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

November 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 November 28, 2018, Tiziana Life Sciences plc (the "Company") issued a regulatory news service ("RNS") announcement in the United Kingdom announcing the initiation of a Phase 1 clinical trial with nasal administration of Foralumab, a fully human anti-cluster definition 3 monoclonal antibody, in healthy volunteers (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: November 28, 2018

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

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated November 28, 2018

Exhibit 99.1

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

Tiziana Announces Initiation of Phase 1 Clinical Trial with Nasal Administration of Foralumab, a Fully Human Anti-Cluster Definition 3 Monoclonal Antibody (anti-CD3 mAb), in Healthy Volunteers

A breakthrough approach for treatment of neurodegenerative diseases such as progressive multiple sclerosis

London, 28 November 2018 – Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS), a UK biotechnology company that focuses on the discovery and development of novel molecules to treat human disease in oncology and immunology, previously announced that it had submitted an Investigational New Drug (IND) application on 1 June 2018 to the U.S. Food and Drug Administration (FDA). Following approval of the IND application by the FDA, the Company announces that a first-in-human Phase 1 clinical trial in healthy volunteers has been initiated at the Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, USA.

"*Foralumab in a stable formulation will be nasally administered by a dose-escalating regimen starting at 10, 50 and 250 µg/day, using a nasal spray device. This Phase 1 clinical trial in healthy volunteers will evaluate safety and tolerability of Foralumab. The clinical protocol also includes evaluation of unique biomarkers of immunomodulation, induction of T regulatory cells (Tregs) and anti-inflammation to assess therapeutic potential of the treatment.*

Nasal administration with anti-CD3 mAbs induces Tregs in the cervical lymph node that then cross the blood brain barrier and provide an interleukin-10 dependent anti-inflammatory signal to downregulate the activated glial cells in brain and return them to their normal homeostatic state. Thus, this is an exciting, innovative and physiological approach to stimulate the mucosal immune system to induce disease modifying Tregs", commented Dr. Howard Weiner, a member of scientific advisory board of Tiziana.

Intranasal delivery of therapeutic anti-CD3 mAb is a game changer that employs immune mechanisms overcoming the obstacle of the blood brain barrier and it has the potential as entirely new class of therapies for treatment of a wide range of human diseases", said Gabriele Cerrone, Chairman and founder of Tiziana.

"*Filing this IND for nasal administration of Foralumab is a first and major milestone towards the Company's objective to develop innovative therapies with alternative routes of administration whilst maximizing efficacy.*

We also plan to submit a similar IND for a Phase 1b clinical trial with encapsulated and enteric-coated formulation of Foralumab in healthy volunteers to evaluate safety and tolerability in the first quarter of 2019. A well-established panel of blood biomarkers will be examined to assess potential of orally administered Foralumab for treatment of autoimmune and inflammatory diseases such as non-alcoholic fatty liver disease (NASH) and Crohn's disease", commented Kunwar Shailubhai, CEO and CSO of Tiziana.

About Dr. Howard Weiner
Dr. 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 tumors. 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 Tregs for the treatment of these diseases.

About Harvard Medical Centre
Brigham and Women's Hospital (BWH) 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. BWH 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 was acquired by Tiziana. Foralumab (formerly NI-0401), 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 shown that while targeting the T cell receptor, orally administered Foralumab modulates immune responses of the T cells, enhances Tregs 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 Tregs.

About Tiziana Life Sciences
Tiziana 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 mAbs in clinical development in the world. This 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 more information go to http://www.tizianalifesciences.com

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