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 that the FDA Has Allowed Treatment for a Secondary Progressive Multiple Sclerosis (SPMS) Patient for the Nasal Administration of Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, Under an Individual Patient Expanded Access Program (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 Announces the FDA Has Allowed Treatment for a Secondary Progressive Multiple Sclerosis (SPMS) Patient for the Nasal Administration of Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, Under an Individual Patient Expanded Access Program

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 inflammatory diseases and cancers, is pleased to announce that the U.S. Food and Drug Administration (FDA) has allowed evaluation of nasal administration with Foralumab, a fully human anti-CD3 monoclonal antibody, in a secondary progressive multiple sclerosis (SPMS) patient at the Brigham and Women's Hospital (BWH), Harvard University, Boston, MA. This patient will be treated under an Individual Patient Expanded Access IND. This is the first time a nasally administered antibody will be administered to a patient with SPMS. The treatment is planned to start in the second quarter of 2021, and will continue for six months. Investigators at BWH will follow this patient with detailed routine safety, neurological, imaging and PET studies to evaluate microglial imaging. Modification of immunological and neurodegenerative markers is part of standard investigations that will be conducted at the BWH.

Previously, Tiziana completed a Phase 1 trial of a single-site, double-blind, placebo-controlled, multiple ascending dose (MAD) once a day dosing for 5 consecutive days with nasally administered Foralumab in healthy subjects. The treatment was well-tolerated with no drug-related safety issues reported at any doses up to 250 mg of the doses. Nasal foralumab was developed by Professor Howard Weiner at BWH.

Weiner commented, "Nasal anti-CD3 is an exciting, novel approach that has the ability to provide a safe treatment for a form of MS that has no effective treatment. We are pleased that the FDA has allowed us to treat a patient with SPMS who needs a better treatment option than is currently available."

Dr. Tanuja Chitnis, Professor of Neurology at Harvard Medical School and senior neurologist at the BWH, adds, "New treatments for progressive MS are urgently needed. Nasal Foralumab could revolutionize treatment for this disabling form of disease."

The company had previously reported positive data from the Clinical Study of Nasal Administration with Foralumab in COVID-19 patients in Brazil. Nasally administered Foralumab at 100 mg/day for consecutive 10 days treatment was found to be well-tolerated, and there were no apparent severe adverse events. The clinical data suggested that the treatment provided significant reduction of lung inflammation.

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.

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