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 2022

Commission File Number: 0001723069

Tiziana Life Sciences LTD
(Exact Name of Registrant as Specified in Its Charter)

9th Floor
107 Cheapside
London
EC2V 6DN
(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 25, 2022, Tiziana Life Sciences LTD (the "Company") issued a news service announcement in the United States announcing the Initiation of Phase 1b Clinical Trial in Crohn's Disease Patients to Evaluate Oral Capsules of Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody.

The 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 LTD

Date: March 25, 2022

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	News Service Announcement, dated March 25, 2022

Exhibit 99.1

Tiziana Announces Initiation of Phase 1b Clinical Trial in Crohn's Disease Patients to Evaluate Oral Capsules of Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody

- *This clinical trial, the first-ever oral immunotherapy for patients with mild-to-moderately active Crohn's Disease, is anticipated to be completed by Q4, 2022.*

New York, March 25, 2022 – Tiziana Life Sciences (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company enabling breakthrough immunotherapies via novel routes of monoclonal antibody delivery, today announced initiation of a Phase 1b clinical trial to evaluate orally administered enteric-coated capsules of foralumab in patients with mild-to-moderate Crohn's Disease (CD). This revised protocol, as previously outlined in the Company's announcement on February 4, 2022, allows for the study of a broader patient population and a shorter dosing period. These protocol amendments or revisions are intended to expedite patient enrollment with study completion targeted for the fourth quarter of 2022.

This study is the first multiple-dose study with orally administered enteric-coated capsules of foralumab in patients with CD. This study will initiate soon with patient enrollment in the second quarter of 2022. Enteric-coated capsules, containing doses up to 5 mg of foralumab, will be administered once-daily for five consecutive days to patients with mild-to-moderately active CD. While the primary objective is safety and tolerability, additional endpoints are to assess clinical and immune signal responses, including calprotectin measurements in stool. Blood samples will be collected to evaluate pharmacokinetics, including the rate and extent of systemic absorption. The presence of anti-drug antibodies (ADAs) will also be determined.

Typically, therapeutic antibodies are administered either intravenously or subcutaneously, but severe and sometimes life-threatening side effects may occur. Oral administration with foralumab is a novel approach to induce an anti-inflammatory immune response via site-targeted immunomodulation in the gut. Previous mouse and patient studies have demonstrated that orally delivered anti-CD3 antibody effectively ameliorates gut inflammation in a murine model of colitis[1] and in patients with moderate-to-severe ulcerative colitis[2]. Currently, commonly used immunotherapies for CD require intravenous or subcutaneous administration of anti-TNF-alpha antibodies, such as HUMIRA® (NASDAQ: ABBV), REMICADE® (NASDAQ: JNJ), and anti-CD23 antibodies (STELARA®)(NASDAQ: JNJ).

Dr. Kunwar Shailubhai, Chief Executive Officer and Chief Scientific Officer of Tiziana, commented, "The oral route of administration is the preferred route for all pharmaceuticals. The "Holy Grail" for biologics is the "switch" from parenteral (IV, SC) to oral administration as it is the most economical, non-invasive, and convenient route with respect to patient's quality of life and compliance. We have developed proprietary formulation technologies, enabling oral, nasal, and inhalation routes for administration of antibodies, to facilitate local action at the respective target sites. We believe this Phase 1b study is a logical first step towards the clinical validation of oral immunotherapy with foralumab capsules, to provide local action rather than systemic delivery, for CD treatment."

Howard Weiner, M.D., Director of the Multiple Sclerosis Program at the Brigham and Women's Hospital (BWH) and Chairman of Tiziana's Scientific Advisory Board, commented, "Treatment with orally or nasally administered foralumab is a novel physiological approach to stimulate the mucosal immune system to induce disease-modifying benefits while minimizing the toxicities that are commonly associated with the traditional intravenous or subcutaneous immunotherapies. In this regard, the first validation of our innovative approach came from our recently reported clinical results showing positive clinical benefits in a patient with secondary progressive multiple sclerosis (SPMS), who was treated for 6 months with intranasally administered foralumab[3]."

Cited references

1. Forster, K. et al., 2012. Gastroenterology. 143(5):1298-1307.
2. Boden, E.K., et al., Crohn's & Colitis 360, Volume 1, Issue 2, otz009
3. Tiziana Press Release March 10, 2022

About Foralumab
Foralumab (TZLS-401; formerly NI-0401), the only entirely human anti-CD3 mAb, shows reduced release of cytokines after IV administration in healthy volunteers and in patients with Crohn's disease. 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 and enhances regulatory T-cells (Tregs), thereby providing therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy (Ogura et al., *Clin. Immunol.* 183:240-246, 2017). Once a day treatment for 10 consecutive days with intranasal foralumab was not only well tolerated but also produced strong clinical responses in COVID-19 patients (Moreira et al., *Front Immunol* 12: 709861,2021). Based on these studies, the intranasal and oral administration of foralumab offers the potential to become a well-tolerated immunotherapy for autoimmune and inflammatory diseases by the induction of Tregs.

About Crohn's Disease
Crohn's Disease (CD) is a chronic inflammatory bowel disease that affects the digestive tract lining. CD affects men, women, and children and up to a half-million people in the U.S. The CD typically appears in younger people – often in their late teens, 20s, or early 30s. However, this condition can happen at any age. CD cannot be cured, but medications such as steroids and immunosuppressants are used to slow its progression. If these medications aren't effective, a patient may require surgery. CD is also considered an autoimmune disease caused by dysregulation of the immune system.

About Tiziana Life Sciences
Tiziana Life Sciences is a clinical-stage biopharmaceutical company developing breakthrough therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy. Tiziana's innovative nasal, oral, and inhalation approaches in development have the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's two lead candidates, intranasal foralumab, the only fully human anti-CD3 mAb, and milciclib, a pan-CDK inhibitor, have both demonstrated a favorable safety profile and clinical response in patients in studies to date. Tiziana's technology for alternative routes of immunotherapy has been patented with several applications pending and is expected to allow for broad pipeline applications.

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 inquiries:

Tiziana Life Sciences Ltd

Hana Malik, Business Development, and Investor Relations Manager
+44 (0) 207 495 2379
email: info@tizianalifesciences.com

Investors:
Irina Koffler
LifeSci Advisors, LLC
646.970.4681
ikoffler@lifesciadvisors.com