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 2023

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 ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On January 3, 2023, Tiziana Life Sciences LTD (the "Company") issued a press release, announcing the Additional Clinical Improvements in the Second Patient with Non-Active Secondary Progressive Multiple Sclerosis (SPMS) After Eleven Months of Dosing with Intranasal Foralumab.

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 3, 2023

By: /s/ Keeren Shah
Name: Keeren Shah
Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	News Service Announcement, dated January 3, 2023

Exhibit 99.1

Tiziana Life Sciences Announces Additional Clinical Improvements in the Second Patient with Non-Active Secondary Progressive Multiple Sclerosis (SPMS) After Eleven Months of Dosing with Intranasal Foralumab

- **The second Expanded Access patient (EA2) demonstrated additional clinical improvement in the Expanded Disability Status Scale (EDSS), a FDA recognized standard clinical outcome assessment score**

NEW YORK, January 3, 2023 -- 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 second patient ("EA2") with non-active secondary progressive multiple sclerosis (SPMS) receiving intranasal foralumab has shown additional clinical improvements since their last reported improvement in September 2022. The improvements were measured by the Expanded Disability Status Scale (EDSS), a U.S. Food and Drug Administration (FDA) - recognized standard clinical outcome assessment that is a measure of neural network functioning, rating different measures from 1 to 10 (disability increasing with higher scores).

Before foralumab treatment, EA2's non-active SPMS disability had progressed and EDSS worsened from 3.5 in 2018 to 6.0 in 2021 despite ocrelizumab therapy. Ocrelizumab was discontinued in 2021. At this point, EA2 required a cane to walk 100 meters. EA2 was subsequently enrolled in the intranasal foralumab Expanded Access program in January 2022. In September 2022, 8 months after starting treatment with nasal foralumab, EA2 was able to walk 100 meters without a cane. EDSS score improved from 6.0 to 5.5. EA2's pyramidal score remained stable during this time. In December 2022, 11 months after starting treatment with intranasal foralumab, EA2 was able to walk 200 meters without a cane, resulting in an even greater improvement in EDSS; with EDSS falling from a score of 5.5 to 5.0. EA2's pyramidal score continued to remain stable.

Dr. Tanuja Chitnis, M.D., Professor of Neurology and the Principal investigator of the clinical study at BWH said, "The sustained improvement in EDSS score starting at 6 months and further improving after 11 months on foralumab treatment in patient EA2 is impressive and warrants further study in a Phase 2 trial. Patients with non-active SPMS normally do not improve by a sustained reduction of 1.0 on their EDSS score, so this finding is noteworthy."

Howard L. Weiner, M.D., Co-Director of the Ann Romney Center for Neurologic Diseases at BWH and Chairman of Tiziana's Scientific Advisory Board, stated, "SPMS represents an advanced stage of multiple sclerosis with few treatment options and creates a severe burden on patients. It is gratifying to see a 1.0 EDSS improvement in patient EA2 following treatment with intranasal foralumab."

"Six patients are currently enrolled and are being followed in our intranasal foralumab program. EA2's clinical improvement justifies Tiziana's decision to make intranasal foralumab for non-active SPMS our top priority," commented Gabriele Cerrone, Executive Chairman and interim Chief Executive Officer of Tiziana.

About Foralumab

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, has shown reduced release of cytokines after IV administration in healthy volunteers and in patients with Crohn's disease. In a humanized mouse model (NOD/SCID IL2γc-/-), it was shown that while targeting the T-cell receptor, orally administered foralumab modulates immune responses of the T-cells and enhances regulatory T-cells (Tregs), thereby providing therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy. Once a day treatment for 10 consecutive days with intranasal foralumab was both well tolerated and produced clinical responses in COVID-19 patients. Based on these studies, the intranasal and oral administration of foralumab offers the potential to become a well-tolerated immunotherapy for autoimmune and inflammatory diseases by the induction of Tregs.

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, oral and inhalation approaches in development have the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's two lead candidates, intranasal foralumab, the only fully human anti-CD3 mAb, and milciclib, a pan-CDK inhibitor, have both 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:

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