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

July 2019

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 o

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): o

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): o

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On July 1, 2019, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement, announcing the publication of an Independent Third Party Article in New England Journal of Medicine reports on Intravenous Treatment with a Humanized Anti-CD3 mAb showing delays in progression of Type 1 Diabetes (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: July 1, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated July 1, 2019

Tiziana Life Sciences plc

Independent Third Party Article in New England Journal of Medicine reports on Intravenous Treatment with a Humanized Anti-CD3 mAb showing delays in progression of Type 1 Diabetes; Findings may have the potential to expand therapeutic benefits of Tiziana's Foralumab, the only known fully human anti-CD3 mAb

Independent third party Phase 2 results show Teplizumab, a mouse derived humanized anti-CD3 monoclonal antibody (mAb) significantly slowed progression of Type 1 diabetes in high risk population

Tiziana Life Sciences plc (Nasdaq: TLSA/ AIM: TILS ("Tiziana" or the "Company"), a biotechnology company focusing on the discovery and development of innovative therapeutics for inflammation and oncology indications, notes that a recently published study in *The New England Journal of Medicine* titled, "**An Anti-CD3 Antibody, Teplizumab, in Relatives at Risk for Type 1 Diabetes,**" provides clinical evidence for the potential use of an anti-CD3 mAb in the prevention or treatment of Type 1 diabetes. Teplizumab is being developed by Provention Bio. The published study was funded by the National Institute of Health and others, and was conducted by investigators at numerous institutions in the field of immunology and pediatrics including Yale University and Vanderbuilt University.

The published results from a Phase 2 trial of Teplizumab, a mouse derived anti-CD3 mAb delivered intravenously, evaluated 76 patients who had relatives with Type 1 diabetes. 72% of subjects were under the age of 18. Patients were randomized and treated with either a 14-day course of Teplizumab or placebo. At 6 month intervals, the study tested subjects for the onset of Type 1 diabetes. Teplizumab was found to significantly slow progression to clinical Type 1 diabetes, with a median delay in the diagnosis of diabetes of 2 years. At the end of the trial, 57% of the group treated with Teplizumab were diabetes free, while 28% of the group treated with placebo remained diabetes free.

"Children and adults at high risk of developing Type 1 diabetes may benefit from safe and effective prophylactic use of anti-CD3 mAb's. We congratulate Prof. Kevan Herold, a member of Tiziana's Scientific Advisory Board, and the research team that conducted the published study. Tiziana's proprietary technology for the oral and nasal delivery of mAb's in general, and Foralumab specifically, have strong potential indications in autoimmune diseases including Type 1 diabetes," stated Kunwar Shailubhai, CEO & CSO of Tiziana.

Tiziana's Foralumab offers potential safety and efficacy advantages over other anti-CD3 mAb's because it is the only fully human anti-CD3 mAb, as compared to mouse derived anti-CD3s which have been shown to cause immune reactions in humans. Tiziana's proprietary platform technology for oral and nasal administration of mAb's could provide clinical benefits by mimicking the body's natural immune modulation processes and thereby increasing patient compliance.

Foralumab is currently in a Phase 1 trial at the Harvard Medical School in healthy volunteers to study safety, tolerability and biomarkers of neurodegenerative disease through nasal delivery. An upcoming Phase 1 trial will evaluate oral Foralumab's safety, tolerability and biomarkers in Crohn's disease and NASH. A Phase 2 trial in Crohn's and NASH is expected to commence next year.

About Teplizumab

Teplizumab (hOKT3γ1 (Ala-Ala) is a humanized version of the mouse monoclonal antibody, OKT3, which retains the same binding regions of OKT3. Being humanized, the antibody appears to have a decreased cytokine release potential since its Fc region has been changed (mutated) to not bind to the FcR on T cells but successfully maintains its immunomodulatory properties. Teplizumab is being evaluated in autoimmune diseases such as Type I diabetes and clinical trials have shown promise in lowering HbA1c levels and lower insulin requirements in new onset Type I diabetes patients as well as slowing progression of Type I diabetes in high risk patients.

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 , it was shown that while targeting the T cell receptor, orally administered Foralumab modulates immune responses of the T cells, enhances 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. 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 UK biotechnology company that focuses on the discovery and development of novel molecules to treat human disease in oncology and immunology. The Company is also developing Foralumab for liver diseases. Foralumab is the only fully human anti-CD3 monoclonal antibody in clinical development in the world. This Phase 2 compound has potential application in a wide range of autoimmune and inflammatory diseases, such as nonalcoholic steatohepatitis (NASH), primary biliary cholangitis (PBS), ulcerative colitis, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable.

Receive news and updates from Tiziana Life Sciences plc by signing up to get email alerts straight to you email on https://ir.tizianalifesciences.com/

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