# Tiziana Life Sciences PLC (TLSA)
## Rating: Buy

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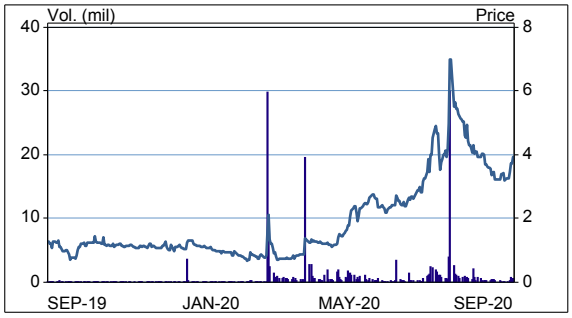
## Foralumab Clinical Progress; Modulating PT to $11 on Adjusted ADS Ratio

| Stock Data | 09/18/2020 |
|---|---|
| Price | $3.93 |
| Exchange | NASDAQ |
| Price Target | $11.00 |
| 52-Week High | $12.17 |
| 52-Week Low | $0.62 |
| Market Cap (M) | $376 |
| Public Market Float (M) | 25.1 |
| Shares Outstanding (M) | 88.9 |
| 3 Month Avg Volume | 1,150,284 |
| Short Interest (M) | 0.37 |
| **Balance Sheet Metrics** | |
| Cash (M) | $48.6 |
| Total Debt (M) | $0.0 |
| Total Cash/Share | $0.55 |
| Book Value/Share | $(0.08) |

*General: Shares quoted in pence on London Exchange; American Depositary Shares trade on NASDAQ in dollars; Cash: pro forma.*

| EPS Diluted | | | |
|---|---|---|---|
| Full Year - Dec | 2019A | 2020E | 2021E |
| 1st Half | (0.04) | (0.04) | (0.04) |
| 2nd Half | (0.03) | (0.04) | (0.06) |
| FY | (0.07) | (0.08) | (0.10) |




**Intriguing clinical program poised to begin in Brazil.** Last week, Tiziana indicated that it has signed an agreement for a collaborative clinical study investigating nasally-administered foralumab in COVID-19 patients in Brazil, either alone or in combination with orally administered dexamethasone. This study is slated to begin enrollment within the coming weeks and may report top-line data before the end of 2020. Investors are reminded that on July 31, 2020, Tiziana reported its filing of a patent application for the potential use of nasally administered foralumab, a fully human anti-CD3 monoclonal antibody (mAb), for the treatment of COVID-19 either alone or in combination with other antiviral drugs. Cytokine storm (also known as cytokine release syndrome) 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. Since the reduction in Tregs and activation of the immune system are commonly observed in patients with Middle Eastern Middle Respiratory Syndrome (MERS), Severe Acute Respiratory Syndrome (SARS-CoV-1), COVID-19 and Acute Respiratory Distress Syndrome (ARDS), Tiziana scientists believe that stimulation of Tregs represents a highly innovative approach for the treatment of patients with these 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).

**Change in ratio of American Depositary Shares to ordinary shares catalyzes revision to price target.** Tiziana also recently effected a change in the ratio of ordinary shares of the company's stock to its American Depositary Shares (ADSs). The ratio was revised to two ordinary shares per ADS from the prior five ordinary shares per ADS. Each ADS holder of note at the time of the ratio change thus received 1.5 additional ADSs for each ADS that they held. This change, which did not involve issuance of additional underlying share capital, was effected to increase the level of liquidity on the NASDAQ Global Market. We also note that Tiziana completed a $57.3M equity financing that involved the issuance of roughly 11M ADSs at a price per ADS of $5.20. This extends the operational runway through 2022. The combined effect of the ADS-to-ordinary shares ratio adjustment and the dilution from the most recent financing transaction lowers our price target to $11.00 per share from the previous $25.00 per share.

**Spinout date fixed—new firm to be known as Accustem Sciences.** Plans to effect the demerger of Accustem Sciences (formerly known as StemPrintER) from Tiziana are continuing to advance. We expect shares of the new company to be issued on a *pari passu* basis to Tiziana shareholders of record at the time of the spinout. Accustem Sciences intends to list on the London Stock Exchange (LSE) late in 4Q20, and potentially establish a dual listing on NASDAQ in 2021. In order to effect the demerger, Tiziana plans to distribute a 1:1 share dividend to its shareholders with a record date of 0700 London time on October 30, 2020. Accustem Sciences shall begin the process of seeking CE Mark approval in November 2020, with commercialization slated to start in Europe during 2Q21. Accustem also intends to seek FDA approval thereafter. As we have stated previously, Accustem may be publicly listed upon completion of the spinout; its valuation could be fairly reckoned at $280M—10% of the valuation placed upon Genomic Health at the time of its acquisition by EXACT Sciences (EXAS; not rated) last year. This would imply that the value of StemPrintER could be considered close to the entire current market cap of Tiziana, meaning that Tiziana's current pipeline of drug candidates is being assigned only nominal value. This still provides a compelling incentive to consider an investment in Tiziana shares, in our view.

**Multiple patents granted covering different elements of Tiziana's product candidate portfolio.** Investors are reminded that Tiziana reported the grant of three patents last month. These cover the following: (1) the use of foralumab in treatment of Crohn's disease; (2) the use of Tiziana's second pipeline candidate, the small molecule cyclin-dependent kinase (Cdk) inhibitor milciclib, in combination with tyrosine kinase inhibitors (e.g., sorafenib and regorafenib) to treat hepatocellular carcinoma and other malignancies; and (3) methods and use of a fully human monoclonal antibody (mAb; TZLS-501) that recognizes both the IL-6 receptor (IL-6R) and IL-6 receptor complex with IL-6 (IL-6R/IL-6) for prophylactic and therapeutic intervention for human diseases. This last patent is slated to provide protection for the use of TZLS-501 in treatment of COVID-19-infected patients. We believe that these patent grant notices clearly demonstrate how rapidly and broadly the company's patent estate is growing.

**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 $11 per ADS, given 181M projected shares outstanding (roughly 90.5M ADSs based on two ordinary shares per ADS) as of mid-2021. Exchange rate: 1 US$ = £0.78. 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 Accustem Sciences (formerly 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

| | 2019A | | | | | 2020E | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1HA | | 2HA | 2019A | 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 | - | 1,857 | - | 1,857 | 3,714 | 1,000 | 1,200 | 1,500 | 1,800 | 5,500 | 11,000 |
| General and administrative | - | 2,713 | - | 3,494 | 6,207 | 1,600 | 1,600 | 1,700 | 1,900 | 6,800 | 8,000 |
| **Total expenses** | - | 4,569 | - | 5,352 | 9,921 | 2,600 | 2,800 | 3,200 | 3,700 | 12,300 | 19,000 |
| **Gain (loss) from operations** | - | (4,569) | - | (5,352) | (9,921) | (2,600) | (2,800) | (3,200) | (3,700) | (12,300) | (19,000) |
| Other income/expense | | | | | | | | | | | |
| Interest income/expense | - | (6) | - | (85) | (91) | - | - | - | - | - | - |
| Realized loss on marketable securities | - | - | - | - | - | - | - | - | - | - | - |
| Other income/expense | - | - | - | - | - | - | - | - | - | - | - |
| **Total investment income and other** | - | (6) | - | (85) | (91) | - | - | - | - | - | - |
| **Loss before provision for income taxes** | - | (4,576) | - | (5,436) | (10,012) | (2,600) | (2,800) | (3,200) | (3,700) | (12,300) | (19,000) |
| Provision for tax | | 33 | | 656 | 689 | | | | | - | - |
| **Net loss/income** | - | (4,542) | - | (4,781) | (9,323) | (2,600) | (2,800) | (3,200) | (3,700) | (12,300) | (19,000) |
| **Net loss per share (basic)** | - | (0.04) | - | (0.03) | (0.07) | (0.02) | (0.02) | (0.02) | (0.02) | (0.08) | (0.10) |
| Net loss per share (diluted) | - | (0.04) | - | (0.03) | (0.07) | (0.02) | (0.02) | (0.02) | (0.02) | (0.08) | (0.10) |
| Weighted average number of shares outstanding (basic) | - | 126,049 | - | 136,655 | 136,483 | 153,149 | 154,568 | 166,799 | 179,359 | 163,469 | 180,984 |
| Weighted average number of shares outstanding (diluted) | - | 126,049 | - | 136,655 | 136,483 | 153,149 | 154,568 | 166,799 | 179,359 | 163,469 | 180,984 |

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

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**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.

**Market Perform (Neutral):** The common stock of the company is expected to mimic the performance of a passive index comprised of all the common stock of companies within the same sector.

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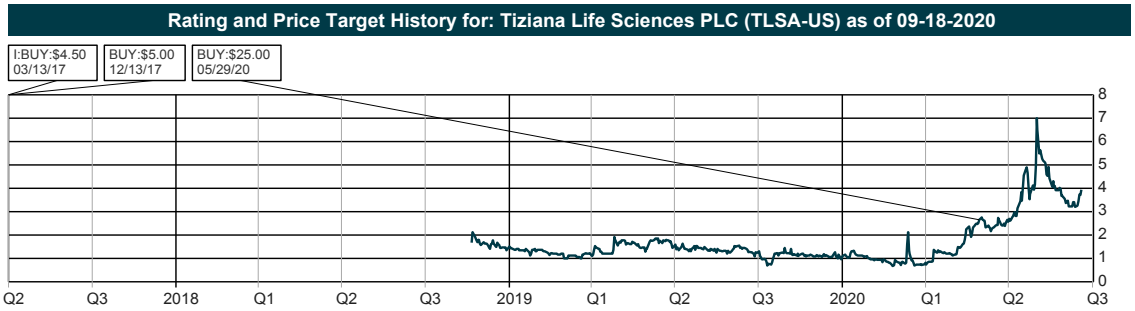


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**Distribution of Ratings Table as of September 18, 2020**

| | | | IB Service/Past 12 Months | |
|---|---|---|---|---|
| Ratings | Count | Percent | Count | Percent |
| Buy | 416 | 90.63% | 156 | 37.50% |
| Neutral | 40 | 8.71% | 7 | 17.50% |
| Sell | 0 | 0.00% | 0 | 0.00% |
| Under Review | 3 | 0.65% | 3 | 100.00% |

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