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 10, 2019, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom Reporting Phase 1 Clinical Data Demonstrating Nasal Treatment with Foralumab was Well-tolerated and Produced Positive Trend in Biomarkers of Immunomodulation and Anti-inflammation 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 10, 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 10, 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 plc

Tiziana Reports Phase 1 Clinical Data Demonstrating Nasal Treatment with Foralumab was Well-tolerated and Produced Positive Trend in Biomarkers of Immunomodulation and Anti-inflammation in Healthy Volunteers

New York, 10 September 2019 – Tiziana Life Sciences plc (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for inflammatory diseases and cancers, is pleased to report Phase 1 clinical data demonstrating that nasally administered Foralumab, a fully human anti-CD3 monoclonal antibody (mAb), was well-tolerated at all doses. Importantly, the treatment showed significant positive effects on the biomarkers for activation of mucosal immunity, which is capable of inducing site-targeted immunomodulation to elicit anti-inflammatory effects. These clinical data are consistent with the findings from numerous pre-clinical studies.[1-3]

This Phase 1 trial, conducted at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, was a single-site, double-blind, placebo-controlled, dose-ranging study with nasally administered Foralumab at 10, 50 and 250 µg per day, consecutively for 5 days in healthy volunteers for the treatment of progressive multiple sclerosis (pMS). 18 subjects received Foralumab treatment and 9 patient received placebo. All nasal doses were well tolerated. Biomarker analysis showed significant positive immune effects, that were most prominent in the 50 mg cohort with minimal immunomodulatory effects at the 10 µg and 250 µg doses.

Major Highlights

- Treatment was well-tolerated and no drug-related safety issues were reported at any of the doses.
- No drug-related changes were observed in vital signs among subjects at predose, during treatment and at discharge. The mean blood pressure (BP) during the 5 days of treatment were; Cohort A (10 µg/d):124/73, Cohort B (50 µg/d): 119/67 and Cohort C (250 µg/d):113/65 compared to placebo:118/67). Heart rates, respiratory rates and oral temperatures were unchanged among the 3 cohorts compared to the placebo.
- Nasally administered Foralumab at the 50 µg dose suppressed cytotoxic CD8+ as well as perforin secreting CD8+ cells, which have been implicated in neurodegeneration in multiple sclerosis (MS).
- Treatment at 50 mg stimulated production of anti-inflammatory cytokine IL-10 and suppressed production of pro-inflammatory cytokine IFN-γ.
- Taken together, these results suggest stimulation of Tregs that are needed to provide clinical benefits

“Nasal administration of Foralumab is a revolutionary approach to treat patients with neurodegenerative diseases such as progressive MS (pro-MS) and amyotrophic lateral sclerosis (ALS). Extensive data from animal studies with intranasal delivery of anti-CD3 demonstrate that this route of administration induces anti-inflammatory and immunomodulatory effects. This study demonstrates for the ***first-time*** that nasally administered Foralumab, at the identified optimal dose of 50 mg, induces immunomodulatory effects capable of providing clinical benefit to treated subjects. This is a major accomplishment providing the scientific rationale to move forward with further clinical development of nasally administered Foralumab in patients with neurodegenerative diseases,” commented Dr. Howard L. Weiner, a member of scientific advisory board of Tiziana Life Sciences. He added that “both oral and nasal administration routes are physiologic approaches to stimulate the mucosal immune system to induce disease modifying immunomodulation. Our immediate focus is on developing Foralumab for treatment of pro-MS.”

“The demonstration of the positive immunomodulatory effects provides the scientific rationale to move forward with further studies in the pro-MS population, stated Dr. Tanuja Chitnis, the study PI at the Brigham and Women’s Hospital.

“We are very pleased with what we believe is the first-ever demonstration that nasally administered Foralumab is not only well-tolerated, but it also exhibited significantly positive immunomodulatory effects that are indicative of stimulation of Tregs. We are excited as these results provide the scientific rationale for the nasal and oral treatment with Foralumab, our core proprietary platform technologies which could potentially revolutionize treatment with antibodies” stated Kunwar Shailubhai, CEO & CSO of Tiziana.

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

About Foralumab

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-/-), 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.

Preclinical studies on nasal and oral administration with Anti-CD3 mAbs

Preclinical and clinical studies have shown that mucosal induction of Tregs by oral or nasal administration of anti-CD3 mAbs is an innovative approach to treat autoimmune and anti-inflammatory diseases (Kuhn and Weiner 2016)[4]. Nasally administered anti-CD3 mAbs were shown to ameliorate disease in an animal model of multiple sclerosis by inducing IL-$10^{+}$$LAP^{+}$ (latency-associated peptide) T cells[3], demonstrating nasal anti-CD3 mAbs as a new approach to treat progressive forms of multiple sclerosis and other types of chronic CNS inflammation. Additionally, nasally administered anti-CD3 mAbs suppressed lupus in lupus-prone mice (BWF1) by inducing IL-10 and TGF-β dependent mechanisms associated with a suppression of IL-17 and IL-21 pro-inflammatory cytokines[5].

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), ulcerative colitis, multiple sclerosis, type-1 diabetes (T1D), crohn's disease, 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.

Cited References

1. Weiner HL et al. Oral tolerance. Immunol Rev. 2011; 241(1):241-259

2. Ochi H, Abraham M, Ishikawa H et al. New immunosuppressive approaches: Oral administration of CD3-specific antibody to treat autoimmunity. J Neurol Sci 2008; 274(1- 2):9-12

3. Mayo, L et al. IL-10-dependent TrI cells attenuate astrocyte activation and ameliorate chronic central nervous system inflammation. Brain. 2016: 139; 1939-1957

4. Kuhn C. and Weiner HL. Therapeutic anti-DC3 monoclonal antibodies: from bench to bedside. Immunotherapy 2016; 8(8):889-906

5. Wu, H.Y, Quintana, F.J and Weiner, H.L. Nasal Anti-CD3 Antibody Ameleorates Lupus by Inducing an IL-10-Secreting CD4+CD25-LAP+ Regulatory T cell and Is Associated with Down-Regulation of IL-17+CD4+ICOS+CXCR5+ Follicular Helper T Cells. J Immunol 2008; 181:6038-6050

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