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

November 2020

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 November 2, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the Initiation of Clinical Trial with Covid-19 Patients in Brazil with Nasally Administered 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: November 2, 2020

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated November 2 2020

Exhibit 99.1

Tiziana Life Sciences plc

("Tiziana" or the "Company")

Tiziana Announces Initiation of Clinical Trial with Covid-19 Patients in Brazil with Nasally Administered Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody

- ***Highly innovative first-in-class study for treating COVID-19 disease with nasally administered drug***
- ***Trial facilitated with collaboration of Harvard Medical School and one of the world's top Neurologist, Dr. Howard Weiner***
- ***Patent for potentially revolutionary nasally administered delivery system already filed***
- ***Clinical Data Expected by End of Year***

New York/London, November 2, 2020 - Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for oncology, inflammation and infectious diseases, announces initiation of a collaborative clinical study investigating nasally administered Foralumab either alone or in combination with orally administered dexamethasone in COVID-19 patients in Brazil. In view of the importance and urgency, scientific teams at the Harvard Medical School, Santa Casa de Misericórdia de Santos Hospital (Jabaquara, Santos, Brazil) and at Tiziana are closely collaborating to facilitate initiation of this study in expedited time frames. This clinical trial will be coordinated by the team at the *INTRIALS*, a leading, full-service Latin America Clinical Research Organization (CRO), based in Sao Paulo City, Brazil. The clinical data from this trial is expected to available by the end of this year.

"Brazil has reported almost 5.5M Coronavius cases and 159,000 deaths and is considered a global epicenter of the outbreak. Brazil is now experiencing almost 1000 deaths per day. Thus, our clinical study is both timely and potentially a life changer for the COVID-19 patients. The scientific concept, to activate nasal mucosal immunity by nasally administered Foralumab, is to fight against the virus in the respiratory tract and lungs," stated Dr. Shailubhai, CEO and CSO of Tiziana Life Sciences.

- *Clinical study will start dosing patients on November 3rd, 2020 with clinical data expected to be available before the end of 2020*
- *Since reduced or defective levels of T regulatory (Tregs) cells in the blood seem to be associated with the severity of COVID-19 and acute respiratory distress syndrome (ARDS), nasally administered Foralumab, by acting locally, could potentially suppress excessive cytokine storm and hyperinflammation in respiratory tract and lungs of COVID-19 patients*
- *A patent application was filed in July 2020 to protect the potential use of nasally administered Foralumab for the treatment of COVID-19 either alone or in combination with other anti-viral drugs.*

Dr Howard Weiner, who is 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 diseases with dysregulated immune systems. Results from studies, conducted in our laboratory have established that nasal administration of anti-CD3 induces Tregs that can suppress inflammation and ameliorate diseases in animal models. Furthermore, nasal anti-CD3 dampens cytotoxic CD8 T cell responses shown to cause lung damage in COVID-19. This scientific advancement provides the basis to move forward with clinical development of nasally administered Foralumab in COVID-19 disease." He continued, "My colleague Dr. Thais Moreira worked very closely with clinicians at the Brazilian hospital and the team at the INTRIALS to expedite this highly innovative first-in-class study for treating COVID-19 disease."

Dr. Rogério Dedivitis, the Clinical director of Santa Casa de Santos, stated: "The Santa Casa hospital, the first hospital founded in Brazil almost 500 years ago, is very pleased to be involved in such an important international clinical study. We are excited and confident that this study will contribute to the better understanding of COVID-19 disease, and importantly also benefit our patients."

The cytokine storm and hyperinflammation resulting in severe lung damage, followed by respiratory failure are the main underlying reasons for morbidity and mortality in COVID-19 patients (1). Recent clinical evidence suggests that the level of peripheral Tregs is prominently reduced in severely ill COVID-19 patients (2). The clinical data from a recently completed clinical study indicated that the nasal administration of Foralumab stimulated production of Tregs in healthy volunteers (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), suggesting that nasal treatment with Foralumab might improve clinical outcome by stimulating Tregs in patients. This is a highly innovative approach, which could also be useful for treatment of patients with Middle Eastern Respiratory Syndrome (MERS), Severe Acute Respiratory Syndrome (SARS-CoV-1), COVID-19 and Acute Respiratory Distress Syndrome (ARDS) because depletion of functional Tregs are commonly observed in these diseases.

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.

Cited References

1. Huang C, Wang Y, Li X, *et al*. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. Lancet 2020; 395: 497–506. doi:10.1016/S0140-6736(20)30183-5

2. Chen G, Wu D, Guo W, *et al*. Clinical and immunological features of severe and moderate coronavirus disease 2019. J Clin Invest 2020; 130: 2620–2629. doi:10.1172/JCI137244

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 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 AIMS: 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.

For further enquiries:

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