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

December 2018

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 December 3, 2018, Tiziana Life Sciences plc (the "Company") issued a regulatory news service ("RNS") announcement in the United Kingdom disclosing details of the Company's patient enrollment of a Phase 2a trial to evaluate the tolerability and anti-tumor activity of Milciclib in Sorafenib-refractory or -intolerable, unresectable or metastatic hepatocellular carcinoma (the "RNS").

The RNS 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: December 3, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated December 3, 2018

Exhibit 99.1

Tiziana Life Sciences plc

("Tiziana" or the "Company")

Tiziana Completes Patient Enrollment in a Phase 2a Trial to Evaluate Tolerability and Anti-Tumor Activity of Milciclib in Hepatocellular Carcinoma (HCC)

New York/London, 3 December 2018 – Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS), a biotechnology company focusing on the discovery and development of innovative therapeutics for inflammation and oncology indications, announces that patient enrollment in the ongoing Phase 2a clinical trial (CDKO-125A-010) is completed. This is a single-arm, repeated-dose, 6-month duration study to evaluate safety, tolerability and anti-tumor activity of Milciclib in Sorafenib-refractory or -intolerant patients with unresectable or metastatic HCC. Topline data from this multi-center trial, being conducted in Italy, Greece and Israel, will be available in the second quarter of 2019.

Previously we reported interim analysis data from the first 10 patients, following 6 months of treatment, showing that Milciclib (100 mg once daily; 4 days on/3 days off every 4 weeks defining each cycle) was well-tolerated in this HCC patient population. It was concluded by an Independent Data Monitoring Committee (IDMC) that there were no major signals of tolerability concerns, and the IDMC allowed continuation of patient enrollment in the trial. Following completion of 6 months of treatment, three patients opted to continue treatment under the compassionate use program. Notably, one patient is still continuing treatment in the 14^{th} month and the other two patients received treatment until 9^{th} month and 13^{th} month, respectively.

About HCC

HCC is the 5^{th} most common cancer and the 3^{rd} cause of cancer mortality worldwide. In 2007 the approval by the European Medical Agency (EMA) and Food and Drug Administration (FDA) of Sorafenib (Nexavar®), an inhibitor of several receptor tyrosine kinases, in HCC represented the first systemic therapy for improving outcome in patients unsuitable for loco-regional and surgical therapies and created a new standard of treatment for the disease. However, although significant in respect to placebo, the benefits of Sorafenib are modest; the response rate is less than 3%, the improvement in median survival is 2-3 months and the drug-related symptoms are not ordinary. The complex multi-factorial etiology of HCC warrants a need for systemic therapies that target different signaling cascades to provide improved efficacy and safety for both naive patients presenting with unresectable, advanced stage and those who suffer recurrence after curative treatments (resection, ablation and transplantation).

About Milciclib

Milciclib (PHA-848125AC) is a small molecule inhibitor of several cyclin dependent kinases such as CDK1, CDK4, CDK5 and CDK7. CDKs are serine threonine kinases that play crucial roles in progression of the cell cycle from G1 to S phase. Overexpression of CDKs and other downstream signaling pathways that regulate cell cycles have been frequently associated with development of resistance towards chemotherapies. In a Phase 1 study, oral treatment with Milciclib was 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. Additionally, milciclib met its primary endpoint in two separate Phase 2 multi-center clinical trials (CDKO-125A-006: 72 patients and CDKO-125A-007: 30 patients) in thymic carcinoma and thymoma patients.

About Sorafenib

Sorafenib (co-developed and co-marketed by Bayer and Onyx Pharmaceuticals as Nexavar®) is a small molecular multi-tyrosine kinase inhibitor drug approved for the treatment of primary kidney cancer (advanced renal cell carcinoma), HCC, and radioactive iodine resistant advanced thyroid carcinoma. Treatment with Sorafenib induces autophagy, which may suppress tumor growth. However, autophagy can also cause drug resistance.

About Tiziana Life Sciences

Tiziana Life Sciences plc is a UK biotechnology company that focuses on the discovery and development of novel molecules to treat human disease in oncology and immunology. In addition to Milciclib, the Company is also developing Foralumab for liver diseases. Foralumab is the only fully human anti-CD3 monoclonal antibody in clinical development in the world. This Phase 2 compound has potential application in a wide range of autoimmune and inflammatory diseases, such as nonalcoholic steatohepatitis (NASH), primary biliary cholangitis (PBS), ulcerative colitis, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable.

For further enquiries:

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