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

January 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 January 9, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom Reporting Phase 1 Clinical Data Demonstrating Oral Treatment with Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, is Well-tolerated in Healthy Volunteers (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: January 9, 2020

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated January 9, 2020

Exhibit 99.1

Tiziana Life Sciences plc

("Tiziana" or the "Company")

Tiziana Reports Phase 1 Clinical Data Demonstrating Oral Treatment with Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, is Well-tolerated in Healthy Volunteers

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014.

New York/London, 9 January 2020 – Tiziana Life Sciences plc (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for inflammatory diseases and cancers, is pleased to report completion of a Phase 1 clinical study of Foralumab, a fully human anti-CD3 monoclonal antibody ("mAb"), in healthy subjects. The proprietary oral formulation, comprising the lyophilized and stabilized free-flowing powder of formulated Foralumab encapsulated in an enteric-coated capsule, was well-tolerated at all doses tested and there were no drug-related safety issues even at the highest dose of 5 mg in this trial.

This Phase 1 trial, conducted at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, USA, was a single-site, double-blind, placebo-controlled, single ascending dose ("SAD") study in healthy subjects in which Foralumab was orally administered at 1.25, 2.5 and 5.0 mg per dose as enteric-coated capsules. Each cohort comprised of 4 subjects, of whom 3 received Foralumab treatment and 1 received a placebo capsule. All subjects completed the trial without any safety concerns at any of the doses.

It has previously been shown that orally administered Foralumab to NOD/SCID IL2γc-/- mice (which have human immune systems) with skin xenografts was well-tolerated up to 15 μg/day (n=20; human equivalent dose of 3.66 mg/dose in a 60 kg human) for 5 days then weekly, prevented skin xenograft rejection indefinitely. Clinical studies conducted by other researchers have also shown that oral administration of OKT3, a murine anti-CD3 mAb, was well-tolerated up to 5 mg/day for 5 days to healthy subjects, to patients with nonalcoholic steatohepatitis ("NASH") for 30 days and to hepatitis C virus (HCV) non-responders for 30 days. Data from a recently completed clinical study indicated that oral administration of OKT3 was well tolerated at 1 mg/day for 30 consecutive doses in patients with moderate-to-severe ulcerative colitis. Importantly, the treatment resulted in clinical responses in 3 out of 6 patients, including one patient with a complete clinical response.

"This is the first -ever study demonstrating that orally administered Foralumab is well-tolerated at all doses up to 5.0 mg/dose. This ground breaking study opens a novel avenue for future development of oral mAb therapeutics " commented Dr. Howard L. Weiner, a member of the scientific advisory board of Tiziana Life Sciences. Recently, we also successfully demonstrated that nasally administered Foralumab is not only well-tolerated but also produced the desirable immunological responses. He added that "both oral and nasal administration routes are physiologic approaches to stimulate the mucosal immune system to induce disease modifying benefits."

"We are very pleased with the tolerability of both oral and nasally administered Foralumab" added Dr. Tanuja Chitnis, Professor of Neurology at Harvard Medical School, and study Principal Investigator (PI).

"Successful completion of this study is a significant milestone to validate our proprietary technologies of oral and nasal administration of mAbs, which we believe could potentially be transformational for future development of mAbs therapeutics. We are excited to note that oral administration was well-tolerated and that the treatment did not result in severe toxicities that are commonly observed with intravenous (IV) administration of anti-CD3 mAbs. These findings provide the scientific rationale for our core technologies of oral and nasal formulations of mAb therapeutics, said Dr. Shailubhai, CEO & CSO of Tiziana Life Sciences.

The person who arranged for the release of this announcement on behalf of the Company was Dr Kunwar Shailubhai, CEO & CSO of Tiziana.

About Foralumab

Foralumab (formerly NI-0401), the only entirely human anti- CD3 mAb, demonstrated a 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 improved overall safety profile of Foralumab. In a humanized mouse model (NOD/SCID IL2γc-/-), 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.

Preclinical studies on oral and nasal administration with Anti-CD3 mAbs

Preclinical and clinical studies have shown that mucosal induction of Tregs by oral or nasal administration of anti-CD3 mAbs is an innovative approach to treat autoimmune and anti-inflammatory diseases (Kuhn and Weiner 2016). Administration of anti-CD3 antibody orally in SLJ mice was shown to suppress autoimmune encephalomyelitis and nasally administered anti-CD3 mAbs were shown to ameliorate disease in an animal model of multiple sclerosis by inducing IL-$10^{+}$$LAP^{+}$ ("latency-associated peptide") T cells, demonstrating oral and nasal anti-CD3 mAbs as a new approach to treat progressive forms of multiple sclerosis and other types of chronic CNS inflammation. Additionally, mucosal administered anti-CD3 mAbs suppressed lupus in lupus-prone mice ("BWF1") by inducing IL- 10 and TGF- β ("Transforming Growth Factor") dependent mechanisms associated with a suppression of IL-17 and IL-21 pro-inflammatory cytokines.

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. In addition to Milciclib, 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"), ulcerative colitis, multiple sclerosis, type-1 diabetes ("T1D"), Crohn's disease, psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable.

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.

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