COMPANY NUMBER 03508592

# TIZIANA LIFE SCIENCES PLC ANNUAL REPORT & FINANCIAL STATEMENTS YEAR ENDED 31 DECEMBER 2019

# FINANCIAL STATEMENTS FOR THE YEAR ENDED 31ST DECEMBER 2019

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# STATUTORY AND OTHER INFORMATION

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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 2019.

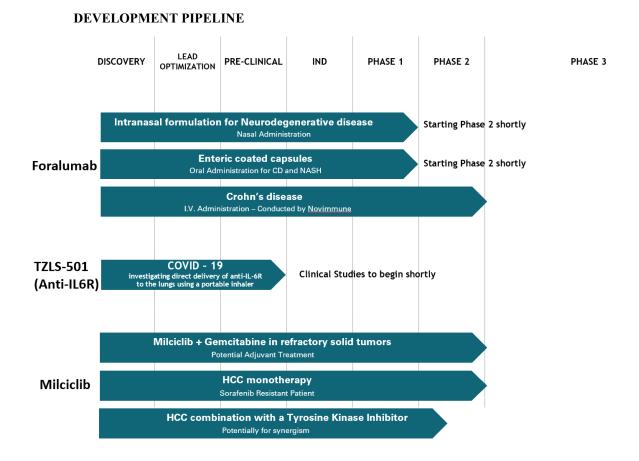
## Background

Tiziana Life Sciences plc is a publicly-listed (NASDAQ: TLSA; AIM:TILS) biotechnology company focused on the discovery and clinical development of innovative therapeutics for cancers, autoimmune and inflammatory diseases. The Group combines field-leading medical scientists, providing deep knowledge and novel insights into disease mechanisms, together with a highly experienced clinical development team. Since its foundation in 2013, Tiziana Life Sciences has expanded its pipeline of assets to include clinical stage development therapeutic candidates in both oncology and immunology, as well as a pre-clinical drug discovery pipeline.

#### **Clinical Programmes**

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 lead product candidate in immunology are 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. In addition, we are accelerating development of another fully human monoclonal antibody anti-IL6R (TZLS-501) to treat acute inflammation resulting from infection with viral agents such as Coronaviruses. Antibodies produced in animals for use in humans, lead to strong, immune responses limiting their effectiveness and potentially leading to severe side effects. A process known as "humanization" removes most of the animal components of the antibody thereby lowering the immune response from the human immune system. The entire omission of other animal material, as in fully human antibodies, is the optimal goal to avoid incompatibility with the human immune system. Our lead product candidate in oncology is Milciclib (TZLS-201), which is an orally bioavailable, small molecule broad spectrum inhibitor of cyclin-dependent kinases, or CDKs, and Src family kinases. CDKs are a highly conserved family of enzymes that phosphorylate a specific group of proteins that are involved in regulating the cell cycle. The cell cycle is a series of events that takes place in cells leading to division and duplication of its DNA to produce two daughter cells. Src family kinases are non-receptor tyrosine kinase proteins encoded by the Src gene also involved in regulating cell growth and potential transformation of normal cells to cancer cells. 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. 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.



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

Foralumab is a fully human engineered anti-CD3 monoclonal antibody (mAB). It was in-licensed in December 2014 from Novimmune. In January 2016, Tiziana outlined its clinical development plan for Foralumab with initial plans to evaluate the drug in two clinical indications: non-alcoholic steatohepatitis (NASH) and inflammatory bowel disease (IBD).

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. With completion of the intravenous dosing for our 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 GvHD, ulcerative colitis, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis.

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 the Company's TZLS-501, a fully human anti-IL-6R mAB in development to target autoimmune and inflammatory diseases.

In November 2016, Tiziana announced new data for oral efficacy in humanized mouse models with Foralumab, a major milestone and a potential breakthrough for the treatment of NASH 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).

On 16 April, 2018, the Group 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 (IND) for the first-in-human evaluation of the nasal administration of Foralumab in healthy volunteers for progressive multiple sclerosis 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 conducted at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, in healthy volunteers. 18 subjects received Foralumab treatment and 9 patients received placebo. All nasal doses were well tolerated. The study was completed in

September 2019. Phase 1 clinical 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 pre-dose, during treatment and at discharge. The mean blood pressure (BP) during the 5 days of treatment were; Cohort A (10  $\mu$ g/d):124/73, Cohort B (50  $\mu$ g/d): 119/67 and Cohort C (250  $\mu$ g/d):113/65 compared to placebo:118/67). Heart rates, respiratory rates and oral temperatures were unchanged among the 3 cohorts compared to the placebo. Nasally administered Foralumab at the 50  $\mu$ g dose suppressed cytotoxic CD8+ as well as perforin secreting CD8+ cells, which have been implicated in neurodegeneration in multiple sclerosis (MS). Treatment at 50 mg stimulated production of anti-inflammatory cytokine IL-10 and suppressed production of pro-inflammatory cytokine IFN- $\gamma$ . 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.

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 has been submitted in March 2019.

On September 9, 2019, the FDA granted approval to initiate the 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. The study was completed in December 2019 at Brigham and Women's Hospital (Boston, MA USA). 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 second half of 2020.

### Milciclib (TZLS-201)

Milciclib, Tiziana's lead small molecule drug, was exclusively licenced in January 2015 from Nerviano Medical Sciences. Milciclib is an orally bioavailable, broad spectrum inhibitor of Cyclin Dependent Kinases (CDKs): 1, 2, 4, 5 and 7 and Src family kinases. Cyclin dependent kinases are a family of highly conserved enzymes that are involved in regulating the cell cycle. Src family kinases regulate cell growth and potential transformation of normal cells to cancer cells. A unique feature of Milciclib is its ability to reduce microRNAs, miR- 221 and miR-222, which silence gene expression. miR-221 and miR-222 promote the formation of blood vessels (angiogenesis) that are important for the spread of cancer cells (metastasis). Levels of these microRNAs are consistently increased in hepatocellular carcinoma ("HCC") patients and may contribute towards resistance to treatment with Sorafenib. As a result, the Group are investigating Milciclib both as a monotherapy and as a combination treatment with Sorafenib.

To date, Milciclib has been studied in a total of eight completed and ongoing 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-tumour action. Prior to in-licensing, Milciclib was granted orphan designation by the European Commission and by the U.S. Food and Drug Administration ("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.

The Group 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 3-5 months In May 2018, the Independent Data Monitor committee (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 Independent Monitoring Committee, or 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 diarrhea, ascites, nausea, fatigue, asthenia, fever, ataxia, headache, and rash were manageable. No drug-related deaths were recorded.

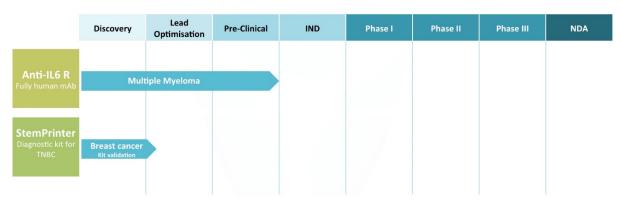
The clinical activity assessment in evaluable patients was based on the independent radiological review using the modified Response Evaluation Criteria in Solid Tumors (mRECIST).

- ·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).

The Phase 2a trial was completed in June 2019 with clinical safety and efficacy result reported in July 2019.

Since overexpression of 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 refractory to gemcitabine. We plan to explore a combination approach in patients with HCC.

## **Pre-Clinical Programmes**



In pre-clinical development, the Group has two programmes:

## 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.

## 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.

#### **Financial summary**

#### Consolidated Statement of Comprehensive Income

The Group has made a loss for the year of £7,178k (2018 restated: £6,063k). The loss is detailed in the consolidated statement of comprehensive income on page 32.

Research and development costs were £2.9 million for the year ended December 31, 2019 as compared to £4.1 million for the year ended December 31, 2018, a decrease of £1.2 million. The decrease in cost is a result of the completion of the Miciclib Phase 2a of clinical trials during the first half of 2019.

#### Consolidated Statement of Financial Position

At the end of the year the Group cash balance amounted to £153k (2018: £4,165k) and the total assets of the Group amounted to £1,808k (2018: £5,436k). To bolster our cash reserves, the Group raised \$10m via a public offering of American Depositary Shares ("ADSs") on the NASDAQ Global Market in March 2020

#### Fund raising

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

On 1 November 2019, the Company announced that it had raised £1,434,000 cash by issue of convertible unsecured loan notes, with warrants attached. The Loan Notes are expected to be 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. 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 issue.

#### Resignations

#### Non-Executive Directors

On 7 February 2019, the Group announced the resignation of Riccardo Dalla-Favera MD as a non-executive director.

On 20 November 2019, the Group announced the resignation of Mr Leopoldo Zambeletti as a non-executive director, noting the significant business interests of Mr Zambeletti in a wide range of life sciences companies.

### 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 its ongoing "At the Market" or "ATM" Sales Agreement with Think Equity (a division of Fordham Financial Management, Inc.) to raise up to US\$20m from the sale of ADSs.

We are also aware of the responsibility we have as a member of the global healthcare community we have developed investigational new technology 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 have developed 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 handheld inhaler or nebulizer. Preclinical studies are ongoing and we hope to commence a trial investigating the direct delivery of an anti-IL-6 mAb to the lungs using a portable inhaler.

We have outlined our clinical development plan for Foralumab and anticipate to commence Phase 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.

We are continuing development of StemPrint ER diagnostic tester. Recently, StemPrintER results were announced, from a poster selected for discussion session at the American Society of Clinical Oncology (ASCO) Virtual Conference, demonstrating the superiority of StemPrintER stem cell based genomic prognostic tool versus the market leader, Oncotype DX, in predicting recurrence in ER+/HER2- postmenopausal breast cancer patients. Looking ahead, Tiziana is confident that it is well positioned to advance these programs to their next respective value inflection points.

We would like to thank the staff and Board members for all their contributions and shareholders for their continued support during a successful year.

## **Gabriele Cerrone**

Executive Chairman

June 17th, 2020

### **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. 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 2019 the main use of the Group's funds was completion of Phase II for Milciclib on single agent trials, involving recruitment of patients across different countries (Italy, Greece and Israel) and completion of Phase I clinical trials with nasally and orally administered Foralumab in healthy volunteers. 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 2019 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.

#### Share price

The Group monitors its share price to determine whether the market view of the Group's position and prospects is aligned with the view of management, and to consider the most appropriate time to raise further capital in the interest of the Group and current shareholders. The Group raised funds via an initial public offering of American Depository Shares on the Nasdaq Global market in November 2018 at a share price of \$0.99 per share and ended the financial period at \$0.75 per share.

### **Non-financial KPIs**

#### Successful Progress in clinical trials

Completion of the Phase 2a Milciclib clinical trial.

- In March 2019, the Independent Monitoring Committee, or 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.
- In June 2019, the Group completed the Phase 2a Milciclib clinical trial, with clinical safety and efficacy result reported in July 2019.

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

- 27 healthy subjects were enrolled in and completed a Phase 1 clinical trial for progressive multiple sclerosis indication for nasally administered Foralumab.
- 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 has been submitted in March 2019.
- On September 9, 2019, the FDA granted approval to initiate the 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. The study was completed in December 2019

### 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
- 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 2019.

### Principal risks and uncertainties

The Group assesses and monitors the inherent risks in the life sciences industry, as well as other micro and macroeconomic factors that may present risk to the Group's progression. The Group also considers Group-specific risks such as research progress, personnel and operational facilities and collaborations.

There are significant risks associated with any life science business. The Board believes that the following risks are the most significant, however, the risks listed do not necessarily comprise all those associated with an investment in the Group. In particular, the Group's performance may be affected by changes in market or economic conditions and in legal, regulatory and/or tax requirements. The risks listed are not set out in any particular order of priority and this is not an exhaustive list of risks.

If any of the following risks were to materialise, the Group's business, financial condition, results or future operations could be materially and adversely affected. In such cases, the Group's share price may decline and an investor may lose part or all of their investment.

The main risks have been identified as follows:

Risks Related to the Development of our Product Candidates

- If we encounter substantial delays in clinical trials of our product candidates, we may be unable to obtain
  required regulatory approvals, and therefore will be unable to commercialize our product candidates on a
  timely basis or at all.
- We may fail to demonstrate the safety and therapeutic utility of our product candidates to the satisfaction of applicable regulatory authorities, which would prevent or delay regulatory approval and commercialization.
- We depend on enrolment of patients in our clinical trials for our product candidates and may find it difficult to enrol patients in our clinical trials, which could delay or prevent us from proceeding with clinical trials of our product candidates and could materially adversely affect our R&D efforts and business, financial condition and results of operations.
- Our product candidates and the process for administering our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences following any potential marketing approval.
- Any contamination in our manufacturing process, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules.

Risks Related to Our Financial Position and Need for Capital

- We have incurred net losses in every year since our inception. We anticipate that we will continue to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We need substantial additional funding to complete the development of our product candidates, which may not be available on acceptable terms, if at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate certain of our product development, research operations or future commercialization efforts, if any.
- Our limited operating history and no history of commercializing pharmaceutical products may make it difficult to evaluate the success of our business to date and to assess the prospects for our future viability.

Risks Related to Our Reliance on Third Parties

- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.
- Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.
- We utilize, and expect to continue to utilize, third parties to conduct our product manufacturing for the foreseeable future, and these third parties may not perform satisfactorily.
- To the extent we rely on a third-party manufacturing facility for commercial supply, that third party will be subject to significant regulatory oversight with respect to manufacturing our product candidates.

#### Risks Related to Commercialization of Our Product Candidates

- We currently have no marketing and sales force. If we are unable to establish effective sales, marketing and distribution capabilities or enter into agreements with third parties to market, sell and distribute our product candidates that may be approved, we may not be successful in commercializing our product candidates if and when approved, and we may be unable to generate any product revenue.
- The market opportunities for our product candidates may be smaller than we anticipate.
- The future commercial success of our product candidates will depend upon the degree of each product candidates' market acceptance by physicians, patients, third-party payors and others in the medical community.
- The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market those products.

Risks Related to Our Intellectual Property

- Our rights to develop and commercialize our product candidates are subject to the terms and conditions of licenses granted to us by others. If we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to the business.
- If we are unable to obtain and maintain patent protection for our current product candidates, any future
  product candidates we may develop and our technology, or if the scope of the patent protection obtained
  is not sufficiently broad, our competitors could develop and commercialize products and technology similar
  or identical to ours.
- Our intellectual property licenses with third parties may be subject to disagreements over contract interpretation, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.
- If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.
- We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.
- Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of non-compliance with these requirements.
- We may not be able to protect our intellectual property rights throughout the world.
- We may not be able to protect our trade secrets in court.
- Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights.
- Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.
- We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.
- If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest.
- Intellectual property rights and regulatory exclusivity rights do not necessarily address all potential threats.

Risks Related to Government Regulation

- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates and the approval may be for a narrower indication than we seek.
- Delays in obtaining regulatory approval of our manufacturing process and facility or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts.
- If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our product candidates, we may not be able to have competing products approved by applicable regulatory authorities for a significant period of time. In addition, even if we obtain orphan drug exclusivity for any of our products, such exclusivity may not protect us from competition.
- Even if we obtain regulatory approval for a product candidate, our product candidates will remain subject to regulatory oversight.
- Even if we obtain and maintain approval for our product candidates in a major pharmaceutical market such as the United States, we may never obtain approval for our product candidates in other major markets.
- We may seek a conditional marketing authorization in Europe for some or all of our current product candidates, but we may not be able to obtain or maintain such designation.
- Healthcare legislative reform measures may have a negative impact on our business and results of
  operations.
- We are subject to governmental regulation and other legal obligations related to privacy, data protection and data security. Our actual or perceived failure to comply with such obligations could harm our business.
- We are subject to the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.
- Our relationships with customers, physicians and third-party payors will be subject, directly or indirectly, to
  federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and
  security laws and other healthcare laws and regulations. If we are found in violation of these laws and
  regulations, we may be required to pay a penalty or be suspended from participation in federal or state
  healthcare programs, which may adversely affect our business, financial condition and results of
  operations.
- If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur substantial costs.

Risks Related to our Business Operations

- We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may be a greater commercial opportunity or for which there is a greater likelihood of success.
- Our future success depends on our ability to retain key employees, consultants and advisors and to recruit, retain and motivate qualified personnel.
- If we are unable to manage expected growth in the scale and complexity of our operations, our performance may suffer.
- Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have a material adverse impact on our business.
- Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop.
- Legal, political and economic uncertainty surrounding the planned exit of the United Kingdom or the U.K., from the European Union, or EU, may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the U.K. and pose additional risks to our business, revenue, financial condition, and results of operations.
- Exchange rate fluctuations may materially affect our results of operations and financial condition.
- Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.

### 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. We note that there are no women on the board but that we 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, 2019, was as follows:

	December 31, 2019		
	Male	Female	Total
Number or persons who were Directors or officers of the Company	4	-	4
Number of persons who were other employees of the Company	2	4	6
Total employees at December 31,2019	6	4	10

## 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.

#### Long term value

The aim of all business resources allocation is to create a long-term value, being a development and commercialisation of novel drugs.

#### Our people

Being a small group with only on average 8 employees (including Executive Directors), there is a high level of visibility between Board and employees.

#### Business relationships

The Board is aware of the importance of maintaining good relationship with its key suppliers whilst safeguarding its resources.

For further details, please see page 15 for stakeholder engagement.

#### Community and environment

The Board seeks to support as many interactions with research and development community as possible through regular meetings and continuous collaborations. For further details, please see page 16 for stakeholder engagement.

#### Shareholders

Shareholder communications are conducted via press releases or annual and interim reports on timely manner. For further details, please see page 15 for stakeholder engagement.

#### **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 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.

### **Greenhouse Gas Emissions**

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).

However, we are aware that our activities do have an impact on GHG emissions through the work of our partners and our activities such as business travel. (Scope 3 disclosures). We have discussed with our partners the impact of our operations on emissions but they have not been able to provide the information for us to provide a meaningful analysis.

Whilst we have few employees, we have activities in the US and Europe and we need to fly our employees, directors and consultants to effectively manage our business and operations. We recognize that we do have control over business travel and have therefore chosen to disclose our estimated related greenhouse gas emissions.

By order of the Board Mr Willy Simon June 17<sup>th</sup> 2020

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

The Directors present their report and the financial statements of the Group and its Company for the year ended 31<sup>st</sup> December 2019.

### **Results and dividend**

The results of the Group for the year are set out on page 31. No dividends were declared or paid in the year (2018: 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 Dr Kunwar Shailubhai	Executive Chairman Chief Executive Officer
Mr Willy Simon	Non-Executive Director,
Dr Riccardo Dalla Favera	Non-Executive Director (resigned, 7 <sup>th</sup> February 2019)
Mr Leopoldo Zambeletti	Non-Executive Director (resigned, 20th November 2019)
Mr Gregor MacRae	Non-Executive Director (appointed, 21st January 2020)

#### 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 at 31<sup>st</sup> December 2019:

	Ordinary shares	
	Number	Percentage
Planwise Group Limited*	63,680,404	46.60%
The Bank of New York (Nominees)	32,970.762	24.13%
Guaranty Nominees Limited	15,543,630	11.37%
Security Services Nominees	4,946,568	3.62%
Nerviano Medical Sciences Srl	4,233,616	3.10%

\*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 Executive Directors, Non-Executive Directors and employees.

## Political and charitable contributions

There were no political or charitable contributions made by the Company during the year ended December 31, 2019 (2018: £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.

As an AIM listed company, 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 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.

## **Board Structure**

The Board is currently comprised of four directors, the Executive Chairman, one Executive director 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 issued 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 Directors 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 and AIM markets, and Kunwar Shailubhai who 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 Greg MacRae, 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.

## Stakeholder engagement

The Board seeks to understand and consider the views of the Group's key stakeholders in Board discussions and decision making.

Key Stakeholders and concerns	Board Considerations	Key Outcomes
Employees		Staff turnover has been very low.
Our present and future employees are key for the future success of the business	Executive directors update the Board with details of employee changes, concerns and recruitment prospects. An open, collaborative working environment with attractive remuneration packages aligns employees' with shareholders' goals.	All our employees participate in shar based incentives.
Shareholders		The Company meets periodically with
Our Shareholders have been highly supportive. We are actively encouraging	The Board is in regular communication with its Shareholders via press releases, Annual and Interim Report.	its Shareholders. Summary of these events are below:
retention of their investment whilst trying to secure new Shareholders and	Annual and Internit Report.	• AGM, 31 May 2019
funding		<ul> <li>Investor conferences, San Francisco USA, January 2019</li> </ul>
<b>Business Partners</b> We have worked closely with our suppliers to set up new commercial and development agreements	The Board is aware of the importance of maintaining good relationships with key suppliers while safeguarding the Group's assets. It receives regular updates on main supply agreements.	<ul> <li>Interviews: both audio and TV with Proactive Investor, [Directors Talk, Vox Markets and Investor meet Company].</li> <li>New supplier agreements with materia threshold need to be approved by tw directors.</li> </ul>
Research and Development Community	The Board seeks to support as many interactions with research and development community as possible through regular meetings and continuous collaborations.	With the budgets, the Board supported the research and development community to mee these objectives.
Environment	Tiziana's operations are relatively low in	During the year, employees reduced
The Group is conscious of the need to protect the environment	their impact on the environment.	their travel wherever reasonably practical, phone - conferencing instead
<b>Reputation</b> 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 an assesses all regulatory development to ensure that any issues are being addressed in decision making.

## Internal Control and Risk Management

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.
- 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.

## 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.

#### **Diversity Policy**

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.

The full QCA Compliance Statement can be found on the Company's, Tiziana Life Sciences Plc, website.

#### Audit Committee

The Audit Committee of the Board comprises of Greg MacRae and Willy Simon. It is chaired by Greg MacRae, 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;

- Receipt and review of reports from the Company's management and 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
- 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.

## **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;
- 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.

## **Remuneration Committee**

The Remuneration Committee of the Board comprises of Willy Simon and Greg MacRae. 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.

## 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 AIM Rules of the London Stock Exchange to prepare group financial statements in accordance with International Financial Reporting Standards ("IFRS") as adopted by the European Union ("EU") and have elected to prepare the Company financial statements in accordance with IFRS as adopted by the EU.

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 complied with IFRS as adopted by the European Union, subject to any material departures disclosed and explained in the Group financial statements;
- prepare the accounts on the going concern basis unless it is inappropriate to presume that the company will continue in business.

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.

#### **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.

#### Assessment of likely impact of the UK's proposed withdrawal from the European Union ('Brexit')

The Directors have assessed the impact of Brexit on the Group. The Group's key personnel are located outside of the European Union so Brexit will not have a material impact on its personnel or its ability to recruit appropriately qualified staff.

The Italian Medicines Agency (AIFA) have advised all sponsors of clinical trials who have engaged with UK companies that they will be obliged to appoint a legal representative who is established in an EU member state. Whilst the Group is impacted by this, it has accommodated this request via the appointment of Longevia Genomics SRL as the legal representative of the Group in this regard and will use this approach for any similar future requirements.

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

The recent outbreak of COVID-19 originated in Wuhan, China, in December 2019 and has since spread to multiple countries, including the United States and several European countries. On March 11, 2020, the World Health Organization declared the outbreak a pandemic.

The Company does not believe that the recent outbreak of COVID-19 pandemic will have an adverse effect on the Company' 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 6 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 6.

#### **Relations with shareholders**

The Board values good relations with the Company's shareholders and understands the importance of effectively communicating the Company's operational and financial performance as well as its future strategy. The Company's website provides financial information as well as historical news releases and matters relating to corporate governance.

The Chairman of the Board and the CEO maintain ongoing dialogue with shareholders and communicate their views to the Board. The Board recognizes it is accountable to shareholders and ensures that their views are taken into account in agreeing the Company's strategy and other operational matters. The Board also recognizes the importance of treating all shareholders equally.

Annual and interim results are communicated by regulatory news services as are ad hoc operational and regulatory releases. Shareholders may also attend the Annual General Meeting where they can discuss matters with the board.

#### Post balance sheet events

Subsequent to the year end the Group announced that it had appointed advisers in relation to an intended redomicile of the Company to Bermuda, as a consequence of the redomicile the Company will not be seeking to re-admit its ordinary shares on AIM and will therefore seek shareholder consent for its shares to be cancelled from AIM when the redomicile occurs. The timing of this exercise has been delayed due to COVID-19.

The Group also appointed Gregor MacRae as a non-executive director in January 2020.

The Group also announced that it had appointed advisers in relation to an intended redomicile of the Company to Bermuda, as a consequence of the redomicile the Company will not be seeking to re-admit its ordinary shares on AIM and will therefore seek shareholder consent for its shares to be cancelled from AIM when the redomicile occurs. The timing of this exercise has been delayed due to COVID-19.

The Group also raised \$10m in a public offering of American Depositary Shares ("**ADSs**") on the NASDAQ Global Market, that closed in March 2020.

The Group expedited the development of TZLS-501, (anti-IL6R) monoclonal antibody (mAb) for treatment of patients infected with coronavirus COVID-19 (SARS-CoV-2). Tiziana plans to administer TZLS-501 using a proprietary formulation technology.

The Group acquired all of the intellectual property relating to a nanoparticle-based formulation of Actinomycin D (Act D; a.k.a. Dactinomycin), from Rasna Therapeutics, Inc, a related party, to expand its pipeline for a consideration of an initial \$120,000 upfront payment and milestone payments of up to an additional aggregate \$630,000. The Group has also filed a provisional patent application on the combination of nanoparticle-Actinomycin D (NP-ACT D) with anti-interleukin-6 receptor monoclonal antibody (anti-IL-6R) as a potential therapy for management of COVID-19 disease.

The Group entered into an "At the Market" or "ATM" Sales Agreement with Think Equity (a division of Fordham Financial Management, Inc.) to raise up to US\$20m from the sale of ADSs (each representing 5 new ordinary shares). During the month of May 2020, the Group raised \$1,985,004 under this agreement.

In addition, the Group has raised an additional £710,843 from the conversion of warrants during the months of May and June 2020.

#### **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 8 to 11, and at note 2 to the financial statements.

By order of the Board

Mr Willy Simon June 17<sup>th</sup> 2020

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

### 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, 2019 which will be subject to an advisory vote under a resolution to be proposed at the 2020 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, 2019

Since January 1, 2019, the Committee has undertaken the following key decisions and activities.

- The Chairman drew the attention to the Company's financial position and its financing plans and noted that certain executive officers had accepted temporary salary reductions.
- Resolved that in light of the Company's financial situation, decisions regarding compensation and share options should be deferred until the Company's financing strategy had been implemented.

The Company has made significant progress during 2019 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 Chair of the Remuneration Committee June 17<sup>th</sup>, 2020

## Annual report on Remuneration

The information in this part of the Directors Remuneration Report ("DRR") is subject to audit.

# Single total figure of remuneration of each Director

The Directors received the following remuneration for the years ended December 31, 2019 and December 31, 2018:

Year Ended December 31, 2019 £'000	Base Salary	Bonus	Share-based payment <sup>(3)</sup>	Other (4)	2019 Total
Executive					
Gabriele Cerrone	80	143 <sup>(5)</sup>	296	-	519
Kunwar Shailubhai	470	159	695	32	1,356
Non - Executive					
Willy Simon	38	-	-	-	38
Leopoldo Zambeletti	-	-	-	-	-
Riccardo Dalla Favera	2	-	-	-	2
Total	590	302	991	32	1,915

Year Ended December 31, 2018 £'000	Base Salary	Bonus	Share-based payment <sup>(3)</sup>	Other <sup>(4)</sup>	2018 Total
Executive					
Gabriele Cerrone	93	-	272	-	365
Kunwar Shailubhai	225	79	618	15	937
Non - Executive					
Willy Simon	38	-	-	-	38
Riccardo Dalla Favera	20	-	1	-	21
Leopoldo Zambeletti	-	-	46	-	46
Total	376	79	937	15	1,407

- (1) Resigned 20<sup>th</sup> November 2020
- <sup>(2)</sup> Resigned 7<sup>th</sup> February 2019
- <sup>(3)</sup> Shares based payments represent the fair value of options that vested during the years ended December 31, 2019 and December 31, 2018.
- <sup>(4)</sup> Other benefits represent healthcare benefits
- <sup>(5)</sup> Bonus covers the period June 9, 2016 to December 31, 2019

No payments were made towards a pension plan for our executive directors.

A share price appreciation of 50% would have no impact on performance related pay.

### Statement of Directors' Shareholding and Share Interests

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, 2019:

Year Ended December 31, 2019	Shares	Options – not yet vested	Options – vested not yet exercised	Total (Shares and options)
Executive				
Gabriele Cerrone	64,225,925	3,809,403	3,200,000	71,235,328
Kunwar Shailubhai	5,000	5,700,000	1,500,000	7,205,000
Non - Executive				
Willy Simon	-	-	-	
Total	64,230,925	9,509,403	4,700,000	78,440,328

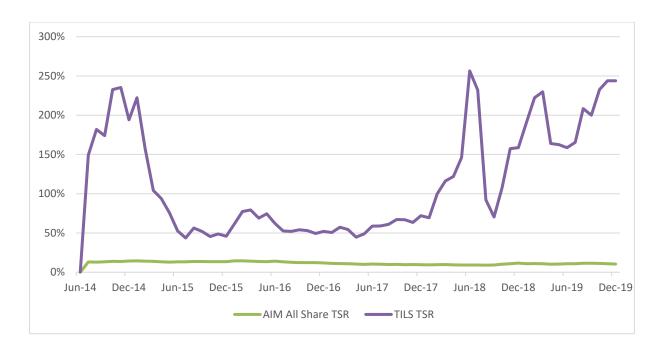
The interests of the Directors in the Company's share options are as follows:

Director	Granted	Date of grant	Price per share £	Vesting Criteria	Expiry Date
Gabriele Cerrone	1,200,000	25 April 2014	0.15	25 per cent. Will vest on each of 24/04/2015, 24/04/2016, 24/04/2017, 24/04/2018	10 years from date of vesting
	2,000,000	26 January 2016	0.35	Immediate	10 years from date of vesting
	3,259,403	9 June 2016	1.50	weighted average of an ordinary share must be greater than £3 for 120 consecutive dealing days	9 June 2026
	550,000	1 May 2018	0.8175	share price reaching £1.635 on a volume weighted average for 5 trading days	1 May 2028
Kunwar Shailubhai	300,000	25 April 2014	0.15	25 per cent. Will vest on each of 24/04/2015, 24/04/2016, 24/04/2017, 24/04/2018	10 years from date of vesting
	400,000	30 August 2017	1.595	25 per cent. will vest on each of 30 August 2018, 2019, 2020 and 2021	30 August 2027
	2,500,000	1 May 2018	0,8175	Vesting only on change of control	1 May 2028
	4,000,000	1 May 2018	0,8175	25 per cent. will vest on each of 30 April 2019, 2020, 2021 and 2022	10 years from date of vesting

## **Total Shareholder Return**

The graph below shows the Company's performance, measured by total shareholder return, for UK ordinary shares listed on AIM against the AIM All Share Index (AIM: TILS). 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 is considered to be the most suitable comparator index.

Total Shareholder Return (Source: Investing.com)



#### **Chief Executive Officer Total Remuneration History**

2018 was the first year that Tiziana Life Sciences PLC prepared a Directors' Remuneration Report and took the exemption not to disclose 5 years of history of remuneration. The Company has chosen to disclose remuneration history from 2018 onwards.

	2019	2018	
Total CEO Renumeration (£000)	938	858	

## Percentage change of Chief Executive Officer Total Remuneration

		Percentage increase for the year ended December 31, 2019 compared to the year ended December 31, 2018	
	CEO	Average Employee	
Base Salary	0%	0%	
Short term incentives	0%	0%	
Taxable Benefits <sup>(1)</sup>	0%	n/a	

(1) All average employees did not receive taxable benefits so a comparison is not possible.

## Payments to past directors (audited)

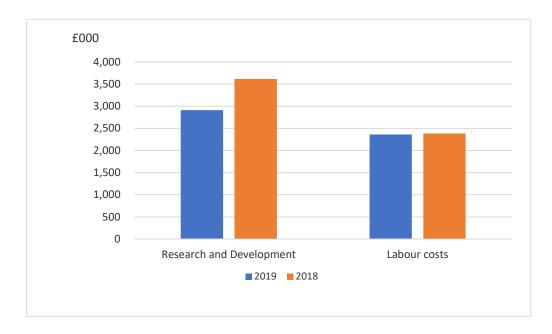
In the period there were no payments to past Directors.

#### 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.



## Structure and role of Remuneration Committee

The Remuneration Committee of the Board comprises of Willy Simon and Greg MacRae. 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.

The information in this part of the Directors' Remuneration Report ('DRR') is not subject to audit.

#### **Directors' remuneration policy**

The Policy was approved 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

Purpose and Link to Strategy	<ul> <li>To provide fixed remuneration to</li> <li>help recruit and retain key individuals;</li> <li>reflect the individual's experience, role and contribution within the Company.</li> </ul>	
Operation	<ul> <li>The Remuneration Committee considers a number of factors when setting salaries, including:</li> <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.	
Performance conditions	None.	
	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

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

# Element of reward - Annual Bonus

Purpose and Link to	To incentivise and reward the achievement of annual financial, operational and individual	
Strategy	objectives which are key to the delivery of the Company's short-term strategy.	

Operation	<ul> <li>Executive Directors and staff are eligible to participate in a discretionary bonus plan.</li> </ul>
	<ul> <li>The Remuneration Committee will determine on an annual basis the level of deferral, if any, of the bonus payment into Company shares.</li> </ul>
	<ul> <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> </ul>
	Bonuses are not pensionable.
	<ul> <li>The Remuneration Committee sets targets which require appropriate levels of performance, considering internal and external expectations of performance.</li> </ul>
	<ul> <li>As soon as practicable after the year-end, the Remuneration Committee meets to review performance against objectives and determines payout levels.</li> </ul>
	<ul> <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>
Performance conditions	<ul> <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> </ul>
	<ul> <li>A scale between 0% and 100% of the maximum award is paid dependent on the level of performance.</li> </ul>
Maximum opportunity	The maximum potential bonus entitlement for Executive Directors under the plan will be equal to 50% of the base salary.

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

Purpose and Link to Strategy	<ul> <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>
-	<ul> <li>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.</li> <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 employees under the plan.</li> </ul>
	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.

## 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, i 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.

Leaving Event	Time period	Conditions
Injury, disability, ill-health, redundancy	Option may be exercised within 3 months of leaving.	Exercise and time vesting provisions per the option certificate.
		Board can waive if satisfied that such waiver is not rewarding failure.
Death	Option may be exercised by personal representatives within	Exercise and time vesting provisions per the option certificate.
	12 months of death.	Board can waive if satisfied that such waiver is not rewarding failure.
Resignation or any other	Lapse of option unless	If allowed to exercise;
reason not mentioned above.	Board exercises discretion to allow exercise of option in which case within 3 months of leaving/notice.	Exercise and time vesting provisions per the option certificate.
		Board can waive if satisfied that such waiver is not rewarding failure.

#### Annual report on Remuneration

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 2019 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 Financial Reporting Standards (IFRSs) as adopted by the European Union and, as regards the Parent Company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the Parent Company's affairs as at 31 December 2019 and of the Group's loss for the year then ended;
- the Group's financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union;
- the Parent Company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

#### **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 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 SME listed 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.

#### Material uncertainty related to going concern

We draw attention to Note 2 in the financial statements concerning the applicability of the going concern basis of preparation. 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. In the period to 31 December 2019 the Group incurred losses after taxation of £7,306,000. At 31 December 2019, the Group and the Company had net liabilities of £4,180,000 and £1,705,000, and cash and cash equivalents of £153,000 and £116,000 respectively. In Note 2, the directors explain that to date they have successfully raised funds to finance clinical trials. Since the year end the Group has raised approximately \$12m in new equity. However, further significant funding will be required to continue their development programmes and to meet liabilities as they fall due. As the directors are confident that the Group will raise the additional funding they have prepared the accounts on the going concern basis. The Group needs to secure sufficient investment to fund their clinical trials in full and ongoing working capital requirements. These conditions indicate that a material uncertainty exists that may cast significant doubt on the Group's and Parent Company's ability to continue as a going concern.

Our opinion is not modified in respect of this matter.

### 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.

In addition to the matter described in the "Material uncertainty related to going concern" section, we have determined the matter described below to be the key audit matter to be communicated in our report. This matter was 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 this matter.

## Key Audit Matter 1 - Valuation and accounting of options, warrants, and convertible loan notes (Parent Company)

The Group's accounting policy in respect of "share based payments and convertible loan notes" are set out in the accounting policy notes on pages 45 and 46.

The Parent Company operates share-based payments arrangements to remunerate directors and employees in the form of share options. Additionally, warrants were granted in lieu of fundraising fees in 2015 which are exercisable over a four year period. Subsequently, additional warrants were granted as part of incentive attached to the convertible loans notes issued in 2019. These warrants are exercisable over a five year period.

With regards to the convertible loan notes, IAS 32 requires liability and equity components to be presented separately on 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.

Due to the complexity in calculation and judgement involved in underlying assumptions for the valuation of share options and warrants, there is a risk that these instruments are not accounted for correctly.

#### Our response:

Our audit procedures over options, warrants, and convertible loan notes included but were not restricted to:

- We obtained management's valuation of options and warrants based on an appropriate Model and reviewed for completeness and accuracy of information used;
- We reviewed the mechanics of the options and warrants calculations, and validated the inputs to the model;
- We obtained and reviewed 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;
- We examined 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;
- We reviewed the calculation for convertible debt instrument and ensured the principal of loan note and accrued interest are recorded appropriately on the financial statements;
- We reviewed Regulatory News Service (RNS) announcements per the London Stock Exchange website for purposes of concluding the completeness and accuracy of current year equity instrument issuances and/or other equity related transactions and conversion of convertible loan notes; and
- We reviewed the disclosure in the financial statements to ensure disclosure is sufficient and appropriate.

#### **Our findings:**

Our audit identified material errors in the accounting for warrants and share options in the year ended 31 December 2019. Management concurred with our findings and appropriate adjustments were made to the financial statements.

As a consequence of our 2019 findings, together with management, we reviewed the accounting for warrants and share options in prior periods and concluded that prior period adjustments were needed to reclassify entries between certain reserves. The overall impact on net assets was not significant. The reclassifications made are detailed in note 4.

Following the above adjustments we are able to conclude that warrants, share options and convertible loan notes were all appropriately accounted for under relevant accounting standards.

#### Our application of materiality

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:

Group and Parent Company materiality	Group - £452,000 Parent Company - £276,000

# How we determined materiality

In determining our materiality, we considered financial metrics which we believed to be relevant. We believe that the benchmark of losses is most appropriate for both Group & Parent Company as the users of the accounts were likely to be most concerned with the annual and accumulated losses of the Group and Parent Company and the Group and Parent Company's ability to continue as a going concern.

#### Rationale for benchmark applied

Having considered factors such as the Group and Parent Company's AIM and (NASDAQ) listing, we determined materiality at 6.0% of Group and Parent Company's losses for the year.

# Performance materiality – Group and Parent Company

We performed our audit procedures using a lower level of materiality – termed 'performance materiality' – which is set to reduce to an appropriate level the probability that the aggregate of uncorrected and undetected misstatements in the financial statements exceeds materiality for the financial statements as a whole. Having considered factors such as the Group's control environment, we set performance materiality at 65% of overall materiality.

## **Reporting threshold – Group and Parent Company**

We agreed with the Audit Committee that we would report to that committee all identified corrected and uncorrected audit differences in excess of this level, together with differences below that level that, in our view, warranted reporting on qualitative grounds. Group - £13,000 Parent Company £8,000

The range of financial statement materiality across components, audited to the lower of local statutory audit materiality and materiality capped for group audit purposes, was between £173,000 and £276,000, being all below group financial statement materiality.

## An overview of the scope of our audit

As part of designing our audit, we determined materiality and assessed the risk of material misstatement in the financial statements. In particular, we looked at where the directors made subjective judgements such as making assumptions on significant accounting estimates.

We gained an understanding of the legal and regulatory framework applicable to the Group and Parent Company, the structure of the Group and the Parent Company and the industry in which it operates. We considered the risk of acts that could be considered to be contrary to applicable laws and regulations, including fraud. We designed our audit procedures to respond to those identified risks, including non-compliance with laws and regulations (irregularities) that are material to the financial statements.

We focused on laws and regulations that could give rise to a material misstatement in the financial statements, including, but not limited to, the Companies Act 2006. We tailored the scope of our Group 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 Parent Company and Group's accounting processes and controls and its environment and considered qualitative factors in order to ensure that we obtained sufficient coverage across all financial statement line items.

Our tests included, but were not limited to, obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by irregularities including fraud, review of minutes of directors' meetings in the year and enquiries of management. As a result of our procedures, we did not identify any Key Audit Matters relating to irregularities, including fraud.

The risks of material misstatement that had the greatest effect on our audit, including the allocation of our resources and effort, are discussed under "Key audit matters" within this report.

Our Group audit scope included an audit of the Group and Parent Company financial statements. Based on our risk assessment, each of the Group's key subsidiaries (Tiziana Life Sciences Plc & Tiziana Pharma Limited) considered to be a significant component of the Group were subject to a full scope audit by the Group engagement team and other Group entities not considered to be significant components (Tiziana Therapeutics Inc & Longevia Srl), were subject to analytical review and limited audit procedures.

At the Parent Company level we also tested the consolidation process and carried out overall analytical procedures to confirm our conclusion that there were no material misstatements in the aggregated financial information.

### Other information

The directors are responsible for the other information. The other information comprises the information included in the Annual Report other than the financial statements and our auditor's report thereon. 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 audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material

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

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
- the Strategic Report and the Directors' Report have been prepared in accordance with applicable legal requirements.

#### 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.

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 parts 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.

#### **Responsibilities of Directors**

As explained more fully in the directors' responsibilities statement set out on pages 17 and 18, 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.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at <u>www.frc.org.uk/auditorsresponsibilities</u>. This description forms part of our auditor's report.

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

## Use of the audit report

This report is made solely to the 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 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 Company and the Company's members as a body for our audit work, for this report, or for the opinions we have formed.

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

17th June 2020

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2019

Continuing Operations	Note	<b>2019</b> £'000	<b>2018</b> £'000 (Restated)
Research and development costs Operating expenses		(2,910) (4,864)	(4,132) (3,268)
Operating loss	5	(7,774)	(7,400)
Finance costs	10	(72)	(9)
Loss before taxation		(7,846)	(7,409)
Taxation	11	540	1,459
Loss for the year attributable to equity owners		(7,306)	(5,950)
Other comprehensive income that may be classified to profit and loss in subsequent periods Exchange differences on translation of foreign operations		129	(113)
Total comprehensive loss for the year attributable to equity owners		(7,177)	(6,063)
Loss per share Basic and diluted (loss) per share on continuing operations	12	(5.4p)	(4.7p)

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2019

ASSETS	Note	<b>2019</b> £'000	<b>2018</b> £'000 (Restated)	<b>1 January</b> <b>2018</b> £'000 (Restated)
Non-Current assets				
Property, plant and equipment	13	5	6	18
Finance lease receivable	15	113	-	-
Right of use asset	27	329	-	-
Other non-current assets	16	217	217	217
Total non-current assets		664	223	235
Current assets				
Finance lease receivable	15	109	-	-
Related party receivable	26	245	20	20
Other receivables	14	124	228	94
Taxation receivable	11	513	800	1,434
Cash and cash equivalents		153	4,165	48
Total current assets		1,144	5,213	1,596
TOTAL ASSETS		1,808	5,436	1,831
EQUITY AND LIABILITIES Equity Capital and reserves attributable to equity holders of the company Called up share capital Share premium Capital reduction reserve Shares to be issued reserve (convertible notes) Share based payment reserve (options) Share based payment reserve (warrants) Other reserve	18 22 21 19,22 19,22 22	4,099 25,194 31,183 1,099 3,850 1,812 (28,286)	4,094 25,117 31,183 - 2,857 1,399 (28,286)	3,752 18,113 31,183 - 2,354 1,075 (28,286)
Translation reserve		15	(113)	-
Retained earnings	22	(43,146)	(35,840)	(29,874)
Total equity		(4,180)	411	(1,683)
Liabilities Non-Current liabilities Lease Liability	27	411	-	-
Current liabilities				
Trade and other payables	25	4,851	4,673	3,270
Lease liability	27	212	-	-
Related party payable	26	451	352	244
Other liabilities		63	-	
Total current and non-current liabilities	_	5,988	5,025	3,514
TOTAL EQUITY AND LIABILITIES		1,808	5,436	1,831

The financial statements were approved by the Board of directors and authorised for issue on 17<sup>th</sup> June 2020.

Mr W Simon Director

Company Number: 03508592 (England and Wales)

# COMPANY STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2019

		2019	2018	1 January 2018
	Notes	£'000	£'000 Restated	£'000 Restated
ASSETS			Nestated	Nestated
Non-current assets Investment in subsidiaries	17	-	20,305	16,005
Other non- current assets	16	217	217	217
Property, plant and equipment Current assets		-	-	6
Other receivables	14	62	343	1,055
Related party receivable Cash and cash equivalents	26	243 116	44 3,593	- 22
	_		3,595	
TOTAL ASSETS	-	638	24,502	17,305
EQUITY AND LIABILITIES Equity Capital and reserves attributable to equity holders of the company				
Called up share capital	18	4,099	4,094	3,752
Share premium		25,194	25,117	18,113
Shares to be issued reserve (convertible notes)	21	1,099	-	-
Share based payment reserve (options)	19,22	3,915	2,922	2,419
Share based payment reserve (warrants) Capital reduction reserve	19,22 22	1,875 31,183	1,462 31,183	1,138 31,183
Retained earnings	22	(69,070)	(42,387)	(40,522)
	_	(1,705)	22,391	16,083
Total equity				
Liabilities Current liabilities				
Trade and other payables	25	2,091	1,869	988
Related party payable	26 _	252	242	234
	_	2,343	2,111	1,222
TOTAL EQUITY AND LIABILITIES	_	638	24,502	17,305

The Company reported a loss for the financial year ended 31 December 2019 of £26,683k (2018: £1,849k, restated).

The financial statements were approved by the Board of directors and authorised for issue on 17<sup>th</sup> June 2020.

Mr W Simon Director

Company Number: 03508592 (England and Wales)

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 31 DECEMBER 2019

Cash flows from operating activities	<b>2019</b> £'000	<b>2018</b> £'000
Loss for the year before taxation	(7,846)	(7,409)
Adjustments for: Convertible loan interest accrued Loan interest paid as equity Shares issued in lieu of fees Share based payment – options Share based payment – warrants Net (increase) in related party receivables Net increase in related party payables Net decrease/(increase) in other receivables Net (decrease)/increase in trade and other payables Depreciation of property, plant and equipment Depreciation of right-of-use asset (Gain)/Loss on foreign exchange Lease adjustment Loss on disposal of right of use asset	39 - 82 992 - (225) 342 125 (17) 4 194 129 - 56	9 16 41 504 45 - 108 (135) 1,483 12 - (222) 3 -
CASH USED IN OPERATING ACTIVITIES	(6,125)	(5,544)
Increase in taxation receivable	800	2,093
NET CASH USED IN OPERATING ACTIVITIES	(5,325)	(3,451)
<b>Cash flows from financing activities</b> Proceeds from issuance of ordinary shares Proceeds from issuance of warrants Repayment of leasing liabilities Fundraising costs	1,473 (157) -	7,437 1,132 (1,001)
NET CASH GENERATED FROM FINANCING ACTIVITIES	1,316	7,568
<b>Cash flows from investing activities</b> Acquisition of property, plant and equipment Acquisition of other investments	(3)	- -
NET CASH GENERATED FROM INVESTING ACTIVITIES	(3)	-
NET (DECREASE)/ INCREASE IN CASH AND CASH EQUIVALENTS	(4,012)	4,117
Cash and cash equivalents at beginning of year	4,165	48
CASH AND CASH EQUIVALENTS AT END OF YEAR	153	4,165

# COMPANY STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 31 DECEMBER 2019

Cash flows from operating activities	<b>2019</b> £'000	<b>2018</b> £'000
cash hows nom operating activities		
Loss for the year before taxation	(26,683)	(2,427)
Adjustments for:		
Convertible loan interest accrued	39	9
Loan interest paid as equity	-	16
Shares issued in lieu of fees	82	41
Share based payment - options	992	503
Share based payment - warrants	-	45
Depreciation	-	6
Net (increase) in related party receivables	(243)	(44)
Net increase in related party payables Net decrease/(increase) in operating assets/other receivables	- 24	8 (35)
Net increase in trade and other payables	24	971
(Gain) on foreign exchange	-	(116)
Impairment of investment	21,966	(110)
	_ ,,	
CASH USED IN OPERATING ACTIVITIES	(3,589)	(1,023)
Increase in taxation receivable	300	1,326
NET CASH GENERATED (USED IN)/ GENERATED FROM	(3,289)	303
OPERATING ACTIVITIES		
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	-	7,437
Proceeds from issuance of warrants	-	1,132
Proceeds from issuance of warrants	1,473	-
Fundraising costs	-	(1,001)
-		
NET CASH GENERATED FROM FINANCING ACTIVITIES	1,473	7,568
Cash flows from investing activities		
Acquisition of property, plant and equipment	-	-
Acquisition of other investments	-	-
Capital contribution to subsidiaries	(1,661)	(4,300)
NET CASH USED IN INVESTING ACTIVITIES	(1,661)	(4,300)
	(1,001)	(4,000)
NET (DECREASE)/INCREASE IN CASH AND CASH	(3,477)	3,571
EQUIVALENTS		,
		_
Cash and cash equivalents at beginning of year	3,593	22
CASH AND CASH EQUIVALENTS AT END OF YEAR	116	3,593

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 31 DECEMBER 2019

	Share Capital	Share Premium	Capital Reduction Reserve	Share Based Payment Reserve (options)	Share Based Payment Reserve (warrants)	Convertible Loan Note Reserve	Other Reserve	Translation Reserve	Retained Earnings	Total Equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Balance at 1 January 2018	3,752	18,650	31,183	2,354	419	-	(28,286)	-	(29,755)	(1,683)
Prior period adjustment	-	(537)	-	-	656	-	-	-	(119)	-
Balance at 1 January 2018 (restated)	3,752	18,113	31,183	2,354	1,075		(28,286)	-	(29,874)	(1,683)
Transactions with owners										
Issue of share capital (private placement and IPO)	232	4,864	-	-	-	-	-	-	-	5,096
Issue of share capital (warrants)	44	1,085	-	-	-	-	-	-	-	1,129
Issue of share capital (loan conversion)	64	1,240	-	-	-	-	-	-	-	1,304
Share based payment (options)	-	-	-	503	-	-	-	-	-	503
Issue of share capital in lieu of fees	1	40	-	-	-	-	-	-	-	41
Convertible loan note interest	1	15	-	-	-	-	-	-	(16)	-
Share based payment (warrants)	-	(240)	-	-	324	-	-	-	-	84
Total transactions with owners	342	7,004	-	503	324	-	-	-	(16)	8,158
Comprehensive income										
Exchange differences on translating foreign operations	-	-	-	-	-	-	-	(113)	-	(113)
Comprehensive loss for the year	-	-	-	-	-	-	-	-	(5,950)	(5,950)
Total comprehensive income	-	-	-	-	-	-	-	(113)	(5,950)	(6,063)
Balance as at 31 December 2018 (Restated) Transactions with owners	4,094	25,117	31,183	2,857	1,399	-	(28,286)	(113)	(35,840)	411
Issue of share capital (in lieu of fees)	5	77	-	-	-	-	-	-	-	82
Convertible loan notes issued	-	-	-	-	-	1,473	-	-	-	1,473
Convertible loan note interest	-	-	-	-	-	39	-	-	-	39
Share based payment (options)	-	-	-	993	-	-	-	-	-	993
Issuance of warrants	-	-	-	-	413	(413)	-	-	-	-
Total transactions with owners	5	77	-	993	413	1,099	-	-	-	2,587
Comprehensive income										
Exchange differences on translating foreign operations	-	-	-	-	-	-	-	128	-	128
Comprehensive loss for the year	-	-	-	-	-	-	-	-	(7,306)	(7,306)
Total comprehensive income	-	-	-	-	-	-	-	128	(7,306)	(7,178)
Balance as at 31 December 2019	4,099	25,194	31,183	3,850	1,812	1,099	(28,286)	15	(43,146)	(4,180)

# COMPANY STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 31 DECEMBER 2019

	Share Capital	Share Premium	Capital Reduction Reserve	Share Based Payment Reserve	Share Based Payment Reserve (warrants)	Convertible Loan Note Reserve	Retained Earnings	Total Equity
	£'000	£'000	£'000	(options) £'000	£'000	£'000	£'000	£'000
Balance at 1 January 2018	3,752	18,650	31,183	2,419	482	-	(40,403)	16,083
Prior period adjustment	-	(537)	-	-	656	-	(119)	-
Balance at 1 January 2018 (restated)	3,752	18,113	31,183	2,419	1,138	-	(40,522)	16,083
Transactions with owners								
Issue of share capital	232	4,864	-	-	-	-	-	5,096
Issue of share capital (warrants)	44	1,085	-	-	-	-	-	1,129
Issue of share capital (loan conversion)	64	1,240	-	-	-	-	-	1,304
Share based payment (options)	-	-	-	503	-	-	-	503
Issue of share capital in lieu of fees	1	40	-	-	-	-	-	41
Convertible loan note interest	1	15	-	-	-	-	(16)	-
Share based payment (warrants)	-	(240)	-	-	324	-	-	84
Total transactions with owners	342	7,004	-	503	324	-	(16)	8,157
Comprehensive income								
Comprehensive loss for the year	-	-	-	-	-	-	(1,849)	(1,849
Total comprehensive income	-	-	-	-	-	-	(1,849)	(1,849)
Balance as at 31 December 2018	4,094	25,117	31,183	2,922	1,462	-	(42,387)	22,391
Transactions with owners								
Issue of share capital	5	77	-	-	-	-	-	82
Convertible loan notes issued	-	-	-	-	-	1,473	-	1,473
Convertible loan note interest	-	-	-	-	-	39	-	39
Share based payment (options)	-	-	-	993	-	-	-	993
Issuance of warrants	-	-	-	-	413	(413)	-	
Total transactions with owners	5	77	-	993	413	1,099		2,587
Comprehensive income								
Comprehensive loss for the year	-	-	-	-	-	-	(26,683)	(26,683)
Total comprehensive income	-	-	-	-	-	-	(26,683)	(26,683)
Balance as at 31 December 2019	4,099	25,194	31,183	3,915	1,875	1,099	(69,070)	(1,705)

## 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 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.

The ultimate parent of the group is Planwise Group Limited, incorporated in the British Virgin Islands. Gabriele Cerrone is the ultimate beneficial owner of the entire issued share capital of Planwise Group Limited.

## 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 Financial Reporting Standards (IFRS) as adopted by the European Union, IFRIC interpretations and the Companies Act 2006 as applicable to companies reporting under IFRS. 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 liabilities 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 is in the process of securing 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 for the next 12 months from the date when these financial statements are issued.

Until and unless the Group and Company secures sufficient investment to fund their clinical pipeline, there is a material uncertainty about the Group and Company's ability to continue as a going concern after the next 12 months, and therefore about the applicability of the going concern basis of preparation. The financial statements do not include the adjustments that would be required if the going concern basis of preparation was considered inappropriate.

The directors do not believe that Brexit will have an impact on the Group and Company'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 2019

IFRS 16 'Leases' has come into effect from January 1, 2019 and has been adopted by the Group. The impact of the adoption of the leasing standard is disclosed in Note 4 below.

### 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.

In addition, IFRS 2 Share-based Payment: classification and measurement of share-based payment transactions is an additional standard that will impact the Group, management are still in the process of assessing their impact, if any.

Beyond the information above, it is not practicable to provide a reasonable estimate of the effect of these standards until a detailed review has been completed.

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.

### **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. Tiziana Pharma Limited was incorporated on 4 November 2013 and prepared its first set of financial statements to 31 December 2014. Therefore, the parent and subsidiary had the same reporting date but Tiziana Pharma Limited had a long period of account. No adjustment was made in the consolidated financial statements for the difference in length of reporting period because the only transaction in Tiziana Pharma Limited at 31 December 2013 was the issue of ordinary share capital of £1.

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.

### 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.

### **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 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.

### Warrants

Warrants issued by the Group to investors as part of a share subscription are compound financial instruments where the warrant meets the definition of a financial liability.

The financial liability component is initially measured at fair value in the Consolidated Statement of Financial Position. Equity is measured at the residual between the subscription price for the entire instrument and the liability component. The financial liability component is remeasured depending on its classification. Equity 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.

#### 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 5	years
-------------------------	-------

IT and equipment 3 years

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.

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.

#### Leases

IFRS 16 Leases was issued in January 2016 and was implemented by the Group from 1 January 2019. The Standard replaces IAS 17 and requires lease liabilities and 'right of use' assets to be recognised on the balance sheet for almost all leases. The adoption methodology of IFRS 16 is the cumulative catch-up method, and the impact of adoption was to recognise a right of use asset of £833k and a lease liability of £833k on 1 January, 2019.

#### 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, directors or advisers 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.

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.

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

### 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. Convertible loan notes are treated differently depending upon a number of factors.

# 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.

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.

The only other critical accounting estimates and judgements made in the preparation of the financial statements were fair value estimates used in the calculation of share based payments and warrants which have been detailed above in note 2, accounting policies, and note 17, share based payments, to the accounts.

The Group has also made a judgement on the impact of Brexit during the preparation of the financial statements and considered it to not be significant.

# 4. CHANGES IN ACCOUTING POLICIES AND PRIOR YEAR ADJUSTMENTS

# IFRS 16 Leases

The group has adopted IFRS 16 retrospectively from 1 January 2019 but has not restated comparatives for the 2018 reporting period, as permitted under the specific transitional provisions in the standard. The reclassifications and the adjustments arising from the new leasing rules are therefore recognised in the opening balance sheet on 1 January 2019.

On adoption of IFRS 16, the group recognised lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 Leases. These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of 1 January 2019. The weighted average lessee's incremental borrowing rate applied to the lease liabilities on 1 January 2019 was 3.35%.

The Group assesses whether a contract is or contains a lease at inception of the contract. The Group recognises a right-of-use assets and corresponding lease liabilities at the lease commencement date, except for short term leases and leases of low value. For these leases, the lease payments are recognised as an operating expense on a straight-line basis over the term of term of the lease.

The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liabilities adjusted for any lease payments made at or before the commencement date, plus any initial costs incurred. The right-of-use assets are subsequently measured at cost less accumulated depreciation and impairment losses. The right-of-use assets are from the commencement date depreciated over the shorter period of lease term and useful life of the

underlying asset. The estimated useful lives of right-of-use assets are determined on the same basis as those of property and equipment. In addition, the right-of-use assets are periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liabilities, e.g. revised discount rate, change in the lease term or change in future lease payments resulting from a change in an index.

The lease liabilities are initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate determined by the Group's borrowing rate.

	2019
	£000
Operating lease commitments disclosed under IAS17 as at 31 December 2018	897
Remaining lease commitments discounted using the Group's incremental borrowing	833
rate as at the date of initial application	
Lease Liability recognised as at 1 January 2019	833
Of which:	
Current lease liabilities	197
Non-current lease liabilities	636

The associated right-of-use assets for all leases were measured at the amount equal to the lease liability.

The recognised right-of-use assets relate to the following types of assets:

	31 December 2019	1 January 2019
	£000	£000
Properties	329	833
Total right-of-use assets	329	833

In applying IFRS 16 for the first time, the group has used the following practical expedients permitted by the standard:

• the use of a single discount rate of 3.35% to a portfolio of leases with reasonably similar characteristics;

• the use of hindsight in determining the lease term where the contract contains options to extend or

terminate the lease.

# Accounting for Warrants – Prior period adjustment

During the year, the Group reviewed its accounting treatment for warrants. The Group has warrants that had been issued in lieu of fees and warrants that had been issued as an additional incentive for investors to enter into a Convertible Loan Note agreement.

### Warrants issued in lieu of fees

In prior years the fair value at date of grant had been expensed to the Statement of Income based on the vesting period of the warrant. The Group recognises that the fair value at the date of grant should be recognised over the life of the service for which the warrant was provided.

### Warrants issued as incentive

In prior years the fair value at date of grant had been expensed to the Statement of Income based on the vesting period of the warrant. The Group recognises that the fair value of the warrants should be recognised as a cost of fundraising and fully recognised at the date of issuance of the Convertible Loan Note.

The adjustments have impacted the prior period and earlier periods and the impact on the financial statements is as follows:

	1 January 2018	Adjustment	1 January 2018
Consolidated Balance Sheet (Extract)	£'000	£'000	£'000 (Restated)
Share Premium Share based payment reserve (warrants)	18,650 419	(537) 656	18,113 1,075
Retained Earnings	(29,755)	(119)	(29,874)
Total Equity	(1,683)	-	(1,683)

Consolidated Balance Sheet (Extract)	<b>31 December</b> <b>2018</b> £'000	Adjustment £'000	<b>31 December</b> <b>2018</b> £'000 (Restated)
Share Premium Share based payment reserve (warrants)	25,894 548	(777) 851	25,117 1,399
Retained Earnings	(35,766)	(30)	(35,796)
share Total Equity	411	44	411

Consolidated Comprehensive Inc	Statement come (Extract)	of	<b>31 December 2018</b> £'000	Adjustment £'000	<b>31 December</b> <b>2018</b> £'000 (Restated)
Operating Expense	es	_	(3,313)	44	(3,269)
Loss before taxati	ion	_	(7,454)	44	(7,409)

# 5. OPERATING LOSS

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

	<b>2019</b> £'000	<b>2018</b> £'000
License fees	433	781
Depreciation of Property, Plant and Equipment	4	12
Depreciation (Right-of-use asset)	192	-
Foreign exchange (gains)/losses	129	(222)
	758	571

# 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>2019</b> £'000	<b>2018</b> £'000
Remuneration receivable by the Company's auditor for the audit of the consolidated and Company financial statements, including £16k (2017:£8k) for the audit of Company subsidiaries.	56	34
Remuneration receivable by the Company's auditor for other assurance services	82	56
8. EMPLOYEES		
Group	2019	2018
Staff costs comprised:	£'000	£'000
Directors' salaries including bonus	892	455
Employees, wages, salaries and bonus	554	948
Social security costs	477	447
Share based payment charge	992	503
	2,912	2,353
The average monthly number of employees, including directors, employed by the Group during the year was:		
Research and Development	5	6
Corporate and administration	4	5
	9	11
A charge for share based payments totalling £586k (2018: £503k) was made in the yea	r.	
<u>Company</u>	2019	2018
Staff costs comprised:	£'000	£'000
	2000	2 000
Directors' salaries	892	151
Recharge of US Salaries (including social security costs)	745	-
Share based payment charge	992	503
	2,629	654

# 9. REMUNERATION OF KEY MANAGEMENT PERSONNEL

	2019			2018		
Director	Directors' fee £'000	Bonus £'000	Salary £'000	Directors' fee £'000	Bonus £'000	Salary
W Simon	38	-	-	38	-	-
G. Cerrone (1)	80	143	-	93		-
R. Dalla-Favera	2	-	-	20	-	-
K. Shailubhai (2)	-	159	470	-	79	225
	120	302	470	151	79	225

(1) Gabriele Cerrone's 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	2019 Number of options	2018 Number of options
R. Dalla-Favera	-	-
W. Simon	-	-
G. Cerrone	-	550,000
L Zambeletti	-	550,000
K Shailubhai	-	6,500,000
		7,600,000

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.

No director exercised share options in the year.

The Company made £12k (2018: £13k) of payments to a defined contribution pension schemes on behalf of directors or employees.

# **10. FINANCE INCOME AND COSTS**

Group	<b>2019</b> £'000	<b>2018</b> £'000
Finance Income	2000	2000
Finance income received on net investment in lease	1	-
Total finance income	1	-
Finance Expenses		
Finance charge accrued on convertible loan notes	49	9
Interest expense on lease liabilities	24	-
Total finance expenses	73	9
Net finance expense recognised in Statement of Comprehensive Income	72	9

### **11. TAXATION**

	<b>2019</b> £'000	<b>2018</b> £'000
<b>Group</b> Current year tax (credit) Adjustments in respect of prior periods	(518) (22)	(800) (659)
Deferred tax Origination and reversal of timing differences	Nil	Nil
Total tax (credit) for period	(540)	(1,459)

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	(7,846)	(7,454)
Loss charged at standard rate of corporation tax 19%	(1,491)	(1,416)
Tax losses arising in the year not recognised Movement in unrecognised deferred tax Expenses not deductible for taxation Adjustments due to prior periods Research and development claim Consolidation adjustment in relation to foreign exchange movements	(189) 1,353 (22) (223) 32	828 132 (659) (344)
	(540)	(1,459)

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 £2,756k (2018: 2,946k).

# 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.

	2019	2018 (restated)
(Loss) attributable to equity holders of the Company $(\pounds)$	(7,306,423)	(5,950,061)
Weighted average number of ordinary shares in issue	136,482,627	127,553,866
Basic loss per share (pence per share)	(5.4)	(4.7)

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:

Group	Furniture and fixtures £'000	IT equipment £'000	<b>Total</b> £'000
<b>Cost</b> At 1 January 2019 Additions Disposals	12 -	25 3	37 3 -
At 31 December 2019	12	28	40
Depreciation At 1 January 2019 Charge in year At 31 December 2019	7 2 9	24 2 	31 4 35
Net book value as at 31 December 2019	3_	2	5
Net book value as at 31 December 2018	5_	1	6

### 14. OTHER RECEIVABLES

4. OTHER RECEIVABLES	0040	0040
	2019	2018
	£'000	£'000
<u>Group</u>		
Other receivables	103	195
Taxation receivable	513	800
Related party receivable	246	20
Prepayments	21	33
	883	1,048

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

<u>Company</u>	<b>2019</b> £000	<b>2018</b> £000
Taxation receivable Related party receivable Prepayments and accrued income	53 243 9	300 44 43
	305	387

# 15. 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.

Finance lease receivable	<b>31 Dec 2019</b> £000	<b>1 Jan 2019</b> £000
Current Non-current	109 113	-
	222	

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

	1 Year	2 years	3 or more years
	£000	£000	£000
Undiscounted lease payments receivable	113	114	-
	113	114	-

The undiscounted lease payments do not include a discount factor charge of £5k.

During the year ending December 31, 2019, the Group received £27k of income from its subleasing activities.

Finance Lease Receivable	<b>31 December</b> <b>2019</b> £000
<u>Finance Lease receivable as at 1 Nov 2018</u> Sublease income	249 (27)
	222

### **16. 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 recognizes 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. The Company is still unable to utilise these assets until the resolution of the outstanding data protection legal action. For this reason, the investment has been recognised as a non-current asset until such a time that the Company is able to use this asset.

The Company has not recognised a contingent liability in respect of the legal action as the outcome is uncertain and cannot be considered as probable to occur.

### **17. INVESTMENTS IN SUBSIDIARIES**

Company	Shares in group undertakings	Capital Contribution	Total
	£'000	£'000	£'000
Cost			
At 1 January 2019	7,509	12,796	20,305
Additions	-	1,661	1,661
Disposals	-	-	-
Less provision			
At 31 December 2019	7,509	12,796	21,966
Impairment			
Charge in year	(7,509)	(12,796)	(21,966)
At 31 December 2019	(7,509)	(12,796)	(21,966)
Net book value as at 31 December 2019			
	<u> </u>	<u> </u>	
Net book value as at 31 December 2018			
	7,509	12,796	20,305

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:

Name	Principal activity	Registered Address	Percentage shareholding	Country of incorporation
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

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.

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.

# 18. SHARE CAPITAL

Company and Group	2019 Ordinar	2018 y Shares	2019 £000	2018 £000
In issue at 1 January	136,463,818	125,054,805	4,094	3,752
Issued for cash Issued in lieu of consultancy	-	7,742,167	-	232
fees	190,698	-	5	-
Conversion of warrants	-	1,454,644	-	45
Conversion of Loan	-	2,137,625	-	65
Commission and Interest		74,577	-	-
In issue at 31 December	136,654,516	136,463,818	4,099	4,094

### **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.

#### Issuance of ordinary shares

In November 2019, 190,968 new ordinary shares were issued in lieu of a consultancy fee of £82,000.

### **19. 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.

	201	19	201	18
	Options ('000)	Weighted Average exercise price (pence)	Options ('000)	Weighted Average exercise price (pence)
Outstanding at 1 January	18,617	84	10,717	93
Granted Forfeited Cancelled	(2,238)	(115)	9,500 (1,600) 	82 (172) 
Outstanding at 31 December	16,379	86	18,617	84
Exercisable at 31 December	5,521	51	5,236	39

No options were exercised during the period ending 31 December 2019 and 31 December 2018.

The total outstanding fair value charge of the share option instruments is deemed to be approximately £3,800k (2018: £5,175k).

The Directors have used the Black-Scholes option pricing model to estimate the fair value of most of the options applying the assumptions below.

Historical volatility relies in part on the historical volatility of a group of peer companies that management believes is generally comparable to the Company.

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.

	10 March 2017	30 August 2017	30 April 2018
Grant date share price Exercise share price Vesting periods	£1.725 £1.725 Yr1, Yr 2, Yr 3, Yr4	£1.595 £1.595 Yr 1, Yr 2, Yr 3, Yr4	£0.8175 £0.8175 Yr 1, Yr 2, Yr 3, Yr4
Risk free rate Expected volatility Option life	0.38% to 1.09% 80% to 167% 10 years	0.69% to 1.09% 58% to 60% 10 years	0.69% to 1.03% 58% to 59.7% 10 years
Weighted average share price	£1.725	£1.595	£0.8175
Weighted average fair value per share option	£1.06	£0.57	£0.38

For the options issued 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 15 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.

## <u>Warrants</u>

On 2nd March 2015, warrants were granted over 600,000 shares at an exercise price of £0.50 per share in lieu of the issue of options. The warrants are exercisable until 31 December 2021.

On 31st May 2015, warrants were granted over 292,500 shares at an exercise price of £0.66 per share in lieu of fundraising fees. The warrants are exercisable until 31 May 2022.

On 11<sup>th</sup> November 2017, warrants were granted over 100,000 shares at an exercise price of £1.60 per share in conjunction with a Convertible Loan Note. The warrants are exercisable until 20 November 2022.

On 11<sup>th</sup> December 2017, warrants were granted over 183,333 shares at an exercise price of £1.60 per share in conjunction with a Convertible Loan Note. The warrants are exercisable until 11 December 2023.

On 15<sup>th</sup> December 2017, warrants were granted over 196,667 shares at an exercise price of £1.60 per share in conjunction with a Convertible Loan Note. The warrants are exercisable until 15 December 2023.

On 16<sup>th</sup> January 2018, warrants were granted over 63,334 shares at an exercise price of £1.60 per share in lieu of fundraising fees. The warrants are exercisable until 15 January 2024.

On 22<sup>nd</sup> January 2018, warrants were granted over 133,333 shares at an exercise price of £1.60 per share in conjunction with a Convertible Loan Note. The warrants are exercisable until 22 January 2024.

On 5<sup>th</sup> March 2018, warrants were granted over 78,000 shares at an exercise price of £1.60 per share in lieu of fundraising fees. The warrants are exercisable until 5 March 2024.

On 19<sup>th</sup> April 2018, warrants were granted over 51,563 shares at an exercise price of £0.8 per share in lieu of fundraising fees. The warrants are exercisable until 19 April 2024.

On 28<sup>th</sup> November 2018, warrants were granted over 185,000 shares at an exercise price of £0.8 per share in lieu connection with the issuance and conversion of a loan. The warrants are exercisable until 27 November 2023.

On 28<sup>th</sup> November 2018, warrants were granted over 150,000 shares at an exercise price of £0.8 per share in connection with the issuance and conversion of a loan. The warrants are exercisable until 27 November 2023.

On 31<sup>st</sup> October 2019, warrants were granted over 185,950 shares at an exercise price of £0.42 per share in in lieu of fundraising fees. The warrants are exercisable until 31 October 2024.

On 31<sup>st</sup> October 2019, warrants were granted over 1,289,372 shares at an exercise price of £0.42 per share in connection with the issuance of a convertible loan note. The warrants are exercisable until 31 October 2024.

As disclosed in Note 3, the Group has made an adjustment to its accounting treatment of warrants this year.

The Directors have estimated the fair value of the warrants in services provided using the Black-Scholes valuation model and assumptions above.

	2019	2018	2017	2015
Weighted average share price	£0.42	£0.67	£1.60	£0.55

For each set of warrants, the charge has been expensed over the service period. A share-based payment charge for the year of £nil (year to December 2018, restated: £45k) has been expensed in the statement of comprehensive income.

## 20. 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 settle the obligation via a cash settlement and is not limited to settling the obligation in shares in the Company.

### 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 2019 is;

	2019 £000	2018 £000
Convertible loan notes issued	243	234
Accrued interest	9	9
	252	243

### 21. 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:

	£000
Par value of Convertible loan notes issued	1,473
Less: Fair value of warrants issued to note holders	(413)
	1,060
Accrued interest	39
	1,099

# 22. 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.

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.

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 the capital reduction exercise.

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

### 23. 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:

	2019		
£000	Less than 3 months	3 to 12 months	Total
Trade and other payables	439	2,739	3,178
Related party payables	200	252	452
	641	2,989	3,630

#### 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 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, 2019	Profit or loss and equity			
	Strengthening	Weakening		
EUR (5% movement)	62	(68)		
USD (5% movement)	35	(39)		

### 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 Allied Irish 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 2019 or 31 December 2018.

## 24. 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.

# 25. TRADE AND OTHER PAYABLES

Group	<b>2019</b> £000	<b>2018</b> £000
Trade payables Accruals	3,178 1,673	2,860 1,813
	4,851	4,673
<u>Company</u>	<b>2019</b> £000	<b>2018</b> £000
Trade payables Accruals	970 1,121	569 1,299
	2,091	1,868

### 26. RELATED PARTY TRANSACTIONS

Tiziana Pharma Limited is a wholly owned subsidiary of Tiziana Life Sciences plc. During the year, Tiziana Life Sciences Plc transferred a cash amount of £1,841k (2018: £3,079k) in total to Tiziana Pharma Limited. Included within Investment in subsidiaries of Tiziana Life Sciences Plc's company financial statements at the balance sheet date is £11,672k (2018: £9,831k) owed by Tiziana Pharma Limited.

Tiziana Therapeutics Inc. is a wholly owned subsidiary of Tiziana Life Sciences plc. During the year, Tiziana Life Sciences Plc transferred a cash amount of  $\pounds1,551k$  (2018:  $\pounds1,204k$ ) to Tiziana Therapeutics Inc. Included within investment in subsidiaries of Tiziana Life Sciences plc's company financial statements at the balance sheet date is  $\pounds4,498k$  (2018:  $\pounds2,948k$ ) owed Tiziana Therapeutics Inc.

Longevia Genomics SRL. is a wholly owned subsidiary of Tiziana Life Sciences plc. During the year, Tiziana Life Sciences Plc transferred a cash amount of £5k (2018: £18k) to Longevia Genomics SRL. Included within investment in subsidiaries of Tiziana Life Sciences plc's company financial statements at the balance sheet date is £23k (2018: £18k) owed by Longevia Genomics SRL.

Rasna Therapeutics Inc is a related party as Tiziano Lazzaretti, CFO of Tiziana, is also CFO of Rasna as Kunwar Shailubhai, director of our Company, is also a director 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. As of December 31, 2019, £4k (2018: £102k) was owed to Tiziana Life Sciences PLC.

OKYO Pharma Ltd is a related party as Kunwar Shailubhai, director of our Company, is also a director of OKYO. In addition, Tiziano Lazzaretti, CFO of Tiziana, is also CFO 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, 2019, £21k (2018: £102k) was owed to Tiziana Life Sciences PLC in respect of this agreement. OKYO Pharma Ltd has also extended a short term loan facility of £400k to Tiziana with interest payable of 20% per annum, as Tiziana failed to repay the amount owed by the repayment date. In respect of this loan, £200k was due as of December 31, 2019.

Gensignia Lifesciences Inc is a related party as Kunwar Shailubhai, director of our Company, is also a director of Gensignia. In addition, Tiziano Lazzaretti, CFO of Tiziana, is also CFO of Gensignia. As of December 31, 2019, £241k (2018: £43k) was owed to Tiziana Life Sciences PLC.

Planwise Group Limited is a related party as Gabriele Cerrone, Executive Chairman, is considered to have a beneficial interest in the shares and voting rights held Planwise Group Limited. As described in Note 20, the Company has a Convertible Debt Instrument outstanding with Planwise and as of December 31, 2019, Tiziana owed £252k (2018: £243k) with respect to this instrument.

# 27. 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.

IFRS16 was adopted 1 January 2019 without restatement of comparative figures. For an explanation of the transitional requirements that were applied as at I January 2019, see Note 4. The following policies apply subsequent to the date of initial application, 1 January 2019.

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.

During the course of 2019, 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.

Right-of-use assets At 1 January 2019 Additions Depreciation Finance lease receivable Loss on disposal Foreign exchange movements	<b>31 Dec 2019</b> £000 833 - (194) (249) (56) (5)
	329
Lease Liabilities At 1 January 2019 Additions Interest expense Lease payments	<b>31 Dec 2019</b> £000 833 - 24 (234)
	623

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

Current Non-current	£000 212 411	£000 197 636
	623	833

The lease liabilities are secured by the related underlying assets. Future minimum lease payments as at 31 December 2019 were as follows:

	Minimum lease payment due				
	Within 1 year	1-2 years	2-5 years	Over 5 years	Total
31 December 2019					
Lease payments	230	208	224	-	662
Finance Charges	(17)	(10)	(11)	-	(39)
Net Present Values	213	198	213		623

The total net cash outflow for leases in the year to 31 December 2019 was £156,748.

# 28. POST BALANCE SHEET EVENTS

On 13 January 2020, the Company announced that its intention to redomicile the Company to Bermuda and its proposed cancellation from AIM.

On 21 January 2020, the Company announced the appointment of Greg MacRae to the Board of Directors.

On 23 January 2020, the Company announced the filing of a Form F-3 with the Securities Exchange Commission to enable the Company to potentially conduct a future fundraise in the US. A General meeting was subsequently called to seek general authorities to issue shares which would be required in the event that the Company were to utilise the shelf registration.

On 11 March 2020, the Company announced that it is expediting development of TZLS-501, a novel, fully human anti-interleukin-6 receptor (anti-IL6R) monoclonal antibody (mAb) for treatment of patients infected with coronavirus COVID-19 (SARS-CoV-2). Tiziana plans to administer TZLS-501 using a proprietary formulation technology. The Company entered into a world-wide license for composition-of-matter of TZLS-501, a fully human mAb targeting IL-6R, with Novimmune, SA, a Swiss biotechnology company in January 2017.

On 16 March 2020, the Company announced the closing of its underwritten follow-on public offering of American Depositary Shares ("ADSs") on the NASDAQ Global Market. The Company issued 3,333,333 ADSs (representing 16,666,665 new ordinary shares of nominal value £0.03 each in the capital of the Company) at a price to the public of \$3.00 per ADS raising gross proceeds of approximately \$10 million (before deducting underwriting discount, commissions and offering expenses). Each ADS offered represents five (5) Ordinary Shares (reduced from 10 ordinary shares in a stock split that took place in October 2019. In addition, the Company has granted the underwriters a 45-day option to purchase up to an additional 499,999 ADSs on the same terms and conditions (the "Option"). All ADSs sold in the Offering were offered by the Company. The number of Ordinary Shares represented by ADSs comprised in the Offering (including by way of the exercise of the Option) were within existing shareholder authorities.

On 9 April 2020, the Company announced that it had developed 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 handheld inhaler or nebulizer. Development of this novel technology is a step forward toward expediting development of TZLS-501, a fully-human anti-interleukin-6 receptor (anti-IL6R) monoclonal antibody (mAb) for treatment of patients infected with COVID-19 (SARS-CoV-2) coronavirus. The Company believes the technology could also be applicable for use with other FDA approved mAbs and drugs. The Company has submitted a provisional patent application for the delivery technology. At this time, an estimate of the financial effect cannot be determined.

On 15 April 2020 the Company entered into an "At the Market" or "ATM" Sales Agreement with Think Equity (a division of Fordham Financial Management, Inc.) to raise up to US\$20m from the sale of ADSs (each representing 5 new ordinary shares).

On 15 April 2020, the Company issued 420,000 new Ordinary Shares of 3 pence each in connection with the exercise of options by a former director granted under the Company's 2014 share option scheme.

On 24 April 2020, the Company issued 6,118,797 new Ordinary Shares of 3 pence each in paid in respect of (i) the conversion of £1,595,322 in face value of its outstanding convertible notes at a conversion price of 42 pence per share (including accrued interest of 16 per cent.); and (ii) the exercise of 1,712,672 warrants at a price of 35 pence per share, yielding £599,435.20 in cash proceeds for the Company and retiring £1,595,322 of indebtedness.

On 6 May, 2020, the Company held a General Meeting and announced that all resolutions had been passed. The resolutions included the grant of options under the Company's long-term incentive plan or US sub-plan (as appropriate) over 9,000,000 Shares to Dr Kunwar Shailubhai, the Company's Chief Executive Officer and Chief Scientific Officer; (b) options over 400,000 Shares to Tiziano Lazzaretti, the Company's Chief Financial Officer; and (c) options over a further 327,000 Shares to other staff members, all at an exercise price of 35p per share and all conditional on the surrender of all existing share options held by those individuals. The resolutions also included the grant by the Company's long-term incentive plan at an exercise price of 35p per share and conditional on the surrender of all existing share options at an exercise price of 35p per share and conditional on the surrender of all existing share options held by those individuals. The resolutions also included the grant by the Company's long-term incentive plan at an exercise price of 35p per share and conditional on the surrender of all existing share options held by Mr Cerrone.

On 18 May 2020, the Company issued 264,286 ordinary shares of 3 pence each in respect of the exercise of 264,286 warrants at a price of 50 pence per share, yielding £132,143 in cash proceeds for the Company.

On 2 June 2020, the Company issued 1,234,399 ordinary shares in respect of the exercise of 1,234,399 warrants at a price of 39 pence and 50 pence per share, yielding £578,700 in cash proceeds for the Company. The Company also announced that during the calendar month of May, the Company issued a total of 1,743,445 ordinary shares under the Company's ATM sales agreement announced on 15 April 2020 to meet sales of a total of 348,689 ADSs under the ATM sales agreement, totalling gross proceeds of \$1,985,004.

The Company does not believe that the recent outbreak of COVID-19 pandemic will have an adverse effect on the Company' 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.

## **29. 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.
- 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.

The Group also has financial commitments with a realisation bonus due to its Executive Chairman. The Executive Chairman is also eligible to receive two realisation bonuses as follows:

- (a) in the event that, either: (i) the Group raises, in one or a series of transactions, new equity capital in excess of £20,000,000 (after expenses); or (ii) 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 Companies (or a licence of the same on an exclusive or non-exclusive basis), where the Enterprise Value equals or exceeds £150,000,000; or (iii) there is a change of control where the Enterprise Value equals or exceeds £150,000,000, in which case the Realisation Bonus will be the amount equal to the Enterprise Value multiplied by two and a half (2.5) per cent;
- (b) In addition to the payment of the Realisation Bonus outlined above, 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 consideration payable to the Shareholders.