# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

1	$\Gamma$	N	R	M	6	$_{\mathbf{K}}$
ı	η,	.,		IVI	w	-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)

9<sup>th</sup> 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 8, 2025, Tiziana Life Sciences LTD (the "Company") issued this 6K announcing, that a review article titled "Immune mechanisms and shared immune targets in neurodegenerative diseases" was published in Nature Reviews Neurology, highlighting the therapeutic potential of intranasal foralumab in various neurodegenerative diseases including Multiple Sclerosis (MS), Alzheimer's disease, ALS, and Parkinsons disease., 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.

Date: January 8, 2025

## TIZIANA LIFE SCIENCES LTD

By: /s/ Keeren Shah

Name: Keeren Shah

Title: Chief Financial Officer

# EXHIBIT INDEX

Exhibit No.	Description
99.1	<u>Tiziana Life Sciences LTD Press Release, dated January 8, 2025</u>
	3



#### Tiziana Life Sciences Announces Review Article Published in Nature Highlighting Foralumab's Potential in the Treatment of Neurological Disease

NEW YORK, January 8, 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 that a review article titled "Immune mechanisms and shared immune targets in neurodegenerative diseases" was published in Nature Reviews Neurology, highlighting the therapeutic potential of intranasal foralumab in various neurodegenerative diseases including Multiple Sclerosis (MS), Alzheimer's disease, ALS, and Parkinsons disease.

The immune system plays a significant role in neurodegenerative diseases. In some, such as multiple sclerosis, it is the primary driver of the disease. In others, such as Alzheimer's disease, amyotrophic lateral sclerosis, and Parkinson disease, it has an amplifying role. Immunotherapeutic approaches that target the adaptive and innate immune systems are being explored for the treatment of almost all neurological diseases, and the targets and approaches are often common across diseases. Therapeutic approaches target components of the peripheral immune system, such as regulatory T cells and monocytes, which in turn act within the CNS. Microglia are the primary immune cells in the brain that contribute to disease pathogenesis and are consequently a common immune target for therapy. The article highlights the dampening of microglia activation in MS by intranasal Foralumab.

The Review considers in detail how microglia, monocytes and T cells contribute to the pathogenesis of multiple sclerosis, Alzheimer disease, amyotrophic lateral sclerosis and Parkinson disease, and their potential as shared therapeutic targets across these diseases. The microbiome is also highlighted as an emerging therapeutic target that indirectly modulates the immune system. Therapeutic approaches being developed to target immune function in neurodegenerative diseases are discussed, highlighting how immune-based approaches developed to treat one disease could be applicable to multiple other neurological diseases.

Article Author, 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, commented, "The intranasal delivery of Foralumab represents one of the most promising approaches for the treatment of several of the most important neurodegenerative diseases including MS, Alzheimer's disease, ALS and Parkinson's disease. This novel approach acts by dampening microglial activation, a key driver of disease in all these neurologic conditions. Furthermore, intranasal Foralumab acts without apparent side effects and is easily administered. It is a promising therapeutic avenue for patients with neurologic diseases that have limited treatment options."

Tiziana's CEO, Ivor Elrifi, added, "We are encouraged by the insights presented in this article, which underscore the potential of Foralumab as a groundbreaking therapy for neurodegenerative diseases. At Tiziana, we are committed to advancing innovative treatments that address significant unmet medical needs, and this publication reinforces our dedication to improving patient outcomes in progressive MS and other neurological diseases."

The full Review Article can be accessed here: https://www.nature.com/articles/s41582-024-01046-7

#### **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]

- [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 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:

#### Tiziana Life Sciences Ltd

Paul Spencer, Business Development, and Investor Relations +44 (0) 207 495 2379

email: info@tizianalifesciences.com