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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 6-K**

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**REPORT OF FOREIGN PRIVATE ISSUER  
PURSUANT TO RULE 13a-16 OR 15d-16  
UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**June 2020**

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**Commission File Number:** 0001723069

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**Tiziana Life Sciences plc**

(Exact Name of Registrant as Specified in Its Charter)

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**3<sup>rd</sup> Floor,  
11-12 St James's Square  
London SW1Y 4LB  
United Kingdom**

(Address of registrant's principal executive office)

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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):

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**INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K**

On June 04, 2020, Tiziana Life Sciences plc (the “Company”) issued a regulatory news service announcement in the United Kingdom announcing that its Scientific Advisory Board Chairman Dr. Howard Weiner received an NIH grant to investigate Nasal Anti-CD3 for the treatment of Alzheimer’s disease (the “RNS Announcement”).

The RNS Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibit 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 PLC**

Date: June 04, 2020

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai

Title: Chief Executive Officer

EXHIBIT INDEX

| <u>Exhibit No.</u> | <u>Description</u>  |
|--------------------|---|
| 99.1               | <a href="#">Regulatory News Service Announcement, dated June 04, 2020</a> |

## Tiziana Life Sciences plc

("Tiziana" or the "Company")

**Tiziana Life Sciences announces that its Scientific Advisory Board Chairman Dr. Howard Weiner received NIH grant To investigate Nasal Anti-CD3 for the treatment of Alzheimer's disease**

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014.

New York/London, 4 June 2020 - Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS), biotechnology company focused on innovative therapeutics for oncology, inflammation and infectious diseases, announces that the Chairman of the Company's Scientific Advisory Board, Dr. Howard Weiner, has received a competitive research grant from the National Institutes of Health (NIH) to investigate nasal anti-CD3 for the treatment of Alzheimer's disease.

The demonstration that nasally administered anti-CD3 retards disease processes underlying the progression of Alzheimer's disease in animal models, further expands clinical development of nasally administered Foralumab, the only entirely human anti-CD3 monoclonal antibody, for the potential treatment of Alzheimer's and other neurodegenerative diseases in humans.

The Company has a worldwide exclusive license for nasal administration of anti-CD3 mAbs for treatment of neurodegenerative diseases, including Alzheimer's disease, from Brigham and Women's Hospital, Harvard Medical School, Boston. To date the Company has successfully completed two phase 1 trials and intends to initiate two phase 2 trials with nasally and orally administered Foralumab shortly for treatment of progressive multiple sclerosis (pro-MS) and Crohn's disease, respectively.

"Nasal administration of Foralumab is a potentially revolutionary approach to treat patients with Alzheimer's disease. Preclinical animal studies have established that nasal administration of anti-CD3 can modulate brain microglia and ameliorate disease in animal models. This is a major scientific advancement that provides the basis to move forward with clinical development of nasally administered Foralumab in Alzheimer's disease," commented Dr. Weiner, who is the Robert L. Kroc Professor of Neurology at the Harvard Medical School, Director and Founder of the Partners Multiple Sclerosis Center and Co-Director of the Ann Romney Center for Neurologic Diseases at the Brigham & Women's Hospital. "Targeting microglia with nasal anti-CD3 is a first-in-class immunotherapeutic approach to treat Alzheimer's disease."

Alzheimer's disease is the most common cause of dementia, which affects millions of people worldwide. It is now recognized that brain microglia have a critical role in Alzheimer's disease. In an unexpected discovery, Dr. Weiner found that nasal anti-CD3 modulates brain microglia in animal models. Treatment with anti-CD3 is known to stimulate T regulatory (Tregs) cells, which have the ability to cross the blood-brain barrier (1) The effect of nasal anti-CD3 in dampening microglial activation led Dr. Weiner's team at the Ann Romney Center for Neurologic Diseases at Brigham and Women's Medical Center to evaluate nasally administered Foralumab for pro-MS (2). In 2019, Dr. Weiner successfully completed a Phase 1 study with nasally administered Foralumab in healthy volunteers in a dose-ranging trial. A subsequent Phase 2 trial in patients with pro-MS will be initiated shortly.

“Alzheimer’s disease is considered to be the disease of the century, presenting multiple challenges and limited therapeutic successes so far,” added Gabriele Cerrone, Chairman and Founder of Tiziana Life Sciences. “For this reason, combined with Dr. Weiner’s expertise and the encouragement by the NIH to explore it, we are excited to further expand our proprietary novel approach to treat neurodegenerative diseases with nasal administration of Foralumab, a first-in-class approach that has shown retardation of Alzheimer’s disease progression in preclinical models.”

## Sources

- (1) Ogura M, et al. Oral treatment with foralumab, a fully human anti-CD3 monoclonal antibody, prevents skin xenograft rejection in humanized mice. *Clin Immunol.* 2017 Oct;183:240-246. doi: 10.1016/j.clim.2017.07.005. Epub 2017 Jul 21.
- (2) Mayo, L. et al. IL-10-dependent Tr1 cells attenuate astrocyte activation and ameliorate chronic central nervous system inflammation. *Brain.* 2016; 139; 1939-1957.

## About Dr. Howard Weiner

Dr. Howard L. Weiner is the Robert L. Kroc Professor of Neurology at the Harvard Medical School, Director and Founder of the Partners Multiple Sclerosis (MS) Center and Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham & Women's Hospital in Boston. He has pioneered immunotherapy in MS and has investigated immune mechanisms in nervous system diseases including MS, Alzheimer's disease, amyotrophic lateral sclerosis, stroke and brain tumors. He has also pioneered the investigation of the mucosal immune system for the treatment of autoimmune and other diseases and the use of anti-CD3 to induce regulatory T-cells (Tregs) for the treatment of these diseases.

## About Neurodegenerative diseases

Neurodegenerative diseases include Alzheimer’s, progressive multiple sclerosis, Huntington's disease, Parkinson’s disease, ALS and others. Among these, Alzheimer’s is the most prevalent disease. In 2013 the global market for AD was \$4.9 billion and expected to rise to \$13 billion by the end of 2023. Current treatments for neurodegenerative diseases are mainly symptomatic, but new disease-modifying drugs to slow or stop the progression of the disease are now emerging. Three Acetylcholinesterase inhibitors are currently in use for AD, i.e. donepezil (Aricept), rivastigmine (Exelon) and galantamine (Reminyl). It is recognized that localized CNS inflammation plays a critical role in neurodegenerative diseases of the brain. Immune-directed therapies for neurodegenerative diseases that target localized CNS microglial inflammation show promise. It has been shown in animal models of progressive MS that anti-CD3 antibody targeting T cells ameliorates disease. These effects were shown to be IL-10 dependent, mediated by regulatory T cells leading to suppression of the disease. There is great promise in ongoing studies of inflammation-targeted neuroprotective strategies, which may ultimately be used across neurodegenerative diseases.

## About Foralumab

Foralumab (formerly NI-0401), the only entirely human anti-CD3 mAb, shows reduced release of cytokines after IV administration in patients with Crohn's disease with decreases in the classic side effects of cytokine release syndrome (CRS) and improves the overall safety profile of Foralumab. In a humanized mouse model (NOD/SCID IL2 $\gamma$ c<sup>-/-</sup>), it was shown that while targeting the T cell receptor, orally administered Foralumab modulates immune responses of the T cells, enhances regulatory T-cells (Tregs) and thus provides therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy (Ogura M. et al., 2017). Based on animal studies, the nasal and oral administration of Foralumab offers the potential for the immunotherapy of autoimmune and inflammatory diseases in a safe manner by the induction of Tregs.

## About Tiziana Life Sciences

Tiziana Life Sciences plc is a dual listed (NASDAQ: TLSA & UK AIMS: TILS) biotechnology company that focuses on the discovery and development of novel molecules to treat human diseases in oncology, inflammation and infectious diseases. In addition to milciclib, the Company will be shortly initiating phase 2 studies with orally administered foralumab for Crohn's disease and nasally administered foralumab for progressive multiple sclerosis. Foralumab is the only fully human anti-CD3 monoclonal antibody (mAb) in clinical development in the world. This phase II compound has potential application in a wide range of autoimmune and inflammatory diseases, such as Crohn's disease, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable. The company is accelerating development of anti-Interleukin 6 receptor (IL6R) mAb, a fully human monoclonal antibody for treatment of IL6-induced inflammation, especially for treatment of hospitalized COVID-19 patients with severe respiratory symptoms.

The person who arranged for the release of this information was Dr Kunwar Shailubhai, Chief Executive Officer and Chief Scientific Officer of the Company.

### Contacts:

#### **Tiziana Life Sciences plc**

##### **United Kingdom:**

Gabriele Cerrone, Chairman and founder

+44 (0)20 7495 2379

##### **Cairn Financial Advisers LLP (Nominated adviser)**

Liam Murray / Jo Turner

+ 44 (0)20 7213 0883

##### **Optiva Securities Limited (Broker)**

Robert Emmet

+44 (0)20 7601 6125

##### **United States:**

Investors

CORE IR

ir@coreir.com

Media

Jules Abraham

CORE IR

(917) 885-7378

julesa@coreir.com