# 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 2021**

**Commission File Number:** 0001723069

## Tiziana Life Sciences plc
(Exact Name of Registrant as Specified in Its Charter)

**3rd Floor,**
**11-12 St James's Square**
**London SW1Y 4LB**
**United Kingdom**
(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 o

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): o

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): o

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

On January 4, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the completion of the clinical trial with nasally administered Foralumab, its proprietary fully human anti-CD3 monoclonal antibody, for the treatment of COVID-19 patients in Brazil (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: January 4, 2021

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai
Title: Chief Executive Officer

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Regulatory News Service Announcement, dated January 4, 2021 |

**Exhibit 99.1**

**Tiziana Life Sciences plc**

("Tiziana" or the "Company")

**Tiziana announces completion of the clinical trial with nasally administered Foralumab, its proprietary fully human anti-CD3 monoclonal antibody, for the treatment of COVID-19 patients in Brazil**

- ***Anecdotal feedback from Foralumab-treated patients was positive and suggests that the treatment was well-tolerated***
- ***The scientific approaches underlying this clinical study could potentially be effective against SARs, MERS, and all variants of coronaviruses***
- ***This trial is the first to evaluate nasally administered Foralumab to improve the immune system's fight against coronaviruses***

New York/London, 4 January 2021 - Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for oncology, inflammation, and infectious diseases, announces the completion of its clinical study in Brazil investigating nasally administered Foralumab, its proprietary human monoclonal antibody, either alone or in combination with orally administered dexamethasone in COVID-19 patients.

The clinical study was completed in collaboration with scientific teams at the Harvard Medical School (Boston, USA), Santa Casa de Misericórdia de Santos Hospital (Santos, Brazil) and INTRIALS, a world-class, full-service Latin American CRO based in São Paulo, Brazil. The last patients in the trial received their final dose on 21 December 2020.

The topline data from the trial is expected to be available in January 2021.

Because COVID-19 enters through the nasal and respiratory passage, the proprietary nasal formulation and nasal delivery of Foralumab is an innovative approach to provide immediate relief to COVID-19 patients.

Dr. Howard Weiner (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) commented:

> "Nasal administration of Foralumab to modulate the human immune system is a potentially transformative approach for treating patients with a variety of human diseases with dysregulated immune systems. Preclinical data from our laboratory have shown that the nasal administration of anti-CD3 stimulates Tregs that can suppress inflammation and ameliorate inflammatory diseases. Furthermore, nasal anti-CD3 dampens cytotoxic CD8 T cell responses that are known to cause lung damage in COVID-19 patients."

Dr Thais Moreira, the lead scientist and coordinator of the clinical trial, stated:

> "We are delighted to receive positive feedback from patients treated in the clinical trial. Among the positive results patients reported, the most common was that the treatment resulted in the rapid improvement in smell sensation, which is frequently lost in COVID-19 patients."

Dr. Kimble Matos, the lead coordinating physician of the study, commented:

> "The observations made during the Clinical study did not show any adverse events."

*The clinical study enrolled a total of 39 patients with moderate to severe COVID-19 who did not require the use of a ventilator at the beginning of the study. This study had three cohorts: control (n=16), nasally administered Foralumab (n=12), and nasally administered Foralumab with 3 days of priming with orally administered 6 mg dexamethasone (n=11).*

- *The primary endpoint of this study was safety of the treatment, and secondary endpoints were to evaluate the effect of treatment on disease severity symptoms, nasal tolerance, sense of smell, and biomarkers for disease progression. The pharmacokinetics of nasally administered Foralumab will also be evaluated.*
- *Patient reported outcome to assess clinical responses related to COVID-19 symptoms, as per the FDA guidelines, will also be collected.*

Dr. Kunwar Shailubhai, CEO and CSO of Tiziana Life Sciences, commented:

> "While we expect to get the topline data in January 2021, we are delighted with the positive feedback received from the treated patients. This is the first-in-class and scientifically logical approach to improve the human immune system by stimulating Tregs to suppress lung inflammation, and to dampen cytotoxic CD8+ T cell responses in the nasal and respiratory tract, the primary sites of the COVID-19 virus.
>
> "We believe this approach could potentially provide benefits to patients already infected with COVID-19 and its newly identified variants. Thus, our therapeutic approach to provide rapid relief to patients already suffering with the diseases is particularly important, because vaccination is primarily to prevent COVID-19 infection, but it may not be useful for treatment of COVID-19 patients."

A further announcement will be made in due course.

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

**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 IL2γc-/-), it was shown that whilst 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 2 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 COVID-19 patients.

**For further enquiries:**

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