**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**

**June 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 ☐

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 June 29, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing an agreement with STC Biologics (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: June 29, 2020

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

**EXHIBIT INDEX**

| Exhibit No. | Description |
|---|---|
| 99.1 | Regulatory News Service Announcement, dated June 29, 2020 |

**Exhibit 99.1**

**Tiziana Life Sciences plc**

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

**Agreement with STC Biologics**

**Tiziana Life Sciences Announces Agreement with STC Biologics for GMP Manufacturing of an anti-Interleukin-6-Receptor Monoclonal Antibody for Clinical Studies in Patients with COVID-19.**

- *This proprietary inhalation technology for direct delivery of mAbs or other small molecule drugs such as Remdesivir® (Roche) to lungs could potentially be a transformational therapy for developing a rapid treatment for COVID-19*

New York/London – 29 June 2020 – Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS) ("Tiziana" or the "Company"), a clinical stage biotechnology company developing targeted drugs for cancer, inflammatory diseases and COVID-19, today announces the execution of an agreement with STC Biologics, Inc. ("STC") for GMP manufacturing of TZLS-501, an anti-IL-6 receptor (anti-IL-6R) monoclonal antibody (mAb) acquired from Novimmune in 2017, currently in agreement with Bristol Myers Squibb (BMS).

Tiziana is simultaneously developing an inhalation technology, in collaboration with Sciarra Laboratories, for the direct delivery of TZLS-501 into the lungs using a handheld inhaler or nebulizer for treatment of patients with COVID-19. The proprietary novel technology to administer TZLS-501 directly into the nasal passages or lungs by inhaler or nebulizer has potentially significant clinical advantages for the treatment of COVID-19 patients.

The Company recently submitted a patent application for the inhalation delivery of anti-IL6R-monoclonal antibody for the treatment of COVID-19.

TZLS-501, a unique and best-in-class anti-IL-6R mAb, follows a dual mechanism by not only blocking downstream signaling pathways from membrane-bound and soluble IL-6 receptors, but it also rapidly depletes blood-stream levels of IL-6, the major culprit for cytokine release syndrome (CRS) in lungs of COVID-19 patients. In receptor binding assays, TZLS-501 is considerably more potent than the other anti-IL-6R mAb in this class, such as Actemra® (Roche)[1,2]. These biochemical features, differentiating TZLS-501 from other mAbs in this class, offer potential distinctive clinical advantages in effecting a rapid suppression of the cytokine storm at much lower doses.

The proprietary inhalation technology for direct delivery of mAbs or other small molecule drugs such as Remdesivir® (Roche) to lungs could potentially be a transformational therapy for developing a rapid treatment of COVID-19

"We are aggressively advancing GMP manufacturing of TZLS-501 concurrently with the development of inhalation technology using a hand-held nebulizer and safety toxicology studies in cynomolgus monkeys. Our objective is to submit an Investigational New Drug (*IND*) Application in the first quarter of 2021 for the treatment of COVID-19 patients," said Kunwar Shailubhai, Ph.D., CEO and CSO of Tiziana Life Sciences.

"The initiation of GMP manufacturing of TZLS-501 with STC is a timely step forward toward expediting development of a potentially innovative treatment for COVID-19 patients. We are very excited and well positioned to accelerate the development of TZLS-501 for COVID-19 patients in such extraordinary times," added Dr. Magdalena Leszczyniecka, President and CEO of STC Biologics. "Our state-of-the-art single use production facility, highly cross-trained experienced personnel, and nimble decision-making has provided unprecedented speed to clinic in prior GMP campaigns. Together with a strong track record of pharmaceutical, regulatory and process development know-how, we are uniquely positioned to advance TZLS-501 to the clinic."

Sciarra Laboratories, Inc., has been developing and manufacturing pharmaceutical aerosol products for over 25 years. Previously, Sciarra worked with Tiziana to successfully manufacture clinical supplies for the nasal administration of Foralumab, a fully human anti-CD3 mAb, for the recently completed Phase 1 trial[3], and the company is currently working with Tiziana to manufacture Foralumab for nasal administration using a medical device, which will also be used for the upcoming Phase 2 trial in progressive multiple sclerosis. This phase 2 trial will commence shortly at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA.

Cited References


1. Lacroix, M. et al., Novel Insights into Interleukin 6 (IL-6) Cis- and Trans-signaling Pathways by Differentially Manipulating the Assembly of the IL-6 Signaling Complex. J Biol Chem. 2015 Nov 6; 290(45): 26943–26953.

2. **Chaolin Huang, MD., et al.,** Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet, volume 395, pages 497-506. 2020. Published January 24, 2020.

3. **Tiziana Life Sciences Press Release:** https://www.tizianalifesciences.com/news-item?s=2019-09-10-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


**About TZLS-501 (anti-IL-6R mAb)**

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 (IL-6R alpha) can be shed as a soluble entity, sIL6Rα, which binds to circulating IL-6 cytokine in the blood. The downstream signaling from this complex mediates the 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 TZLS-501 in patient management and treatment of COVD-19. The Company licensed TZLS-501 from Novimmune, a Swiss biotechnology company, in 2017.

**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.

**About STC Biologics, Inc.**

STC Biologics, Inc. is a boutique biologics CDMO located in Newton, MA that provides full CMC services to enable its partners advance their biologic products from discovery to commercial approval. Founded in 2009, STC has established its reputation as a flexible organization that clients can turn to for accelerated low cost programs or custom development when template processes don't work. STC's new 4000 sq ft state-of-the-art, single-use manufacturing suites and a second smaller clean room suite provides flexibility and cost saving for clients with vastly different product demands. STC's team brings 100+ years of collective expertise in biologics drug development from global biopharmaceutical companies. The cross-training of its scientists in diverse fields with integration of biology and regulatory sciences into process development is what makes STC unique in its ability to efficiently develop complex biological products. STC Biologics strives to realize "Speed to Clinic" through integrated product development, technical rigor, and flexibility.

**About Sciarra Laboratories**

Sciarra Laboratories, Inc., has been a leader in the development of aerosol pharmaceutical products since 1957 and has been developing and manufacturing pharmaceutical aerosol products at its FDA-approved, cGMP manufacturing facility located in Hicksville, New York since 1991. Its product line ranges from topical foams, gels, and sprays to metered dose inhalers (MDI) and nasal sprays. Sciarra manufactures OTC, NDA and medical device products. Sciarra has developed over 50 formulations. Sciarra offers a turnkey operation from development, validation, and manufacturing services.

**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.

**For further enquiries:**

**United Kingdom:**

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|---|---|
| **Tiziana Life Sciences plc**<br>Gabriele Cerrone, Chairman and founder | +44 (0)20 7495 2379 |
| **Cairn Financial Advisers LLP (Nominated adviser)**<br>Liam Murray / Jo Turner | +44 (0)20 7213 0880 |
| **Optiva Securities Limited (Broker)**<br>Robert Emmet | + 44 (0)20 3981 4173 |

**United States:**

**Investors**

| | |
|---|---|
| Jules Abraham | Dave Gentry |
| CORE IR | RedChip Companies Inc. |
| 917- 885-7378 | 407-491-4498 |
| julesa@coreir.com | Dave@redchip.com |