trimeris Inc. and XTL Biopharmaceuticals and worked in HIV Medical Affairs at Glaxo Wellcome—now part of GlaxoSmithKline plc (GSK; not rated), one of the world's largest and best-known pharmaceutical companies. Earlier in his career, Dr. Graham was an Associate Professor of Medicine and Epidemiology at John Hopkins University's School of Hygiene and Public Health. He is the author of five chapters and books and more than 140 peer-reviewed journal articles. Dr. Graham earned an M.D., M.B.B.S. and M.P.H. from the University of Adelaide in Australia. In our view, his appointment clearly signals Tiziana's intent to build a world-class drug development organization and support the advancement of foralumab and other clinical candidates rapidly across multiple indications.

Valuation methodology, risks and uncertainties. We use a discounted cash flow (DCF)-driven risk-adjusted net present value (rNPV) approach, which yields a ~$1.25B total firm value and price target of $11 per share, given 181.1M projected shares outstanding as of end-2021E. Exchange rate: 1 US$ = £0.74. Investors should note that our valuation excludes all contribution from foralumab beyond Crohn's disease; milciclib in cancers beyond HCC; and TZLS-501 for any indication. 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

	2019A					2020E					
		1HA		2HA	2019A		1HA		2HE	2020E	2021E
Revenue											
Product revenue	-	-	-	-	-	-	-	-	-	-	-
Service revenue	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	-	-	-	-	-
Total revenue	-	-	-	-	-	-	-	-	-	-	-
Expenses											
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-
Research & development	-	1,857	-	1,857	3,714	-	1,034	-	3,000	4,034	13,000
General and administrative	-	2,713	-	3,494	6,207	-	4,310	-	4,400	8,710	10,000
Total expenses	-	4,569	-	5,352	9,921	-	5,344	-	7,400	12,744	23,000
Gain (loss) from operations	-	(4,569)	-	(5,352)	(9,921)	-	(5,344)	-	(7,400)	(12,744)	(23,000)
Other income/expense											
Interest income/expense	-	(6)	-	(85)	(91)	-	-	-	-	-	-
Realized loss on marketable securities	-	-	-	-	-	-	-	-	-	-	-
Other income/expense	-	-	-	-	-	-	(7)	-	-	(7)	-
Total investment income and other	-	(6)	-	(85)	(91)	-	(7)	-	-	(7)	-
Loss before provision for income taxes	-	(4,576)	-	(5,436)	(10,012)	-	(5,351)	-	(7,400)	(12,751)	(23,000)
Provision for tax		33		656	689					-	-
Net loss/income	-	(4,542)	-	(4,781)	(9,323)	-	(5,351)	-	(7,400)	(12,751)	(23,000)
Net loss per share (basic)	-	(0.04)	-	(0.03)	(0.07)	-	(0.04)	-	(0.04)	(0.08)	(0.13)
Net loss per share (diluted)	-	(0.04)	-	(0.03)	(0.07)	-	(0.04)	-	(0.04)	(0.08)	(0.13)
Weighted average number of shares outstanding (basic)	-	126,049	-	136,655	136,483	-	150,224	-	173,079	161,652	180,984
Weighted average number of shares outstanding (diluted)	-	126,049	-	136,655	136,483	-	150,224	-	173,079	161,652	180,984

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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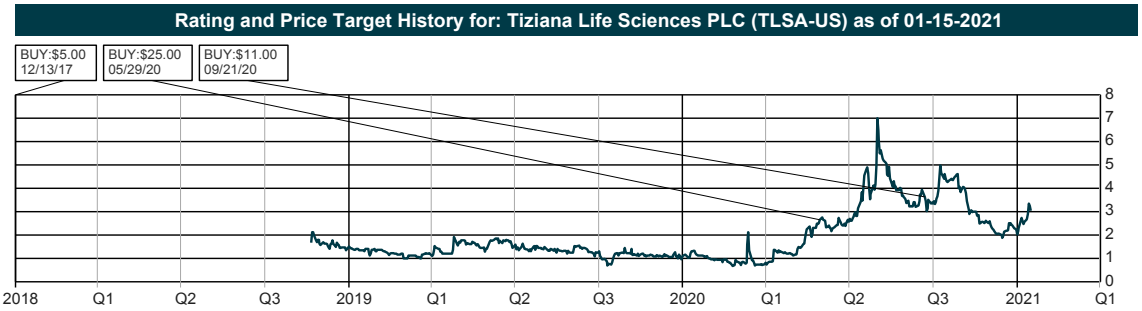

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Distribution of Ratings Table as of January 18, 2021

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	437	91.23%	168	38.44%
Neutral	38	7.93%	11	28.95%
Sell	0	0.00%	0	0.00%
Under Review	4	0.84%	2	50.00%

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