

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

Updated Interim Results for the Six Months Ended 30 June 2023

NEW YORK, December 29, 2023 – Tiziana Life Sciences, Ltd. (Nasdaq: TLSA) ("Tiziana" or the "Company"), a biotechnology company developing breakthrough immunomodulation therapies via novel routes of drug delivery, today announced interim financial results for the six months ended June 30, 2023, and provided a corporate update on its lead programs in development.

Gabriele Cerrone, Executive Chairman, founder and interim Chief Executive Officer of Tiziana, commented, "After announcing our focus on the development of intranasal foralumab in CNS-mediated inflammatory diseases at the end of last year, we began 2023 with a stream of continuous, positive developments in these programs. Intranasal foralumab's unique action on regulatory T-cells, along with its potential to treat multiple inflammatory-driven diseases, has been published in major medical journals and recognized in the media on multiple occasions. In September, we also recently announced intranasal foralumab's progress in Alzheimer's disease with study data published in the *Proceedings of the National Academy of Sciences* and clearance to proceed with clinical testing in this indication following an IND submission."

Mr. Cerrone continued, "Our near-term strategic focus is to prioritize resources for the clinical development of this unique therapeutic candidate, beginning with CNS focused indications, to maximize shareholder value, while still maintaining optionality for our other research programs, including milciclib in oncology. We remain steadfast towards our goal to become a leading company pioneering intranasal therapies for inflammatory diseases."

First Half 2023 Developments Related to Foralumab

In January:

Tiziana announced that the second patient ("EA2") in its Expanded Access trial receiving intranasal
foralumab to treat non-active secondary progressive multiple sclerosis (na-SPMS) showed additional
clinical improvements since the patient's last reported improvement in September 2022. The
improvements were measured by the Expanded Disability Status Scale (EDSS), a U.S. Food and Drug
Administration (FDA) - recognized standard clinical outcome assessment.

In March:

Tiziana announced a publication in the preeminent¹, peer-reviewed journal, *Proceedings of the National Academy of Sciences* (PNAS), that illustrates the immunological basis of the mechanism of action (MoA) for intranasal foralumab. The publication highlights that the immunological basis of the MoA for intranasal foralumab is based on increasing production of naïve-like T cells and Tregs, while simultaneously decreasing the production of effector T cells. Further, the publication demonstrates that intranasal foralumab has similar immune gene expression effects in COVID patients, MS patients and in heathy volunteers. The study concludes that immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of inflammatory human diseases. The publication can be found at https://www.pnas.org/doi/10.1073/pnas.2220272120.

 As a result of this publication, Dr. Tanuja Chitnis, M.D., Professor of Neurology at Brigham Women's Hospital, a founding member of Mass General Brigham Healthcare System, and lead investigator of the study, noted that foralumab also "makes a promising therapeutic candidate for several rare Orphan pediatric neuroinflammatory diseases, which currently remain untreated."

- Tiziana announced its intention to start a Phase 2a study in the third quarter of 2023 in patients with na-SPMS employing intranasal foralumab, which it then began in September with the initiation of its first clinical site. Tiziana expects to conduct the Phase 2a study at six to ten clinical sites and dosed its first patient in December.
- Tiziana announced data from a pre-clinical study on the effects of intranasal foralumab in Alzheimer's disease which were presented on April 1, 2023, at the *International Conference on Alzheimer's and Parkinson's Disease and Related Neurological Disorders* by Dr. Howard Weiner, M.D., Co-Director of the Ann Romney Center for Neurologic Diseases at Brigham and Women's Hospital. The data showed reduction of microglia activation and improvement in behavior in animal models of Alzheimer's disease. In September, these data were published in the journal, *Proceedings of the National Academy of Sciences* (PNAS). The publication can be found at https://www.pnas.org/doi/10.1073/pnas.2309221120.
- Additionally, Tiziana's foralumab was highlighted in a <u>Forbes magazine article</u> entitled "New T Cell Antibody Treatment Improves Outcomes for Covid Patients" authored by contributing author, thought leader and pioneer in genomic sciences, William A. Haseltine, who stated "Foralumab induces many factors that impact improved tissue remodeling, induction of immune cells, and restriction of effector function, improving disease outcomes while fighting the virus to full strength. These benefits are not limited to COVID-19 patients, as similar results were observed in patients with multiple sclerosis."

In April:

- Tiziana announced data from a pre-clinical study on the effects of intranasal foralumab in intracerebral hemorrhage (hemorrhagic stroke) that demonstrated one-month behavioral outcomes improvement and modulation of neuroinflammation. These data were presented in a podium presentation by Dr. Saef Izzy, M.D., MBCHB, Assistant Professor of Neurology at Harvard Medical School on April 23, 2023, at the American Academy of Neurology (AAN) annual meeting.
- Tiziana plans to investigate intranasal foralumab for the treatment of Long COVID. The work is supported by foralumab's well-established role in de-activating microglia cells, a key component in the pathogenesis of this disease.

In June:

• The Company announced a reduction in microglial activation as seen in three-month Positron Emission Tomography (PET) scans - in a total of five of the six patients with non-active secondary-progressive multiple sclerosis (na-SPMS) treated with intranasal foralumab in its Expanded Access program (EAP). Microglial activation is believed to play a prominent role in the pathogenesis of neuroinflammatory diseases - including multiple sclerosis, Alzheimer's disease and amyotrophic lateral sclerosis (ALS). In na-SPMS, microglia serve as the brain's immune cells, and their activation causes inflammation, which, in turn drives the neurodegeneration of brain cells. Specifically, during the inflammatory process associated with na-SPMS, activated microglia are involved in the destruction of myelin, the protective sheath covering of nerve fibers, and contribute to the formation of MS lesions.

2023 First Half of Year Operational Updates

In June, the Company announced the appointment of its Chief Medical Officer (CMO), Matthew Davis, M.D., R.Ph., to Chief Operating Officer (COO). In this additional role, Dr. Davis will further drive the Company's growth and strategic initiatives. As COO, Dr. Davis now reports to Gabriele Cerrone, Executive Chairman, Founder, and Acting Chief Executive Officer of Tiziana.

In August, the Company announced the appointment of William A. Clementi, Pharm.D., FCP as Chief Development Officer (CDO), effective September 1, 2023. In this role, Dr. Clementi is responsible for overseeing the Company's development strategies and advancing its portfolio of therapeutic candidates.

2023 Recent Clinical Program Updates

In August:

• Tiziana announced that the FDA has cleared the Investigational New Drug (IND) application for intranasal foralumab to be studied in Alzheimer's disease. A Phase 2 trial is expected to begin in 2024.

In October:

- Tiziana announced that a reduction in activated microglia, as seen in six-month Positron Emission
 Tomography (PET) scans, has now been observed in a total of five of the six patients with non-active
 secondary-progressive multiple sclerosis (na-SPMS) treated with intranasal foralumab in its EAP.
 Activated microglia are believed to play a prominent role in the pathogenesis of neuroinflammatory
 and neurodegenerative diseases including multiple sclerosis, Alzheimer's disease, and amyotrophic
 lateral sclerosis, or ALS.
- Tiziana announced six-month data showing positive clinical improvements related to Modified
 Fatigue Impact Scale (MFIS) scores and similar important clinical measures of physical function in
 foralumab-treated, non-active Secondary Progressive Multiple Sclerosis (na-SPMS) patients
 participating in its EAP. This result follows the previously announced positive six-month PET scan
 data which was presented at the 39th Congress of the European Committee for Treatment and
 Research in Multiple Sclerosis (ECTRIMS) 2023.
- Tiziana announced patients in the multiple sclerosis intermediate-size patient population (EAP) may
 now take home and self-administer intranasal foralumab as part of the at-home dosing initiative.
 Patients will be trained in the use of the nasal device in accordance with FDA instructions. Delivery
 Device Training materials have been developed and refined in collaboration with the FDA. Tiziana
 considers this a significant milestone since the allowance of at-home dosing could improve
 compliance and patient outcomes for those participating in the program.

2023 First Half Financial Results

- For the six months ended June 30, 2023 Tiziana reported a loss of \$6.9 million compared to \$8.3 million for the same period in 2022.
- Tiziana had \$6.6 million in cash as of the six months ended 30 June 2023 compared to \$18.1 million on December 31, 2022. Additionally, Tiziana had \$7.9 million of other receivables as of the six months ended 30 June 2023 compared to \$5.9 million on December 31, 2022.

Tiziana's Interim Report can be accessed by visiting the Investors section of the Company's website at https://ir.tizianalifesciences.com/financial-information/interim-reports.

Tiziana's Annual Report on Form 20-F can be accessed by visiting either the SEC's website at <u>www.sec.gov</u> or the Investors section of the Company's website at https://ir.tizianalifesciences.com/financial-information/annual-reports.

About Foralumab

Activated T cells play an important role in the inflammatory process. Foralumab, the only fully human anti-CD3 monoclonal antibody (mAb), binds to the T cell receptor and dampens inflammation by modulating T cell function, thereby suppressing effector features in multiple immune cell subsets. This effect has been demonstrated in patients with COVID and with multiple sclerosis, as well as in healthy normal subjects. The non-active SPMS intranasal foralumab Phase 2 trial began screening patients in November of 2023. Immunomodulation by nasal anti-CD3 mAb represents a novel avenue for treatment of neuroinflammatory and neurodegenerative human diseases.^{[1],[2]}

About Tiziana Life Sciences

Tiziana Life Sciences is a clinical-stage biopharmaceutical company developing breakthrough therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy. Tiziana's innovative nasal approach has the potential to provide an improvement in efficacy as well as safety and tolerability compared to intravenous (IV) delivery. Tiziana's lead candidate, intranasal foralumab, which is the only fully human anti-CD3 mAb, 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.

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[1] https://www.pnas.org/doi/10.1073/pnas.2220272120

[2] https://www.pnas.org/doi/10.1073/pnas.2309221120

EXECUTIVE CHAIRMAN'S STATEMENT

I am pleased to report on the Group's financial results for the six months ended 30 June 2023.

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

After announcing our focus on the development of intranasal foralumab in CNS-mediated inflammatory diseases at the end of last year, we began 2023 with a stream of continuous, positive developments in these programs. Intranasal foralumab's unique action on regulatory T-cells, along with its potential to treat multiple inflammatory-driven diseases, has been published in major medical journals and recognized in the media on multiple occasions. In September, we also recently announced intranasal foralumab's progress in Alzheimer's disease with study data published in the Proceedings of the National Academy of Sciences and clearance to proceed with clinical testing in this indication following an IND submission .

Our near-term strategic focus is to prioritize resources for the clinical development of this unique therapeutic candidate, beginning with CNS focused indications, to maximize shareholder value, while still maintaining optionality for our other research programs, including milciclib in oncology.

We remain steadfast towards our goal to become a leading company pioneering intranasal therapies for inflammatory diseases.

Gabriele Cerrone

Consolidated Statement of Comprehensive Income for the six months ended 30 June 2023

	Notes	6 months to 30 June 2023 \$'000 (Unaudited)	6 months to 30 June 2022 \$'000 (Unaudited)	12 months to 31 Dec 2022 \$'000
Research and development Operating expenses	4	(3,287) (5,405)	(7,463) 2,950	(12,955) (1,631)
Operating loss		(8,692)	(4,513)	(14,586)
Finance expense Other income/(losses)	8	(5) 80	-	(7) (804)
Total Other income/expense	-	75	-	(811)
Operating loss before taxation		(8,617)	(4,513)	(15,397)
Taxation	_	-	-	-
Loss for the period		(8,617)	(4,513)	(15,397)
Net loss for the period attributable to equity owners		(8,617)	(4,513)	(15,397)
Other comprehensive income for the period Items that may be reclassified to profit or loss Translation of foreign operations		1,697	(3,767)	(3,582)
Total comprehensive loss attributable to equity owners	-	(6,920)	(8,280)	(18,979)
	=			
Earnings per share Basic and diluted loss per share on continuing operations	_	\$(0.08)	\$(0.05)	\$(0.15 <u>)</u>
	-	7(0.00)	+(0.00)	+(00)

Consolidated Statement of Financial Position as at 30 June 2023

as at 30 June 2023	Notes -	30 June 2023 \$'000 (unaudited)	30 June 2022 \$'000 (unaudited)	31 Dec 2022 \$'000
Assets				
Non-Current assets: Property, plant and equipment, net Intangible asset Investment in related party Right-of-use assets Total Non-current assets	8 9	13 - 1,886 338 2,237	13 118 2,676 - 2,807	17 1,806 372 2,195
Currents assets: Prepayments and Other receivable Related party receivables Taxation receivable Cash and cash equivalents Total current assets	-	691 3,647 4,246 6,597 15,181	871 608 4,296 26,543 32,318	300 1,614 4,246 18,122 24,282
Total assets	-	17,418	35,125	26,477
Equity and liabilities Shareholder's equity:				
Called up share capital (102,272,614 shares are issued and outstanding) Share premium Share based payment reserve - options Shares based payment reserve – Warrants Merger relief reserve Treasury shares Translation reserve Retained earnings	,	102 15,596 6,088 697 118,697 (1,574)] (1,431)] (124,880)]	102 15,596 11,453 697 118,697 (808) (3,316) (112,574)	102 15,596 5,190 697 118,697 (1,320) (3,128) (116,263)
Equity attributed to the owners of the Company	=	13,295	29,847	19,571
Current liabilities: Accounts payable and accrued expenses Lease liability Other liabilities	9 -	3,764 170 6 3,940	5,270 - 8 5,278	6,532 122 9 6,663
Long term liabilities: Lease Liability	9	183	-	243
Total Liabilities	-	4,123	5,278	6,906
Total Equity and Liabilities	- -	17,418	35,125	26,477

Consolidated Statement of Cash Flows for the 6 months ended 30 June 2023

Cash flows from operating activities	6 months to 30 June 2023 \$'000 (unaudited)	6months to 30 June 2022 \$'000 (unaudited)	12 months to 31 December 2022 \$'000
Operating loss for the period before tax	(8,617)	(4,513)	(15,397)
Share based payment – options	917	(2,344)	1,811
Depreciation	4	5	1
FV movement on investment	(80)	-	869
(Gain)/Loss on foreign exchange	1,540	(3,681)	(3,183)
Depreciation of right of use asset	51	-	50
Options forfeited during the year	(19)	-	(3,221)
Loss on disposal of asset	-	-	129
Cash inflow from taxation	-	440	490
Net (increase) in related party receivables	(2,033)	(153)	(1,158)
Net (decrease)/increase in related party payables	-	(1,355)	(1,355)
Net (increase)/decrease in operating assets/other receivables	(389)	603	1,002
Net (decrease)/ increase in operating liabilities/other liabilities	(2,766)	(915)	347
Net cash used in operating activities	(11,392)	(11,913)	(19,615)
Cash flow from financing activities			
Repayment of leasing liabilities	(37)	-	(55)
Net cash used in financing activities	(37)	-	(55)
Cash flows from investing activities			
Investment in Related Party	-	(2,675)	(2,676)
Purchase of Treasury Shares	(254)	(808)	(1,320)
Net cash (outflow)/inflow from investing activities	(254)	(3,483)	3,996
Net decrease in cash and cash equivalents	(11,683)	(15,643)	(23,666)
Cash and cash equivalents at beginning of period	18,122	42,186	42,186
Exchange difference	158	247	(398)
Cash and cash equivalents at end of period	6,597	26,543	18,122

Consolidated Statement of Changes in Equity - for the six months ended 30 June 2023

(Unaudited)	Share Capital \$'000	Share Premium \$'000	Share Based Payment Reserve (Options) \$'000	Share Based Payment Reserve (Warrants) \$'000	Merger Reserve	Treasury Shares	Translation Reserve \$'000	Retained Earnings \$'000	Total Equity \$'000
Balance at 1 January 2023	102	15,596	5,190	697	118,697	(1,320)	(3,128)	(116,263)	19,571
Purchase of Treasury Shares Share based payments charge (options)	-	-	917	- -	-	(254)	-	-	(254) 917
Options forfeited in the year	-	-	(19)	-	-	-	-	-	(19)
Total transactions with owners	-	-	898	-	-	(254)	-	-	644
Comprehensive income Loss for the period	-	-	-	-	-	-	-	(8,617)	(8,617)
Foreign currency translation	-	-	-	-	-	-	1,697	-	1,697
Total comprehensive income	-	-	-	-	-	-	1,697	(8,617)	(6,920)
Balance at 30 June 2023	102	15,596	6,088	697	118,697	(1,574)	(1,431)	(124,880)	13,295

Consolidated Statement of Changes in Equity - for the period ended 30 June 2022

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

Consolidated Statement of Changes in Equity - for the year ended 31 December 2022

	Share Capital	Share Premium	Share Based Payment Reserve	Share Based Payment Reserve	Merger Reserve	Treasury Shares	Translation Reserve	Retained Earnings	Total Equity
Balance as at 31 December 2021	\$'000 102	\$'000 15,596	(Options) \$'000 13,797	(Warrants) \$'000 697	\$'000 118,697	\$'000 -	\$'000 454	\$'000 (108,063)	\$'000 41,280
Issue of share capital									
Treasury Shares	-	-	-	-	-	(1,320)	-	-	(1,320)
Share based payment charge (options)	-	-	1,811	-	-	-	-	-	1,811
Options forfeited in the year	-	-	(3,221)	-	-	-	-	-	(3,221)
Reclass of FV for options forfeited/Cancelled			(7,197)					7,197	-
Transactions with Owners Comprehensive Income	-		(8,607)	-	-	(1,320)	-	7,197	(2,730)
Loss of the period Foreign currency translation	-	- -	- -	- -	-	-	(3,582)	(15,397)	(15,397) (3,582)
Total comprehensive income	-	-	-	-	-	-	(3,582)	(15,397)	(18,979)
Balance as at 31 December 2022	102	15,596	5,190	697	118,697	(1,320)	(3,128)	(116,263)	19,571

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 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 developing breakthrough therapies using transformational drug delivery technologies to enable alternative routes of immunotherapy.

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

Going Concern

The Group has experienced net losses and significant cash outflows from cash used in operating activities over the past years, and as of June 30, 2023, had cash and cash equivalents of \$6.6m, a net loss for the period ended June 30, 2023, of \$8.6m and net cash used in operating activities of \$11.4m.

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 not be able to meet its liabilities as they fall due within the next 12 months from the date when these financial statements are issued.

The Directors are however aware, through their own extensive experience in the sector, that this position is not uncommon in the context of a pre-revenue life sciences company principally involved in cash consuming research and development activity.

The top line data for the clinical trial is expected in Q4 2024 and the Directors are taking steps to put engagements and plans into place to ensure that sufficient funds will be forthcoming. These steps include possible deferred payments of existing liabilities, working capital cost reductions and raising additional equity.

Until and unless the Group and Company secures sufficient investment to fund their clinical pipeline, there is a material uncertainty that may cast significant doubt on the Group and Company's ability to continue as a going concern, and therefore, that it may be unable to realize its assets and discharge its liabilities in the normal course of business. Despite this material uncertainty, the Directors conclude that it is appropriate to continue to adopt the going concern basis of accounting as the Directors are confident, based on the previous fund-raising history as well as additional measures being planned, that sufficient funds will be forthcoming and accordingly they have prepared these financial statements on a going concern basis.

New and Revised Standards

Standards in effect in 2023

There are no new IFRS standards, amendments to standards or interpretations that are mandatory for the financial year beginning on January 1, 2023, that are relevant to the Group and that have had any impact in the period to June 30, 2023. 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.

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.

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:

- o Assets and liabilities at the rate of exchange ruling at the period-end date.
- o 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.

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.

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.

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 9).

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.

Share based payments

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

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

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

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

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

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

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

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

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:

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	6 months to	12 months to
	30 June	30 June	31 December
	2023	2022	2022
	(unaudited)	(unaudited)	
	\$'000	\$'000	\$'000
Depreciation of Property, Plant and Equipment	4	5	1
Depreciation (Right-of-use asset)	51	-	50
Foreign exchange gains/(losses)	1,540	3,216	3,183

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 2023	6 months to 30 June 2022	12 months to 31 Dec 2022
	(unaudited)	(unaudited)	
Total comprehensive loss for the period (\$'000)	(8,617)	(4,513)	(15,397)
Basic and diluted weighted average number of shares	102,272,614	97,932,055	101,526,389
Basic and diluted loss per share - cents	(8)	(5)	(15)

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.

6. Share based payments

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. The Company is currently operating two plans (Tiziana Life Sciences PLC) Share Option Plan which is closed for any new issuances and the Tiziana Life Sciences Ltd 2021 Equity Incentive Plan.

Tiziana Life Sciences PLC Share Option Plan

	Jun 2	2023	Jun 2022		
	Weighted Average exercise price (cents)	Options ('000)	Weighted Average exercise price (cents)	Options ('000)	
Outstanding at 1 January	49	15,324	90	22,234	
Granted Forfeited/Cancelled Exercised	185	(8,676)	157	(5,210)	
Outstanding at 30 June	62	6,648	60	17,024	
Exercisable at 30 June	59	2,349	50	6,249	

	Dec 2	2022
	Weighted Average exercise price (cents)	Options ('000)
Outstanding at 1 January Granted	90	22,234
Forfeited/Cancelled Exercised	176	(6,910)
Outstanding at 31 December	49	15,324
Exercisable at 31 December	48	6,249

No options were exercised during the 6 months to June 2023, 6 months to 30 June 2022 and the year to 31 December 2022.

The total outstanding fair value charge of the share option instruments is deemed to be approximately \$4,798k (Dec 2022 \$5,075k (restated), June 2022 \$470k).

Under the Tiziana Life Sciences PLC Share Option Plan, the total expense recognized for the period to June 2023 was \$377k of which \$19k relate to option forfeitures. During the year ending 31 December 2022 the total expense recognized was (\$1,479k) of which \$3,221k relate to forfeitures during the year. The total expenses recognised for the period ending 30 June 2022 arising from share based payment transactions was \$2,344k.

Share options outstanding at 30 June 2023 have the following expiry dates and exercise prices:

Grant Date	Expiry Date	Exercise Price	Options at 30 June 2023 ('000)
26 June 2014	26 June 2024	\$ 0.47	1,831
30 April 2018	30 April 2028	\$ 1.10	500
6 May 2020	5 May 2028	\$ 0.47	3,717
23 July 2020	26 July 2030	\$ 2.11	100
25 August 2020	24 August 2030	\$ 1.98	500
Total			6,648

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<u>Tiziana Life Sciences Ltd 2021 Equity Incentive Plan</u>

	Jun	2023	Jun 2022			
	Weighted Average exercise price (cents)	Options ('000)	Weighted Average exercise price (cents)	Options ('000)		
Outstanding at 1 January Granted Forfeited/Cancelled Exercised	69 57 -	2,575 1,053	- - -	- - - -		
Outstanding at 30 June	67	3,628				
Exercisable at 30 June	69	500				
	Dec 2	022				
	Weighted Average exercise price (cents)	Options ('000)				
Outstanding at 1 January Granted Forfeited/Cancelled Exercised	69	2,575				
Outstanding at 31 December	69	2,575				
Exercisable at 31 December		<u>-</u>				

No options were exercised during the six months to June 2023, the six months to June 2022 and for the year ending 31 December 2022.

The total outstanding fair value charge of the share option instruments is deemed to be approximately \$1,105k.

Under the Tiziana Life Sciences Ltd 2021 Equity Incentive Plan, the total expense recognized for the period ended 30 June 2023 was \$540k and for the year ending 31 December 2022 the total expense recognized was \$332k.

Share options outstanding at 30 June 2023 have the following expiry dates and exercise prices:

			Share Options as	
Grant Date	Expiry Date	Exercise Price	at 30 June 2023('000)	
01 August 2022	01 August 2032 \$	0.74	725	
04 November 2022	04 November 2032 \$	0.67	1,850	
14 March 2023	14 March 2033 \$	0.57	1,053	
Total			3,628	

Warrants

For each set of warrants, the charge has been expensed over the service period. The share-based payment charge for the period was \$nil (2022; \$nil).

	6 months to 30 June 2023 (Unaudited)	6 months to 30 June 2022 (Unaudited)
\$000		
Outstanding at 1 January	697	697
Granted	-	-
Transfer to share premium on exercise of warrants	-	-
Outstanding at 30 June	697	697

\$000
Outstanding at 1 January
Granted
Transfer to share premium on exercise of warrants
Outstanding at 31 December

12 months to 31 Dec 2022

7. Trade and other payables

	(unaudited) 30 June 2023 \$'000	(unaudited) 30 June 2022 \$'000	31 December 2022 \$'000
Trade payables Other payables Accruals	2,948 - 816 3,764	4,424 - 845 5,270	4,962 - 1,570 6,532

8. Investment in related party

	(unaudited) 30 June 2023 \$'000	(unaudited) 30 June 2022 \$'000	31 December 2022 \$'000
Investment in Accustem Sciences Inc		-	2,675
	1,806		
Movement in fair value	80	-	(869)
	1,886		1,806

9. Leases

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

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

The Group has leases for its offices. Each lease is reflected on the balance sheet as a right-of-use asset and a lease liability. The Group does not have 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.

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

During the course of 2022, the Group entered into a new lease agreement for its London office. Any leases that have a term shorter than 12 months the Group has applied the exemption allowed by paragraph 5a in IFRS16 in respect of short – term leases.

Right-of-use assets	30 Jun 2023 \$000	30 Jun 2022 \$000
At 1 January	372	-
Additions	-	-
Depreciation	(51)	-
Disposal of lease	-	-
Exchange differences	(16)	_
At 30 June	337	_
Right-of-use assets At 1 January		31 Dec 2022 \$000
Additions		448
Depreciation		(50)
Disposal of lease		-
Exchange differences		(26)
At 31 December		372

Lease Liabilities	30 June 2023 \$000	30 June 2022 \$000
At 1 January	365	-
Additions	-	-
Interest expense	12	-
Lease payments	(37)	-
Exchange differences	13	-
Disposal of lease	-	
At 30 June	353	
Lease Liabilities		31 Dec 2022 \$000
At 1 January		-
Additions		448
Interest expense		6
Lease payments		(61)
Exchange differences		(28)
Disposal of lease		
At 31 December		365

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

	30 Jun 2023	30 June 2022	31 Dec 2022
	\$000	\$000	\$000
Current	170	-	122
Non-current	183	_	243
	353	-	365

The lease liabilities are secured by the related underlying assets. Future minimum lease payments as of 30 June 2023 were as follows:

Minimum lease payment due				
Within			Over	
1 year	1-2 years	2-5 years	5 years	Total
183	146	36		365
(8)	(4)		<u> </u>	(12)
175	142	36	<u> </u>	353
	1 year 183 (8)	Within 1 year 1-2 years 183 146 (8) (4)	Within 1 year 1-2 years 2-5 years 183 146 36 (8) (4) -	Within 1 year 1-2 years 2-5 years 5 years 183 146 36 - (8) (4) - -

The total net cash outflow for leases in the period ended 30 June 2023 was \$37k and in the year to 31 December 2022 was \$55k.

10. Treasury Shares

The Company acquired 1,964,797 of its own shares through purchases on the NASDAQ stock exchange during the six month period ended 30 June 2023. The total amount paid to acquire the shares was \$254k. 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.

11. Related party transactions

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. During 2022, Tiziana extended a further loan to Rasna for \$85,000 at an interest rate of 16% per annum. As of June 30, 2023, \$333k (Dec 2022: \$206k, Jun 2022: \$187k) was owed to Tiziana Life Sciences Ltd in respect of the loan, accrued interest and the shared services agreement. The total charged under the shared services agreement in the year ending 30 June 2023 was \$3k (Dec 2022: \$7k, Jun 2022: \$11k).

OKYO Pharma Ltd ("OKYO") 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, 2023 \$385k (Dec 2022, \$274k, Jun 2022: \$52k) was owed to Tiziana Life Sciences Ltd in respect of this agreement. The total charged under the shared services agreement in the period ended Jun 2023 was \$69k (Dec 2022: \$125k, Jun 2022: \$94k).

In August 2022, the Group issued a short-term credit facility to OKYO, a related party, for \$2,000k 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. As of June 30, 2023 the amount under the loan agreement owed was \$2,314k (Dec 2022 \$1,056k) and \$181k (Dec 2022 \$19k) of interest had been accrued.

In February 2023 a further short – term loan facility was issued to OKYO of \$500k, which was drawn down during the period ended June 30, 2023 and was fully repaid by March 23, 2023.

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 and 3rd party suppliers. As of June 30, 2023, \$614K (Dec 22: 72k, Jun 21: 51Kl) was the net amount owed by Accustem.

12. Ultimate controlling Party

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

13. Post balance sheet events

On October 25, 2023, the Company agreed to waive all its rights in respect of the Loan it had made to OKYO Pharma Ltd, a related party, in consideration of the issue and allotment of 2.1 million equity shares, representing \$3.15 million, which represented the principal element of the underlying loan, interest in accordance with the original loan agreement and supplemental interest to reflect the arm's length principle established in the OECD Guidelines