# 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
April 2023
Commission File Number: 001-38723
Tiziana Life Sciences LTD (Exact Name of Registrant as Specified in Its Charter)
9 <sup>th</sup> 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 $\boxtimes$ Form 40-F $\square$
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 April 13, 2023, Tiziana Life Sciences LTD (the "Company") issued a press release, announcing that they are to Pursue Development of Intranasal Foralumab for the Treatment of Long COVID.

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

By: /s/ Keeren Shah

Date: April 13, 2023

Name: Keeren Shah

Title: Chief Financial Officer

# EXHIBIT INDEX

Exhibit No.		Description	
99.1	News Service Announcement, dated April 13, 2023		
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# Tiziana Life Sciences to Pursue Development of Intranasal Foralumab for the Treatment of Long COVID

- Long COVID remains a high unmet need causing a myriad of complications for patients and costing the U.S. healthcare system an estimated \$2.6 trillion
- The role of activated microglia is well-established in the pathogenesis of Long COVID and Tiziana's first-in-class intranasal foralumab dampens activated microglia

NEW YORK, April 13, 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 it plans to investigate intranasal foralumab for the treatment of Long COVID. The work is supported by foralumab's well-established role in de-activating microglia cells, a key component in the pathogenesis of this disease.

"We anticipate entering into a Phase 2a placebo-controlled clinical trial upon successful feedback from the FDA", commented Matthew W. Davis, M.D., RPh, Chief Medical Officer of Tiziana. "I am excited to test intranasal foralumab in this medically important condition. The use of PET Scans will allow us to determine if intranasal foralumab will decrease activated microglia in patients with Long COVID after 3 months of administration. After refining our clinical protocols, we need to discuss this approach with the FDA and plan to file an IND in 4Q 2023."

"Long COVID constitutes an unmet need in society. The estimated over 9 million people in the U.S. with Long COVID will cost the healthcare system a projected \$2.6 trillion dollars. I believe there is substantial evidence to support further study of intranasal foralumab in this debilitating and economically disruptive condition," commented Gabriele Cerrone, Executive Chairman and interim Chief Executive Officer of Tiziana. "The ability to modulate pathogenic activated microglia may have many applications in inflammatory disease states."

Howard L. Weiner, M.D., Chairman of Tiziana's Scientific Advisory Board and Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System, stated, "The role of activated microglia is well-established in the pathogenesis of Long COVID.2,3,4,5,6,7,8 Our research using intranasal foralumab in patients with non-active Secondary Progressive Multiple Sclerosis (SPMS), patients with COVID-19 and in healthy volunteers showed induction of a tolerogenic immune response by stimulating T regulatory cells while dampening CD3+ T effector function. In essence, intranasal foralumab modulates activated microglia while returning effector T cells to a naïve state. If this finding is replicated in patients with Long COVID, I believe that foralumab could represent a novel treatment for this devasting condition."

<sup>&</sup>lt;sup>1</sup> https://jamanetwork.com/journals/jama-health-forum/fullarticle/2792505

### **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. 9

### **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 further inquiries:

### Tiziana Life Sciences Ltd

Paul Spencer, Business Development and Investor Relations +44 (0) 207 495 2379 email: info@tizianalifesciences.com

### **Investors:**

Irina Koffler LifeSci Advisors, LLC 646.970.4681 ikoffler@lifesciadvisors.com

<sup>&</sup>lt;sup>2</sup> Neuron. 2022 Nov 2; 110(21): 3484–3496.

<sup>&</sup>lt;sup>3</sup> Oxford Open Immunology, Volume 3, Issue 1, 2022, iqac007

<sup>&</sup>lt;sup>4</sup> N Engl J Med 2022; 387:1813-1815

<sup>&</sup>lt;sup>5</sup> Neuron 110, November 2, 2022:3484-3496

<sup>&</sup>lt;sup>6</sup> Front. Cell. Neurosci., 15 June 2021;Sec. Non-Neuronal Cells: Volume 15

<sup>&</sup>lt;sup>7</sup> Molecular Psychiatry (2022) 27:3939 – 3950

<sup>&</sup>lt;sup>8</sup> Boldrini M, Canoll PD, Klein RS. How COVID-19 Affects the Brain. JAMA Psychiatry. 2021;78(6):682–683. doi:10.1001/jamapsychiatry.2021.0500

<sup>&</sup>lt;sup>9</sup> https://www.pnas.org/doi/10.1073/pnas.2220272120