
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

July 2020

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

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 July 31, 2020, Tiziana Life Sciences plc (the “Company”) issued a regulatory news service announcement in the United Kingdom announcing the Submission of a Patent Application for Nasal Administration of Foralumab, A Fully Human Anti-CD3 Monoclonal Antibody, for Treatment of COVID-19 Patients (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: July 31, 2020

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated July 31, 2020

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF REGULATION (EU) NO 596/2014

Tiziana Life Sciences plc

(“Tiziana” or the “Company”)

Tiziana Announces Submission of a Patent Application for Nasal Administration of Foralumab, A Fully Human Anti-CD3 Monoclonal Antibody, for Treatment of COVID-19 Patients

New York/London, July 31, 2020 - 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, is pleased to announce that it has submitted a patent application for the potential use of nasally administered Foralumab, a fully human anti-CD3 monoclonal antibody (mAb), for the treatment of COVID-19 either alone or in combination with other anti-viral drugs. Recent clinical studies imply that a combination of anti-inflammatory and anti-viral drugs may be more effective to treat patients at different stages of COVID-19 disease.

- *Nasal administration with Foralumab could potentially modulate or stimulate immune system to suppress cytokine storm and reduce respiratory failure in COVID-19 patients*
- *Nasal administration of Foralumab may be combined with other anti-viral drugs to improve treatment efficacy*

Tiziana has a worldwide exclusive license for nasal administration of Foralumab and other anti-CD3 mAbs for the treatment of neurodegenerative and other diseases. The Company previously announced development of a robust formulation and delivery of Foralumab using a nasal spray device and the successful completion of a Phase 1 trial demonstrating that the treatment was well-tolerated and showed positive immunomodulatory effects as measured by biomarker analysis (<https://www.tizianalifesciences.com/news-item?s=2018-11-28-tiziana-announces-initiation-of-phase-1-clinical-trial-with-nasal-administration-of-foralumab-a-fully-human-anti-cluster-definition-3-monoclonal-antibody-anti-cd3-mab-in-healthy-volunteers>).

Additionally, Tiziana also reported the successful completion of a Phase 1 trial with oral administration of Foralumab, demonstrating that the treatment was well-tolerated up to a 5 mg dose (<https://www.tizianalifesciences.com/news-item?s=2020-01-09-tiziana-reports-phase-1-clinical-data-demonstrating-oral-treatment-with-foralumab-a-fully-human-anti-cd3-monoclonal-antibody-is-well-tolerated-in-healthy-volunteers>). Importantly, both clinical studies conducted at the Brigham and Women’s Hospital and Harvard Medical School, Boston, MA., indicated that the severe toxicities that are commonly associated with intravenous administration of anti-CD3 mAbs were not observed with either oral or nasal administration of Foralumab.

“Nasal administration of Foralumab is a potentially transformative immunomodulatory approach for treating patients with a variety of human diseases. Results from animal studies, conducted in our laboratory have established that nasal administration of anti-CD3 induces regulatory T cells that suppress inflammation and ameliorate diseases in animal models. This scientific advancement provides the basis to move forward with clinical development of nasally administered Foralumab in COVID-19 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. He continued, “modulating the immune system with nasal anti-CD3 is a first-in-class immunotherapeutic approach to treat COVID-19 disease.”

“Our proprietary immunotherapeutic approach using nasal, inhalation and oral administration of mAbs are novel and promising therapies that stimulate or modulate the immune system so that T regulatory cells (Tregs) are supercharged to inhibit inflammation. The common underlying concept in these alternative delivery approaches is to strengthen one’s own body defense to fight against inflammation in these diseases. Being a fully human anti-CD3 mAb, we believe Foralumab is most suitable for immunotherapies, as it does not produce an immune response unlike other humanized anti-CD3 mAbs” commented Dr. Shailubhai, CEO and CSO of Tiziana Life Sciences.

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 IL2 γ c^{-/-}), 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 COVID-19 patients.

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. 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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