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

May 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 May 5, 2021, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing it would be Tiziana Announces Strategic Initiative with Takanawa Japan K.K., Pharma Team, to Identify a Partner in Japan and Other Asian Countries for Further Clinical Development of Milciclib in Patients with Advanced Hepatocellular (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: May 5, 2021

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated May 5, 2021

Exhibit 99.1

Tiziana Announces Strategic Initiative with Takanawa Japan K.K., Pharma Team, to Identify a Partner in Japan and Other Asian Countries for Further Clinical Development of Milciclib in Patients with Advanced Hepatocellular Carcinoma.

- ***Objective of this partnership with Takanawa Japan K.K., Pharma Team, is to identify a strategic partner in Japan for further development of Milciclib either alone or in combination with a tyrosine kinase inhibitor (TKI) for treatment of advanced HCC patients in Asian countries where prevalence of HCC is high, and the available therapeutic options are not entirely satisfactory.***
- ***Milciclib, a broad-spectrum cyclin dependent kinase (pan-CDK) inhibitor, has successfully completed eight phase 1 and phase 2 trials in thymic carcinoma, thymoma and hepatocellular carcinoma (HCC), showing tolerability and positive clinical responses.***
- ***Clinical data from Phase 2a trial, presented at the American Society of Clinical Oncology 2020, indicated that orally administered Milciclib in Sorafenib-resistant patients was well-tolerated, and it produced positive clinical responses.***
- ***Tiziana was recently awarded a patent to use Milciclib in combination with a TKI or other drugs for treatment of HCC and other cancers.***

New York/London, 5 May 2021 - Tiziana Life Sciences plc (Nasdaq: TLSA / LSE: TILS) (“Tiziana” or the “Company”), a biotechnology company focused on innovative therapeutics for oncology, inflammation, and infectious diseases, announces that it has 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.

Previously, Tiziana successfully completed a Phase 2 clinical trial with orally administered Milciclib in sorafenib-resistant or intolerant HCC patients. The clinical data, presented at the American Society of Clinical Oncology (ASCO)[1], demonstrated that the treatment was well-tolerated and produced clinical activity. Recently, a patent covering the use of Milciclib in combination with a tyrosine kinase inhibitor (TKI) or other drugs was granted[2]. The granted claims provide complete freedom to further develop a combination of Milciclib with an approved TKI for treatment of patients with advanced HCC or other cancers. Because the prevalence of HCC in Asian countries is large and there are no satisfactory therapeutic options for treatment of advanced HCC in Asian countries, the strategic initiative with Takanawa is particularly important to further develop Milciclib for the treatment of advanced HCC patients.

“We are pleased and excited to work with Takanawa, a firm with a distinguished history of business development activities in the Japanese pharmaceutical industry, to identify an appropriate partner in Japan for further clinical development of Milciclib. We believe the positive clinical activity in advanced HCC and other cancers warrant immediate further development in Japan and other Asian countries where the prevalence of this cancer is relatively high, and the current available therapies are not entirely satisfactory” said Dr. Kunwar Shailubhai, CEO and CSO of Tiziana Life Sciences.

“We are honored to get the opportunity to identify a strategic partner for Milciclib for the treatment of advanced hepatocellular carcinoma (HCC) patients. Tiziana has managed to develop a product that will really have an impact and save lives since HCC affects about 200,000 people in the world and 40,000 people in Japan every year. Therefore, we hope to receive a lot of interest from leading pharmaceutical companies ” said Dr. Kaoru Nozu, Executive Representative of the Takanawa Pharma Team.

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.

Cited References:

1. ***Abstract #298561:*** *Phase 2a Safety and Efficacy of Milciclib, a Pan-Cyclin Dependent Kinase Inhibitor, in Unresectable, Sorafenib-Refractory or -Intolerant Hepatocellular Carcinoma Patients.*
   First Author: Erica Villa, MD., et al.
2. **US Patent** (10,758,541 B2 (Inventor: Shailubhai) Issue Date: September 1, 2020

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION FOR THE PURPOSES OF ARTICLE 7 OF REGULATION 2014/596/EU (WHICH FORMS PART OF DOMESTIC UK LAW PURSUANT TO THE EUROPEAN UNION (WITHDRAWAL) ACT 2018 (THE "EUWA")) ("UK MAR"). UPON THE PUBLICATION OF THIS ANNOUNCEMENT, THIS INSIDE INFORMATION (AS DEFINED IN UK MAR) IS NOW CONSIDERED TO BE IN THE PUBLIC DOMAIN.

About Milciclib

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 signalling 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 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.

About Takanawa

Takanawa is a global consulting, development and trading company, with a very strong Pharma Team. In that area Takanawa develops its own pharma projects, advises cross border pharma transactions, licensing, and alliances. Takanawa also supports companies entering the Japanese and Asian market as well as Japanese companies to enter overseas markets. Takanawa's seasoned pharma specialists are both high level scientists with research background from USA (Bethesda), NCI and NIH, and from Japan, the Japanese Foundation for Cancer Research, Japan National Institute of Radiological Medicines, Tokyo University and Kyoto University, as well as experienced business people from leading pharma companies like Sanofi, Kyowa Kirin, Yakult and Actavis, with an extensive track record and network. Examples of known oncology products Takanawa specialists have been involved with in their previous positions are oxaliplatin, camptothecin (irinotecan), G-CSF, docetaxel, epirubicin, gemcitabine, vinorelbine and 5-FU. For further information please see www.takanawa.is/pharmaceuticals.

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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