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 21, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing it was granted a Patent on the Use of Milciclib in Combination with Tyrosine Kinase Inhibitors for Treatment of Hepatocellular Carcinoma and other Cancers (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 21, 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 21 2020

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

Tiziana Life Sciences plc

("**Tiziana**" or the "**Company**")

Tiziana Granted a Patent on the Use of Milciclib in Combination with Tyrosine Kinase Inhibitors for Treatment of Hepatocellular Carcinoma and other Cancers

New York/London, 21 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 of Milciclib in combination with tyrosine kinase inhibitors (TKIs) such as Sorafenib (Nexavar®), Regorafenib (Stivarga®) and Lenvatinib (Lenvima®) for the treatment of hepatocellular carcinoma (HCC) and other cancers in humans. *This patent will be published by the USPTO on 1 September 2020 as Patent No.* 10,758,541 (Inventor: Kunwar Shailubhai). Like most human cancers, HCC is a complex multi-factorial cancer with multiple underlying mechanisms causing enormous heterogeneity in patient populations. Consequently, patients with HCC often develop resistance towards the monotherapies of existing therapeutics. Thus, there is an urgent need for combination drug treatment approaches targeting different mechanisms to achieve better clinical outcomes.

Recently, the Company presented two posters on clinical evaluation of Milciclib at the American Society of Clinical Oncology 2020 (ASCO2020). The poster on Phase 2a clinical evaluation of Milciclib, a broad-spectrum inhibitor of cyclin dependent kinases, indicated that the treatment was well-tolerated, and it produced encouraging clinical activity in sorafenib-resistant patients of HCC(1). The second poster was on the evaluation of Milciclib in combination with Regorafenib, a specific TKI drug, in liver transplant patients with HCC recurrence in the MiHRCO (Milciclib and Half Regorafenib CO administration) trial. The combination treatment was safe and produced promising clinical response(2) in these delicate and difficult to treat patients. Additionally, the Company earlier reported data from an animal study suggesting that the combination of Milciclib with Sorafenib, both acting via different mechanisms, suppressed expression of protooncogene c-Myc to produce pronounced synergistic anti-HCC activity(3).

Dr. Kunwar Shailubhai, CEO & CSO of Tiziana Lifesciences, commented, "Advanced cases of patients with HCC have limited therapeutic options because of the heterogeneity of the multiple mechanisms underlying the development of drug resistance and limited clinical responses. Thus, combination of drugs with different mechanism of actions are necessary to achieve superior clinical outcome. We are delighted that we now have this key patent on use of Milciclib in combination with other HCC drugs, including a TKI. Issuance of this patent strengthens our clinical strategy as we move forward with the combination of Milciclib and a TKI for the clinical evaluation of advanced cases of HCC as well as in patients with recurrent HCC after liver transplantation."

The person who arranged for the release of this announcement was Dr Kunwar Shailubhai, Chief Executive Officer and Chief Scientific Officer of the Company

Cited References:

1. Villa, E., Piscaglia, F., Geva, R., Dalecos, G., Papatheodoridis, G., Ciomei, M., Davite, C., Crivori, P., Palejwala, V., Jacob, J., Hamzeh, F., Shailubhai, K., Santoro, A., and A., S. (2020) Phase 2a Safety and Efficacy of Milciclib, a Pan-Cyclin Dependent Kinase Inhibitor, in Unresectable, Sorafenib-Refractory or -Intolerant Hepatocellular Carcinoma Patients. ASCO Abstract #29856

2. Pivetti, A., Di Marco, L., Bristot, L., Milosa, F., Maria Critelli, R., De Maria, N., Di Benedetto, F., Palejwala, V., Jacob, J., Shailubhai, K., and Villa, E. (2020) Safety and Clinical Activity of Combination Treatment with Regorafenib and Milciclib in Liver Transplant Patients with Hepatocellular Carcinoma Recurrence. ASCO Abstract #307309

3. Jindal, A., Palejwala, V. a., and Shailubhai, K. (2018) Oral Treatment with Milciclib Either Alone or in Combination with Sorafenib Inhibited Tumor Growth in an Orthotopic Model of Hepatocellular Carcinoma. Hepatology 68, 879A

About Milciclib (TZLS-201)

Milciclib (PHA-848125AC) is a small molecule inhibitor of several cyclin dependent kinases such as CDK1, CDK2, CDK4, CDK5 and CDK7. CDKs are serine threonine kinases that play crucial roles in progression of the cell cycle from G_1 to S phase. Overexpression of CDKs and other downstream signaling pathways that regulate cell cycles have been frequently found to be associated with development of resistance towards chemotherapies. In a phase I study, oral treatment with Milciclib was found to be well-tolerated and the drug showed promising clinical responses in patients with advanced solid malignancies such as in NSCLC, pancreatic and colon cancer, thymic carcinoma and thymoma.

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.

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