## 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  March 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)
PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934  March 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
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
Tiziana Life Sciences LTD  (Exact Name of Registrant as Specified in Its Charter)  9th Floor 107 Cheapside London EC2V 6DN
(Exact Name of Registrant as Specified in Its Charter)  ——————  9 <sup>th</sup> Floor 107 Cheapside London EC2V 6DN
107 Cheapside London EC2V 6DN
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 March 28, 2023, Tiziana Life Sciences LTD (the "Company") issued a press release, announcing Tiziana Life Sciences to Proceed with Phase 2 Clinical Trial in Patients with Non-Active Secondary Progressive Multiple Sclerosis (SPMS).

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: March 28, 2023 By: /s/ Keeren Shah

Name: Keeren Shah

Title: Chief Financial Officer

## EXHIBIT INDEX

Exhibit No.	<b>Description</b>	
99.1	News Service Announcement, dated March 28, 2023	
	4	



# Tiziana Life Sciences to Proceed with Phase 2 Clinical Trial in Patients with Non-Active Secondary Progressive Multiple Sclerosis (SPMS)

## FDA Provides Positive Feedback on Intranasal Foralumab Program in Patients with Non-Active SPMS

- First Phase 2 trial employing intranasal foralumab for treating inflammatory neurological disease
- Tiziana received FDA Type C Meeting Minutes for proposed Phase 2 clinical trial in patients with non-active SPMS
- Phase 2 protocol to be submitted to the FDA in April
- Phase 2 clinical trial expected to start in Q3 2023

NEW YORK, March 28, 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 has received feedback based on the U.S. Food and Drug Administration (FDA) Type C meeting minutes related to the Phase 2 clinical trial of intranasal foralumab in patients with non-active SPMS. Tiziana plans to accept the FDA's recommendations and intends to start a Phase 2 study in the third quarter of 2023 as previously announced. Foralumab is the only fully human anti-CD3 monoclonal antibody (mAb).

"Tiziana has reached an important regulatory milestone as it proceeds with the first ever intranasal foralumab clinical trial," commented Gabriele Cerrone, Executive Chairman and interim Chief Executive Officer. "The FDA's response to our proposed Phase 2 program allows Tiziana's to advance foralumab through the regulatory process as we strive to bring this novel treatment to patients with non-active SPMS."

"I am grateful for the FDA's thoughtful review of our Phase 2 plans for intranasal foralumab," stated Matthew W. Davis, M.D., RPh, Chief Medical Officer. "This upcoming quarter, we will update the Phase 2 protocol with the FDA's suggestions and plan to start the Phase 2 clinical trial by holding our first investigator's meeting in Q3 2023."

## **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. <sup>1</sup>

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