

**TIZIANA LIFE SCIENCES PLC  
ANNUAL REPORT & FINANCIAL STATEMENTS  
YEAR ENDED 31 DECEMBER 2018**

**FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31ST DECEMBER 2018**

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## STATUTORY AND OTHER INFORMATION

Directors:	Mr G. M. A. Cerrone Dr K. Shailubhai Mr W. Simon Mr L. Zambelletti
Secretary:	Mr P J. Cooper (FCA)
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Principal Bankers:	Allied Irish Bank, Ealing Cross, 85 Uxbridge Road, London, W5 5TH
Auditors:	Mazars LLP, Tower Bridge House, St Katharine's Way, London, E1W 1DD
Nominated Advisors:	Cairn Financial Advisers LLP, 62-63 Cheapside, London, EC2V 6AX
Nominated Brokers:	Stockdale Securities Ltd 100 Wood Street, London EC2V 7AN
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Registrars:	Link Asset Services, The Registry, 34 Beckenham Road, Beckenham, BR3 4TU

## EXECUTIVE CHAIRMAN'S STATEMENT

I am pleased to report on the Company (Tiziana Life Sciences PLC) and its subsidiaries, together the 'Group', results for the year ended 31 December 2018.

### 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 of small molecule New Chemical Entities.

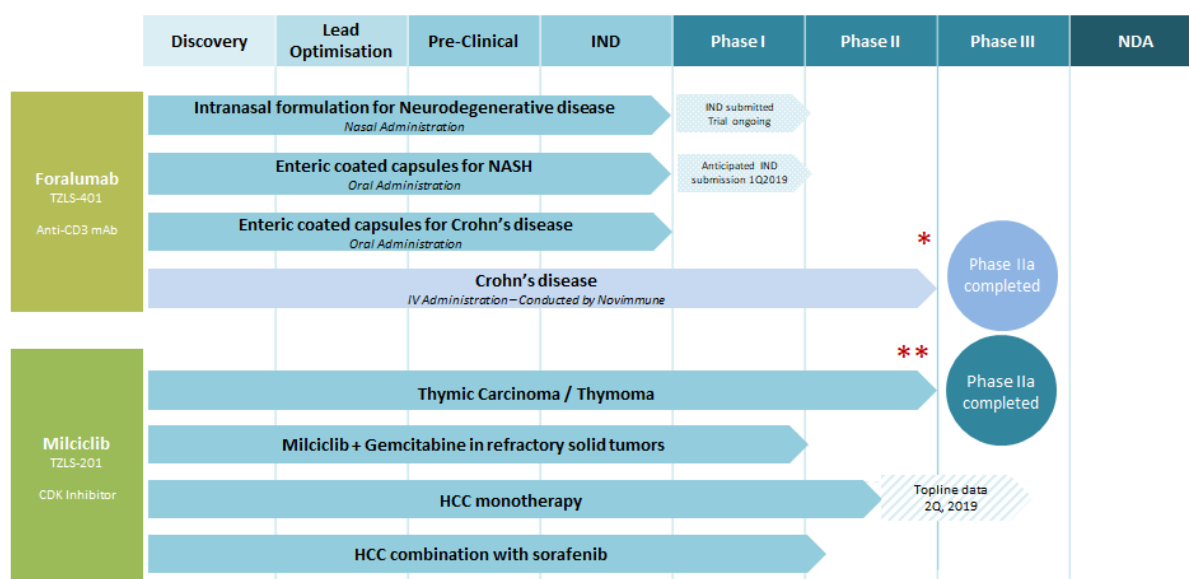
### Clinical Programmes

The Group is focused on targeting large markets with a high unmet medical need. Driven by an obesity and diabetes epidemic, non-alcoholic fatty liver disease (NAFLD) has become the most common liver disease, affecting one-third of the Western world. Between 3% and 5% of NAFLD patients progress to a more severe form of inflammatory disease, known as NASH (non-alcoholic steatohepatitis), a progressive disease associated with chronic inflammation, fibrosis and cirrhosis in the liver. Based on data from US adult Liver Transplant (LT) databases, since 2004 the number of adults with NASH awaiting LTs has almost tripled. In 2013, NASH became the second-leading disease among liver transplant waiting list registrants, after the Hepatitis C virus. It is predicted that NASH may become the leading cause of liver transplantation in the United States by 2020.

The market for NASH therapies is estimated to reach £16.2 billion by 2025 (10.7% CAGR from 2015 to 2025). This anticipated growth has resulted in several high-profile M&A transactions, including four announced deals in 2016 totalling more than £2.3 billion in value. Around 20% of NASH patients progress further to cirrhosis of the liver, which may ultimately develop into fatal HCC, the primary cause of obesity-related cancer death in middle-aged men in the U.S. Liver transplants are the only effective option for end-stage patients, including HCC patients. More effective therapeutic agents to treat Hepatocellular Carcinoma ("HCC") are needed. Currently approved therapeutic agents are marginally effective and have significant safety issues.

Tiziana Life Sciences is focused on developing novel drugs for treatment of liver diseases with a pipeline of two clinical-stage drug candidates, Foralumab and Miliclib:

## CLINICAL DEVELOPMENT PIPELINE



\* The trial in Crohn's Disease (IV administration) conducted by Novimmune produced encouraging clinical response. TILS strategy is to pursue oral administration with foralumab in NASH and CD.

\*\* We will seek guidance from regulatory authorities for next steps

## EXECUTIVE CHAIRMAN'S STATEMENT

### *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 April 16, 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 was filed in the second quarter of 2018, and a Phase 1 trial to evaluate biomarkers of immunomodulation of clinical responses was initiated in November 2018. The study is expected to be completed by May 2019.

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.

### *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 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.

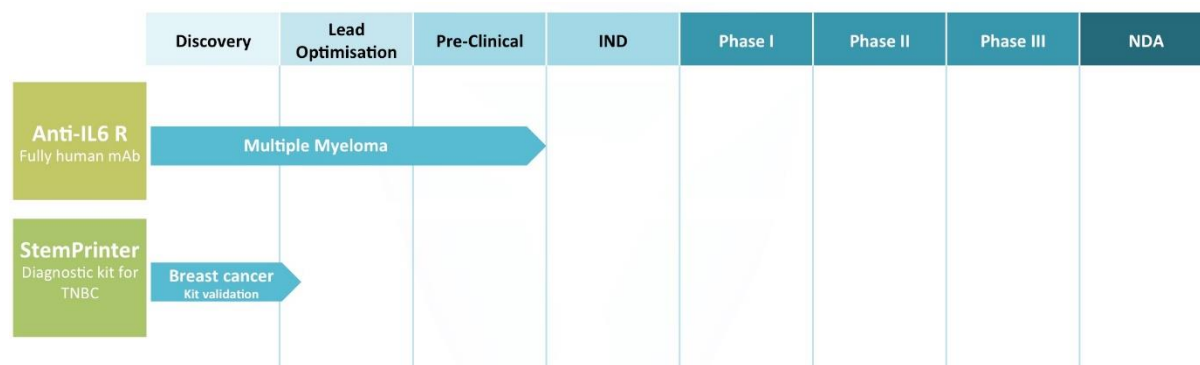
The Group initiated a Phase 2a trial (CDKO-125a-010) of Milciclib safety and tolerability as a single therapy in Sorafenib-resistant patients with HCC in the first half of 2017. In May 2018, the Independent Data Monitor committee (IDMC) completed an interim analysis of tolerability data from the first 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. Top-line data is expected in the second quarter of 2019. This trial is conducted in Sorafenib-resistant HCC patients. 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. It is important to emphasize that 4 out of the 11 patients on treatment, completed 6 months in the trial and then requested continued treatment on a compassionate use basis. Subsequently, 3 patients were approved under the compassionate use program by the respective ethical committees. Among these three patients, one patient completed 9 months, and another completed 13 months of treatment with no apparent signs of toxicity. The third patient continued to receive the treatment and recently reached 16 months of treatment.

## EXECUTIVE CHAIRMAN'S STATEMENT

Preclinical data presented at the AASLD meeting in November 2018, demonstrated significant tumour reduction in an orthotopic mouse model of HCC following five weeks of treatment with Milciclib (-20% reduction, 30mg/kg/day), Sorafenib (-20% reduction, 20 mg/kg/day) and the combination of Milciclib and Sorafenib (-38% reduction) relative to vehicle control.

Based on the expected synergistic anti-tumour effect of Milciclib and Sorafenib, the Group expects to initiate a Phase 2b trial (TZLS (201)-125a-011) dosing Milciclib in combination with Sorafenib (the standard of care) in patients with HCC in 2019.

### 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 signalling 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 transsignalling via the agonistic soluble IL-6 receptor in human diseases". *Biochimica et Biophysica Acta*. 1592 (3): 323–343.).

#### *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.

## EXECUTIVE CHAIRMAN'S STATEMENT

### Financial summary

#### *Consolidated Statement of Comprehensive Income*

The Group has made a loss for the year of £6,108k (2017: £6,770k). The loss is detailed in the consolidated statement of comprehensive income on page 31.

#### *Consolidated Statement of Financial Position*

At the end of the year the Group cash balance amounted to £4,165k (2017: £48k) and the total assets of the Group amounted to £5,436k (2017: £1,831k).

### Fund raising

In the period, the Group successfully raised funds to further progress its on-going clinical trials and give the Group the resources to expand its presence internationally.

On 16 January 2018, the Company announced that it had raised £150,000 in cash by the issue of 100,000 new ordinary shares at a price of 150p per share, each new ordinary share having a warrant attached entitling the holder to subscribe for one new ordinary share at a price of 160p per share, exercisable until 15 January 2024. Fees in connection with the placing were satisfied through the issue of an additional 63,334 warrants on the same terms.

On 22 January 2018, the Company announced that it had raised £100,000 in cash by the issue of 66,667 new ordinary shares at a price of 150p per share, each new ordinary share having a warrant attached entitling the holder to subscribe for one new ordinary share at a price of 160p per share, exercisable until 22 January 2024. Fees in connection with the placing were satisfied through the issue of an additional 13,333 warrants on the same terms.

On 5 March 2018, the Company announced that it had raised £600,000 in cash by the issue of 600,000 new ordinary shares at a price of 100p per share. Fees in connection with the placing were satisfied through the issue of 78,000 warrants each exercisable at a price of £1.00 each at any time up to 5 March 2023.

On 19 April 2018, the Company announced that it had raised £825,000 in cash by the issue of 1,301,250 new ordinary shares at a price of 80p per share. In addition, the Company issued 51,563 new ordinary shares credited as fully paid and 51,563 warrants exercisable at a price of 80p per share to intermediaries in lieu of commissions on the funds raised.

On 26 October 2018, the Company announced that it had raised £1,136,363 in cash by the issue of 1,515,150 new ordinary shares at a price of 75p per share.

In November 2018, the Company announced pricing of its initial public offering of American Depositary Shares ("ADSs") representing ordinary shares of nominal value £0.03 each on the Nasdaq Global Market. The United States Securities and Exchange Commission declared it effective with a registration statement relating to such securities on 19 November 2018 and the ADSs were listed for trading on such market under the symbol "TLSA" on 20 November 2018. The Company raised gross proceeds of £3.42 million (or \$4.39 million at a GBP1 : US\$1.2839 exchange rate), by offering 442,910 ADS's at \$9.90.

On 20 November 2018, in addition to the £3.42 million raised in the US IPO, the Company also announced the issue of 607,500 Ordinary Shares at a price of 75p each and 793,144 Ordinary Shares at a price of 80p each to certain persons who had agreed to exercise warrants to acquire Ordinary Shares at a revised exercise price, the proceeds of which were £1.09 million.

On 20 November 2018, the Company also announced the issue of 2,137,625 Ordinary Shares at a price of 60p each to certain persons who had made loans to the Company on terms that the loans would be converted (without interest) into Ordinary Shares in the Company completing a qualifying public offering on Nasdaq, equating to the extinguishment of £1.39 million.

On 11 December 2018, the Company announced that further to its announcement regarding a temporary reduction to exercise prices of outstanding warrants issued on 20 November 2018, it had received a notification from warrant holders to exercise warrants over 54,000 ordinary shares of nominal value 3p each in the capital of the Company at an exercise price between 75p and 80p per share, providing the Company with gross proceeds of £41,567.

Funds raised by the Company were used to fund the development of the Group's clinical stage assets, Milciclib and Foralumab, to meet the Group's ongoing liabilities in respect of licence agreements, and for general working capital purposes.

## EXECUTIVE CHAIRMAN'S STATEMENT

### Appointments

#### *Non-Executive Director*

On 4 April, 2018, the Group announced the addition of Mr Leopoldo Zambelletti as a non-executive director with responsibility for strategic development. Mr Zambelletti will also chair the Nomination Committee.

During a 19 year career as an investment banker, Mr Zambelletti led the European Healthcare Investment Banking team at J.P. Morgan for eight years before taking up the same position at Credit Suisse for a further five years. Since 2013 he has been an independent strategic advisor to life science companies on merger and acquisitions, out-licensing deals and financing strategy. He is a non-executive director of, Qardio Inc., Summit Therapeutics plc, Nogra Pharma Limited, Faron Pharmaceuticals OY and DS Biopharma Limited. Mr. Zambelletti started his career at KPMG as an auditor. Mr. Zambelletti received a B.A. in Business from Bocconi University in Milan, Italy. He serves as a trustee to Barts and the London Charity, which helps to fund the hospitals of the Barts NHS Trust including St Bartholomew, the Royal London and the London Chest Hospitals. He is the founder of the cultural initiative 5x5 Italy.

### Resignations

#### *Non-Executive Director*

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

### Outlook

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

We have outlined our clinical development plan for Foralumab with initial plans to evaluate orally-dosed Foralumab in two clinical indications: NASH and Crohn's disease. The IND for nasal administration for neurodegenerative diseases was submitted in November 2018 and the trial is ongoing smoothly. The IND for oral administration is anticipated to be submitted by March 15, 2019.

For Milciclib, two Phase 2 clinical trials for thymic carcinoma (thymoma) in patients previously treated with chemotherapy were completed. A Phase 2 monotherapy trial using Milciclib to treat patients with hepatocellular carcinoma (HCC) is ongoing and the topline data from this trial is anticipated to be available by July 2019. We expect to commence a Phase 2b combination therapy trial dosing HCC patients with Milciclib and the standard of care, Sorafenib, in the second quarter of 2019.

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

### **Gabriele Cerrone**

#### *Executive Chairman*

April 3<sup>rd</sup> 2019



## STRATEGIC REPORT

### Business review

A review of the business, its results and 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 2018 the main use of the Group's funds was progressing Phase II for Milciclib on single agent trials, involving recruitment of patients across different countries (Italy, Greece and Israel), and progressing Foralumab for oral and nasal application. The Company has also continued to fund the continuation of the StemPrintER project in anticipation of a pre-submission meeting with the FDA. 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 2018 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 advancement of the Phase 2a Miciclib clinical trial.*

In May 2018, the Independent Data Monitoring Committee ("IDMC"), favourably analysed the Phase 2a Miciclib tolerability data and recommended the expansion of the cohort with an additional 20 patients to continue the ongoing clinical trial. Enrolment for the trial was completed in December 2018.

#### *Initiation of Phase 1 Clinical Trials of Nasal Administration of Foralumab.*

The FDA approved the IND application for the nasal administration of Foralumab in September 2018. Phase 1 in healthy volunteers was initiated in November 2018.

### 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 2018.

## STRATEGIC REPORT

### Principal risks and uncertainties

The Group assesses and monitors the inherent risks in the life sciences industry, as well as other micro and macro-economic 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

- Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.
- 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.

## STRATEGIC REPORT

### 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.

## STRATEGIC REPORT

- 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 at December 31, 2018, was as follows:

	December 31, 2018		
	Male	Female	Total
Number of persons who were Directors of the Company	5	1	6
Number of persons who were other employees of the Company	-	4	4
<b>Total employees at December 31, 2018</b>	<b>5</b>	<b>5</b>	<b>10</b>

A senior manager is an employee who has the responsibility for planning, directing or controlling the activities of the Group and are considered to be Directors of the Company.

## STRATEGIC REPORT

### 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  
April 3<sup>rd</sup> 2019

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

## DIRECTORS REPORT

The Directors present their report and the financial statements of the Group and its Company for the year ended 31<sup>st</sup> December 2018.

### 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 (2017: nil).

### Directors

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

Mr Gabriele Cerrone	Executive Chairman
Dr Kunwar Shailubhai	Chief Executive Officer
Dr Riccardo Dalla-Favera	Non-Executive Director (resigned, 7 <sup>th</sup> February 2019)
Mr Willy Simon	Non-Executive Director,
Mr Leopoldo Zambetti	Non-Executive Director (appointed, 4 <sup>th</sup> April 2018)

### 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> March 2019:

	Ordinary shares	
	Number	Percentage
Planwise Group Limited*	63,680,404	46.68%
Mayflower Medical Ventures Ltd	4,486,748	3.29 %
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.

### 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.

## **DIRECTORS REPORT**

### **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 issues in the foreseeable future. To ensure the Company's future growth, all directors are subject to re-election at least once every three years, confirming the current directors all have the necessary experience and skills. The skills of each director complement each other 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 follows a formal schedule of matters, and meet quarterly every year. All Directors are expected to provide a sufficient amount of time to the Company to fully exhibit and fulfil their duties. Each Director's time spent is reviewed annually prior to recommending their re-election to the shareholders.

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

The roles of the directors differ between Executive and Non-Executive directors, while both have fiduciary duties towards the group. The board is made up of Executive Chairman, Gabriele Cerrone, who has extensive experience in the financing and restructuring of micro-cap biotechnology companies and has successfully taken several companies to the NASDAQ 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 Leopoldo Zambetti, have many years of experience in the finance industry as bankers, 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 undertake 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.

### **Relationship with Shareholders**

The Group endeavours to maintain a two-way communication between both institutional and private investors, this is to resolve any queries as quickly as possible and to meet and understand the needs and expectations of the shareholders. The Chairman regularly updates the Company's major shareholders on the financial and operational performance as well as the Company's future strategies. The Chairman ensures their views are communicated with the Board. The Board recognises 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 recognises the importance of annual AGMs, as this is an opportunity to meet private investors, the Directors are available to address any issues immediately following the AGM. If the voting at the AGM is not as the Board expected, the Directors will engage with these shareholders to understand and address their concerns. The company secretary is the first point of contact for these such matters.

The Company's website provides financial information as well as historical news releases and matters relating to corporate governance. Annual and interim results are communicated by regulatory news services as are ad hoc operational and regulatory releases.

In addition to recognising the importance of the Company's relationship with the shareholders, the Board acknowledges the significance of its employees and consistently evolves to align with their well-being.

### **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

## **DIRECTORS REPORT**

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.

### **Whistle-blowing**

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.



## DIRECTORS REPORT

### Audit Committee

The Audit Committee of the Board comprises Riccardo Dalla-Favera (resigned 7<sup>th</sup> February 2019), Leopoldo Zambelletti and Willy Simon. It is chaired by Mr Simon, and is responsible for:

- i. Monitoring the quality of internal controls and ensuring the financial performance of the Group is properly measured and reported on;
- ii. Consideration of the Directors' risk assessment and suggesting items for discussion at the full Board;
- iii. Receipt and review of reports from the Company's management and 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, Willy Simon and Leopoldo Zambelletti. It is chaired by Leopoldo Zambelletti, 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 Leopoldo Zambelletti. 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;

## DIRECTORS REPORT

- 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 a 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.

### 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.

## **DIRECTORS REPORT**

### **Post balance sheet events**

Subsequent to the year end the Group announced the resignation of Riccardo Dalla-Favera MD from his role as Non-Executive Director of the Company.

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

By order of the Board  
Mr Willy Simon

April 3<sup>rd</sup> 2019

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

## DIRECTORS REMUNERATION REPORT

### Letter from the Chair of the Remuneration Committee

Dear Shareholders,

On behalf of the Remuneration Committee, I am pleased to present our Directors' Remuneration Report for the year ended December 31, 2018, which will be subject to an advisory vote under a resolution to be proposed at the 2019 Annual General Meeting ("AGM"). The results of this vote will be carefully considered by the Remuneration Committee to formulate and approve the Company's future Remuneration Policy.

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

### Remuneration Policy

This is the first year the Company has been required to present the Remuneration Policy ("Policy") to the Shareholders for approval. The Policy is set out in full within the Directors Remuneration Report and will be proposed as a resolution at the 2019 AGM. A notice of the AGM will be sent to all shareholders in due course stating the time, date and location of the meeting, along with an agenda outlining resolutions relating to the business which the Company proposes to conduct at the meeting.

### Key activities and decisions in the year ended December 31, 2018

Since January 1, 2018 the Committee has assumed the following key decisions and activities.

- The contractual obligations to the Executive Director and Chief Executive Officer were reviewed and it was noted that in the initial offer letter provided, it stated the Chief Executive Officer should receive an option grant to acquire 4,000,000 ordinary shares in the capital of the Company on a 4-year vesting profile. Considering this has been delayed, the company decided to immediately make a grant of 4,000,000 options at market price on a 4-year vesting profile. In addition, it was noted that due to the high tax implications of the UK Market the contractual realisation bonus to be granted to the Chief Executive Officer in 2016 was highly inefficient, therefore the Company considered it appropriate to grant the Chief Executive Officer a further option over 2,500,000 ordinary shares (which equated to approximately 2% of issued share capital on an undiluted basis). These options were granted at market price and will vest immediately on a change of control.
- Awarded options to a newly appointed Non-Executive Director based on the Company's intent to pay less than what might be considered to be market compensation to a Non-Executive Director. The members of the Committee further noted the extensive experience in the biotechnology sector and decided that it was appropriate to make an award of 550,000 options at market price vesting in equal tranches over 4 years.
- The Company reviewed the compensation to the Chairman, and based on the continual effort to raise finance for the Company and the Committee considered it appropriate to consider and make an award of options to acquire a further 550,000 shares at market price vesting conditional on the share price being equal to 200% of the exercise price on an average volume weighted basis for a period of at least 5 consecutive trading days.

The Company has made significant progress during 2018 in the clinical development on Foralumab, with the filing of the IND for the first in-human evaluation of the nasal administration of Foralumab and the progress in Phase 2a trials in Miliciclib, along with the strengthening of the financial position of the Company through an IPO offering on the Nasdaq.

To support this progress, the Company expanded its competencies by hiring an additional member to its senior management team, Fayez Hamzeh MD, who joins the Company as a Senior Vice President of Clinical Development.

Yours faithfully,

Willy Simon  
Chair of the Remuneration Committee  
April 3<sup>rd</sup>, 2019

### Directors' remuneration policy

## DIRECTORS REMUNERATION REPORT

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.

The policy, as outlined below, is to obtain shareholder approval at the 2019 AGM. Upon approval, the company will continue to put forward the remuneration policy to be approved every three years, however the company will update it when necessary and will be sent for approval before the three-year approval.

### Policy Table

#### Element of reward - Base Salary

<b>Purpose and Link to Strategy</b>	To provide fixed remuneration to <ul style="list-style-type: none"> <li>▪ help recruit and retain key individuals;</li> <li>▪ reflect the individual's experience, role and contribution within the Company.</li> </ul>
<b>Operation</b>	The Remuneration Committee considers a number of factors when setting salaries, including: <ul style="list-style-type: none"> <li>▪ scope and complexity of the role</li> <li>▪ the skills and experience of the individual</li> <li>▪ salary levels for similar roles within the industry</li> <li>▪ pay elsewhere in the Company</li> </ul> <p>Salaries are reviewed, but not necessarily increased, annually.</p>
<b>Performance conditions</b>	None.
<b>Maximum opportunity</b>	Salary increases are normally made with reference to the average increase for the wider Company. The Board retains discretion to make higher increases in certain circumstances, for example, following an increase in the scope and/or responsibility of the role or the development of the individual in the role or by benchmarking.

#### Element of reward- Other benefits

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

#### Element of reward - Annual Bonus

## DIRECTORS REMUNERATION REPORT

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

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

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

## DIRECTORS REMUNERATION REPORT

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 will be subject to a binding Shareholder vote at the 2019 AGM and, if approved, would be expected to remain 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 12 months of death.	Exercise and time vesting provisions per the option certificate. Board can waive if satisfied that such waiver is not rewarding failure.
Resignation or any other reason not mentioned above.	Lapse of option unless Board exercises discretion to allow exercise of option in which case within 3 months of leaving/notice.	If allowed to exercise; Exercise and time vesting provisions per the option certificate. Board can waive if satisfied that such waiver is not rewarding failure.

### 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.

## DIRECTORS REMUNERATION REPORT

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.

### 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, 2018 and December 31, 2017:

Year Ended December 31, 2018 £'000	Base Salary	Share-based payment <sup>(2)</sup>	Other <sup>(3)</sup>	2018 Total
<b>Executive</b>				
Gabriele Cerrone	93	272	-	365
Kunwar Shailubhai	225	618	15	858
<b>Non - Executive</b>				
Willy Simon	38	-	-	38
Riccardo Dalla Favera <sup>(1)</sup>	20	1	-	21
Leopoldo Zambelletti	-	46	-	46
<b>Total</b>	<b>376</b>	<b>937</b>	<b>15</b>	<b>1,328</b>

Year Ended December 31, 2017 £'000	Base Salary	Share-based payment <sup>(2)</sup>	Other <sup>(3)</sup>	2017 Total
<b>Executive</b>				
Gabriele Cerrone	67	226	-	293
Kunwar Shailubhai	230	49	-	279
<b>Non - Executive</b>				
Willy Simon	38	-	-	38
Riccardo Dalla Favera	20	4	-	24
<b>Total</b>	<b>355</b>	<b>279</b>	<b>-</b>	<b>634</b>

<sup>(1)</sup> Resigned 7<sup>th</sup> February 2019

<sup>(2)</sup> Shares based payments represent the fair value of options that vested during the years ended December 31, 2018 and December 21, 2017.

<sup>(3)</sup> Other benefits represent healthcare benefits

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



## DIRECTORS REMUNERATION REPORT

### 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, 2018:

Year Ended December 31, 2018	Shares	Options – not yet vested	Options – vested not yet exercised	Total (Shares and options)
<b>Executive</b>				
Gabriele Cerrone	64,187,745	3,809,403	3,200,000	71,197,148
Kunwar Shailubhai	5,000	6,800,000	400,000	7,205,000
<b>Non - Executive</b>				
Willy Simon	-	-	-	
Riccardo Dalla Favera	-	-	420,000	420,000
Leopoldo Zambelletti	-	550,000	-	550,000
<b>Total</b>	<b>64,192,745</b>	<b>11,159,403</b>	<b>4,020,000</b>	<b>79,372,148</b>

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

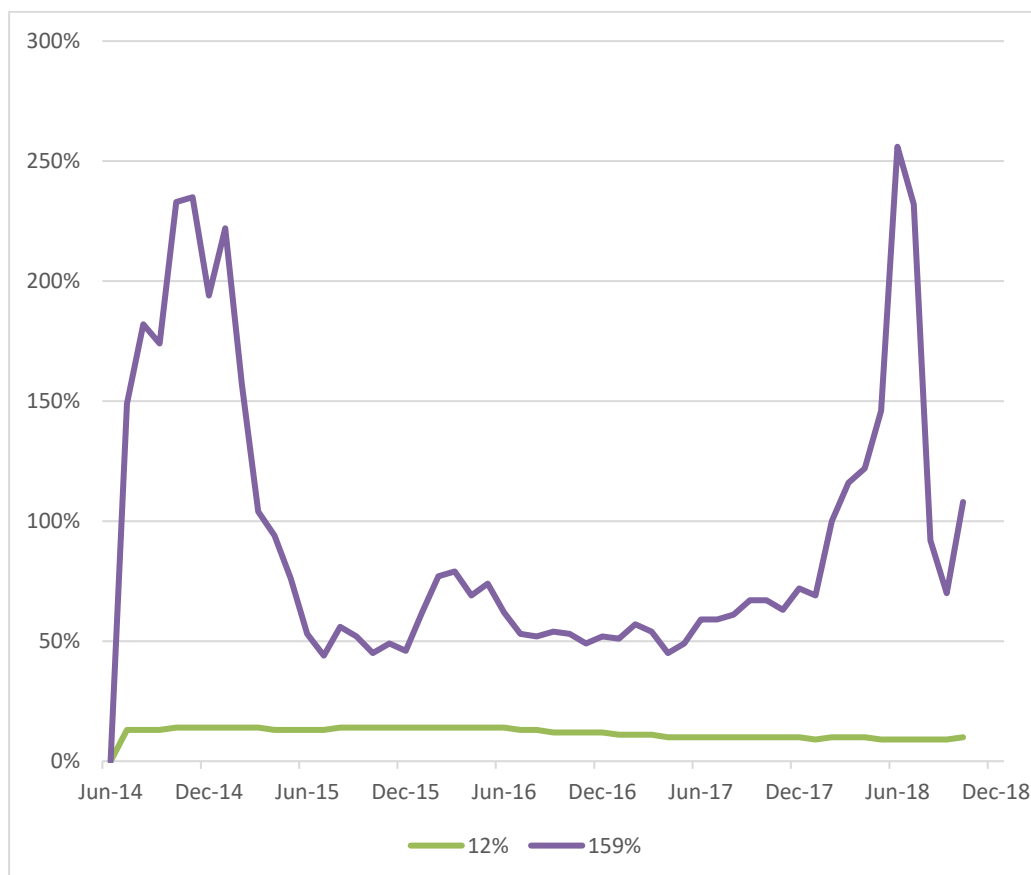
Director	Granted	Date of grant	Price per share £	Vesting Criteria	Expiry Date
Gabriele Cerrone	1,200,000	25 April 2014	0.15	25 per cent. Will vest on each of 24/04/2015, 24/04/2016, 24/04/2017, 24/04/2018	10 years from date of vesting
	2,000,000	26 January 2016	0.35	Immediate	10 years from date of vesting
	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
	<b>550,000</b>	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
Leopoldo Zambelletti	550,000	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

## DIRECTORS REMUNERATION REPORT

### 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

As this is the first year that Tiziana Life Sciences PLC has prepared a Directors Remuneration Report, the exemption not to disclose 5 years of history of remuneration has been taken.

### Percentage change of Chief Executive Officer Total Remuneration

	Percentage increase for the year ended December 31, 2018 compared to the year ended December 31, 2017	
	CEO	Average Employee
Base Salary	0%	0%
Short term incentives	0%	0%
Taxable Benefits <sup>(1)</sup>	0%	n/a

## DIRECTORS REMUNERATION REPORT

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

### Payments to past directors (audited)

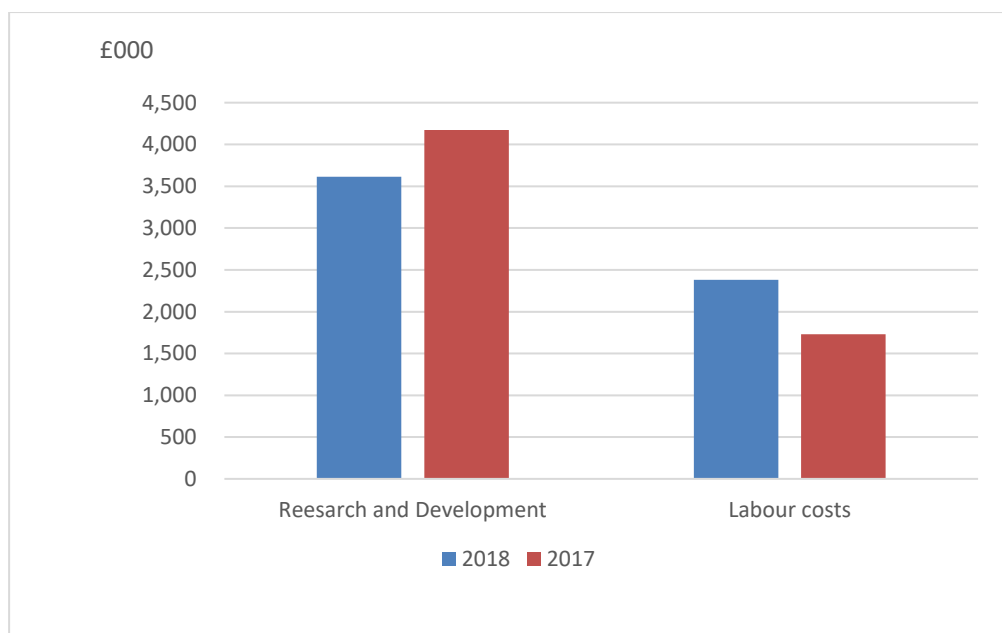
In the period there were no payments to past Directors.

### 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 Leopoldo Zambelletti. 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.

# 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 2018 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 2018 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.

## The impact on our audit of uncertainties due to Britain exiting the European Union ('Brexit')

The directors' view on the impact of Brexit is disclosed on page 16.

The terms on which the United Kingdom may withdraw from the European Union are not clear and it is therefore not currently possible to evaluate all the potential implications for the Group's and Parent Company's trade, customers, and suppliers, and to the wider economy.

We considered the impact of Brexit on the Group and Parent Company as part of our audit procedures, applying a standard firm wide approach in response to the uncertainty associated with the Group's and Parent Company's future prospects and performance. However, no audit should be expected to predict unknowable factors or all possible implications for the Group and Parent Company, and this is particularly the case in relation to Brexit.

## 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 in the early stages of development and its business model requires significant ongoing expenditure on research and development. At 31 December 2018, the Group had net assets of £411,000 and cash and cash equivalents of £4,165,000. In Note 2, the directors explain that to date they have successfully raised funds to finance clinical trials but further funding will be required within the foreseeable future to continue their development programmes and to meet other 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. However, until the Group secures sufficient investment to fund their clinical trials and ongoing working capital requirements, these events or 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.

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

### 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. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

#### **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 42 and 43.

The Parent Company operates share-based payments arrangements to remunerate directors and employees in the form of a share options. Additionally, warrants were granted in lieu of fundraising fees in 2015 which are exercisable over four 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:**

Based on our procedures performed, the options, warrants and convertible loan notes were all appropriately accounted for under relevant accounting standards. Management's assumptions were deemed to be reasonable.

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

### 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:

<b>Group and Parent Company materiality</b>	<b>Group - £424,000</b> <b>Parent Company - £250,000</b>
<b>How we determined materiality</b> 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.	
<b>Rationale for benchmark applied</b> 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.	
<b>Performance materiality – Group and Parent Company</b> 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.	Group - £275,000 Parent Company - £162,500
<b>Reporting threshold – Group and Parent Company</b> 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 - £12,737 Parent Company £7,500
<b>Component performance materiality range</b> All components have been audited by the group engagement team. Materiality is allocated to components based on size and risk.	£133,904 - £149,500

### 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. .

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

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 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, 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 the 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 where 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 15 and 16, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

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 [www.frc.org.uk/auditorsresponsibilities](http://www.frc.org.uk/auditorsresponsibilities). 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 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

3<sup>rd</sup> April 2019



**CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME  
FOR THE YEAR ENDED 31 DECEMBER 2018**

	Note	<b>2018</b> £'000	<b>2017</b> £'000
<b>Continuing Operations</b>			
Research and development costs		(4,132)	(4,672)
Operating expenses		(3,313)	(3,574)
<b>Operating loss</b>	4	<u>(7,445)</u>	<u>(8,246)</u>
Finance costs	9	(9)	(9)
<b>Loss before taxation</b>		<u>(7,454)</u>	<u>(8,255)</u>
Taxation	10	1,459	1,485
<b>Loss for the year attributable to equity owners</b>		<u><u>(5,995)</u></u>	<u><u>(6,770)</u></u>
<b>Other comprehensive income that may be classified to profit and loss in subsequent periods</b>			
Exchange differences on translation of foreign operations		(113)	-
<b>Total comprehensive loss for the year attributable to equity owners</b>		<u><u>(6,108)</u></u>	<u><u>(6,770)</u></u>
<b>Loss per share</b>			
Basic and diluted (loss) per share on continuing operations	11	<u>(4.7p)</u>	<u>(6.4p)</u>

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION  
AS AT 31 DECEMBER 2018**

	Note	2018 £'000	2017 £'000
<b>ASSETS</b>			
<b>Non-Current assets</b>			
Property, plant and equipment	12	<u>6</u>	<u>18</u>
Total non-current assets		<u>6</u>	<u>18</u>
<b>Current assets</b>			
Other receivables	13	1,048	1,548
Other current assets	14	217	217
Cash and cash equivalents		<u>4,165</u>	<u>48</u>
Total current assets		<u>5,430</u>	<u>1,813</u>
<b>TOTAL ASSETS</b>		<u><u>5,436</u></u>	<u><u>1,831</u></u>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity</b>			
<b>Capital and reserves attributable to equity holders of the company</b>			
Called up share capital	16	4,094	3,752
Share premium		25,894	18,650
Capital reduction reserve	19	31,183	31,183
Share based payment reserve (options)	17,19	2,857	2,354
Share based payment reserve (warrants)	17,19	548	419
Other reserve	19	(28,286)	(28,286)
Translation reserve		(113)	-
Retained earnings	19	(35,766)	(29,755)
<b>Total equity</b>		<u>411</u>	<u>(1,683)</u>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	22	5,025	3,514
		<u>5,025</u>	<u>3,514</u>
<b>TOTAL EQUITY AND LIABILITIES</b>		<u><u>5,436</u></u>	<u><u>1,831</u></u>

The financial statements were approved by the Board of directors and authorised for issue on 3<sup>rd</sup> April 2019.

Mr W Simon

Director

Company Number: 03508592 (England and Wales)

**COMPANY STATEMENT OF FINANCIAL POSITION  
AS AT 31 DECEMBER 2018**

	Notes	2018 £'000	2017 £'000
<b>ASSETS</b>			
<b>Non-current assets</b>			
Investment in subsidiaries	15	20,305	16,005
Property, plant and equipment		-	6
<b>Current assets</b>			
Other receivables	13	387	1,055
Other current assets	14	217	217
Cash and cash equivalents		3,593	22
<b>TOTAL ASSETS</b>		<u>24,502</u>	<u>17,305</u>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity Capital and reserves attributable to equity holders of the company</b>			
Called up share capital	16	4,094	3,752
Share premium		25,894	18,650
Share based payment reserve (options)	17,19	2,922	2,419
Share based payment reserve (warrants)	17,19	611	482
Capital reduction reserve	19	31,183	31,183
Retained earnings	19	(42,313)	(40,403)
<b>Total equity</b>		<u>22,391</u>	<u>16,083</u>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Trade and other payables	22	<u>2,111</u>	<u>1,222</u>
		<u>2,111</u>	<u>1,222</u>
<b>TOTAL EQUITY AND LIABILITIES</b>		<u>24,502</u>	<u>17,305</u>

The Company reported a loss for the financial year ended 31 December 2018 of £1,894k (2017: £2,988k).

The financial statements were approved by the Board of directors and authorised for issue 3<sup>rd</sup> April 2019.

Mr W Simon  
Director

Company Number: 03508592 (England and Wales)

**CONSOLIDATED STATEMENT OF CASH FLOWS  
FOR THE YEAR ENDED 31 DECEMBER 2018**

	<b>2018</b>	<b>2017</b>
	£'000	£'000
<b>Cash flows from operating activities</b>		
<b>Loss for the year before taxation</b>	(7,454)	(8,255)
Adjustments for:		
Convertible loan interest accrued	9	9
Loan interest paid as equity	16	-
Shares issued in lieu of fees	41	-
Share based payment – options	504	419
Cancellation of options	-	(105)
Share based payment – warrants	128	228
Net (increase)/decrease in other receivables	(135)	40
Net increase in trade and other payables	1,592	1,790
Depreciation	12	11
(Gain)/Loss on foreign exchange	(222)	35
Lease adjustment	3	(24)
<b>CASH USED IN OPERATING ACTIVITIES</b>	<u>(5,506)</u>	<u>(5,852)</u>
<b>Cash inflow from taxation</b>	2,093	-
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<u>(3,413)</u>	<u>(5,852)</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of ordinary shares	7,437	1,198
Proceeds from issuance of warrants	1,132	-
Fundraising costs	(1,039)	-
<b>NET CASH GENERATED FROM FINANCING ACTIVITIES</b>	<u>7,530</u>	<u>1,198</u>
<b>Cash flows from investing activities</b>		
Acquisition of property, plant and equipment	-	(1)
Acquisition of other investments	-	-
<b>NET CASH GENERATED FROM INVESTING ACTIVITIES</b>	<u>-</u>	<u>(1)</u>
<b>NET INCREASE/ (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	4,117	(4,655)
Cash and cash equivalents at beginning of year	48	4,703
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<u><u>4,165</u></u>	<u><u>48</u></u>

**COMPANY STATEMENT OF CASH FLOWS  
FOR THE YEAR ENDED 31 DECEMBER 2018**

	<b>2018</b> £'000	<b>2017</b> £'000
<b>Cash flows from operating activities</b>		
<b>Loss for the year before taxation</b>	(2,472)	(2,988)
Adjustments for:		
Convertible loan interest accrued	9	9
Loan interest paid as equity	16	-
Shares issued in lieu of fees	41	-
Share based payment - options	503	419
Cancellation of options	-	(105)
Share based payment - warrants	128	228
Depreciation	6	6
Net (increase)/decrease in operating assets/other receivables	(79)	4
Net increase in trade and other payables	979	67
(Gain) on foreign exchange	(116)	(2)
<b>CASH USED IN OPERATING ACTIVITIES</b>	<u>(985)</u>	<u>(2,362)</u>
<b>Cash inflow from taxation</b>	1,326	-
<b>NET CASH GENERATED FROM/USED IN OPERATING ACTIVITIES</b>	<u>341</u>	<u>(2,362)</u>
<b>Cash flows from financing activities</b>		
Proceeds from issuance of ordinary shares	7,437	1,198
Proceeds from issuance of warrants	1,132	-
Fundraising costs	(1,039)	-
<b>NET CASH GENERATED FROM FINANCING ACTIVITIES</b>	<u>7,530</u>	<u>1,198</u>
<b>Cash flows from investing activities</b>		
Acquisition of property, plant and equipment	-	-
Acquisition of other investments	-	-
Capital contribution to subsidiaries	(4,300)	(3,463)
<b>NET CASH GENERATED USED IN INVESTING ACTIVITIES</b>	<u>(4,300)</u>	<u>(3,463)</u>
<b>NET INCREASE IN CASH AND CASH EQUIVALENTS</b>	3,571	(4,627)
Cash and cash equivalents at beginning of year	22	4,649
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<u>3,593</u>	<u>22</u>

**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY  
FOR THE YEAR ENDED 31 DECEMBER 2018**

	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
<b>Balance at 1 January 2017</b>	2,832	2,071	31,183	1,935	191	13,535	(28,286)	-	(20,147)	3,314
<u>Transactions with owners</u>										
Issue of share capital under share-based payment scheme	66	1,131	-	-	-	-	-	-	-	1,197
Share based payment (options)	-	-	-	980	-	-	-	-	-	980
Share based payment (warrants)	-	-	-	-	228	-	-	-	-	228
Options forfeited/cancelled in the year	-	-	-	(561)	-	-	-	-	(105)	(666)
Convertible loan note interest	-	-	-	-	-	2,767	-	-	(2,767)	-
Convertible loan note conversion	854	15,448	-	-	-	(16,302)	-	-	-	-
Prior year adjustments	-	-	-	-	-	-	-	-	34	34
Total transactions with owners	920	16,579	-	419	228	(13,535)	-	-	(2,838)	1,773
<u>Comprehensive income</u>										
Comprehensive loss for the year	-	-	-	-	-	-	-	-	(6,770)	(6,770)
Total comprehensive income	-	-	-	-	-	-	-	-	(6,770)	(6,770)
<b>Balance as at 31 December 2017</b>	3,752	18,650	31,183	2,354	419	-	(28,286)	-	(29,755)	(1,683)
<u>Transactions with owners</u>										
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)	-	-	-	-	129	-	-	-	-	129
Total transactions with owners	342	7,244	-	503	129	-	-	-	(16)	8,202
<u>Comprehensive income</u>										
Exchange differences on translating foreign operations	-	-	-	-	-	-	-	(113)	-	(113)
Comprehensive loss for the year	-	-	-	-	-	-	-	-	(5,995)	(5,995)
Total comprehensive income	-	-	-	-	-	-	-	(113)	5,995	(6,108)
<b>Balance as at 31 December 2018</b>	4,094	25,894	31,183	2,857	548	-	(28,286)	(113)	(35,766)	411

**COMPANY STATEMENT OF CHANGES IN EQUITY  
FOR THE YEAR ENDED 31 DECEMBER 2018**

	Share Capital	Share Premium	Merger Relief Reserve	Capital Redemption Reserve	Capital Reduction Reserve	Share Based Payment Reserve (options) £'000	Share Based Payment Reserve (warrants) £'000	Convertible Loan Note Reserve	Retained Earnings	Total Equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
<b>Balance at 1 January 2017</b>	2,832	2,071	-	-	31,183	2,000	254	13,535	(35,626)	16,249
<u>Transactions with owners</u>										
Issue of share capital	66	1,131	-	-	-	-	-	-	-	1,197
Share based payment (options)	-	-	-	-	-	980	-	-	-	980
Share based payment (warrants)	-	-	-	-	-	-	228	-	-	228
Options forfeited in the year	-	-	-	-	-	(561)	-	-	-	(561)
Options cancelled in the year	-	-	-	-	-	-	-	-	(105)	(105)
Convertible loan note interest	-	-	-	-	-	-	-	2,767	(2,767)	-
Convertible loan note conversion	854	15,448	-	-	-	-	-	(16,302)	-	-
Prior year adjustments	-	-	-	-	-	-	-	-	34	34
<b>Total transactions with owners</b>	<b>920</b>	<b>16,579</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>419</b>	<b>228</b>	<b>(13,535)</b>	<b>(2,838)</b>	<b>1,773</b>
<u>Comprehensive income</u>										
Loss for the year	-	-	-	-	-	-	-	-	(1,939)	(1,939)
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(1,939)</b>	<b>(1,939)</b>
<b>Balance as at 31 December 2017</b>	<b>3,752</b>	<b>18,650</b>	<b>-</b>	<b>-</b>	<b>31,183</b>	<b>2,419</b>	<b>482</b>	<b>-</b>	<b>(40,403)</b>	<b>16,083</b>
<u>Transactions with owners</u>										
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)	-	-	-	-	-	-	129	-	-	129
<b>Total transactions with owners</b>	<b>342</b>	<b>7,244</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>503</b>	<b>129</b>	<b>-</b>	<b>(16)</b>	<b>8,202</b>
<u>Comprehensive income</u>										
Comprehensive loss for the year	-	-	-	-	-	-	-	-	(1,894)	(1,894)
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(1,894)</b>	<b>(1,894)</b>
<b>Balance as at 31 December 2018</b>	<b>4,094</b>	<b>25,894</b>	<b>-</b>	<b>-</b>	<b>31,183</b>	<b>2,922</b>	<b>611</b>	<b>-</b>	<b>(42,313)</b>	<b>22,391</b>

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

### 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 assets at the year end.

As discussed in the Strategic Report, the Group and Company is in the early stages of developing its business focusing on the discovery and development of novel molecules that treat human disease in oncology and immunology. The Directors expect the Group and Company to incur further losses and to require significant capital expenditure in continuing to develop clinical stage development therapeutic candidates in both oncology and immunology. The Group and Company has successfully funded clinical trials to date and 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. These projections identify that the Directors need to raise further funds within the foreseeable future in order to fund commitments with respect to its clinical trials and ongoing business operations. The Directors are confident, based on the status of the clinical trials and previous fund-raising history that sufficient funds will be forthcoming and accordingly they have prepared these financial statements on a going concern basis.

However, until and unless the Group and Company secures sufficient investment to fund their clinical trials, there is a material uncertainty about the Group and Company's ability to continue as a going concern, 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 2018***

IFRS 9 Financial Instruments was mandatorily applicable from 1 January 2018. The impact of applying IFRS 9 as of 1 January 2018 had no material impact on the accounting or measurement of any of the financial instruments the Group currently holds.



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

### ***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, except IFRS 16 *Leases* which will impact on the recognition of leases currently classified as operating leases. The Group currently has 4 lease agreements in place of which two lease agreements are deemed to be within scope. Management are in the process of assessing the impact of these two lease agreements.

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.

A number of 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 exercises control. The Group has control when it can demonstrate all of the following: (a) power over the investee; (b) exposure, or rights, to variable returns from its involvement with the investee; and (c) the ability to use its power over the investee to affect the amount of the investor's return.

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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

### 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

#### *Financial assets*

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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

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.

### **Other current assets**

Other 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.

### **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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

### **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.

### **Operating leases**

Payments made under operating leases are recognised in profit and loss on a straight-line basis over the term of the lease. Lease incentives received are recognised as an integral part of the total lease expense, over the term of the lease.

### **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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

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.

### Convertible loan notes

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.

*Where there is no option to repay as cash 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 there is an option to repay as cash and the interest rate is variable*

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.

### 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. OPERATING LOSS

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

	2018 £'000	2017 £'000
License fees	781	514
Depreciation	12	11
Foreign exchange (gains)/losses	(222)	35
	<u>571</u>	<u>560</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2018**

**5. 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.

**6. AUDITOR'S REMUNERATION**

	<b>2018</b>	<b>2017</b>
	£'000	£'000
Remuneration receivable by the Company's auditor for the audit of the consolidated and Company financial statements, including £8k (2017:£9k) for the audit of Company subsidiaries.	34	42
Remuneration receivable by the Company's auditor for other assurance services	56	19

**7. EMPLOYEES**

<u>Group</u>	<b>2018</b>	<b>2017</b>
Staff costs comprised:	£'000	£'000
Directors' salaries	151	164
Wages and salaries	1,252	860
Social security costs	447	381
Share based payment charge	503	419
	<hr/>	<hr/>
	2,353	1,824
	<hr/> <hr/>	<hr/> <hr/>

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

Research and Development	6	6
Corporate and administration	5	5
	<hr/>	<hr/>
	11	11
	<hr/> <hr/>	<hr/> <hr/>

A charge for share based payments totalling £503k (2017: £419k) was made in the year.

<u>Company</u>	<b>2018</b>	<b>2017</b>
Staff costs comprised:	£'000	£'000
Directors' salaries	151	93
Share based payment charge	503	419
	<hr/>	<hr/>
	654	512
	<hr/> <hr/>	<hr/> <hr/>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
FOR THE YEAR ENDED 31 DECEMBER 2018**

**8. REMUNERATION OF KEY MANAGEMENT PERSONNEL**

Director	2018		2017	
	Directors' fee £'000	Salary £'000	Directors' fee £'000	Salary
W Simon	38	-	38	-
G. Cerrone	93	-	67	-
R. Dalla-Favera	20	-	20	-
K. Shailubhai (1)	-	225	8	222
	<u>151</u>	<u>225</u>	<u>133</u>	<u>222</u>

(1) 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	2018 Number of options	2017 Number of options
R. Dalla Favera	-	-
W. Simon	-	-
G. Cerrone	550,000	-
L Zambeletti	550,000	-
K Shailubhai	6,500,000	-
	<u>7,600,000</u>	<u>400,000</u>

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 £13k (2017: £5k) of payments to a defined contribution pension schemes on behalf of directors or employees.

**9. FINANCE COSTS**

<u>Group</u>	2018 £'000	2017 £'000
Finance charge accrued on convertible loan notes (recognised as debt)	9	9
	<u>9</u>	<u>9</u>

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**10. TAXATION**

	<b>2018</b> £'000	<b>2017</b> £'000
<b>Group</b>		
Current year tax (credit)	(800)	(380)
Adjustments in respect of prior periods	(659)	(1,105)
Deferred tax		
Origination and reversal of timing differences	Nil	Nil
<b>Total tax (credit) for period</b>	<b>(1,459)</b>	<b>(1,485)</b>

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	(7,454)	(8,255)
Loss charged at standard rate of corporation tax 19% (2017: 19.25%)	(1,416)	(1,589)
Tax losses arising in the year not recognised	828	2,244
Expenses not deductible for taxation	132	24
Adjustments due to prior periods	(659)	(1,105)
Research and development claim	(344)	(1,061)
Other timing differences	-	2
	<b>(1,459)</b>	<b>(1,485)</b>

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 £2,946k (2017: £3,680k).

**11. LOSS PER SHARE**

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

	<b>2018</b>	<b>2017</b>
(Loss) attributable to equity holders of the Company (£)	(5,995,153)	(6,769,365)
Weighted average number of ordinary shares in issue	127,553,866	106,403,903
<b>Basic loss per share (pence per share)</b>	<b>(4.7)</b>	<b>(6.4)</b>

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.



**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**12. PROPERTY, PLANT AND EQUIPMENT**

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

<u>Group</u>	<b>Furniture and fixtures</b> £'000	<b>IT equipment</b> £'000	<b>Total</b> £'000
<b>Cost</b>			
At 1 January 2018	12	25	37
Additions	-	-	-
Disposals	-	-	-
<b>At 31 December 2018</b>	<u>12</u>	<u>25</u>	<u>37</u>
<b>Depreciation</b>			
At 1 January 2018	3	16	19
Charge in year	4	8	12
<b>At 31 December 2018</b>	<u>7</u>	<u>24</u>	<u>31</u>
<b>Net book value as at 31 December 2018</b>	<u>5</u>	<u>1</u>	<u>6</u>
Net book value as at 31 December 2017	<u>9</u>	<u>9</u>	<u>18</u>

**13. OTHER RECEIVABLES**

<u>Group</u>	<b>2018</b> £'000	<b>2017</b> £'000
Other receivables	195	85
Taxation receivable	800	1,435
Related party receivable	20	-
Prepayments	33	28
	<u>1,048</u>	<u>1,548</u>

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

<u>Company</u>	<b>2018</b> £000	<b>2017</b> £000
Taxation receivable	300	1,048
Prepayments and accrued income	87	7
	<u>387</u>	<u>1,055</u>

**14. OTHER CURRENT ASSETS**

In June 2016, the Board approved the purchase of the data repository of DNA 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 to be owned by Tiziana Life Sciences PLC and will be loaned to its subsidiary Longevia SRL for no extra cost.

As there is current legal action pending against the liquidators as to the validity to the sale of the assets, the Company is unable to utilise these assets until the legal action is resolved. For this reason, the investment has been recognised as a current asset until such a time that the Company is able to use this asset. In the event the Company is unable to use the asset as a result of the legal action denoted above, the Company will receive their money back.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

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.

### 15. INVESTMENTS IN SUBSIDIARIES

<u>Company</u>	<b>Shares in group undertakings</b>	<b>Capital Contribution</b>	<b>Total</b>
	£'000	£'000	£'000
<b>Cost</b>			
At 1 January 2018	7,509	8,496	16,005
Additions	-	4,300	4,300
Disposals	-	-	-
<b>At 31 December 2018</b>	7,509	12,796	20,305
<b>Provisions</b>			
At 1 January 2018	-	-	-
Charge in year	-	-	-
<b>At 31 December 2018</b>	-	-	-
<b>Net book value as at 31 December 2018</b>	7,509	12,796	20,305
Net book value as at 31 December 2017	7,509	8,496	16,005

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:

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

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.

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**16. SHARE CAPITAL**

<u>Company and Group</u>	<b>2018</b>	<b>2017</b>	<b>2018</b>	<b>2017</b>
	<b>Ordinary Shares</b>		<b>£000</b>	<b>£000</b>
In issue at 1 January	125,054,805	94,393,401	3,752	2,832
Issued for cash	7,742,167	2,206,190	232	66
Conversion of Convertible Loan Notes	-	28,455,214	-	854
Conversion of warrants	1,454,644	-	45	-
Conversion of Loan	2,137,625	-	65	-
Commission and Interest	74,577	-	-	-
In issue at 31 December	<u>136,463,818</u>	<u>125,054,805</u>	<u>4,094</u>	<u>3,752</u>

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 January 2018, 166,667 new ordinary shares were issued by way of a placing of ordinary shares to raise finance.

In March 2018, 600,000 new ordinary shares were issued by way of a further placing of ordinary shares to raise finance.

An additional 1,031,250 new ordinary shares were issued in April 2018 by way of a further placing of ordinary shares to raise finance. In addition, 51,563 new ordinary shares were issued to intermediaries in lieu of commissions on the funds raised.

Also in April 2018, 23,014 new ordinary shares were issued in relation to a shortfall in capitalized interest due to a former holder of the Company's Class C Convertible Loan Notes which was discovered during the annual audit process.

In October 2018, 1,515,150 new ordinary shares were issued by way of a further placing of ordinary shares to raise finance.

In November 2018, 4,429,100 new ordinary shares were issued as part of the initial public offering of American Depositary Shares on the Nasdaq Global Market. In addition to the IPO, 2,137,625 new ordinary shares were issued to extinguish £1.3 million in debt.

In November 2018, notification was also received from warrant holders to exercise warrants over 1,400,644 ordinary shares.

In conjunction with the IPO, the Company resolved to allow the holders of its warrants to exercise at reduced exercise prices in the period ending on 30 November 2018. Notification was also received from warrant holders to exercise warrants over 54,000 ordinary shares in connection with this offer.

**17. 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.

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	2018		2017	
	Options ('000)	Weighted Average exercise price (pence)	Options ('000)	Weighted Average exercise price (pence)
Outstanding at 1 January	10,717	93	12,449	33
Granted	9,500	82	668	161
Forfeited	(1,600)	(172)	(2,250)	(15)
Cancelled	-	-	(150)	(15)
	<hr/>	<hr/>	<hr/>	<hr/>
Outstanding at 31 December	<u>18,617</u>	<u>84</u>	<u>10,717</u>	<u>93</u>
Exercisable at 31 December	<u>5,236</u>	<u>39</u>	<u>5,011</u>	<u>42</u>

No options were exercised during the period ending 31 December 2018 and 31 December 2017.

The total outstanding fair value charge of the share option instruments is deemed to be approximately £5,175k (2017: £4,600k).

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.

	<u>10 March 2017</u>	<u>30 August 2017</u>	<u>30 April 2018</u>
Grant date share price	£1.725	£1.595	£0.8175
Exercise share price	£1.725	£1.595	£0.8175
Vesting periods	Yr1, Yr 2, Yr 3, Yr4	Yr 1, Yr 2, Yr 3, Yr4	Yr 1, Yr 2, Yr 3, Yr4
Risk free rate	0.38% to 1.09%	0.69% to 1.09%	0.69% to 1.03%
Expected volatility	80% to 167%	58% to 60%	58% to 59.7%
Option life	10 years	10 years	10 years

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.

## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

### Warrants

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 in 25% portions until 22 January 2016, 22 January 2017, 22 January 2018, and 22 January 2019.

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 lieu of fundraising fees. 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 lieu of fundraising fees. 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 lieu of fundraising fees. 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 13,333 shares at an exercise price of £1.60 per share in lieu of fundraising fees. 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 of fundraising fees. 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.

The Directors have estimated the fair value of the warrants in services provided using the Black-Scholes valuation model. The remaining fair value of the warrant instruments is deemed to be approximately £697,000 (2017: £655,000). For each set of warrants, the charge has been expensed over the vesting period. A share based payment charge for the year of £128k (year to December 2017: £228k) has been expensed in the statement of comprehensive income.

## 18. CONVERTIBLE LOAN NOTES

### 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 and the debt liability. The liability for the convertible debt instrument at 31 December 2018 is;

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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	<b>2018</b>	<b>2017</b>
	<b>£000</b>	<b>£000</b>
Convertible loan notes issued	234	225
Accrued interest	9	9
	<u>243</u>	<u>234</u>

**19. 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 other reserve was created as a result of the reverse acquisition of Alexander David Investments Plc in the year and the accounting treatment required, 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.

**20. 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:

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£000	2018		
	Less than 3 months	3 to 12 months	Total
Trade and other payables	2,066	793	2,859
Convertible Loan Notes (debt)	2	241	243
Related party payables	110	-	110
	<u>2,178</u>	<u>1,034</u>	<u>3,212</u>

Due to the nature of the Group, it is difficult to forecast financial liabilities greater than 12 months out as said liabilities are subject to change based upon a multitude of variables.

*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, 2018	Profit or loss and equity	
	Strengthening	Weakening
EUR (5% movement)	62	(68)
USD (5% movement)	35	(39)

**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.

**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 2018 or 31 December 2017.

**21. CAPITAL RISK MANAGEMENT**

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

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

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

**NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS  
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**22. TRADE AND OTHER PAYABLES**

<u>Group</u>	<b>2018</b> £000	<b>2017</b> £000
Trade payables	2,859	2,766
Accruals	1,813	505
Related party payable	110	9
Convertible loan note liability	243	234
	5,025	3,514

<u>Company</u>	<b>2018</b> £000	<b>2017</b> £000
Trade payables	569	596
Accruals	1,299	392
Convertible loan note liability	243	234
	2,111	1,222

**23. RELATED PARTY TRANSACTIONS**

Tiziana Pharma Limited is a wholly owned subsidiary of Tiziana Life Sciences plc. During the year, Tiziana Life Sciences Plc transferred £3,079k (2017: £2,566k) 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 £9,831k (2017: £6,752k) 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 £1,204k (2017: £1,744k) to Tiziana Therapeutics Inc. Included within investment in subsidiaries of Tiziana Life Sciences plc's company financial statements at the balance sheet date is £2,948k (2017: £2,702k) 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 £18k (2017: nil) to Longevia Genomics SRL. Included within investment in subsidiaries of Tiziana Life Sciences plc's company financial statements at the balance sheet date is £18k (2017:nil) owed by Longevia Genomics SRL.

Rasna Therapeutics Inc is a related party as Kunwar Shailubhai, director of our Company, is also a director of Rasna. In addition, Tiziano Lazzaretti, CFO of Tiziana, is also CFO 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, 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, 2018, £7k was owed to Tiziana Life Sciences PLC.

Gensignia Lifesciences Inc 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, 2018, £43k was owed to Tiziana Life Sciences PLC.



## NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2018

### 24. OPERATING LEASES

The Group leases a number of office premises under operating lease. The future minimum rentals payable under non-cancellable operating leases as at 31 December are as follows:

	<b>2018</b>	<b>2017</b>
	£000	£000
Less than one year	317	216
Between one and five years	518	447
	<hr/>	<hr/>
	<u>835</u>	<u>663</u>

Lease expenses during the period amount to £115k (2017: £110k).

### 25. POST BALANCE SHEET EVENTS

On 7 February 2019, the Company announced that Riccardo Dalla-Favera MD had resigned from his role as Non-Executive Director of the Company.

On 20 March 2019, the Company announced that it had submitted an Investigational New Drug application ("IND") to the U.S. Food and Drug Administration (FDA) to initiate a Phase 1 clinical trial of enteric-coated capsules of Foralumab in healthy volunteers. This single-site clinical study is expected to enroll 36 subjects and it will be conducted at the Brigham and Women's Hospital (BWH), Harvard Medical School.

### 26. 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.

- Miliclib project research funding of approximately £1m has been committed to for 2019 and beyond. Diligence obligations are payable to BMS/Medarex should the project continue. Other 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.