# 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

June 2024

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  $\boxtimes$  Form 40-F  $\square$ 

### **INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K**

On June 26, 2024, Tiziana Life Sciences LTD (the "<u>Company</u>") issued this 6K announcing, Tiziana Life Sciences to Dose First Patient with Moderate Alzheimer's Disease with 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: June 26, 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 June 26, 2024 |
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#### Tiziana Life Sciences to Dose First Patient with Moderate Alzheimer's Disease with Foralumab

NEW YORK, June 26, 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 that the U.S. Food and Drug Administration (FDA) has allowed intranasal foralumab to be used under an Expanded Access (EA) IND in its first patient with moderate Alzheimer's disease. Expanded access IND's provide a pathway for patients to gain access to investigational drugs, biologics, and medical devices used to diagnose, monitor, or treat patients with serious diseases or conditions for which there are no comparable or satisfactory therapy options available outside of clinical trials.

Howard L. Weiner, M.D., Principal Investigator, 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 stated, "I am excited to treat this first patient with moderate AD with nasal foralumab as early as July. These patients have no other treatment options including newly approved antiamyloid drugs and continue to deteriorate. Given that nasal foralumab dampens microglial inflammation in subjects with advanced progressive MS and microglial activation is a prominent feature of Alzheimer's disease, Tiziana is hopeful that nasal foralumab will help slow the progression of cognitive decline in this first patient. We will work closely with FDA to evaluate the treatment responses in this patient with moderate AD while we initiate our Phase 2 study Alzheimer's Disease in patients with early symptomatic disease."

Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences commented, "In addition to our previously announced IND clearance of the Phase 2a early symptomatic Alzheimer's Disease study, this additional FDA clearance allows Tiziana to also study intranasal foralumab in patients with moderate Alzheimer's Disease who do not qualify for approved therapies." Gabriele Cerrone further commented, "Foralumab could be a potentially groundbreaking treatment for Alzheimer's disease, given it targets the disease's underlying pathology by addressing the resulting neuroinflammation caused by the accumulation of toxic proteins in the brain."

#### **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.<sup>1,2</sup>

#### **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 please visit our website: www.tizianalifesciences.com

For further inquiries:

#### **Tiziana Life Sciences Ltd**

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

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