
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 24, 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-IL-6/IL-6 receptor Monoclonal Antibodies as Prophylactic and Therapeutic Interventions for COVID-19 and other pulmonary 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: August 24, 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 24 2020

Tiziana Granted a Patent on Methods and Use of Anti-IL-6/IL-6 receptor Monoclonal Antibodies as Prophylactic and Therapeutic Interventions for COVID-19 and other pulmonary diseases

New York/London, 24 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 for methods and use of fully human monoclonal antibody (mAb; TZLS-501) that recognizes both IL-6 receptor (IL-6R) and IL-6 receptor complex with IL-6 (IL-6R/IL-6) for prophylactic and therapeutic intervention for human diseases. The Company initially entered into a world-wide exclusive license from Novimmune, SA., a Swiss Biotechnology company in 2017. The license is currently maintained with Bristol Myers Squibb. The patent (No. 10,759,862) will be published by the USPTO on September 1, 2020. The grant of this additional patent on TZLS-501 is of particular significance for the potential treatment of COVID-19 and other pulmonary diseases such as acute respiratory distress syndrome (ARDS).

The major distinguishing feature of TZLS-501 is that it acts via a dual mechanism by not only inhibiting IL-6R signaling but also depleting circulating levels of IL-6. This distinctive feature of TZLS-501, a fully human anti-IL-6R mAb, makes it potentially suitable for treatment of COVID-19 and ARDS. For example, COVID-19 patients often develop an uncontrolled immune response (“cytokine storm”) resulting in severe damage to the lung tissue which could lead to respiratory failure. Many studies have also indicated excessive levels of IL-6 in the lungs and in the blood of these patients, and it is believed that the cytokine storm in lungs is primarily due to excessive levels of IL-6. Hence, direct inhalation delivery of TZLS-501 to the lungs using a hand-held nebulizer has the potential to deplete circulating levels of IL-6 and inhibit IL-6R signaling thus providing immediate relief to COVID-19 patients.

“The granting of this patent along with our previously filed patent application on inhalation delivery of anti-IL-6 mAbs strengthens our intellectual property for the treatment of lung diseases. We are expediting the clinical development of TZLS-501, GMP manufacturing, simultaneously developing inhalation delivery directly to the lungs using a nebulizer and conducting the inhalation safety toxicology studies in Cynomolgus monkeys. Completion of these studies will enable us to file an IND and initiate a clinical trial in COVID-19 patients by Q1 2021. Subsequently, we plan to use TZLS-501 with the same inhalation delivery technology for the treatment of patients with ARDS”, added Dr. Kunwar Shailubhai, CEO & CSO of Tiziana.

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

About TZLS-501

TZLS-501, a fully human mAb, was acquired from Novimmune, SA, a Swiss biotechnology company, in 2017. The cytokine, IL-6, a major determinant in the priming of pathogenic T cells to produce an inflammatory response, binds to its receptor subunit IL-6R α on the cell membrane. The receptor IL-6R α can be shed in soluble form, sIL6R α , which binds to circulating IL-6 cytokine in the blood. The downstream signaling from this complex mediates pro-inflammatory effects underlying inflammatory diseases such as rheumatoid arthritis (RA) and acute respiratory distress syndrome (ARDS). The Company believes that the features of TZLS-501 consisting of its dual mechanism of action to inhibit signaling by the membrane-bound and soluble IL-6 receptor and the rapid depletion of circulating IL-6 cytokines, a major cause of lung damage, suggests a potential role for TZLS-501 in patient management and treatment of COVID-19.

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 miliclib, 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 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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