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

June 2024

Commission File Number: 001-38723

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 ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On June 11, 2024, Tiziana Life Sciences LTD (the "Company") issued this 6K announcing, it has received acceptance of its submission for intranasal foralumab to receive Fast Track Designation approval for the treatment of non-active, secondary-progressive multiple sclerosis (na-SPMS) to the U.S. Food and Drug Administration (FDA)., a copy of which is furnished as Exhibit 99.1

The Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibits 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: June 11, 2024

By: /s/ Keeren Shah
Name: Keeren Shah
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Tiziana Life Sciences LTD Press Release, dated June 11, 2024

Exhibit 99.1

FDA Accepts Tiziana Life Sciences Fast Track Designation Submission for Treatment of Multiple Sclerosis

NEW YORK, June 11, 2024 – Tiziana Life Sciences, Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough immunomodulation therapies via novel routes of drug delivery, today announced it has received acceptance of its submission for intranasal foralumab to receive Fast Track Designation approval for the treatment of non-active, secondary-progressive multiple sclerosis (na-SPMS) to the U.S. Food and Drug Administration (FDA).

Foralumab, a fully human anti-CD3 monoclonal antibody, is a biological drug candidate shown to cause T regulatory (Treg) cell induction when dosed intranasally. At present, ten (10) na-SPMS patients have been dosed in an Intermediate-Sized Patient Population Expanded Access (ISPPEA) Program with clinically meaningful reduction in fatigue scores (MFIS) in 70% of patients, and stability of disease noted within six months in all ten patients. In addition, intranasal foralumab is currently being studied in a Phase 2a, double-blind randomized, placebo-controlled, multicenter trial in patients with na-SPMS (NCT06292923). The Fast Track Designation request provided data from both animal models and clinical experience from the ISPPEA program. Foralumab would be the only intranasal monoclonal antibody designated as other Multiple Sclerosis monoclonal antibody therapies require intravenous or subcutaneous dosing. Fast Track Designation, if granted will affirm the serious disease condition and progressive disability seen in na-SPMS, and also the unmet medical need, as no therapies are currently approved for na-SPMS.

"Fast track is designed to expedite the review of drugs in development to treat serious conditions for which there are limited or no therapies," commented Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences. "The progressive nature of na-SPMS and lack of FDA-approved therapies for this disease aligns with the Food and Drug Administration's criteria for Fast Track Designation. The increased interaction and partnership with the FDA afforded by this designation would be a tremendous asset to our foralumab development program, if granted," he added.

About FDA Fast Track Designation

At this stage of development, a drug that receives Fast Track designation is eligible for some or all of the following[1]:

- *More frequent meetings with FDA to discuss the drug's development plan and ensure collection of appropriate data needed to support drug approval*
- *More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers*
- *Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met*

[1] https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track

About Foralumab

Activated T cells play an important role in the inflammatory process. Foralumab, the only fully human anti-CD3 monoclonal antibody (mAb), binds to the T cell receptor and dampens inflammation by modulating T cell function, thereby suppressing effector features in multiple immune cell subsets. This effect has been demonstrated in patients with COVID and with multiple sclerosis, as well as in healthy normal subjects. The non-active SPMS intranasal foralumab Phase 2 trial (NCT06292923) began screening patients in November of 2023. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of neuroinflammatory and neurodegenerative human diseases.[2],[3]

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 approach has the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's lead candidate, intranasal foralumab, which is the only fully human anti-CD3 mAb, has 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.

For more information please visit our website: www.tizianalifesciences.com

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[2] https://www.pnas.org/doi/10.1073/pnas.2220272120
[3] https://www.pnas.org/doi/10.1073/pnas.2309221120