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

January 2025

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 January 22, 2025, Tiziana Life Sciences LTD (the "Company") issued this 6K announcing, the discovery of new immune biomarkers in patients with non-active secondary progressive multiple sclerosis (na-SPMS) treated with nasal foralumab. We believe these findings contribute substantially to our understanding of the immune mechanisms underlying the effects of nasal foralumab., 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: January 22, 2025

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 January 22, 2025

Exhibit 99.1

Tiziana Life Sciences Announces Discovery of New Immune Biomarkers in Multiple Sclerosis Patients Treated with Nasal Foralumab

NEW YORK, January 22, 2025 – 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 discovery of new immune biomarkers in patients with non-active secondary progressive multiple sclerosis (na-SPMS) treated with nasal foralumab. We believe these findings contribute substantially to our understanding of the immune mechanisms underlying the effects of nasal foralumab.

The study identified gene expression changes which were detected beginning three months after intranasal dosing of foralumab in our ongoing ISPPEA (or expanded access program). Key findings include modulation of:

- FoxP3 T regulatory cells (Tregs)
- CD4+ and CD8+ central memory T cells
- CD14+ and CD14- monocytes
- Naïve B cells

These pathways are known to be associated with antigen presentation, interferon responses, and other regulatory immune mechanisms.

In this study, single-cell RNA sequencing (scRNAseq) of peripheral blood samples taken before and at three and six months after drug administration has revealed relevant gene expression changes associated with nasal foralumab, which has been associated with a reduction in microglial brain inflammation, as measured by advanced microglial PET scans in these same patients.

"We are excited to announce this breakthrough in understanding how nasal foralumab induces immune modulation in Secondary Progressive MS patients," said Dr. Tanuja Chitnis, M.D., Principal Investigator and Professor of Neurology at Harvard Medical School and senior neurologist at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System. "These findings highlight the potential of nasal foralumab in modulating critical immune pathways and offer new insights into its clinical effects. This discovery represents a pivotal step toward personalized treatment strategies for MS. We look forward to submitting these data to a peer reviewed journal"

"The observed clinical stabilization and microglial PET findings are supported by these new biomarker discoveries, providing compelling evidence of nasal foralumab's biological effects," said Dr. Howard Weiner, Chairman of Tiziana's Scientific Advisory Board and co-director of the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital, a founding member of Mass General Brigham healthcare system. "The identification of these biomarkers not only strengthens our understanding of the treatment's mechanism but also establishes a framework for monitoring its efficacy in future trials and may establish a framework for monitoring a patient's response to foralumab treatment."

"This data, and its implications, underscores our commitment to advancing innovative therapies for neurodegenerative diseases," commented Ivor Elrifi, CEO of Tiziana Life Sciences. "Foralumab, the first fully human anti-CD3 monoclonal antibody, is in a Phase 2 trial as a groundbreaking immunomodulatory therapy with applications in autoimmune and neurodegenerative diseases. These findings further confirm its potential and set the stage for broader clinical exploration."

The FDA defines a biomarker as a defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes, or responses to an exposure or intervention, including therapeutic interventions. Molecular, histologic, radiographic, or physiologic characteristics are types of biomarkers. A biomarker is not an assessment of how an individual feels, functions, or survives.

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. 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).

Activated T cells play an important role in the inflammatory process. Foralumab, the only fully human anti-CD3 monoclonal antibody (mAb) currently in clinical development, 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 observed 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 currently in clinical development, 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. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled 'Risk Factors' in Tiziana's Annual Report on Form 20-F for the year ended December 31, 2023, and other periodic reports filed with the Securities and Exchange Commission.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:

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

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