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

March 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 March 30, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing Plans for a Phase 2 Clinical Study in Moderate to Severe Covid-19 Patients with Nasal Administration of 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: March 30, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated March 30, 2021

Exhibit 99.1

Tiziana Plans Phase 2 Clinical Study in Moderate to Severe Covid-19 Patients with Nasal Administration of Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody

- ***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 could be useful for newly identified Covid-19 variants in the UK, South Africa and Brazil.***

- ***Foralumab is 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 rapid delivery of Foralumab to the nasal passage and respiratory tract was shown in a previous study of mild to moderate Covid-19 patients to suppress lung inflammation, as evident from CT scans and reduced systemic markers of inflammation including interleukin-6 and C-reactive protein.***

New York/London, 30 March 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 that it plans further development of Foralumab, its proprietary anti-CD3 human monoclonal antibody in Covid-19. A recent clinical study in mild to moderate Covid-19 patients showed evidence that the nasally administered anti-CD3 monoclonal antibody reduced pulmonary and systemic inflammation and it was well tolerated. That 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. Tiziana now plans a phase 2 randomized, placebo-controlled trial in Brazil for moderate to severe hospitalized Covid-19 patients to test the drug in a more compromised group of patients. All patients will receive standard of care background therapy.

Recent studies suggest that the pathogenesis of pulmonary inflammation in Covid-19 includes an abnormal host response or overreaction of the immune system in patients. 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.

"I am pleased to see this novel dosing concept for anti-CD3 advance to a phase 2 clinical trial. These types of human trials are important to validate the successful studies we conducted in animal models of several inflammatory diseases," said Professor 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.

This study is expected to serve as a further proof of concept for Foralumab's novel method of nasal delivery, as well as its safety and efficacy as a potent, systemic anti-inflammatory therapeutic in more severe Covid-19 patients.

Covid-19 enters through the nasal and respiratory passage; accordingly, the proprietary nasal formulation and nasal delivery of Foralumab to modulate immunity are expected to delay progression of the disease and to provide immediate relief to Covid-19 patients.

Dr Neil Graham, Chief Medical Officer at Tiziana Life Sciences, commented, “We are excited about this next important step in our goal to validate our drug candidate and our novel delivery system as a promising and innovative approach to immunomodulatory therapy for Covid-19 and other mutant variants. By focusing on moderating the inflammatory consequences of the SARS CoV2 virus, we hope to have a therapy that has efficacy irrespective of local viral variants.”

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 & 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.

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