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

February 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 February 2, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing 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 (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: February 2, 2021

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated February 2, 2021

Exhibit 99.1

THIS ANNOUNCEMENT INCLUDES INSIDE INFORMATION

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

- ***Since the anti-inflammatory effect of the nasally administered Foralumab is through the modulation of the immune system and not by directly targeting COVID-19, this therapeutic approach might also be useful for newly identified Covid-19 variants in UK, South Africa and Brazil.***

- ***Foralumab is also the first monoclonal antibody that can be dosed nasally or orally due to its ability to effect systemic immunity via the epithelial lining of the nose, respiratory tract and gut.***

- ***The direct delivery of Foralumab to the nasal passage and respiratory tract rapidly suppresses lung inflammation, as evident from the CT scans. The treatment also improved the senses of smell and taste in treated patients. The nasal administration of Foralumab can be done at home by patients.***

- ***The positive effects of the treatment are also supported by the data indicating a trend toward greater reduction in systemic biomarkers of inflammation, such as the levels of Interleukins-6 ("IL-6") and c-reactive protein ("CRP") in blood samples of Foralumab treated patients as compared to those in the control cohort.***

New York/London, 2 February 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, reports positive data from the exploratory clinical study in Brazil investigating nasally administered Foralumab, its proprietary anti-CD3 human monoclonal antibody, either alone or in combination with orally administered dexamethasone ("Dexa") in COVID-19 patients. The clinical 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.

Recent studies suggest that the pathogenesis of COVID-19 includes an abnormal host response or overreaction of the immune system in patients. It should also be noted that obesity is also one of the risk factors for COVID-19, and data from obese subjects have shown that levels of circulating T regulatory cells ("Tregs") are depleted in obese patients compared with those in lean patients[1]. Consequently, there is a higher state of inflammation and insulin resistance, which results in local production of high levels of inflammatory cytokines, chemokines, and free radicals locally that cause severe damage to the lungs and other organs. Therefore, nasal treatment with Foralumab, a fully human anti-CD3 mAb, to modulate the immune system and to stimulate Tregs is a scientifically logical approach for the treatment of COVID-19. Foralumab is also the only monoclonal antibody that can be dosed nasally or orally due to its ability to effect systemic immunity via the epithelial lining of the nose, respiratory tract and gut. This study served as proof of concept for Foralumab's unique method of delivery as well as its safety and efficacy as a potent systemic anti-inflammatory therapeutic.

The objectives of the trial were to assess safety of the treatment and to evaluate if progression of the diseases is delayed with nasally administered Foralumab. As this was an exploratory clinical study, it was not powered for statistical analysis. This study enrolled 39 patients randomized in three cohorts: cohort 1, control with no treatment (n=16); cohort 2; nasally administered Foralumab plus 3 days of priming with orally administered 6 mg Dexa (n=12) and cohort 3; nasally administered Foralumab (n=12). The Foralumab treatment regimen was once a day dosing for 10 consecutive days. Many patients had received steroids prior to enrollment in the trial but those patients stopped taking steroids on enrolling in the study. Thus, the cohort 2 included priming with 3 days of orally administered dexa along with 10 days of treatment with nasally administered Foralumab to assess if inclusion of Dexa may affect the action of Foralumab. There were no significant differences between cohort 2 and 3.

Clinical Data

Cohort (evaluable patients)	Lung CT Scan (% Improvement)	Cytokine IL-6 (% Reduction)	C-Reactive Protein (% Reduction)
Control (n=14)	43	37	40
Foralumab + Dexa (n=12)	75	41	55
Foralumab (n=10)	80	69	85

- ***All treatments were well-tolerated. There were no grade 3 or 4 severe adverse events ("SAEs") in any of the cohorts.***

- ***The CT scans of the lungs showed the improvement was approximately double that shown in patients treated with Foralumab as compared to those in the control group.***

- ***Medical records of patients also showed a more rapid recovery in senses of smell and taste in Foralumab treated patients, as compared to those in the control group.***

- ***Data on pharmacokinetics of nasally administered Foralumab, immunological biomarkers, stimulation of Tregs and anti-drug antibody ("ADA") is expected to be reported in a few weeks.***

COVID-19 enters through the nasal and respiratory passage, accordingly the proprietary nasal formulation and nasal delivery of Foralumab to modulate immunity is expected to delay progression of the disease and to provide immediate relief to COVID-19 patients. Dr. 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) commented: "Nasal administration of Foralumab to modulate the human immune system is a potentially transformative approach for treating patients with a variety of human infectious diseases with an overreactive immune systems, such as acute respiratory distress syndrome caused by COVID-19, its variants and other viruses causing Middle East Respiratory Syndrome ("MERS") and Severe Acute Respiratory Syndrome ("SARS")".

Dr Thais Moreira, the lead scientist and coordinator of the clinical trial, and Dr. Kimble Matos, the lead coordinating physician of the study commented: "We are delighted to see that patients treated with nasally administered Foralumab showed a positive trend in the reduction of lung inflammation, and supportive data indicating significant reduction in cytokine IL-6 and C-reactive protein. In addition, there are indications from patients who reported that treatment with Foralumab rapidly improved the smell and taste sensations that are frequently lost with severity of COVID-19 disease".

Dr. Kunwar Shailubhai, CEO and CSO of Tiziana Life Sciences, commented: "We are delighted with the promising clinical data showing evidence of the positive effect of nasally administered Foralumab in Covid-19 mediated pulmonary and systemic inflammation. This is a first-in-class and scientifically logical approach to modulate the host immune system to fight the inflammatory reaction to SARS-CoV2 (Covid-19 virus). Thus, this approach may be effective against patients infected with the newly identified Covid-19 variants in UK, South Africa and Brazil, but there is no data on this yet. The clinical data demonstrates the safety of nasally administered Foralumab and provides evidence of anti-inflammatory effects which will further support our upcoming Phase 2 clinical study with nasally administered Foralumab in patients with secondary progressive multiple sclerosis.

Cited Reference

1. Stephen-Victor E, Das M, Karnam A, et al. Potential of regulatory T-cell-based therapies in the management of severe COVID-19. Eur Respir J 2020; 56: 2002182 [https://doi.org/ 10.1183/13993003.02182-2020].

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 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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