# 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 2019**

**Commission File Number:** 0001-38723

# 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 1, 2019, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement, announcing an update on IND application for oral formulation of foralumab for treatment of NASH (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 1, 2019

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

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Regulatory News Service Announcement, dated May 1, 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**

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

**Update on IND Application for Oral Formulation of Foralumab for Treatment of NASH**

Tiziana Life Sciences plc (NASDAQ: TLSA; AIM: TILS), a US and UK biotechnology company that focuses on the discovery and development of novel molecules to treat human diseases in oncology and immunology, announces an update regarding its Investigational New Drug application ("IND") to the U.S. Food and Drug Administration (FDA) to initiate a Phase 1 clinical trial of enteric-coated capsules of Foralumab in healthy volunteers.

Following completion of the 30 calender day review, FDA has requested more information and safety data from the ongoing phase 1 trial with nasal administration of foralumab to justify the proposed dose-range for the phase 1 trial with oral administration of enteric-coated capsules of foralumab in healthy volunteers. The stability data on the dose-range of 10-250 mg of foralumab was included in the submitted IND for the ongoing phase 1 trial with nasal administration. FDA also advised us to adequately cross-reference the submitted IND with nasal administration. Accordingly, we have withdrawn the current IND to include safety data from the ongoing trial with nasal administration and adequately cross-reference the IND for nasal administration with solution of foralumab.

The ongoing phase 1 trial with nasal administration of foralumab has completed the first two doses (10 and 50 mg) and the highest dose 250 mg is currently ongoing, and is expected to be completed by May 15, 2019. Upon completion, the safety data from this ongoing phase 1 trial with nasal administration will be provided to FDA as part of the revised IND for oral administration of enteric-coated capsules of foralumab in healthy volunteers. A further announcement will be made in due course following receipt of a response from FDA.

Dr Kunwar Shailubhai, Chief Executive Officer and Chief Scientific Officer of the Company stated "We are in agreement and believe that FDA recommendations will further strenghthen our IND for evaluation of oral enteric-coated capsules of foralumab in healthy volunteers."

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

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