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

August 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 August 18, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing it was granted a Patent on Methods and Use of Anti-CD3 Monoclonal Antibodies for Treatment of Crohn's (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: August 18, 2020

By: /s/ Kunwar Shailubhai
Name: Kunwar Shailubhai
Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated August 18 2020

Tiziana Life Sciences plc

("Tiziana" or the "Company")

Tiziana Granted a Patent on Methods and Use of Anti-CD3 Monoclonal Antibodies for Treatment of Crohn's Disease

New York/London, 18 August, 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 on use and methods of treatment of Crohn's disease with 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 the regulation of the immune system. The patent will be published by the USPTO on 1 September, 2020 as Patent No.* 10,759,858. *Recently, Tiziana also announced the issuance of the first-ever patent on oral administration of anti-CD3 mAbs for treatment of human diseases (Patent No.* 10,688,186). *The grant of this additional composition-of-matter and use patent further strengthens the Company's intellectual property, consisting of proprietary technologies on oral and nasal administration of Foralumab and other anti-CD3 mAbs for the treatment of human diseases.*

Tiziana previously reported the successful completion of a Phase 1 trial utilizing oral administration of Foralumab on 9 January 2020, 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 a phase 2 trial in the 4th quarter of 2020 with orally administered Foralumab for the evaluation of moderate-to-severe patients with Crohn's Disease.

Dr. Kunwar Shailubhai, CEO & CSO of Tiziana Lifesciences, commented, "We are delighted that this key patent on composition-of-matter and use for treatment of Crohn's Disease is granted. We are very excited about the continued development of the oral administration of Foralamab for the treatment of Crohn's disease because this alternative route of administration seems to minimize toxicity and we believe it would maximize clinical activity by acting topically in the gut to inhibit inflammation."

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 on 28 November 2018 (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, a Phase 2 trial in patients with progressive multiple sclerosis will commence in the 4th quarter. 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.

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.

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

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