
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 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 January 10, 2022, Tiziana Life Sciences LTD (the “Company”) issued a news service announcement in the United States announcing that Tiziana Enrolls Second Patient in Ongoing Intranasal Foralumab Evaluation for Secondary Progressive Multiple Sclerosis.

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: January 10, 2022

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

EXHIBIT INDEX

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

Tiziana Enrolls Second Patient in Ongoing Intranasal Foralumab Evaluation for Secondary Progressive Multiple Sclerosis

- *Clinical data from the first patient, after completing 3 out of 6 months, suggest that the treatment was well tolerated with a favorable clinical response*
- *FDA allows for continued enrollment under the Individual Patient Expanded Access Program*

New York, January 10, 2022 – Tiziana Life Sciences (Nasdaq: TLSA) (“Tiziana” or the “Company”), a biotechnology company enabling breakthrough immunotherapies via novel routes of drug delivery, is pleased to announce that the U.S. Food and Drug Administration (FDA) allowed enrollment of a second patient in the ongoing clinical treatment of secondary progressive multiple sclerosis (SPMS) with intranasally administered foralumab, a fully human anti-CD3 monoclonal antibody, at the Brigham and Women’s Hospital (BWH), Harvard University, Boston, MA.

Dr. Kunwar Shailubhai, Chief Executive Officer of Tiziana noted, “We have been systematically building a database of evidence to support both the safety and clinical potential of intranasal and oral forms of foralumab in close collaboration with the FDA, and during 2022 plan to initiate several new trials across areas of large unmet need, including MS, Crohn’s Disease, and Type 1 Diabetes. Today’s update marks important progress in the advancement of our MS program, and supports our novel approach to provide local, rather than systemic delivery of antibodies.”

The first patient treated under this program completed 3 out of 6 months of dosing. Interim data suggest that the treatment was well-tolerated with a favorable clinical response. As part of the regulatory process, three-month safety data were submitted to the FDA, seeking permission to treat an additional patient under an Individual Patient Expanded Access Investigational New Drug Application (IND), which has been allowed. Treatment of the second patient is expected to begin during January 2022 with interim clinical data after 3 out of 6 months of treatment expected in April 2022. The treatment plan will remain unchanged as per the original IND. The Investigators at BWH will be monitoring detailed safety, neurological, and Positron Emission Tomography (PET) to evaluate microglial activation in this patient. Modification of immunological and neurodegenerative markers will also be included as part of the standard investigation to be conducted by BWH.

The ongoing treatment of the first patient continues, and six months of dosing is expected to be completed by the end of March 2022. To date, this patient has not shown signs of treatment intolerance or toxicities and appears to be responding well to treatment. The brain imaging data, as analyzed by PET, show reduction in microglial cell activation. Published PET studies have shown an increase in activated microglial cells in patients with SPMS, and that their increased presence in the brain is associated with higher scores on the Expanded Disability Status Scale (EDSS), a scale that is widely used to assess cognitive disability¹. Consistent with these findings, Tysabri[®] (natalizumab) (NASDAQ: BIIB), an approved drug for treatment of MS, is also believed to act via reduction in microglial activation.

Howard Weiner, M.D., 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 promising and novel approach to provide a potentially safe treatment of SPMS that currently has no effective treatment. We are extremely pleased with the tolerability of the treatment seen to date as well as with the positive clinical responses observed after completion of three months of dosing in the first patient, and we look forward to clinical data after completion of six months of treatment."

Tanuja Chitnis, M.D., Principal Investigator and Professor of Neurology at Harvard Medical School 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."

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 IL2 γ c $^{-/-}$), it was shown that whilst targeting the T cell receptor, orally administered foralumab modulates immune responses of the T-cells and enhances regulatory T-cells (Tregs) and thus provides therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy (Ogura M. et al., 2017. [Clin Immunol](#).183:240-246). 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 (Moreira et al., 2021. [Front Immunol](#). 2021; 12: 709861). 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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Cited Reference

1. Politis M, et al., Increased PK11195 PET binding in the cortex of patients with MS correlates with disability. *Neurology*. 2012; 79(6): 523-30