
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

June 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 June 4, 2024, Tiziana Life Sciences LTD (the “Company”) issued this 6K announcing, it has been honored with an invitation to apply for a prestigious grant from the ALS Association head by 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. The grant is offered as part of the Hoffman ALS Clinical Trial Awards Program, which is specifically designated to support a groundbreaking clinical trial., 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: June 4, 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 June 4, 2024



**Tiziana Life Sciences Submits Grant Application
to ALS Association to Fund Clinical Trial
of Intranasal Foralumab**

NEW YORK, June 4, 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 it has been honored with an invitation to apply for a prestigious grant from the ALS Association head by 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. The grant is offered as part of the Hoffman ALS Clinical Trial Awards Program, which is specifically designated to support a groundbreaking clinical trial.

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).

The Hoffman ALS Clinical Trial Awards Program 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.

Dr. Berry commented, “Tiziana’s study goal is to give people living with amyotrophic lateral sclerosis (ALS) the opportunity to participate in a 6-month, dose-titration trial of intranasal foralumab.” Dr. Babu expanded, “This study is aimed at advancing novel treatment approaches for ALS by evaluating its effect using cutting-edge image biomarkers like positron emission tomography (PET) and key clinical outcome assessments.”

ALS, also known as Lou Gehrig's disease, affects nerve cells in the brain and spinal cord, progressively weakening muscles. It is classified as an Orphan Disease due to its sporadic nature and lack of clear risk factors. With limited treatment options available, Tiziana Life Sciences is committed to developing novel therapies that address the underlying causes of ALS.

“The invitation to submit a letter of intent and apply for this grant with Drs. Berry and Babu underscores the recognition of Tiziana Life Sciences' dedication to scientific innovation and commitment to improving patient outcomes. If successful, the grant will support a clinical trial involving 20 patients, focusing on the evaluation of intranasal foralumab, a promising therapeutic candidate developed by the company.” commented Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences, expressing his gratitude for the opportunity, “We are deeply honored to be invited by the ALS Association to apply for this grant, which represents a significant milestone in our ongoing efforts to develop an effective treatment for ALS. This funding would allow us to advance our clinical program and accelerate the development of our potential therapy that could make a meaningful difference in the lives of ALS patients.”

Tiziana Life Sciences remains committed to advancing research and development efforts aimed at addressing the unmet needs of patients suffering from ALS and other debilitating diseases. The company looks forward to the possibility of collaborating with the ALS Association to bring new hope to individuals affected by this devastating condition.

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 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}

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

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

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.

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.

For further inquiries:

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