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

June 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 June 19, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing a Patent Granted for Oral Administration of all Anti-CD3 Monoclonal Antibodies for Treatment of Human Diseases (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 19, 2020

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated June 19, 2020

Exhibit 99.1

Tiziana Life Sciences plc

("Tiziana" or the "Company")

Tiziana Granted First-Ever Patent on a Transformational Technology for Oral Delivery of all Anti-CD3 Monoclonal Antibodies for Treatment of Human Diseases

- ***First-ever granted patent on oral administration of anti-CD3 monoclonal antibodies for immunotherapies***
- ***Transformational oral formulation technologies applicable to other antibodies***

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

New York/London, 19 June 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, announces that the United States Patent and Trademark Office ("USPTO") has granted a patent covering its proprietary platform technology for the oral administration of Foralumab, its proprietary fully human monoclonal antibody, and all other anti-CD3 monoclonal antibodies (mAb). The CD3 (cluster of differentiation 3) is a protein complex on T-cells, which is important for regulation of immune system. The patent will be issued by the USPTO on 23 June 2020.

"The issuance of this first-ever patent on formulation for oral administration of mAbs is a very exciting and timely development, as it facilitates a transformational avenue for immunotherapies" commented Dr. Howard L. Weiner, Chairman of Tiziana's Scientific Advisory Board, 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 and Women's Hospital. "We also recently successfully demonstrated that nasally-administered Foralumab is not only well tolerated but also produced desirable immunological responses. In addition, both oral and nasal administration routes are physiologic approaches to stimulate the mucosal immune system to induce disease modifying benefits, while minimizing the severe toxicities commonly associated with the traditional intravenous administration of anti-CD3 mAbs."

"The granting of this patent on first-in-class formulation technology allows us to work on bringing patients the first non-intravenous or subcutaneous treatment with antibodies to treat major gastrointestinal and neurodegenerative diseases such as Crohn's Disease, pro-MS and Alzheimer's disease. We believe development of the alternative administration routes of antibodies such as oral, nasal and inhalation could potentially be transformational for immunotherapies," added Gabriele Cerrone, chairman and founder of Tiziana.

The patent titled ***"Anti-CD3 formulations; patent No. 10,688,186, Inventor: Kunwar Shailubhai"***, is the first-ever to be granted on **anti-CD3 formulations** and covers oral administration with lyophilized and stabilized free-flowing powder of Foralumab or any other anti-CD3 mAb, encapsulated in enteric-coated capsules, for treatment of human diseases. In addition, the stabilized liquid formulation of Foralumab and other anti-CD3 mAbs for nasal administration is also covered in this patent. These formulation technologies have the potential to transform immunotherapies, which currently can only be administered through intravenously or subcutaneously

Tiziana previously reported the successful completion of a Phase 1 trial utilizing oral administration of Foralumab, which was designed to evaluate its safety and tolerability in healthy subjects. The trial was conducted at Brigham and Women's Hospital, Harvard Medical School, Boston, Mass., and indicated that oral administration of Foralumab 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) .. The Company plans to move forward with further development of orally administered Foralumab for evaluation in moderate-to-severe patients with Crohn's Disease. Additionally, Tiziana previously reported the successful completion of a Phase 1 study evaluating safety and analysis of biomarkers for clinical activity of nasally administered stabilized solution of Foralumab (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) .. A Phase 2 trial in patients with progressive multiple sclerosis will commence shortly. Importantly, in both clinical studies, the severe toxicities commonly associated with intravenous administration of anti-CD3 mAbs were not observed with oral or nasal administration of Foralumab.

The person who arranged for the release of this announcement on behalf of the Company was Dr Kunwar Shailubhai, CEO & CSO of Tiziana.

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 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 AIM: 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.

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