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

July 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 July 24, 2024, Tiziana Life Sciences LTD (the "Company") issued this 6K announcing, that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its intranasal formulation of foralumab, a fully human anti-CD3 monoclonal antibody, for the treatment of non-active Secondary Progressive Multiple Sclerosis (na-SPMS)., 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: July 24, 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 July 24, 2024

Exhibit 99.1

Tiziana Life Sciences Granted FDA Fast Track Designation

NEW YORK, July 24, 2024 – Tiziana Life Sciences, Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough immunomodulation therapies with its lead development candidate, intranasal foralumab, a fully human, anti-CD3 monoclonal antibody, today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for its intranasal formulation of foralumab, a fully human anti-CD3 monoclonal antibody, for the treatment of non-active Secondary Progressive Multiple Sclerosis (na-SPMS).

The Fast Track designation is a significant milestone for Tiziana Life Sciences, providing an expedited review process and increased interaction with the FDA. This designation is intended to facilitate the development of and expedite the review of drugs that treat serious conditions and fill an unmet medical need. Only four Fast Track designations have been granted in 2024 by FDA's Center for Drug Evaluation and Research as of March 31, 2024.

"We are thrilled to receive Fast Track designation from the FDA for intranasal foralumab for the treatment of Multiple Sclerosis," said Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences. "This designation underscores the potential of foralumab to address critical unmet needs in the treatment of neurodegenerative diseases. We are committed to advancing this promising therapy as quickly as possible to benefit patients."

The Fast Track designation provides several benefits, including more frequent meetings with the FDA to discuss the drug's development plan, eligibility for Accelerated Approval and Priority Review if relevant criteria are met, and a potential Rolling Review of the New Drug Application (NDA).

"Receiving Fast Track designation is a testament to the innovative approach we are taking with foralumab," said Dr. William Clementi, Chief Development Officer of Tiziana Life Sciences. "We believe that the intranasal delivery method offers a novel way to effectively target neuroinflammation, and we look forward to working closely with the FDA to bring this therapy to patients in need."

Intranasal foralumab is designed to modulate the immune system and reduce neuroinflammation, which is a key factor in the progression of neurodegenerative diseases such as Multiple Sclerosis, Alzheimer's Disease and Amyotrophic Lateral Sclerosis (ALS). Early clinical data have shown that intranasal Foralumab can deliver therapeutic benefits with a favorable safety profile. The company aims to accelerate these programs and capitalize on opportunities to address significant unmet medical needs.

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. At present, 10 patients with Non-Active Secondary Progressive Multiple Sclerosis (na-SPMS) have been dosed in an open-label intermediate sized Expanded Access (EA) Program with either an improvement or stability of disease seen within 6 months in all patients. The FDA has recently allowed an additional 20 patients to be enrolled in this EA program. In addition, intranasal foralumab is currently being studied in a Phase 2a, randomized, double-blind, placebo-controlled, multicenter, dose-ranging trial in patients with non-active secondary progressive multiple sclerosis (NCT06292923).

Receipt of Notice from Nasdaq and Plan to Appeal

On July 19, 2024, the Company received written notice (the "Notice") from The Nasdaq Stock Market LLC ("Nasdaq") stating that the Company did not maintain a minimum bid price of at least $1.00 for a minimum of ten (10) consecutive business days before the end of the Nasdaq grace period and, therefore, did not regain compliance with Listing Rule 5550(a)(2) by July 15, 2024, as required.

As a result of the foregoing, the Staff informed the Company that its ordinary shares would be subject to delisting from The Nasdaq Capital Market on July 29, 2024, unless the Company timely requests a hearing before the Nasdaq Hearings Panel (the "Panel"). Accordingly, the Company intends to timely request a hearing before the Panel, which request will stay any delisting action by Nasdaq at least pending the issuance of the Panel's decision following the hearing and the expiration of any additional extension period granted by the Panel following the hearing. At the hearing, the Company will present its plan to evidence compliance with the minimum bid price requirement.

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.[1,2]

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 about Tiziana Life Sciences and its innovative pipeline of therapies, please visit www.tizianalifesciences.com

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.

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1 https://www.pnas.org/doi/10.1073/pnas.2220272120
2 https://www.pnas.org/doi/10.1073/pnas.2309221120