
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 2024

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

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On November 19, 2024, Tiziana Life Sciences LTD (the “Company”) issued this 6K announcing, announced that its grant application to the ALS Association has been approved for funding. The grant is awarded as part of the Hoffman ALS Clinical Trial Awards Program and is titled “Modulation of ALS neuroinflammation by nasal anti-CD3 monoclonal Antibody”. The Association’s grant will fund a 20-patient clinical trial of two doses of Tiziana’s novel and patented therapeutic candidate, intranasal foralumab, aimed at evaluating the safety and early-stage parameters of disease improvement in Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig’s disease., a copy of which is furnished as Exhibit 99.1

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: November 19, 2024

By: /s/ Keeren Shah

Name: Keeren Shah

Title: Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Tiziana Life Sciences LTD Press Release, dated November 19, 2024



Tiziana Life Sciences Announces Groundbreaking ALS Trial Grant Awarded by the ALS Association

NEW YORK, November 19, 2024 – Tiziana Life Sciences, Ltd. (Nasdaq: TLSA) (“Tiziana” or the “Company”), a biotechnology company developing breakthrough immunomodulation therapies with its lead development candidate, intranasal foralumab, a fully human, anti-CD3 monoclonal antibody, today announced that its grant application to the ALS Association has been approved for funding. The grant is awarded as part of the Hoffman ALS Clinical Trial Awards Program and is titled “Modulation of ALS neuroinflammation by nasal anti-CD3 monoclonal Antibody”. The Association’s grant will fund a 20-patient clinical trial of two doses of Tiziana’s novel and patented therapeutic candidate, intranasal foralumab, aimed at evaluating the safety and early-stage parameters of disease improvement in Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig’s disease.

ALS is a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord, ultimately leading to muscle weakness and paralysis. ALS is an orphan disease, but its clinical course can be rapid with marked disability even at an early stage. Over the course of the disease, people lose the ability to move, to speak, and eventually, to breathe. The disease is always fatal, usually within five years of diagnosis. Few treatment options exist, resulting in a high unmet need for new therapies to address functional deficits and disease progression.

“The Hoffman ALS Clinical Trial Awards Program supports early-stage clinical trials of potential new therapies that hold promise for those living with ALS,” said Kuldip Dave, Ph.D., Senior Vice President of Research at the ALS Association. “With this award, we are pleased to help advance the development of intranasal foralumab for ALS. By funding programs at this early stage, we hope to accelerate the development of therapeutic candidates that can help make ALS a livable disease.”

James Berry, MD, MPH, and Suma Babu, MBBS, MS, the Director and Co-Director of the Neurological Clinical Research Institute (NCRI) at Mass General Hospital, a founding member of Mass General Brigham commented: “We are incredibly grateful to the ALS Association for recognizing the promise of intranasal foralumab, and we are excited to initiate clinical development in ALS in hopes of identifying a novel therapy for ALS and other neurodegenerative diseases. We will be using PET imaging to detect neuro inflammation in this study of patients with ALS. We hope to replicate the previous positive findings of the PET imaging approach that Tiziana has seen in studies of patients with multiple sclerosis, in this new potential indication for intranasal foralumab.”

“We are honoured to receive this prestigious grant from the ALS Association, which underscores the promising potential of our therapeutic platform in addressing the urgent needs of ALS patients. This funding will accelerate our clinical development efforts and bring us closer to potentially transformative treatment options for ALS,” said Ivor Elrifi, CEO of Tiziana Life Sciences. “Tiziana Life Sciences’ innovative approach targets the underlying mechanisms of ALS with the aim of halting or slowing disease progression. The company’s commitment to rigorous scientific research and patient-centric innovation aligns with the ALS Association’s mission to discover treatments and a cure for ALS, as well as to serve, advocate for, and empower people affected by ALS.”

The Hoffman ALS Clinical Trial Awards Program, named in honor of the late philanthropist Hugh Hoffman, helps develop new and improved ALS therapies by supporting early-stage clinical trials. These trials produce data on safety, dosing, and biomarkers that are essential for advancing an investigational therapy one step closer to being evaluated by the FDA. Positive results at this stage also “de-risk” the next stage of drug development, typically large clinical trials, and help attract the follow-on funding necessary to complete this work.

Foralumab, a fully human anti-CD3 monoclonal antibody, is a biological drug candidate that has been shown to stimulate T regulatory cells when dosed intranasally. At present, 10 patients with Non-Active Secondary Progressive Multiple Sclerosis (na-SPMS) have been dosed in an open-label intermediate sized Expanded Access (EA) Program with either an improvement or stability of disease seen within 6 months in all patients. The FDA has recently allowed an additional 20 patients to be enrolled in this EA program. In addition, intranasal foralumab is currently being studied in a Phase 2a, randomized, double-blind, placebo-controlled, multicenter, dose-ranging trial in patients with non-active secondary progressive multiple sclerosis (NCT06292923).

About the ALS Association

The ALS Association is the largest philanthropic funder of ALS research in the world. The Association funds global research collaborations, assists people with ALS and their families through its nationwide network of care and certified clinical care centers, and advocates for better public policies for people with ALS. The ALS Association is working to make ALS a liveable disease while urgently searching for new treatments and a cure. For more information about the ALS Association, visit our website at www.als.org

About the Massachusetts General Hospital

Massachusetts General Hospital, founded in 1811, is the original and largest teaching hospital of Harvard Medical School. The Mass General Research Institute conducts the largest hospital-based research program in the nation, with annual research operations of more than \$1 billion and comprises more than 9,500 researchers working across more than 30 institutes, centers and departments. In July 2022, Mass General was named #8 in the U.S. News & World Report list of “America’s Best Hospitals.” MGH is a founding member of the Mass General Brigham healthcare system.

About Foralumab

Activated T cells play an important role in the inflammatory process. Foralumab, the only fully human anti-CD3 monoclonal antibody (mAb), binds to the T cell receptor and dampens inflammation by modulating T cell function, thereby suppressing effector features in multiple immune cell subsets. This effect has been demonstrated in patients with COVID and with multiple sclerosis, as well as in healthy normal subjects. The non-active SPMS intranasal foralumab Phase 2 trial (NCT06292923) began screening patients in November of 2023. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of neuroinflammatory and neurodegenerative human diseases.^{[1],[2]}

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 approach has the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana’s lead candidate, intranasal foralumab, which is the only fully human anti-CD3 mAb, has 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 more information about Tiziana Life Sciences and its innovative pipeline of therapies, please visit www.tizianalifesciences.com

For further inquiries:

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[1] <https://www.pnas.org/doi/10.1073/pnas.2220272120>

[2] <https://www.pnas.org/doi/10.1073/pnas.2309221120>