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 4, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing an Expedited Clinical Development Plan for Its Anti-Interleukin-6-Receptor, a Fully Human Monoclonal Antibody, for the 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: August 4, 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 4, 2020

Exhibit 99.1

Tiziana Life Sciences plc

("Tiziana" or the "Company")

Tiziana Life Sciences Announces an Expedited Clinical Development Plan for Its Anti-Interleukin-6-Receptor, a Fully Human Monoclonal Antibody, for the Treatment of COVID-19 Patients

- ***Recently signed agreements with four contract research organizations ("CROs") to initiate GMP manufacturing, develop inhalation technology, conduct inhalation safety toxicity study in monkeys, and initiate a human clinical trial in COVID-19 patients***

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

New York/London, August 4, 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, today announced that it has signed agreements with four CROs to expedite clinical development of TZLS-501, a novel fully human anti-interleukin-6 receptor (anti-IL6R) monoclonal antibody (mAb) for the treatment of COVID-19 (SARS-CoV-2) patients. The Company intends to initiate the clinical study in Q1 2021 and will work with the following CROs:

- ***FHI Clinical***: A subsidiary of FHI 360, FHI Clinical is a multinational CRO specializing in clinical development of drugs for infectious diseases (https://www.fhiclinical.com). This company has conducted several recent trials in COVID-19 patients and has a large network of clinical sites throughout the US and abroad to expedite clinical trials with COVID-19 patients. In this trial, TZLS-501 will be delivered as an aerosol directly to the lungs using a hand-held nebulizer.

- ***STC Biologics***: STC Biologics, Inc. is a boutique Good Manufacturing Practice (GMP) CRO that provides full chemistry, manufacturing and control (CMC) services to enable its partners to advance their biologic products from discovery to commercial approval. GMP manufacturing of TZLS-501 is ongoing.

- ***Sciarra Labs***: Sciarra Laboratories, Inc., is an FDA-approved, current GMP manufacturer of drug solutions used in nebulizers, inhalers, metered dose inhalers ("MDI") and nasal sprays. Tiziana worked with Sciarra Labs to establish clinical supply of nasal sprays of Foralumab used in the recently completed Phase 1. Sciarra Labs will be developing and testing a hand-held nebulizer and GMP manufacturing the anti-IL6R mAb solution to be used as clinical trial material for the clinical study in COVID-19 patients.

- ***ITR Laboratories Canada***: ITR has been in operation for the last 30 years and is known for its reputation in toxicology testing and other specialized testing services for biotechnology and pharmaceutical industries in North America, Europe and beyond. ITR is a Canadian Council on Animal Care (CCAC) and American Association for Accreditation of Laboratory Animal Care (AAALAC) CRO and is a fully compliant Good Laboratory Practices (GLP) CRO. ITR will be conducting safety and toxicity studies with TZLS-501 delivered by a nebulizer directly into the lungs of cynomolgus monkeys.

Tiziana holds a worldwide exclusive license for TZLS-501 (a.k.a NI-1201) from Bristol Myers Squibb™. TZLS-501 is a novel fully human mAb that binds to both the membrane-bound and soluble forms of IL-6R and rapidly depletes circulating levels of IL-6 in the blood (1). Excessive production of IL-6 is regarded as a key driver of cytokine release syndrome (CRS) and chronic inflammation in the lungs of patients with COVID-19 and acute respiratory illness such as Acute Respiratory Distress Syndrome (ARDS). Tiziana's novel and proprietary approach to treatment is to deliver TZLS-501 directly to the lung via inhalation.

Executive Chairman of Tiziana, Gabriele Cerrone, commented: “We have moved quickly to accelerate our clinical development plan for TZLS-501 using our innovative delivery platform, which was developed by Howard Weiner, a world-renowned neurologist and Chairman of our Scientific Advisory Board. I look forward to beginning our human clinical trials in the first quarter of 2021.”

Dr. Kunwar Shailubhai, CEO and CSO of Tiziana Life Sciences, commented**,** “Our proprietary inhalation technology for delivery of TZLS-501 to the lungs in COVID-19 patients is an attractive and most logical approach to deplete excessive levels of IL-6 to provide rapid relief. We are focusing on the development of oral, nasal and inhalation routes of mAb administration for immunotherapy. The common underlying concept in these alternative delivery approaches is to enable local or topical actions to maximize clinical action and minimize undesirable side effects commonly associated with intravenous and subcutaneous administration. Being a fully human anti-IL-6 receptor mAb, TZLS-501 is most suitable for long-term immunotherapies.

Cited Reference

(1) Lacroix, M. et al., Novel Insights into Interleukin 6 (IL-6) Cis- and Trans-signaling Pathways by Differentially Manipulating the Assembly of the IL-6 signaling Complex. J Biol Chem. 2015 Nov 6; 290 (45): 26943-26953

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 TZLS-501

TZLS-501, a fully human mAb, was acquired from Novimmune, 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-6Rα (IL-6R alpha) on the cell membrane. IL-6 appears be a major determinant in the priming of pathogenic T cells to produce an inflammatory response. The receptor IL-6Rα can be shed as a soluble entity, sIL6Rα, which binds to circulating IL-6 cytokine in the blood. The downstream signaling from this complex is believed to mediate the pro-inflammatory effects underlying the inflammatory diseases such as rheumatoid arthritis (RA) and acute respiratory distress syndrome (ARDS). The Company believes that the novel 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 the patient management and treatment of COVID-19.

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.

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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