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 16, 2019, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom Reporting FDA Approval to Initiate Phase I Clinical Trial with Orally Administered Foralumab in Healthy Volunteers (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 16, 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 16, 2019

Exhibit 99.1

THE INFORMATION CONTAINED IN THIS ANNOUNCEMENT IS DEEMED BY THE COMPANY TO CONSTITUTE INSIDE INFORMATION AS STIPULATED UNDER THE EU MARKET ABUSE REGULATION (596/2014). UPON PUBLICATION OF THE ANNOUNCEMENT VIA A REGULATORY INFORMATION SERVICE, THIS INFORMATION IS CONSIDERED TO BE IN THE PUBLIC DOMAIN.

Tiziana Life Sciences Announces FDA Approval to Initiate Phase I Clinical Trial with Orally Administered Foralumab in Healthy Volunteers.

A breakthrough approach for treatment of autoimmune and inflammatory diseases

London, 16 September, 2019 - Tiziana Life Sciences plc (NASDAQ:TLSA and AIM: TILS), a clinical stage biotechnology company focused on developing targeted drugs for cancer and inflammatory diseases, is pleased to announce (further to the announcement made on 1 May 2019) that the U.S. Food and Drug Administration (FDA) has allowed the initiation of a Phase I clinical trial in healthy volunteers using a novel oral enteric-coated capsule formulation of Foralumab, a fully human monoclonal antibody (mAb), in collaboration with the Brigham and Women's Hospital (BWH), Harvard Medical School, Boston, MA. This is the first clinical trial in which Foralumab will be administered orally to healthy subjects. Our objective is to develop orally administered Foralumab for treatment of autoimmune and inflammatory diseases.

The scientific rationale for this approach was originally discovered by Dr. Howard Weiner, professor at the Brigham and Women's Hospital, Harvard Medical School. Dr. Weiner discovered that oral or nasal administration of anti-CD3 mAb induces mucosal tolerance to upregulate T regulatory cells (Tregs) capable of providing site-targeted immunomodulation to suppress inflammation. Therefore, this scientific concept could be effective for the treatment of a variety of autoimmune and inflammatory diseases[1-5].

"The therapeutic approach of oral administration with Foralumab should greatly enhance our ability to treat neurodegenerative and inflammatory diseases. We have also explored the nasal administration of Foralumab for the treatment of progressive MS. We believe nasal and oral administration with Foralumab opens innovative avenues to treat inflammatory and autoimmune diseases by inducing different classes of Tregs. Thus, mucosal activation stimulating Tregs is a physiological mechanism which we think might be safer than other treatment approaches," commented Dr. Weiner.

Cited References

1. Wu HY, Maron R, Tukpah AM, Weiner HL. Mucosal anti-CD3 monoclonal antibody attenuates collagen-induced arthritis that is associated with induction of LAP+ regulatory T cells and is enhanced by administration of an emulsome-based Th2-skewing adjuvant. *J Immunol.* 2010; 185(6):3401-3407.
2. Ochi, H.,et al., Oral CD3-specific antibody suppresses autoimmune encephalomyelitis by inducing CD4+CD25-LAP+ T cells. Nature Medicine 2006: 12: (6); 627-635
3. Lior Mayo, Andre Pires Da Cunha, Asaf Madi, Vanessa Beynon, Zhiping Yang,Jorge I. Alvarez, Alexandre Prat, Raymond A. Sobel, Lester Kobzik, Hans Lassmann, Francisco J. Quintana and Howard L. Weiner. IL-10-dependent Tr1 cells attenuate astrocyte activation and ameliorate chronic central nervous system inflammation. Brain 2016: 139; 1939–1957
4. Chantal Kuhn, Rafael M. Rezende, Andre Pires da Cunha, Fabrice Valette, Francisco J. Quintana, Lucienne Chatenoud, Howard L. Weiner. Mucosal administration of CD3-specific monoclonal antibody inhibits diabetes in NOD mice and in a preclinical mouse transgenic for the CD3 epsilon chain. Journal of Autoimmunity (2016) 76: 1-8
5. Ogura M, et al., Prevention of human xenograft rejection with oral anti-CD3 mAb. Clinical Immunology 183: 2017; 240-246

About Howard Weiner

Howard L. Weiner is the Robert L. Kroc Professor of Neurology at the Harvard Medical School, Director and Founder of the Partners Multiple Sclerosis (MS) Center and Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham & Women's Hospital in Boston. He has pioneered immunotherapy in MS and has investigated immune mechanisms in nervous system diseases including MS, Alzheimer's disease, amyotrophic lateral sclerosis, stroke and brain tumours. He has also pioneered the investigation of the mucosal immune system for the treatment of autoimmune and other diseases and the use of anti-CD3 to induce regulatory T cells for the treatment of these diseases.

About Harvard Medical Centre

Brigham and Women's Hospital (BWH, "The Brigham") is located adjacent to Harvard Medical School, of which it is the second largest teaching affiliate. It is the largest hospital of the Longwood Medical and Academic Area in Boston, Massachusetts, USA. With Massachusetts General Hospital, it is one of the two founding members of Partners HealthCare, the largest healthcare provider in Massachusetts. Brigham and Women's Hospital conducts the second largest hospital-based research program in the world, with an annual research budget of more than $630 million. Pioneering milestones include the world's first successful heart valve operation and the world's first solid organ transplant.

About Autoimmune Diseases and Foralumab

Autoimmune diseases constitute a major medical problem and include diseases such as multiple sclerosis, type 1 diabetes, rheumatoid arthritis and inflammatory bowel disease. Other diseases, that have inflammatory components include diseases such as NASH, atherosclerosis and stroke. The induction of regulatory cells at mucosal surfaces by the oral or nasal administration of antigens has been shown to treat a large variety of autoimmune and inflammatory diseases in animal models with minimal toxicity. Foralumab was developed by Novimmune and has been acquired by Tiziana Life Sciences PLC. Foralumab (formerly NI-0401) is thus far the only entirely human anti-CD3 mAb, shows reduced release of cytokines after IV administration in patients with Crohn's disease with decreases in the classic side effects of cytokine release syndrome (CRS) and improves the overall safety profile of foralumab.

In a humanized mouse model (NOD/SCID IL2γc-/-) developed in Dr Kevan Herold's laboratory, it was show that while targeting the T cell receptor, orally administered foralumab modulates immune responses of the T cells, enhances regulatory T cells and thus provides therapeutic benefit in treating inflammatory and autoimmune diseases without the occurrence of potential adverse events usually associated with parenteral mAb therapy (Ogura M. et al., 2017). Based on animal studies, the nasal and oral administration of foralumab offers the potential for the immunotherapy of autoimmune and inflammatory diseases in a safe manner by the induction of regulatory T cells.

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 known to the company in clinical development in the world. This compound has potential application in a wide range of autoimmune and inflammatory diseases, such as non-alcoholic 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.

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

For more information go to http://www.tizianalifesciences.com

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

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