**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**

**August 2023**

**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 August 15, 2023, Tiziana Life Sciences LTD (the "Company") issued a press release, announcing that, the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for intranasal foralumab to be studied in Alzheimer's disease. Foralumab could be a potentially groundbreaking treatment for Alzheimer's disease, given it targets the disease's underlying pathology by addressing the resulting neuroinflammation caused by the accumulation of toxic proteins in the brain.

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: August 15, 2023

By: /s/ Keeren Shah
Name: Keeren Shah
Title: Chief Financial Officer

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | News Service Announcement, dated August 15, 2023 |

**Exhibit 99.1**

# Tiziana Life Sciences Announces FDA IND Clearance of Intranasal Foralumab for the Treatment of Alzheimer's Disease

- Foralumab to advance into Phase 2 human clinical trials using the world's only fully human intranasal anti-CD3 monoclonal antibody
- Trial to be overseen by Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System

NEW YORK, August 15, 2023 -- 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 that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for intranasal foralumab to be studied in Alzheimer's disease. Foralumab could be a potentially groundbreaking treatment for Alzheimer's disease, given it targets the disease's underlying pathology by addressing the resulting neuroinflammation caused by the accumulation of toxic proteins in the brain.

Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences, stated, "The IND clearance is a significant milestone for Tiziana that highlights the strength and the therapeutic potential of foralumab. We are deeply committed to advancing the field of neurodegenerative diseases and bringing much-needed relief to patients suffering from Alzheimer's with a novel therapeutic approach. We are thrilled to have reached this critical juncture and are eager to move forward with the necessary trials to evaluate the effectiveness of foralumab in Alzheimer's disease in combination with an FDA approved therapy or as a single agent."

Professor Howard L. Weiner, the Robert L. Kroc Professor of Neurology at the Harvard Medical School, Director and Founder of the Partners Multiple Sclerosis Center and Co-Director of the Center for Neurologic Diseases at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System, added "The IND clearance is a significant step forward in the fight against Alzheimer's disease. Foralumab shows great promise in targeting the pathological hallmarks of the disease, and I am optimistic about its potential to offer a breakthrough treatment option for patients suffering from this devastating condition. I look forward to witnessing the progress of this important therapy."

**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. Intranasal foralumab Phase 2 trials are expected to start in the third quarter of 2023 in patients with non-active SPMS. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of inflammatory human diseases.[1]

**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.

**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.

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

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