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

May 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 May 13, 2024, Tiziana Life Sciences LTD (the "Company") issued this 6K announcing, it has submitted an FDA request to obtain Orphan Drug Designation for intranasal foralumab for the treatment of non-active secondary progressive Multiple Sclerosis (na-SPMS). This request would make foralumab the first therapy for na-SPMS to receive Orphan Drug Designation., 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: May 13, 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 May 13, 2024

Tiziana Life Sciences Files for Orphan Drug Designation for Intranasal Foralumab

NEW YORK, May 13, 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 submitted an FDA request to obtain Orphan Drug Designation for intranasal foralumab for the treatment of non-active secondary progressive Multiple Sclerosis (na-SPMS). This request would make foralumab the first therapy for na-SPMS to receive Orphan Drug Designation. Our request is supported by clinical and non-clinical evidence of Foralumab's effectiveness in na-SPMS. The prevalence estimates, in part, are supported from the Brigham & Women's Hospital, Boston, Massachusetts, longitudinal study, the CLIMB data of which allowed the estimate of na-SPMS in the population.

Foralumab, a fully human anti-CD3 monoclonal antibody, is a biological drug candidate that has been shown to stimulate T regulatory cells when dosed intranasally.[1] At present, 10 patients with na-SPMS have been dosed in an open-label intermediate- size Expanded Access (EA) Program with an additional 20 patients recently allowed to enter the program by the FDA. All patients in this expanded access program have either improved or stabilized on treatment with foralumab. 70% of patients have seen an improvement in fatigue after six months of treatment. Fatigue is a debilitating symptom for many MS patients and is measured by the Modified Fatigue Impact Scale (MFIS). None of the patients have declined in key clinical measures. In addition, intranasal foralumab is being studied in a Phase 2a, randomized, double-blind, placebo-controlled, multicenter, dose-ranging trial (NCT06292923) with a data readout planned for 2025.

"Orphan Drug Designation is granted by the FDA to drugs or biologics intended to treat a rare disease or condition, defined as one that affects fewer than 200,000 people in the U.S.," commented Gabriele Cerrone, Chairman, acting CEO, and founder of Tiziana Life Sciences. "Orphan Drug Designation allows for up to seven years of marketing exclusivity if the product is ultimately approved for its designated indication, as well as providing the opportunity for other financial incentives to assist with development. It therefore carries significant value to our company and shareholders," he concluded.

Once submitted, applications are reviewed by the FDA's Orphan Drug Designation program, which determines whether all criteria for Orphan Drug Designation approval have been met. Applications are reviewed by the Orphan Drug Designation program within 90 days of receipt.

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 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. [1,2]

1 https://www.pnas.org/doi/10.1073/pnas.2220272120

2 https://www.pnas.org/doi/10.1073/pnas.2309221120

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 further inquiries:

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