# 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 6, 2024, Tiziana Life Sciences LTD (the "<u>Company</u>") issued this 6K announcing, the qualitative results for all 10 non-active Secondary Progressive Multiple Sclerosis (na-SPMS) patients enrolled in the intermediate-size patient population Expanded Access (EA) Program receiving foralumab for at least six months., 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

By: /s/ Keeren Shah

Name: Keeren Shah Title: Chief Financial Officer

Date: June 6, 2024

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# EXHIBIT INDEX

Exhibit No.	Description
99.1	Tiziana Life Sciences LTD Press Release, dated June 6, 2024
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#### Tiziana Life Sciences Announces Six-Month Qualitative Improvement in Neuroimaging in 80% of Multiple Sclerosis Patients Receiving Intranasal Foralumab

- Qualitative improvements in PET imaging seen in 80% of non-active Secondary Progressive Multiple Sclerosis (na-SPMS) Expanded Access patients receiving intranasal foralumab for at least 6-months.
- FDA Allowance for an additional 20 Patients to be enrolled in the intranasal foralumab Multiple Sclerosis Expanded Access Program will allow further data collection and analysis.
- Applied for FDA Orphan Drug Designation of foralumab for na-SPMS

NEW YORK, June 6, 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 the qualitative results for all 10 non-active Secondary Progressive Multiple Sclerosis (na-SPMS) patients enrolled in the intermediate-size patient population Expanded Access (EA) Program receiving foralumab for at least six months.

Tarun Singhal, M.B.B.S., M.D., Director of the PET Imaging Program in Neurologic Diseases, associate neurologist and nuclear medicine physician at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System, and Associate Professor of Neurology at Harvard Medical School, commented, "Based on currently available data from the latest cohort of four Expanded Access patients, three out of the four subjects had findings that suggest a qualitative reduction in the microglial PET signal over a period of six months of treatment with nasal foralumab. When combined with my assessment of the first six Expanded Access patients at six months, eight of the ten suggest a qualitative reduction in microglial PET signal. Further studies are needed to confirm these findings using additional cases and quantitative approaches."

Gabriele Cerrone, Chairman, acting CEO, and founder of Tiziana Life Sciences, added, "I am thrilled that 80% of the na-SPMS patients who received intranasal foralumab treatment for at least 6-months have a qualitative reduction of microglial activity as confirmed in these latest PET images. I am also greatly appreciative of Dr. Singhal's research and look forward to the additional quantitative analysis of the data. With the allowance of an additional 20 patients in the EA program, the application for Orphan Drug Designation for na-SPMS, and the ongoing Phase 2a trial, Tiziana is rapidly progressing its intranasal foralumab program in multiple sclerosis."

#### **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 further inquiries:

### **Tiziana Life Sciences Ltd**

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#### **Investors:**

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

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