# 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 2020

Commission File Number: 0001723069

# Tiziana Life Sciences plc

(Exact Name of Registrant as Specified in Its Charter)

3<sup>rd</sup> 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 o

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): o

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): o

#### INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On May 14, 2020, Tiziana Life Sciences plc (the "<u>Company</u>") issued a regulatory news service announcement in the United Kingdom announcing that Tiziana Life Sciences has data demonstrating StemPrintER's superiority compared to OncotypeDX in providing prognostic information to conventional clinical parameters in breast cancer patients in poster discussion session at ASCO (the "<u>RNS Announcement</u>").

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

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai Title: Chief Executive Officer

Date: May 14, 2020

## EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated May 14, 2020
	3

#### Tiziana Life Sciences plc

("Tiziana" or the "Company")

Tiziana Life Sciences Announces Data Demonstrating StemPrintER's Superiority Compared to OncotypeDX in Providing Prognostic Information to Conventional Clinical Parameters in Breast Cancer Patients in Poster Discussion Session at the American Society of Clinical Oncology (ASCO)

Virtual Conference

Additional data to be presented validating the SPARE Model for Distant Metastasis Prediction utilizing the Company's StemPrintER Platform

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

New York/London – May 14, 2020 – Tiziana Life Sciences plc (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for oncology, inflammation and infectious diseases, announces today that a new study will be presented by scientists from the European Institute of Oncology in Milan in collaboration with the Royal Marsden Hospital and Queen Mary University in London on the Company's stem cell biology-based genomic tool, StemPrintER, for the prediction of disease recurrence in breast cancer patients during a poster discussion session at the American Society of Clinical Oncology (ASCO) Virtual Conference. The study demonstrates greater refinement and superiority of StemPrintER over current market leader Oncotype DX in delivering prognostic information as part of the therapeutic decision-making process in ER+/HER2- breast cancer patients. An additional abstract from the scientists at the European Institute of Oncology will be presented in a separate poster session, which details a further refined risk model, the SPARE model, based on the combination of StemPrintER with clinical parameters for distant metastasis prediction. Both abstracts, became available May 13, 2020, while the posters and discussion session will be held during The American Society of Clinical Oncology (ASCO) Virtual Conference May 29-31, 2020.

Each of these studies independently provides significant additional information on the value of StemPrintER -- and its derivative SPARE (detailed below) - as clinical tools to aid personalized therapeutic decision-making in women with ER+/HER2- breast cancer. Of particular note is the comparative precision of StemPrintER over Oncotype DX in predicting the potential recurrence of certain types of breast cancer following treatment. The two studies highlight the importance of the stem cell approach to develop a potentially powerful prognostic tool to predict breast cancer prognosis.

Abstract #1020, "Comparison of StemPrintER, a novel biology-based genomic predictor of distant recurrence in breast cancer, with Oncotype DX in the TransATAC cohort," is an independent validation of the prognostic value of StemPrintER in a cohort of more than 800 luminal ER+/HER2-postmenopausal breast cancer patients from the international TransATAC study and a head-to-head comparison of the prognostic power of StemPrintER with OncotypeDx. Results provide independent validation of StemPrintER as a potentially powerful prognostic tool to stratify patients for the risk of early or late recurrence independently of other clinicopathological parameters. Importantly, the study also shows that StemPrintER is superior to OncotypeDX in the prediction of 10-year recurrence risk in all patients, as well as in N0 and N1-3 patients. The study further demonstrates that StemPrintER is capable of outperforming OncotypeDX in providing additional prognostic information to the standard clinicopathological parameters.

Abstract #1057, "Integration of the stem cell biology-based genomic tool, StemPrintER, with clinicopathological parameters for the prediction of distant recurrence in ER+/HER2- breast cancer (BC) patients," develops a more refined risk model for distant metastasis prediction, which combines StemPrintER with tumor size (pT) and nodal status (pN). The new model is termed SPARE (StemPrintER for Personalized Adjuvant Therapy in Endocrine Receptor-Expressing Patients) and, in the analysis of a consecutive-retrospective cohort of more that 1,800 ER+/HER2- breast cancer patients with 15-year complete follow-up from the European Institute of Oncology (IEO) in Milan, revealed to be an even more powerful tool, compared to the original StemPrintER for predicting early and late distant metastasis risk independently of standard clinical parameters.

"These data sets demonstrate that StemPrintER has the potential to become an essential prognostic tool that will help clinicians to tailor more or less aggressive therapy based on a more accurate risk assessment of disease recurrence compared to what we have seen to date," added Dr. Kunwar Shailubhai, CEO & CSO of Tiziana Life Sciences. "This product also represents an important addition to our existing therapeutic pipeline as it opens Tiziana into the area of precision medicine, creating an entirely new business line beyond our current patented technology in offering new delivery mechanisms for monoclonal antibodies."

#### About StemPrintER

StemPrintER is a multi-gene prognostic assay intended for the prediction of the risk of recurrence in luminal, estrogen receptor-positive HER2-negative breast cancer patients, based on the detection of 20 cancer stem cell markers. The assay has been evaluated in an initial retrospective validation study using a consecutive cohort of approximately 2,400 patients with breast cancer.

The person who arranged for the release of this information is Dr Kunwar Shailubhai, the Company's Chief Executive Officer and Chief Scientific Officer.

#### **About Tiziana Life Sciences**

Tiziana Life Sciences plc is a dual listed (NASDAQ: TLSA & UK AIMS: TILS) biotechnology company that focuses on the discovery and development of novel molecules to treat human diseases in oncology, inflammation and infectious diseases. In addition to milciclib, the Company will be shortly initiating phase 2 studies with orally administered foralumab for Crohn's Disease and nasally administered foralumab for progressive multiple sclerosis. Foralumab is the only fully human anti-CD3 monoclonal antibody (mAb) in clinical development in the world. This phase II compound has potential application in a wide range of autoimmune and inflammatory diseases, such as Crohn's Disease, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable. The company is accelerating development of anti-Interleukin 6 receptor (IL6R) mAb, a fully human monoclonal antibody for treatment of IL6-induced inflammation, especially for treatment of COVID-19 patients.

Receive news and updates from Tiziana Life Sciences plc by signing up to get email alerts at 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.

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