
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

January 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)

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 January 5, 2023, Tiziana Life Sciences LTD (the "Company") issued this 6K announcing the release of an updated corporate deck, that can also be found on the Tiziana Life Sciences LTD website.

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: January 5, 2023

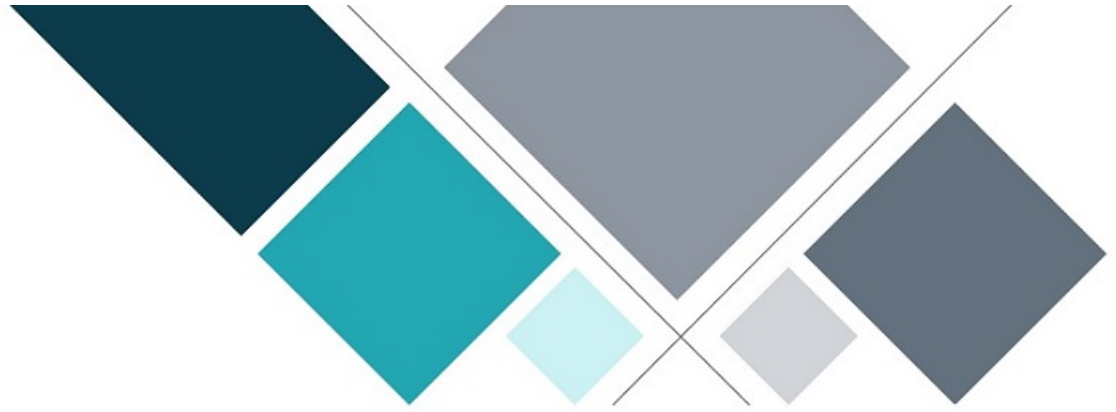
By: /s/ Keeren Shah

Name: Keeren Shah

Title: Chief Financial Officer

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	News Service Announcement, dated January 5, 2023



Intranasal Foralumab Update

*Enabling Breakthrough Immunomodulation Approaches to
Enhance the Functionality of Treg-Based Therapies*

NASDAQ: TLSA



Disclaimer and Forward-Looking Statement

The content of this presentation has been prepared for the purpose of providing general information about, and an overview of, the Company and its business. It is not intended to be a complete review of all matters concerning the Company and nor has it been independently verified. Whilst the presentation has been prepared in good faith and the Company has taken all reasonable care to ensure the information and facts contained in this presentation are accurate and up-to-date, it does not make any representation or warranty, express or implied, as to the accuracy or completeness of any information included in this presentation. Neither the Company nor any of its directors, officers, employees or agents shall be liable for any loss arising directly or indirectly from the use of or reliance upon this presentation or in relation to the adequacy, accuracy, completeness or reasonableness of the information it contains. All and any such liability is expressly excluded to the fullest extent permitted by law. The information in this presentation is subject to updating, completion, revision, further verification and amendment without notice.

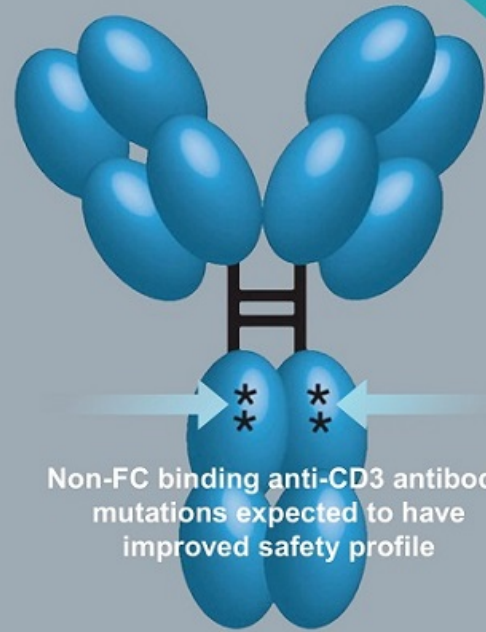
This presentation does not constitute or form part of any offer for sale or solicitation of any offer to buy or subscribe for any securities including ordinary shares in the Company nor does it constitute an invitation or inducement to engage in investment activity in relation to any securities, including the ordinary shares of the Company. It does not purport to contain information that shall form the basis of or be relied upon in making such investment decisions. If you require any advice, please consult with a professional financial adviser. All investments are subject to risk. The value of securities may go down as well as up. Past performance cannot be relied on as a guide for future performance.

This presentation may contain certain forward-looking statements concerning the financial condition, results of operations and businesses of the Company. All statements other than statements of historical fact are, or may be deemed to be, forward-looking statements. Forward-looking statements are statements of future expectations that are based on management's current expectations and assumptions and involve known and unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in these statements. All forward-looking statements contained in this presentation are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. You should not place undue reliance on forward-looking statements. Each forward-looking statement speaks only as of the date of this presentation. The Company does not undertake any obligation to publicly update or revise any forward-looking statement as a result of new information, future events or other information. In light of these risks, results could differ materially from those stated, implied or inferred from the forward-looking statements contained in this presentation.

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Lead Asset: Foralumab

The only **fully human** anti-CD3
monoclonal antibody in clinical studies

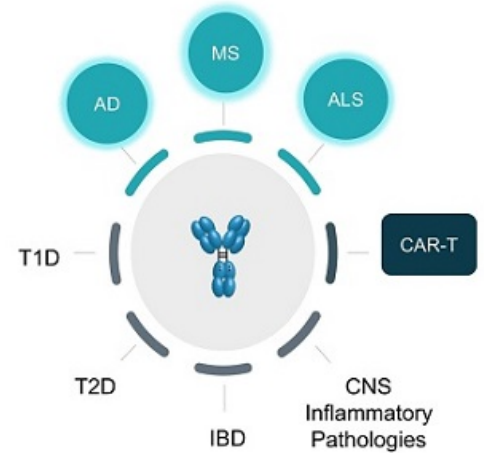


Non-FC binding anti-CD3 antibody
mutations expected to have
improved safety profile

Foralumab is the Only Fully Human Anti-CD3 mAb in Clinical Trials

CD3-specific Monoclonal Antibodies in Clinical Development

OKT3 Muromonab*	ChAglyCD3 Otelixizumab	(Ala-Ala) hOKT3γ1 Teplizumab	Nuvion Visilizumab	Foralumab
IgG2a	IgG1 N297/A	IgG2 L234/A, L235A	IgG2 L234/A, V237/A	IgG1 L234/A, V335E
Fully Murine	Chimeric & Humanized	Humanized	Humanized	Fully Human



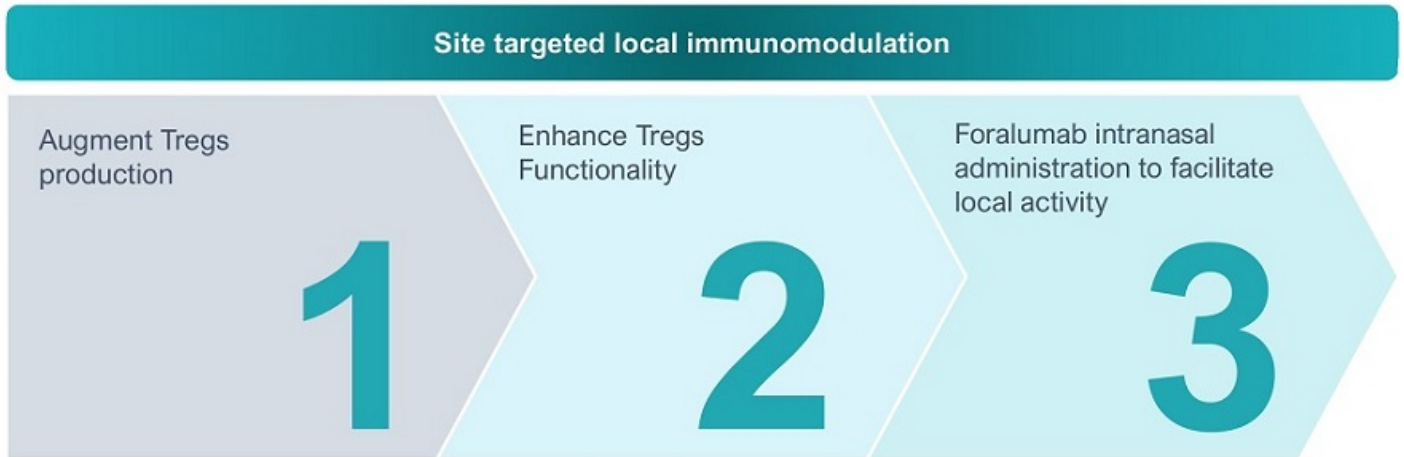
*Approved by the FDA for solid organ transplantation immunosuppression



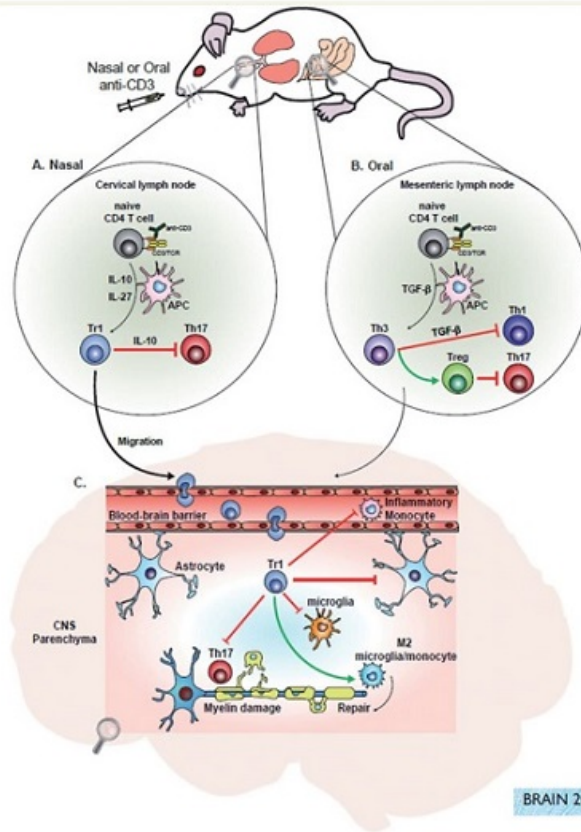
Adapted from: Kuhn, Chantal, and Howard L. Weiner. "Therapeutic anti-CD3 monoclonal antibodies: from bench to bedside." *Immunotherapy* 8.8 (2016): 889-906.

Foralumab Facilitates Locally Targeted Immunomodulation to Improve Tregs Production and Enhance their Functionality

Our Therapeutic Approach



The binding of foralumab to the T-cell receptor complex, through either the nasal or oral route, results in suppression of effector T-cells involved in various inflammatory and autoimmune diseases along with a reduction in inflammatory cytokines and increase in Tregs anti-inflammatory cytokines.



Intranasal Foralumab



Safety Profile

- 13-week toxicology showed ample safety margin
- 26-month toxicology has begun with unaudited data expected Dec 2023
- No significant adverse events have been reported to date in preclinical or human studies



Pharmacology

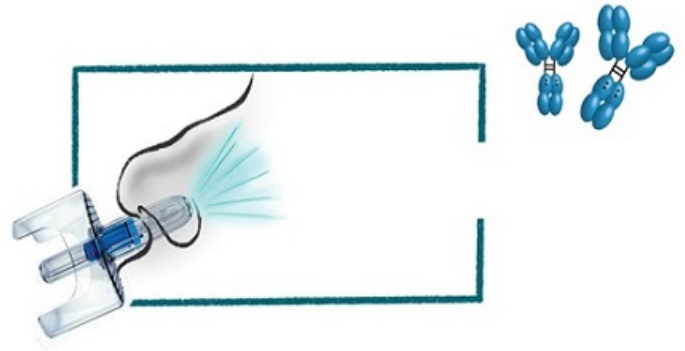
- Phase 1 study (healthy subjects) - saw an inverted U-shaped dose effect curve
 - Mid-range dose with greatest pharmacologic response
- Additional clinical support
 - Foralumab demonstrated clinical proof of concept for intranasal delivery in mild-to-moderate COVID-19 patients

**Intranasal Foralumab for
Treatment of Neurodegenerative
Diseases (Multiple Sclerosis)**

Local action with improved
safety and lowered dosing

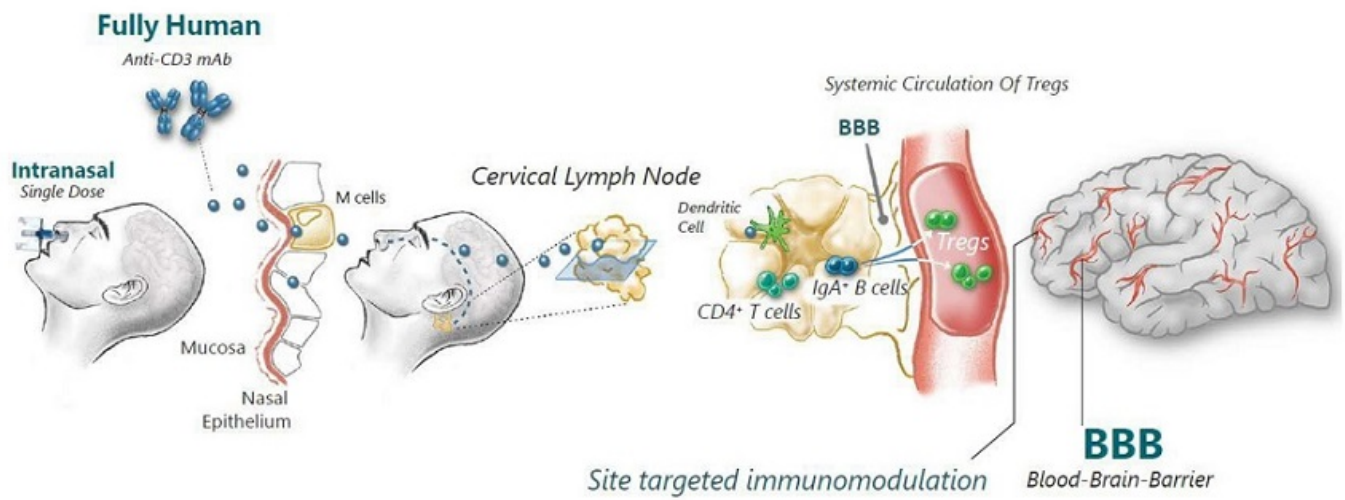
**Fully Human
Anti-CD3 mAb**

Intranasal

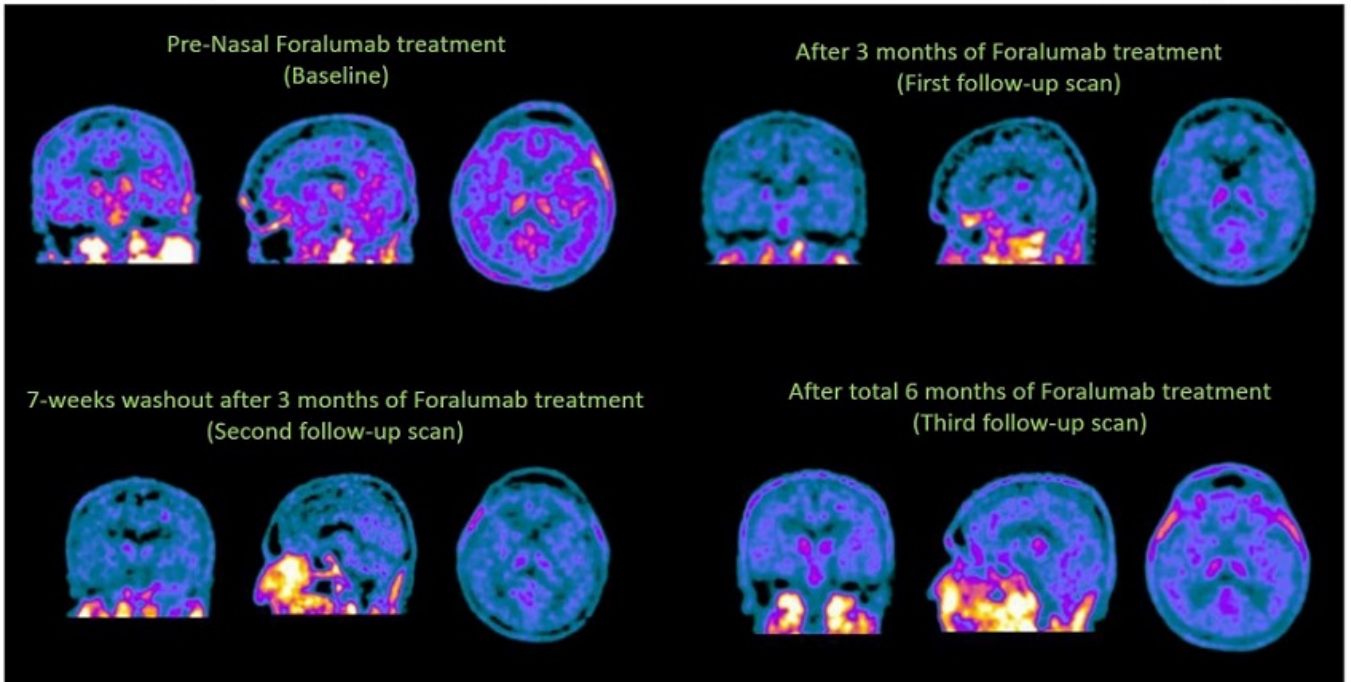


Intranasally-Administered Foralumab for Neurodegenerative Diseases

An Innovative Approach to Penetrate the Blood Brain Barrier (BBB)



Assessment of Inhibition of Microglial Activation by PET Imaging Following Treatment with Nasally Administered Foralumab in First Non-Active SPMS Patient (EA1)



Intranasally Administered Foralumab in Non-Active SPMS Patients

Two patients were dosed with intranasal foralumab M-W-F for two weeks with a subsequent 1-week washout period (regimen then repeated).

Positive Results: The regimen was well-tolerated with associated beneficial clinical and biomarker changes

Clinical Results

PET imaging data

- Indicated continued inhibition of microglial cell activation
- The reduction in microglial activation was seen in all parts of brain
- Suppression of microglial activation further increased after six months of treatment

Clinical Test Evaluation

- 9-Hole Peg Test (9HPT)
- Expanded Disability Status Scale (EDSS)
- Improvement in Timed 25-Foot Walk Test (T25FW)
- Symbol Digit Modality Test (SDMT)

Biologic Response

Biomarker changes

Downregulated serum levels of pro-inflammatory cytokines*, including:

- Interferon-gamma (IFN-g)
- Interleukin (IL)-18
- IL-1b
- IL-6

**These biomarkers are known to be associated with multiple sclerosis pathogenesis and progression*

Clinical Update on EA2

2018 – 2021

- Patient's non-active SPMS disability progressed
 - EDSS worsened from 3.5 to 6.0 despite ocrelizumab therapy
- Ocrelizumab was discontinued in 2021
- **At this time, EA2 required a cane to walk 100 meters.**

2022

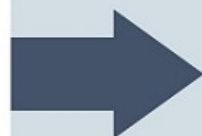
- Enrolled in the intranasal foralumab Expanded Access Program (EAP) in January 2022
- **EA2 able to walk 100 meters without a cane in September 2022**
 - EDSS score improved from 6.0 to 5.5
- **EA2 able to walk 200 meters without a cane in December 2022**
 - EDSS score improved from 5.5 to 5.0
- Pyramidal score continued to remain stable

Expanded Access (EA) Non-Active MS Program Expanded to 8 Total Non-Active SPMS Patients

Patient Progress

EA3 through EA6
(4 patients)

- ✓ All patients enrolled
- ✓ Baseline PET scans finished



All patients scheduled to receive first dose Jan 2023

EA7 through EA10
(additional 4 patients)



Enrollment scheduled for Q2 2023

Phase 2 Planning and Design

**TYPE C FDA meeting request for a Phase 2 study in
Non-Active Secondary Progressive MS Submitted Jan 2023**

Design

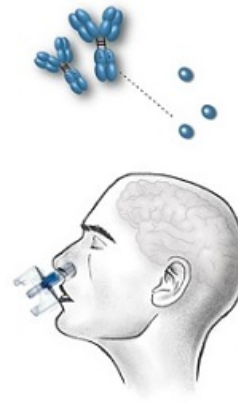
- ✓ Placebo-controlled
- ✓ Multi-center
- ✓ Dose-ranging
- ✓ Established outcome measures

Endpoints

- 9-Hole Peg Test (9HPT)
- Expanded Disability Status Scale (EDSS)
- Improvement in Timed 25-Foot Walk Test (T25FW)

First patient expected to enroll Q3 2023

**Other Potential CNS-related
Indications
(Alzheimer's and ALS)**



Intranasal anti-CD3 provides a unique approach for treating progressive neurologic diseases by modulating microglial cells. The intranasal route of immunotherapy has minimal toxicity and induces regulatory T cells locally, that then migrate to the brain to dampen brain inflammation.

Proof-of-Concept Demonstrated in Alzheimer's Disease

Study Presented at the Alzheimer's Association International Conference® (AAIC®)

"Treatment of Alzheimer's disease by modulation of microglial neuroinflammation by nasal anti-CD3 mAb" (presented by Weiner, M.D., Co-Director of the Ann Romney Center for Neurologic Disease at the Brigham and Women's Hospital (BWH) and Chairman of Tiziana's Scientific Advisory Board)

In this study animal models of Alzheimer's disease (AD) demonstrated that microglia activity was restored and cognition was improved following the dosing of intranasal anti-CD3 monoclonal antibody.

- Clinical measures were assessed in the mouse models using the Y-maze and Morris water maze tests which showed improvements in cognition. Biological improvements were also observed based on restoration of genetic phenotypes as measured by the presence of homeostatic microglia genes detected by Nanostring. In addition, it was found that intranasal anti-CD3 induced the migration of regulatory T cells (Tregs) to the brain which then interacted with microglia.
- Alzheimer's is another potentially valuable application of anti-CD3 based on its ability to stimulate the immune system to promote homeostatic microglial cells while decreasing degenerative microglial cells in the brain.

Alzheimer's Disease Plan is Underway

Received (August 2022) an affirmative written response from the FDA on a Pre-Investigational New Drug Application (PIND)

Submit an Investigational New Drug Application (IND) to conduct a Phase 2 study intranasal foralumab in Alzheimer's disease patients Q2 2023

Requested 13-Week toxicology studies completed
Requested 6-Month toxicology studies ongoing

Start Phase 2 program in 2H of 2023

Intranasal Foralumab in Amyotrophic Lateral Sclerosis (ALS)

ALS patients have limited therapeutic options and high unmet need

- In September, a Lawrence & Isabel Barnett Drug Development Program Grant was awarded to the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital (BWH) by the ALS Association.
- This prestigious research grant supports the study of an intranasal anti-CD3 monoclonal antibody (mAb) in an animal model of Amyotrophic Lateral Sclerosis (ALS).
- The grant will allow further study the role of intranasal anti-CD3 mAb in dampening the microglial activation which amplifies ALS disease progression.

“We have now seen the potential of intranasal foralumab to dampen microglial activation in three major neuroinflammatory-related diseases, which creates significant optionality for exploring its benefits in some of the most important and burdensome medical conditions of our time.”

Tiziana Life Sciences Announced Near-Term Strategic Focus on Intranasal Foralumab for Diseases of the Central Nervous System (CNS)

Focus on intranasal foralumab allows for efficient use of funds and staff

Sufficient cash reserves to perform Phase 2 MS trial

- Plan to use **non-dilutive** funding for Alzheimer's Disease, ALS, and T1D studies
- No anticipated requirement to raise capital in 2023

Deprioritized program development in oral foralumab, milciclib, and our fully human anti IL-6 receptor inhaled antibody

We believe this decision is the most pragmatic and value creating path forward for the near-term

Contact Us

US Headquarters (Pennsylvania)

Tiziana Life Science Ltd.
601 New Britain Road
Building 100, Suite 102
Doylestown PA 18901

UK Headquarters (London)

Tiziana Life Sciences Ltd.
14/15 Conduit Street
London
W1S 2XJ

+44 7769 88 4020

hmalik@tizianalifesciences.com

