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 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 April 22, 2024, Tiziana Life Sciences LTD (the "Company") issued this 6K announcing, additional positive clinical results from its intermediate sized Expanded Access Program (EAP) for non-active secondary progressive multiple sclerosis (na-SPMS) patients. The data demonstrate multiple improvements in foralumab-treated patients, with 70% showing an improvement in fatigue after six months of follow-up. Fatigue is a debilitating symptom for many MS patients and is measured by the Modified Fatigue Impact Scale (MFIS)., 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: April 22, 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 April 22, 2024

Exhibit 99.1

Tiziana Life Sciences Announces Additional Clinical Improvements Among Multiple Sclerosis Patients in its Expanded Access Program

- **70% of Patients in the Expanded Access Program (EAP) Have Seen Measurable Clinical Improvement in Their Fatigue After Six Months of Follow-up**

- **All Patients Have Either Stabilized or Improved on Foralumab Treatment and No Patients Declined in Key Clinical Measures**

NEW YORK, April 22, 2024 – 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 additional positive clinical results from its intermediate sized Expanded Access Program (EAP) for non-active secondary progressive multiple sclerosis (na-SPMS) patients. The data demonstrate multiple improvements in foralumab-treated patients, with 70% showing an improvement in fatigue after six months of follow-up. Fatigue is a debilitating symptom for many MS patients and is measured by the Modified Fatigue Impact Scale (MFIS).

"All patients in this na-SPMS study had previously clinically progressed on ocrelizumab. They subsequently were enrolled in our EA program and received 6-months of intranasal foralumab," stated Dr. Tanuja Chitnis, M.D., Principal Investigator and Professor of Neurology at Harvard Medical School and senior neurologist at Brigham and Women's Hospital, a founding member of Mass General Brigham Healthcare System. "All 10 foralumab-treated patients stabilized or improved in key clinical measures, and seven showed clinical meaningful improvement in their fatigue at six months as measured by the MFIS. Other key clinical outcome measures included the Expanded Disability Status Scale (EDSS), Timed 25-Foot Walk Test (T25WT) and Pyramidal Scores in a disease state that typically shows a decline in function over time. I am pleased to see the continued clinical response to intranasal foralumab from patients enrolled in our expanded access na-SPMS program."

Gabriele Cerrone, Chairman, acting CEO and founder of Tiziana Life Sciences, commented "Fatigue is a pervasive and challenging symptom for individuals living with MS, impacting their daily lives in profound ways. The clinically meaningful improvement in fatigue levels seen in seven out of ten patients, as well as the stabilization or improvements in other key clinical outcome measures that were seen in all patients, underscores the potential of Tiziana's investigational therapy to address this critical unmet need."

Fatigue in MS, as measured via the MFIS, refers to an overwhelming sense of physical, mental, and emotional exhaustion that is disproportionate to the level of activity or effort exerted. It is a major, common, and often debilitating symptom experienced by many individuals with MS. It differs from the typical tiredness that everyone experiences from time to time. In the context of MS, it is called 'primary fatigue' and is a direct result of damage to the central nervous system. This kind of fatigue can significantly impact a person's daily life and functioning.

The findings, which are summarized in Table 1 below, show broad-based six-month improvements across various key measures for multiple sclerosis. Secondary progressive multiple sclerosis is hallmarked by an increase of disability over time. The table below shows a stabilization or an improvement in physical function of the various clinical measures over a six-month period.

Table 1.

	EDSS	Pyramidal score	T25FW	MFIS
EA1	—	↓	—	—
EA2	↓	—	↓	↓
EA3	—	—	↓	—
EA4	↓	—	—	↓
EA5	—	↓	↓	↓
EA6	—	—	—	↓
EA7	—	—	↓	↓
EA8	↓	↓	—	↓
EA9	↓	—	—	↓
EA10	—	↓	—	—

— Denotes stabilization
↓ Denotes improvement

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.

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. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties related to market conditions and other factors described more fully in the section entitled 'Risk Factors' in Tiziana's Annual Report on Form 20-F for the year ended December 31, 2022, and other periodic reports filed with the Securities and Exchange Commission. 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.

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