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

September 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 September 17, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing it is to conduct a clinical study with nasally administered Foralumab, a fully human Anti-CD3 Monoclonal Antibody, for treatment of 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: September 17, 2020

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated September 17 2020

Exhibit 99.1

Tiziana Life Sciences plc

("Tiziana" or the "Company")

Tiziana to Conduct a Clinical Study with Nasally Administered Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, for Treatment of COVID-19 Patients in Brazil

Nasal Administration of Foralumab is a potentially transformative approach for treating patients with Covid-19.

New York/London, September 17, 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 that it has signed an agreement for a collaborative clinical study investigating nasally administered Foralumab in COVID-19 patients in Brazil, either alone or in combination with orally administered dexamethasone. The Company announced on July 31, 2020 its filing of a patent application for the potential use of nasally administered Foralumab, a fully human anti-CD3 monoclonal antibody (mAb), for the treatment of COVID-19 either alone or in combination with other anti-viral drugs.

- ***Clinical study anticipated to start in the next few weeks with clinical data potentially available before the end of 2020***
- ***Scientific rationale for use of Foralumab as a treatment for COVID-19 patients is to help modulate the human immune system to suppress a possible "Cytokine storm" and to potentially reduce respiratory failure in COVID-19 patients***

The "Cytokine storm" (aka cytokine release syndrome) 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 T regulatory cells (Tregs) is prominently reduced in severely ill COVID-19 patients (2), which could be one of the reasons for the hyperactivated immune system and damaged lungs in these patients. Since the reduction in Tregs and activation of the immune system are commonly observed in patients with Middle Eastern Middle Respiratory Syndrome (MERS), Severe Acute Respiratory Syndrome (SARS-CoV-1), COVID-19 and Acute Respiratory Distress Syndrome (ARDS), we believe that stimulation of Tregs is a highly innovative approach for the treatment of patients with these diseases.

The Company has developed a robust formulation for delivery of Foralumab using a nasal spray device and has successfully completed a Phase 1 clinical trial demonstrating that the treatment was well-tolerated up to 250 microg/day and that it stimulated Tregs (https://www.tizianalifesciences.com/news-item?s=2018-11-28-tiziana-announces-initiation-of-phase-1-clinical-trial-with-nasal-administration-of-foralumab-a-fully-human-anti-cluster-definition-3-monoclonal-antibody-anti-cd3-mab-in-healthy-volunteers). Thus, we believe the clinical strategy with nasal administration of Foralumab either alone or in combination with dexamethasone to treat COVID-19 patients is highly innovative and scientifically very sound.

"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," commented 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. He continued, "modulating the immune system with nasal anti-CD3 is a first-in-class immunotherapeutic approach to treat COVID-19 disease."

"Our proprietary immunotherapeutic approach, employing nasal administration of Foralumab to modulate the immune system, aims to supercharge Tregs to suppress inflammation, and to dampen cytotoxic CD8+ T cell responses in the nasal and respiratory tract, the primary sites of Covid-19. In view of the importance and urgency to develop an effective therapy for COVID-19 immediately, our Tiziana Life Sciences team, scientists at the Harvard Medical School and the scientific team at Santa Casa de Misericórdia de Santos Hospital (Jabaquara, Santos, Brazil) are working very quickly to start this clinical study in the next few weeks such that clinical data could be available before the end of this year." commented Dr. Shailubhai, CEO and CSO of Tiziana Life Sciences.

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF REGULATION (EU) NO 596/2014

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:

United Kingdom:
Tiziana Life Sciences plc +44 (0)20 7495 2379
Gabriele Cerrone, Chairman and founder

Cairn Financial Advisers LLP (Nominated adviser) +44 (0)20 7213 0880
Liam Murray / Jo Turner

Optiva Securities Limited (Broker) +44 (0)20 3981 4173
Robert Emmet

United States:
Investors:
Dave Gentry, CEO
RedChip Companies Inc.
407-491-4498
dave@redchip.com