

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

December 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 December 4, 2024, Tiziana Life Sciences LTD (the “Company”) issued this 6K announcing, announced the expansion of its Phase 2 clinical trial evaluating intranasal foralumab for non-active secondary progressive multiple sclerosis (SPMS). The trial sites include esteemed institutions across the Northeast of the United States,, 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: December 4, 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 December 4, 2024



**Tiziana Life Sciences Expands Phase 2 Clinical Trial for Non-Active
Secondary Progressive Multiple Sclerosis to Additional Prestigious U.S. Medical Centers**

NEW YORK, December 4, 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 expansion of its Phase 2 clinical trial evaluating intranasal foralumab for non-active secondary progressive multiple sclerosis (SPMS). The trial sites include esteemed institutions across the Northeast of the United States.

Additional trial sites include:

- **Yale University**
- **Johns Hopkins University**
- **Cornell University**
- **University at Buffalo (SUNY)**
- **University of Massachusetts (UMass)**
- **Thomas Jefferson University**

These universities represent leaders in medical research and neurology, with a history of pioneering studies in multiple sclerosis. Their inclusion enhances the trial's reach and brings together top-tier expertise with innovative facilities to evaluate Tiziana's promising approach to addressing SPMS. The rationale in selecting sites in the Northeast is to have all trial participants receive their PET scans at a single imaging site at Invicro, located at New Haven, Connecticut to minimize the variability of the PET scans.

Non-active SPMS remains a significant unmet need within the multiple sclerosis community, with no FDA approved therapeutic options available. Tiziana's intranasal foralumab offers a unique approach, targeting inflammation and modulating the immune system without systemic immune suppression.

“We are honored to collaborate with these prestigious institutions as we further expand our clinical trial,” said Ivor Elrifi, CEO of Tiziana Life Sciences. “This milestone demonstrates our dedication to advancing innovative treatments for patients living with SPMS and underscores the potential of our platform to address complex neurodegenerative diseases.”

The Phase 2 trial aims to generate robust, high-quality data to support Tiziana's regulatory strategy. For further information on the trial, including enrollment criteria and site details, visit <https://clinicaltrials.gov/study/NCT06292923>.

About Foralumab

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. 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. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of neuroinflammatory and neurodegenerative human diseases.^{[1],[2]}

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). 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.

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

For further inquiries:

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[1] <https://www.pnas.org/doi/10.1073/pnas.2220272120>

[2] <https://www.pnas.org/doi/10.1073/pnas.2309221120>
