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

May 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 May 26, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom reporting Data Indicating Significant Immunomodulation effects on Immune and Inflammatory Biomarkers with Nasally Administered Foralumab in Healthy Volunteers (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.

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated May 26, 2021

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: May 26, 2021

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

Exhibit 99.1

Tiziana Reports Data Indicating Significant Immunomodulation effects on Immune and Inflammatory Biomarkers with Nasally Administered Foralumab in Healthy Volunteers.

New York/London, 26 May 2021 – Tiziana Life Sciences plc (NASDAQ: TLSA, LSE: TILS) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for inflammatory diseases and cancers, today provided an update on further analysis of lymphocyte subsets from blood samples from a Phase 1 study with nasally administered Foralumab in healthy volunteers. Results exhibiting statistically significant immunomodulatory effects on CD8 cytotoxic T-lymphocytes and other inflammatory biomarkers were observed. This Phase 1 trial, conducted at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, was a single-site, double-blind, placebo-controlled, dose-ranging study with nasally administered Foralumab at 10, 50 and 250 mcg per day, consecutively for 5 days in healthy volunteers. The treatment was well-tolerated at all doses and there were no apparent symptoms of severe toxicity. Importantly, the treatment showed significant positive effects at 50 mcg/day dose (compared to other dose and placebo groups) on T-cell subsets and inflammatory biomarkers. These data support other clinical and pre-clinical studies showing that this route of administration is capable of inducing site-targeted immunomodulation and anti-inflammatory effects. Furthermore these pharmacodynamic data point to a clinical dose range that Tiziana intends to test in further clinical development among MS patients.

Highlights of clinical and immunologic data

- Nasally administered Foralumab was well tolerated and there were no apparent symptoms of severe toxicity or cytokine release syndrome.
- Systemic levels of Foralumab were below the lower quantitation limit of 8 ng/mL suggesting that nasally administered Foralumab appears to exert its effects via nasal epithelium utilizing local and lymphatic immune systems directly.
- Most prominent effects among cytotoxic T-cell subsets were observed in the 50mcg group compared to 10mcg, 250mcg and placebo groups.
- The observed effects in the 50mcg dose group were the following:
    a. Statistically significant reductions from baseline in CD8_Tem cytotoxic T-cell subset through 14 days and CD8_TEMRA, CD8_GranzymeB, CD8_Perforin subsets through 21 days
    b. Statistically significant increase from baseline in CD8_naive subset through day 21
    c. Statistically significant stimulation in production of anti-inflammatory cytokine IL-10 along with suppressed production of pro-inflammatory cytokine IFN-γ, suggested a positive trend for immunomodulation and anti-inflammatory effect.

These observed clinical responses on biomarkers, indicative of immunomodulation and anti-inflammatory, are consistent with the positive clinical data observed with nasally administered Foralumab in COVID-19 patients in Brazil. Results from this clinical study demonstrated that nasally administered Foralumab at 100 mcg/day for 10 consecutive days was not only well-tolerated but it also showed significant reduction of lung inflammation along with statistically reduced levels of interleukin-6 (IL-6) and C-reactive protein (CRP), in the blood samples taken from patients (https://www.tizianalifesciences.com/news-item?s=2021-02-02-tiziana-reports-positive-data-from-the-clinical-study-of-nasal-administration-with-foralumab-its-proprietary-fully-human-anti-cd3-monoclonal-antibody-in-covid-19-patients-in-brazil).

“Nasal administration of Foralumab is a unique approach to treat patients with neurodegenerative diseases such as progressive MS , amyotrophic lateral sclerosis (ALS) and Alzheimer’s Disease (AD). This study demonstrates for the first-time that nasally administered Foralumab, at the identified optimal dose of 50 mcg/day, induces immunomodulatory effects capable of providing clinical benefit to treated subjects. These data along with results from our recently completed trial in COVID-19 patients in Brazil suggest a dose-range of 50 mcg-150mcg could be used for future clinical development of nasally administered Foralumab. This is a major accomplishment providing the scientific rationale to move forward with further clinical development of nasally administered Foralumab in patients with neurodegenerative diseases,” commented Dr. Howard L. Weiner, Chair of the Scientific Advisory Board of Tiziana Life Sciences and Professor of Neurology at Harvard Medical School. He added that “both oral and nasal administration routes are physiologic approaches to stimulate the mucosal immune system to induce disease modifying immunomodulation. Our immediate focus is on developing Foralumab for treatment of progressive MS.”

“The demonstration of the positive immunomodulatory effects providing a recommended dose-range is important to move forward with further studies in the progressive MS population”, stated Dr. Tanuja Chitnis, the study PI at the Brigham and Women’s Hospital.

The person who arranged for the release of this announcement on behalf of the Company was Dr Kunwar Shailubhai, CEO & CSO of Tiziana.

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF REGULATION 2014/596/EU (WHICH FORMS PART OF DOMESTIC UK LAW PURSUANT TO THE EUROPEAN UNION (WITHDRAWAL) ACT 2018) (“UK MAR”). UPON THE PUBLICATION OF THIS ANNOUNCEMENT, THIS INSIDE INFORMATION (AS DEFINED IN UK MAR) IS NOW CONSIDERED TO BE IN THE PUBLIC DOMAIN.

About Foralumab

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, shows reduced release of cytokines after IV administration in patients with Crohn’s disease with decreases in the classic side effects of cytokine release syndrome (CRS) 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 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). 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.

Preclinical studies on nasal and oral administration with Anti-CD3 mAbs

Preclinical and clinical studies have shown that mucosal induction of Tregs by oral or nasal administration of anti-CD3 mAbs is an innovative approach to treat autoimmune and anti-inflammatory diseases (Kuhn and Weiner 2016). Nasally administered anti-CD3 mAbs were shown to ameliorate disease in an animal model of multiple sclerosis by inducing IL-$10^{+}$$LAP^{+}$ (latency-associated peptide) T cells, demonstrating nasal anti-CD3 mAbs as a new approach to treat progressive forms of multiple sclerosis and other types of chronic CNS inflammation. Additionally, nasally administered anti-CD3 mAbs suppressed lupus in lupus-prone mice (BWF1) by inducing IL-10 and TGF-β dependent mechanisms associated with a suppression of IL-17 and IL-21 pro-inflammatory cytokines.

About Tiziana Life Sciences

Tiziana Life Sciences plc is a UK biotechnology company that focuses on the discovery and development of novel molecules to treat human disease in oncology and immunology. In addition to Milciclib, the Company is also developing Foralumab for liver diseases. Foralumab is the only fully human anti-CD3 monoclonal antibody in clinical development in the world. This Phase 2 compound has potential application in a wide range of autoimmune and inflammatory diseases, such as multiple sclerosis, crohn's disease, COVID-19, type-1 diabetes (T1D), ulcerative colitis, , psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable.

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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