# 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**

**April 2020**

**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 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 April 24, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the acquisition of a Nanoparticle-Based Formulation Technology for Controlled Delivery of Actinomycin D for Treatment of Myelodysplastic syndrome and Acute Myeloid Leukemia (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: April 24, 2020

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

**EXHIBIT INDEX**

| Exhibit No. | Description |
| --- | --- |
| 99.1 | Regulatory News Service Announcement, dated April 24, 2020 |

**Exhibit 99.1**

24 April 2020

**Tiziana Life Sciences plc**

**("Tiziana" or the "Company")**

Tiziana Life Sciences Acquires a Nanoparticle-Based Formulation Technology for Controlled Delivery of Actinomycin D for Treatment of Myelodysplastic syndrome and Acute Myeloid Leukemia

***Nanoparticle Actinomycin formulation minimizes toxicity and enhances tolerability by slow release of drug to control Cmax in blood***

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

New York/London - April 24, 2020 – Tiziana Life Sciences plc (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company focused on innovative therapeutics for inflammatory, autoimmune and infectious diseases, announced today that it pursuant to an asset purchase agreement it has acquired all of the intellectual property relating to a nanoparticle-based formulation of Actinomycin D (Act D; a.k.a. Dactinomycin), from Rasna Therapeutics, Inc. ("Rasna") to expand its pipeline for a consideration of an initial $120,000 upfront payment and milestone payments of up to an additional aggregate $630,000.

This formulation technology was invented by Dr. Kunwar Shailubhai when he was previously an executive officer at Rasna, which he remains a director.

Act D, an antibiotic drug, was approved initially for infectious diseases in the United States in 1964. Subsequently, this antibiotic was shown to exhibit anti-cancer activity in 1974 (1). Since then the drug has been used to treat various types of cancer, including Wilms tumor, rhabdomyosarcoma, Ewing's sarcoma, trophoblastic neoplasm, and testicular cancer. The drug is on the *World Health Organization's List of Essential Medicines* as the most effective medicines needed in a health system (2). Falini et al., reported in *New England Journal of Medicine* that intravenous administration of Act D could be used for treatment of patients with Acute Myeloid Leukemia (AML) carrying NPM1 gene mutation (3). Recent studies have also suggested that Act D, being a potent inhibitor of RNA synthesis, may have potential for treatment of COVID-19 patients (4). Currently, the drug is intravenously (IV) administered, which produces severe toxicities possibly due to excessive Cmax in blood during the first couple of hours after administration.

The nanoparticle-based Act D (NP-ACT D) is formulated such that the release of Act D is slow and Cmax in blood may be pre-adjusted to a desired level. In pharmacokinetics (PK) and safety studies in rats, free Act D or an equivalent dose of NP-Act D were intravenously administered side-by-side to compare PK, tolerability, and toxicity. Results from these animal studies indicated that the PK of NP-Act D was slow, and sustained for over 32 hours, whereas the PK in blood within an equivalent dose of free Act D activity was rapid. Importantly, another study comparing side-by-side free Act D with an equivalent dose of NP-Act D, showed 0% mortality in rats dosed with NP-Act D for up to 13 days. By contrast, mortality in rats dosed with free Act D began on 6th day, reaching >90% mortality on $13^{th}$ day of the study. These results demonstrate that PK of IV administered NP-Act D is slow and sustained for extended period and it is relatively well-tolerated with minimal toxicities. However, safety and tolerability of NP-Act D needs to be evaluated in healthy volunteers prior to clinical studies.

**It is important to note that the Company has not, at the current time, conducted any clinical or pre-clinical research into the use of NP-ACT D as a treatment for COVID-19 but is basing its assessment for potential on research involving NP-ACT D with other strains of coronavirus.**

Citations


1. *Hollstein U (1974). "Actinomycin. Chemistry and mechanism of action". Chemical Reviews.* ***74*** *(6): 625–652.*
2. World Health Organization (2019). *World Health Organization model list of essential medicines: 21st list 2019*. Geneva: World Health Organization. hdl:10665/325771. WHO/MVP/EMP/IAU/2019.06. License: CC BY-NC-SA 3.0 IGO
3. Falini B, Mecucci C, Tiacci E, et al. Cytoplasmic nucleophosmin in acute myelogenous leukemia with a normal karyotype. N Engl J Med 2005; 352:254-66.
4. Kennedy, D.A., and Johnson-Lussenburg (1978). Inhibition of Coronavirus 229E Replication by Actinomycin D JOURNAL OF VIROLOGY, Jan. 1978, p. 401-404.


**About NP-Act D**

Broad-spectrum antibiotics that have been deemed ‘safe-in-man’ through testing in early phase clinical trials have been touted as good drug repurposing candidates for treatment of emerging infectious diseases. Actinomycin D, an inhibitor of RNA-dependent RNA polymerase, is a potent antibiotic with therapeutic utilities in infectious diseases and cancer. As intravenous administration of Actinomycin D is known to produce severe toxicities, its therapeutic utility has been limited. The nanoparticle-based Actinomycin D (NP-ACT D) is formulated to control and slow release of Act D such that the Cmax in blood can be adjusted to a desired level. In animal studies, NP-Act D was found to produce minimal toxicities and it was found to safe and well-tolerated.

**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.

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

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

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