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

November 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 November 23, 2022, Tiziana Life Sciences LTD (the "Company") issued a news service announcing the publication of a peer-reviewed article on the intranasal administration of foralumab demonstrating modulated effector CD8+ T cell function and an induced T cell regulatory response in human subjects.

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: November 23, 2022

By: /s/ Keeren Shah
Name: Keeren Shah
Title: Finance Director

EXHIBIT INDEX

Exhibit No.	Description
99.1	News Service Announcement, dated November 23, 2022

Exhibit 99.1

Tiziana Announces Publication of a Peer-Reviewed Article on the Intranasal Administration of Foralumab Demonstrating Modulated Effector CD8+ T cell Function and an Induced T Cell Regulatory Response in Human Subjects

- Third-party research conducted by leading U.S. academic institutions published in a peer reviewed journal *Frontiers in Immunology* shows a favorable safety profile for intranasally administered foralumab and immunological activity in humans

- Finding supports Tiziana's intranasal foralumab monoclonal antibody platform as a new modality for the treatment of autoimmune and CNS diseases

- Tiziana's fully human foralumab is the first anti-CD3 mAb which has not shown an anti-drug antibody (immune reaction) in humans

New York, 23 November 2022 - Tiziana Life Sciences Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company enabling breakthrough CNS immunomodulation approaches to enhance the functionality of Treg-based therapies, announces publication of a scientific article in the peer-reviewed journal *Frontiers in Immunology* entitled "**Nasal administration of anti-CD3 monoclonal antibody modulates effector CD8+ T cell function and induces a regulatory response in T cells in human subjects"**[(1)] . The study was completed by researchers at the Brigham and Womens Hospital (BWH) and Harvard Medical School. The goal of the study was to assess safety and the immune effects of an entirely human, previously uncharacterized nasal anti-CD3 mAb (foralumab) in humans and its *in vitro* stimulatory properties. The findings support Tiziana's intranasal foralumab platform as a new modality for the treatment of autoimmune and CNS diseases.

About the Study

The study evaluated 27 healthy volunteers (nine per group) who received either intranasal foralumab at a dose of 10ug, 50ug, or 250ug daily for 5 days or placebo. Safety was assessed and immune parameters were measured on day one (pre-treatment), and days 7, 14, and 30 by Fluorescence-Activated single Cell Sorting (FACS) and by Single-cell RNA sequencings (cRNAseq).

No adverse events or safety signals were found when foralumab was dosed at the amounts of 10ug, 50ug and 250ug given for 5 consecutive days. Immunomodulatory effects were predominantly observed at the 50ug dose. At the 50ug dose a reduction of CD8+ effector memory cells, an increase in naive CD8+ and CD4+ T cells, and reduced CD8+ T cell granzyme B and perforin expression were observed. A dose effect with 50ug being more immunomodulatory than 250ug is consistent with previously conducted animal studies of mucosal tolerance in which higher doses do not induce immune regulation. This is likely due to the partial signaling that occurs at intermediate doses which favors the induction of regulatory cells.

No anti-drug antibodies in humans were detected.

Conclusion

When intranasal foralumab was dosed in humans at the above levels, immunological activity and a favorable safety profile were observed. The findings present a new modality for the treatment of autoimmune and CNS diseases. Tiziana's intranasal monoclonal antibody (mAb) technology is applicable to marketed mAbs which are currently available only through IV & SC administration, addressing enourmous market potential.

A notable finding from this research is that the biologic effect of intranasal anti-CD3 is different from IV anti-CD3. IV anti-CD3 is associated with modulation of CD3 from the cell surface, a decrease in CD3 cells and with side effects that include cytokine release syndrome and in some instances activation of EBV[(2)]. EBV reactivation was observed with IV foralumab at the 500ug and 1000ug doses. In contrast, intranasal foralumab did not show EBV activation at any of the doses or modulation of CD3 from the cell surface and the researchers did not find foralumab in the bloodstream. From these results it can be concluded thar nasal foralumab acts locally while IV administered anti-CD3 acts systemically.

Confirming these findings, in animal studies, it was observed that nasal anti-CD3 localized to the cervical lymph nodes and as with human studies, nasal anti-CD3 was not observed in the bloodstream of animals.

This article provides a wealth of scientifically rigorous immunologic data on intranasal foralumab," said Matthew Davis, MD, RPh, Chief Medical Officer of Tiziana. "The finding that the immune effects were predominately observed at the 50ug dose rather than the lower and higher doses studied was intriguing. Our current study in non-active Secondary Progressive Multiple Sclerosis is using a 50ug dose and our planned Phase 2 multicentered placebo-controlled dose-ranging study will also include a 50ug dosing arm."

To view the online publication, please click here: https://www.frontiersin.org/articles/10.3389/fimmu.2022.956907/full

Cited References:

(1) Chitnis T, Kaskow BJ, Case J, Hanus K, Li Z, Varghese JF, Healy BC, Gauthier C, Saraceno TJ, Saxena S, Lokhande H, Moreira TG, Zurawski J, Roditi RE, Bergmark RW, Giovannoni F, Torti MF, Li Z, Quintana F, Clementi WA, Shailubhai K, Weiner HL and Baecher-Allan CM (2022) Nasal administration of anti-CD3 monoclonal antibody modulates effector CD8+ T cell function and induces a regulatory response in T cells in human subjects. Front. Immunol. 13:956907. doi: 10.3389/fimmu.2022.956907

(2) Kuhn C, Weiner HL. Therapeutic anti-CD3 monoclonal antibodies: from bench to bedside. Immunotherapy (2016) 8(8):889–906. doi: 10.2217/imt-2016- 0049

About Foralumab

Foralumab, the only entirely human anti-CD3 mAb, has shown reduced release of cytokines after intravenous (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 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 parenterally-administered 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:

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