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

March 2022

Commission File Number: 0001723069

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 March 10, 2022, Tiziana Life Sciences LTD (the "Company") issued a news service announcement in the United States announcing Positive Clinical Data from A Secondary Progressive Multiple Sclerosis Patient Treated for Six Months with Intranasally Administered Foralumab, A Fully Human Anti-CD3 Monoclonal Antibody.

The Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibit 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: March 10, 2022

By: /s/ Kunwar Shailubhai
Name: Kunwar Shailubhai
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	News Service Announcement, dated March 10, 2022

Exhibit 99.1

Tiziana Announces Positive Clinical Data from A Secondary Progressive Multiple Sclerosis Patient Treated for Six Months with Intranasally Administered Foralumab, A Fully Human Anti-CD3 Monoclonal Antibody

- ***Intranasal foralumab was well-tolerated with no adverse reactions or laboratory abnormalities after 6 months of therapy and the patient chose to remain on therapy***

- ***Data show sustained inhibition of microglial activation as assessed by Positron Emission Tomography (PET) along with downregulation of pro-inflammatory cytokines associated with brain inflammation, as well as stabilization of disease as measured by clinical assessments***

- ***Based on these observations the FDA has allowed a second patient to receive intranasal foralumab therapy under a separate Single-Patient Expanded Access IND (SPIND)***

- ***Tiziana to hold Key Opinion Leader (KOL) event to discuss the data on March 14th, 2022, 11 a.m. ET***

New York, March 10, 2022 – Tiziana Life Sciences (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company enabling breakthrough immunotherapies via novel routes of drug delivery, today reported positive clinical data in a patient with Secondary Progressive Multiple Sclerosis (SPMS), following completion of six months of treatment with intranasally administered foralumab, at the Brigham and Women's Hospital (BWH), Harvard University, Boston, MA. In addition to being well-tolerated, both biological and clinical improvements were seen in this patient using Tiziana's novel immunotherapy technology, which, importantly overcame the challenge of delivering this antibody across the blood-brain barrier to affect immunomodulation in the brain.

Prior to treatment, this patient had continued to experience worsening disease progression despite several MS therapies, including B cell depletion. The patient's gait and limb strength had been deteriorating over the prior two years. The patient then started on intranasal foralumab, which stabilized his disease course. Tiziana also received FDA authorization to continue treating this patient for an additional 6 months to determine if 12 months of consistent treatment maintains clinical stabilization and provides sustained clinical benefits.

These data will be presented in a virtual Key Opinion Leader (KOL) event hosted by Tiziana on March 14th, 2022, at 11 a.m. ET entitled "Foralumab Clinical Update in Multiple Sclerosis; A Landmark Study with Intranasal Immunotherapy" featuring four Key Opinion Leaders and a live Q&A session. Further details to follow. ***Register here: https://lifesci.events/TLSA***

Dr. Kunwar Shailubhai, Chief Executive Officer & Chief Scientific Officer of Tiziana commented, "We are very excited about the positive clinical data reported today demonstrating the potential of intranasally administered immunotherapy with foralumab for treatment of SPMS and other neurodegenerative diseases. Importantly, data from this patient serve as the first validation of our breakthrough and potentially transformational approach with a convenient, intranasal 'take home' immunotherapy for SPMS and other neurological diseases. Today's news marks an important first step toward advancing our platform using alternative, novel routes of immunotherapies to provide local rather than systemic delivery of antibodies."

Foralumab was given to an SPMS patient intranasally into each nostril on a regimen of M-W-F for two weeks followed by one week off therapy for a period of six months. This regimen was well-tolerated with associated beneficial clinical and biomarker changes. Importantly, the PET imaging data indicated inhibition of microglial cell activation observed at 3 months following treatment initiation and was sustained at 6 months after treatment start (see Table 1). The reduction in microglial activation was seen in all parts of brain.

Table 1. Percent Reduction* in Activated Microglial Cells (AMCs) PET Signal After Starting Intranasal Foralumab as Compared to Baseline, in Whole Brain and Selected Brain Regions

	WHOLE BRAIN	CEREBRAL CORTEX	THALAMUS	WHITE MATTER	CEREBELLUM
3 MONTHS	-23%	-23%	-20%	-25%	-22%
6 MONTHS	-38%	-38%	-50%	-36%	-38%

* Percent reduction is based on changes from baseline in SUVR-1, a surrogate index for PET binding potential. SUVR=Standardized Uptake Value Ratio, calculated with reference to a pseudo reference region in cerebral white matter that showed minimal change in PET SUV, across time points.

Consistent with clinical and PET observations, intranasally administered foralumab also downregulated serum levels of pro-inflammatory cytokines, including interferon-gamma (IFN-g), interleukin (IL-18), IL-1β and IL-6, which are associated with multiple sclerosis pathogenesis and progression. Clinical evaluation showed improvement in Timed 25-Foot Walk Test (T25FW), 9-Hole Peg Test (9HPT) and Symbol Digit Modality Test (SDMT). Other published PET studies have shown an increase in activated microglial cells (AMCs) in patients with secondary progressive MS (SPMS), and the increase in AMCs associated with higher scores on the Expanded Disability Status Scale (EDSS), a widely-used scale to measure disability[1,2]. Several FDA-approved drugs, such as TYSABRI® (Nasdaq: BIIB), MAYZENT® (NYSE: JNJ) and ZEPOSIA® (NYSE: BMY) have been shown to suppress microglial activation and exert neuroprotective effects in the central nervous system (CNS) in animal studies but longitudinal assessment of drug effects on microglial activation in exclusive cohorts of SPMS patients are lacking.

Howard Weiner, MD, Director of the Multiple Sclerosis Program at BWH and Chairman of Tiziana's Scientific Advisory Board, commented, "The potential for intranasally administered foralumab to suppress microglial activation is a novel and well-tolerated immunologic approach to potentially treat SPMS, a form of MS that currently has no effective treatment. We are extremely pleased with the tolerability of intranasal foralumab and with the positive clinical and PET imaging responses observed after completion of six months of dosing in the first patient. We look forward to treating additional patients to fill a major unmet need for the treatment of SPMS."

Tanuja Chitnis, MD, Principal Investigator and Professor of Neurology at Harvard Medical School (HMS) and senior neurologist at BWH and Massachusetts General Hospital added, "New treatments for progressive MS are urgently needed. Intranasal foralumab could revolutionize treatment for this disabling form of disease."

Tarun Singhal, MD, Director of PET Imaging Program in Neurologic Diseases, associate neurologist and nuclear medicine physician at BWH commented, "The longitudinal PET imaging results suggesting sustained reduction in microglial activation in the first SPMS patient treated with foralumab, are highly encouraging. We are very excited to further investigate the effects of foralumab in SPMS patients using additional quantitative PET approaches."

About the Role of Microglial Activation in Neurodegenerative Diseases

Activation of microglia is a hallmark of brain inflammation. It is believed to play an important role in the pathway leading to neuronal cell death in several neurodegenerative diseases including Parkinson's disease, Alzheimer's disease, prion diseases, multiple sclerosis and HIV-dementia. The chronic activation of microglia causes neuronal damage through the release of cytotoxic molecules such as pro-inflammatory cytokines, reactive oxygen intermediates, proteinases and complement proteins. Suppression of microglial inflammation has been considered as an important strategy in neurodegenerative disease therapy.

About Foralumab

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, shows 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[3]. Once a day treatment for 10 consecutive days with intranasal foralumab was not only well tolerated but it also produced strong clinical responses in COVID-19 patients[4]. 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.

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. 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.

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