UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

August 2021

Commission File Number: 0001723069

Tiziana Life Sciences plc
(Exact Name of Registrant as Specified in Its Charter)

3rd Floor,
11-12 St James's Square
London SW1Y 4LB
United Kingdom
(Address of registrant's principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On August 17, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the Publication of a Peer Reviewed Article on Data from the Clinical Trial with Intranasally Administered Foralumab, Its Proprietary Fully Human Anti-CD3 Monoclonal Antibody, in Mild to Moderate COVID-19 Patients in Brazil (the "RNS Announcement").

The RNS Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TIZIANA LIFE SCIENCES PLC

Date: August 17, 2021

By: /s/ Kunwar Shailubhai
Name: Kunwar Shailubhai
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated August 17, 2021

Exhibit 99.1

Tiziana Announces Publication of a Peer Reviewed Article on Data from the Clinical Trial with Intranasally Administered Foralumab, Its Proprietary Fully Human Anti-CD3 Monoclonal Antibody, in Mild to Moderate COVID-19 Patients in Brazil

- *Nasally administered Foralumab, once a day for 10 consecutive days, was well-tolerated and produced significant reduction in lung inflammation as assessed by computerized tomography (CT) scanning*

- *This anti-inflammatory effect of treatment was strongly supported by a reduction in serum levels of pro-inflammatory biomarkers Interleukin-6 (IL-6), IL-18 and C-reactive protein (CRP)*

- *As a next step, Tiziana will be shortly initiating a Phase 2 Proof-of-concept study in Brazil to evaluate safety, tolerability, and efficacy of intranasal Foralumab in a larger number of hospitalized patients with COVID-19*

New York/London, August 17, 2021 - Tiziana Life Sciences plc (Nasdaq: TLSA / LSE: TILS) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for oncology, inflammation, and infectious diseases, announces publication of a scientific article in the peer-reviewed journal *Frontiers in Immunology* titled "***Nasal Administration of Anti-CD3 Monoclonal Antibody (Foralumab) Reduces Lung Inflammation and Blood Inflammatory Biomarkers in Mild to Moderate COVID-19 Patients: A Pilot Study***"(1). The study was completed in collaboration with scientific teams at the Harvard Medical School (Boston, USA) and INTRIALS, a full-service Latin American CRO based in São Paulo, Brazil. The aim of the study was to assess safety of intranasal Foralumab and evaluate its potential benefits in treating immune hyperactivity and lung inflammation in mild to moderate COVID-19 patients who were outpatients at the Santa Casa de Misericordia de Santos Hospital in Brazil. Thirty-nine patients were randomized into three cohorts: no Foralumab treatment (control), nasal Foralumab (100 ug) + Dexamethasone (6 mg orally on days 1-3), and nasal Foralumab (100 ug) alone administered for 10 consecutive days. All arms were allowed to continue standard of care medications. To view the online publication, please click here:
http://journal.frontiersin.org/article/10.3389/fimmu.2021.709861/full?
&utm_source=Email_to_authors_&utm_medium=Email&utm_content=T1_11.5e1_author&utm_campaign=Email_publication&field=&journalName=Frontiers_in_Immunology&id=709861

Clinical Data

Treatment with Foralumab was well-tolerated, and all patients completed the study. No serious adverse events were observed. Eleven patients (28%) experienced an adverse event, including headache (n=4), burning in the nostril (n=1), retrosternal pain (n=2), pustular lesions and itching in cervical area (n=1), dysuria (n=1), tachycardia associated with anxiety (n=1), and insomnia (n=1). Treatment with Foralumab resulted in significant reduction in lung inflammation. The CT scan of the lungs obtained prior to the start of treatment and at study completion revealed a marked improvement in clearance of lung infiltrates, predominantly in patients receiving Foralumab alone as compared to patients in the control cohort. The CT scanning data strongly correlated with significant reduction in levels of inflammatory markers, such as IL-6 levels (69%; p=0.031) and CRP (85%; p=0.032) at day 10.

"Dr. Thais Moreira and other researchers at the Brigham and Women's Hospital (BWH) have been engaged with the development of nasal spray of anti-CD3 monoclonal antibodies for treatment of neurodegenerative diseases. I am pleased our research has led to the development of this novel approach with Foralumab nasal spray for the treatment of COVID-19 patients. This technology is particularly important, because COVID-19 causes immune hyperactivity, and we believe nasal delivery of Foralumab could rapidly suppress inflammation both in the lung and systemically to provide immediate relief to COVID-19 patients," said Professor Howard Weiner, the Robert L. Kroc Professor of Neurology at the Harvard Medical School, Director and Founder of the Partners Multiple Sclerosis Center, and Co-Director of the Ann Romney Center for Neurologic Diseases at the Brigham & Women's Hospital.

Dr. Kunwar Shailubhai, CEO and CSO of Tiziana Life Sciences, commented: "We are very pleased with the publication of the article in a peer-reviewed journal. The clinical findings reported in the article suggest that the nasal spray of Foralumab could be developed as a take home treatment, circumventing the obstacles associated with intravenous treatments for COVID-19 and its variants. We are looking forward to initiating shortly the next clinical study evaluating Foralumab nasal spray in hospitalized COVID-19 patients."

Cited Reference

1. Moreira TG, Matos KTF, De Paula GS, Santana TMM, Da Mata RG, Pansera FC, Cortina AS, Spinola MG, Keppeke GD, Jacob J, Palejwala V, Chen K, Izzy S, Healey BC, Rezende RM, Dedivitis RA, Shailubhai K and Weiner HL (2021) Nasal administration of Anti-CD3 Monoclonal Antibody (Foralumab) Reduces Lung Inflammation and Blood Inflammatory Biomarkers in Mild to Moderate COVID-19 Patients: A Pilot Study. Front. Immunol. 12:709861. doi: 10.3389/fimmu.2021.709861

The person who arranged for the release of this announcement on behalf of the Company was Dr Kunwar Shailubhai, Chief Executive Officer and Chief Scientific Officer of the Company.

About Foralumab

Foralumab (TZLS-401, formerly NI-0401), the only entirely human anti-CD3 mAb, shows reduced release of cytokines as compared to other anti-CD3 mAbs after IV administration in patients with Crohn's disease with decreases in the classic side effects of cytokine release syndrome and improves the overall safety profile of Foralumab. In a humanized mouse model (NOD/SCID IL2γc-/-), it was shown that while targeting the T cell receptor, orally administered Foralumab modulates immune responses of the T cells, enhances regulatory T-cells (Tregs) and thus provides therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy (Ogura M. et al., 2017 Clin Immunol 183, 240-246). Based on animal studies, the nasal and oral administration of Foralumab offers the potential for the immunotherapy of autoimmune and inflammatory diseases in a safe manner by the induction of Tregs.

About Tiziana Life Sciences

Tiziana Life Sciences plc is a dual listed (NASDAQ: TLSA & UK LSE: TILS) biotechnology company that focuses on the discovery and development of novel molecules to treat human diseases in oncology, inflammation and infectious diseases. In addition to Milciclib, the Company will be shortly initiating Phase 2 studies with orally administered Foralumab for Crohn's Disease and nasally administered Foralumab for progressive multiple sclerosis. Foralumab is the only fully human anti-CD3 monoclonal antibody ("mAb") in clinical development in the world. This Phase 2 compound has potential application in a wide range of autoimmune and inflammatory diseases, such as Crohn's Disease, multiple sclerosis, type-1 diabetes ("T1D"), inflammatory bowel disease ("IBD"), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable. The Company is accelerating development of anti-Interleukin 6 receptor ("IL6R") mAb, a fully human monoclonal antibody for treatment of IL6-induced inflammation, especially for treatment of COVID-19 patients.

Forward-Looking Statements

Certain statements made in this announcement are forward-looking statements. These forward-looking statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections about its industry; its beliefs; and assumptions. Words such as 'anticipates,' 'expects,' 'intends,' 'plans,' 'believes,' 'seeks,' 'estimates,' and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the Company's control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements. The Company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of the Company only as of the date of this announcement. The forward-looking statements made in this announcement relate only to events as of the date on which the statements are made. The Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

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