
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

September 2026

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 September 30, 2026, Tiziana Life Sciences LTD (the “Company”) issued this 6K announcing, that it has submitted a request to the U.S. Food and Drug Administration (FDA) for Orphan Drug Designation for intranasal foralumab for the treatment of Multiple System Atrophy (MSA).

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: September 30, 2026

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 September 30, 2026
3	



Tiziana Life Sciences Files for Orphan Drug Designation with the FDA for Intranasal Foralumab for the Treatment of Multiple System Atrophy (MSA)

BOSTON, MA, September 30, 2026 – Tiziana Life Sciences, Ltd. (Nasdaq: TLSA) (“Tiziana” or the “Company”), a biotechnology company developing breakthrough immunomodulation therapies with its lead development candidate, intranasal foralumab, a fully human, anti-CD3 monoclonal antibody, today announced that it has submitted a request to the U.S. Food and Drug Administration (FDA) for Orphan Drug Designation for intranasal foralumab for the treatment of Multiple System Atrophy (MSA).

MSA is a rare, rapidly progressive neurodegenerative disorder that affects autonomic functions (such as blood pressure and bladder control) and motor control, leading to severe disability and shortened life expectancy. There are currently no FDA-approved disease-modifying therapies for MSA. The disease has a mean incidence in the U.S. of approximately 0.6 per 100,000 person-years, rising to about 3 per 100,000 in those aged 50 and older, with prevalence estimates of roughly 1.9–4.9 per 100,000 worldwide. Median survival is typically 6–9 years. Neuroinflammation and microglial activation are increasingly recognized as key contributors to MSA pathogenesis.

Orphan Drug Designation is granted by the FDA to drugs or biologics intended to treat rare diseases or conditions affecting fewer than 200,000 people in the United States. The FDA’s Office of Orphan Products Development (OOPD) aims to complete its review of an orphan drug designation (ODD) request within 90 days of receipt. If granted, the designation would provide potential benefits including seven years of market exclusivity upon approval, tax credits for qualified clinical testing, waiver of certain FDA application fees, and eligibility for protocol assistance.

Tiziana is currently evaluating intranasal foralumab in a Phase 2a open-label clinical trial (ClinicalTrials.gov Identifier: NCT06868628) in patients with MSA. The six-month study is designed to assess effects on microglial activation (via PET imaging), clinical outcomes, and safety. Foralumab is administered via nasal spray across eight 3-week dosing cycles. The Phase 2a trial is being conducted within the MyTrial Program at Brigham and Women’s Hospital in Boston under the leadership of Principal Investigator Vikram Khurana, MD, PhD, Tracy T. Batchelor Endowed Chair and Division Chief of Movement Disorders at Mass General Brigham.

Dr Khurana commented: “Multiple system atrophy remains one of the most challenging neurodegenerative diseases we face, with rapid progression and no approved therapies that alter its course. The growing recognition of neuroinflammation and microglial activation as central drivers of MSA pathology makes intranasal foralumab a particularly compelling candidate. By harnessing the immune system’s regulatory pathways in a targeted, non-systemic way, this approach has the potential to address a critical unmet need. The ongoing clinical study, which includes PET imaging of microglial activity, will provide important early insights into whether this strategy can meaningfully impact the disease process.”

Ivor Elrifi, Chief Executive Officer of Tiziana Life Sciences, commented: “Filing for Orphan Drug Designation for intranasal foralumab in MSA represents an important regulatory step as we advance this novel therapy for patients facing a devastating disease with no approved disease-modifying options. Foralumab administered intranasally induces regulatory T cells and modulates T-cell-driven inflammation. Its ability to reduce microglial activation offers a promising strategy to slow neuronal damage in neuroinflammatory and neurodegenerative conditions including MSA. This non-systemic approach is designed to promote immune tolerance while minimizing systemic immune suppression.”

About Foralumab

Foralumab, a fully human anti-CD3 monoclonal antibody, is a biological drug candidate that has been shown to stimulate T regulatory cells when dosed intranasally. At present, 14 patients with Non-Active Secondary Progressive Multiple Sclerosis (na-SPMS) have been dosed in an open-label intermediate sized Expanded Access (EA) Program (NCT06802328) with either an improvement or stability of disease seen within 6 months in all patients. In addition, intranasal foralumab is currently being studied in a Phase 2a, randomized, double-blind, placebo-controlled, multicenter, dose-ranging trial in patients with non-active secondary progressive multiple sclerosis (NCT06292923), as well as additional Phase 2 trials in AD and MSA.

Intranasal foralumab is the only fully human anti-CD3 monoclonal antibody (mAb) currently in clinical development. Immunomodulation by intranasal foralumab represents a novel avenue for the treatment of neuroinflammatory and neurodegenerative human diseases.^{[1],[2]}

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 intranasal 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 currently in clinical development, 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 more information about Tiziana Life Sciences and its innovative pipeline of therapies, please visit www.tizianalifesciences.com.

Forward-Looking Statements

Statements in this press release may be "forward-looking statements" within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, and Section 21E of the U.S. Securities Exchange Act of 1934, as amended, that concern matters that involve risks and uncertainties that could cause actual results to differ materially from those anticipated or projected in the 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 forward-looking statements reflect the current beliefs and expectations of Tiziana's management and include statements regarding the closing of the Offering. 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, 2025, and other periodic reports filed with the SEC from time to time. 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.

For further inquiries:

Tiziana Life Sciences Ltd

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

[1] <https://www.pnas.org/doi/10.1073/pnas.2220272120>

[2] <https://www.pnas.org/doi/10.1073/pnas.2309221120>
