**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 12, 2022, Tiziana Life Sciences LTD (the "Company") issued a news service announcing it plans to submit an IND for Phase 1 trial of intranasal foralumab in Alzheimer's disease 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 12, 2022

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

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | News Service Announcement, dated October 12, 2022 |

**Exhibit 99.1**

# Tiziana Life Sciences Plans to Submit IND for Phase 1 Trial of Intranasal Foralumab in Alzheimer's Disease Patients

- **Company continues to advance foralumab in CNS-related inflammatory diseases**

NEW YORK, Oct. 12, 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 that it plans to submit an Investigational New Drug Application (IND) for a Phase 1 Trial of intranasal foralumab in Alzheimer's disease patients after receiving an affirmative written response from the FDA on a Pre-Investigational New Drug Application (PIND). Tiziana plans on filing the IND for Alzheimer's disease by the third quarter of 2023 upon the completion of requested toxicology studies, then starting its Phase 1 program by the end of 2023.

"I am thrilled to see the company advancing foralumab into another promising central nervous system (CNS) -related therapeutic area with high unmet need," commented Gabriele Cerrone, Executive Chairman and interim Chief Executive Officer of Tiziana Life Sciences. "Intranasal foralumab's unique action on regulatory T-cells should allow us to study multiple CNS inflammatory pathology indications for this unique drug, including in Multiple Sclerosis (MS) and Amyotrophic Lateral Sclerosis (ALS)."

"We have spent years studying intranasal anti-CD3, or foralumab, in inflammatory CNS-related disease models in animals," said Howard L. Weiner, M.D., Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital. "We look forward to evaluating intranasal foralumab in patients with early symptomatic Alzheimer's disease, where we believe its locally acting anti-inflammatory mechanism of action will be relevant."

"Tiziana strongly believes that many inflammatory CNS disease pathologies could improve with intranasally administered foralumab and as such, we hope to study additional neurological disease states over time,", stated Matthew Davis, M.D., RPh, Chief Scientific Officer and Chief Medical Officer of Tiziana Life Sciences.

**About Foralumab**

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, has shown reduced release of cytokines after 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 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 therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy. 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**

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