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

June 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 June 23, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing it had entered into a Collaboration Agreement with FHI Clinical to Conduct a Phase 2 Clinical Trial for Treating Hospitalized Severe COVID-19 Patients with Intranasal Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody (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: June 23, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated June 23, 2021

Exhibit 99.1

Tiziana Enters a Collaboration Agreement with FHI Clinical to Conduct a Phase 2 Clinical Trial for Treating Hospitalized Severe COVID-19 Patients with Intranasal Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody

NEW YORK & LONDON, June 23, 2021 - Tiziana Life Sciences plc (NASDAQ: TLSA, LSE: TILS), ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for oncology, neurology, inflammation and infectious diseases, announces that it has signed an agreement with FHI Clinical, a global clinical contract research organization (CRO), to conduct a Phase 2 ***Proof-of-concept*** study in Brazil to evaluate the safety, tolerability and efficacy of intranasal Foralumab in hospitalized patients with severe coronavirus disease 2019 (COVID-19) and pulmonary inflammation.

A subsidiary of FHI 360, FHI Clinical specializes in the clinical development of drugs for infectious diseases (https://www.fhiclinical.com). The company's involvement with COVID-19 includes Phase 1 to Phase 3 clinical trials for vaccines and therapeutics, as well as observational studies to collect data about the characteristics and course of infection. With experience conducting related studies across 16 countries and 43 states in the United States, FHI Clinical has a large network of clinical sites throughout the world to expedite COVID-19 trials.

In this clinical trial, Foralumab will be delivered intranasally through a metered-dose nasal atomization device. Nasal administration of Foralumab is a highly innovative approach to treat patients with autoimmune diseases where the immune system may be dysregulated. Several studies have suggested that there is dysregulation in the immune system of patients with COVID-19.

This randomized, placebo-controlled, double-blind, ***proof-of-concept*** study is designed to expand on the preliminary findings of safety, tolerability and efficacy of intranasal administration of Foralumab observed in mild to moderate non-hospitalized COVID-19 patients (https://ir.tizianalifesciences.com/news-releases/news-release-details/tiziana-life-sci-plc-positive-data-nasal-administration). Thus, this study will examine attenuation of pulmonary pathology in hospitalized patients with severe COVID-19. Up to seven sites in Brazil will be engaged to conduct this study. Eighty hospitalized patients with severe COVID-19 and evidence of pulmonary involvement on a computed tomography (CT) scan at screening will be enrolled. Patients will be randomized 1:1 to receive intranasal Foralumab 100 µg. Additionally, the study will also evaluate the effect of Foralumab on resolution of symptoms by chest CT, inflammatory biomarkers, T-cell subpopulations, safety and mucosal inflammatory response following 14 days of intranasal administration.

"Our experience is uniquely suited to the needs of this Phase 2 study as we are able to pull from past outbreak experience, including rapid study start-up in research-naïve areas to leveraging existing global research networks and contributing to local health systems," said Ted FitzGerald, FHI Clinical President and CEO. "We excel at addressing the complex aspects of infectious disease trials that require thorough planning and contingency planning."

“We are pleased to move forward with FHI Clinical on our next COVID-19 trial. After a successful proof-of-mechanism trial in mild to moderate COVID-19 outpatients with intranasal Foralumab earlier this year, the next step is to test it in more severe hospitalized patients with pulmonary inflammation,” said Dr. Neil Graham, Chief Medical Officer at Tiziana Life Sciences.

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 (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 (NASDAQ: **TLSA, LSE: TILS**) 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 (a CDK inhibitor being developed in oncology), the Company is also developing Foralumab in COVID-19, multiple sclerosis, and Crohns Disease. Foralumab is the only second generation 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 nonalcoholic steatohepatitis (NASH), ulcerative colitis, multiple sclerosis, type-1 diabetes (T1D), Crohn’s disease, 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 inflammatory pulmonary diseases.

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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