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

April 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 April 5, 2022, Tiziana Life Sciences LTD (the "Company") issued a news service announcement in the United States announcing that the FDA Grants Permission to Enroll up to 8 Additional Secondary Progressive Multiple Sclerosis (SPMS) Patients in the Expanded Access Program with Intranasal Foralumab.

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: April 5, 2022

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	News Service Announcement, dated April 5, 2022

Exhibit 99.1

FDA Grants Permission to Enroll up to 8 Additional Secondary Progressive Multiple Sclerosis (SPMS) Patients in the Expanded Access Program with Intranasal Foralumab

- *This Intermediate-Size Patient Population Expanded Access program will follow the same clinical dosing regimen as the two ongoing single-patient expanded access programs in SPMS patients.*

- *Tiziana recently reported clinical data from the first SPMS patient showing beneficial responses following six months of treatment with intranasal foralumab, a fully human anti-CD3 monoclonal antibody*

- *The clinical data update from the second SPMS patient is expected in May 2022, representing 3 months of intranasal foralumab therapy.*

New York, April 5, 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 that its collaborators at the Brigham and Women's Hospital (BWH) Boston MA have received a 'Study May Proceed Letter' from the U.S. Food and Drug Administration (FDA) permitting initiation of treatment in up to an additional eight SPMS patients as part of an Intermediate-Size Patient Population Expanded Access IND.

The safety, tolerability, and clinical responses from the first two SPMS patients were submitted to the FDA to seek permission to treat up to an additional eight SPMS patients with the goal of obtaining more clinical data to assess robustness of the clinical responses. As part of the original treatment plan, the foralumab dose will remain 50 mcg three times a week (MWF), which is the same dose administered previously to the first two SPMS patients. The dosing regimen in this IND also has a provision for dose escalation up to 100 mcg three times a week (MWF) as an option to improve clinical benefit, if needed.

The treatment plan will be submitted to the Institutional Review Board (IRB) of BWH prior to initiation of patient enrollment and initiation of the study, which is anticipated to be initiated in July 2022. While the primary objectives are safety, tolerability and patient benefits, additional measures will assess clinical and immune responses, including imaging by positron emission tomography (PET), specifically to assess inhibition of microglial activation.

Excessive activation of microglial cells is well-known to be associated with neurodegenerative diseases such as multiple sclerosis (MS), Alzheimer's disease and Parkinson[1]. The underlying causes of these diseases lead to microglial activation and brain inflammation[2]. Thus, inhibition of microglial activation is an important target for drug discovery and development for neurodegenerative diseases. Several FDA-approved drugs, such as TYSABRI® (Nasdaq: BIIB), MAYZENT® (NYSE: JNJ) and ZEPOSIA® (NYSE: BMY) suppress microglial activation and exert neuroprotective effects in the central nervous system (CNS) in animal studies but longitudinal assessment of drug effects on microglial activation in SPMS patients remains to be determined. On March 10, 2022, Tiziana reported clinical data from a SPMS patient treated with intranasal foralumab for six months, which showed that foralumab inhibited microglial cell activation in all areas of the brain as assessed by PET imaging[3].

Howard Weiner, M.D., Director of the Multiple Sclerosis Program at the BWH and Chairman of Tiziana's Scientific Advisory Board, commented, "Treatment with intranasal foralumab is a novel physiological approach to stimulate the mucosal immune system to induce disease-modifying benefits in the CNS by dampening microglial inflammation. The first validation of our innovative approach came from our recently reported results showing positive clinical benefits and microglial modulation in a patient with secondary progressive multiple sclerosis who was treated for six months with nasal Foralumab[3]. This now opens the door to treat other neurologic diseases which have microglial inflammation - such as Alzheimer's disease - with intranasal foralumab."

Dr. Tanuja Chitnis, M.D., Professor at the BWH and a member of Tiziana's Scientific Advisory Board, commented, "Therapies to slow progression in multiple sclerosis are much needed. We are grateful to have the opportunity to offer intranasal foralumab to progressive MS patients."

Cited references

1. Luo, C., et al., Neuropsychiatric Dis Treat. 2017; 13: 1661–1667.
2. Alan, C-B., et al., Neuron 2018 Feb 21;97(4):742-768
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 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