
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

October 2022

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 October 26, 2022, Tiziana Life Sciences LTD (the “Company”) issued a news service announcing that it starts enrollment of the first patient cohort in its Intermediate-Size Patient Population Expanded Access Program to evaluate foralumab in Non-Active Secondary Multiple Sclerosis patients

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: October 26, 2022

By: /s/ Keeren Shah

Name: Keeren Shah

Title: Finance Director

EXHIBIT INDEX

Exhibit No.	Description
99.1	News Service Announcement, dated October 26, 2022

Tiziana Life Sciences Starts Enrollment of the First Patient Cohort in its Intermediate Size Patient Population Expanded Access Program to Evaluate Foralumab in Non-Active Secondary Multiple Sclerosis Patients

NEW YORK, October 26, 2022 -- 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 start of enrollment of the first patient cohort (n=4) in its Intermediate Size Patient Population Expanded Access Program to evaluate foralumab in non-active Secondary Progressive Multiple Sclerosis (SPMS) patients. This treatment program will evaluate dosing at the “standard” dosing of 50 mcg and, if needed, a higher 100 mcg dose of intranasal foralumab in two separate cohorts of four non-active SPMS patients each. The program is being conducted at Brigham and Women’s Hospital in Boston, Massachusetts.

“In addition to this exciting news about starting this new treatment program in non-active SPMS, we are pleased to report that we are on track to conduct PET scans on our first two patients from our original study in the upcoming months,” commented Gabriele Cerrone, Executive Chairman and interim Chief Executive Officer of Tiziana. “These data will be vital to confirming the durable clinical benefits of intranasal foralumab and will support our efforts to begin our Phase 2 study of foralumab in SPMS patients in mid-to-late 2023.”

Dr. Tanuja Chitnis, M.D., Professor of Neurology and senior neurologist in the Ann Romney Center for Neurologic Diseases, Brigham & Women’s Hospital and a member of Tiziana’s Scientific Advisory Board, added, “We are looking forward to fully enrolling this important new treatment program. It will be the first time that non-active Secondary Progressive Multiple Sclerosis patients may receive higher, 100 mcg dosing of intranasal foralumab. To date, we have only studied 50 mcg dosing in patients with non-active SPMS. Given the strong feedback we’ve received relative to evaluating foralumab in the non-active Secondary Progressive Multiple Sclerosis patient population, I am anticipating swift enrollment of our first patient cohort.”

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 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 immunomodulation therapies via novel routes of drug delivery. 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:

Tiziana Life Sciences Ltd

Hana Malik, Business Development, and Investor Relations Manager
+44 (0) 207 495 2379
email: info@tizianalifesciences.com

Investors:

Irina Koffler
LifeSci Advisors, LLC
646.970.4681
ikoffler@lifesciadvisors.com
