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 2019

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 4, 2019, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom Reporting Positive Phase 2a Clinical Data Exhibiting Positive Clinical Activity with Milciclib Monotherapy in Advanced Sorafenib-refractory or -intolerant Patients with Unresectable or Metastatic Hepatocellular Carcinoma (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 4, 2019

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated September 4, 2019

Exhibit 99.1

Tiziana Life Sciences plc

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

Tiziana Life Sciences Reports Positive Phase 2a Clinical Data Exhibiting Positive Clinical Activity with Milciclib Monotherapy in Advanced Sorafenib-refractory or -intolerant Patients with Unresectable or Metastatic Hepatocellular Carcinoma

New York, 4 September 2019 – Tiziana Life Sciences plc (NASDAQ: TLSA), a biotechnology company focusing on the discovery and development of innovative therapeutics for inflammation and oncology indications, today announced additional positive Phase 2a clinical data exhibiting impressive clinical activity of Milciclib monotherapy in patients with advanced Sorafenib-resistant or -intolerant patients with unresectable or metastatic hepatocellular carcinoma (HCC).

This Phase 2a multi-center, single-arm, repeated-dose (100 mg once daily; 4 days on/3 days off for 4 weeks; defining each cycle) and 6-month duration study was conducted to evaluate the safety, tolerability and anti-tumor activity of Milciclib in Sorafenib-resistant patients with unresectable or metastatic advanced HCC. The trial enrolled 31 patients in Italy, Greece and Israel, of which 28 patients were evaluable. While the primary endpoint of this study was overall safety, secondary endpoints were also evaluated.

As previously announced on 22 July 2019, the clinical data from the Phase 2a trial indicated that Milciclib was well tolerated with manageable toxicities and no recorded drug related deaths, thereby meeting the trial's primary endpoint. The Company now announces all the major highlights of the clinical data from the trial, which also indicate positive clinical activity relating to the secondary endpoints including progression-free survival ("PFS") and time to progression ("TTP").

MAJOR HIGHLIGHTS OF THE CLINICAL DATA

As per the study protocol, data collection was limited to 6-months. Thus, clinical data were not collected from patients under compassionate use treatment. The clinical activity assessment in evaluable patients was based on the investigators' review using the modified Response Evaluation Criteria in Solid Tumors (mRECIST).

- 14 out of 28 (50%) evaluable patients completed 6-month duration of the trial.
- 9 out of 14 patients (64.2%) were approved by their respective ethical committees to continue the treatment.
- 5 of the 9 patients on compassionate use had received Milciclib for a total of 9, 9, 11, 13 and 16 months.
- As of 1 September 2019, the remaining 4 patients continuing the treatment are in their 10^{th}, 11^{th}, 11^{th} and 12^{th} months.
- Both median TTP and PFS were 5.9 months (95% Confidence Interval ("CI") 1.5-6.7 months) out of the 6-months duration of the trial.
- 17 of 28 (60.7%) evaluable patients showed 'Stable Disease' (SD; met at least once in an 8-week interval).
- One patient (3.6%) showed 'Partial Response' (PR).
- 18 of 28 (64.3%) evaluable patients showed 'Clinical Benefit Rate' defined as CBR=CR+PR+SD (with CR representing Complete Remission).

Sorafenib® (Bayer) was approved, based on the clinical data from the pivotal Phase 3 (SHARP) clinical trial[1], as the first line therapy for naive HCC patients. The clinical data from that study showed median TTP of 5.5 months (95% CI 4.1-6.9 months), CBR of 43% and 71% SD by RECIST criteria[1]. Conversely, the clinical data from a phase 2 trial with Sorafenib in patients with advanced HCC, showed SD (33.6%), TTP of 4.2 months and median OS of 9.2 months[2].

Regorafenib was approved, based on the clinical data from the pivotal Phase 3 (RESORCE) clinical trial[3], as the second line therapy for sorafenib-resistant HCC patients. In this study, Regorafenib showed median PFS of 3.1 months (95% CI 2.8-4.2 months), median TTP of 3.2 months (95% CI 2.9-4.2 months) and disease control rate (DCR, similar to CBR) of 65% by mRECIST. On the other hand, the clinical data from a Phase 2 study in patients with intermediate and advanced HCC, Regorafenib showed median TTP of 4.3 months (95% CI 2.9-13.1 months), SD (69%) and PR was 3%[4].

“The current therapies for HCC are often associated with severe toxicities, resulting in poor patient compliance. Hence, there is an immediate need for efficacious therapies that will not compromise patients’ quality of life. We believe that the overall safety profile of Milciclib is an important competitive advantage over existing therapies currently used for treating HCC” said Gabriele Cerrone, Chairman and founder of Tiziana Life Sciences.

“The positive clinical activity and tolerability data of Milciclib in Sorafenib-resistant and advanced HCC patients are very encouraging and provides affirmation for continued development of Milciclib, either as monotherapy or combination therapy” said Dr. Kunwar Shailubhai, CEO & CSO of Tiziana. “We reported last year at AASLD that Milciclib produced pronounced synergistic anti-HCC activity in combination with any one of the FDA approved tyrosine kinase inhibitor (TKI) class of drugs, including Sorafenib (Nexavar®), Regorafenib (Stivarga®), and Lenvatinib (Lenvima®)[5]. Thus, we believe that Milciclib in combination with any one of the TKI drugs has good potential to expand the Clinical Benefit Rate in HCC patients.”

Cited References

1. Llovet, J., Ricci, S., Mazzaferro, V., Hilgard, P., Gane, E., Blanc, J-F., de Oliveira, A., Santoro, A., Raoul, J-L, Forner, A., Schwartz, M., Porta, C., Zeuzem, S., Bolondi, L., Greten, T., Galle, P., Seitz, J-F., Borbatch, I., Haussinger, D., Giannaris, T., Shan, M., Moscovici, M., Voliotiz, D., and J. Bruix. (2008) *Sorafenib in Advance Hepatocellular Carcinoma*. N Engl. J Med. 359:378.

2. Abou-Alfa, G., Schwartz, L., Ricci., S., Amadori, D., Santoro, A., Figer, A. De Greve, J., Douillard, J-Y., Lathia, C., Schwartz, B., Taylor, I., Moscovici, M. and L. Saltz. (2006). *Phase II Study of Sorafenib in Patients with Advanced Hepatocellular Carcinoma.* J. Clin. Oncol. 24:4293.

3. Bruix, J, Qin, S., Merle, P., Granito, A., Huang, Y-H, Bodoky, G., Pracht, M., Yokosuka, O., Rosmorduc, O., Breder, V., Gerolami, R., Masi, G., Ross, P., Song, T., Bronowicki, J-P., Ollivier-Hourmand, I., Kudo, M., Cheng, A-L., Llovet, J.M., Finn, R., LeBerre, M-A., Baumhauer, A., Meinhardt, G. and Han, G. (2017) *Regorafenib for patients with hepatocellular carcinoma who progressed on sorafenib treatment (RESORCE): a randomized, double-blind, placebo-controlled, phase 3 trial*. Lancet 389: 56.

4. Bruix, J., Tak, W-Y., Gasbarrini, A., Santoro, A., Colombo, M., Lim, H-Y., Mazzaferro, V., Wiest, R., Reig, M., Wagner, A., and Bolondi, L.(2013) *Regorafenib as Second-Line Therapy for Intermediate or Advanced Hepatocellular Carcinoma: Multicentre, Open-Label Phase II Safety Study*. Eur.J. Cancer 49:3412.

5. Jindal, A., Palejwala, V. 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 Number 1 (Suppl): 879A (Abstract 1543)

The person who arranged for the release of this announcement on behalf of the Company was Dr Kunwar Shailubhai, CEO & CSO of Tiziana.

Contacts:

Tiziana Life Sciences plc	
Gabriele Cerrone, Chairman and founder	+44 (0)20 7495 2379
Cairn Financial Advisers LLP (Nominated adviser)	
Liam Murray / Jo Turner	+44 (0)20 7213 0883
Shore Capital (Broker)	
Andy Crossley / Antonio Bossi	+44 (0)20 7601 6125

Receive news and updates from Tiziana Life Sciences plc by signing up to get email alerts straight to you on https://ir.tizianalifesciences.com

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.

About HCC

HCC is the fifth most common cancer and the third highest cause of cancer mortality worldwide. The primary risk factor for HCC is hepatic cirrhosis. Between 2003 to 2012, rates of new liver cancer cases went up 38% according to the Centers for Disease Control and Prevention. Most HCC patients present with advanced disease and do not benefit from transplantation, surgical resection, or locoregional therapies. Sorafenib (standard of care) and Lenvatinib are approved in the United States and EU as first line-treatment for advanced HCC patients.

Regorafenib (Stivarga®) and Nivolumab (Opdivo®) are both approved by the FDA for second line treatment of advanced HCC. 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, CDK2, 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 Tiziana Life Sciences

Tiziana Life Sciences plc is a 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.