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 25, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the Initiation of Clinical Trial in a Secondary Progressive Multiple Sclerosis (SPMS) Patient with Nasal Administration of Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, Under an Individual Patient Expanded Access Program (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: May 25, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated May 25, 2021

Exhibit 99.1

Tiziana Life Sciences Announces Initiation of Clinical Trial in a Secondary Progressive Multiple Sclerosis (SPMS) Patient with Nasal Administration of Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, Under an Individual Patient Expanded Access Program

- ***The first patient with SPMS was dosed on May 24, 2021 with nasally administered Foralumab. The treatment regimen will continue for six months to examine long-term safety, tolerability and clinical responses.***

- ***Previous clinical studies in healthy volunteers and COVID-19 patients showed that nasally administered Foralumab is well-tolerated with no apparent severe adverse events (SAEs) when dosed for up to 10 consecutive days. Results from these studies showed strong anti-inflammatory effects of the treatment regimen.***

New York/London, 25 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, is pleased to announce that the first patient with secondary progressive multiple sclerosis (SPMS) was dosed with nasally administered Foralumab, a fully human anti-CD3 monoclonal antibody, at the Brigham and Women's Hospital (BWH), Harvard Medical School, Boston, MA. Nasal Foralumab 50 mcg (25 mcg/nostril) will be administered in 3-week cycles, with 3 times/week dosing for the first 2 weeks followed by 1 week of rest period. This first-ever clinical study in SPMS patients, under an Individual Patient Expanded Access IND, will continue for six months to evaluate routine safety, tolerability, and neurological behaviors. The study will also examine microglial activation, by positron emission tomography (PET), immunological and neurodegenerative markers to assess clinical responses following the treatment regimen.

Previously, Tiziana completed a Phase 1 trial of a single-site, double-blind, placebo-controlled, multiple ascending dose (MAD) once a day dosing for 5 consecutive days with nasally administered Foralumab in healthy subjects. The treatment was well-tolerated with no drug-related safety issues reported at doses of up to 250 mcg. (https://www.tizianalifesciences.com/news-item?s=2019-09-10-tiziana-reports-phase-1-clinical-data-demonstrating-nasal-treatment-with-foralumab-was-well-tolerated-and-produced-positive-trend-in-biomarkers-of-immunomodulation-and-anti-inflammation-in-healthy-volunteers)

Subsequently, Tiziana reported positive data from a clinical study 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 consecutive 10 days was well-tolerated and there were no apparent severe adverse events. The clinical results demonstrated that the treatment provided significant reduction of lung inflammation together with a reduction in interleukin-6 (IL-6) and C-reactive protein (CRP), biomarkers of inflammation, 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)

Dr. Howard Weiner, Robert Kroc Professor of Neurology at Harvard Medical School said, "Nasally administered anti-CD3 is an exciting, novel approach that has the ability to provide safe treatment for a form of MS that currently has no effective treatment. We are excited to examine this first-in-class approach to treat patients with SPMS for whom no effective treatment option is currently available."

Dr. Tanuja Chitnis, Professor of Neurology at Harvard Medical School and senior neurologist at the BWH, adds, “Effective and targeted treatments for progressive MS are urgently needed. Nasal Foralumab could revolutionize treatment for this disabling form of disease.”

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.

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 and improves the overall safety profile of Foralumab. In a humanized mouse model (NOD/SCID IL2γc-/-), it was shown that whilst 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). 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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