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# TIZIANA PHARMA LIMITED FINANCIAL STATEMENTS YEAR ENDED 31 DECEMBER 2020

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# TIZIANA PHARMA LIMITED FOR THE YEAR ENDED 31 DECEMBER 2020

# **FINANCIAL STATEMENTS**

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# STATUTORY AND OTHER INFORMATION FOR THE YEAR ENDED 31 DECEMBER 2020

Director:

Mr G. M. A. Cerrone

Secretary:

Accomplish Secretaries Limited

Registered Office:

91H Floor 107 Cheapside London EC2V 6DN

Principal Bankers:

Barclays Bank PLC, PO Box 69999, 1 Churchill Place, Canary Wharf, London, E14 1QE

Auditors:

Mazars LLP, Tower Bridge House, St Katharine's Way, London,

E1W 1DD

Nominated Brokers:

Optiva Securities Limited, 49 Berkeley Square, London, W1J 5AZ

Solicitors:

Orrick, Herrington & Sutcliffe (UK) LLP, 107 Cheapside, London, EC2V 6DN

Registrars:

Link Asset Services, The Registry, 34 Beckenham Road, Beckenham, Kent BR3 4TU

# DIRECTOR'S REPORT FOR THE YEAR ENDED 31 DECEMBER 2020

The director presents his report and the financial statements of the Company for the year ended 31 December 2020.

#### Results and dividend

The results of the Company for the year are set out on page 12. No dividends were declared or paid in the year.

#### **Directors**

The director of the Company during the year was:

Mr G. M. A. Cerrone

#### Staff policy

The company 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. Where existing employees become disabled, it is the company's policy, wherever possible, to provide continuing employment under normal terms and conditions and to provide training, career development and promotion wherever appropriate.

#### Statement of director's responsibilities

The director is responsible for preparing the Director's Report and the financial statements in accordance with applicable law and regulations.

Company law requires the directors to prepare financial statements for each financial year. Under that law the directors have elected to prepare the financial statements in accordance with International Financial Reporting Standards as adopted by the European Union.

Under company law the director 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 the financial performance of the company for that year. In preparing these financial statements, the director is required to:

- · select suitable accounting policies and then apply them consistently;
- · make judgements and accounting estimates that are reasonable and prudent;
- state w hether in preparation of the financial statements the company has complied with IFRS as adopted by the European Union, subject to any material departures disclosed and explained in the financial statements; and
- prepare the accounts on the going concern basis unless it is inappropriate to presume that the company will continue in business.

The director is responsible for keeping adequate accounting records that are sufficient to show and explain the Company's transactions and disclose with reasonable accuracy at any time the financial position of the Company 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 company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The director is 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.

### 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 Company. The Company's key personnel are located within the United Kingdom so Brexit will not have a material impact on its personnel or its ability to recruit appropriately qualified staff. The Company's operations are driven by the parent company and the parent company's operations are not expected to be impacted by Brexit.

#### **Post Balance Sheet Events**

# COVID-19

We remain cognisant of the potential impact of coronavirus (COVID-19) on our operations and have taken the steps necessary to maintain the integrity of the Company's assets and the health and w ellbeing of our employees. The Company continues to support its parent, Tiziana Life Sciences, towards progressing its clinical pipeline. COVID-19 has not had an adverse impact on the Company.

# DIRECTOR'S REPORT FOR THE YEAR ENDED 31 DECEMBER 2020

# Disclosure of Information to Auditors

So far as the director is aw are, there is no relevant audit information of w hich the company's auditors are unaw are, and he has taken all steps that they ought to have taken as director in order to make himself aw are of any relevant audit information and to establish that the company's auditors are aw are of that information.

# **Auditors**

Mazars LLP were appointed as auditors in the year and have indicated their willingness to continue in office. 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 of the parent company, Tiziana Life Sciences PLC.

By order of the Board

Mr Gabriele Cerrone

Date: 16 December 2021

# STRATEGIC REPORT FOR THE YEAR ENDED 31 DECEMBER 2020

#### **Business review**

Tiziana Pharma Ltd was established in November 2013 with the aim of developing novel therapeutics for cancer with a focus on late stage metastases. During the year, and subsequent to the year end, the continued activity on its two research projects and two clinical programmes together with research into a cancer stem cell diagnostic which give a solid foundation for the Company's growth. Tiziana Pharma is a subsidiary company of the Group and houses all costs relating to the UK operations of the Group. R&D Activities are mainly driven and carried out by the parent company.

#### Financial Summary

The Company made a loss of £1,433k for the year, with £389k having been spent on Research and Development.

#### Key performance indicators

Key performance indicators for the company are those that are relevant to the Group.

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

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

#### Financial KPIs

### Cash consumption

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

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

#### 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 started the financial period at a share price of 51.5p per share and ended the financial period at 91.5p per share.

# Non-financial KPIs

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

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

# STRATEGIC REPORT FOR THE YEAR ENDED 31 DECEMBER 2020

#### 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 2020.

### Principal risks and uncertainties

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

The risk factors are summarised below:

Risks relating to the Group's business strategy.

The Group's business is relatively undeveloped.

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

# **Business strategy of the Group**

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

# Staffing and key personnel

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

#### Costs of commercialisation

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

### Clinical studies and timelines risk

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

The development of clinical products for new medical treatments is inherently uncertain, with high failure rates in clinical studies for both early- and late-stage development products. Furthermore, such clinical studies (Phase 1,

# STRATEGIC REPORT FOR THE YEAR ENDED 31 DECEMBER 2020

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

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

# Research and development risk

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

# Environmental and other regulatory requirements

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

#### Financino

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

# Market conditions

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

# STRATEGIC REPORT FOR THE YEAR ENDED 31 DECEMBER 2020

#### Pandemic and business disruption risk

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

#### **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.

#### Going Concern

The Company is dependant on parental support of the Group.

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

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

This report was approved by the Board on 16th of December 2021 and signed on its behalf:

Mr G. M. A. Cerrone

# Independent Auditors' Report to the Shareholders of Tiziana Pharma Limited

#### Opinion

We have audited the financial statements of (the 'company') for the year ended 31 December 2020 w hich comprise Statement of Comprehensive Income, Statement of Financial Position, Statement of Changes in Equity and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framew ork that has been applied in their preparation is applicable law and United Kingdom Accounting Standards, including FRS 101 "Reduced Disclosure Framework" (United Kingdom Generally Accepted Accounting Practice).

In our opinion, the financial statements:

- give a true and fair view of the state of the company's affairs as at 31 December 2020 and of its loss for the year then ended;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- 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, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

#### Conclusions relating to going concern

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

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

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

# Other information

The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, wield 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 know ledge obtained in the course of 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.

# Independent Auditors' Report to the Shareholders of Tiziana Pharma Limited

# Matters on which we are required to report by exception

In light of the knowledge and understanding of the company and its environment obtained in the course of the audit, we have not identified material misstatements in the Strategic Report or the Directors' Report.

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

- adequate accounting records have not been kept, or returns adequate for our audit have not been received from branches not visited by us; or
- the financial statements 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.
- the directors were not entitled to prepare the financial statements in accordance with the small companies regime and take advantage of the small companies' exemption in preparing the Directors' Report and from the requirement to prepare a Strategic Report.

# Responsibilities of Directors

As explained more fully in the Directors' Responsibilities Statement set out on page 4, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the 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 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 the financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. Based on our understanding of the company and its industry, we identified that the principal risks of non-compliance with laws and regulations related to the UK tax legislation, employment regulation and health and safety regulation, and we considered the extent to which non-compliance might have a material effect on the financial statements. We also considered those laws and regulations that have a direct impact on the preparation of the financial statements, such as the Companies Act 2006.

We evaluated the directors' and management's incentives and opportunities for fraudulent manipulation of the financial statements (including the risk of override of controls) and determined that the principal risks were related to posting manual journal entries to manipulate financial performance, management bias through judgements and assumptions in significant accounting estimates, in particular in relation to loss reserves, and significant one-off or unusual transactions.

Our audit procedures were designed to respond to those identified risks, including non-compliance with laws and regulations (irregularities) and fraud that are material to the financial statements. Our audit procedures included but were not limited to:

- Discussing with the directors and management their policies and procedures regarding compliance with laws and regulations;
- Communicating identified laws and regulations throughout our engagement team and remaining alert to any indications of non-compliance throughout our audit; and
- Considering the risk of acts by the company which were contrary to applicable laws and regulations, including fraud.

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

 Making enquiries of the directors and management on whether they had knowledge of any actual, suspected or alleged fraud;

# Independent Auditors' Report to the Shareholders of Tiziana Pharma Limited

- · Gaining an understanding of the internal controls established to mitigate risks related to fraud;
- · Discussing amongst the engagement team the risks of fraud; and
- Addressing the risks of fraud through management override of controls by performing journal entry testing.

There are inherent limitations in the audit procedures described above and the primary responsibility for the prevention and detection of irregularities including fraud rests with management. As with any audit, there remained a risk of non-detection of irregularities, as these may involve collusion, forgery, intentional omissions, misrepresentations or the override of internal controls.

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. This description forms part of our auditor's report.

Use of the audit report

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

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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

16th December 2021

# STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2020

· · · · · · · · · · · · · · · · · · ·	Notes	<b>2020</b> £'000	<b>2019</b> £'000
Continuing operations		·	
Research and development Administrative expenses		(389) (1,202)	(2,283) (597)
Operating loss	4 -	(1,591)	(2,880)
Finance costs	7	(7)	(8)
Loss before taxation	_	(1,598)	(2,888)
Taxation	8	98	463
Loss for the year		(1,500)	(2,425)
Other comprehensive income			,
Total comprehensive loss for the year	_	(1,500)	(2,425)

The notes on pages 16 to 24 are an integral part pf these financial statements.

# STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2020

10	* *		
		2020	2019
	Notes	£,000	£'000
ASSETS	4 8		÷
Fixed assets	9	1	2
Right of use asset	15	186	232
right of use asset	13	100	202
Total non-current assets		187	234
Current assets			
Trade and other receivables	10	.72	43
Taxation receivable		558	460
Cash and cash equivalents		2,032	2
the transfer of the transfer o			
Total current assets		2,662	505
		0.040	720
TOTAL ASSETS		2,849	739
EQUITY AND LIABILITIES Equity Capital and reserves attributable to equity holders of the company			
Ordinary share capital		. <del>.</del>	` <u>-</u>
Share premium	12	55	55
Retained earnings		(14,816)	(13,316)
Total equity		(14,761)	(13,261)
Liabilities			
Current liabilities		v	, , , ,
Trade and other payables	13	17,419	13,764
Lease liability	15	46	44
		17,465	13,808
Non-current liabilities			
Lease liability	15	145	192
Total current and non-current liabilities		17,610	14,000
TOTAL EQUITY AND LIABILITIES		2,849	739
		<del></del>	

The financial statements were approved by the board of directors and authorised for issue on 16th December 2021.

Mr G. M. A. Cerrone

Director

Company Number: 08760354 (England and Wales)

The notes on pages 16 to 24 are an integral part of these financial statement

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

	Ordinary share capital	Share premium	Retained Earnings	Total
	£'000	Ó00′£	£.000	£'000
Balance at 1 January 2020	-	55	(13,316)	(13,261)
Loss for year  Transactions with owners: ssue of share capital	-	-	(1,500)	(1,500)
Balance as at 31 December 2020	-	55	(14,816)	(14,761)
	Ordinary share capital	Share premium	Retained Earnings	Total
•	£,000	£'000	£'000	£'000
Balance at 1 January 2019	-	55	(10,891)	(10,836)
Loss for year	-	-	(2,425)	(2,425)
Transactions with owners: ssue of share capital	-	•	-	• -
Balance as at 31 December 2019		55	(13,316)	(13,261)

The notes on pages 16 to 24 are an integral part of these financial statements.

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

#### 1. GENERAL INFORMATION

Tiziana Pharma Limited is a limited company incorporated on 4<sup>th</sup> November 2013 in England and Wales under the Companies Act. The address of its registered office is given on page 3. The principal activity of the company is that of a clinical stage biotechnology company focused on targeted drugs to treat diseases in oncology and immunology.

These financial statements are presented in pounds sterling because that is the functional currency of the primary economic environment in which the company operates.

#### 2. ACCOUNTING POLICIES

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

### Basis of preparation

These financial statements were prepared in accordance with Financial Reporting Standard 101 Reduced Disclosure Framework. These accounts have been prepared under the historical cost convention.

The results of Tiziana Pharma Limited have been consolidated into the financial statements of the parent entity, Tiziana Life Sciences PLC. The consolidated Group financial statements can be obtained at 55 Park Lane, Mayfair, London, W1K 1NA.

#### **Going Concern**

The financial statements have been prepared on the going concern basis, which contemplates continuity of normal business activities and the realisation of assets and discharge of liabilities in the normal course of business.

As disclosed in the financial statements, the Company incurred losses of £1,433k for the year ended 31 December 2020, and is a direct subsidiary of Tiziana Life Sciences PLC from which it receives its operational funding. The 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 director expects the 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. Through support from its parent the 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 Company's parent company Tiziana Life Sciences PLC has pledged financial support for the company to meet its obligations as and when they fall due. In 2020 Tiziana Life Sciences PLC raised additional finances of £62.1m, sufficient to meet the ongoing requirements of the Group.

The director has prepared cash flow projections that include the costs associated with the continued clinical trials and additional investment required to fund that operation. On the basis of those projections, and the director's confidence that the company will be able to meet its liabilities as they fall due for the foreseeable future and therefore that it is appropriate to prepare the financial statements under the going concern basis of preparation.

# 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 Company in future periods.

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

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

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

#### ACCOUNTING POLICIES (CONTINUED)

Disclosure exemptions adopted under FRS 101

The company has taken advantage of the following disclosure exemptions under FRS 101:

#### Requirements of:

- IFRS 7 Financial Instruments: Disclosures;
- AS 7 Statement of Cash Flows;
- paragraphs 30 and 31 of IAS 8 Accounting Policies, Changes in Accounting Estimates and Errors paragraph
   17 of IAS 24 Related Party Disclosures; and
- IFRS 13 Fair value measurement.

#### Leases

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

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

IFRS16 was adopted 1 January 2019 without restatement of comparative figures. The following policies apply subsequent to the date of initial application, 1 January 2019.

Tiziana Pharma Ltd has a lease for its office. The lease is reflected on the balance sheet as a right-of-use asset and a lease liability. Tiziana Pharma Ltd does not have any short-term leases or leases of low value assets. Variable lease payments which do not depend on an index or a rate (such as lease payments based on a percentage of sales) are excluded from the initial measurement of the lease liability and asset. Tiziana Pharma Ltd classifies its right-of-use assets in a consistent manner to its property, plant and equipment (see Note 15).

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

# Measurement and recognition of leases as a lessee

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

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

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

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

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

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

#### ACCOUNTING POLICIES (CONTINUED)

#### **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 Statement of comprehensive income, as adjusted for items of income or expenditure which are not deductible or chargeable for tax purposes. The current tax receivable 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 base of assets and liabilities and their carrying values in the financial statements. The deferred tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects either accounting nor taxable profit or loss. Deferred tax is determined using tax rates which have been enacted or substantively enacted at the balance sheet date and are expected to apply when the related deferred tax asset is realised or the deferred income tax liability is settled.

Deferred tax assets are recognised to the extent that it is probable that future taxable profits will be available against which the temporary differences can be utilised.

### 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 Statement of comprehensive income.

#### License fees

License fees related to research and development projects are recognised as an expense in the income statement.

# 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 submitted for regulatory approval and it is probable that future economic benefit will flow to the Group. The Group currently has no qualifying expenditure.

# Trade and other receivables

Trade and other receivables are stated at their original invoiced value, less any appropriate allowance for estimated irrecoverable amounts.

# Cash and cash equivalents

Cash and cash equivalents comprise cash at bank and in hand and other short term highly liquid deposits with original maturities of three months or less. Bank overdrafts are shown within borrowings in current liabilities on the Balance Sheet.

#### Share capital

Ordinary shares of the company are classified as equity. Mandatorily redeemable preference shares and other classes of shares where an obligation exists to transfer economic benefits are classified as liabilities.

### Trade payables

Trade payables are recognised initially at fair value and are subsequently measured at amortised cost using the effective interest method. As the payment period of trade payables is shortfuture cash payments are not discounted as the effect is not material.

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

#### 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.

### 3. CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The preparation of financial information in accordance with generally accepted accounting practice, in the case of the Company being FRS 101 International Financial Reporting Standards as applied in the UK under FRS101 Reduced Reporting Framework, requires the directors to make estimates and judgements that affect the reported amount of assets, liabilities, income and expenditure and the disclosures made in the financial statements. Such estimates and judgements must be continually evaluated based on historical experience and other factors, including expectations of future events.

The following are considered to be critical accounting judgments:

#### Income taxes

Deferred tax assets are recognised for unused tax losses to the extent that it is probable that taxable profit will be available against which the losses can be utilised. Significant management judgment is required to determine the amount of deferred tax assets that can be recognised based upon the likely timing and the level of future taxable profits together with future tax planning strategies. No deferred tax asset has been recognised on losses.

#### Research and development costs

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

# Leases

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

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

# 4. OPERATING LOSS

	2020	2019
	£,000	£'000
Depreciation of Property, Plant and Equipment	1.	. 1
Depreciation (Right-of-use asset)	46	47
Foreign exchange losses	250	1
	297	49

# 5. AUDITOR'S REMUNERATION

Operating loss for the year is stated after charging the following:

	£'000	£'000
Remuneration receivable by the company's auditor for the audit of the		•
financial statements	10	10
	10	10

2020

2019

# 6. EMPLOYEES

Claff agata paggarinad	<b>2020</b> £'000	2019 £'000
Staff costs comprised:	£000	£000
Wages and salaries	276	164
Social security	. 42	. 27
(Reversal of) / bonus	(74)	31
Pension & Other	38	62
rension & other	282	284
The average monthly number of employees, including directors, employed by the company during the year was:		
	4	
Corporate and administration	4	3

The key management personnel of the Company are considered to be represented by the directors and officers of the Company. The total remuneration received was paid by Tiziana Life Sciences PLC in 2020.

Directors remuneration paid in the year was £nil (2019: £nil).

# 7. FINANCE COSTS

	<b>2020</b> £'000	<b>2019</b> £'000
Finance Expenses Interest expense on lease liabilities	7.	8
Total finance expenses	7	8
Net finance expense recognised in Statement of Comprehensive Income	7	8

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

# 8. TAXATION

	<b>2020</b> £'000	<b>2019</b> £'000
UK corporation tax on loss in the period Adjustments in respect of previous periods	(84) (14)	(460)
Total tax credit for year	(98)	(463)
The tax charge for the year is different from the standard rate of corporation tax in the United Kingdom of 20%. The difference can be reconciled as follows:		
Loss before taxation	(1,598)	(2,888)
Loss charged at the standard rate of Corporation Tax 19%	(304)	(549)
Movement in unrecognised deferred tax		284
Expenses not deductible for taxation Adjustments due to prior periods Research and development claim	254 1 (14) (36)	(3) (200)

# 9. TANGIBLE FIXED ASSETS

Details of the tangible fixed assets are as follows:

	IT equipment	Total
	£'000	£,000
Cost		
At 1 January 2020	6	6
Additions	-	-
Disposals	-	• •
At 31 December 2020	6	6
Depreciation		,
At 1 January 2020	4	4
Charge in year	1	1
At 31 December 2020	5	5
Net book value as at 31 December 2020	1	1
Net book value as at 31 December 2019	2	2

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

# 10. TRADE AND OTHER RECEIVABLES

	<b>2020</b> £'000	<b>2019</b> £'000
		. , , , , ,
Other debtors	32	23
Prepayments and accrued income	33	20
Related Party receivable	7	
	72	43

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

# 11. SHARE CAPITAL

2020 £000	2019 £000
1,204	1,204
£1.20	£1.20
1,204	1,204
£1.20	£1.20
	£000 1,204 £1.20 1,204

On 19th February 2014 the company issued 100 ordinary shares at 1 pence each.

On 14<sup>th</sup> March 2014 the company subdivided its issued ordinary shares into 1,000 ordinary shares of 0.1 pence each.

On 20th March 2014 the company issued a further 204 shares at 26,961 pence each in order to provide additional working capital.

All shares have full voting, dividend and capital distribution (including on winding up) rights. They do not confer any rights of redemption.

# 12. SHARE PREMIUM

	<b>2020</b> £'000	<b>2019</b> £'000
Balance brought forward Premium on issue of shares	55	55
Balance carried forward	55	55

#### 13. TRADE AND OTHER PAYABLES

	<b>2020</b> £'000	<b>2019</b> £'000
Trade payables	174	2,370
Related party payable Accruals and deferred income	17,208 37	11,261 <sub>2</sub> 133
Was the second of the second o	-	· · · · · · · · · · · · · · · · · · ·
	17,419	13,764

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

# 14. RELATED PARTY TRANSACTIONS

Tiziana Pharma Limited is a wholly owned subsidiary of Tiziana Life Sciences PLC. At the year end, included within other payables at the Balance Sheet date is £17,208k (2019: £11,261k) owed to Tiziana Life Sciences PLC. There is no interest due on this balance.

The ultimate parent entity is Planwise Group Limited, incorporated in the British Virgin Islands. There were no transactions with Planwise Group Limited in the period. Gabriele Cerrone is the ultimate beneficial owner of the entire issued share capital of Planwise Group Ltd.

#### 15. LEASES

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

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

IFRS16 was adopted 1 January 2019 without restatement of comparative figures. For an explanation of the transitional requirements that were applied as at I January 2019, see Note 3. The following policies apply subsequent to the date of initial application, 1 January 2019.

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

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

Right-of-use assets At 1 January 2020 Additions Depreciation	31 Dec 2020 £000 232 - (46)	
	186	
Lease Liabilities  At 1 January 2020 Additions Interest expense Lease payments	31 Dec 2020 £000 236 7 (52)	
Lease liabilities are presented in the statement of financial; position as follows:		
Current Non-current	31 Dec 2020 £000 46 145	1 Jan 2020 £000 44 192 

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

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

	Minimum lease payment due				
	Within 1 year	1-2 years	2-5 years	Over 5 years	Total
31 December 2020					
Lease payments	51	51	± 102	<b>-</b> ,	204
Finance Charges	(6)	(4)	(3)	•	(13)
Net Present Values	45	47	, 99		191

The total net cash outflow for leases in the year to 31 December 2020 w as £51,237.

# 16. ULTIMATE PARENT AND CONTROLLING PARTY

Tiziana Pharma Limited is a wholly owned subsidiary of Tiziana Life Sciences PLC. The ultimate parent of the Group is Planwise Group Limited which owns 32.52% of the issued share capital of Tiziana Life Sciences PLC. Gabriele Cerrone is the ultimate beneficial owner of the entire issued share capital of Planwise Group Ltd.