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

September 2021

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 September 24, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the publication of the Interim Results for the Six Months Ended 30 June 2021 (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: September 24, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated September 24, 2021

Tiziana Life Sciences plc
("Tiziana" or "the Company")

Interim Results for the Six Months Ended 30 June 2021
Advancing pipeline of next generation therapeutics and diagnostics for oncology and immune diseases of high unmet need

London, 24 September 2021 – Tiziana Life Sciences plc ("Tiziana", LSE: TILS, NASDAQ: TLSA), a biotechnology company a biotechnology company focused on innovative therapeutics for oncology, inflammation, and infectious diseases today announces its interim results for the six months ended 30 June 2021.

Highlights during the period:

CLINICAL PROGRAMMES

Foralumab
TZLS-401

- Announced an update on further analysis of lymphocyte subsets from blood samples from a Phase 1 study with nasally administered Foralumab in healthy volunteers. Results exhibiting statistically significant immunomodulatory effects on CD8 cytotoxic T-lymphocytes and other inflammatory biomarkers were observed. Systemic levels of Foralumab were below the lower quantitation limit of 8 ng/mL suggesting that nasally administered Foralumab appears to exert its effects via nasal epithelium utilizing local and lymphatic immune systems directly.These data support other clinical and pre-clinical studies showing that this route of administration is capable of inducing site-targeted immunomodulation and anti-inflammatory effects. Furthermore these pharmacodynamic data point to a clinical dose range that Tiziana intends to test in further clinical development among MS patients.

- Announced positive data from the exploratory clinical study in Brazil investigating nasally administered Foralumab, its proprietary anti-CD3 human monoclonal antibody, either alone or in combination with orally administered dexamethasone ("Dexa") in COVID-19 patients. The clinical study was completed in collaboration with scientific teams at the Harvard Medical School (Boston, USA), and INTRIALS, a full-service Latin American CRO based in São Paulo, Brazil. The objectives of the trial were to assess safety of the treatment and to evaluate if progression of the diseases is delayed with nasally administered 100mcg/day Foralumab (50mcg/nostril). This study enrolled 39 patients randomized in three cohorts: cohort 1, control with no treatment (n=16); cohort 2; nasally administered Foralumab plus 3 days of priming with orally administered 6 mg Dexamethasone (n=11) and cohort 3; nasally administered Foralumab (n=12). The Foralumab treatment regimen was once a day dosing for 10 consecutive days There were no significant differences between cohort 2 and 3. All treatments were well-tolerated. There were no grade 3 or 4 severe adverse events ("SAEs") in any of the cohorts. The CT scans of the lungs showed the improvement was approximately double that shown in patients treated with Foralumab as compared to those in the control group. The results of the study were published in the peer-reviewed journal, *Frontiers in Immunology* entitled "Nasal Administration of Anti-CD3 Monoclonal Antibody (Foralumab) Reduces Lung Inflammation and Blood Inflammatory Biomarkers in Mild to Moderate COVID-19 Patients: A Pilot Study" in August 2021.

- Signed an agreement with FHI CRO to conduct a follow-up, "proof of concept" Phase 2 study in hospitalized patients with severe COVID-19 and lung inflammation that is planned to begin in Q4 2021. Foralumab will be delivered intranasally using a metered dose delivery device.

- Announced that the first patient with secondary progressive multiple sclerosis (SPMS) was dosed with nasally administered Foralumab at the Brigham and Women's Hospital (BWH), Harvard Medical School, Boston, MA. Nasal Foralumab 50 mcg (25 mcg/nostril) was administered in 3-week cycles, with 3 times/week dosing for the first 2 weeks followed by 1 week of rest period. This first-ever clinical study in SPMS patients, under an Individual Patient Expanded Access IND, will continue for six months to evaluate routine safety, tolerability, and neurological behaviors. The study will also examine microglial activation, by positron emission tomography (PET), immunological and neurodegenerative markers to assess clinical responses following the treatment regimen.

Anti IL-6R mAb
TZLS-501, formerly NI-1201

- Working with Sciarra Laboratories to evaluate two hand-held nebulizer devices for use in the study and characterizing physical/performance characteristics. Once a device has been selected, a few candidate formulations of anti-IL6R mAb, from formulation development studies at STC Biologics, will be manufactured at small scale and evaluated using the devices.

- Engaged ITR Laboratories in Canada to complete inhalation safety toxicology studies in Cynomolgous monkeys using the purified, characterized anti-IL6R mAb test item. Results from the study will be used to establish dosing fora Phase 1 study in healthy volunteers. Additional parenteral administration safety toxicology studies are in progress at ITR Laboratories to support clinical studies for treatment of autoimmune and inflammatory diseases.

Milciclib
TZLS-201

- Announced that it had executed an agreement with Takanawa Japan K.K, Pharma Team, (Takanawa) for a strategic business development plan to Identify a clinical partner in Japan and other Asian countries for further clinical development of Milciclib for treatment in advanced hepatocellular carcinoma (HCC) patients. HCC is the most common type of liver cancer and affects approximately 200,000 people per year.

Intellectual Property

- As of September 2021, the Company has a total of 306 granted patents, 281 foreign and 25 US patents.

New appointments

- Appointed Dr Neil Graham MBBS, MD, MPH as Chief Medical Officer, Dr Thomas Adams Ph.D. as Head of Drug Development and an executive director and Dr. Kevin Schutz, PharmD, as Vice-President of Regulatory Affairs.

Highlights post period end:

- On September 2, 2021, Tiziana and Precision Biosciences announced an exclusive license agreement to explore Tiziana's foralumab as an agent to induce tolerance of allogeneic CAR T cells to potentially improve the clinical outcome of CAR T cell therapy. Precision's approach to manufacturing produces CAR T cells that are virtually CD3-negative. Foralumab will be used as a lymphodepletion or tolerizing agent, either alone or in combination with other co-stimulatory molecules, to improve the long-term survival of CAR T cells in cancer treatment.

- Tiziana has formally commenced its strategic plan to change its corporate structure by establishing Tiziana Life Sciences Ltd, a Bermuda-incorporated company, as the ultimate parent company of the of the Tiziana Group. The reorganisation will be achieved by a scheme of arrangement under Part 26 of the Companies Act 2006.

FINANCIAL

- For the six months to 30 June 2020 the consolidated Group made a loss of £12.59m (six months to 30 June 2020: £3.9m).

- The Group ended the period with £38.6m cash as at 30 June 2021 (31 December 2020: £48.2m).

- Research and development (R&D) expenses increased to £12.6m compared to £3.9m in the first half of 2020. The increase is primarily expenses related to the advancement of our proprietary programs, TZLS-401 and TZLS-501.

- The Company cancelled the admission of its Ordinary Shares to trading on AIM and admitted its shares to trading on the main market for listed securities (of London Stock Exchange plc in January 2021.

The Company continues to carefully manage its working capital position and continues the process, as referred to below, to evaluate opportunities to raise further funds through the issue of additional equity capital.

To view the complete Interim Accounts click here: https://ir.tizianalifesciences.com/financial-information/interim-reports

Contacts:

Tiziana Life Sciences plc +44 (0)20 7495 2379
Gabriele Cerrone, Chairman and founder

About Tiziana Life Sciences

Tiziana Life Sciences plc is a dual listed (NASDAQ:TLSA, UK LSE: 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.