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

November 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 November 11, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the collaboration with Parexel Biotech to conduct phase 1b/2 clinical trial in patients with Crohn's Disease (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: November 11, 2020

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated November 11 2020

Exhibit 99.1

Tiziana Life Sciences PLC

("Tiziana" or "the Company")

Phase 1b/2 Clinical Trial – Crohn's Disease

Tiziana Life Sciences announces collaboration with Parexel Biotech to conduct phase 1b/2 clinical trial in patients with Crohn's Disease

First Ever Study with take-home capsules of Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody

- ***Potential to be a safer and effective alternative to the intravenous immunotherapies currently used for Crohn's Disease***
- ***Crohn's Disease Therapeutics Market Size $4.7 Billion by 2025***

Phase1b/2 clinical study to be conducted in the United States and several European countries

NEW YORK and LONDON, 11 November 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, today announced it is collaborating with Parexel Biotech ("Parexel"), a division of a leading global clinical research organization ("CRO"), Parexel International (IRL) Limited, to conduct a global Phase 1b/2 trial with enteric-coated capsules of formulated Foralumab, the only fully human anti-CD3 monoclonal antibody ("mAb") - as a therapy for patients with moderate to severe Crohn's Disease ("CD"). This clinical study will evaluate the safety, tolerability, and clinical activity of escalating doses of orally administered capsules of Foralumab. The trial is a dose-ranging, open-label study that will enroll 60 patients in the U.S. and Europe.

Dr. Howard L. Weiner, chairman of the scientific advisory board of Tiziana Life Sciences, commented:

"We understand that this will be the first-ever study with 'take-home' capsules of any mAb for immunotherapies for human diseases. We believe the scientific rationale for oral treatment with Foralumab is logical to facilitate topical action at the inflamed sites in the gastrointestinal tract. This potentially ground-breaking approach for immunotherapies originated in my laboratory and was subsequently reported by other researchers in the field"

"Recently, we also successfully demonstrated that nasally administered Foralumab is not only well-tolerated, but also produced desirable immunological responses. Oral and nasal administration routes are both physiologic approaches to stimulate the mucosal immune system to induce disease modifying benefits."

The CD therapeutic market size will be worth $4.7 Billion by 2025, according to Grand View Research [1]. CD is a chronic disorder of the immune system that causes inflammation throughout the digestive tract. Although the specific causes of CD are still not clearly understood, severe gut inflammation caused by an overactive immune system attacking the intestines, colon and other organs appears to contribute to disease pathology. Thus, immunosuppressive agents and anti-TNF (Tumour Necrosis Factor) immunotherapies represent the main therapeutic options to maintain remission in CD. However, severe toxicities and poor patient compliance limit the long-term use for intravenous immunotherapies. Oral administration with take-home capsules of Foralumab is a very attractive approach as it may provide local action to treat gut inflammation in patient with CD. Additionally, oral capsules provide the convenience of home use, and increase patient compliance by eliminating the need for infusions in a clinic or hospital setting.

“The prevalence of inflammatory bowel disease is rising globally, imposing a significant burden both on patients as well as healthcare systems worldwide,” said Sy Pretorius, MD, Parexel Executive Vice President and Chief Medical & Scientific Officer. “We’re excited to be collaborating with Tiziana to support the development of a novel, oral therapy that could provide Crohn’s patients with another option in their repertoire of treatments to combat this devastating disease.”

Recently, Tiziana announced positive results from its Phase 1 study showing that oral treatment with Foralumab was well-tolerated in healthy volunteers, with no drug-related safety issues even at the highest dose of 5 mg[2]. Oral administration of anti-CD3 monoclonal antibody is a novel approach to induce an anti-inflammatory immune response to suppress inflammation by inducing T regulatory (Tregs) cells in animal studies[3,4]. Importantly, oral treatment with OKT3, a mouse anti-CD3 mAb, showed clinical responses which were reversed following discontinuation of treatment, suggesting oral treatment with OKT3 may have potential for treatment of moderate to severe ulcerative colitis[5].

Dr. Shailubhai, CEO & CSO of Tiziana Life Sciences, commented:
“Previously, we reported that oral administration of Foralumab was well-tolerated and that the treatment did not result in severe toxicities that are so commonly observed with intravenous (IV) administration of anti-CD3 mAbs, suggesting that oral administration may be able to minimize toxicities and thereby improve clinical outcome. Our patent on the core formulation technologies covering alternative routes of administration for immunotherapies has been already granted in the USA and it is pending in other countries world-wide. We believe switching to oral, nasal and inhalational administration of mAbs from the traditional intravenous administration could potentially be transformational for the future development of immunotherapies.”

This announcement contains inside information for the purposes of Article 7 of EU Regulation 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. Grand View Research August 2018 (https://www.grandviewresearch.com/press-release/global-crohns-disease-therapeutics-market).

2. Tiziana Life Sciences January 9, 2020 Press Release (https://ir.tizianalifesciences.com/news-releases/news-release-details/tiziana-life-sci-plc-further-re-foralumab-phase-1-trial)

3. da Cunha, A. P., and Weiner, H. L. (2012) Induction of immunological tolerance by oral anti-CD3. Clin Dev Immunol 2012, 425021

4. Ogura, M., Deng, S., Preston-Hurlburt, P., Ogura, H., Shailubhai, K., Kuhn, C., Weiner, H. L., and Herold, K. C. (2017) Oral treatment with foralumab, a fully human anti-CD3 monoclonal antibody, prevents skin xenograft rejection in humanized mice. Clin Immunol 183, 240-246

5. Boden, E. K., Canavan, J. B., Moran, C. J., McCann, K., Dunn, W. A., Farraye, F. A., Ananthakrishnan, A. N., Yajnik, V., Gandhi, R., Nguyen, D. D., Bhan, A. K., Weiner, H. L., Korzenik, J. R., and Snapper, S. B. (2019) Immunologic Alterations Associated With Oral Delivery of Anti-CD3 (OKT3) Monoclonal Antibodies in Patients With Moderate-to-Severe Ulcerative Colitis. Crohn's & Colitis 360, Volume 1, Issue 2, July 2019, otz009

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 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 (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 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. 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.

About Parexel
Parexel Biotech is a division of leading global clinical research organization (CRO), Parexel International (IRL) Limited, and provides tailored solutions for biotech and medical device companies to accelerate their development goals and help them achieve faster market access.

Parexel is focused on supporting the development of innovative therapies to improve patient health. During the COVID-19 crisis, we continue to be committed to our customers' business while putting the safety of patients, client partners and our employees at the heart of everything we do. To learn more about our efforts related to COVID-19, as well as the experts, innovations and processes we have in place to navigate the rapidly changing landscape, visit us at website and follow us on LinkedIn, Twitter and Instagram.

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:

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