

**TIZIANA LIFE SCIENCES PLC  
ANNUAL REPORT & FINANCIAL STATEMENTS  
YEAR ENDED 31 DECEMBER 2020**

**FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31ST DECEMBER 2020**

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## STATUTORY AND OTHER INFORMATION

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## STRATEGIC REPORT: EXECUTIVE CHAIRMAN'S STATEMENT

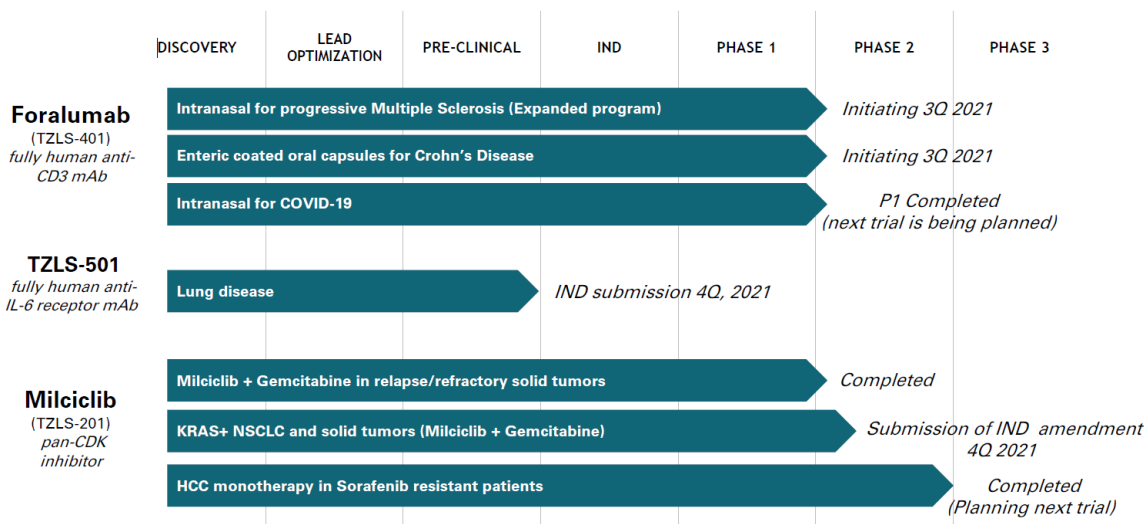
I am pleased to report on the Company (Tiziana Life Sciences PLC) and its subsidiaries, together the 'Group', results for the year ended 31 December 2020.

Tiziana Life Sciences is a dual-listed (NASDAQ: TLSA, LSE:TILS) clinical stage biotechnology company that specializes in the developing transformative therapies for autoimmune and inflammatory diseases, degenerative diseases and cancer related to the liver. Our clinical pipeline includes drug assets for Crohn's Disease, COVID-19, Secondary Progressive Multiple Sclerosis and Hepatocellular Carcinoma. Tiziana is led by a team of highly qualified executives with extensive drug development and commercialization experience.

### Background

The Group is focused on the discovery and development of novel molecules and related diagnostics to treat high unmet medical needs in oncology and immunology. Our mission is to design and deliver next generation therapeutics and diagnostics for oncology and immune diseases of high unmet medical need by combining deep understanding of disease biology with clinical development expertise. We have a drug discovery pipeline of small molecule new chemical entities, or NCEs, and biologics. We employ a lean and virtual research and development, or R&D, model using highly experienced teams of experts for each business function to maximize value accretion by focusing resources on the drug discovery and development processes.

### Development Pipeline



#### Foralumab (TZLS-401 / NI-0401)

Our lead product candidate in immunology is Foralumab (TZLS-401), which we believe is the only fully human anti-CD3 monoclonal antibody, or mAb, in clinical development. MAbs represent a single pure antibody produced by single clones and are an important class of human therapeutics for treating cancers and autoimmune diseases. We are developing Foralumab, for which we in-licensed the intellectual property from Novimmune, SA, a Swiss biotechnology company, or Novimmune, as a potential treatment for neurodegenerative diseases such as progressive Multiple Sclerosis, or MS, and Crohn's disease. As the only fully human engineered human anti-CD3 mAb in clinical development, Foralumab has significant potential advantages such as a shorter treatment duration and reduced immunogenicity. We believe that oral or intranasal administration of Foralumab has the potential to reduce inflammation while minimizing the toxicity and related side effects.

To date, Foralumab has been studied in one Phase 1 and two Phase 2a clinical trials conducted by Novimmune in 68 patients dosed by the intravenous route of administration. In these trials, Foralumab was observed to be safe and well-tolerated and produced immunologic effects consistent with potential clinical benefit while demonstrating mild to moderate infusion related reactions. With completion of the intravenous dosing for Phase 2a trial in Crohn's Disease, Foralumab's ability to modulate T-cell response enables potential extension into a wide range of other autoimmune and inflammatory diseases, such as graft versus host disease, ulcerative colitis, MS, type-1 diabetes, inflammatory bowel disease, psoriasis and rheumatoid arthritis.

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Foralumab is being developed as both an immunosuppressive and immunomodulatory agent, with therapeutic benefits of rendering T-cells unable to orchestrate an immune response and induction of immune tolerance via maintenance of regulatory T-cells. There is further potential for Foralumab to be combined with our TZLS-501, a fully human anti-IL-6R mAb in development to target autoimmune and inflammatory diseases. In November 2016, we announced new data for oral efficacy in humanized mouse models with Foralumab, a major milestone and a potential breakthrough for the treatment of nonalcoholic steatohepatitis and autoimmune disease. This unique oral technology stimulates the natural gut immune system and potentially provides a therapeutic effect in inflammatory and autoimmune diseases with greatly reduced toxicity. Positive therapeutic effects with Foralumab were consistently demonstrated in animal studies conducted by Prof. Kevan Herold (Yale University) and Prof. Howard Weiner (Harvard University).

In April 2018, we entered into an exclusive license agreement with The Brigham and Women's Hospital, Inc. relating to a novel formulation of Foralumab dosed in a medical device for nasal administration. An investigational new drug application, or IND, for the first-in-human evaluation of the nasal administration of Foralumab in healthy volunteers for progressive MS indication was filed in the second quarter of 2018. Subsequent to IND approval, a single-site, double-blind, placebo-controlled, dose-ranging Phase 1 trial with nasally administered Foralumab at 10, 50 and 250 µg per day, consecutively for 5 days to evaluate biomarkers of immunomodulation of clinical responses was initiated in November 2018. The trial was conducted at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, in healthy volunteers in which 18 subjects received Foralumab treatment and 9 patients received placebo. The study was completed in September 2019, and data demonstrated that nasally administered Foralumab was well-tolerated and no drug-related safety issues were reported at any of the doses. No drug-related changes were observed in vital signs among subjects at predose during treatment and at discharge. Nasally administered Foralumab at the 50 µg dose suppressed cytotoxic CD8+ as well as perforin-secreting CD8+ cells, which have been implicated in neurodegeneration in MS. Treatment at 50 µg stimulated production of anti-inflammatory cytokine IL-10 and suppressed production of pro-inflammatory cytokine interferon-gamma (IFN-γ). Taken together, the treatment showed significant positive effects on the biomarkers for activation of mucosal immunity, which are capable of inducing site-targeted immunomodulation to elicit anti-inflammatory effects. Based on the results we intend to conduct a Phase 2 trial in progressive MS patients starting in the third quarter of 2021.

On July 31, 2020, we announced that we had submitted a patent application for the potential use of nasally administered Foralumab, a fully human anti-CD3 mAb, for the treatment of COVID-19 either alone or in combination with other anti-viral drugs. Recent clinical studies implied that a combination of anti-inflammatory and anti-viral drugs may be more effective to treat patients at different stages of COVID-19 disease.

A collaborative clinical study was initiated on November 2, 2020, investigating nasally administered Foralumab either alone or in combination with orally administered dexamethasone in COVID-19 patients in Brazil. In view of the importance and urgency, scientific teams at the Harvard Medical School, Santa Casa de Misericórdia de Santos Hospital (Jabaquara, Santos, Brazil) and at our company closely collaborated to facilitate initiation of this study in expedited time frames. The clinical trial was coordinated by the team at INTRIALS, a leading, full-service Latin America Clinical Research Organization, (CRO) based in Sao Paulo City, Brazil. The trial was completed in January 2021, and the clinical data from this trial is expected to be available by the first quarter of 2021. This trial, the first-ever trial on nasal administration of Foralumab for treatment of COVID-19, is of enormous significance given the underlying scientific approach is to modulate the immune system, which is dysregulated and crippled to protect against the virus. If successful, we believe this approach could be good for treatment of all COVID-19 variants and potentially other viruses.

An enteric-coated capsule formulation using a proprietary and novel technology has been developed for oral administration of Foralumab. cGMP manufacturing of clinical trial materials for a Phase 1 study has been completed and an IND was submitted in March 2019.

On September 9, 2019, the U.S. Food and Drug Administration, or FDA, granted approval to initiate the Phase 1 clinical trials to evaluate the safety and pharmacokinetics of oral Foralumab at 1.25, 2.5 and 5.0 mg/day as a single ascending dose study. The study was completed in December 2019 at the Brigham and Women's Hospital. Formulated Foralumab powder encapsulated in enteric-coated capsule was well-tolerated at all doses tested and there were no drug-related safety issues observed even at the highest dose of 5 mg in this trial. Based on successful Phase 1 data, we intend to conduct a Phase 2 study using Crohn's Disease patients starting in the third quarter of 2021.

In addition, on August 18, 2020 the United States Patent and Trademark Office, or USPTO, granted us a patent on use and methods of treatment of Crohn's disease with Foralumab, its proprietary fully human monoclonal antibody, and all other anti-CD3 mAbs. The CD3 (cluster of differentiation 3) is a protein complex on T-cells, which is important for the regulation of the immune system. The patent was published by the USPTO on September 1, 2020 as Patent No. 10,759,858. Recently, we also announced the issuance of the first-ever patent on oral administration of anti-CD3 mAbs for treatment of human diseases (Patent No. 10,688,186). We believe the grant of this additional composition-of-matter and use patent further strengthens our intellectual property, consisting of proprietary technologies on oral and nasal administration of Foralumab and other anti-CD3 mAbs for the treatment of human diseases.

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On July 16, 2020, we announced that we had submitted a patent application on the potential use of Foralumab, a fully human anti-CD3 mAbs, to improve success of chimeric antigen receptor T-cell, or CAR-T, therapy for cancer and other human diseases. The patent application claims inventions related to lymphodepletion to improving CAR-T expansion and/or survival using anti-CD-3 mAbs administered either alone or in combination with other costimulatory molecules, such as an anti-IL-6R mAb, an anti-CD28 mAb or specific inhibitors of signaling pathways of phosphatidylinositol 3-kinase (PI3K), protein kinase B (AKT), or mammalian target of rapamycin (mTOR).

### *Milciclib (TZLS-201)*

We are developing Milciclib, for which we in-licensed the intellectual property from Nerviano Medical Sciences S.r.l. in 2015, as a potential treatment for hepatocellular carcinoma, or HCC. A novel feature of Milciclib is its ability to reduce levels of microRNAs, miR-221 and miR-222. MicroRNAs are small RNA molecules that play a significant role in the regulation of gene expression. miR-221 and miR-222 are believed to be linked to the development of blood supply (angiogenesis) in cancer tumors. Levels of these microRNAs are consistently elevated in HCC patients and may contribute towards resistance to treatment with Sorafenib, a multikinase inhibitor (a drug which may inhibit the cellular division and proliferation associated with certain cancers) often prescribed to HCC patients as the Standard of Care.

To date, Milciclib has been studied in a total of eight completed Phase 1 and 2 clinical trials in 316 patients. In these trials, Milciclib was observed to be well-tolerated and showed initial signals of anti-tumor action. Prior to in-licensing, Milciclib was granted orphan designation by the European Commission and by the FDA for the treatment of malignant thymoma and an aggressive form of thymic carcinoma in patients previously treated with chemotherapy. In two Phase 2a trials, CDKO-125a-006 and CDKO125a-007, Milciclib showed signs of slowing disease progression and acceptable safety. We initiated a Phase 2a trial (CDKO-125a-010) of Milciclib safety and tolerability as a single therapy in Sorafenib-resistant patients with HCC in the first half of 2017. Typically, this population of patients have an advanced form of the disease with poor prognosis and an average overall survival expectancy of three to five months. In May 2018, the Independent Data Monitor committee, or IDMC, completed an interim analysis of tolerability data from the first eleven treated patients and recommended expansion of the initial cohort to an additional 20 patients to complete the trial enrolment, which was completed in December 2018. In March 2019, the IDMC reviewed safety data from patients as of February 26, 2019 and concluded that the administration of Milciclib to patients with advanced HCC was not associated with unexpected signs or signals of toxicity. 28 out of 31 treated patients were evaluable, 14 completed the 6-month duration study. The most frequent adverse events such as diarrhoea, ascites, nausea, fatigue, asthenia, fever, ataxia, headache, and rash were manageable. No drug-related deaths were recorded.

The Phase 2a trial was completed in June 2019 with clinical safety result reported in July 2019 and efficacy results reported in September 2019. The clinical activity assessment in evaluable patients was based on the independent radiological review using the modified Response Evaluation Criteria in Solid Tumors.

- 14 out of 28 (50%) evaluable patients completed 6-month duration of the trial.
- Both median TTP and PFS were 5.9 months (95% Confidence Interval ("CI") 1.5-6.7 months) out of the 6-months duration of the trial.
- 16 of 28 (57.1%) evaluable patients showed 'Stable Disease'
- One patient (3.6%) showed unconfirmed 'Partial Response' (PR).
- 17 of 28 (60.7%) evaluable patients showed 'Clinical Benefit Rate' defined as CBR=CR+PR+SD (with CR representing Complete Remission).

Since overexpression of cyclin-dependent kinases, or CDKs, and dysregulation in pRB pathway (regulates transcription factors critical for cell cycle progression) are prominently associated with tumor cell resistance to certain chemotherapeutic drugs, inhibition of multiple CDKs is an appealing approach to improve clinical responses in cancer patient's refractory to existing treatment options. A Phase 1 dose-escalation study of Milciclib in combination with gemcitabine in patients with refractory solid tumors exhibited clinical activity in patients, including those who were refractory to gemcitabine. We plan to explore a combination treatment of Milciclib and a tyrosine kinase inhibitor (either Sorafenib or Regorafenib) in patients with HCC in the third quarter of 2021.

On August 21, 2020 we announced that the USPTO had granted us a patent on use of Milciclib in combination with tyrosine kinase inhibitors, or TKIs, such as Sorafenib (Nexavar®), Regorafenib (Stivarga®) and Lenvatinib (Lenvima®) for the treatment of hepatocellular carcinoma, or HCC, and other cancers in humans. This patent was published by the USPTO on September 1, 2020 as Patent No. 10,758,541. Like most human cancers, HCC is a complex multi-factorial cancer with multiple underlying mechanisms causing enormous heterogeneity in patient populations. Consequently, patients with HCC often develop resistance towards the monotherapies of existing therapeutics. Thus, there is an urgent need for combination drug treatment approaches targeting different mechanisms to achieve better clinical outcomes. We are planning to conduct a Phase 2b trial with Milciclib in

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combination with a TKI or immunotherapy in sorafenib-resistant HCC patients. We also successfully completed a Phase 1 trial in patients with refractory solid cancers. The patients enrolled in this trial had demonstrated resistance to the mainstream chemotherapies for refractory solid cancer. The trial data showed that Milciclib in combination with gemcitabine provided 36% clinical response to these patients who had shown no response to gemcitabine when administered alone. These data suggest that Milciclib may be able to overcome drug-resistance. This novel attribute of Milciclib may have application as an adjuvant therapy in combination with chemotherapies for treatment of refractory, malignant and advanced cases of cancers. The data from this trial also showed that the combination treatment delayed onset in a patient with non-small cell lung carcinoma (NSCLC). The preclinical data from an animal study also suggest that orally administered Milciclib might also be effective in Kras+ (G12C) mutants of NSCLC cancer. We are further exploring the use of Milciclib in combination with other drugs for treatment of Kras+ (G12C) NSCLC, which is an unmet medical need.

### *Anti-IL6R (TZLS-501)*

TZLS-501 is a fully human engineered mAb targeting the interleukin-6 receptor (IL-6R). Tiziana Life Sciences licensed the intellectual property from Novimmune in January 2017. This fully human mAb has a unique mechanism of action that binds to both the membrane-bound and soluble forms of the IL-6R resulting in lowering of circulating levels of IL-6 in the blood. Excessive production of IL-6 is regarded as a key driver of chronic inflammation, associated with autoimmune diseases such as multiple myeloma, oncology indications and rheumatoid arthritis, and the Group believes that TZLS-501 may have potential therapeutic value for these indications.

In preclinical studies, TZLS-501 demonstrated the potential to overcome limitations of other IL-6 blocking pathway drugs. Compared to Tocilizumab and Sarilumab, while binding to the membrane-bound IL-6R complex TZLS-501 has shown a higher affinity for the soluble IL-6 receptor as seen from the antibody binding studies conducted in cell culture. TZLS-501 also demonstrated the potential to block or reduce IL-6 signaling in mouse models of inflammation. The soluble form of IL-6 has been implicated to have a larger role in disease progression compared to the membrane-bound form. (Kallen, K.J. (2002). "The role of trans signaling via the agonistic soluble IL-6 receptor in human diseases". *Biochimica et Biophysica Acta*. 1592 (3): 323–343.).

Recently, chronic inflammation is believed to be associated with severe lung damage observed with COVID-19 infections and acute respiratory illness. China's National Health Commission has recommended the use of anti-IL6-R mAbs for treatment of inflammation and elevated cytokine levels ("cytokine storm") in COVID-19 patients.

On April 9, 2020 The Company announced that it had developed investigational new technology to treat COVID-19 infections, consisting of direct delivery of anti-IL-6 receptor (anti-IL-6R) monoclonal antibodies (mAbs) into the lungs using a handheld inhaler or nebulizer for treatment of patients infected with COVID-19 (SARS-CoV-2) coronavirus. On June 29, 2020 the Company announced that it was advancing GMP manufacturing of TZLS-501 with STC Biologics concurrently with the development of inhalation technology using a hand-held nebulizer with Sciarra Laboratories and safety toxicology studies in Cynomolgus monkeys with ITR Canada Laboratories. GMP batches were initiated in January 2021 and completed in March 2021. Safety inhalation toxicology studies were initiated in November 2020 and completed in March 2021. Technological assessment of nebulizers for inhalation treatment of patients was initiated in September 2020 and completed in February 2021.

### *StemPrintER*

StemPrintER is a multi-gene signature assay intended for use in patients diagnosed with estrogen-receptor positive ER+/HER2 negative breast cancers. The Group believes this in-vitro prognostic test will be used in conjunction with clinical evaluation to identify those patients at increased risk for early and/or late metastasis. StemPrintER is designed to help physicians distinguish ER+/HER2 negative patients:

- with an elevated risk of early recurrence (<5 years) who could benefit from chemotherapy in addition to hormonal therapy
- with a high risk of late recurrence who could benefit from prolonged endocrine treatment up to 10 years
- with a low risk of early recurrence who might be spared chemotherapy or be eligible for less aggressive treatments

The diagnostic has a unique biological basis, being based on the detection of cancer stem cell markers, uses a reliable platform (qRT-PCR, FFPE), and has been evaluated in an initial retrospective validation study using a consecutive cohort of approximately 2,400 patients with breast cancer. The development team is preparing for a retrospective validation study using an independent cohort and has conducted a pre-submission meeting with the FDA.

Recently, StemPrintER results were announced, from a poster selected for discussion session at the American Society of Clinical Oncology (ASCO) Virtual Conference, demonstrating the favourable performance of the StemPrintER stem cell based genomic prognostic tool versus the market leader, Oncotype DX, in predicting

## STRATEGIC REPORT: EXECUTIVE CHAIRMAN'S STATEMENT

recurrence in ER+/HER2- postmenopausal breast cancer patients

Tiziana has during this year demerged the StemPrintER technology by the transfer of the Intellectual Property rights and patents to its wholly owned subsidiary, Stemprinter Sciences Ltd, which was then sold to Accustem Sciences Ltd. The process was effected by way of a Court sanctioned capital reduction and statutory demerger. Accustem will develop and commercialise the StemPrintER diagnostic tester.

### Financial summary

#### *Consolidated Statement of Comprehensive Income*

The Group has made a loss for the year of £20,162k (2019: £7,177k). The loss is detailed in the consolidated statement of comprehensive income on page 39.

Research and development costs were £4.7 million for the year ended December 31, 2020 as compared to £2.9 million for the year ended December 31, 2019, an increase of £1.8 million. The increase in cost is a result of the development of anti-IL-6R monoclonal antibodies (mAbs) compounds.

Operating expenses were £19.01 million for the year ended December 31, 2020 as compared to £4.9 million for the year ended December 31, 2019, an increase of £14.11 million. The increase in cost is a result of a realisation bonus that became payable for £10.29m, additional fair value charges of £2.7m relating to modification of existing options and the issuance of additional options, plus additional compliance, professional fees and legal costs of £1.12m due to increased activity in the Company.

#### *Consolidated Statement of Financial Position*

At the end of the year the Group cash balance amounted to £48,217k (2019: £153k) and the total assets of the Group amounted to £51,766k (2019: £1,808k). To bolster our cash reserves, the Group raised £52.1m via a public offering of American Depositary Shares ("ADSs") on the NASDAQ Global Market during 2020.

### Fund raising

In the year, the Group successfully raised funds to further progress its on-going clinical and pre-clinical pipeline.

During the year to 31 December 2020, Tiziana raised £62.1m funds: £52.1m was raised through a public offering on the NASDAQ Global Market, £6.2m through an 'At the market' sales agreement, £0.1m through the issuance of a Convertible Loan Note and £3.7m through the exercise of warrants and options. Funds raised by Tiziana will be used to fund the development of the Group's clinical stage assets Milciclib and Foralumab, to meet the Group's ongoing liabilities in respect of license agreements, and for general working capital purposes.

### Going Concern

The Group has experienced net losses and significant cash outflows from cash used in operating activities over the past years, and as of December 31, 2020, had an accumulated loss of £62,313k, a net loss for the year ended December 31, 2020 of £20,348k and net cash used in operating activities of £9,297k.

Based upon the current forecasts prepared by Management, the potential use of cash flows from operations for the next 20 months is £38.6 million. When compared to the current cash balance at April 30, 2021 including the anticipated receipts for R&D tax credits for 2020, the Group has enough cash to sustain operations to December 2022. The Group noted that included in its cash projections to December 2022 was £21.8m of uncommitted expenditure, which Management could repurpose or delay the expenditure as required.

### Appointments

#### *Non-Executive Directors*

On 21 January 2020, the Group announced the appointment of Mr. Gregor MacRae to its Board as a Non-executive Director.

On 20 July 2020, the Group announced the appointment of Mr. John Brancaccio to its Board as a Non-executive Director. Mr Brancaccio will Chair the Audit, Risk and Disclosure Committee.

Mr. Brancaccio, retired CPA, is a financial executive with extensive international and domestic experience in pharmaceutical and biotechnology for privately and publicly held companies. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From April 2004 until May 2017, Mr. Brancaccio was the Chief Financial Officer of



## STRATEGIC REPORT: EXECUTIVE CHAIRMAN'S STATEMENT

Accelerated Technologies, Inc., an incubator for medical device companies. Mr. Brancaccio is currently a director of Cardiff Oncology, Inc., Rasna Therapeutics, Inc., OKYO Pharma LTD and Hepion Pharmaceuticals, Inc.

### Resignations

#### *Non-Executive Directors*

On 18 June 2020, the Group announced that Mr. Gregor MacRae was standing down as a director of the Company with immediate effect to concentrate on his other business interests and activities; Mr MacRae felt his position was better filled by an individual with a background and greater experience in life sciences sector.

### COVID-19

We remain cognisant of the potential impact of coronavirus (COVID-19) on our operations and have taken the steps necessary to maintain the integrity of the Company's assets and the health and wellbeing of our employees. The Company is well financed, resilient and well positioned to weather any financial downturn occurring as a result of the outbreak. Indeed, the Company has raised additional funds through an "At the Market" or "ATM" Sales Agreement with Think Equity (a division of Fordham Financial Management, Inc.) which raised \$7.7m from the sale of ADSs.

We are also aware of the responsibility we have as a member of the global healthcare community to develop investigational new technologies to treat COVID-19 infections.

### Outlook and strategy

We have continued to progress our pipeline of drugs to treat rare cancers and autoimmune and inflammatory diseases.

We are developing investigational new technology to treat COVID-19 infections, which consists of direct delivery of anti-IL-6 receptor (anti-IL-6R) monoclonal antibodies (mAbs) into the lungs using a nasal delivery system. Preclinical studies are ongoing and we hope to commence a trial investigating the direct delivery of an anti-IL-6R mAb to the lungs using a portable nasal delivery system. This treatment could be useful for different variants of COVID-19 and we are exploring these in an upcoming preclinical study.

The Company also plans to develop subcutaneous delivery of anti\_IL-6R mAb for treatment of ARDS and other inflammatory conditions.

We have outlined our clinical development plan for Foralumab and anticipate to commence Phase 1b and 2 trials for oral administered Foralumab in Crohn's disease patients and nasally administered Foralumab in multiple sclerosis patients.

For Milciclib, we are planning to initiate a Phase 2b clinical trial in HCC patients with Milciclib in combination with a Tyrosine kinase inhibitors such as Regorafenib or Sorafenib. The Company also intends to evaluate milciclib in combination with standard of care treatments for other solid tumour indications.

We recently announced an agreement we have entered into with Takanawa Japan K.K, Pharma Team, (Takanawa) for a strategic business development plan to identify a clinical partner in Japan and other Asian countries for further clinical development of Milciclib for treatment in advanced hepatocellular carcinoma (HCC) patients. We believe the positive clinical activity in advanced HCC and other cancers warrant immediate further development in Japan and other Asian countries where the prevalence of this cancer is relatively high, and the current available therapies are not entirely satisfactory.

Looking ahead, Tiziana is confident that it is well positioned to advance these programs to their next respective value inflection points.

*Gabriele Cerrone*

### **Gabriele Cerrone**

*Executive Chairman*

May 17, 2021

## STRATEGIC REPORT

### Business review

A review of the business, its results and strategic outlook is included in the Executive Chairman's Statement on page 2.

### Key performance indicators

The Board monitors the Key Performance Indicators (KPIs) that it considers appropriate for the industry and stage of development of the Group. The Group is a research and development-based biotechnology company concerned with a number of pre-clinical and clinical assets. These assets require sufficient investment to reach defined milestones by which the Group and its investors can judge the chances of ultimate success and thereby the value of the Group. These relate to reviewing, on a regular basis, the scientific and technical progress of the research and development programmes and protection of the intellectual property arising from them together with monitoring the progress being made with the Group's upcoming clinical trials which are discussed in the Chairman's statement from page 2.

At this stage of Group development significant sources of revenue generation are unlikely and the Group is cash consuming. The Group KPIs are therefore chosen to monitor the progress of the individual scientific programmes, the external market environment for the potential drugs being developed and the cash requirements of the Group.

### Financial KPIs

#### *Cash consumption*

The cash position of the business is measured on a continual basis with reference both to the general and administrative expenses required to run the Group, and more particularly to the cash required for ongoing research, development and acquisition of the Group's scientific assets. During 2020 the main use of the Group's funds was for developing investigational new technology to treat COVID-19 infections, consisting of direct delivery of anti-IL-6 receptor (anti-IL-6R) monoclonal antibodies (mAbs) into the lungs using a handheld inhaler or nebulizer and the formulation and manufacturing of nasally and orally administered Foralumab to be used in clinical trials commencing in 2021. Management monitors its cash consumption on a monthly basis and a cash projection is presented at every quarterly board meeting.

The Group monitors current and projected cash consumption to ensure that there are sufficient funds available to develop the Group's scientific assets. The Group successfully raised additional cash during 2020 to fund research and development, to meet the Group's ongoing liabilities in respect of licence agreements, and for general working capital purposes. The Group maintains a virtual operating model resulting in low cash consumption for general and administrative expenses during the period.

### Non-financial KPIs achieved during 2020

#### *Completion of Various Phase 1 Clinical Trials for Nasally and Orally Administered Foralumab.*

- Completion of a Phase 1 clinical trial for progressive multiple sclerosis indication for nasally administered Foralumab.
- Completion of Phase I clinical trials to evaluate the safety and pharmacokinetics of oral Foralumab at 1.25, 2.5 and 5.0 mg/day as a single ascending dose study
- Completion of Phase 1 clinical trial for COVID-19 patients in Brazil with demonstration of clinical benefit and safety

Non-financial KPIs for 2021:

The group intends to monitor its progress during 2021 with reference to the objectives set out below:

- Orally administered Foralumab for the treatment of Crohn's disease milestone delivery
- Intranasal administration of Foralumab milestone delivery (including COVID 19 inpatients and outpatients)
- Progress the clinical development for our lead oncology candidate Milciclib in combination with other therapeutics for KRAS+ NSCLC.

### Other Considerations

#### *External (life sciences) market environment*

The Group monitors the life sciences market for a number of factors;

- New developments in drug research and development
- New medical treatment paradigms
- Patent filings by third parties pertinent to the Group's programmes

## STRATEGIC REPORT

- Existing and novel drugs in development by third parties
- Healthcare regulation and policy in the major territories
- Private and public financings of life science companies to indicate investor appetite for life science risk

The Group is developing its scientific assets within the European and US territories, but for potential global application. The environment for life science companies was positive throughout 2020.

### Principal risks and uncertainties

The Group operates in an uncertain environment and is subject to a number of risk factors. The Directors have carried out a robust assessment of the principal risks facing the Group, including those that threaten its business model, future performance, solvency or liquidity. They consider the following risk factors are of particular relevance to the Group's activities and to any investment in the Group. It should be noted that the list is not exhaustive and that other risk factors not presently known or currently deemed immaterial may apply.

The risk factors are summarised below:

#### Risks relating to the Group's business strategy.

The Group's business is relatively undeveloped.

The operations of Tiziana are at a relatively early stage and, to date, no commercial sales of its products have been made. The ability of the Group to achieve commercialisation is dependent on a number of factors, many of which are outside of the Group's control. Examples of factors outside of the Group's control are the impact of Brexit, capital market conditions, FDA approval and competition.

#### Business strategy of the Group

The development of clinical products for new medical treatments is inherently uncertain, with high failure rates in clinical studies for both early and late stage development products and such clinical studies can be expensive, time-consuming and complicated and there is no certainty as to the outcome of such studies. Even once clinical studies have been successfully carried out, later phase trials may not successfully replicate or improve on such outcomes.

#### Staffing and key personnel

The Group is reliant on a number of the key personnel. Whilst the Group has endeavoured to ensure that it has contractual arrangements which include non-compete restrictions in place with such persons to lessen the risk of them ceasing to be involved with the Group, in the event that the Group was to lose the services of such individuals, its results could be adversely affected.

#### Costs of commercialisation

The ability of the Group to bring its products to first commercial sale will be dependent in part on the overall costs of manufacturing and the costs involved could be significant and there is no guarantee that the sale prices achievable for its products will be viable and sustainable.

#### Clinical studies and timelines risk

Tiziana is currently progressing its product candidates through preclinical development. Although encouraging results have been achieved so far, there can be no certainty that these results can be reproduced in clinical trials.

The development of clinical products for new medical treatments is inherently uncertain, with high failure rates in clinical studies for both early- and late-stage development products. Furthermore, such clinical studies (Phase 1, Phase 2a/2b, Phase 3) are typically expensive, complex, can take considerable time to complete and have uncertain outcomes. Furthermore, as a result of adverse, undesirable, unintended or inconclusive results from any testing or clinical trials (which have yet to be designed), the future progress, planning and potential treatment outcome of the products and clinical programmes may be affected and may potentially prevent or limit the commercial use of one, many or all of the Company's products. In addition, later phase clinical trials may fail to show the desired safety and efficacy obtained in earlier studies, and a successful completion of one stage of clinical development of an investigational clinical product does not ensure that subsequent stages of clinical development will be successful. Failure can occur at any stage of clinical development and, as a result, enforced delays to the clinical development plan could delay or prevent commercialisation of the Company's product candidates. Various factors associated with the potential failure or delay in completing a clinical programme include, but are not limited to:

## STRATEGIC REPORT

- Delays in securing clinical investigators or clinical study sites;
- Delays in securing any regulatory authority, hospital ethics committee, or institutional review board approval or approvals necessary to commence a clinical study;
- Delays or failure to recruit a sufficient number of clinical study participants in accordance with the clinical study protocol;
- Difficulty or inability to monitor subjects adequately during or after treatment;
- Inability to replicate in Phase 3 controlled studies any safety and efficacy data obtained from controlled Phase 2a/2b clinical studies;
- Difficulty or inability to secure clinical investigator compliance to follow the approved clinical study protocol; and
- Unexpected adverse events or any other safety or related issues.

### Research and development risk

The Group operates in the biotechnology and bio-pharmaceutical development sectors and carries out complex scientific research. If the research or preclinical testing or clinical trials of any of Tiziana' product candidates fail, meaning that these candidates will not be licensed or marketed, this would result in a complete absence of revenue from these failed candidates. Positive results from preclinical and early clinical studies do not guarantee positive results from clinical trials required to permit application for regulatory approval. Furthermore, the Group may discontinue the development of candidates if results are not positive or unlikely to further its progress towards a meaningful outcome or collaboration.

### Intellectual property (IP) infringement

The Group may be subject to future litigation concerning its own IP and the IP of others. Adverse judgements in relation to its IP would likely have negative outcomes for its results of operations. Intellectual property (IP) control The Group is partially reliant on an exclusive, world-wide licence of a patents from [ ] and [ ].

### Environmental and other regulatory requirements

The event of a breach with any environmental or regulatory requirements may give rise to reputational, financial or other sanctions against the Group, and therefore the Board considers these risks seriously and designs, maintains and reviews its policies and processes so as to mitigate or avoid these risks. Whilst the Board has a good record of compliance, there is no assurance that the Group's activities will always be compliant.

### Financing

The Group's ability to develop its product through to commercial sale will depend upon the Group's ability to obtain financing primarily through a further raising of new equity capital. Although the Group has been successful in raising new equity capital, there can be no guarantee that it will be able to do so in the future. The Group may not be successful in procuring the requisite funds on terms which are acceptable to it (or at all) and, if such funding is unavailable, would raise questions over its ability to further develop its products through to commercialisation. Further, Shareholders' holdings of Ordinary Shares may be materially diluted if debt financing is not available.

### Market conditions

Market conditions, including general economic conditions and their effect on exchange rates, interest rates and inflations rates, may impact the ultimate value of the Group regardless of its operating performance. The Group also faces competition from other organisations, some of which may have greater resources or be more established in a particular territory. The Board considers and reviews all market conditions to try and mitigate any risks that may arise from these.

### Political and country risk – UK departure from the EU

The Company is quoted in the United Kingdom (UK) and operates in the UK, in addition to other territories. Since a significant proportion of the regulatory framework in the UK applicable to the Group's business and its product candidates is derived from EU directives and regulations, Brexit and any ultimate trade deals struck between the UK and EU could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialisation of the Group's product candidates in the UK or the EU. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the UK is no longer covered by the centralised procedures for obtaining EU-wide marketing authorisation from the EMA and, unless a specific agreement is entered into, a separate process for authorisation of drug products, including the Company's drug candidates, will be required in the UK, the potential process for

## STRATEGIC REPORT

which is currently unclear. Moreover, in the US, tariffs on certain US imports have recently been imposed, and the EU and other countries have responded with retaliatory tariffs on certain US exports. In addition, the Group may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of the Group's candidates into the EU, or the Group may incur expenses in establishing a manufacturing facility in the EU in order to circumvent such hurdles. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on the Group. As a result, given the ongoing uncertainty surrounding the situation, the Company is monitoring matters and seeking advice as to how to mitigate the risks arising.

### Pandemic and business disruption risk

The Company may be affected by disruptions to its operations in one or more locations, particularly in the near future in light of responses to the novel coronavirus or other potential pandemics. The Company's US operations are classed as an essential business and have not been subject to closure, and work has continued to date with prudent hygiene and distancing measures in place including limited work in the laboratory on rota and work from home. [All laboratory staff have been fully vaccinated.] The Company is allowing for extended delivery times for some supplies, and for slower progress with collaboration partners. The Board and UK management continue to operate remotely, as usual. At present the Company believes that there should be no significant material disruption to its work, but the Board continues to monitor these risks and the Company's business continuity plans.

### Gender of Directors and employees

We recruit individuals who have the skills, experience and integrity needed to perform the roles to make Tiziana Life Sciences PLC a successful company. There are currently no women on the board, although we note that among our senior management team our finance director is female. We are committed and continue to recruit without regard to sex or ethnic origin, appointing and thereafter promoting staff based upon merit.

The profile of the Group's employees and directors at December 31, 2020, was as follows:

	December 31, 2020		
	Male	Female	Total
Number of persons who were Directors or officers of the Company	4	1	5
Number of persons who were other employees of the Company	2	4	6
<b>Total employees at December 31, 2020</b>	<b>6</b>	<b>5</b>	<b>11</b>

### Directors' duties in relation to s172 Companies Act 2006

The directors consider, that they have acted in the way they believe, in good faith, to promote the success of the Company for the benefit of its members as a whole and, in doing so, have regard (amongst other matters) to:

- the likely consequences of any decisions in the long-term,
- the interests of the Company's employees,
- the need to foster the Company's business relationships with suppliers, customers and others,
- the impact of the Company's operations on the community and environment,
- the desirability of the Company maintaining a reputation for high standards of business conduct, and
- the need to act fairly between the shareholders of the Company.

Key Stakeholders and concerns	Board Considerations	Key Outcomes
<b>Employees</b>  Our employees are based on three sites in London, New York and Pennsylvania.	Ensuring all sites view themselves as one Company; communicating performance of the Company; motivating staff	Regular Company meetings with all sites; weekly meetings at individual sites; easy access to Executive Directors; granting of share options
<b>Investors and shareholders</b>  Tiziana is a pre-revenue Company and is dependent upon existing and future		Use of PR consultants; interviews with Proactive investors the release of

## STRATEGIC REPORT

investors to fund its research and development products

Business Strategy clearly setting out the progress with projects in development and cash requirement

information through the Group's website; the Regulatory News Service of the London Stock Exchange; meeting individual shareholders at AGM

### Suppliers

Tiziana has a wide range of suppliers for consumable items and a few key suppliers who are key to our manufacturing of product

Management of supplier relationships ensuring consumable and other items are delivered on time and at right price

Key suppliers are managed in-house with regular meetings being held with Tiziana management

### Contract Research Organisations

CROs are key to managing Tiziana's clinical trial programmes

Management of clinical trials and recruitment of patients; Regulatory and pre-clinical services

Rigorous selection process before engaging CRO and then regular project meetings

### Environment

The Group is conscious of the need to protect the environment

Tiziana's operations are relatively low in their impact on the environment.

During the year, employees reduced their travel wherever reasonably practical, phone - conferencing instead

### Reputation

Maintaining a strong reputation and acting within laws and regulations impacts the Group's relationships with all stakeholder

Policies and procedures approved by the Board are concentrated on maintaining the strong reputation of the Group within its employees, Shareholders, suppliers, regulators and other key stakeholders.

Tiziana continuously monitors and assesses all regulatory developments to ensure that any issues are being addressed in decision making.

## Principal decisions in 2020

We have considered the decisions taken by the Board which will have an impact on the longer-term performance and prospects for the Group. The Board believes that the following decisions taken during the year and since the year end fall into this category and were made with full consideration of both internal and external stakeholders. The Group's aim is to meet the needs of the key stakeholders who ultimately wish for us to progress our pipeline of drugs to treat rare cancers and autoimmune and inflammatory diseases to commercial deployment.

Significant events/decisions	Key s172 matter(s) affected	Actions and impact
Raised £62m of investment from existing and new investors, to enable Group to progress its clinical trials	Shareholders	Consultation with major shareholder and approval from shareholders at General Meeting
Successfully demerged its StemPrintER asset into a separate and independently listed public company, Accustem Sciences Limited which will focus exclusively on the commercialization of StemPrintER	Shareholders	Consultation with major shareholder and approval from shareholders at General Meeting
Agreement with STC Biologics for GMP Manufacturing of an anti-Interleukin-6-Receptor Monoclonal Antibody for Clinical Studies in Patients with COVID-19.	Staff	Decisions were made by the executive team in consultation with the Board after carefully considering impact upon existing staff resources and available funding.
Clinical Study with Nasally Administered Foralumab, a Fully Human Anti-CD3 Monoclonal Antibody, for Treatment of COVID-19 Patients in Brazil	Employees, Local Research and Medical Organisations	Consulted with employee development teams and Local Organisations in Brazil to initiate the clinical study

## Environmental Matters

We currently outsource our research, development, testing and manufacturing activities. These activities are subject to various environmental, health and safety laws and regulations, which govern, among other things, the

## STRATEGIC REPORT

controlled use, handling, release and disposal of and the maintenance of a registry for, hazardous materials and biological materials. If we or our partners fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed.

*Willy Simon*

By order of the Board  
Mr Willy Simon  
May 17, 2021

3rd Floor, 11-12 St James's Square, London, SW1Y 4LB

## DIRECTORS REPORT

The Directors present their report and the financial statements of the Group and its Company for the year ended 31<sup>st</sup> December 2020.

### Results and dividend

The results of the Group for the year are set out on page 39. No dividends were declared or paid in the year (2019: nil).

### Directors

The directors of the Company who were in office during the year and to the date of these financial statements were:

Mr Gabriele Cerrone	Executive Chairman
Dr Kunwar Shailubhai	Chief Executive Officer
Mr Willy Simon	Non-Executive Director,
Mr Gregor MacRae	Non-Executive Director (appointed 21 January 2020, resigned 18 June 2020)
Mr John Brancaccio	Non-Executive Director (appointed 20 July 2020)
Dr Thomas Adams	Executive Director (appointed 5 February 2021)

### Significant shareholdings

The directors have been notified or are aware of the following interests in 3% or more of the ordinary share capital of the company as at 31<sup>st</sup> December 2020:

	Ordinary shares	
	Number	Percentage
Planwise Group Limited*	63,297,647	32.52%
Empery Asset Master, Ltd	10,153,770	5.22%
Laura Fonda	7,971,966	4.10%
Morris Silverman	7,944,457	4.08%
Howard Freedberg	6,296,221	3.24%

\* Mr Gabriele Cerrone, a director, is the ultimate beneficial owner of the entire issued share capital of Planwise Group Limited.

### Pensions

The Group operates a defined contribution pension scheme open to all salaried Executive Directors, Non-Executive Directors and employees. There is currently one director participating in the Defined Contribution Scheme.

### Political and charitable contributions

There were no political or charitable contributions made by the Company during the year ended December 31, 2020 (2019: £nil).

### Staff policy

The Group is committed to a policy of recruitment and promotion on the basis of aptitude and ability. Applications for employment by disabled persons are given full and fair consideration having regard to their particular aptitudes and abilities. Where existing employees become disabled, it is the Group's policy, wherever possible, to provide continuing employment under normal terms and conditions and to provide training, career development and promotion wherever appropriate.

### Corporate governance

The Group is firmly committed to business integrity, high ethical values, and professionalism in its activities and operations. The Board is committed to maintaining the highest standards of corporate governance and is accountable to the Company's shareholders. The role of the Board is to provide strategic leadership to the Group within a framework of sensible and effective controls, which enables risk to be assessed and managed. The Board sets the Group's strategic aims, ensures that the necessary financial and human resources are in place for the Group to meet its objectives, and reviews executives' performance. The Board make certain that its obligations to its shareholders and others are understood and met.



## DIRECTORS REPORT

As a company listed on the Main Market of the Standard Segment of the London Stock Exchange, Tiziana Life Sciences plc is required to adopt a corporate governance code. The Board of Directors of Tiziana Life Sciences plc has adopted the Quoted Companies Alliance Corporate Governance Code which they believe is the code that is most suitable for the Company, its subsidiaries and subsidiary undertakings having regard to its strategy, size, stage of development and resources. The code can be found at [www.theqca.com](http://www.theqca.com). The Company's corporate governance is reviewed on a regular basis by the Directors of the company. Tiziana Life Sciences Plc operates within the life science sector in an effective and efficient way, with integrity and due regard for the interests of shareholders and applies principles of general governance applicable to the size and stage of development of the Group.

### How does the Board apply the ten principles set out in the QCA Code?

#### 1. Establish a strategy and business model which promote long-term value for shareholders

The Board has a clear strategy, which is set out in the Chairman's statement on page 2. To support the execution of this strategy, the Board performs the following key tasks:

- setting the Company's values and standards;
- approval of long-term objectives and strategy;
- approval of revenue, expense and capital budgets and plans; a
- approval for therapeutic candidate progression through key development and clinical stages;
- oversight of operations ensuring that adequate systems of internal controls and risk management are in place, ensuring maintenance of accounting and other records, and compliance with statutory and regulatory obligations;

#### 2. Seek to understand and meet shareholder needs and expectations

Contact with major shareholders has been principally maintained by the CEO and the Chairman during the reporting period, and they have ensured that their views are communicated to the Board as a whole. The Board believes that appropriate steps have been taken during the reporting period to ensure that the members of the Board, and in particular the Non-Executive Directors, develop an understanding of the views of major shareholders about the Company. We are holding our Annual General Meeting in June 2021. A Notice of Annual General Meeting will be issued in due course and will be available on our website. Separate resolutions will be provided on each issue so that they can be given proper consideration. Proxy votes are counted and the level of proxies lodged on each resolution reported after it has been dealt with by a show of hands.

#### 3. Take into account wider stakeholder and social responsibilities and their implications for long-term success

Tiziana is committed to engaging with and maintaining good relations with all of our stakeholders (employees, investors, participants in clinical trials, collaboration partners and suppliers).

Tiziana is also compliant with safety and other regulations in its laboratories and in treating patients on Clinical Trials.

Tiziana has annual appraisals for all staff and regular meetings between staff and senior management to discuss business related issues.

#### 4. Embed effective risk management, considering both opportunities and threats, throughout the organisation

A Risk Register is maintained for regular review by the Audit and Risk Committee and the Board. Principal risks are set out on page 9 where mitigating activities are also explained.

### Audit, Risk and Disclosure Committee

The Audit Committee of the Board comprises of John Brancaccio and Willy Simon. It is chaired by John Brancaccio, and is responsible for:

- i. Monitoring the quality of internal controls and ensuring the financial performance of the Group is properly measured and reported on;
- ii. Consideration of the Directors' risk assessment and suggesting items for discussion at the full Board;
- iii. Receipt and review of reports from the Company's management and external auditors relating to the interim and annual accounts, including a review of accounting policies, accounting treatment and disclosures in the financial reports;
- iv. Consideration of the accounting and internal control systems in use throughout the Company and its subsidiaries; and

## DIRECTORS REPORT

- v. Overseeing the Company's relationship with external auditors, including making recommendations to the Board as to the appointment or re-appointment of the external auditors, reviewing their terms of engagement, and monitoring the external auditors' independence, objectivity and effectiveness.

The audit committee meets not less than twice in each financial year and has unrestricted access to the Company's auditors.

### 5. Maintain the Board as a well-functioning, balanced team led by the Chairman

The Board is currently comprised of five directors, the Executive Chairman, two Executive directors and two Non-Executive Directors. The directors of the Company have all been selected for their extensive experience in their specialised fields, making the Board well rounded and balanced. The composition of the Board is regularly reviewed through the Nomination committee. The wide range of skills among the directors helps to further the business and strategic development of the Company as well as address any anticipated issues in the foreseeable future. To ensure the Company's future growth, all directors are subject to re-election at least once every three years, confirming the current directors all have the necessary experience and skills. The skills of each director complement one another guaranteeing a well-functioning balanced board, led by the Executive Chairman. The Company maintains its governance structure through the Nomination Committee, Audit, Risk and Disclosure Committee and the Remuneration Committee. These Committees also support the Board in making the best decisions in the interest of the Company, shareholders and employees. The Board follow a formal schedule of matters and meet quarterly every year. All Directors are expected to provide a sufficient amount of time to the Company to fully exhibit and fulfil their duties. Each Director's time spent is reviewed annually prior to recommending their re-election to the shareholders.

The board is responsible to the shareholders and to ensure acceptable management to the group.

The roles of the directors differ between Executive and Non-Executive directors, while both have fiduciary duties towards the group. The board is made up of Executive Chairman, Gabriele Cerrone, who has extensive experience in the financing and restructuring of micro-cap biotechnology companies and has successfully taken several companies to the NASDAQ, AIM and LSE markets, Kunwar Shailubhai who has many years of scientific and research development experience and Thomas Adams who also has many years of scientific and research development experience. The Executive directors are responsible for the operation and business development of the company. The Non-Executive officers, Willy Simon and John Brancaccio, have many years of experience in the finance industry, who act as independent directors providing objective judgment and constructively challenge the management to ensure all strategies are completely considered.

For the Board to carry out their duties in their entirety, they have full and timely access to all the relevant information they need. Directors, if necessary, are also permitted to take independent professional advice to further their roles at the expense of the Group. All Board members have access to the advice of the Company Secretary.

The Code requires that a smaller company should have at least two Independent Non-Executive Directors. As at 31 December 2020 the Board consisted of two Executive Directors and two Non-Executive Directors. The Non-Executive Directors are interested in either ordinary shares in the Company, options over ordinary shares in the Company, or both, and cannot therefore be considered fully independent under the Code. The remuneration of the Non-Executive Directors includes options and this is contrary to best practice, and thus the Company is not in full compliance. However, the Directors consider the present structure and arrangements to be adequate given the size and stage of development of the Company, and all are considered to be independent in character and judgement.

The Company does not have an independent Chairman given the substantial shareholding of the Chairman. It is the Board's opinion that the current arrangements are appropriate to the Company at this stage of development and that there are sufficient compliance structures within the Company to ensure that the governance functions that would be part of an independent Chairman's responsibility are met. The Board is satisfied with the balance between Executive and Non-Executive Directors which allows it to exercise objectivity in decision making and proper control of the Company's business. The Board considers its composition appropriate in view of the size and requirements of the Company's business and the need to maintain a practical and efficient balance between Executive and Non-Executive Directors.

### 6. Ensure that between them the Directors have the necessary up-to-date experience, skills and capabilities

The Board has delegated the tasks of reviewing Board composition, searching for appropriate candidates and making recommendations to the Board on candidates to be appointed as Directors, to the Nomination Committee.

The Nomination Committee of the Board comprises of Gabriele Cerrone and Willy Simon. It is chaired by Gabriele Cerrone, and is responsible for:

- i. drawing up selection criteria and appointment procedures for directors;

## DIRECTORS REPORT

- ii. recommending nominees for election to our board of directors and its corresponding committees;
- iii. assessing the functioning of individual members of our board of directors and executive officers and reporting the results of such assessment to the board of directors; and
- iv. developing corporate governance guidelines.

With regard to the re-election of Directors, the Company is governed by its Articles of Association (the Articles). Under the Articles, the Board has the power to appoint a Director during the year, but any person so appointed must stand for election at the next Annual General Meeting, along with the rest of the Board.

The Board understands the value in having directors of diverse gender, race and ethnicity, along with varied skills, perspectives and experiences. We are constantly looking for opportunities to improve our diversity and inclusion practices.

### 7. Evaluate Board performance based on clear and relevant objectives, seeking continuous improvement

The Tiziana Life Sciences plc Board remains mindful that it needs to continually monitor and identify ways in which it might improve its performance and recognises that board evaluation is a useful tool for enhancing a board's effectiveness.

The Remuneration Committee of the Board comprises of Willy Simon and John Brancaccio. It is chaired by Willy Simon, and is responsible for:

- i. The review of the performance of the executive directors;
- ii. Recommendations to the Board on matters relating to the remuneration and terms of service of the executive directors; and
- iii. Recommendations to the Board on proposals for the granting of share options and other equity incentives pursuant to any share option scheme or equity incentive scheme in operation from time to time.

In making their recommendations the Remuneration Committee will have due regard to the interests of the Shareholders and the performance of the Company.

### 8. Promote a corporate culture that is based on ethical values and behaviours

The Company is fully committed to the elimination of unlawful and unfair discrimination and values the differences that a diverse workforce brings to the organisation. The Company endeavours to not discriminate because of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race (which includes colour, nationality and ethnic or national origins), religion or belief, sex, or sexual orientation. The Company will undertake an annual review of its policies and procedures to establish its position about compliance and best practice and monitor and promote a healthy corporate culture.

### 9. Maintain governance structures and processes that are fit for purpose and support good decision-making by the Board

The Board is supported by the Committees, explained above, in the task of maintaining governance processes and structures. Furthermore, the following governance matters support good decision-making by the Board.

The Directors are responsible for the Company's internal control and reviewing its effectiveness. The Directors confirm that the Board has acknowledged this responsibility. The Directors confirm that there is an ongoing process for reviewing internal controls and effectiveness as well as identifying, evaluating, and managing the significant risks facing the Group and its subsidiaries. This process has been in place from 1 January 2017 and continues to be in place, the internal controls are reviewed on a regular basis.

The Group's system of internal control is designed to provide the Directors with reasonable assurance that the Group's assets are safeguarded, that transactions are authorised and properly recorded, and that material errors and irregularities are either prevented or would be detected within a timely period. However, no system of internal control can eliminate the risk of failure to achieve business objectives or provide absolute assurance against material misstatement or loss.

The key elements of the internal control system in operation are:

- The Board meets regularly with an agenda of matters reserved for their decision and has put in place an organisational structure with clear lines of responsibility defined and with appropriate delegation of authority. The Board receives periodic updates from both the Audit and Remuneration Committees.

## DIRECTORS REPORT

- The Management team is responsible for the identification and evaluation of significant risks and for the design, implementation and monitoring of appropriate internal controls, including, but not limited to, financial and computer systems, business operations, and compliance.
- Management regularly reports to the Board on the key risks inherent in the business and on the way in which these risks are managed.
- There are established procedures for planning, approving, and monitoring large expenditures, including capital expenditures, as well as processes for monitoring the Group's financial perform.
- A comprehensive forecasting process is completed four times a year, prior to each board meeting, which is reviewed and approved by the Board. Detailed management accounts are produced on a monthly basis, with all significant variances investigated promptly. The management accounts are reviewed and commented on a monthly basis by the management team.
- The Group maintains appropriate insurance cover, including in respect of actions taken against the Directors because of their roles, as well as against material loss or claims against the Group. The insured values and type of cover are comprehensively reviewed on an annual basis.

10. Communicate how the Company is governed and is performing by maintaining a dialogue with shareholders and other relevant stakeholders

Contact with major shareholders is principally maintained by the Chairman and CEO, and additionally the Senior Independent Non-Executive Directors are available to discuss governance and other matters directly with major shareholders, both private and institutional.

The Company uses its corporate website ([www.tizianalifesciences.com](http://www.tizianalifesciences.com)) to communicate with institutional shareholders and private investors, and the website also contains the latest announcements, press releases, published financial information, current projects and other information about the Company. The annual report which includes the financial statements is a key communication document and is available on the Company's website.

### Whistleblowing

The company has formal arrangements in place to facilitate 'whistle-blowing' by employees. If a complaint is made, the content is sent anonymously by email to the Company's Compliance Officer, so that appropriate action can be taken.

### Employment

The company endeavours to appoint employees with appropriate skills, knowledge and experience for the roles they undertake and thereafter to develop, incentivise and retain staff. The Board recognises its legal responsibility to ensure the well-being, safety and welfare of the company's employees and maintain a safe and healthy working environment for them and our visitors. If an employee has a concern about unsafe conditions or tasks, they are encouraged to report their concerns immediately to their manager.

### Statement of directors' responsibilities

The Directors are responsible for preparing the Directors' Report and the financial statements in accordance with applicable law and regulations.

Company Law requires the directors to prepare group and company financial statements for each financial year. The directors are required by the Rules of the London Stock Exchange to prepare group financial statements in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006.

Under Company Law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Company and of the Group and the financial performance and cash flows of the Group for that year. In preparing these financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and accounting estimates that are reasonable and prudent;
- state whether in preparation of the Group and Company financial statements the Group and Company has conformed with the requirements of the Companies Act 2006;
- prepare the accounts on the going concern basis unless it is inappropriate to presume that the company will continue in business.

## DIRECTORS REPORT

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Group's transactions and disclose with reasonable accuracy at any time the financial position of the Group and enable them to ensure that the financial statements comply with the Companies Act 2006. They are also responsible for safeguarding the assets of the Group and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the United Kingdom governing the preparation and dissemination of the financial statements may differ from legislation in other jurisdictions.

### Statement of Directors' responsibilities pursuant to Disclosure and Transparency Rules

Each of the Directors, whose names and functions are listed on page 2 confirm that, to the best of their knowledge and belief:

- the financial statements prepared in accordance with IFRS as adopted by the European Union, give a true and fair view of the assets, liabilities, financial position and loss of the Company; and
- the Annual Report and financial statements, including the Strategic Report, includes a fair review of the development and performance of the business and the position of the Company, together with a description of the principal risks and uncertainties that they face.

### Directors indemnity

The Company's Articles of Association provide, subject to the provisions of UK legislation, an indemnity for directors and officers of the Company in respect of liabilities they may incur in the discharge of their duties or in the exercise of their powers, including any liabilities relating to the defence of any proceedings brought against them which relate to anything done or omitted, or alleged to have been done or omitted, by them as officers or employees of the Company.

Appropriate directors and officer's liability insurance cover is in place in respect of all Company directors.

### DISCLOSURES REQUIRED BY PUBLICLY TRADED COMPANIES UNDER RULE 7.2.6R OF THE UK LISTING AUTHORITY'S DISCLOSURE GUIDANCE AND TRANSPARENCY RULES

The following disclosures are made pursuant to Rule 7.2.6.R of the UK Listing Authority's Disclosure Guidance and Transparency Rules (DTR). As at 31 December 2020:

- a) Details of significant direct or indirect holdings of securities of the Company are set out in the Directors Report outlined in this document. The Company is not aware of any agreements between shareholders which may result in restrictions on the transfer of securities or on voting rights.
- b) There are no persons who hold securities carrying special rights regarding control of the Company.
- c) All ordinary shares carry one vote per share without restriction.
- d) The Company's rules about the appointment and replacement of Directors are contained in the Company's constitution and accord with the Companies Act 2006. Amendments to the Company's constitution must be approved by the Company's shareholders by passing a special resolution.
- e) The Company may exercise in any manner permitted by the Companies Act 2006 any power which a public company limited by shares may exercise under the Companies Act 2006. The business of the Company is managed by or under the direction of the Directors. The Directors may exercise all the powers of the Company except any powers that the Companies Act 2006 or the constitution requires the Company to exercise.
- f) Subject to any rights and restrictions attached to a class of shares and in compliance with the Companies Act 2006, the Company may allot and issue unissued shares and grant options over unissued shares, on any terms, at any time and for any consideration, as the Directors resolve. This power of the Company can only be exercised by the Directors. The Company may reduce its share capital and buy-back shares in itself on any terms and at any time. However, the Companies Act 2006 sets out certain procedures which must be followed in relation to reductions in share capital and the buy-back of shares.

## **DIRECTORS REPORT**

### **Assessment of the impact of COVID-19**

The COVID-19 virus has swept the globe and has claimed many thousands of lives. It is clear that the pandemic has had a far more severe impact on markets than previous virus outbreaks, with governments having taken strict measures to contain the virus.

Despite the risks of a global recession with associated volatility in world stock markets, the Company believes that healthcare as a defensive sector should fare better than other parts of the economy and it does not believe that the recent outbreak of COVID-19 pandemic will have an adverse effect on the Company's operations. Indeed, the Company has raised substantial funds during the pandemic to enable it to expedite development of TZLS-501 as well as other initiatives within its project pipeline.

### **Disclosure of information to auditor**

So far as the Directors are aware, there is no relevant audit information of which the Company's auditor is unaware, and they have taken all steps that they ought to have taken as Directors in order to make themselves aware of any relevant audit information and to establish that the Company's auditors are aware of that information.

### **Auditor**

Mazars LLP have indicated their willingness to continue in office as auditor for another year. In accordance with section 489 of the Companies Act 2006, a resolution proposing that Mazars LLP be reappointed as auditors of the Company will be put to the Annual General Meeting.

### **Future developments**

The Executive Chairman's Statement on pages 2 to 7 provides a summary of future developments of the Group.

### **Research and development activities**

The research and development activities of the Group are described in the Executive Chairman's Statement on page 2 to 7.

### **Greenhouse Gas Emissions**

The Companies Act 2006 (Strategic Report and Directors' Reports) Regulations 2013 require companies listed on the Main Market of the London Stock Exchange to report on the greenhouse gas emissions for which they are responsible.

We are a company with a small number of employees. We have serviced offices and we currently outsource our research, development, testing and manufacturing activities. As a result, we do not emit greenhouse gases from our own activities, nor do we purchase electricity, heat or steam for our own use. (Scope 1 and scope 2 disclosures).

Accordingly, there are no greenhouse gas emissions to report from the Company's operations, nor does it have responsibility for any other emissions. Further, for the same reason, the Company considers that it is a 'low energy user' under the Streamlined Energy & Carbon Reporting regulations and therefore a disclosure on energy and carbon emissions is not required.

### **Post balance sheet events**

On 4 January 2021, the Company announced that it had completed its clinical study in Brazil investigating nasally administered Foralumab, its proprietary human monoclonal antibody, either alone or in combination with orally administered dexamethasone in COVID-19 patients.

On 13 January 2021, the Company announced the appointment of Dr Neil Graham MBBS, MD, MPH as Chief Medical Officer.

On 20 January 2021, the Company announced the cancellation of admission of its Ordinary Shares to trading on AIM and admission to listing of its ordinary shares on the standard listing segment of the Official List of the Financial Conduct Authority and admission to trading on the main market for listed securities of London Stock Exchange plc. The last day of trading of the Company's Ordinary Shares on AIM was 20 January 2021 and the AIM Delisting was

## DIRECTORS REPORT

effective from 7.00 am 21 January 2021. Admission of shares to the Official List and commencement of dealing in the Ordinary Shares of the Company on the Main Market was effective from 8.00 am on 21 January 2021.

On 5 February 2021, the Company announced the appointment of Dr Thomas Adams, Ph.D. as an executive director. Dr Adams assumed the position of Head of Drug Development with immediate effect and his executive role is to manage and oversee all matters relating to the Company's pre-clinical and clinical drug development programs and associated intellectual property.

On 30 March 2021, the Company announced that the U.S. Food and Drug Administration (FDA) has allowed evaluation of nasal administration with Foralumab, a fully human anti-CD3 monoclonal antibody, in a secondary progressive multiple sclerosis (SPMS) patient at the Brigham and Women's Hospital (BWH), Harvard University, Boston, MA. This patient will be treated under an Individual Patient Expanded Access IND. This is the first time a nasally administered antibody will be administered to a patient with SPMS. The treatment is planned to start in the third quarter of 2021 and will continue for six months. Investigators at BWH will follow this patient with detailed routine safety, neurological, imaging and PET studies to evaluate microglial imaging. Modification of immunological and neurodegenerative markers is part of standard investigations that will be conducted at the BWH.

### Financial instruments

The use of financial instruments is considered by the Board and the exposure of the Group to price, credit, liquidity and cash flow risks are considered. Details of the risks and mitigation can be found in the Strategic Report on pages 9 to 11, and at note 2 to the financial statements.

*Willy Simon*

By order of the Board

Mr Willy Simon  
May 17 2021  
3rd Floor, 11-12 St James's Square, London, SW1Y 4L

## DIRECTORS REMUNERATION REPORT

### Letter from the Chair of the Remuneration Committee

Dear Shareholders,

On behalf of the Remuneration Committee, I am pleased to present our Directors' Remuneration Report for the year ended December 31, 2020 which will be subject to an advisory vote under a resolution to be proposed at the 2021 Annual General Meeting ("AGM"). Shareholders approved the Remuneration Policy at the 2018 AGM.

I hope that you will be supportive of our remuneration approach and will vote in favour of the Directors' Remuneration Report.

### Key activities and decisions in the year ended December 31, 2020

Since January 1, 2020, the Committee has undertaken the following key decisions and activities.

- The Committee reviewed the compensation paid to the Executive Chairman which had not been reviewed since it was fixed in June 2016. Looking at various reports regarding compensation for the role of Executive Chairman across both Europe and the US, it was considered appropriate that the compensation for this role was revised.

The Committee acknowledged that a realisation bonus due to the Executive Chairman had become payable due to the fundraise that took place on August 5, 2020 and satisfied the cash bonus with a non-cash award payable in shares.

- Resolved that Dr Howard Weiner, a key partner, be awarded an additional option award, in addition to having amendments made to existing performance conditions on an existing award, in order to further promote the success of the Company.

The Company has made significant progress during 2020 in the clinical development on Foralumab, with the completion of Phase I clinical trials for the first in-human evaluation of the nasal and oral administration of Foralumab and the completion of Phase 2a trials in Milciclib, along with the strengthening of the financial position of the Company through fundraising.

I hope that you remain supportive of our remuneration approach and will vote in favour of the Directors' Remuneration Report.

Yours faithfully,

*Willy Simon*

Willy Simon  
Chair of the Remuneration Committee  
May 17 2021



## DIRECTORS REMUNERATION REPORT

### Annual report on Remuneration

#### Single total figure of remuneration of each Director (Audited)

The Directors received the following remuneration for the years ended December 31, 2020 and December 31, 2019:

Year Ended December 31, 2020 £'000	Base Salary	Bonus	Share-based payment <sup>(3)</sup>	Other <sup>(4)</sup>	2020 Total	Total fixed remuneration	Total variable remuneration
<b>Executive</b>							
Gabriele Cerrone	133	10,357 <sup>(5)</sup>	121	-	10,601	133	10,468
Kunwar Shailubhai <sup>(5)</sup>	468	164	1,611	14	2,257	482	1,775
<b>Non - Executive</b>							
Willy Simon	38	-	24	2	64	40	24
Gregor MacRae <sup>(1)</sup>	21	-	-	-	21	21	-
John Brancaccio <sup>(2)</sup>	17	-	24	-	41	17	24
<b>Total</b>	<b>677</b>	<b>10,521</b>	<b>1,780</b>	<b>16</b>	<b>12,994</b>	<b>693</b>	<b>12,301</b>

Year Ended December 31, 2019 £'000	Base Salary	Bonus	Share-based payment <sup>(3)</sup>	Other <sup>(4)</sup>	2019 Total	Total fixed remuneration	Total variable remuneration
<b>Executive</b>							
Gabriele Cerrone	80	143 <sup>(6)</sup>	296	-	519	80	439
Kunwar Shailubhai <sup>(7)</sup>	470	159	695	32	1,356	502	854
<b>Non - Executive</b>							
Willy Simon	38	-	-	-	38	38	-
Leopoldo Zambeletti <sup>(8)</sup>	-	-	-	-	-	-	-
Riccardo Dalla Favera <sup>(9)</sup>	2	-	-	-	2	2	-
<b>Total</b>	<b>590</b>	<b>302</b>	<b>991</b>	<b>32</b>	<b>1,915</b>	<b>622</b>	<b>1,293</b>

(1) Resigned 18th June 2020

(2) Appointed 20<sup>th</sup> July 2020

(3) Shares based payments represent the fair value of options that vested during the years ended December 31, 2020 and December 31, 2019.

(4) Other benefits represent healthcare benefits and pension contributions.

(5) This bonus includes a £10.29m realisation bonus which became payable on 5<sup>th</sup> August 2020

(6) Bonus covers the period June 9, 2016 to December 31, 2019

(7) Kunwar Shailubhai's base salary is \$600,000. Any variation is due to exchange rates

(8) Resigned 20<sup>th</sup> November 2019

(9) Resigned 7<sup>th</sup> February 2019

No payments were made towards a pension plan for our executive directors, £2,800 was made for our salaried non-executive directors, who receives the same pension benefit as the UK based employees, namely a matching contribution of 6% of salary, if a 3% minimum contribution is made.

## DIRECTORS REMUNERATION REPORT

### Statement of Directors' Shareholding and Share Interests (Audited)

The table below details the total number of shares owned (including their beneficial interests), the total number of share options held and the number of share options vested but not yet exercised as at December 31, 2020:

Year Ended December 31, 2020	Shares	Options – not yet vested	Options – vested not yet exercised	Total (Shares and options)
<b>Executive</b>				
Gabriele Cerrone	66,304,893	3,259,403	1,830,775	71,395,071
Kunwar Shailubhai	405,000	4,700,000	3,900,000	9,005,000
<b>Non - Executive</b>				
Willy Simon	16,500	-	250,000	266,500
John Brancaccio	-	-	250,000	250,000
<b>Total</b>	<b>66,726,393</b>	<b>7,959,403</b>	<b>6,230,775</b>	<b>80,916,571</b>

The interests of the Directors in the Company's share options are as follows:

Director	Granted	Date of grant	Price per share £	Vesting Criteria	Expiry Date
Gabriele Cerrone	1,830,775	26 January 2016	0.35	Immediate	25 June 2024
	3,259,403*	6 May 2020	0.35	weighted average of an ordinary share must be greater than £3 (or ADS price exceeds \$6) for 120 consecutive dealing days	5 May 2028
Kunwar Shailubhai	2,500,000*	6 May 2020	0.35	Fully vested	5 May 2028
	1,400,000*	6 May 2020	0.35	Fully vested as performance criteria met	5 May 2030
	4,700,000*	6 May 2020	0.35	25 per cent. will vest on each of 6 May 2021, 2022, 2023 and 2024	5 May 2030
Willy Simon	250,000	20 August 2020	1.475	5% of the options vest each year PROVIDED THAT total shareholder return (as set out in the annual report) is equal to or greater than 10%. If the total shareholder return target is not met in any single year but, in any subsequent year or years, the total shareholder return criteria is met on an aggregated basis, the vesting condition for those aggregated periods shall be deemed satisfied.	19 August 2030
John Brancaccio	250,000	20 August 2020	1.475	5% of the options vest each year PROVIDED THAT total shareholder return (as set out in the annual report) is equal to or greater than 10%. If the total shareholder return target is not met in any single year but, in any subsequent year or years, the total shareholder return criteria is met on an aggregated basis, the vesting condition for those aggregated	19 August 2030

## DIRECTORS REMUNERATION REPORT

				periods shall be deemed satisfied.	
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- A resolution was passed at a General Meeting of shareholders on May 6, 2020 to favourably reprice these options to £0.35.

### Annual performance bonus – 2020

In 2020, all employees were eligible for an annual discretionary cash bonus, whereby performance objectives are established at the beginning of the financial year by reference to suitably challenging corporate goals.

In relation to the Directors, Kunwar Shailubhai's bonus was fixed at 35% of salary for 2020. Gabriele Cerrone's on-target bonus for 2020 was 50% of salary.

In addition to the target bonus mentioned above, Gabriele Cerrone also had a realisation bonus in his contract whereby he was entitled to a realisation bonus amount equal to the Enterprise Value multiplied by 2.5% in the event of a new equity capital raise in excess of £20,000,000. This bonus became payable upon a £44m fundraise carried out on August 5, 2020. The Company equated its market capitalisation on this date to the enterprise value, resulting in a bonus payment of £10,290,230. Gabriele Cerrone agreed to receive this bonus in the form of equity, amounting to 4,763,995 shares. The number of shares to be issued is fixed.

For all other staff (other than the Executive Directors and Non-Executive Directors) the maximum bonus opportunities ranged from 10% to 20% of salary. Bonus payments are not pensionable.

For 2020 for all staff (other than the Executive Directors and Non-Executive Directors) 100% of the annual bonus was by reference to individual goals, which are based on corporate goals.

Gabriele Cerrone is also eligible to receive an additional realisation bonuses as follows:

In the event that, during this Agreement, either: (i) there is a sale, in one or a series of transactions, of all or substantially all of the assets (calculated on the basis of book values) of the Group (or a licence of the same on an exclusive or non-exclusive basis), where the Enterprise Value equals or exceeds £300,000,000; or (ii) there is either a change of control where the Enterprise Value equals or exceeds £300,000,000, the Chairman will be entitled to receive an additional Realisation Bonus in the amount equal to the Enterprise Value multiplied by three and a half (3.5) per cent.

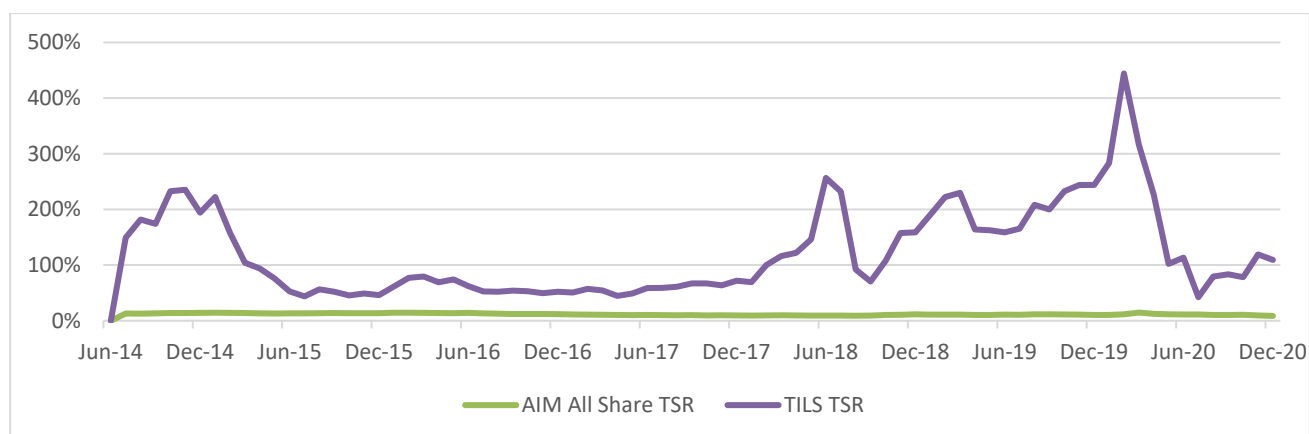
The Enterprise Value means: (i) in the case of a change of control resulting in consideration payable to the Group (for example, on a sale of its assets or licensing transaction), the total cash and non-cash consideration received by the Group; or (ii) in the case of a change of control resulting in consideration payable to the shareholders of the ordinary shares in the issued share capital of the Group from time to time, the total cash and non-cash consideration payable to the Shareholders.

### Total Shareholder Return

The graph below shows the Company's performance, measured by total shareholder return, for UK ordinary shares listed on AIM: TILS) against the AIM All Share Index. The AIM All Share Index has been selected for this comparison because Tiziana Life Sciences PLC has been trading on this exchange for five years and the AIM All Share is considered to be the most suitable comparator index.

### Total Shareholder Return (Source: Investing.com)

## DIRECTORS REMUNERATION REPORT



### Percentage change in remuneration of the Directors and employees

Set out below is the change over the prior period in base salary, benefits, pension and annual performance bonus for the CEO, for all the directors and the Company's employees. Only directors in office during any part of the 2020 year have been included below.

	Salary % change 2019 vs 2020	Benefits % change 2019 vs 2020	Bonus % change 2019 vs 2020
Kunwar Shailubhai (CEO)	0%	0%	0%
Gabriele Cerrone (Chairman)	67%	See note 2	67% (see note 1)
Willy Simon	0%	0%	0%
John Brancaccio	See note 3	See note 2	See note 3
Gregor MacRae	See note 3	See note 2	See note 3
All employees excluding directors	<b>16%</b>	See note 4	<b>16%</b>

- (1) For comparison purposes, Gabriele Cerrone's realisation bonus has been excluded
- (2) John Brancaccio and Gregor MacRae did not receive any benefits in 2020. Gabriele Cerrone and Willy Simon did not receive any benefits in 2020 or 2019.
- (3) John Brancaccio and Gregor MacRae did not receive any salary or bonus in 2019.
- (4) All average employees did not receive taxable benefits, so a comparison is not possible.

The following table sets out the Company's performance objectives for 2021.

Objective Weighting	Weighting
Orally administered Foralumab for the treatment of Crohn's disease milestone delivery	30%
Intranasal administration of Foralumab milestone delivery (including COVID 19 inpatients and outpatients)	30%
Progress the clinical development for our lead oncology candidate Milciclib in combination with other therapeutics for KRAS+ NSCLC.	15%

**DIRECTORS REMUNERATION REPORT**

Achievement of financial targets	10%
New business development deals	5%
Secure additional funding	10%
	<b>100%</b>

Specific targets are commercially sensitive and therefore are not disclosed in advance. However, full details of the targets and performance against them will be disclosed when they are no longer considered commercially sensitive.

**Payments to past directors (audited)**

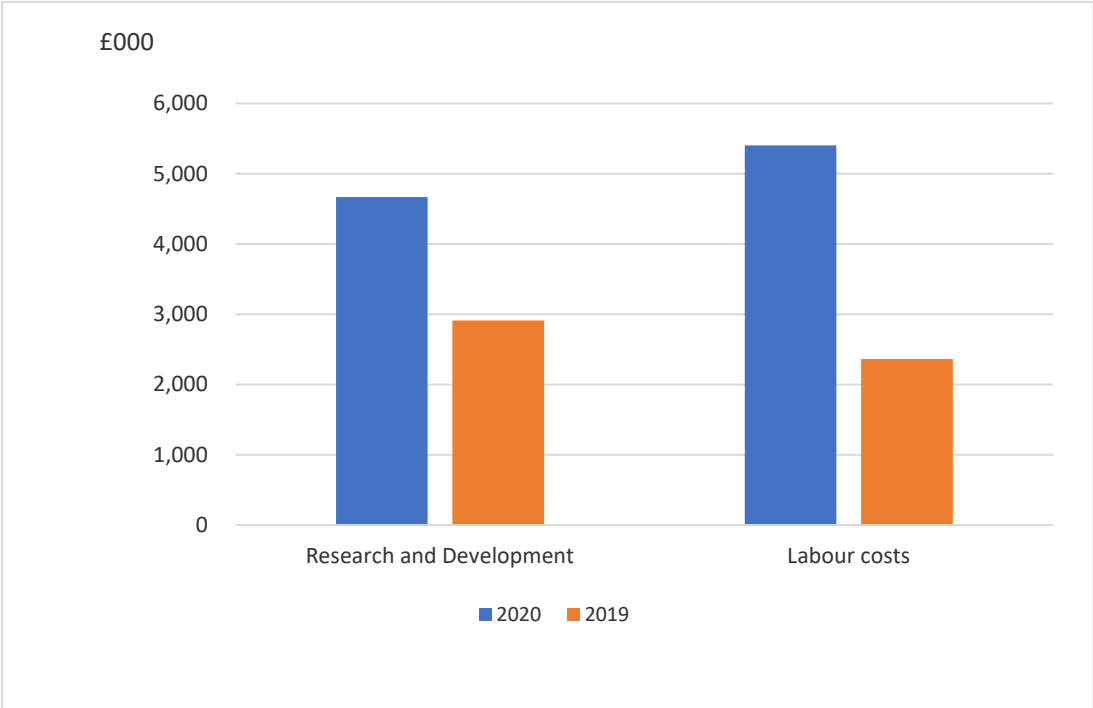
In the period there were no payments to past Directors.

**Payments for loss of office (audited).**

No payments were made to Directors for loss of office in the period.

**Relative Importance of spend on pay**

The Committee considers the company’s research and development expenditure relative to salary expenditure for all employees, to be the most appropriate metric for assessing overall spend on pay due to the nature and stage of the company’s business. Dividend distribution and share buy-back comparators have not been included as the company has no history of such transactions. The graph below illustrates the gross pay to all employees per year as compared to research and development expenditure and illustrates the year-on-year change.



# DIRECTORS REMUNERATION REPORT

## Employment conditions across the Group

The Committee is kept regularly updated on pay and conditions across the Group, although when setting the Directors’ remuneration policy, the wider employee group is not formally consulted. In determining any adjustments to the pay of the Executive Directors and the senior executive salaries, the Committee considers the increases to pay levels across the broader employee population.

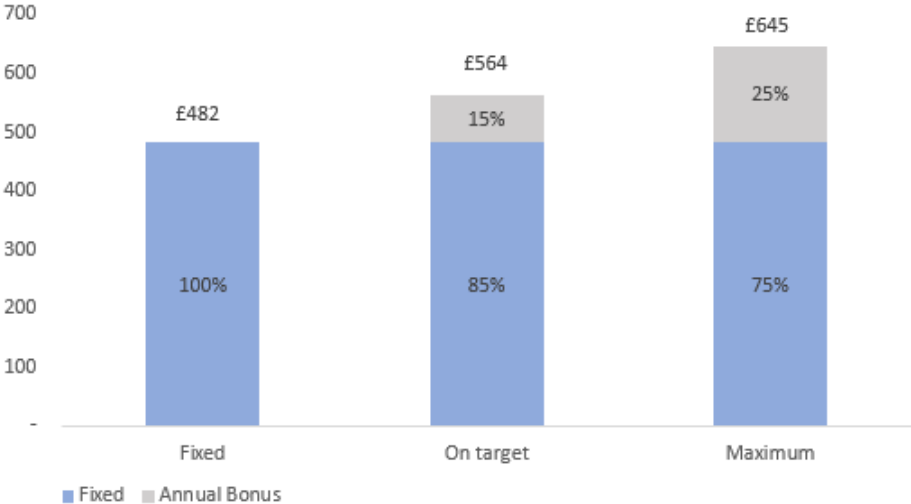
## Consideration of shareholder views

The Committee considers shareholder feedback received in relation to the Annual General Meeting each year at its first meeting following the Annual General Meeting. This feedback, as well as any additional feedback received during other meetings with shareholders and representative bodies, is then considered when reviewing remuneration policy. When any material changes are proposed by the Group to the remuneration policy, the Committee will consult major shareholders.

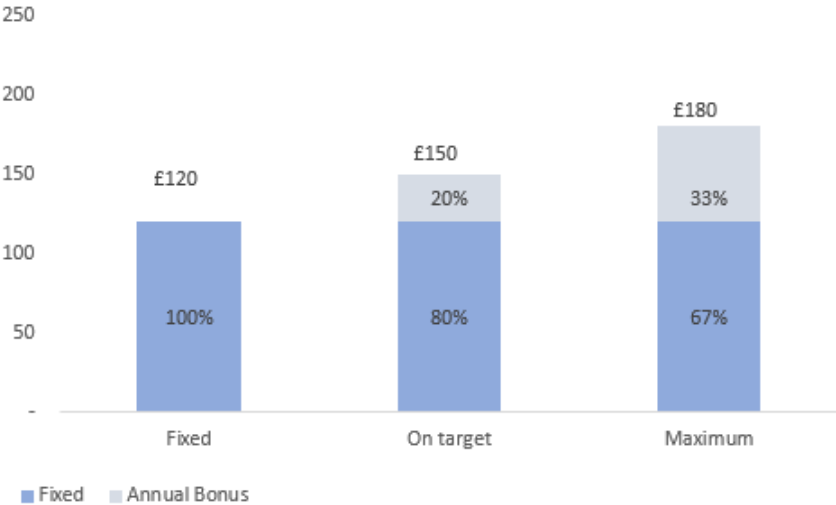
## Illustration of application of remuneration policy

The charts below set out the minimum (i.e. ‘fixed’) remuneration receivable by each Executive Director as at the date of this Annual Report, as well as the potential remuneration for ‘on-target’ and ‘maximum’ performance, as a result of the remuneration paid in or awarded for the year ending December 31, 2021.

Chief Executive (£000s)



Chairman (£000s)



## DIRECTORS REMUNERATION REPORT

The scenarios set out in the above charts reflect or assume the following:

- 'Fixed' remuneration comprises:
  - base salary and
  - the estimated value of taxable benefits to be provided in 2021

A base salary of £120,000 for the Chairman for the full 2021 financial year (although such salary will be effective from 1 August 2020).

- The 'on-target' remuneration assumes an annual bonus payment of 50% of the maximum opportunity.
- The 'maximum' remuneration assumes maximum performance is achieved and therefore awards under the annual bonus pay out at their maximum levels.

### Structure and role of Remuneration Committee

The Remuneration Committee of the Board comprises of John Brancaccio and Willy Simon. It is chaired by Willy Simon, and is responsible for:

- i. The review of the performance of the executive directors;
- ii. Recommendations to the Board on matters relating to the remuneration and terms of service of the executive directors; and
- iii. Recommendations to the Board on proposals for the granting of share options and other equity incentives pursuant to any share option scheme or equity incentive scheme in operation from time to time.

In making their recommendations the Remuneration Committee will have due regard to the interests of the Shareholders and the performance of the Company.

### Directors' remuneration policy

The Policy was approved (with no significant vote against) by the Company's shareholders at the 2019 AGM and will remain in force for three years from that date (until the AGM in 2022), or until a revised Remuneration Policy is approved by shareholders.

The Company's policy is to maintain levels of remuneration sufficient to attract, motivate and retain senior executives of the highest calibre who can deliver growth in shareholder value. Executive Director's remuneration currently consists of basic salary and benefits. An annual bonus, and long-term incentives will be introduced in line with the Company's expansion. The Company will seek to strike an appropriate balance between fixed and performance-related reward so that the total remuneration package is structured to align a significant proportion to the achievement of performance targets, reinforcing a clear link between pay and performance. The performance targets for staff, senior executives and the Executive Directors will be aligned to the key drivers of the business strategy, thereby creating a strong alignment of interest between staff, Executive Directors and shareholders. The Remuneration Committee will continue to review the Company's remuneration policy and make amendments, as and when necessary, to ensure it remains fit for purpose and continues to drive high levels of executive performance and remains both affordable and competitive in the market.

### Policy Table

#### Element of reward - Base Salary

<b>Purpose and Link to Strategy</b>	To provide fixed remuneration to <ul style="list-style-type: none"><li>■ help recruit and retain key individuals;</li><li>■ reflect the individual's experience, role and contribution within the Company.</li></ul>
<b>Operation</b>	The Remuneration Committee considers a number of factors when setting salaries, including: <ul style="list-style-type: none"><li>■ scope and complexity of the role</li><li>■ the skills and experience of the individual</li><li>■ salary levels for similar roles within the industry</li><li>■ pay elsewhere in the Company</li></ul> Salaries are reviewed, but not necessarily increased, annually.

## DIRECTORS REMUNERATION REPORT

<b>Performance conditions</b>	None.
<b>Maximum opportunity</b>	Salary increases are normally made with reference to the average increase for the wider Company. The Board retains discretion to make higher increases in certain circumstances, for example, following an increase in the scope and/or responsibility of the role or the development of the individual in the role or by benchmarking.

### Element of reward- Other benefits

<b>Purpose and Link to Strategy</b>	To provide a basic benefits package.
<b>Operation</b>	The Company provides Executive Directors with medical insurance for themselves and their family.
<b>Performance conditions</b>	None.
<b>Maximum opportunity</b>	Maximum opportunity will be whatever it costs to provide the benefit.

### Element of reward - Annual Bonus

<b>Purpose and Link to Strategy</b>	To incentivise and reward the achievement of annual financial, operational and individual objectives which are key to the delivery of the Company's short-term strategy.
<b>Operation</b>	<ul style="list-style-type: none"> <li>Executive Directors and staff are eligible to participate in a discretionary bonus plan.</li> <li>The Remuneration Committee will determine on an annual basis the level of deferral, if any, of the bonus payment into Company shares.</li> <li>Maximum bonus levels and the proportion payable for on target performance are considered in the light of market bonus levels for similar roles among the industry sector.</li> <li>Bonuses are not pensionable.</li> <li>The Remuneration Committee sets targets which require appropriate levels of performance, considering internal and external expectations of performance.</li> <li>As soon as practicable after the year-end, the Remuneration Committee meets to review performance against objectives and determines payout levels.</li> <li>From 2019 in terms of bonus targets a balanced scorecard approach will be operated which focuses on a mixture of strategic, operational, financial and non-financial metrics.</li> </ul>
<b>Performance conditions</b>	<ul style="list-style-type: none"> <li>At least 50% of the award will be assessed against Company metrics including operational, financial and non-financial performance. The remainder of the award will be based on performance against individual objectives.</li> <li>A scale between 0% and 100% of the maximum award is paid dependent on the level of performance.</li> </ul>
<b>Maximum opportunity</b>	The maximum potential bonus entitlement for Executive Directors under the plan will be equal to 50% of the base salary.



## DIRECTORS REMUNERATION REPORT

### **Element of reward - Long Term Incentive Plan (LTIP)**

<b>Purpose and Link to Strategy</b>	<ul style="list-style-type: none"> <li>To incentivise and reward the creation of long-term shareholder value.</li> <li>To align the interests of the Executive and Non- Executive Directors with those of shareholders.</li> </ul>
<b>Operation</b>	<p>Under the terms of the non-tax advantaged share option plan (the "Share Option Plan"), the Remuneration Committee may issue options over shares up to 15% of the issued share capital of the Company from time to time. Directors and employees are eligible for awards.</p> <ul style="list-style-type: none"> <li>The exercise of options may be subject to the satisfaction of such performance conditions, if any, as may be specified and subsequently varied and/or waived by the Remuneration Committee.</li> <li>The Remuneration Committee determines on an annual basis, and from time to time as needed (i.e., new employee or promotion), the type of awards to be granted to executives and other employees under the plan.</li> </ul>
<b>Performance conditions</b>	<p>Vesting of the awards is dependent on financial, operational and/or share price measures, as set by the Remuneration Committee, which are aligned with the long-term strategic objectives of the Company. The relevant performance conditions will be set by the Remuneration Committee on the award of each grant but will include a mixture of strategic, operational, financial and non-financial metrics.</p>

#### **Notes on Table**

The Remuneration Committee may make minor amendments to the Policy set out above for regulatory, exchange control, tax or administrative purposes or to take account of a change in legislation without obtaining shareholder approval for that amendment. Any major changes will be put to a shareholder vote at the next AGM or an EGM.

The Policy was approved by a Shareholder vote at the 2019 AGM and, it remains in force until the AGM in 2022 with no requirement to vote again on the Policy in the intervening years provided that no changes are proposed.

#### **Policy on payment for loss of office**

In the event that the employment of an Executive Director is terminated, any compensation payable will be determined in accordance with the terms of the service contract between the Company and the employee, as well as the rules of any incentive plans. Notice periods are set at up to a maximum of twelve months by either party.

The Company considers a variety of factors when considering leaving arrangements for an Executive Director, including individual and business performance, the obligation for the Director to mitigate loss (for example by gaining new employment) and other relevant circumstances (e.g. ill health).

If the Executive Director's employment is terminated by the Company, the Executive Director may receive a time pro-rated bonus to the period worked subject to performance in that period, subject to the Remuneration Committee's discretion.

The treatment of outstanding share awards is governed by the relevant share plan rules. The following table summarises the leaver provisions of share plans under which Executive Directors may currently hold awards.

<b>Leaving Event</b>	<b>Time period</b>	<b>Conditions</b>
Injury, disability, ill-health, redundancy	Option may be exercised within 3 months of leaving.	<p>Exercise and time vesting provisions per the option certificate.</p> <p>Board can waive if satisfied that such waiver is not rewarding failure.</p>
Death	Option may be exercised by personal representatives within 12 months of death.	<p>Exercise and time vesting provisions per the option certificate.</p> <p>Board can waive if satisfied that such waiver is not rewarding failure.</p>

**DIRECTORS REMUNERATION REPORT**

Resignation or any other reason not mentioned above.	Lapse of option unless Board exercises discretion to allow exercise of option in which case within 3 months of leaving/notice.	If allowed to exercise; Exercise and time vesting provisions per the option certificate. Board can waive if satisfied that such waiver is not rewarding failure.
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**Annual report on approach to remuneration on recruitment**

In determining remuneration for new appointments to the Board, the Board will consider all relevant factors including, but not limited to, the calibre of the individual and their existing package, the external market and the existing arrangements for the Company's current Executive Directors, with a view that any arrangements offered are in the best interests of the Company and shareholders and without paying any more than is necessary.

Where the new appointment is replacing a previous Executive Director, salaries and total remuneration opportunity may be higher or lower than the previous incumbent. If the appointee is expected to develop into the role, the Board may decide to appoint the new Executive Director to the Board at a lower than typical salary. Larger increases (above those of the wider company) may be awarded over time to move closer to the market level as their experience develops.

Benefits and other elements of remuneration will normally be limited to those outlined in the remuneration policy table above. However, additional benefits may be provided by the Company where the Board considers it reasonable and necessary to do so.

It is expected that the structure and various pay elements would reflect those set out in the policy table above. However, the Board recognises that, as an independent life sciences company, it is competing with global firms for its talent. As a result, the Board considers it important that the recruitment policy has sufficient flexibility in order to attract the calibre of individual that the Company requires to grow a successful business. The Company recognises that in many cases, an external appointee may forfeit significant cash bonuses and/or share awards from a prior employer. The Board believes that it needs the ability to compensate new hires for bonuses and/ or incentive awards lost on joining the Company. The Board will use its discretion in settling any such compensation, which will be decided on a case-by-case basis, provided that in no event shall such compensation exceed the value of compensation forfeited by the external appointee, as confirmed by the appointee in a written agreement with the Company.

# INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF TIZIANA LIFE SCIENCES PLC

## Opinion

We have audited the financial statements of Tiziana Life Sciences Plc (the 'Parent Company') and its subsidiaries (the 'Group') for the year ended 31 December 2020 which comprise the Consolidated Statement of Comprehensive Income; the Consolidated and Company Statements of Financial Position; the Consolidated and Company Statements of Cash Flows; the Consolidated and Company Statements of Changes In Equity and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and international accounting standards in conformity with the requirements of the Companies Act 2006 and, as regards the parent company financial statements, as applied in accordance with the provisions of the Companies Act 2006 and, as regards the Group financial statements, international financial reporting standards adopted pursuant to Regulation (EC) No 1606/2002 as it applies in the European Union.

In our opinion, the financial statements have been prepared in accordance with the requirements of the Companies Act 2006 and:

- give a true and fair view of the state of the Group's and of the parent company's affairs as at 31 December 2020 and of the Group's loss for the year then ended; and
- have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 and, as regards the Group financial statements, international financial reporting standards adopted pursuant to Regulation (EC) No 1606/2002 as it applies in the European Union.

## Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the Group and the parent company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, as applied to public interest entities and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

## Conclusions relating to going concern

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

In addition to those matters set out in the "Key audit matters" section below, we identified going concern of the Group and of the parent company as a key audit matter. As detailed in the financial statements and the Strategic Report, the Group and Parent Company are pre-revenue and its business model requires significant ongoing expenditure on research and development. For the year ended 31 December 2020, the Group incurred losses after taxation of £20,348,000. Although the net assets of the Group at 31 December 2020 are £35,419,000, with a cash position of £48,217,000, the forecast prepared by management indicate that further funds will be required by the end of 2022, in order to support the ongoing researches.

Our audit procedures to evaluate the directors' assessment of the Group's and the parent company's ability to continue to adopt the going concern basis of accounting included but were not limited to:

- Undertaking an initial assessment at the planning stage of the audit to identify events or conditions that may cast significant doubt on the Group's and the parent company's ability to continue as a going concern;
- Obtaining an understanding of the relevant controls relating to the directors' going concern assessment;
- Making enquiries of the directors to understand the period of assessment considered by them, the assumptions they considered and the implication of those when assessing the Group's future financial performance;

## INDEPENDENT AUDITOR’S REPORT TO THE MEMBERS OF TIZIANA LIFE SCIENCES PLC

- Challenging the appropriateness of the directors’ key assumptions in their cash flow forecasts, as described in Note 2, by reviewing supporting and contradictory evidence in relation to these key assumptions and assessing the directors’ consideration of severe but plausible scenarios;
- Testing the accuracy and functionality of the model used to prepare the directors’ forecasts;
- Engaging in regular discussions with the directors regarding the status of negotiations in respect of new financing options;
- Assessing and evaluating key assumptions and mitigating actions put in place in response to COVID-19; and
- Evaluating the appropriateness of the directors’ disclosures in the financial statements on going concern

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the Group’s and the parent company’s ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

### Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

We summarise below the key audit matters in forming our audit opinion above, together with an overview of the principal audit procedures performed to address each matter and key observations arising from those procedures. The matters set out below are in addition to going concern which, as set out in the “Conclusions relating to going concern” section above, was also identified as a key audit matter.

These matters, together with our findings, were communicated to those charged with governance through our Audit Completion Report.

Key Audit Matter	How our scope addressed this matter
<p><b>Valuation and accounting of options, warrants, and convertible loan notes</b></p> <p>The Group operates share-based payments arrangements to remunerate directors and employees in the form of share options. Additionally warrants were granted as part of incentives attached to the convertible loans notes issued in 2019. These warrants are exercisable over a five year period.</p> <p>With regards to the convertible loan notes, IAS 32 requires liability and equity components to be presented separately in the Statement of Financial Position. As a result, particular attention is required when reviewing the contractual obligations of the notes in order to conclude as to their accounting as debt or equity classified.</p> <p>The nature of certain of the Group’s options, warrants and convertible loan notes are complex requiring both judgement and probability analysis to determine their valuation and accounting.</p>	<p>Our audit procedures over options, warrants, and convertible loan notes included but were not restricted to:</p> <ul style="list-style-type: none"> <li>• Obtaining management’s valuation of options and warrants, evaluating the appropriateness of management’s model and reviewing for completeness and accuracy of information used;</li> <li>• Obtaining and reviewing the option and warrant agreements for all current year issuances and determined whether or not they were to be accounted for under IFRS 2 Share-Base Payments;</li> <li>• Examining the contractual obligations of the convertible loan note to ensure that management’s accounting for the aforementioned notes under IAS 32 Financial Instruments as debt classified was appropriate;</li> <li>• Reviewing the calculation for convertible debt instruments and ensured the loan note principal and accrued interest are recorded appropriately on the financial statements; and</li> </ul>

## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF TIZIANA LIFE SCIENCES PLC

	<ul style="list-style-type: none"> <li>Reviewing the disclosure in the financial statements to ensure disclosure is sufficient and appropriate.</li> </ul> <p>In performing the work above where appropriate we used internal valuation and technical experts.</p> <p><b>Our observations</b> The audit team have not identified any material issue to be reported.</p>
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### Our application of materiality and an overview of the scope of our audit

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and on the financial statements as a whole. Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

Overall materiality	Group: £698,000 Parent: £335,000
How we determined it	Materiality is based on 6.0% of the Group's and the Parent Company's losses for the year, before the impact of a realisation bonus payable to one of the directors as this is an unusual one-off expense.
Rationale for benchmark applied	We believe that the benchmark of losses is most appropriate for both Group & Parent Company as the users of the accounts are likely to be most concerned with the annual and accumulated losses of the Group and Parent Company and the Group's and Parent Company's ability to continue as a going concern. Losses are also representative of the Group's investment into research and development to deliver its objectives. Having considered factors such as the Group's LSE and NASDAQ listings, we determined materiality at 6.0% of Group and Parent Company's losses for the year to be appropriate.
Performance materiality	Performance materiality is set to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements in the financial statements exceeds materiality for the financial statements as a whole.  Performance materiality was set at £454,000 (£218,000 for the parent company), being 65% of overall materiality.
Reporting threshold	We agreed with the directors that we would report to them misstatements identified during our audit above £20,000 (£10,000 for the parent company) as well as misstatements below that amount that, in our view, warranted reporting for qualitative reasons.

As part of designing our audit, we assessed the risk of material misstatement in the financial statements, whether due to fraud or error, and then designed and performed audit procedures responsive to those risks. In particular, we looked at where the directors made subjective judgements such as making assumptions on significant accounting estimates.

## **INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF TIZIANA LIFE SCIENCES PLC**

We tailored the scope of our audit to ensure that we performed sufficient work to be able to give an opinion on the financial statements as a whole. We used the outputs of a risk assessment, our understanding of the Group and the parent company, its environment, controls and critical business processes, to consider qualitative factors in order to ensure that we obtained sufficient coverage across all financial statement line items.

Our Group audit scope included an audit of the Group and parent financial statements of Tiziana Life Sciences plc. Based on our risk assessment, only the parent company within the Group was subject to full scope audit which was performed by the Group audit team. For the Group's subsidiaries review procedures were performed by the Group audit team as deemed necessary based on Group materiality.

At the parent level we also tested the consolidation process and carried out analytical procedures to confirm our conclusion that there were no significant risks of material misstatement of the aggregated financial information.

### **Other information**

The other information comprises the information included in the annual report other than the financial statements and our auditor's report thereon. The directors are responsible for the other information. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the course of audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

### **Opinions on other matters prescribed by the Companies Act 2006**

In our opinion, the part of the directors' remuneration report to be audited has been properly prepared in accordance with the Companies Act 2006.

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the Strategic Report and the Directors' Report for the financial year for which the financial statements are prepared is consistent with the financial statements and those reports have been prepared in accordance with applicable legal requirements;
- the information about internal control and risk management systems in relation to financial reporting processes and about share capital structures, given in compliance with rules 7.2.5 and 7.2.6 in the Disclosure Guidance and Transparency Rules sourcebook made by the Financial Conduct Authority (the FCA Rules), is consistent with the financial statements and has been prepared in accordance with applicable legal requirements; and
- information about the parent company's corporate governance code and practices and about its administrative, management and supervisory bodies and their committees complies with rules 7.2.2, 7.2.3 and 7.2.7 of the FCA rules.

### **Matters on which we are required to report by exception**

In light of the knowledge and understanding of the Group and the parent company and its environment obtained in the course of the audit, we have not identified material misstatements in;

- the Strategic Report or the Directors' Report; or
- the information about internal control and risk management systems in relation to financial reporting processes and about share capital structures, given in compliance with rules 7.2.5 and 7.2.6 of the FCA Rules

## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF TIZIANA LIFE SCIENCES PLC

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- the parent company financial statements and the part of the directors' remuneration report to be audited are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit; or
- a corporate governance statement has not been prepared by the parent company

### Responsibilities of Directors

As explained more fully in the directors' responsibilities statement set out on pages 18 and 19, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the Group's and the parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or the parent company or to cease operations, or have no realistic alternative but to do so.

### Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below.

Based on our understanding of the Group and the parent company and its industry, we identified that the principal risks of non-compliance with laws and regulations related to the UK tax legislation, employment regulation and health and safety regulation, anti-bribery, corruption and fraud, money laundering, Listing rules, Disclosure Guidance and Transparency Rules, and we considered the extent to which non-compliance might have a material effect on the financial statements.

In identifying and assessing risks of material misstatement in respect to irregularities including non-compliance with laws and regulations, our procedures included but were not limited to:

- At the planning stage of our audit, gaining an understanding of the legal and regulatory framework applicable to the Group and parent company, the structure of the Group, the industry in which they operate and considered the risk of acts by the Group and the parent company which were contrary to the applicable laws and regulations;
- Discussing with the directors and management the policies and procedures in place regarding compliance with laws and regulations;
- Discussing amongst the engagement team the identified laws and regulations, and remaining alert to any indications of non-compliance; and
- During the audit, focusing on areas of laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general commercial and sector experience and through discussions with the directors (as required by auditing standards), from inspection of the company's and Group's regulatory and legal correspondence and review of minutes of directors' meetings in the year. We also

## INDEPENDENT AUDITOR'S REPORT TO THE MEMBERS OF TIZIANA LIFE SCIENCES PLC

considered those other laws and regulations that have a direct impact on the preparation of financial statements, such as the Companies Act 2006 and UK tax legislation.

Our procedures in relation to fraud included but were not limited to:

- Making enquiries of the directors and management on whether they had knowledge of any actual, suspected or alleged fraud;
- Gaining an understanding of the internal controls established to mitigate risks related to fraud;
- Discussing amongst the engagement team the risks of fraud such as opportunities for fraudulent manipulation of financial statements, and determined that the principal risks were related to posting manual journal entries to manipulate financial performance, management bias through judgements and assumptions in significant accounting estimates; and
- Addressing the risks of fraud through management override of controls by performing journal entry testing.

The primary responsibility for the prevention and detection of irregularities including fraud rests with both those charged with governance and management. As with any audit, there remained a risk of non-detection of irregularities, as these may involve collusion, forgery, intentional omissions, misrepresentations or the override of internal controls.

As a result of our procedures, we did not identify any key audit matters relating to irregularities. The risks of material misstatement that had the greatest effect on our audit, including fraud, are discussed under "Key audit matters" within this report.

A further description of our responsibilities is available on the Financial Reporting Council's website at [www.frc.org.uk/auditorsresponsibilities](http://www.frc.org.uk/auditorsresponsibilities).

### **Other matters which we are required to address**

Following the recommendation of the audit committee, we were appointed by the directors on 22 June 2020 to audit the financial statements for the year ending 31 December 2020 and subsequent financial periods. The period of total uninterrupted engagement is 5 years, covering the year ending 31 December 2020.

The non-audit services prohibited by the FRC's Ethical Standard were not provided to the Group or the parent company and we remain independent of the Group and the parent company in conducting our audit.

Our audit opinion is consistent with the additional report to the audit committee.

### **Use of the audit report**

This report is made solely to the parent company's members as a body in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the parent company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the parent company and the parent company's members as a body for our audit work, for this report, or for the opinions we have formed.

*Robert Neate*

Robert Neate (Senior Statutory Auditor) for and on behalf of Mazars LLP

Chartered Accountants and Statutory Auditor

Tower Bridge House

St Katharine's Way

London

E1W 1DD

17 May 2021



**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME  
FOR THE YEAR ENDED 31 DECEMBER 2020**

<b>Continuing Operations</b>	Note	<b>2020</b> £'000	<b>2019</b> £'000
Research and development costs		(4,667)	(2,910)
Operating expenses		(8,724)	(4,864)
Realisation bonus	5	(10,290)	-
Impairment of asset	17	(217)	-
Gain on disposal of Intellectual Property	4	2,074	-
<b>Operating loss</b>	5	<u>(21,824)</u>	<u>(7,774)</u>
Finance costs	10	(243)	(72)
<b>Loss before taxation</b>		<u>(22,067)</u>	<u>(7,846)</u>
Taxation	11	1,719	540
<b>Loss for the year attributable to equity owners</b>		<u>(20,348)</u>	<u>(7,306)</u>
<b>Other comprehensive income that may be classified to profit and loss in subsequent periods</b>			
Exchange differences on translation of foreign operations		<u>186</u>	<u>129</u>
<b>Total comprehensive loss for the year attributable to equity owners</b>		<u>(20,162)</u>	<u>(7,177)</u>
<b>Loss per share</b>			
Basic and diluted (loss) per share on continuing operations	12	<u>(12.0p)</u>	<u>(5.4p)</u>

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION  
AS AT 31 DECEMBER 2020**

	Note	2020 £'000	2019 £'000
<b>ASSETS</b>			
<b>Non-Current assets</b>			
Property, plant and equipment	13	1	5
Finance lease receivable	16	-	113
Intangible asset	14	97	-
Right of use asset	28	262	329
Other non-current assets	17	-	217
<b>Total non-current assets</b>		<u>360</u>	<u>664</u>
<b>Current assets</b>			
Finance lease receivable	16	111	109
Related party receivable	27	270	245
Other receivables	15	576	124
Taxation receivable	11	2,232	513
Cash and cash equivalents		48,217	153
<b>Total current assets</b>		<u>51,406</u>	<u>1,144</u>
<b>TOTAL ASSETS</b>		<u>51,766</u>	<u>1,808</u>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<b>Capital and reserves attributable to equity holders of the company</b>			
Called up share capital	19	5,838	4,099
Share premium		81,227	25,194
Capital reduction reserve	22	31,958	31,183
Shares to be issued reserve (convertible notes)	21	-	1,099
Share based payment reserve (options)	19,22	6,319	3,850
Share based payment reserve (warrants)	19,22	475	1,812
Shares to be issued	5,22	10,290	-
Other reserve	22	(28,286)	(28,286)
Translation reserve		201	15
Retained earnings	22	(62,313)	(43,146)
<b>Total equity</b>		<u>45,709</u>	<u>(4,180)</u>
<b>Liabilities</b>			
<b>Non-Current liabilities</b>			
Lease Liability	27	212	411
<b>Current liabilities</b>			
Trade and other payables	26	4,095	4,851
Lease liability	28	195	212
Related party payable	27	1,493	451
Other liabilities		62	63
Total current and non-current liabilities		<u>6,057</u>	<u>5,988</u>
<b>TOTAL EQUITY AND LIABILITIES</b>		<u>51,766</u>	<u>1,808</u>

The financial statements were approved by the Board of directors and authorised for issue on May 17 2021.

*Willy Simon*

Mr W Simon  
Director

Company Number: 03508592 (England and Wales)

**COMPANY STATEMENT OF FINANCIAL POSITION  
AS AT 31 DECEMBER 2020**

	Notes	2020 £'000	2019 £'000
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible asset		97	-
Other non-current assets	16	-	217
<b>Current assets</b>			
Related party receivable	26	244	243
Other receivables	15	434	9
Taxation receivable		1,674	53
Intercompany receivable		39,945	-
Cash and cash equivalents		5,944	116
<b>TOTAL ASSETS</b>		<b>48,338</b>	<b>638</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity Capital and reserves attributable to equity holders of the company</b>			
Called up share capital	18	5,838	4,099
Share premium	23	81,227	25,194
Shares to be issued reserve (convertible notes)	22	-	1,099
Share based payment reserve (options)	20,23	6,384	3,915
Share based payment reserve (warrants)	20,23	537	1,875
Shares to be issued	5,22	10,290	-
Capital reduction reserve	23	31,958	31,183
Retained earnings	23	(91,624)	(69,070)
<b>Total equity</b>		<b>44,610</b>	<b>(1,705)</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	26	2,235	2,091
Related party payable	27	1,494	252
		<b>3,728</b>	<b>2,343</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>48,338</b>	<b>638</b>

The Company reported a loss for the financial year ended 31 December 2020 of £23,735k (2019: £26,683k).

The financial statements were approved by the Board of directors and authorised for issue on May 17 2021.

*Willy Simon*

Mr W Simon  
Director

Company Number: 03508592 (England and Wales)

**CONSOLIDATED STATEMENT OF CASH FLOWS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

	<b>2020</b>	<b>2019</b>
	£'000	£'000
<b>Cash flows from operating activities</b>		
<b>Loss for the year before taxation</b>	(22,067)	(7,846)
Adjustments for:		
Convertible loan interest accrued	216	39
Shares issued in lieu of fees	360	82
Share based payment – options	3,740	992
Share based payment – warrants	20	-
Options forfeited/cancelled in the year	(26)	-
Bonus to be settled in equity	10,290	-
Net (increase) in related party receivables	(24)	(225)
Net increase in related party payables	892	342
Net decrease/(increase) in other receivables	(340)	125
Net (decrease)/increase in trade and other payables	(757)	(17)
Depreciation of property, plant and equipment	4	4
Depreciation of right-of-use asset	67	194
(Gain)/Loss on foreign exchange	185	129
Loss on disposal of right of use asset	-	56
Impairment of SharDNA Spa	217	-
Gain from disposal of intellectual property	(2,074)	-
<b>CASH USED IN OPERATING ACTIVITIES</b>	(9,297)	(6,125)
Cash inflow from taxation	-	800
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<u>(9,297)</u>	<u>(5,325)</u>
<b>Cash flows from investing activities</b>		
Acquisition of property, plant and equipment	(2)	(3)
Acquisition of intangible asset	(97)	-
<b>NET CASH GENERATED FROM INVESTING ACTIVITIES</b>	<u>(99)</u>	<u>(3)</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of ordinary shares	57,283	-
Fundraising costs	(3,136)	-
Proceeds from issuance of convertible loan notes	120	1,473
Proceeds from exercise of warrants	2,682	-
Proceeds from conversion of options	727	-
Repayment of leasing liabilities	(216)	(157)
<b>NET CASH GENERATED FROM FINANCING ACTIVITIES</b>	<u>57,460</u>	<u>1,316</u>
<b>NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS</b>	48,064	(4,012)
Cash and cash equivalents at beginning of year	153	4,165
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<u>48,217</u>	<u>153</u>

**COMPANY STATEMENT OF CASH FLOWS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

	<b>2020</b> £'000	<b>2019</b> £'000
<b>Cash flows from operating activities</b>		
<b>Loss for the year before taxation</b>	(25,356)	(26,683)
Adjustments for:		
Convertible loan interest accrued	216	39
Shares issued in lieu of fees	360	82
Share based payment - options	3,739	992
Share based payment - warrants	20	-
Options forfeited/cancelled in the year	(26)	-
Bonus to be settled in equity	10,290	-
Net (increase) in related party receivables	(1)	(243)
Net increase in related party payables	-	-
Net decrease/(increase) in operating assets/other receivables	(424)	24
Net increase in trade and other payables	1,233	234
Impairment of investment	-	21,966
Impairment of SharDNA Spa	216	-
Gain from disposal of intellectual property	(2,074)	-
<b>CASH USED IN OPERATING ACTIVITIES</b>	(11,806)	(3,589)
Cash inflow from taxation	-	300
<b>NET CASH GENERATED (USED IN)/ GENERATED FROM OPERATING ACTIVITIES</b>	<u>(11,806)</u>	<u>(3,289)</u>
<b>Cash flows from investing activities</b>		
Acquisition of intangible asset	(97)	-
Capital contribution to subsidiaries	-	(1,661)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<u>(97)</u>	<u>(1,661)</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of ordinary shares	17,338	-
Fundraising costs	(3,136)	-
Proceeds from exercise of warrants	2,682	-
Proceeds from issuance of convertible loan notes	120	1,473
Proceeds from conversion of options	727	-
<b>NET CASH GENERATED FROM FINANCING ACTIVITIES</b>	<u>17,731</u>	<u>1,473</u>
<b>NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS</b>	5,828	(3,477)
Cash and cash equivalents at beginning of year	116	3,593
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<u>5,944</u>	<u>116</u>

**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY  
FOR THE YEAR ENDED 31 DECEMBER 2020**

	Share Capital	Share Premium	Capital Reduction Reserve	Share Based Payment Reserve (options) £'000	Share Based Payment Reserve (warrants) £'000	Convertible Loan Note Reserve £'000	Other Reserve £'000	Shares to be issued Reserve £'000	Translation Reserve £'000	Retained Earnings £'000	Total Equity £'000
<b>Balance at 1 January 2019</b>	4,094	25,117	31,183	2,857	1,399	-	(28,286)	-	(113)	(35,840)	411
Issue of share capital (private placement and IPO)	5	77	-	-	-	-	-	-	-	-	82
Warrants issued with CLN	-	-	-	-	413	(413)	-	-	-	-	-
Share based payment (options)	-	-	-	993	-	-	-	-	-	-	992
Convertible loan notes issued	-	-	-	-	-	1,472	-	-	-	-	1,473
Convertible loan note interest	-	-	-	-	-	39	-	-	-	-	39
<b>Total</b>	<b>5</b>	<b>77</b>	<b>-</b>	<b>993</b>	<b>413</b>	<b>1,099</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>2,586</b>
<u>Comprehensive income</u>											
Exchange differences on translating foreign operations									128		129
Comprehensive loss for the year										(7,306)	(7,306)
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>128</b>	<b>(7,306)</b>	<b>(7,177)</b>
<b>Balance as at 31 December 2019</b>	<b>4,099</b>	<b>25,194</b>	<b>31,183</b>	<b>3,850</b>	<b>1,812</b>	<b>1,099</b>	<b>(28,286)</b>	<b>-</b>	<b>15</b>	<b>(43,146)</b>	<b>(4,180)</b>
Issue of share capital (Fundraise & ATM)	1,319	56,964	-	-	-	-	-	-	-	-	58,283
Issue of share capital (Warrants)	191	2,491	-	-	-	-	-	-	-	-	2,682
Issue of share capital (in lieu of fees)	9	351	-	-	-	-	-	-	-	-	360
Issue of share capital (exercise of options)	88	640	-	-	-	-	-	-	-	-	728
Issue of share capital (Loan conversion)	132	1,716	-	-	-	(1,848)	-	-	-	-	-
Cost of fundraise	-	(3,136)	-	-	-	-	-	-	-	-	(3,136)
Convertible loan notes issued	-	-	-	-	-	120	-	-	-	-	120
Convertible loan note interest	-	-	-	-	-	216	-	-	-	-	216
Share based payments charge (warrants)	-	-	-	-	259	(240)	-	-	-	-	19
Share based payment charge (options)	-	-	-	3,740	-	-	-	-	-	-	3,740
Options forfeited/cancelled in the year	-	-	-	(26)	-	-	-	-	-	-	(26)
Exercise of options	-	64	-	(1,245)	-	-	-	-	-	1,181	-
Exercise of warrants	-	943	-	-	(1,596)	653	-	-	-	-	-
Shares issued in lieu of cash for realisation bonus	-	-	-	-	-	-	-	10,290	-	-	10,290
Reduction in share capital	-	(4,000)	4,000	-	-	-	-	-	-	-	-
Capital distribution	-	-	(3,225)	-	-	-	-	-	-	-	(3,225)
<b>Total</b>	<b>1,739</b>	<b>56,033</b>	<b>775</b>	<b>2,469</b>	<b>(1,337)</b>	<b>(1,099)</b>	<b>-</b>	<b>10,290</b>	<b>-</b>	<b>1,181</b>	<b>70,051</b>
<u>Comprehensive loss (Items that will be reclassified to the Statement of Income in future periods)</u>											
Exchange differences on translating foreign operations	-	-	-	-	-	-	-	-	186	-	186

**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY  
FOR THE YEAR ENDED 31 DECEMBER 2020**

Net loss for the year	-	-	-	-	-	-	-	-	-	-	(20,348)	(20,348)
Total Comprehensive loss for the year	-	-	-	-	-	-	-	-	-	186	(20,348)	(20,162)
<b>Balance as at 31 December 2020</b>	5,838	81,227	31,958	6,319	475	-	(28,286)	10,290	201	(62,313)		45,709

**COMPANY STATEMENT OF CHANGES IN EQUITY  
FOR THE YEAR ENDED 31 DECEMBER 2020**

	Share Capital	Share Premium	Capital Reduction Reserve	Share Based Payment Reserve (options)	Share Based Payment Reserve (warrants)	Convertible Loan Note Reserve	Shares to be issued Reserve	Retained Earnings	Total Equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
<b>Balance at 1 January 2019</b>	4,094	25,117	31,183	2,922	1,462	-	-	(42,387)	22,391
<b>Transactions with owners</b>									
Issue of share capital	5	77	-	-	-	-	-	-	82
Share based payment (options)	-	-	-	993	-	-	-	-	993
Convertible loan notes issued	-	-	-	-	-	1,473	-	-	1,473
Convertible loan note interest	-	-	-	-	-	39	-	-	39
Warrants issued with CLN	-	-	-	-	413	(413)	-	-	-
Total transactions with owners	5	77	-	993	413	1,099	-	-	2,587
<b>Comprehensive income</b>									
Comprehensive loss for the year	-	-	-	-	-	-	-	(26,683)	(26,683)
Total comprehensive income	4,099	25,194	31,183	3,915	1,874	1,099	-	(69,070)	(1,706)
<b>Balance as at 31 December 2019</b>									
<b>Transactions with owners</b>									
Issue of share capital (Fundraise & ATM)	1,319	56,964	-	-	-	-	-	-	58,283
Issue of share capital (In lieu of fees)	9	351	-	-	-	-	-	-	360
Cost of fundraise	-	(3,136)	-	-	-	-	-	-	(3,136)
Issue of share capital (Warrants)	191	2,491	-	-	-	-	-	-	2,682
Issue of share capital (Loan conversion)	132	1,716	-	-	-	(1,848)	-	-	-
Issue of share capital (Options)	88	640	-	-	-	-	-	-	728
Convertible loan notes issued	-	-	-	-	-	120	-	-	120
Convertible loan note interest	-	-	-	-	-	216	-	-	216
Share based payments charge (warrants)	-	-	-	-	259	(240)	-	-	19
Share based payment charge (options)	-	-	-	3,740	-	-	-	-	3,740
Options forfeited/cancelled in the year	-	-	-	(26)	-	-	-	-	(26)
Exercise of options	-	1,245	-	(1,245)	-	-	-	-	-
Exercise of warrants	-	943	-	-	(1,596)	653	-	-	-
Shares issued in lieu of cash for realisation bonus	-	-	-	-	-	-	10,290	-	10,290
Reduction in share capital	-	(4,000)	4,000	-	-	-	-	-	-
Capital Distribution	-	-	(3,225)	-	-	-	-	-	(3,225)
Total transactions with owners	1,739	57,214	775	2,469	(1,337)	(1,099)	-	-	70,051
<b>Comprehensive loss</b>									
Net loss for the year	-	-	-	-	-	-	-	(23,735)	(23,735)
Total comprehensive loss	-	-	-	-	-	-	-	(23,735)	(23,735)
<b>Balance as at 31 December 2020</b>	5,838	82,408	31,958	6,384	537	-	10,290	(92,805)	44,610



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

## 1. GENERAL INFORMATION

Tiziana Life Sciences PLC is a public limited company incorporated in the United Kingdom under the Companies Act and quoted on the AIM market of the London Stock Exchange (AIM: TILS) and on the NASDAQ Capital Market (NDAQ: TLSA). The Company delisted from AIM on 21<sup>st</sup> January 2021 and is now trading on the main market of the London Stock Exchange (LSE: TILS). The address of its registered office is given on page 1. The principal activities of the Company and its subsidiaries (the Group) are that of a clinical stage biotechnology company focussed on targeted drugs to treat diseases in oncology and immunology.

These financial statements are presented in thousands of pounds sterling (£'000) which is the functional currency of the primary economic environment in which the Company operates.

## 2. ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been applied consistently to all the years presented unless otherwise stated.

### **Basis of preparation**

The consolidated financial statements of the Group and Company have been prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006. These accounts have been prepared under the historical cost convention.

As permitted by section 408 of the Companies Act 2006, a separate profit and loss account for the Company has not been presented in these financial statements.

### **Going Concern**

The Group and Company incurred losses during the year and has net assets at the year end.

As discussed in the Strategic Report, the Group and Company is in the early stages of developing its business focusing on the discovery and development of novel molecules that treat human disease in oncology and immunology. The Directors expect the Group and Company to incur further losses and to require significant capital expenditure in continuing to develop clinical stage development therapeutic candidates in both oncology and immunology. The Group and Company has successfully funded clinical trials to date and will seek to secure additional investment for purposes of continuing to fund their clinical trials moving forward.

The Directors have prepared cash flow projections that include the costs associated with the continued clinical trials and additional investment to fund that operation. On the basis of those projections, the directors conclude that the company will be able to meet its liabilities as they fall due a period beyond the next 12 months from the date when these financial statements are issued and accordingly the Directors have prepared the financial statements on a going concern basis.

The directors do not believe that Brexit will have an impact on the Group's ability to raise funds as it has access to the US market due to its listing on the Nasdaq.

### ***New and Revised Standards***

#### ***Standards in effect in 2020***

An amendment to IFRS 3 'Definition of a business' has come into effect from January 1, 2020. The Company has applied the new definition to any relevant transactions.

#### ***IFRS in issue but not applied in the current financial statements***

The directors do not expect that the adoption of new IFRS Standards, Interpretations and Amendments that have been issued but are not yet effective will have a material impact on the financial statements of the Group in future periods.

Several IFRS and IFRIC interpretations are also currently in issue which are not relevant for the Group's activities and which have not therefore been adopted in preparing these financial statements.

## **NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020**

### **Basis of consolidation**

Subsidiary undertakings are all entities over which the Group has the power to govern the financial and operating policies of the subsidiary and therefore exercises control. The existence and effect of both current voting rights and potential voting rights that are currently exercisable or convertible are considered when assessing whether control of an entity is exercised. Subsidiaries are consolidated from the date at which the Group obtains control and are de-consolidated from the date at which control ceases.

### **Business combination**

The consolidated position of the Group is as a result of the reverse acquisition of Alexander David Investments plc by Tiziana Pharma Ltd and the subsequent listing of the Company as Tiziana Life Sciences Plc on 24 April 2014 on the London Stock Exchange.

Inter-company transactions, balances and unrealised gains on transactions between group companies are eliminated upon consolidation. Unrealised losses are also eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

### **Segment reporting**

Operating segments are reported in a manner consistent with the internal reporting provided to the Board. The Board allocates resources to and assess the performance of the segments. The Board considers there to be only one operating segment being the research and development of biotechnological and pharmaceutical products.

### **Taxation**

The tax expense for the year represents the total of current taxation and deferred taxation. The charge in respect of current taxation is based on the estimated taxable profit for the year. Taxable profit for the year is based on the profit as shown in the income statement, as adjusted for items of income or expenditure which are not deductible or chargeable for tax purposes. The current tax liability for the year is calculated using tax rates which have either been enacted or substantively enacted at the balance sheet date.

Deferred tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and expected to apply when the related deferred tax is realized, or the deferred liability is settled. Deferred tax assets are recognized to the extent that it is probable that the future taxable profit will be available against which the temporary differences can be utilized.

Research and Development tax credits are provided for in the year that the costs are incurred. These are estimated based on eligible research and development expenditure. Any difference rebated are recognized in the following year, when the cash is received from the UK tax authorities.

### **Foreign currency translation**

Foreign currency transactions are translated using the rate of exchange applicable at the date of the transaction. Foreign exchange gains and losses resulting from the settlement of such transactions and from the re-translation at the year end of monetary assets and liabilities denominated in foreign currencies are recognised in the income statement.

On consolidation, the assets and liabilities of foreign subsidiaries are translated into Pound Sterling at the rate of exchange prevailing at the reporting date and their statements of comprehensive income are translated at exchange rates prevailing at the dates of the transactions. The exchange differences arising on translation for consolidation are recognised in other comprehensive income. On disposal of a foreign subsidiary, the component of other comprehensive income relating to that particular foreign subsidiary is recognised in profit or loss.

### **License fees**

Payments related to the acquisition of rights to a product or technology are capitalised as intangible assets if it is probable that future economic benefits from the asset will flow to the entity and the cost of the asset can be reliably measured.

Payments made which provide the right to perform research are carefully evaluated to determine whether such payments are to fund research or acquire an asset. Licence fees expenses are recognised as incurred.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### Research and development

All on-going research and development expenditure is currently expensed in the period in which it is incurred. Due to the regulatory environment inherent in the development of the Group's products, the criteria for development costs to be recognised as an asset, as set out in IAS 38 'Intangible Assets', are not met until a product has been granted regulatory approval and it is probable that future economic benefit will flow to the Group. The Group currently has no qualifying expenditure.

### Financial instruments

The Group classifies a financial instrument, or its component parts, as a financial liability, a financial asset or an equity instrument in accordance with the substance of the contractual arrangement and the definitions of a financial liability, a financial asset and an equity instrument.

The Group evaluates the terms of the financial instrument to determine whether it contains an asset, a liability or an equity component. Such components shall be classified separately as financial assets, financial liabilities or equity instruments.

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

#### (a) Financial assets, initial recognition and measurement and subsequent measurement

All financial assets not recorded at fair value through profit or loss, such as receivables and deposits, are recognized initially at fair value plus transaction costs. Financial assets carried at fair value through profit or loss (FVTPL) are initially recognized at fair value, and transaction costs are expensed in the income statement. The measurement of financial assets depends on their classification. Financial assets such as receivables and deposits are subsequently measured at amortized cost using the effective interest method, less loss allowance. The Group does not hold any financial assets at fair value through profit or loss or fair value through other comprehensive income.

#### (b) Financial liabilities, initial recognition and measurement and subsequent measurement

Financial liabilities are classified as measured at amortized cost or FVTPL.

A financial liability is classified as at FVTPL if it is a derivative. Financial liabilities at FVTPL are measured at fair value and net gains and losses, including any interest expense, are recognized in profit or loss. Other financial liabilities are subsequently measured at amortized cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognized in profit or loss. Any gain or loss on derecognition is also recognized in profit or loss.

The Group's financial liabilities include trade and other payables.

The Company has an intercompany receivable balance with its subsidiaries which is impaired in full on an annual basis as there is no expectation of recoverability. As at the year end, there was an intercompany receivable balance of £39.9m which was not impaired as it related to the cash proceeds from the August 2020 fundraise which were received by the US entity. These funds have been transferred to the Company post the year end balance sheet date.

### Warrants

Warrants are issued by the Group in return for services and as part of a financing transaction.

#### *Warrants issued in return for services.*

Warrants issued in return for services fall within scope of IFRS 2. The financial liability component is measured at fair value and charged to the Consolidated Statement of Income. There is no remeasurement of fair value.

#### *Warrants issued as part of a financing transaction.*

Warrants issued as part of a financing transaction fall outside the scope of IFRS 2. These are classified as equity instruments because a fixed amount of cash is exchanged for a fixed amount of equity. The fair value is recognised within equity and is not remeasured.

### Investments

Investments are held as non-current assets and comprise investments in subsidiary undertakings and are stated at cost less provision for any impairment.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### **Share capital**

Ordinary shares of the Company are classified as equity.

### **Property, plant and equipment**

#### *(i) Recognition and measurement*

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset. Purchased software that is integral to the functionality of the related equipment is capitalised as part of that equipment.

When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment, and are recognised in profit or loss.

#### *(ii) Depreciation*

Depreciation is calculated on the depreciable amount, which is the cost of an asset, or other amount substituted for cost, less its residual value.

Depreciation is recognised in profit or loss on a straight-line basis over the estimated useful life of each part of an item of property, plant and equipment. Leased assets are depreciated over the shorter of the lease term and their useful lives unless it is reasonably certain that the Company will obtain ownership by the end of the lease term.

The estimated useful lives for the current period and the comparative period are as follows.

Fixtures and fittings	<b>5 years</b>
IT and equipment	<b>3 years</b>
Right of use assets	<b>Economic life of contractual relationship</b>

Depreciation methods, useful lives and residual values are reviewed at each reporting date. Depreciation is allocated to the operating expenses line of the income statement.

### **Impairment**

#### *Impairment of financial assets measured at amortised cost*

At each reporting date the Group recognises a loss allowance for expected credit losses on financial assets measured at amortised cost.

In establishing the appropriate amount of loss allowance to be recognised, the Group applies either the general approach or the simplified approach, depending on the nature of the underlying group of financial assets.

#### *General approach*

The general approach is applied to the impairment assessment of refundable lease deposits and other refundable lease contributions, restricted cash and cash and cash equivalents.

Under the general approach the Group recognises a loss allowance for a financial asset at an amount equal to the 12-month expected credit losses, unless the credit risk on the financial asset has increased significantly since initial recognition, in which case a loss allowance is recognised at an amount equal to the lifetime expected credit losses.

#### *Simplified approach*

The simplified approach is applied to the impairment assessment of trade receivables.

Under the simplified approach the Group always recognises a loss allowance for a financial asset at an amount equal to the lifetime expected credit losses.

The Company assesses for impairment in its investment in its subsidiaries on an annual basis.

#### *Impairment of non-financial assets*

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

Non-financial assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.

Non-financial assets are impaired when its carrying amount exceed its recoverable amount. The recoverable amount is measured as the higher of fair value less cost of disposal and value in use. The value in use is calculated as being net projected cash flows based on financial forecasts discounted back to present value at a pre-tax discount rate.

Intangible assets with indefinite useful lives that are acquired separately are carried at cost less accumulated impairment losses.

### **Leases**

All leases are accounted for by recognising a right-of-use asset and a lease liability except for:

- Leases of low value assets; and
- Leases with a duration of 12 months or less.

The Group has leases for its offices. Each lease is reflected on the balance sheet as a right-of-use asset and a lease liability. The Group does not have any short-term leases or leases of low value assets. Variable lease payments which do not depend on an index or a rate (such as lease payments based on a percentage of Group sales) are excluded from the initial measurement of the lease liability and asset. The Group classifies its right-of-use assets in a consistent manner to its property, plant and equipment (see Note 12).

For leases over office buildings and factory premises the Group must keep those properties in a good state of repair and return the properties in their original condition at the end of the lease.

#### Measurement and recognition of leases as a lessee

At lease commencement date, the Group recognises a right-of-use asset and a lease liability in its consolidated statement of financial position. The right-of-use asset is measured at cost, which is made up of the initial measurement of the lease liability, any initial direct costs incurred by the Group, an estimate of any costs to dismantle and remove the asset at the end of the lease, and any lease payments made in advance of the lease commencement date (net of any incentives received).

The Group depreciates the right-of-use asset on a straight-line basis from the lease commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The Group also assesses the right-of-use asset for impairment when such indicators exist.

At the commencement date, the Group measures the lease liability at the present value of the lease payments unpaid at that date, discounted using the Group's incremental borrowing rate because as the lease contracts are negotiated with third parties it is not possible to determine the interest rate that is implicit in the lease. The incremental borrowing rate is the estimated rate that the Group would have to pay to borrow the same amount over a similar term, and with similar security to obtain an asset of equivalent value. This rate is adjusted should the lessee entity have a different risk profile to that of the Group.

Lease payments included in the measurement of the lease liability are made up of fixed payments (including in substance fixed), variable payments based on an index or rate, amounts expected to be payable under a residual value guarantee and payments arising from options reasonably certain to be exercised.

Subsequent to initial measurement, the liability will be reduced by lease payments that are allocated between repayments of principal and finance costs. The finance cost is the amount that produces a constant periodic rate of interest on the remaining balance of the lease liability.

#### The Group as a lessor

As a lessor the Group classifies its leases as either operating or finance leases. A lease is classified as a finance lease if it transfers substantially all the risks and rewards incidental to ownership of the underlying asset and classified as an operating lease if it does not.

During the course of 2020, the Group sublet one of its office spaces. This has been recognised as a writeback of the associated right of use asset and the recognition of a finance lease receivable for the value of the sublease (see note 16).

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### ***Fair Value Measurement***

Management have assessed the categorisation of the fair value measurements using the IFRS 13 fair value hierarchy. Categorisation within the hierarchy has been determined on the basis of the lowest level of input that is significant to the fair value measurement of the relevant asset as follows;

Level 1 - valued using quoted prices in active markets for identical assets

Level 2 - valued by reference to valuation techniques using observable inputs other than quoted prices included within Level 1;

Level 3 - valued by reference to valuation techniques using inputs that are not based on observable market data.

### **Share-based payments**

The calculation of the fair value of equity-settled share-based awards and the resulting charge to the statement of comprehensive income requires assumptions to be made regarding future events and market conditions. These assumptions include the future volatility of the Company's share price. These assumptions are then applied to a recognised valuation model in order to calculate the fair value of the awards.

Where employees and directors are rewarded using share-based payments, the fair value of the employees', directors' or advisers' services are determined by reference to the fair value of the share options/warrants awarded. Their value is appraised at the date of grant and excludes the impact of any nonmarket vesting conditions (for example, profitability and sales growth targets). Warrants issued in association with the issue of Convertible Loan Notes are also considered as share based payments and a share-based payment charge is calculated for these too.

Where advisers are rewarded using share based payments, the fair value of the advisers' services are determined by reference to the fair value of the share options/warrants awarded, unless it can be measured based on their services. Their value is appraised at the date of grant and excludes the impact of any nonmarket vesting conditions (for example, profitability and sales growth targets)..

In accordance with IFRS 2, a charge is made to the statement of comprehensive income for all share-based payments including share options based upon the fair value of the instrument used. A corresponding credit is made to a share-based payment reserve - options, in the case of options/warrants awarded to employees, directors, advisers and other consultants.

If vesting periods or other vesting conditions apply, the expense is allocated over the vesting period, based on the best available estimate of the number of share options/warrants expected to vest. Non market vesting conditions are included in assumptions about the number of options / warrants that are expected to become exercisable.

Estimates are subsequently revised, if there is any indication that the number of share options/warrants expected to vest differs from previous estimates. No adjustment is made to the expense or share issue cost recognised in prior periods if fewer share options ultimately are exercised than originally estimated.

Upon exercise of share options/warrants, the proceeds received are allocated to share capital with any excess being recorded as share premium.

Where share options are cancelled, this is treated as an acceleration of the vesting period of the options. The amount that otherwise would have been recognised for services received over the remainder of the vesting period is recognised immediately within the Statement of Comprehensive Income.

Where share options are forfeited prior to the completion of the vesting or service period to which they relate, the forfeiture results in the reversal of the previously recognised share-based payment cost.

Where share options are modified, the fair value of the option immediately prior to modification and upon modification is calculated. Where the modification increases the fair value of the option, the incremental fair value is recognised over the remaining modified vesting period, whereas the balance of the original grant-date fair value is recognised over the remaining original vesting period. The 'incremental fair value' is the difference between the fair value of the modified share-based payment and that of the original share-based payment, both measured at the date of the modification – i.e. the fair values as measured immediately before and after the modification.

Modifications that decrease the fair value of the option are generally ignored. The original grant-date fair value of the equity instruments granted is recognised over the original vesting period.

All goods and services received in exchange for the grant of any share-based payment are measured at their fair value.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### Other non-current assets

Other non-current assets are currently measured at cost less accumulated impairment. The asset is not yet being amortised since it is not yet in the condition necessary for it to be capable of operating in the manner intended by management.

### Convertible loan notes

*Where there is no option to repay in cash or the Company has the choice of settlement, and the interest rate is fixed*

The Group considers these to be convertible equity instruments and records the principal of the loan note as an equity in a Convertible loan note reserve. The accrued interest on the principal amount, for which there is no obligation to settle in cash, is also recorded in the Convertible loan note reserve. Upon redemption of the instrument and the issue of share capital, the amount is reclassified from the convertible loan note reserve to share capital and share premium.

*Where the above conditions are not met*

The Group considers these to be convertible debt instruments and records the principal of the loan note as a debt liability in the liabilities section of the statement of financial position. The accrued interest on the principal amount is recorded in the income statement and as an increase in the debt liability. Upon redemption of the instrument and the issue of share capital, the amount is reclassified from the debt liability to share capital and share premium.

Under IAS 32 the liability and equity components of convertible loan notes must be presented separately on the statement of financial position. The Group has examined the terms of each issue of convertible loan notes and determined their accounting treatment accordingly.

### 3. CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The preparation of financial information in accordance with generally accepted accounting practice, in the case of the Group being International Financial Reporting Standards as adopted by the European Union, requires the directors to make estimates and judgements that affect the reported amount of assets, liabilities, income and expenditure and the disclosures made in the financial statements. Such estimates and judgements must be continually evaluated based on historical experience and other factors, including expectations of future events.

The following are considered to be critical accounting estimates:

#### *Share-based payments*

The Group accounts for share-based payment transactions for employees in accordance with IFRS 2 Share-based Payment, which requires the measurement of the cost of employee services received in exchange for the options on our ordinary shares, based on the fair value of the award on the grant date.

The Directors selected the Black-Scholes-Merton option pricing model as the most appropriate method for determining the estimated fair value of our share-based awards without market conditions. For performance-based options that include vesting conditions relating to the market performance of our ordinary shares, a Monte Carlo pricing model was used in order to reflect the valuation impact of price hurdles that have to be met as conditions to vesting.

The resulting cost of an equity incentive award is recognised as expense over the requisite service period of the award, which is usually the vesting period. Compensation expense is recognised over the vesting period using the straight-line method and classified in the consolidated statements of comprehensive income.

The assumptions used for estimating fair value for share-based payment transactions are disclosed in note 27 to our consolidated financial statements.

The following are considered to be critical accounting judgments:

#### Income taxes

Deferred tax assets are recognised for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilised. Significant management judgment is required to determine the amount of deferred tax assets that can be recognised based upon the likely timing and the level of future taxable profits together with future tax planning strategies.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### Research and development costs

Research and development costs are charged to expense as incurred and are typically made up of clinical and preclinical activities, drug development and manufacturing costs, and third-party service fees, including for clinical research organizations and investigative sites. When entering into agreements with third parties which provide the rights to conduct research into specific biological processes the Group accounts for these agreements as an expense if the agreements are 'milestone' in nature and relate to the Group's own research and development costs. Such agreements involve periodic payments and are evaluated as representing payments made to fund research.

### Leases

IFRS 16 defines the lease term as the non-cancellable period of a lease together with the options to extend or terminate a lease, if the lessee were reasonably certain to exercise that option. This will take into account the length of time remaining before the option is exercisable, current trading, future trading forecasts as to the ongoing profitability of the organisation and the level and type of planned future capital investment. The judgement is reassessed at each reporting period. A reassessment of the remaining life of the lease could result in a recalculation of the lease liability and a material adjustment to the associated balances.

## 4. DEMERGER OF A SUBSIDIARY

The Company's demerger of its subsidiary Stemprinter Sciences Limited to allow for the creation of a separate business occurred by way of a demerger under English law. It happened in two distinct steps. In the first step, in September 2020, Tiziana transferred all the ownership rights and intellectual property relating to the StemPrintER project, in the form of patents and a license, to a newly formed Tiziana subsidiary, Stemprinter Sciences Limited. In the second step, on October 5, 2020, the Company sold Stemprinter Sciences Limited to Accustem Sciences Ltd.

In September 2020, the Company transferred all the ownership rights and intellectual property relating to StemPrintER™ along with £1.0 million in cash to its newly formed wholly owned subsidiary, StemPrinter Sciences Limited. This was the first step in the creation of the separate business by way of a demerger under English law. In this first step, the transfer of all the ownership rights and intellectual property was treated as an asset transfer (acquired IPR&D). The treatment as a separate asset acquisition at this stage reflected the fact that, immediately prior to transfer, the Company carried out only limited maintenance type activity on the StemPrintER project and the concentration of fair value was in the StemPrintER intellectual property asset.

Stemprinter Sciences Limited recorded the ownership rights and intellectual property as a separately acquired intangible asset in its books at cost under IAS 38, with cost (as defined in the IFRS Glossary), including the fair value of the other consideration given (i.e., shares issued in exchange for intellectual property). Stemprinter Sciences Limited therefore was also required to record the equity capital issued for the StemPrintER asset acquired at fair value as set out in IFRS 13. Prior to the transfer, the intellectual property was an internal project within the Company and was not classified as an asset on the Company's balance sheet or a separate line of business.

The Company tracked the expenses incurred in maintaining this project in the form of patent maintenance fees, CRO fees and project consultancy fees, the total amounts for which between 2014 and the transfer date were £2,073,930. The Company used the aggregate amount of these expenses as its determination of fair value (as further discussed below) to credit an account in the books of Stemprinter Sciences Limited by £2,073,930. Tiziana received 3,070,000 shares in Stemprinter Sciences Limited as consideration for the asset transfer. Tiziana also contributed capital and resources, consisting of £1.0 million in cash.

In the second step of the transaction, on October 5, 2020, Accustem Sciences Ltd entered into an agreement with the Company to acquire Stemprinter Sciences Limited, including the ownership rights and intellectual property relating to StemPrintER™ and cash of £1.0 million contained within the entity. In exchange for the transfer of ownership (shares in Stemprinter Sciences Limited), Accustem Sciences Ltd allotted 194,612,288 ordinary shares of £0.01 par value to Tiziana shareholders on a one for one basis based on the Tiziana ownership as at October 30, 2020.

The Demerger was effected by Tiziana declaring a special dividend on the Tiziana Shares which was satisfied by the transfer to Accustem of the entire issued share capital of Stemprinter Sciences Limited, the company to which all the relevant assets relating to StemPrintER had been transferred.

In order for the Demerger to be effective, the Company cancelled £4,000,000 from its Share Premium account in order to create a distributable reserve in the Company to facilitate the special dividend to shareholders. This was approved by the High Court on October 26, 2020.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

**5. OPERATING LOSS**

The Group and Company's operating loss for the year is stated after charging the following:

	<b>2020</b>	<b>2019</b>
	£'000	£'000
License fees	550	433
Realisation bonus	10,290	-
Depreciation of Property, Plant and Equipment	4	4
Depreciation (Right-of-use asset)	66	192
Foreign exchange (gains)/losses	186	129
	<hr/>	<hr/>
	11,096	758
	<hr/>	<hr/>

The realisation bonus refers to a bonus that became payable to the Executive Chairman in August 2020 upon the raising of funds totalling £44m.

**6. SEGMENTAL REPORTING**

During the year under review management identified the Group's only operating segment as the research and development of biotechnological and pharmaceutical products. This one segment is monitored and strategic decisions are made based upon it and other non-financial data collated from industry intelligence. The form of financial reporting reported to the Board is consistent with those presented in the annual financial statements.

**7. AUDITOR'S REMUNERATION**

	<b>2020</b>	<b>2019</b>
	£'000	£'000
Remuneration receivable by the Company's auditor for the audit of the consolidated and Company financial statements	48	56
Remuneration receivable by the Company's auditor for other assurance services	78	82

**8. EMPLOYEES**

<u>Group</u>	<b>2020</b>	<b>2019</b>
	£'000	£'000
Staff costs comprised:		
Directors' salaries including bonus	11,198	892
Employees, wages, salaries and bonus	824	554
Social security costs	151	477
Recruitment fees	13	-
Share based payment charge	3,506	992
	<hr/>	<hr/>
	15,692	2,912
	<hr/>	<hr/>

The average monthly number of employees, including directors, employed by the Group during the year was:

Research and Development	3	5
Corporate and administration	8	4
	<hr/>	<hr/>
	11	9
	<hr/>	<hr/>

A charge for share based payments totalling £3,506k (2019: £586k) was made in the year.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

<u>Company</u>	<b>2020</b>	<b>2019</b>
Staff costs comprised:	£'000	£'000
Directors' salaries	11,198	892
Recharge of US Salaries (including social security costs)	706	745
Share based payment charge	3,506	992
	<hr/>	<hr/>
	15,410	2,629
	<hr/>	<hr/>

Directors' salaries include a realisation bonus which became payable due to the £44m fundraise that took place in August 2020.

**9. REMUNERATION OF KEY MANAGEMENT PERSONNEL**

Director	2020				2019			
	Directors' fee £'000	Bonus £'000	Salary £'000	Share based payments £'000	Directors' fee £'000	Bonus £'000	Salary £'000	Share based payments £'000
W Simon	38			24	38	-	-	-
G. Cerrone (1)	133	10,357		121	80	143	-	296
R. Dalla-Favera	-	-	-	-	2	-	-	-
J Brancaccio	17	-	-	24	-	-	-	-
K. Shailubhai (2)	-	164	468	1,611	-	159	470	695
	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>
	188	10,521	468	1,780	120	302	470	991
	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>	<hr/>

- (1) Gabriele Cerrone's bonus in 2020 includes his realisation bonus of £10.29m; his 2019 bonus covers the period June 9, 2016 to December 31, 2019
- (2) Kunwar Shailubhai became an employee of the Company on 24th May 2017, at which point he ceased to be a non-executive director.

The following share options were granted to directors in the year:

Director	2020 Number of options	2019 Number of options
K Shailubhai	1,800,000	
G. Cerrone	-	-
W. Simon	250,000	-
J Brancaccio	250,000	-
R. Dalla-Favera		
	<hr/>	<hr/>
	2,300,000	-
	<hr/>	<hr/>

The key management personnel of the Group are considered to be represented by the directors and officers of the Company.

No director has yet benefitted from any increase in the value of share capital since issuance of the options.

2,319,225 share options were exercised by directors in the year for an intrinsic gain of £3.2m.

The Company made £7k (2019: £12k) of payments to a defined contribution pension schemes on behalf of directors or employees.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

**10. FINANCE INCOME AND COSTS**

<u>Group</u>	<b>2020</b>	<b>2019</b>
	£'000	£'000
<u>Finance Income</u>		
Finance income received on net investment in lease	6	1
<b>Total finance income</b>	<u>6</u>	<u>1</u>
<u>Finance Expenses</u>		
Finance charge accrued on convertible loan notes	236	49
Interest expense on lease liabilities	13	24
<b>Total finance expenses</b>	<u>249</u>	<u>73</u>
<b>Net finance expense recognised in Statement of Comprehensive Income</b>	<u>243</u>	<u>72</u>

**11. TAXATION**

	<b>2020</b>	<b>2019</b>
	£'000	£'000
<b>Group</b>		
Current year tax (credit)	(1,204)	(518)
Adjustments in respect of prior periods	(515)	(22)
Deferred tax		
Origination and reversal of timing differences	Nil	Nil
<b>Total tax (credit) for period</b>	<u>(1,719)</u>	<u>(540)</u>

The tax charge for the year is different from the standard rate of corporation tax in the United Kingdom of 19%. The difference can be reconciled as follows:

Loss before taxation	<u>(22,067)</u>	<u>(7,846)</u>
Loss charged at standard rate of corporation tax 19%	(4,193)	(1,491)
Movement in unrecognised deferred tax	1,025	(189)
Expenses not deductible for taxation	3,883	1,353
Adjustments due to prior periods	(515)	(22)
Research and development claim	(518)	(223)
Income not taxable for tax purposes	(1,356)	-
Consolidation adjustment in relation to foreign exchange movements	(45)	32
	<u>(1,719)</u>	<u>(540)</u>

No deferred tax asset has been recognised in respect of trading losses carried forward because of uncertainty as to when these losses will be recoverable.

The amount of tax losses for which no deferred tax assets has been recognised is £4,814k (2019: £2,756k).

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

**12. LOSS PER SHARE**

Basic loss per share is calculated by dividing the loss attributable to equity holders of the company by the weighted average number of ordinary shares in issue during the year.

	<b>2020</b>	<b>2019</b>
(Loss) attributable to equity holders of the Company (£)	(20,348,519)	(7,306,423)
Weighted average number of ordinary shares in issue	169,065,390	136,482,627
<b>Basic loss per share (pence per share)</b>	<u>(12.0)</u>	<u>(5.4)</u>

As the Group is reporting a loss from continuing operations for the year then, in accordance with IAS 33, the share options are not considered dilutive because the exercise of the share options would have an anti-dilutive effect. The basic and diluted earnings per share as presented on the face of the Income Statement are therefore identical. All earnings per share figures presented above arise from continuing and total operations and therefore no earnings per share for discontinued operations are presented.

**13. PROPERTY, PLANT AND EQUIPMENT**

Details of the Groups property, plant and equipment are as follows:

<u>Group</u>	<b>Furniture and fixtures</b> £'000	<b>IT equipment</b> £'000	<b>Total</b> £'000
<b>Cost</b>			
At 1 January 2020	12	28	40
Additions	-	-	-
Disposals			
<b>At 31 December 2020</b>	<u>12</u>	<u>28</u>	<u>40</u>
<b>Depreciation</b>			
At 1 January 2020	9	26	35
Charge in year	2	2	4
<b>At 31 December 2020</b>	<u>11</u>	<u>28</u>	<u>39</u>
<b>Net book value as at 31 December 2020</b>	<u>1</u>	<u>-</u>	<u>1</u>
<b>Cost</b>			
At 1 January 2019	12	25	37
Additions	-	3	3
Disposals	-	-	-
<b>At 31 December 2019</b>	<u>12</u>	<u>28</u>	<u>40</u>
<b>Depreciation</b>			
At 1 January 2019	7	24	31
Charge in year	2	2	4
<b>At 31 December 2019</b>	<u>9</u>	<u>26</u>	<u>35</u>
<b>Net book value as at 31 December 2019</b>	<u>3</u>	<u>2</u>	<u>5</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

**14. PURCHASE OF AN INTANGIBLE ASSET**

In April 2020, the Company acquired all of the intellectual property relating to a nanoparticle-based formulation of Actinomycin D (Act D), from Rasna Therapeutics, Inc. to expand its pipeline for a consideration of an initial \$120,000 upfront payment (approximately £97,000).

**15. OTHER RECEIVABLES**

	<b>2020</b>	<b>2019</b>
	£'000	£'000
<u>Group</u>		
VAT Receivable	61	16
Funds due for options exercised	140	-
Security deposits receivable	99	87
Prepayments	276	21
	<hr/>	<hr/>
	576	124
	<hr/> <hr/>	<hr/> <hr/>

There are no differences between the carrying amount and fair value of any of the trade and other receivables above.

	<b>2020</b>	<b>2019</b>
	£000	£000
<u>Company</u>		
Funds due for options exercised	140	-
VAT Receivable	52	4
Prepayments	242	5
	<hr/>	<hr/>
	434	9
	<hr/> <hr/>	<hr/> <hr/>

**16. FINANCE LEASE RECEIVABLES**

In November 2019, the Group subleased one of its leased office spaces. The sublease has been classified as a finance lease receivable.

	<b>31 Dec 2020</b>	<b>1 Jan 2020</b>
	£000	£000
<u>Finance lease receivable</u>		
Current	111	109
Non-current	-	113
	<hr/>	<hr/>
	111	222
	<hr/> <hr/>	<hr/> <hr/>

The undiscounted lease payments to be received over the next 5 years are as follows:

	<b>1 Year</b>	<b>2 years</b>	<b>3 or more years</b>
	£000	£000	£000
<u>Undiscounted lease payments receivable</u>	111	-	-
	<hr/>	<hr/>	<hr/>
	111	-	-
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

The undiscounted lease payments do not include a discount factor charge of £1k.

During the year ending December 31, 2020, the Group received £111k of income from its subleasing activities.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

<u>Finance Lease Receivable</u>	<b>31 December 2020 £000</b>
<u>Finance Lease receivable as at 1 Jan 2020</u>	222
<u>Sublease income</u>	(111)
	<hr/>
	111
	<hr/> <hr/>

**17. OTHER NON-CURRENT ASSETS**

In June 2016, the Board approved the purchase of the data repository of DNA samples from SharDNA (an Italian entity in liquidation) for EUR 258k, approximately £217k.

Management recognize that the transaction is not the purchase of a business, but the purchase of key assets owned by SharDNA. These assets are owned by Tiziana Life Sciences PLC.

The validity to the sale of the assets has been confirmed by the Italian judicial system however the Company is still unable to utilise these assets until the resolution of the outstanding data protection legal action. This action is unlikely to be resolved for another 2 years so the Company has decided to impair the asset on the basis that it is not available for use for another 2 years, resulting in an impairment charge of £217k.

**18. INVESTMENTS IN SUBSIDIARIES**

<u>Company</u>	<b>Shares in group undertakings</b>	<b>Capital Contribution</b>	<b>Total</b>
	£'000	£'000	£'000
<b>Cost</b>			
At 1 January 2020	7,509	12,796	21,966
Additions	3,225	4,915	8,140
Disposals	(3,225)	-	(3,225)
<b>At 31 December 2020</b>	<hr/> 7,509	<hr/> 17,711	<hr/> 25,220
<b>Impairment</b>			
At 1 January 2020	(7,509)	(12,796)	(21,966)
Charge in year	-	(4,915)	(4,915)
<b>At 31 December 2020</b>	<hr/> (7,509)	<hr/> (17,711)	<hr/> (25,220)
<b>Net book value as at 31 December 2020</b>	<hr/> -	<hr/> -	<hr/> -
Net book value as at 31 December 2019	<hr/> -	<hr/> -	<hr/> -

The capital contribution represents the funding of operations of the subsidiaries by the parent, with the Company acting as the Group's holding company.

The Company's interest in subsidiary undertakings is as follows:

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

<b>Name</b>	<b>Principal activity</b>	<b>Registered Address</b>	<b>Percentage shareholding</b>	<b>Country of incorporation</b>
Tiziana Pharma Limited	Clinical stage biotechnology company	3 <sup>rd</sup> Floor, 11-12 St James's Square, London, SW1Y 4LB	100%	England & Wales
Tiziana Therapeutics Inc	Clinical stage biotechnology company	420 Lexington Avenue Suite 2525 New York, NY 10170	100%	USA
Longevia Genomics SRL	Biotech Discovery Company	Via Constantinopoli 42 09100- Cagliari (CA)	100%	Italy
Stemprinter Sciences Ltd	Specialist medical practice activities	9 <sup>th</sup> Floor, 107 Cheapside, London, UK EC2V 6DN	100%	England & Wales

Tiziana Therapeutics Inc was incorporated on 28 October 2015. This entity was set up to house the Company's US operations.

Longevia Genomics SRL was incorporated on 4 July 2016. This entity was established to enable the Company to carry out R&D activities in Sardinia and acting as the European legal representative of the Group, as per EU regulatory (AIFA) requirements.

Stemprinter Sciences Ltd was incorporated on 3 September 2020. This entity was established to enable the transfer of the ownership rights and intellectual property relating to StemPrintER™. The subsidiary was sold to Accustem Sciences Ltd on 30 October 2020.

During the year, the Company undertook an impairment review of its investments in subsidiaries. The Company has been funding its subsidiary operations from funds raised by the Company for the development of its project portfolio. The subsidiary's activities have all been to support the Company in achieving its goals for progression of the project portfolio. The funding provided to the subsidiaries to date has been recognized in the Company as Investment in its subsidiaries, and the Company does not expect the amounts to be repaid. The IP relating to the project portfolio belongs to the Company and hence any future benefits will also belong to the Company. It is highly unlikely that these benefits will be distributed to the subsidiaries. The Company therefore determined that the investment should be impaired on an annual basis.

**19. SHARE CAPITAL**

<u>Company and Group</u>	<b>2020</b>	<b>2019</b>	<b>2020</b>	<b>2019</b>
	<b>Ordinary Shares</b>		<b>£000</b>	<b>£000</b>
In issue at 1 January	136,654,516	136,463,818	4,099	4,094
Issued for cash	43,979,245	-	1,319	-
Issued in lieu of consultancy fees	281,250	190,698	9	5
Conversion of warrants	6,365,428	-	191	-
Conversion of Loan	4,406,125	-	132	-
Exercise of options	2,925,725	-	88	-
Commission and Interest		-		-
In issue at 31 December	<b>194,612,289</b>	<b>136,654,516</b>	<b>5,838</b>	<b>4,099</b>

Ordinary Shares

Ordinary shares have a par value of £0.03. Every holder of ordinary shares is entitled to one vote, to participate in dividends, and to share in the proceeds of winding up the company in proportion to the number of and amounts paid on the shares held. On a show of hands every holder of ordinary shares present at a meeting in person or by proxy, is entitled to one vote, and upon a poll each share is entitled to one vote. The Company does not have a limited amount of authorised capital.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### Issuance of ordinary shares

In March 2020, 16,666,665 new ordinary shares were issued as part of a fundraise of American Depositary Shares on the Nasdaq Global Market.

In April 2020, 420,000 new ordinary shares were issued in relation to an exercise of options; 1,712,672 new ordinary shares were issued in relation to an exercise of warrants; 4,406,125 new ordinary shares were issued in relation to the conversion of convertible loan notes and 906,905 new ordinary shares were issued in relation to an 'At the market' fundraise of American Depositary Shares.

In May 2020, 264,286 new ordinary shares were issued in relation to an exercise of warrants and 1,568,445 new ordinary shares were issued in relation to an 'At the market' fundraise of American Depositary Shares.

In June 2020, 3,034,399 new ordinary shares were issued in relation to an exercise of warrants and 852,500 new ordinary shares were issued in relation to an 'At the market' fundraise of American Depositary Shares.

In July 2020, 88,580 new ordinary shares were issued in relation to an exercise of warrants and 1,965,500 new ordinary shares were issued in relation to an 'At the market' fundraise of American Depositary Shares.

In August 2020, 22,019,230 new ordinary shares were issued as part of a fundraise of American Depositary Shares on the Nasdaq Global Market and 600,000 new ordinary shares were issued in relation to an exercise of warrants.

In September 2020, 281,250 new ordinary shares were issued in lieu of a consultancy fees of £360,000.

In October 2020, 2,505,725 new ordinary shares were issued in relation to an exercise of options and 665,491 new ordinary shares were issued in relation to an exercise of warrants.

## 20. SHARE BASED PAYMENTS

### Group and Company

#### Options

The Company operates share-based payment arrangements to remunerate directors and key employees in the form of a share option scheme. The exercise price of the option is normally equal to the market price of an ordinary share in the Company at the date of grant.

	2020		2019	
	Options ('000)	Weighted Average exercise price (pence)	Options ('000)	Weighted Average exercise price (pence)
Outstanding at 1 January	16,379	86	18,617	84
Granted	3,870	81	-	-
Forfeited	(300)	(38)	(2,238)	(115)
Exercised	(2,925)	(18)	-	-
Cancelled	-	-	-	-
	17,024	49	16,379	86
Outstanding at 31 December				
Exercisable at 31 December	6,249	41	5,521	51

During the year ending 31 December 2020, 2,925,725 options were exercised. No options were exercised in the year to 31 December 2019.

The total outstanding fair value charge of the share option instruments is deemed to be approximately £5,161k (2019: £3,800k).

Share options outstanding at the end of the year have the following expiry dates and exercise prices:



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

<b>Grant Date</b>	<b>Expiry Date</b>	<b>Exercise Price</b>	<b>Share Options as at 31 December 2020 ('000)</b>
26 June 2014	26 June 2024	£0.35	1,831
30 April 2018	30 April 2028	£0.8175	1,300
6 May 2020	5 May 2028	£0.35	12,393
23 July 2020	26 July 2030	£1.575	1,000
25 August 2020	24 August 2030	£1.475	500
<b>Total</b>			<b>17,024</b>

*Fair value of options granted*

The Directors have used the Black-Scholes option pricing model to estimate the fair value of most of the options granted during the year to December 31, 2020 applying the assumptions below.

Historical volatility is based on the historical volatility of the Company itself.

The Company has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

The Company has estimated a forfeiture rate of zero.

The model inputs for options granted during the year ended 31 December 2020 valued under the Black Scholes Valuation model included:

	<b>6 May 2020</b>	<b>23 July 2020</b>
Grant date share price	£0.625	£1.600
Exercise share price	£0.350	£1.575
Risk free rate	0.04% to 0.05%	0.04% to 0.05%
Expected volatility	92% to 117%	92% to 117%
Option life	10 years	10 years
Weighted average share price	£0.625	£1.600
Weighted average fair value per share option	£0.350	£1.575

For the options issued in August 2020 with a market condition attached, the Directors have used the Monte Carlo simulation to estimate the fair value of these options. The Company uses the following methods to determine its underlying assumptions:

- expected volatilities are based on the historical volatilities of the market;
- the expected term of the award is 4 years and is based on managements' assessment of when the market condition is likely to be achieved; and
- a range of fair value's per share were produced and management have determined the most appropriate value based on their knowledge of the market and vesting conditions being fulfilled.

*Modification of share based payments.*

In May 2020, the Company reduced the exercise price for options issued to employees and directors to £0.35. This was approved by shareholders at a General Meeting held on May 6, 2020.

The fair value of the modified options at the date of modification was determined using the option pricing models as described above. The incremental fair value was recognised as an expense over the period from the modification date to the end of the vesting period. The expense for the original option grant will continue to be recognised as if the terms had not been modified.

The fair value of the modified options was determined using the same models and principles as described above.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### Warrants

#### *Warrants issued in lieu of fees*

On June 1 2020, warrants were granted over 35,714 shares at an exercise price of £0.70 per share in lieu of broker fees. The warrants are exercisable until 1 June 2023.

#### *Warrants issued as incentive*

In January 2020, additional warrants were granted over 2,037,350 shares at an exercise price of £0.42 per share in conjunction with Convertible Loan Note's that were issued in 2019. The warrants are exercisable until 31 October 2024 and were exercised during April and June 2020.

On January 21, 2020, warrants were granted over 285,714 shares at an exercise price of £0.35 per share in conjunction with a Convertible Loan Note. The warrants are exercisable until January 21, 2023 and were exercised in October 2020.

The Directors have estimated the fair value of the warrants using the Black-Scholes valuation model and assumptions below:

	<u>January 2020</u>	<u>21 January 2020</u>	<u>1 June 2020</u>
Grant date share price	£0.43	£0.43	£1.15
Exercise share price	£0.42	£0.35	£0.70
Risk free rate	0.64%	0.40%	0.04%
Expected volatility	61.7%	84.7%	111%

For each set of warrants, the charge has been expensed over the service period. A share-based payment charge for the year of £20k (year to December 2019 £nil) has been expensed in the statement of comprehensive income.

	<b>2020</b> <b>£000</b>	<b>2019</b> <b>£000</b>
Outstanding at 1 January	1,812	1,399
Granted	259	413
Transfer to share premium on exercise of warrants	<u>(1,597)</u>	<u>-</u>
Outstanding at 31 December	<u>474</u>	<u>1,812</u>

## 21. CONVERTIBLE DEBT INSTRUMENT

### Group and Company

#### **Planwise Convertible Loan Notes 2016**

From the date of the reverse acquisition a convertible loan note of £200k was in existence as detailed in the Admission Document dated 31 March 2014. Proceeds of the subscriptions for the notes are to be used exclusively to finance the Company's on-going working capital requirements. The terms of the loan note are that the loan notes, plus accrued interest at a rate of 4 per cent above Bank of England base rate per annum, will convert into ordinary shares in the Company at a price of £0.10 per share at the election of Planwise any time after the second anniversary of the readmission to AIM on 24 April 2014. The Company considers this to be a Convertible Debt Instrument as detailed in the policy described at note 2 as a result of the fact that the Company is obligated to repay the capital amount and the interest of the loan, and Planwise has the right to request the settlement of the obligation via a cash settlement and is not limited to settlement of the obligation in shares in the Company.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### Accounting for the convertible debt instrument

The net proceeds received from the issue of the Planwise Convertible Loan Note has been recorded as a debt liability in the balance sheet and the accrued interest charged to the income statement. The liability for the convertible debt instrument at 31 December is:

	<b>2020</b> <b>£000</b>	<b>2019</b> <b>£000</b>
Convertible loan notes issued	252	243
Accrued interest	8	9
	<u>260</u>	<u>252</u>

### 22. CONVERTIBLE INSTRUMENTS CLASSIFIED AS EQUITY

On 31<sup>st</sup> October 2019, the Company decided to raise convertible equity finance, with warrants attached, from supportive existing shareholders. £1,473,000 was raised from the issuance of Convertible Loan Notes. The Loan Notes are short term instruments and carry a coupon of 16% per annum and are convertible (together with all accrued interest) into ordinary shares of nominal value £0.03 each in the capital of the Company at a conversion price of 42p, they are not convertible into cash. The Loan Notes are convertible on the third anniversary of the date of issue of the Notes, or at the election of the noteholder on completion of the next non-qualifying equity financing or on the making of a takeover offer for the Company (as defined in the City Code on Takeovers and Mergers), and such election may be made on an immediate basis or conditional on any such takeover offer being declared, or becoming, unconditional.

The warrants issued in connection with the Loan Notes entitle the holders to subscribe for one additional share per conversion share at the same price of 42p. The warrants may be exercised for a period of up to 5 years from their date of issue.

The principal amount of the Convertible Equity Instrument that was recorded as in the convertible loan note reserve prior to conversion is as follows:

	<b>2020</b> <b>£000</b>	<b>2019</b> <b>£000</b>
Par value of Convertible loan notes issued	1,593	1,473
Less: Fair value of warrants issued to note holders	(484)	(413)
Less convertible loan note conversion Exercise	1,109	1,060
Accrued interest	255	39
Less: convertible loan note conversion	(1,848)	-
Exercise of Warrants	484	-
	<u>-</u>	<u>1,099</u>

### 23. RESERVES

The share-based payment reserve for warrants represent the value of equity shares which could be issued in future accounting periods if the warrants in issue are exercised.

The share-based payment reserve for options represents the value of equity shares which could be issued in future accounting periods if the share-based payment options in issue are exercised.

The convertible loan note reserve represents the value of equity shares which could be issued in future accounting periods if the convertible loan notes are converted into equity.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

The other reserve was created as a result of the reverse acquisition of Alexander David Investments Plc, which is described in note 2. The reserve is required due to the fact that the reverse acquisition accounting requires the legal parent's equity structure to be shown.

Retained earnings represent the cumulative profits/(losses) of the entity which have not been distributed to shareholders. This reserve has been credited as part of the capital reduction exercise described below.

The shares to be issued reserve represents the equity shares that are to be issued to the Chairman in lieu of his realisation bonus, which became payable during the course of the year.

On the 14 of September 2016 the High Court granted the Company permission to cancel its share premium account and its capital redemption reserve. The order had previously been ratified at the AGM held on 30 June 2016. The £31.1m of distributable reserves arising from this transaction were taken to the capital reduction reserve. The Company also decided to cancel its merger relief reserve as part of this capital reduction exercise.

On October 26, 2020 the High Court granted the Company permission to reduce its share premium account by £4m in order to distribute a dividend to effect the demerger of its subsidiary, Stemprinter Sciences Ltd. The order had previously been ratified at a General Meeting held on October 2, 2020. The £4m of distributable reserves arising from this transaction were taken to the capital reduction reserve. A capital distribution was then made to Tiziana shareholders by way of shares in Accustem of £3,225,314.

The translation reserve represents the unrealised gains or losses from the foreign currency translation of Companies within the Group.

### 24. FINANCIAL INSTRUMENTS

The main risks arising from the Group's financial instruments are liquidity risk, foreign currency risk and credit risk. The directors regularly review and agree policies for managing each of these risks which are summarised below.

#### Market risk

Market risk encompasses three types of risk, being foreign currency exchange risk, price risk and fair value interest rate risk. The Group policies for managing fair value interest rate risk are considered along with those for managing cash flow interest rate risk and are set out in the subsection entitled "interest rate risk" below. The Directors do not consider the Group's exposure to price risk to be significant. The Group's risk management is coordinated by the Directors and focuses on actively securing the Group's short to medium term cash flows by minimising the exposure to financial markets. The Group does not engage in the trading of financial assets for speculative purposes.

#### Credit risk

Credit risk is managed on a Group basis. Credit risk arises principally from cash and cash equivalents and deposits with banks and financial institutions as well as credit exposure to customers including committed transactions and outstanding receivables. The Group reviews its banking arrangements carefully to minimise such risks and currently has no customers and therefore this risk is viewed as minimal. Management monitor loans between members of the Group as part of their internal reporting and assess outstanding receivables for ability to be repaid.

#### Liquidity risk

The Group's policy is to regularly monitor current and expected liquidity requirements to ensure that it maintains sufficient reserves of cash to meet its liquidity requirements in the short and long term. The Group ordinarily finances its activities through cash generated from by private and public offerings of equity and debt securities.

The table below summarises the maturity profile of the Group's financial liabilities based on contractual undiscounted payments:

£000	2020		
	Less than 3 months	3 to 12 months	Total
Trade and other payables	1,920	546	2,466
Related party payables	-	997	997
	<u>1,920</u>	<u>1,543</u>	<u>3,463</u>

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

### Foreign currency risks

The group operates internationally although the majority of its operations are based in the United Kingdom and the majority of assets and liabilities denominated in Pounds Sterling. It therefore is exposed to foreign exchange risk arising from exposure to various currencies primarily the Euro and US Dollar.

The Group monitors currency exchange rates and makes judgments as to whether to enter into currency hedging contracts. Currently no such hedging contracts are in place.

#### *Sensitivity analysis*

A reasonably possible strengthening (weakening) of the Euro, US dollar, or Sterling against all other currencies at 31 December 2020 would have affected the measurement of the financial instruments denominated in a foreign currency and affected equity and profit and loss by the amounts shown below. This analysis assumes that all other variables remain constant.

December 31, 2020	Profit or loss and equity	
	Strengthening	Weakening
EUR (5% movement)	44	(44)
USD (5% movement)	70	(70)

### Interest rate risk

The Group has limited exposure to interest-rate risk arising from its bank deposits. These deposit accounts are held at variable interest rates based on Barclays Bank base rate.

The Directors do not consider the impact of possible interest rate changes based on current market conditions to be material to the net result for the year or the equity position at the year-end for either the year ended 31 December 2020 or 31 December 2019.

## 25. CAPITAL RISK MANAGEMENT

For the purpose of the Group's capital management, capital includes called up share capital, share premium, share based payments for options, share based payments for warrants, convertible loan note reserve, capital reduction reserve and all other equity reserves attributable to the equity holders of the parent as reflected in the statement of financial position.

The Company's objectives when managing capital are to safeguard the Company's ability to continue as a going concern and to maximise shareholder value through the optimisation of the debt and equity balance.

The Group adjusts its capital structure in light of changes in economic conditions and expected business demands on capital. In order to maintain or adjust its capital structure, the Group considers whether or not to pay dividends and adjusts the amount of any dividend payments to shareholders. The Group may also return capital to shareholders or issue additional shares.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

**26. TRADE AND OTHER PAYABLES**

<u>Group</u>	<b>2020</b> £000	<b>2019</b> £000
Trade payables	2,466	3,178
Accruals	1,629	1,673
	4,095	4,851
<u>Company</u>	<b>2020</b> £000	<b>2019</b> £000
Trade payables	847	970
Accruals	1,387	1,121
	2,234	2,091

**27. RELATED PARTY TRANSACTIONS**

Rasna Therapeutics Inc is a related party as Keeren Shah, Finance Director of Tiziana, is also Finance Director of Rasna and John Brancaccio and Willy Simon, directors of our Company, are also directors of Rasna. Rasna is also party to a Shared Services agreement with Tiziana whereby the Company is charged for shared services such as the payroll and rent. During 2020, Tiziana extended a loan to Rasna for \$72,000 at an interest rate of 8% per annum. As of December 31, 2020, £58k (2019: £4k) was owed to Tiziana Life Sciences PLC in respect of the loan and shared services agreement.

In addition to the above, Tiziana also acquired all of the intellectual property relating to a nanoparticle-based formulation of Actinomycin D (Act D; a.k.a. Dactinomycin), from Rasna to expand its pipeline for a consideration of an initial £97k (\$120k) upfront payment and milestone payments of up to an additional aggregate \$630k.

OKYO Pharma Ltd is a related party as Kunwar Shailubhai, director of our Company, is also a director of OKYO. In addition, Keeren Shah, Finance Director of Tiziana, is also Finance Director of OKYO. OKYO is also party to a Shared Services agreement with Tiziana whereby the Company is charged for shared services such as the payroll and rent. As of December 31, 2020, £20k (2019: £21k) was owed to Tiziana Life Sciences PLC in respect of this agreement.

Gensignia Lifesciences Inc is a related party as Kunwar Shailubhai, director of our Company, is also a director of Gensignia. As of December 31, 2020, £258k (2019: £241k) was owed to Tiziana Life Sciences PLC.

Accustem Sciences Ltd is a related party as Kunwar Shailubhai, director of our Company, is also a director of Accustem. In addition, Keeren Shah, Finance Director of Tiziana, is also Finance Director of Accustem. As of December 31, 2020, £1,148k was owed to Accustem, made up of cash payable of £1,151k offset by £3k worth of costs paid by Tiziana on Accustem's behalf.

As at December 31, 2020, Kunwar Shailubhai owed the Company £140,000 for the exercise of his options.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2020**

**28. LEASES**

Right-of-use assets	<b>31 Dec 2020</b>	<b>31 Dec 2019</b>
	<b>£000</b>	<b>£000</b>
At 1 January	329	833
Additions	-	-
Depreciation	(67)	(194)
Finance lease receivable	-	(249)
Loss on disposal	-	(56)
Foreign exchange movements		(5)
	<hr/>	<hr/>
	262	329

Lease Liabilities	<b>31 Dec 2020</b>	<b>31 Dec 2019</b>
	<b>£000</b>	<b>£000</b>
At 1 January 2020	623	833
Additions	-	-
Interest expense	13	24
Lease payments	(235)	(234)
Foreign exchange movement	6	-
	<hr/>	<hr/>
	407	623

Lease liabilities are presented in the statement of financial; position as follows:

	<b>31 Dec 2020</b>	<b>1 Jan 2020</b>
	<b>£000</b>	<b>£000</b>
Current	195	212
Non-current	212	411
	<hr/>	<hr/>
	407	623

The lease liabilities are secured by the related underlying assets. Future minimum lease payments as at 31 December 2020 were as follows:

	<b>Minimum lease payment due</b>				
	Within 1 year	1-2 years	2-5 years	Over 5 years	Total
<b>31 December 2020</b>					
Lease payments	205	74	148	-	427
Finance Charges	(10)	(6)	(4)	-	(20)
<b>Net Present Values</b>	<b>195</b>	<b>68</b>	<b>144</b>		<b>407</b>

The total net cash outflow for leases in the year to 31 December 2020 was £155,549.

**29. POST BALANCE SHEET EVENTS**

On 4 January 2021, the Company announced that it had completed its clinical study in Brazil investigating nasally administered Foralumab, its proprietary human monoclonal antibody, either alone or in combination with orally administered dexamethasone in COVID-19 patients.

On 13 January 2021, the Company announced the appointment of Dr Neil Graham MBBS, MD, MPH as Chief Medical Officer.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2020

On 20 January 2021, the Company announced the cancellation of admission of its Ordinary Shares to trading on AIM and admission to listing of its ordinary shares on the standard listing segment of the Official List of the Financial Conduct Authority and admission to trading on the main market for listed securities of London Stock Exchange plc. The last day of trading of the Company's Ordinary Shares on AIM was 20 January 2021 and the AIM Delisting was effective from 7.00 am 21 January 2021. Admission of shares to the Official List and commencement of dealing in the Ordinary Shares of the Company on the Main Market was effective from 8.00 am on 21 January 2021.

On 5 February 2021, the Company announced the appointment of Dr Thomas Adams, Ph.D. as an executive director. Dr Adams assumed the position of Head of Drug Development with immediate effect and his executive role is to manage and oversee all matters relating to the Company's pre-clinical and clinical drug development programs and associated intellectual property.

On 30 March 2021, the Company announced that the U.S. Food and Drug Administration (FDA) has allowed evaluation of nasal administration with Foralumab, a fully human anti-CD3 monoclonal antibody, in a secondary progressive multiple sclerosis (SPMS) patient at the Brigham and Women's Hospital (BWH), Harvard University, Boston, MA. This patient will be treated under an Individual Patient Expanded Access IND. This is the first time a nasally administered antibody will be administered to a patient with SPMS. The treatment is planned to start in the third quarter of 2021 and will continue for six months. Investigators at BWH will follow this patient with detailed routine safety, neurological, imaging and PET studies to evaluate microglial imaging. Modification of immunological and neurodegenerative markers is part of standard investigations that will be conducted at the BWH.

The Company does not believe that the recent outbreak of COVID-19 pandemic will have an adverse effect on the Company's operations. Indeed, the Company has raised substantial funds during the pandemic to enable it to expedite development of TZLS-501 as well as other initiatives within its project pipeline.

### 30. FINANCIAL COMMITMENTS

The Group's main financial commitments relate to the contractual payments in respect of its licensing agreements. Due to the uncertain nature of scientific research and development and the length of time required to reach commercialisation of the products of this research and development, pre-clinical, clinical and commercial milestone obligations are not detailed until there is a reasonable certainty that the obligation will become payable. Contractual commitments are detailed where amounts are known and certain.

Milciclib project research future payments relate to the achievement of clinical milestones or the payment of royalties. We are obligated to pay Nerviano the following additional amounts in respect of the first licensed product or service which achieves the stated development milestones:

- (a) \$100,000 upon initiation, first patient dosed, or FPD, of the first Phase 3 registration trial in thymic carcinoma.
  - (b) \$4,000,000 upon FPD of the first Phase 3 registration trial in HCC.
  - (c) \$6,000,000 upon FPD of the first Phase 3 registration trial in breast cancer.
  - (d) Upon the first NDA equivalent in: thymic carcinoma, \$900,000; HCC, \$9,000,000; breast cancer, \$15,000,000.
- - Foralumab project – Future payments relate to the achievement of clinical milestones or the payment of royalties. Diligence obligations are payable to BMS/Medarex should the project continue to commercialisation. \$1,500,000 has been accrued in respect of diligence obligations due to Medarex.
  - ACT D - Tiziana will need to make milestone payments of up to \$630k depending on the issuance of a US patent from any US patent application in Transferred IP relating to nanoparticle formulations of Act D and upon the successful completion of a Phase II clinical efficacy trial.