



**Tiziana Life Sciences Ltd**  
("Tiziana" or "the Company")

**Updated Interim Results for the Six Months Ended 30 June 2022**

London, 29 December 2022 – Tiziana Life Sciences Ltd ("Tiziana", NASDAQ: TLSA), a biotechnology company enabling breakthrough CNS immunomodulation approaches to enhance the functionality of Treg-based therapies, today announced its interim results for the six months ended 30 June 2022.

**Development activity during the first six months ended June 2022:**

**Foralumab**

*TZLS-401*

- Received FDA approval for enrollment of a second, Secondary Progressive Multiple Sclerosis (SPMS) patient *under the Individual Patient Expanded Access Program (EAP)* following favorable clinical results after 6 months of treatment of the first patient in the EA program.
- Initiated a Phase 1b clinical trial in Crohn's disease patients to evaluate oral capsules of foralumab, a fully human anti-cd3 monoclonal antibody. The revised protocol allowed for the study of a broader patient population and a shorter dosing period. These protocol amendments or revisions were intended to expedite patient enrollment with study completion targeted for the fourth quarter of 2022. This study was the first multiple-dose study with orally administered enteric-coated capsules of foralumab in patients with Crohn's disease. Due to the refocus of the company subsequent to the first six months of 2022, this study has been placed on hold.
- Granted permission by the FDA to enroll up to eight additional (SPMS) patients in the EAP with intranasal foralumab. As part of the original treatment plan, the foralumab dose will remain 50 mcg three times a week (MWF), which is the same dose administered previously to the first two SPMS patients. The dosing regimen in this IND also has a provision for dose escalation up to 100 mcg three times a week (MWF) as an option to improve clinical benefit, if needed.
- Data from a Secondary Progressive Multiple Sclerosis patient treated with intranasal treatment with foralumab were presented on June 2, 2022 at the consortium of multiple sclerosis centers (CMSC) 2022 annual meeting. Dr. Tanuja Chitnis, MD, Professor of Neurology and the Principal investigator of the clinical study at the at the Brigham and Women's Hospital (BWH), Boston, MA., presented a poster discussing clinical data from a patient with SPMS, who was treated with intranasal foralumab for six months.
- Announced positive clinical results for the second patient (EA2) in the non-active SPMS Expanded Access (EA) Program following three months of dosing with intranasal foralumab. These results confirm the previously reported data, from the first non-active SPMS patient (EA1) after three months of treatment of intranasal foralumab. Foralumab, a fully human anti-CD3 monoclonal antibody, was well-tolerated and improved clinical and PET imaging analyses. The second patient was diagnosed with SPMS in 2014. Since then, the disease has been progressive, resulting in an accumulation of disability. Patient EA2 started ocrelizumab in 2018 and stopped this treatment in 2021. During this time EA2's non-active SPMS progressed as measured by EDSS worsening from 3.5 in 2018 to 6.0 in 2021. At this point in time EA2 needed a cane to walk 100 meters. Patient EA2 was subsequently enrolled in the intranasal foralumab expanded access program. In September 2022, 8 months after starting treatment with intranasal foralumab, EA2 was able to walk 100 meters without a cane or need to rest. This improved the EDSS from 6.0 to 5.5. EA2's pyramidal score remained stable during this time. In December 2022, 11 months after starting treatment with intranasal foralumab, EA2 was able to walk 200 meters without a cane or need to rest, resulting in further improvement in EDSS from 5.5 to 5.0. EA2's pyramidal score continued to remain stable. Lastly preliminary reading of EA2's 11-month PET Scan (December 2022) demonstrated improvement in microglial activation over baseline.

- Initiated five Good Laboratory Practice (GLP) safety toxicology studies of foralumab administered intranasally and subcutaneously in HuGEMM CD3 transgenic mice. The five studies consisted of three intranasal toxicology studies of 14 days, 13 weeks and 26 weeks dosing duration and two subcutaneous safety toxicology studies of 14 days and 28 days dosing duration. On December 15, 2022 the Company announced that it had successfully completed the 13-week toxicology trial and that intranasal foralumab was well-tolerated.
- Completed manufacturing of clinical supplies of foralumab solution for subcutaneous injection and initiated ICH stability studies.
- Completed compatibility, stability and characterization studies of foralumab intranasal solution in unit dose device for nasal administration. Compatibility, stability and characterization studies of foralumab intranasal solution in multi dose device for intranasal administration will be completed in Q1 2023.

### **Anti IL-6R mAb**

*TZLS-501, formerly NI-1201*

- Filed IND for Phase 1 Clinical Trial in Healthy Subjects for treatment of interstitial lung disease associated with systemic sclerosis (SSc ILD).
- Initiated effector function studies..

### **Milciclib**

*TZLS-201*

- Completed the manufacturing of clinical supplies, milciclib capsules, and initiated ICH stability program.

### **Highlights post period end:**

- On September 20, 2022, Tiziana announced that the second patient (“EA2”) with non-active secondary progressive multiple sclerosis (SPMS) receiving intranasal foralumab had shown additional clinical improvements as measured by the Expanded Disability Status Scale (EDSS), a standard clinical assessment. On October 12, 2022, Tiziana announced that it planned to submit an Investigational New Drug Application (IND) for a Phase 1 Trial of intranasal foralumab in Alzheimer’s disease patients after receiving an affirmative written response from the FDA on a Pre-Investigational New Drug Application (PIND). Tiziana plans on filing the IND for Alzheimer’s disease by the third quarter of 2023 upon the completion of requested toxicology studies, then starting its Phase 1 program by the end of 2023.
- On November 2, 2022, Tiziana announced the completion of enrollment of the first patient cohort in its Intermediate Size Patient Population Expanded Access Program to evaluate foralumab in non-active SPMS patients.
- On November 10, 2022, Tiziana announced its near-term focus on developing intranasal foralumab for inflammatory diseases of the Central Nervous System (CNS) such as non-active SPMS, Alzheimer’s disease and amyotrophic lateral sclerosis (ALS).
- On December 15, 2022, Tiziana filed an IND with the FDA pertaining to a Phase 2 study of milciclib in combination with gemcitabine for NSCLC indication. Though further development on milciclib has been paused, the IND filing enables the Company to maximise the asset value with limited additional resources.

### **Intellectual Property**

- As of September 2022, the Company has a total of 298 granted patents.

## Management Changes

- Dr Matthew Davis, MD, RPh was appointed as Chief Medical Officer.
- Dr Kunwar Shailubhai, PhD, resigned as Chief Executive Officer and Chief Scientific Officer and Gabriele Cerrone was appointed as interim Chief Executive Officer.
- Dr. Thomas Adams, PhD, Executive Board Director passed away in January 2022.

## Financial

- For the six months ended 30 June 2022 the consolidated Group reported a loss of \$8.3 million as compared to \$17.0 million in the six months ended 30 June 2021.
- The Group ended the period with \$26.5 million cash as of 30 June 2022 as compared to \$42.2 million on 31 December 2021.
- Research and development (R&D) expenses increased to \$7.5 million compared to \$5.6 million in the first half of 2021. The increase is primarily related to the advancement of our proprietary programs, TZLS-401 and TZLS-501.

## For further inquiries:

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## About Tiziana Life Sciences

Tiziana Life Sciences is a clinical-stage biopharmaceutical company developing breakthrough immunomodulation therapies using transformational drug delivery technologies with a focus on its lead candidate, intranasal foralumab, as a treatment for diseases of the central nervous system (CNS). Tiziana's innovative nasal, oral and inhalation approaches in development have the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's intranasal foralumab is the only fully human anti-CD3 mAb and has demonstrated a favorable safety profile and clinical response in patients in studies to date. Tiziana's technology for alternative routes of immunotherapy has been patented with several applications pending and is expected to allow for broad pipeline applications.

## **EXECUTIVE CHAIRMAN'S STATEMENT**

I am pleased to report on the Group's financial results for the six months ended 30 June 2022.

We have made strong progress advancing our pipeline in the first half of the year.

We have received FDA approval plan to enroll a second, non-active secondary progressive multiple sclerosis (SPMS) patient, based on positive results from treatment of an Expanded Access (EA) progressive MS patient with intranasal foralumab for three and six months at Brigham and Women's Hospital, Boston, MA. The second patient ("EA2") with non-active secondary progressive multiple sclerosis (SPMS) was enrolled in January and following six months of dosing with Intranasal Foralumab, we reported that EA2 had shown additional clinical improvements as measured by the Expanded Disability Status Scale (EDSS), a standard clinical assessment.

Based on the safety, tolerability, and clinical responses from the first two SPMS patients, the FDA granted permission to enroll up to 8 additional (SPMS) patients in the expanded access program. The first patient cohort was fully enrolled in November 2022. The treatment program will evaluate dosing at the "standard" dosing of 50 mcg and, if needed, a higher 100 mcg dose of intranasal foralumab in two separate cohorts of four non-active SPMS patients each and is being conducted at Brigham and Women's Hospital in Boston, Massachusetts.

In order to leverage the exciting clinical and preclinical results from the formulation of intranasal foralumab, the Company has announced its near-term focus on developing intranasal foralumab for inflammatory diseases of the Central Nervous System (CNS) such as non-active secondary-progressive Multiple Sclerosis (SPMS), Alzheimer's disease and amyotrophic lateral sclerosis (ALS).

More recently we have also filed an IND with the FDA pertaining to a phase 2 study of milciclib in combination with gemcitabine for NSCLC indication.

Looking ahead, Tiziana is confident that it is well positioned to advance our clinical pipeline to its next respective value inflection points.

**Gabriele Cerrone**

**Consolidated Statement of Comprehensive Income  
for the six months ended 30 June 2022**

	6 months to 30 June 2022 \$'000 (Unaudited)	6 months to 30 June 2021 \$'000 (Unaudited)	12 months to 31 Dec 2021 \$'000
Research and development	(7,463)	(5,592)	(13,208)
Operating expenses	2,950	(11,399)	(13,311)
Realisation bonus	-	-	(855)
<b>Operating loss</b>	<b>(4,513)</b>	<b>(16,991)</b>	<b>(27,374)</b>
Finance expense	-	(25)	(176)
Other income	-	-	893
Total Other income/expense	-	(25)	717
<b>Operating loss before taxation</b>	<b>(4,513)</b>	<b>(17,016)</b>	<b>(26,657)</b>
Taxation	-	-	3,240
<b>Loss for the period</b>	<b>(4,513)</b>	<b>(17,016)</b>	<b>(23,417)</b>
Net loss for the period attributable to equity owners	(4,513)	(17,016)	(23,417)
Other comprehensive income for the period <i>Items that may be reclassified to profit or loss</i>			
Transalation of foreign operations	(3,767)	(8)	(4,478)
<b>Total comprehensive loss attributable to equity owners</b>	<b>(8,280)</b>	<b>(17,025)</b>	<b>(27,895)</b>
<b>Earnings per share</b>			
Basic and diluted loss per share on continuing operations	<u><u>\$(0.05)</u></u>	<u><u>\$(0.20)</u></u>	<u><u>\$(0.24)</u></u>

**Consolidated Statement of Financial Position  
as at 30 June 2022**

	30 June 2022 \$'000 (unaudited)	30 June 2021 \$'000 (unaudited)	31 Dec 2021 \$'000
<b>Assets</b>			
<b>Non-Current assets:</b>			
Property, plant and equipment, net	13	21	17
Intangible asset	118	134	130
Investment in related party	2,676	-	-
Right-of-use assets	-	560	-
<b>Total Non-current assets</b>	<b>2,807</b>	<b>715</b>	<b>147</b>
<b>Currents assets:</b>			
Prepayments and Other receivable	871	1,624	1,301
Finance lease receivable	-	59	-
Related party receivables	608	465	456
Taxation receivable	4,296	1,725	4,736
Cash and cash equivalents	26,543	53,279	42,186
<b>Total current assets</b>	<b>32,318</b>	<b>57,152</b>	<b>48,679</b>
<b>Total assets</b>	<b>35,125</b>	<b>57,867</b>	<b>48,826</b>
<b>Equity and liabilities</b>			
<b>Shareholder's equity:</b>			
Called up share capital (102,272,614 shares are issued and outstanding; 2021: 97,306,144)	102	97	102
Share premium	15,596	-	15,596
Share based payment reserve - options	11,453	11,635	13,797
Shares based payment reserve – Warrants	697	697	697
Merger relief reserve	118,697	118,697	118,697
Treasury shares	(808)	-	-
Shares to be issued	-	13,503	-
Translation reserve	(3,316)	5,745	454
Retained earnings	(112,574)	(101,671)	(108,063)
<b>Equity attributed to the owners of the Company</b>	<b>29,847</b>	<b>48,703</b>	<b>41,280</b>
<b>Current liabilities:</b>			
Accounts payable and accrued expenses	5,270	6,853	6,181
Lease liability	-	232	-
Related party payable	-	1,576	1,355
Other liabilities	8	83	10
	<b>5,278</b>	<b>8,744</b>	<b>7,546</b>
<b>Long term liabilities:</b>			
Lease Liability – non-current	-	420	-
<b>Total Liabilities</b>	<b>5,278</b>	<b>9,164</b>	<b>7,546</b>
<b>Total Equity and Liabilities</b>	<b>35,125</b>	<b>57,867</b>	<b>48,826</b>

**Consolidated Statement of Cash Flows  
for the 6 months ended 30 June 2021**

	6 months to 30 June 2022 \$'000 (unaudited)	6months to 30 June 2021 \$'000 (unaudited)	12 months to 31 December 2021 \$'000
<b>Cash flows from operating activities</b>			
<b>Operating loss for the period before tax</b>	(4,513)	(17,016)	(26,657)
Convertible loan interest accrued	-	-	163
Share based payment – options	(2,344)	2,987	5,173
Bonus to be settled in equity	-	-	855
Depreciation	5	3	8
(Gain)/Loss on foreign exchange	(3,681)	9	(1,899)
Depreciation of right of use asset	-	-	133
(Gain)/ Loss on disposal of right of use asset	-	74	(28)
Proceeds from finance lease reclassified as an investing activity	-	-	(152)
Finance Lease	-	91	-
Cash inflow from taxation	440	1,354	1,415
Net (increase) in related party receivables	(153)	(92)	(88)
Net (decrease)/increase in related party payables	(1,355)	(486)	(685)
Net decrease/ (increase) in operating assets/other receivables	603	(737)	516
Net (decrease)/ increase in operating liabilities/other liabilities	(915)	1,198	(516)
<b>Net cash used in operating activities</b>	<b>(11,913)</b>	<b>(12,625)</b>	<b>(21,762)</b>
<b>Cash flow from financing activities</b>			
Proceeds from issuance of warrants	-	-	129
Repayment of leasing liabilities	-	-	(152)
Right of use asset	-	(273)	-
<b>Net cash used in financing activities</b>	<b>-</b>	<b>(273)</b>	<b>(23)</b>
<b>Cash flows from investing activities</b>			
Purchase of Property Plant and Equipment (“PPE”)	-	(21)	(22)
Investment in Related Party	(2,675)	-	-
Purchase of Treasury Shares	(808)	-	-
Proceeds from finance lease	-	-	152
<b>Net cash (outflow)/inflow from investing activities</b>	<b>(3,483)</b>	<b>(21)</b>	<b>130</b>
<b>Net decrease in cash and cash equivalents</b>	<b>(15,643)</b>	<b>(12,919)</b>	<b>(21,655)</b>
Cash and cash equivalents at beginning of period	42,186	65,823	65,824
Exchange difference	247	374	(1,983)
<b>Cash and cash equivalents at end of period</b>	<b>26,543</b>	<b>53,279</b>	<b>42,186</b>

**Consolidated Statement of Changes in Equity -  
for the six months ended 30 June 2022**

(Unaudited)	Share Capital	Share Premium	Share Based Payment Reserve (Options)	Share Based Payment Reserve (Warrants)	Merger Reserve	Treasury Shares	Translation Reserve	Retained Earnings	Total Equity
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
<b>Balance at 1 January 2022</b>	<b>102</b>	<b>15,596</b>	<b>13,797</b>	<b>697</b>	<b>118,697</b>	-	<b>454</b>	<b>(108,061)</b>	<b>41,280</b>
Purchase of Treasury Shares	-	-	-	-	-	(808)	-	-	(808)
Share based payments charge (options)	-	-	2,344	-	-	-	-	-	2,344
Total transactions with owners	-	-	2,344	-	-	(808)	-	-	1,536
<u>Comprehensive income</u>	-	-	-	-	-	-	-	(4,513)	(4,513)
Loss for the period	-	-	-	-	-	-	(3,767)	-	(3,767)
Foreign currency translation	-	-	-	-	-	-	(3,767)	(4,513)	(8,280)
Total comprehensive income	-	-	-	-	-	-	(3,767)	(4,513)	(8,280)
<b>Balance at 30 June 2022</b>	<b>102</b>	<b>15,596</b>	<b>11,453</b>	<b>697</b>	<b>118,697</b>	<b>(808)</b>	<b>(3,316)</b>	<b>(112,574)</b>	<b>29,847</b>



**Consolidated Statement of Changes in Equity -  
for the six months ended 30 June 2021**

(Unaudited)	Share Capital	Share Premium	Share Based Payment Reserve (Options)	Share Based Payment Reserve (Warrants)	Shares to be issued reserve	Merger Reserve	Translation Reserve	Retained Earnings	Total Equity
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
<b>Balance at 1 January 2021</b>	<b>97</b>	<b>-</b>	<b>8,624</b>	<b>697</b>	<b>13,503</b>	<b>118,697</b>	<b>5,414</b>	<b>(84,646)</b>	<b>62,386</b>
Share based payments charge (options)	-	-	3,011	-	-	-	-	-	3,011
Total transactions with owners	-	-	3,011	-	-	-	-	-	3,011
<u>Comprehensive income</u>	-	-	-	-	-	-	-	(17,016)	(17,016)
Loss for the period	-	-	-	-	-	-	-	-	-
Foreign currency translation	-	-	-	-	-	-	(8)	-	(8)
Total comprehensive income	-	-	-	-	-	-	(8)	(17,016)	(17,025)
<b>Balance at 30 June 2021</b>	<b>97</b>	<b>-</b>	<b>11,635</b>	<b>697</b>	<b>13,503</b>	<b>118,697</b>	<b>5,745</b>	<b>(101,671)</b>	<b>48,703</b>

**Consolidated Statement of Changes in Equity -  
for the year ended 31 December 2021**

	Share Capital	Share Premium	Share Based Payment Reserve (Options)	Share Based Payment Reserve (Warrants)	Convertible Loan Note Reserve	Merger Reserve	Shares to be issued Reserve	Translation Reserve	Retained Earnings	Total Equity
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
<b>Balance as at 31 December 2020</b>	<b>97</b>	<b>-</b>	<b>8,624</b>	<b>697</b>	<b>-</b>	<b>118,697</b>	<b>13,503</b>	<b>5,414</b>	<b>(84,646)</b>	<b>62,386</b>
Issue of share capital	2	759								761
Share based payment charge (options)			5,173							5,173
Shares issued in lieu of cash realization bonus	3	14,837					(13,503)	(482)		855
Transactions with Owners <u>Comprehensive Income</u>	5	15,596	5,173	-	-	-	(13,503)	(482)		6,789
Loss of the period	-	-	-	-	-	-	-	-	(23,417)	(23,417)
Foreign currency translation								(4,478)		(4,478)
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(4,478)</b>	<b>(23,417)</b>	<b>(27,895)</b>
<b>Balance as at 31 December 2021</b>	<b>102</b>	<b>15,596</b>	<b>13,797</b>	<b>697</b>	<b>-</b>	<b>118,697</b>	<b>-</b>	<b>454</b>	<b>(108,601)</b>	<b>41,280</b>

## Notes to the Interim Financial Statements for the six month period to 30 June 2022

### 1. GENERAL INFORMATION

Tiziana Life Sciences Ltd is a public limited company incorporated in Bermuda and is listed on the NASDAQ Capital Market (NASDAQ: TLSA). The previous parent, Tiziana Life Sciences plc, delisted from the main market of the London Stock Exchange plc (LSE: TILS) on October 21, 2021. The address of its registered office is Clarendon House, 2 Church Street, Hamilton HM 11, Bermuda. The principal activities of the Company and its subsidiaries (the Group) are that of a clinical stage biotechnology company focused on targeted drugs to treat diseases in oncology and immunology.

These financial statements are presented in thousands of dollars (\$'000) which is the presentational currency of the Company. The functional currency for the Company is also US dollars (\$) indicative of the primary economic environment in which the Company operates.

### 2. ACCOUNTING POLICIES

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

#### **Basis of preparation**

The Interim consolidated financial statements of the Group have been prepared in accordance with the valuation and recognition principles of International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB), and IFRIC interpretations as applicable to companies reporting under IFRS. These interim consolidated financial statements have been prepared under the historical cost convention except for the following items:

- Financial instruments – fair value through profit or loss
- Financial instruments – fair value through other comprehensive income

#### **Going Concern**

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

The Group 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 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 company has successfully funded clinical trials to date and is in the process of securing additional investment for purposes of continuing to fund their clinical trials moving forward.

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

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

##### ***Standards in effect in 2022***

There are no new IFRS standards, amendments to standards or interpretations that are mandatory for the financial year beginning on January 1, 2022, that are relevant to the Group and that have had any impact in the period to June 30, 2022. New standards, amendments to standards and interpretations that are not yet effective, which have been deemed by the Group as currently not relevant, and hence are not listed here.

#### **Basis of consolidation**

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

## Notes to the Interim Financial Statements for the six month period to 30 June 2022

### Business combination

The Group undertook a group reorganisation exercise during the year to December 31, 2021. As part of this process, Tiziana Life Sciences Ltd (a Bermudan entity) was inserted above Tiziana Life Sciences Limited (formerly Tiziana Life Sciences plc) in the Group's structure. As both entities were under common control of Planwise Ltd, the transaction does not constitute a business combination under IFRS 3 'Business combinations' and instead has been accounted for as a group reorganization, using the pooling of interest method. This results in assets and liabilities being measured at their carrying amount in Tiziana Life Sciences Limited (formerly Tiziana Life Sciences plc) but share capital being that of Tiziana Life Sciences Ltd (a Bermudan entity). Merger accounting has been used to account for this transaction (See note 15 for details).

On 21 October 2021, Tiziana Life Sciences Ltd. (the 'Company') acquired the entire shareholding of the former Tiziana Life Sciences plc and its related subsidiaries, by a way of a share for share exchange with Tiziana Life Sciences Ltd becoming the Group's immediate parent company.

On 21 October 2021, the Company was admitted for listing on the NASDAQ Capital Market Exchange and the former Tiziana Life Sciences plc was delisted from the main market of the London Stock Exchange plc.

### Segment reporting

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

### Taxation

The tax expense/(credit) for the period 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. Current tax is provided at amounts expected to be paid (or recovered) using the tax rates and laws that have been enacted or substantively enacted by the balance sheet date.

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

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

### Foreign currency translation

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in US dollars, which is the Group's presentational currency.

Foreign currency transactions are translated into the functional currency using exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

The financial statements of overseas subsidiary undertakings are translated into US dollars on the following basis:

- Assets and liabilities at the rate of exchange ruling at the period-end date.
- Profit and loss account items at the average rate of exchange for the period.

Exchange differences arising from the translation of the net investment in foreign entities, borrowings and other currency instruments designated as hedges of such investments, are taken to equity (and recognized in the statement of comprehensive income) on consolidation.

### License fees

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

## Notes to the Interim Financial Statements for the six month period to 30 June 2022

### Research and development

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

### Financial instruments

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

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

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

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

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

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

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

### Warrants

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

Warrants issued in return for services.

These warrants fall within scope of IFRS 2. The Company recognises that the fair value at the date of grant of these warrants should be expensed to the Statement of Income and recognised over the life of the service for which the warrant was provided. These warrants have been valued by reference to the equity instruments granted as they are all tied to Convertible loan notes. The measurement date is therefore the date that the Convertible loan note was entered into.

Warrants issued as part of a financing transaction.

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

### 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.

## Notes to the Interim Financial Statements for the six month period to 30 June 2022

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

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

### (ii) Depreciation

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

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

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

Fixtures and fittings        **5 years**

IT and equipment            **3 years**

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

### **Impairment**

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

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

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

#### *General approach*

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

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

#### *Simplified approach*

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

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

#### Impairment of non-financial assets

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

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

### **Leases**

All leases are accounted for by recognizing 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.

## Notes to the Interim Financial Statements for the six month period to 30 June 2022

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

For leases over office buildings and factory premises the Group must keep those properties in a good state of repair and return the properties in their original condition at the end of the lease. The expected costs of returning to original condition is considered negligible.

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

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

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

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

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

Short term leases exempt from IFRS 16 are classified as operating leases. Payments made under operating leases are recognised in profit and loss on a straight-line basis over the term of the lease.

### **The Group as a lessor**

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

During the course of 2021, the Group continued to sublet one of its office spaces until October 2021. This has been recognised as a finance lease receivable for the value of the sublease.

### **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.

## Notes to the Interim Financial Statements for the six month period to 30 June 2022

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

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

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

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

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

### Treasury Shares

Where any group company purchases the company's equity instruments, for example as the result of a share buy-back or a share-based payment plan, the consideration paid, including any directly attributable incremental costs (net of income taxes), is deducted from equity attributable to the owners of Tiziana Life Sciences Limited as treasury shares until the shares are cancelled or reissued. Where such ordinary shares are subsequently reissued, any consideration received, net of any directly attributable incremental transaction costs and the related income tax effects, is included in equity attributable to the owners of Tiziana Life Sciences Limited.

### Other Intangible Assets

Other intangible assets that are acquired by the Group are stated at cost less accumulated impairment losses.

At each balance sheet date non-financial assets are assessed to determine whether there is an indication that the asset or the asset's cash generating unit may be impaired. If there is such an indication the recoverable amount of the asset or asset's cash generating unit is compared to the carrying amount.

### Convertible loan notes

The Group issues Convertible loan notes which can be classified as equity or a liability depending on whether the fixed for fixed condition is met or not.

*Where the fixed for fixed condition is met*

The Group classifies convertible loan notes that meet the fixed for fixed condition as equity instruments and records the principal of the loan note as a equity in a Convertible loan note reserve. The accrued interest on the principal amount is also recorded in the Convertible loan note reserve. Upon redemption of the instrument and the issue of share capital, the amount is reclassified from the convertible loan note reserve to share capital and share premium.

*Where the fixed for fixed condition is not met*

The Group classifies convertible loan notes that do not meet the fixed for fixed condition as liability 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 issued by the IASB, requires the directors to make estimates and judgements that affect the reported amount of assets, liabilities, income and expenditure and the disclosures made in the financial statements. Such estimates and judgements must be continually evaluated based on historical experience and other factors, including expectations of future events.

The following are considered to be critical accounting estimates:



**Notes to the Interim Financial Statements  
for the six month period to 30 June 2022**

Share-based payments

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

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

The Company makes estimates as to the useful life of an option award, the expected price volatility of the underlying share, risk free interest rate for the term of the award and correlations and volatilities of the shares of peer group companies. The Company also makes estimates as to the vesting period for awards that have performance based criteria.

**4. OPERATING LOSS**

The Group's operating loss for the period/year is stated after charging the following:

	6 months to 30 June 2022 (Unaudited) \$'000	6 months to 30 June 2021 (Unaudited) \$'000	12 months to 31 December 2021 (Unaudited) \$'000
License Fees	-	-	(1,047)
Realisation Bonus	-	-	855
Depreciation of Property, Plant and Equipment	(5)	(2)	8
Depreciation (Right-of-use asset)	-	(33)	133
Foreign exchange gains/(losses)	3,216	(30)	(1,899)

Included in the operating loss for the period ended 30 June 2022, is a credit of \$2,788k for unvested options that were forfeited in the period.

**5. Earnings per share**

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

	6 months to 30 June 2022 (unaudited)	6 months to 30 June 2020 (unaudited)	12 months to 31 Dec 2021
Total comprehensive loss for the period (\$'000)	(4,513)	(17,016)	(23,417)
Basic and diluted weighted average number of shares	97,932,055	85,042,904	97,932,055
Basic and diluted loss per share - cents	(5)	(20)	(24)

As the Group is reporting a loss from continuing operations for the period 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 Statement of comprehensive income 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 Interim Financial Statements  
for the six month period to 30 June 2022**

**6. Share based payments**

**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.

	<b>June 2022</b>		<b>June 2021</b>	
	<b>Options (‘000)</b>	<b>Weighted Average exercise price (cents)</b>	<b>Options (‘000)</b>	<b>Weighted Average exercise price (cents)</b>
Outstanding at 1 January	22,234	90	17,024	68
Granted	-	-	4,750	188
Forfeited	(5,210)	157	-	-
Exercised	-	-	-	-
Outstanding at 30 June	<u>17,024</u>	<u>60</u>	<u>21,774</u>	<u>149</u>
Exercisable at 30 June	<u>6,249</u>	<u>50</u>	<u>6,249</u>	<u>57</u>

	<b>December 2021</b>	
	<b>Options (‘000)</b>	<b>Weighted Average exercise price (cents)</b>
Outstanding at 1 January	17,024	67
Granted	-	-
Forfeited	5,210	166
Exercised	-	-
Outstanding at 31 December	<u>22,234</u>	<u>90</u>
Exercisable at 31 December	<u>7,616</u>	<u>54</u>

During the 6 months to 30 June 2022, no options were exercised. No options were exercised in the year to 31 December 2021 or in the period to 30 June 2021. The total expenses recognised for the period ending 30 June 2022 arising from share based payment transactions is \$2,344k (June 2021: \$3,011k: December 2021: \$5,173k) 2. Included in the share based payment charge for the period ended 30 June 2022, is a credit of \$2,788k for unvested options that were forfeited in the period.

The total outstanding fair value charge of the share option instruments is deemed to be approximately \$470k (June 2021: \$9,992k: December 2021: \$13,298k).

Share options outstanding at the end of June 2022 have the following expiry dates and exercise prices:

**Notes to the Interim Financial Statements  
for the six month period to 30 June 2022**

Grant Date	Expiry Date	Exercise Price	Share Options as at 30 June 2022 ('000)
26 June 2014	26 June 2024	£0.35	1,831
30 April 2018	30 April 2028	£0.8175	1,300
6 May 2020	5 May 2028	£0.35	12,393
23 July 2020	26 July 2030	£1.575	1,000
25 August 2020	24 August 2030	£1.475	500
<b>Total</b>			<b>17,024</b>

Warrants

For each set of warrants, the charge has been expensed over the service period. A share-based payment charge for the year of \$nil (2021:0 \$nil) has been expensed in the statement of comprehensive income.

	6 months to 30 June 2022 (Unaudited)	6 months to 30 June 2021 (Unaudited)	12 months to 31 Dec 2021
\$000			
Outstanding at 1 January	697	697	697
Granted	-	-	-
Transfer to share premium on exercise of warrants	-	-	-
Outstanding at 31 Decemeber	<b>697</b>	<b>697</b>	<b>697</b>

**7. Trade and other payables**

	(unaudited) 30 June 2022 \$'000	(unaudited) 30 June 2021 \$'000	31 December 2021 \$'000
Trade payables	4,424	4,357	4,406
Other payables	-	83	-
Accruals	845	2,496	1,775
	<b>5,270</b>	<b>6,853</b>	<b>6,181</b>

**8. Finance costs**

	(unaudited) 30 June 2022 \$'000	(unaudited) 30 June 2021 \$'000	31 December 2021 \$'000
Finance Expenses			
Finance charge accrued on convertible loan notes	-	18	163
Interest expense on lease liabilities	-	7	13
	-	25	176
	<b>-</b>	<b>25</b>	<b>176</b>

## Notes to the Interim Financial Statements for the six month period to 30 June 2022

### 9. Treasury Shares

The Company acquired 912,825 of its own shares through purchases on the NASDAQ stock exchange during the period ended 30<sup>th</sup> June 2022. The total amount paid to acquire the shares, was \$808k. The shares are held as “treasury shares”. The Company has the right to reissue these shares at a later date. All shares issued by the Company were fully paid.

### 10. Related party transactions

The ultimate controlling party of the Group is Planwise Group Ltd.

Rasna Therapeutics Inc (“Rasna”) is a related party as the entity is controlled by a person that has significant influence over the Group. Rasna is also party to a Shared Services agreement with Tiziana whereby Rasna is charged for shared services such as the payroll and rent. During 2020, Tiziana extended a loan to Rasna for \$72,000 at an interest rate of 8% per annum. As of June 30, 2022 \$187k (Dec 21: \$106k, Jun 21: \$88k) was owed to Tiziana Life Sciences Ltd in respect of the loan and shared services agreement. The total charged under the shared services agreement in the period ended 30 June 2022 was \$81k.

In addition to the above, on April 16, 2020, Tiziana also acquired all of the intellectual property relating to a nanoparticle-based formulation of Actinomycin D (Act D; a.k.a. Dactinomycin), from Rasna to expand its pipeline for a consideration of an initial \$120k upfront payment and milestone payments of up to an additional aggregate \$630k. There were no milestone payments due in the period ended 30 June 2022.

OKYO Pharma Ltd is a related party as the entity is controlled by a person that has significant influence over the Group. OKYO is also party to a Shared Services agreement with Tiziana whereby OKYO is charged for shared services such as the payroll and rent. As of June 30, 2022, \$52k (Dec 21: \$42k, Jun 21: Nil) was owed to Tiziana Life Sciences Ltd in respect of this agreement. The total charged under the shared services agreement in the period ended 30 June 2022 was \$94k.

Gensignia Lifesciences Inc is a related party as the entity is controlled by a person that has significant influence over the Group. As of June 30, 2022, \$270k (Dec 21: \$295k, Jun 21: \$369k) was owed to Tiziana Life Sciences Ltd in respect of a loan facility, which is past due. Interest is due on the loan however the board have waived all interest charges to date. However, the board are considering mechanism’s for settlement and believe this to be likely. There were no transactions during the period ended June 30, 2022. Any differences are a result of foreign exchange movements.

Accustem Sciences Inc is a related party as the entity is controlled by a person that has significant influence over the Group. During the period ended 30 June 2022 an investment for \$2.675k was made in Accustem. Accustem is also party to a Shared Services agreement with Tiziana whereby the Company is charged for shared services such as payroll and rent. As of June 30, 2022, \$51k (Dec 21: 1,341k, Jun 21: Nil) was the net amount owed by Accustem.

### 11. Post balance sheet events

In August 2022, the Group issued a short-term credit facility to Okyo Pharma, a related party, for \$2m in order to support short term liquidity. The loan is available for a period of 6 months upon first draw-down and carries an interest rate of 16% per annum, with additional default interest of 4% if the loan is not repaid after the 6-month period. To date, \$1m has been drawn down against the loan.