# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

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# FORM 6-K

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**REPORT OF FOREIGN PRIVATE ISSUER**
**PURSUANT TO RULE 13a-16 OR 15d-16**
**UNDER THE SECURITIES EXCHANGE ACT OF 1934**

**April 2020**

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**Commission File Number:** 0001723069

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# Tiziana Life Sciences plc

(Exact Name of Registrant as Specified in Its Charter)

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**3rd Floor,**
**11-12 St James's Square**
**London SW1Y 4LB**
**United Kingdom**
(Address of registrant's principal executive office)

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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 27, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the Filing of a Patent on Combination of Nanoparticle-Actinomycin D with Anti-Interleukin-6 Receptor Monoclonal Antibody for Treatment of Coronaviruses (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 27, 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 27, 2020 |

**Exhibit 99.1**

**Tiziana Life Sciences plc**

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

**Tiziana Life Sciences Files Patent on Combination of Nanoparticle-Actinomycin D with Anti-Interleukin-6 Receptor Monoclonal Antibody for Treatment of Coronaviruses**

***Combination of nanoparticle-Actinomycin D acting as an anti-viral treatment, with an anti-inflammatory agent may present a potential therapeutic option for COVID-19 patients.***

New York/London - April 27, 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 has filed a provisional patent application on the combination of nanoparticle-Actinomycin D (NP-ACT D) with anti-interleukin-6 receptor monoclonal antibody (anti-IL-6R) as a potential therapy for management of COVID-19 disease. The underlying invention concepts are based on the hypothesis that a combination of an antiviral drug controlling proliferation of COVID-19, with an anti-inflammatory agent (*e.g.*, anti-IL-6R) suppressing a possible 'Cytokine Storm' may provide immediate relief to severe cases of COVID-19 patients.

Actinomycin D (ACT D), an antibiotic drug approved initially for infectious diseases in the United States in 1964, is on the *World Health Organization's List of Essential Medicines* as the most effective medicine needed in a health system (1). However, severe toxicities associated with the intravenous administration of ACT D limits its widespread therapeutic utility. The NP-ACT D formulation, effectively controlling slow and sustained release, may overcome the severe toxicities of ACT D. Side-by-side animal studies have compared NP-ACT D with free ACT D and demonstrated that the intravenous treatment with NP-ACT D was well-tolerated with minimal apparent toxicities in animal models. Importantly, results from another animal study comparing free ACT D side-by-side with an equivalent dose of NP-ACT D, showed 0% mortality in rats dosed with NP-ACT D as compared to > 90% mortality with free ACT D (2). Nonetheless, safety and tolerability of NP-ACT D needs to be evaluated in healthy volunteers prior to any clinical studies.

Patients infected with COVID-19 are known to develop an uncontrolled immune response ("cytokine storm"), which results in excessive production of pro-inflammatory cytokines such as IL-6 and TNF-a both of which are regarded as key drivers of chronic inflammation and are believed to be associated with severe lung damage commonly observed in patients with COVID-19 infections and acute respiratory distress syndrome (*ARDS*). Therefore, Tiziana believes it is possible to potentially combine TZLS-501 (anti-IL6R) with NP-Act D to inhibit viral proliferation and to suppress inflammation in lungs to halt progression of COVID-19-mediated lung damage and death.

**Citations**


1. 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
2. Shailubhai, K. Dactinomycin compositions and methods for the treatment of myelodysplastic syndrome and acute myeloid leukemia. US PCT: 2018/0092857 A1


**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, either alone or in combination with anti-interleukin-6 receptor monoclonal antibody (anti-IL-6R) as a treatment for COVID-19, but is basing its assessment for the combination's potential on research and anecdotal evidence involving NP-ACT D activity on other strains of coronavirus and established theoretical principles underlying combinations of drugs.**

**About TZLS-501**
TZLS-501, a fully human mAb, was acquired from Novimmune, a Swiss biotechnology company, in 2017. The cytokine, IL-6, a major determinant in the priming of pathogenic T cells to produce an inflammatory response, binds to its receptor subunit IL-6Rα on the cell membrane. The receptor IL-6Rα can be shed as a soluble sIL6Rα, which binds to circulating IL-6 cytokine in the blood. The downstream signaling from this complex mediates pro-inflammatory effects underlying the inflammatory diseases such as rheumatoid arthritis (RA) and acute respiratory distress syndrome (ARDS). The Company believes that the novel features of TZLS-501 consisting of its dual mechanism of action to inhibit signaling by the membrane-bound and soluble IL-6 receptor and the rapid depletion of circulating IL-6 cytokines, a major cause of lung damage, suggests a potential role for this mAb in patient management and treatment of COVID-19.

**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 utility 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 a slow release of Act D such that the Cmax (maximum serum concentration) 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 be 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 IS DR KUNWAR SHAILUBHAI, THE COMPANY'S CHIEF EXECUTIVE AND CHIEF MEDICAL OFFICER.

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