Tiziana Life Sciences PLC

("Tiziana" or the "Company")

Amended - Final Results for the Year Ended 31 December 2020

London / New York 18 May 2021 – Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS), (the "Company" or "Tiziana"), a biotechnology company focused on innovative therapeutics for oncology, inflammation, and infectious diseases, today announces its financial results for the year ended 31 December 2020.

For the complete Annual Report & Financial Statements year ended 31 December 2020 for Tiziana Life Sciences plc, go to https://ir.tizianalifesciences.com/financial-information/annual-reports

This announcement contains inside information for the purposes of Article 7 of Regulation 2014/596/EU (which forms part of domestic UK law pursuant to the European Union (Withdrawal) Act 2018 ("UK MAR"). Upon the publication of this announcement, this inside information (as defined in UK MAR) is now considered to be in the public domain. For the purposes of UK MAR, the person responsible for arranging for the release of this announcement on behalf of the Company is Keeren Shah, Chief Financial Officer.

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About Tiziana Life Sciences plc

Tiziana Life Sciences plc is a dual listed (NASDAQ: TLSA & UK LSE: TILS) biotechnology company that focuses on the discovery and development of novel molecules to treat human diseases in oncology, inflammation, and infectious diseases. In addition to Milciclib, the Company will be shortly initiating Phase 2 studies with orally administered Foralumab for Crohn's Disease and nasally administered Foralumab for progressive multiple sclerosis. Foralumab is the only fully human anti-CD3 monoclonal antibody ("mAb") in clinical development in the world. This Phase 2 compound has potential application in a wide range of autoimmune and inflammatory diseases, such as Crohn's Disease, multiple sclerosis, type-1 diabetes ("T1D"), inflammatory bowel disease ("IBD"), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable. The Company is accelerating development of anti-Interleukin 6 receptor ("IL6R") mAb, a fully human monoclonal antibody for treatment of IL6-induced inflammation, especially for treatment of COVID-19 patients.

For more information go to http://www.tizianalifesciences.com

EXECUTIVE CHAIRMAN'S STATEMENT

I am pleased to report on the Company (Tiziana Life Sciences PLC) and its subsidiaries, together the 'Group', results for the year ended 31 December 2020.

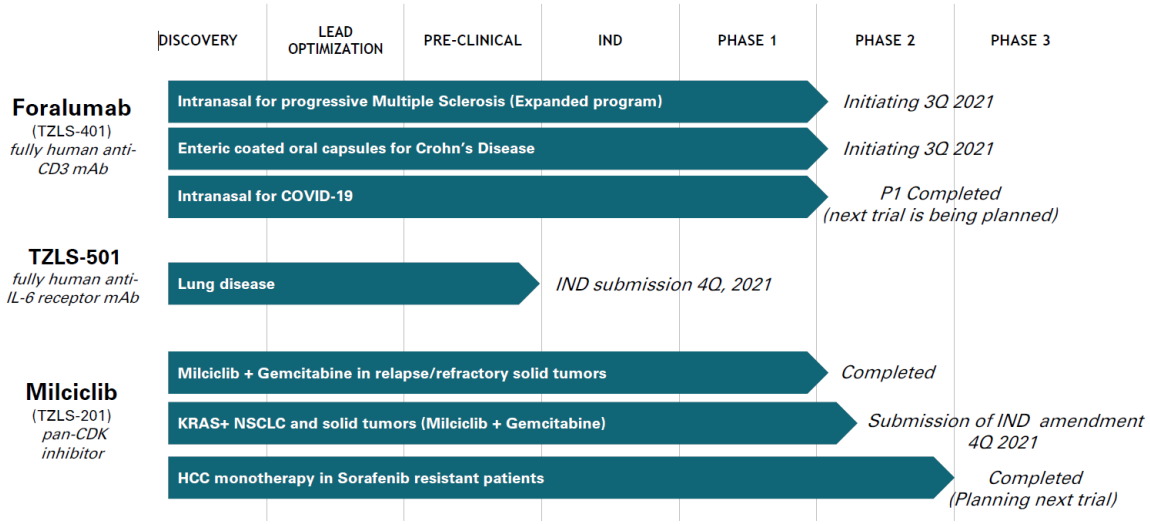
Tiziana Life Sciences is a dual-listed (NASDAQ: TLSA, LSE:TILS) clinical stage biotechnology company that specializes in the developing transformative therapies for autoimmune and inflammatory diseases, degenerative diseases and cancer related to the liver. Our clinical pipeline includes drug assets for Crohn's Disease, COVID-19, Secondary Progressive Multiple Sclerosis and Hepatocellular Carcinoma. Tiziana is led by a team of highly qualified executives with extensive drug development and commercialization experience.

Background

The Group is focused on the discovery and development of novel molecules and related diagnostics to treat high unmet medical needs in oncology and immunology. Our mission is to design and deliver next generation therapeutics and diagnostics for oncology and immune diseases of high unmet medical need by combining deep understanding of disease biology with clinical development expertise. We have a drug discovery pipeline of small molecule new chemical entities, or NCEs, and biologics. We employ a lean and virtual research and development,

or R&D, model using highly experienced teams of experts for each business function to maximize value accretion by focusing resources on the drug discovery and development processes.

Development Pipeline



Foralumab (TZLS-401 / NI-0401)

Our lead product candidate in immunology is Foralumab (TZLS-401), which we believe is the only fully human anti-CD3 monoclonal antibody, or mAb, in clinical development. MAbs represent a single pure antibody produced by single clones and are an important class of human therapeutics for treating cancers and autoimmune diseases. We are developing Foralumab, for which we in-licensed the intellectual property from Novimmune, SA, a Swiss biotechnology company, or Novimmune, as a potential treatment for neurodegenerative diseases such as progressive Multiple Sclerosis, or MS, and Crohn's disease. As the only fully human engineered human anti-CD3 mAb in clinical development, Foralumab has significant potential advantages such as a shorter treatment duration and reduced immunogenicity. We believe that oral or intranasal administration of Foralumab has the potential to reduce inflammation while minimizing the toxicity and related side effects.

To date, Foralumab has been studied in one Phase 1 and two Phase 2a clinical trials conducted by Novimmune in 68 patients dosed by the intravenous route of administration. In these trials, Foralumab was observed to be safe and well-tolerated and produced immunologic effects consistent with potential clinical benefit while demonstrating mild to moderate infusion related reactions. With completion of the intravenous dosing for Phase 2a trial in Crohn's Disease, Foralumab's ability to modulate T-cell response enables potential extension into a wide range of other autoimmune and inflammatory diseases, such as graft versus host disease, ulcerative colitis, MS, type-1 diabetes, inflammatory bowel disease, psoriasis and rheumatoid arthritis.

Foralumab is being developed as both an immunosuppressive and immunomodulatory agent, with therapeutic benefits of rendering T-cells unable to orchestrate an immune response and induction of immune tolerance via maintenance of regulatory T-cells. There is further potential for Foralumab to be combined with our TZLS-501, a fully human anti-IL-6R mAB in development to target autoimmune and inflammatory diseases. In November 2016, we announced new data for oral efficacy in humanized mouse models with Foralumab, a major milestone and a potential breakthrough for the treatment of nonalcoholic steatohepatitis and autoimmune disease. This unique oral technology stimulates the natural gut immune system and potentially provides a therapeutic effect in inflammatory and autoimmune diseases with greatly reduced toxicity. Positive therapeutic effects with Foralumab were consistently demonstrated in animal studies conducted by Prof. Kevan Herold (Yale University) and Prof. Howard Weiner (Harvard University).

In April 2018, we entered into an exclusive license agreement with The Brigham and Women's Hospital, Inc. relating to a novel formulation of Foralumab dosed in a medical device for nasal administration. An investigational new drug application, or IND, for the first-in-human evaluation of the nasal administration of Foralumab in healthy volunteers for progressive MS indication was filed in the second quarter of 2018. Subsequent to IND approval, a single-site, double-blind, placebo-controlled, dose-ranging Phase 1 trial with nasally administered Foralumab at 10, 50 and 250 µg per day, consecutively for 5 days to evaluate biomarkers of immunomodulation of clinical responses was initiated

in November 2018. The trial was conducted at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, in healthy volunteers in which 18 subjects received Foralumab treatment and 9 patients received placebo. The study was completed in September 2019, and data demonstrated that nasally administered Foralumab was well-tolerated and no drug-related safety issues were reported at any of the doses. No drug-related changes were observed in vital signs among subjects at predose during treatment and at discharge. Nasally administered Foralumab at the 50 µg dose suppressed cytotoxic CD8+ as well as perforin-secreting CD8+ cells, which have been implicated in neurodegeneration in MS. Treatment at 50 µg stimulated production of anti-inflammatory cytokine IL-10 and suppressed production of pro-inflammatory cytokine interferon-gamma (IFN-γ). Taken together, the treatment showed significant positive effects on the biomarkers for activation of mucosal immunity, which are capable of inducing site-targeted immunomodulation to elicit anti-inflammatory effects. Based on the results we intend to conduct a Phase 2 trial in progressive MS patients starting in the third quarter of 2021.

On July 31, 2020, we announced that we had submitted a patent application for the potential use of nasally administered Foralumab, a fully human anti-CD3 mAb, for the treatment of COVID-19 either alone or in combination with other anti-viral drugs. Recent clinical studies implied that a combination of anti-inflammatory and anti-viral drugs may be more effective to treat patients at different stages of COVID-19 disease.

A collaborative clinical study was initiated on November 2, 2020, investigating nasally administered Foralumab either alone or in combination with orally administered dexamethasone in COVID-19 patients in Brazil. In view of the importance and urgency, scientific teams at the Harvard Medical School, Santa Casa de Misericórdia de Santos Hospital (Jabaquara, Santos, Brazil) and at our company closely collaborated to facilitate initiation of this study in expedited time frames. The clinical trial was coordinated by the team at INTRIALS, a leading, full-service Latin America Clinical Research Organization, (CRO) based in Sao Paulo City, Brazil. The trial was completed in January 2021, and the clinical data from this trial is expected to be available by the first quarter of 2021. This trial, the first-ever trial on nasal administration of Foralumab for treatment of COVID-19, is of enormous significance given the underlying scientific approach is to modulate the immune system, which is dysregulated and crippled to protect against the virus. If successful, we believe this approach could be good for treatment of all COVID-19 variants and potentially other viruses.

An enteric-coated capsule formulation using a proprietary and novel technology has been developed for oral administration of Foralumab. cGMP manufacturing of clinical trial materials for a Phase 1 study has been completed and an IND was submitted in March 2019.

On September 9, 2019, the U.S. Food and Drug Administration, or FDA, granted approval to initiate the Phase 1 clinical trials to evaluate the safety and pharmacokinetics of oral Foralumab at 1.25, 2.5 and 5.0 mg/day as a single ascending dose study. The study was completed in December 2019 at the Brigham and Women's Hospital. Formulated Foralumab powder encapsulated in enteric-coated capsule was well-tolerated at all doses tested and there were no drug-related safety issues observed even at the highest dose of 5 mg in this trial. Based on successful Phase 1 data, we intend to conduct a Phase 2 study using Crohn's Disease patients starting in the third quarter of 2021.

In addition, on August 18, 2020 the United States Patent and Trademark Office, or USPTO, granted us a patent on use and methods of treatment of Crohn's disease with Foralumab, its proprietary fully human monoclonal antibody, and all other anti-CD3 mAbs. The CD3 (cluster of differentiation 3) is a protein complex on T-cells, which is important for the regulation of the immune system. The patent was published by the USPTO on September 1, 2020 as Patent No. 10,759,858. Recently, we also announced the issuance of the first-ever patent on oral administration of anti-CD3 mAbs for treatment of human diseases (Patent No. 10,688,186). We believe the grant of this additional composition-of-matter and use patent further strengthens our intellectual property, consisting of proprietary technologies on oral and nasal administration of Foralumab and other anti-CD3 mAbs for the treatment of human diseases.

On July 16, 2020, we announced that we had submitted a patent application on the potential use of Foralumab, a fully human anti-CD3 mAbs, to improve success of chimeric antigen receptor T-cell, or CAR-T, therapy for cancer and other human diseases. The patent application claims inventions related to lymphodepletion to improving CAR-T expansion and/or survival using anti-CD-3 mAbs administered either alone or in combination with other co-stimulatory molecules, such as an anti-IL-6R mAb, an anti-CD28 mAb or specific inhibitors of signaling pathways of phosphatidylinositol 3-kinase (PI3K), protein kinase B (AKT), or mammalian target of rapamycin (mTOR).

Milciclib (TZLS-201)

We are developing Milciclib, for which we in-licensed the intellectual property from Nerviano Medical Sciences S.r.l. in 2015, as a potential treatment for hepatocellular carcinoma, or HCC. A novel feature of Milciclib is its ability to reduce levels of microRNAs, miR-221 and miR-222. MicroRNAs are small RNA molecules that play a significant role in the regulation of gene expression. miR-221 and miR-222 are believed to be linked to the development of blood supply (angiogenesis) in cancer tumors. Levels of these microRNAs are consistently elevated in HCC patients and may contribute towards resistance to treatment with Sorafenib, a multikinase inhibitor (a drug which may inhibit

the cellular division and proliferation associated with certain cancers) often prescribed to HCC patients as the Standard of Care.

To date, Milciclib has been studied in a total of eight completed Phase 1 and 2 clinical trials in 316 patients. In these trials, Milciclib was observed to be well-tolerated and showed initial signals of anti-tumor action. Prior to in-licensing, Milciclib was granted orphan designation by the European Commission and by the FDA for the treatment of malignant thymoma and an aggressive form of thymic carcinoma in patients previously treated with chemotherapy. In two Phase 2a trials, CDKO-125a-006 and CDKO125a-007, Milciclib showed signs of slowing disease progression and acceptable safety. We initiated a Phase 2a trial (CDKO-125a-010) of Milciclib safety and tolerability as a single therapy in Sorafenib-resistant patients with HCC in the first half of 2017. Typically, this population of patients have an advanced form of the disease with poor prognosis and an average overall survival expectancy of three to five months. In May 2018, the Independent Data Monitor committee, or IDMC, completed an interim analysis of tolerability data from the first eleven treated patients and recommended expansion of the initial cohort to an additional 20 patients to complete the trial enrolment, which was completed in December 2018. In March 2019, the IDMC reviewed safety data from patients as of February 26, 2019 and concluded that the administration of Milciclib to patients with advanced HCC was not associated with unexpected signs or signals of toxicity. 28 out of 31 treated patients were evaluable, 14 completed the 6-month duration study. The most frequent adverse events such as diarrhoea, ascites, nausea, fatigue, asthenia, fever, ataxia, headache, and rash were manageable. No drug-related deaths were recorded.

The Phase 2a trial was completed in June 2019 with clinical safety result reported in July 2019 and efficacy results reported in September 2019. The clinical activity assessment in evaluable patients was based on the independent radiological review using the modified Response Evaluation Criteria in Solid Tumors.

- 14 out of 28 (50%) evaluable patients completed 6-month duration of the trial.
- Both median TTP and PFS were 5.9 months (95% Confidence Interval ("CI") 1.5-6.7 months) out of the 6-months duration of the trial.
- 16 of 28 (57.1%) evaluable patients showed 'Stable Disease'
- One patient (3.6%) showed unconfirmed 'Partial Response' (PR).
- 17 of 28 (60.7%) evaluable patients showed 'Clinical Benefit Rate' defined as CBR=CR+PR+SD (with CR representing Complete Remission).

Since overexpression of cyclin-dependent kinases, or CDKs, and dysregulation in pRB pathway (regulates transcription factors critical for cell cycle progression) are prominently associated with tumor cell resistance to certain chemotherapeutic drugs, inhibition of multiple CDKs is an appealing approach to improve clinical responses in cancer patient's refractory to existing treatment options. A Phase 1 dose-escalation study of Milciclib in combination with gemcitabine in patients with refractory solid tumors exhibited clinical activity in patients, including those who were refractory to gemcitabine. We plan to explore a combination treatment of Milciclib and a tyrosine kinase inhibitor (either Sorafenib or Regorafenib) in patients with HCC in the third quarter of 2021.

On August 21, 2020 we announced that the USPTO had granted us a patent on use of Milciclib in combination with tyrosine kinase inhibitors, or TKIs, such as Sorafenib (Nexavar®), Regorafenib (Stivarga®) and Lenvatinib (Lenvima®) for the treatment of hepatocellular carcinoma, or HCC, and other cancers in humans. This patent was published by the USPTO on September 1, 2020 as Patent No. 10,758,541. Like most human cancers, HCC is a complex multi-factorial cancer with multiple underlying mechanisms causing enormous heterogeneity in patient populations. Consequently, patients with HCC often develop resistance towards the monotherapies of existing therapeutics. Thus, there is an urgent need for combination drug treatment approaches targeting different mechanisms to achieve better clinical outcomes. We are planning to conduct a Phase 2b trial with Milciclib in combination with a TKI or immunotherapy in sorafenib-resistant HCC patients. We also successfully completed a Phase 1 trial in patients with refractory solid cancers. The patients enrolled in this trial had demonstrated resistance to the mainstream chemotherapies for refractory solid cancer. The trial data showed that Milciclib in combination with gemcitabine provided 36% clinical response to these patients who had shown no response to gemcitabine when administered alone. These data suggest that Milciclib may be able to overcome drug-resistance. This novel attribute of Milciclib may have application as an adjuvant therapy in combination with chemotherapies for treatment of refractory, malignant and advanced cases of cancers. The data from this trial also showed that the combination treatment delayed onset in a patient with non-small cell lung carcinoma (NSCLC). The preclinical data from an animal study also suggest that orally administered Milciclib might also be effective in Kras+ (G12C) mutants of NSCLC cancer. We are further exploring the use of Milciclib in combination with other drugs for treatment of Kras+ (G12C) NSCLC, which is an unmet medical need.

Anti-IL6R (TZLS-501)

TZLS-501 is a fully human engineered mAb targeting the interleukin-6 receptor (IL-6R). Tiziana Life Sciences licensed the intellectual property from Novimmune in January 2017. This fully human mAb has a unique mechanism of action that binds to both the membrane-bound and soluble forms of the IL-6R resulting in lowering of circulating

levels of IL-6 in the blood. Excessive production of IL-6 is regarded as a key driver of chronic inflammation, associated with autoimmune diseases such as multiple myeloma, oncology indications and rheumatoid arthritis, and the Group believes that TZLS-501 may have potential therapeutic value for these indications.

In preclinical studies, TZLS-501 demonstrated the potential to overcome limitations of other IL-6 blocking pathway drugs. Compared to Tocilizumab and Sarilumab, while binding to the membrane-bound IL-6R complex TZLS-501 has shown a higher affinity for the soluble IL-6 receptor as seen from the antibody binding studies conducted in cell culture. TZLS-501 also demonstrated the potential to block or reduce IL-6 signaling in mouse models of inflammation. The soluble form of IL-6 has been implicated to have a larger role in disease progression compared to the membrane-bound form. (Kallen, K.J. (2002). "The role of trans signaling via the agonistic soluble IL-6 receptor in human diseases". Biochimica et Biophysica Acta. 1592 (3): 323–343.).

Recently, chronic inflammation is believed to be associated with severe lung damage observed with COVID-19 infections and acute respiratory illness. China's National Health Commission has recommended the use of anti-IL6-R mAbs for treatment of inflammation and elevated cytokine levels ("cytokine storm") in COVID-19 patients.

On April 9, 2020 The Company announced that it had developed investigational new technology to treat COVID-19 infections, consisting of direct delivery of anti-IL-6 receptor (anti-IL-6R) monoclonal antibodies (mAbs) into the lungs using a handheld inhaler or nebulizer for treatment of patients infected with COVID-19 (SARS-CoV-2) coronavirus. On June 29, 2020 the Company announced that it was advancing GMP manufacturing of TZLS-501 with STC Biologics concurrently with the development of inhalation technology using a hand-held nebulizer with Sciarra Laboratories and safety toxicology studies in Cynomolgus monkeys with ITR Canada Laboratories. GMP batches were initiated in January 2021 and completed in March 2021. Safety inhalation toxicology studies were initiated in November 2020 and completed in March 2021. Technological assessment of nebulizers for inhalation treatment of patients was initiated in September 2020 and completed in February 2021.

StemPrintER

StemPrintER is a multi-gene signature assay intended for use in patients diagnosed with estrogen-receptor positive ER+/HER2 negative breast cancers. The Group believes this in-vitro prognostic test will be used in conjunction with clinical evaluation to identify those patients at increased risk for early and/or late metastasis. StemPrintER is designed to help physicians distinguish ER+/HER2 negative patients:

- with an elevated risk of early recurrence (<5 years) who could benefit from chemotherapy in addition to hormonal therapy
- with a high risk of late recurrence who could benefit from prolonged endocrine treatment up to 10 years
- with a low risk of early recurrence who might be spared chemotherapy or be eligible for less aggressive treatments

The diagnostic has a unique biological basis, being based on the detection of cancer stem cell markers, uses a reliable platform (qRT- PCR, FFPE), and has been evaluated in an initial retrospective validation study using a consecutive cohort of approximately 2,400 patients with breast cancer. The development team is preparing for a retrospective validation study using an independent cohort and has conducted a pre- submission meeting with the FDA.

Recently, StemPrintER results were announced, from a poster selected for discussion session at the American Society of Clinical Oncology (ASCO) Virtual Conference, demonstrating the favourable performance of the StemPrintER stem cell based genomic prognostic tool versus the market leader, Oncotype DX, in predicting recurrence in ER+/HER2- postmenopausal breast cancer patients

Tiziana has during this year demerged the StemPrintER technology by the transfer of the Intellectual Property rights and patents to its wholly owned subsidiary, Stemprinter Sciences Ltd, which was then sold to Accustem Sciences Ltd. The process was effected by way of a Court sanctioned capital reduction and statutory demerger. Accustem will develop and commercialise the StemPrintER diagnostic tester.

Financial summary

Consolidated Statement of Comprehensive Income

The Group has made a loss for the year of £20,162k (2019: £7,177k). The loss is detailed in the consolidated statement of comprehensive income on page 39.

Research and development costs were £4.7 million for the year ended December 31, 2020 as compared to £2.9 million for the year ended December 31, 2019, an increase of £1.8 million. The increase in cost is a result of the development of anti-IL-6R monoclonal antibodies (mAbs) compounds.

Operating expenses were £19.01 million for the year ended December 31, 2020 as compared to £4.9 million for the year ended December 31, 2019, an increase of £14.11 million. The increase in cost is a result of a realisation bonus that became payable for £10.29m, additional fair value charges of £2.7m relating to modification of existing options and the issuance of additional options, plus additional compliance, professional fees and legal costs of £1.12m due to increased activity in the Company.

Consolidated Statement of Financial Position

At the end of the year the Group cash balance amounted to £48,217k (2019: £153k) and the total assets of the Group amounted to £51,766k (2019: £1,808k). To bolster our cash reserves, the Group raised £52.1m via a public offering of American Depositary Shares ("ADSs") on the NASDAQ Global Market during 2020.

Fund raising

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

During the year to 31 December 2020, Tiziana raised £62.1m funds: £52.1m was raised through a public offering on the NASDAQ Global Market, £6.2m through an 'At the market' sales agreement, £0.1m through the issuance of a Convertible Loan Note and £3.7m through the exercise of warrants and options. Funds raised by Tiziana will be used to fund the development of the Group's clinical stage assets Milciclib and Foralumab, to meet the Group's ongoing liabilities in respect of license agreements, and for general working capital purposes.

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 December 31, 2020, had an accumulated loss of £62,313k, a net loss for the year ended December 31, 2020 of £20,348k and net cash used in operating activities of £9,297k.

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

Appointments

Non-Executive Directors

On 21 January 2020, the Group announced the appointment of Mr. Gregor MacRae to its Board as a Non-executive Director.

On 20 July 2020, the Group announced the appointment of Mr. John Brancaccio to its Board as a Non-executive Director. Mr Brancaccio will Chair the Audit, Risk and Disclosure Committee.

Mr. Brancaccio, retired CPA, is a financial executive with extensive international and domestic experience in pharmaceutical and biotechnology for privately and publicly held companies. From 2000 to 2002, Mr. Brancaccio was the Chief Financial Officer/Chief Operating Officer of Eline Group, an entertainment and media company. From May 2002 until March 2004, Mr. Brancaccio was the Chief Financial Officer of Memory Pharmaceuticals Corp., a biotechnology company. From April 2004 until May 2017, Mr. Brancaccio was the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. Mr. Brancaccio is currently a director of Cardiff Oncology, Inc.,Rasna Therapeutics, Inc., OKYO Pharma LTD and Hepion Pharmaceuticals, Inc.

Resignations

Non-Executive Directors

On 18 June 2020, the Group announced that Mr. Gregor MacRae was standing down as a director of the Company with immediate effect to concentrate on his other business interests and activities; Mr MacRae felt his position was better filled by an individual with a background and greater experience in life sciences sector.

COVID-19

We remain cognisant of the potential impact of coronavirus (COVID-19) on our operations and have taken the steps necessary to maintain the integrity of the Company's assets and the health and wellbeing of our employees. The Company is well financed, resilient and well positioned to weather any financial downturn occurring as a result of

the outbreak. Indeed, the Company has raised additional funds through an "At the Market" or "ATM" Sales Agreement with Think Equity (a division of Fordham Financial Management, Inc.) which raised $7.7m from the sale of ADSs.

We are also aware of the responsibility we have as a member of the global healthcare community to develop investigational new technologies to treat COVID-19 infections.

Outlook and strategy

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

We are developing investigational new technology to treat COVID-19 infections, which consists of direct delivery of anti-IL-6 receptor (anti-IL-6R) monoclonal antibodies (mAbs) into the lungs using a nasal delivery system. Preclinical studies are ongoing and we hope to commence a trial investigating the direct delivery of an anti-IL-6R mAb to the lungs using a portable nasal delivery system. This treatment could be useful for different variants of COVID-19 and we are exploring these in an upcoming preclinical study.

The Company also plans to develop subcutaneous delivery of anti_IL-6R mAb for treatment of ARDS and other inflammatory conditions.

We have outlined our clinical development plan for Foralumab and anticipate to commence Phase 1b and 2 trials for oral administered Foralumab in Crohn's disease patients and nasally administered Foralumab in multiple sclerosis patients.

For Milciclib, we are planning to initiate a Phase 2b clinical trial in HCC patients with Milciclib in combination with a Tyrosine kinase inhibitors such as Regorafenib or Sorafenib. The Company also intends to evaluate milciclib in combination with standard of care treatments for other solid tumour indications.

We recently announced an agreement we have entered into with Takanawa Japan K.K, Pharma Team, (Takanawa) for a strategic business development plan to Identify a clinical partner in Japan and other Asian countries for further clinical development of Milciclib for treatment in advanced hepatocellular carcinoma (HCC) patients. We believe the positive clinical activity in advanced HCC and other cancers warrant immediate further development in Japan and other Asian countries where the prevalence of this cancer is relatively high, and the current available therapies are not entirely satisfactory.

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

Gabriele Cerrone

Executive Chairman

May 17, 2021

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

Continuing Operations	Note	£'000	£'000
Research and development costs		(4,667)	(2,910)
Operating expenses		(8,724)	(4,864)
Realisation bonus	5	(10,290)	-
Impairment of asset	17	(217)	-
Gain on disposal of Intellectual Property	4	2,074	-
Operating loss	5	(21,824)	(7,774)
Finance costs	10	(243)	(72)

Loss before taxation		(22,067)	(7,846)
Taxation	11	1,719	540
Loss for the year attributable to equity owners		(20,348)	(7,306)
Other comprehensive income that may be classified to profit and loss in subsequent periods			
Exchange differences on translation of foreign operations		186	129
Total comprehensive loss for the year attributable to equity owners		(20,162)	(7,177)
Loss per share			
Basic and diluted (loss) per share on continuing operations	12	(12.0p)	(5.4p)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2020

	Note	2020 £'000	2019 £'000
ASSETS			
Non-Current assets			
Property, plant and equipment	13	1	5
Finance lease receivable	16	-	113
Intangible asset	14	97	-
Right of use asset	28	262	329
Other non-current assets	17	-	217
Total non-current assets		360	664
Current assets			
Finance lease receivable	16	111	109
Related party receivable	27	270	245
Other receivables	15	576	124
Taxation receivable	11	2,232	513
Cash and cash equivalents		48,217	153
Total current assets		51,406	1,144
TOTAL ASSETS		51,766	1,808
EQUITY AND LIABILITIES			
Equity			
Capital and reserves attributable to equity holders of the company			
Called up share capital	19	5,838	4,099
Share premium		81,227	25,194
Capital reduction reserve	22	31,958	31,183
Shares to be issued reserve (convertible notes)	21	-	1,099
Share based payment reserve (options)	19,22	6,319	3,850
Share based payment reserve (warrants)	19,22	475	1,812
Shares to be issued	5,22	10,290	-
Other reserve	22	(28,286)	(28,286)
Translation reserve		201	15
Retained earnings	22	(62,313)	(43,146)
Total equity		45,709	(4,180)
Liabilities			
Non-Current liabilities			
Lease Liability	27	212	411

Current liabilities			
Trade and other payables	26	4,095	4,851
Lease liability	28	195	212
Related party payable	27	1,493	451
Other liabilities		62	63
Total current and non-current liabilities		6,057	5,988
TOTAL EQUITY AND LIABILITIES		51,766	1,808

CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 31 DECEMBER 2020

	2020	**2019**
	£'000	£'000
Cash flows from operating activities		
Loss for the year before taxation	(22,067)	(7,846)
Adjustments for:		
Convertible loan interest accrued	216	39
Shares issued in lieu of fees	360	82
Share based payment – options	3,740	992
Share based payment – warrants	20	-
Options forfeited/cancelled in the year	(26)	-
Bonus to be settled in equity	10,290	-
Net (increase) in related party receivables	(24)	(225)
Net increase in related party payables	892	342
Net decrease/(increase) in other receivables	(340)	125
Net (decrease)/increase in trade and other payables	(757)	(17)
Depreciation of property, plant and equipment	4	4
Depreciation of right-of-use asset	67	194
(Gain)/Loss on foreign exchange	185	129
Loss on disposal of right of use asset	-	56
Impairment of SharDNA Spa	217	-
Gain from disposal of intellectual property	(2,074)	-
CASH USED IN OPERATING ACTIVITIES	(9,297)	(6,125)
Cash inflow from taxation	-	800
NET CASH USED IN OPERATING ACTIVITIES	(9,297)	(5,325)
Cash flows from investing activities		
Acquisition of property, plant and equipment	(2)	(3)
Acquisition of intangible asset	(97)	-
NET CASH GENERATED FROM INVESTING ACTIVITIES	(99)	(3)
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	57,283	-
Fundraising costs	(3,136)	-
Proceeds from issuance of convertible loan notes	120	1,473
Proceeds from exercise of warrants	2,682	-
Proceeds from conversion of options	727	-
Repayment of leasing liabilities	(216)	(157)
NET CASH GENERATED FROM FINANCING ACTIVITIES	57,460	1,316

NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	48,064	(4,012)
Cash and cash equivalents at beginning of year	153	4,165
CASH AND CASH EQUIVALENTS AT END OF YEAR	48,217	153

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

	Share Capital	Share Premium	Capital Reduction Reserve	Share Based Payment Reserve (options)	Share Based Payment Reserve (warrants)	Convertible Loan Note Reserve	Other Reserve	Shares to be issued Reserve	Translation Reserve	Retained Earnings	Total Equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Balance at 1 January 2019	4,094	25,117	31,183	2,857	1,399	-	(28,286)	-	(113)	(35,840)	411
Issue of share capital (private placement and IPO)	5	77	-	-	-	-	-	-	-	-	82
Warrants issued with CLN	-	-	-	-	413	(413)	-	-	-	-	-
Share based payment (options)	-	-	-	993	-	-	-	-	-	-	992
Convertible loan notes issued	-	-	-	-	-	1,472	-	-	-	-	1,473
Convertible loan note interest	-	-	-	-	-	39	-	-	-	-	39
Total	5	77	-	993	413	1,099	-	-	-	-	2,586
Comprehensive income											
Exchange differences on translating foreign operations									128		129
Comprehensive loss for the year										(7,306)	(7,306)
Total comprehensive income	-	-	-	-	-	-	-	-	128	(7,306)	(7,177)
Balance as at 31 December 2019	4,099	25,194	31,183	3,850	1,812	1,099	(28,286)	-	15	(43,146)	(4,180)
Issue of share capital (Fundraise & ATM)	1,319	56,964	-	-	-	-	-	-	-	-	58,283
Issue of share capital (Warrants)	191	2,491	-	-	-	-	-	-	-	-	2,682
Issue of share capital (in lieu of fees)	9	351	-	-	-	-	-	-	-	-	360
Issue of share capital (exercise of options)	88	640	-	-	-	-	-	-	-	-	728
Issue of share capital (Loan conversion)	132	1,716	-	-	-	(1,848)	-	-	-	-	-
Cost of fundraise	-	(3,136)	-	-	-	-	-	-	-	-	(3,136)
Convertible loan notes issued	-	-	-	-	-	120	-	-	-	-	120
Convertible loan note interest	-	-	-	-	-	216	-	-	-	-	216
Share based payments charge (warrants)	-	-	-		259	(240)	-	-	-	-	19
Share based payment charge (options)	-	-	-	3,740	-	-	-	-	-	-	3,740
Options forfeited/cancelled in the year	-	-		(26)	-	-	-	-	-	-	(26)
Exercise of options	-	64		(1,245)	-	-	-	-	-	1,181	-

Exercise of warrants	-	943			(1,596)	653	-	-	-	-	-
Shares issued in lieu of cash for realisation bonus	-	-	-	-	-	-	-	10,290	-	-	10,290
Reduction in share capital	-	(4,000)	4,000	-	-	-	-	-	-	-	-
Capital distribution	-		(3,225)	-	-	-	-	-	-	-	(3,225)
Total	1,739	56,033	775	2,469	(1,337)	(1,099)	-	10,290	-	1,181	70,051
Comprehensive loss (Items that will be reclassified to the Statement of Income in future periods)											
Exchange differences on translating foreign operations	-	-	-	-	-	-	-	-	186	-	186
Net loss for the year	-	-	-	-	-	-	-	-	-	(20,348)	(20,348)
Total Comprehensive loss for the year	-	-	-		-	-	-	-	186	(20,348)	(20,162)
Balance as at 31 December 2020	5,838	81,227	31,958	6,319	475	-	(28,286)	10,290	201	(62,313)	45,709

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

1. GENERAL INFORMATION

Tiziana Life Sciences PLC is a public limited company incorporated in the United Kingdom under the Companies Act and quoted on the AIM market of the London Stock Exchange (AIM: TILS) and on the NASDAQ Capital Market (NDAQ: TLSA). The Company delisted from AIM on 21st January 2021 and is now trading on the main market of the London Stock Exchange (LSE: TILS). The address of its registered office is given on page 1. The principal activities of the Company and its subsidiaries (the Group) are that of a clinical stage biotechnology company focussed on targeted drugs to treat diseases in oncology and immunology.

These financial statements are presented in thousands of pounds sterling (£'000) which is the functional currency of the primary economic environment in which the Company operates.

2. FINANCE INCOME AND COSTS

Group	**2020**	**2019**
	£'000	£'000
Finance Income		
Finance income received on net investment in lease	6	1
Total finance income	6	1
Finance Expenses		
Finance charge accrued on convertible loan notes	236	49
Interest expense on lease liabilities	13	24
Total finance expenses	249	73
Net finance expense recognised in Statement of Comprehensive Income	243	72

3. TAXATION

	2020	**2019**
	£'000	£'000
Group		
Current year tax (credit)	(1,204)	(518)
Adjustments in respect of prior periods	(515)	(22)
Deferred tax		
Origination and reversal of timing differences	Nil	Nil
Total tax (credit) for period	(1,719)	(540)

The tax charge for the year is different from the standard rate of corporation tax in the United Kingdom of 19%. The difference can be reconciled as follows:

Loss before taxation	(22,067)	(7,846)
Loss charged at standard rate of corporation tax 19%	(4,193)	(1,491)
Movement in unrecognised deferred tax	1,025	(189)

Expenses not deductible for taxation	3,883	1,353
Adjustments due to prior periods	(515)	(22)
Research and development claim	(518)	(223)
Income not taxable for tax purposes	(1,356)	-
Consolidation adjustment in relation to foreign exchange movements	(45)	32
	(1,719)	(540)

No deferred tax asset has been recognised in respect of trading losses carried forward because of uncertainty as to when these losses will be recoverable.

The amount of tax losses for which no deferred tax assets has been recognised is £4,814k (2019: £2,756k).

4. LOSS PER SHARE

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

	2020	**2019**
(Loss) attributable to equity holders of the Company (£)	(20,348,519)	(7,306,423)
Weighted average number of ordinary shares in issue	169,065,390	136,482,627
Basic loss per share (pence per share)	(12.0)	(5.4)

As the Group is reporting a loss from continuing operations for the year then, in accordance with IAS 33, the share options are not considered dilutive because the exercise of the share options would have an anti-dilutive effect. The basic and diluted earnings per share as presented on the face of the Income Statement are therefore identical. All earnings per share figures presented above arise from continuing and total operations and therefore no earnings per share for discontinued operations are presented.

5. OTHER RECEIVABLES

	2020 £'000	**2019** £'000
Group		
VAT Receivable	61	16
Funds due for options exercised	140	-
Security deposits receivable	99	87
Prepayments	276	21
	576	124

6. SHARE CAPITAL

Company and Group	**2020**	**2019**	**2020**	**2019**
	Ordinary Shares		**£000**	**£000**
In issue at 1 January	136,654,516	136,463,818	4,099	4,094
Issued for cash	43,979,245	-	1,319	-
Issued in lieu of consultancy fees	281,250	190,698	9	5
Conversion of warrants	6,365,428	-	191	-
Conversion of Loan	4,406,125	-	132	-
Exercise of options	2,925,725	-	88	-
Commission and Interest		-		-

In issue at 31 December	194,612,289	136,654,516	5,838	4,099

7. TRADE AND OTHER PAYABLES

Group	2020 £000	2019 £000
Trade payables	2,466	3,178
Accruals	1,629	1,673
	4,095	4,851