## UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

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REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number: 0001723069

Tiziana Life Sciences plc
(Exact Name of Registrant as Specified in Its Charter)

London SW1Y 4LB
United Kingdom
(Address of registrant's principal executive office)

3<sup>rd</sup> Floor, 11-12 St James's Square

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F ⊠ Form 40-F □

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):  $\Box$ 

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):  $\Box$ 

#### INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On June 18, 2020, Tiziana Life Sciences plc (the "Company") issued a regulatory news service announcement in the United Kingdom announcing the Filing of its' Final Results for the Year Ended 31 December 2019 (the "RNS Announcement").

The RNS Announcement is furnished herewith as Exhibit 99.1 to this Report on Form 6-K. The information in the attached Exhibit 99.1 is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing made by the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, except as otherwise set forth herein or as shall be expressly set forth by specific reference in such a filing.

### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: June 18, 2020

### TIZIANA LIFE SCIENCES PLC

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai Title: Chief Executive Officer

### EXHIBIT INDEX

Exhibit No.	Description					
99.1	Regulatory News Service Announcement, dated June 18, 2020					
55.1	Negulatory Wews Service Anniouncement, dated June 10, 2020					
	2					

#### **Tiziana Life Sciences PLC**

("Tiziana" or the "Company")

#### Final Results for the Year Ended 31 December 2019

London / New York 18 June 2020 – Tiziana Life Sciences plc (Nasdaq: TLSA / AIM: TILS), (the "Company" or "Tiziana"), the U.S. and U.K. biotechnology company that focuses on the discovery and development of novel molecules to treat human disease in oncology and immunology, today announces its financial results for the year ended 31 December 2019.

This announcement contains inside information for the purposes of Article 7 of EU Regulation 596/2014.

#### For further enquiries:

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Liam Murray / Jo Turner

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Robert Emmet

#### **About Tiziana Life Sciences plc**

Tiziana Life Sciences is a UK biotechnology company that focuses on the discovery and development of novel molecules to treat human disease in oncology and immunology. We believe Foralumab is the only fully human anti-CD3 mAb in clinical development in the world. This compound has potential application in a wide range of autoimmune and inflammatory diseases, such as NASH, primary biliary cholangitis (PBS), ulcerative colitis, MS, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis, where modulation of a T-cell response is desirable.

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 2019.

### **Background**

Tiziana Life Sciences plc is a publicly-listed (NASDAQ: TLSA; AIM: TILS) biotechnology company focused on the discovery and clinical development of innovative therapeutics for cancers, autoimmune and inflammatory diseases. The Group combines field-leading medical scientists, providing deep knowledge and novel insights into disease mechanisms, together with a highly experienced clinical development team. Since its foundation in 2013, Tiziana Life Sciences has expanded its pipeline of assets to include clinical stage development therapeutic candidates in both oncology and immunology, as well as a pre-clinical drug discovery pipeline.

#### **Clinical Programmes**

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 lead product candidate in immunology are 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. In addition, we are accelerating development of another fully human monoclonal antibody anti-IL6R (TZLS-501) to treat acute inflammation resulting from infection with viral agents such as Coronaviruses. Antibodies produced in animals for use in humans, lead to strong, immune responses limiting their effectiveness and potentially leading to severe side effects. A process known as "humanization" removes most of the animal components of the antibody thereby lowering the immune response from the human immune system. The entire omission of other animal material, as in fully human antibodies, is the optimal goal to avoid incompatibility with the human immune system.

Our lead product candidate in oncology is Milciclib (TZLS-201), which is an orally bioavailable, small molecule broad spectrum inhibitor of cyclin-dependent kinases, or CDKs, and Src family kinases. CDKs are a highly conserved family of enzymes that phosphorylate a specific group of proteins that are involved in regulating the cell cycle. The cell cycle is a series of events that takes place in cells leading to division and duplication of its DNA to produce two daughter cells. Src family kinases are non-receptor tyrosine kinase proteins encoded by the Src gene also involved in regulating cell growth and potential transformation of normal cells to cancer cells. 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. 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.

#### DEVELOPMENT PIPELINE

Foralumab (TZLS-401 / NI-0401)

Foralumab is a fully human engineered anti-CD3 monoclonal antibody (mAB). It was in-licensed in December 2014 from Novimmune. In January 2016, Tiziana outlined its clinical development plan for Foralumab with initial plans to evaluate the drug in two clinical indications: non-alcoholic steatohepatitis (NASH) and inflammatory bowel disease (IBD).

As the only fully human engineered human anti-CD3 mAB in clinical development, Foralumab has significant potential advantages such as a shorter treatment duration and reduced immunogenicity. With completion of the intravenous dosing for our Phase 2a trial in Crohn's Disease, Foralumab's ability to modulate T-cell response enables potential extension into a wide range of other autoimmune and inflammatory diseases, such as GvHD, ulcerative colitis, multiple sclerosis, type-1 diabetes (T1D), inflammatory bowel disease (IBD), psoriasis and rheumatoid arthritis.

Foralumab is being developed as both an immunosuppressive and immunomodulatory agent, with therapeutic benefits of rendering T-cells unable to orchestrate an immune response and induction of immune tolerance via maintenance of regulatory T-cells. There is further potential for Foralumab to be combined with the Company's TZLS-501, a fully human anti-IL-6R mAB in development to target autoimmune and inflammatory diseases.

In November 2016, Tiziana announced new data for oral efficacy in humanized mouse models with Foralumab, a major milestone and a potential breakthrough for the treatment of NASH and autoimmune disease. This unique oral technology stimulates the natural gut immune system and potentially provides a therapeutic effect in inflammatory and autoimmune diseases with greatly reduced toxicity. Positive therapeutic effects with Foralumab were consistently demonstrated in animal studies conducted by Prof. Kevan Herold (Yale University) and Prof. Howard Weiner (Harvard University).

On 16 April, 2018, the Group entered into an exclusive license agreement with The Brigham and Women's Hospital, Inc. relating to a novel formulation of Foralumab dosed in a medical device for nasal administration. An investigational new drug application (IND) for the first-in-human evaluation of the nasal administration of Foralumab in healthy volunteers for progressive multiple sclerosis 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  $\mu$ g per day, consecutively for 5 days to evaluate biomarkers of immunomodulation of clinical responses was initiated in November 2018. The trial conducted at the Brigham and Women's Hospital, Harvard Medical School, Boston, MA, in healthy volunteers. 18 subjects received Foralumab treatment and 9 patients received placebo. All nasal doses were well tolerated. The study was completed in September 2019. Phase 1 clinical 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 pre-dose, during treatment and at discharge. The mean blood pressure (BP) during the 5 days of treatment were; Cohort A (10  $\mu$ g/d):124/73, Cohort B (50  $\mu$ g/d): 119/67 and Cohort C (250  $\mu$ g/d):113/65 compared to placebo:118/67). Heart rates, respiratory rates and oral temperatures were unchanged among the 3 cohorts compared to the placebo. Nasally administered Foralumab at the 50  $\mu$ g dose suppressed cytotoxic CD8+ as well as perforin secreting CD8+ cells, which have been implicated in neurodegeneration in multiple sclerosis (MS). Treatment at 50 mg stimulated production of anti-inflammatory cytokine IL-10 and suppressed production of pro-inflammatory cytokine IFN-y. Taken together, the treatment showed significant positive effects on the biomarkers for activation of mucosal immunity, which ar

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

On September 9, 2019, the FDA granted approval to initiate the Phase I clinical trials to evaluate the safety and pharmacokinetics of oral Foralumab at 1.25, 2.5 and 5.0 mg/day as a single ascending dose study. The study was completed in December 2019 at Brigham and Women's Hospital (Boston, MA USA). 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 second half of 2020.

#### Milciclib (TZLS-201)

Milciclib, Tiziana's lead small molecule drug, was exclusively licenced in January 2015 from Nerviano Medical Sciences. Milciclib is an orally bioavailable, broad spectrum inhibitor of Cyclin Dependent Kinases (CDKs): 1, 2, 4, 5 and 7 and Src family kinases. Cyclin dependent kinases are a family of highly conserved enzymes that are involved in regulating the cell cycle. Src family kinases regulate cell growth and potential transformation of normal cells to cancer cells. A unique feature of Milciclib is its ability to reduce microRNAs, miR- 221 and miR-222, which silence gene expression. miR-221 and miR-222 promote the formation of blood vessels (angiogenesis) that are important for the spread of cancer cells (metastasis). Levels of these microRNAs are consistently increased in hepatocellular carcinoma ("HCC") patients and may contribute towards resistance to treatment with Sorafenib. As a result, the Group are investigating Milciclib both as a monotherapy and as a combination treatment with Sorafenib.

To date, Milciclib has been studied in a total of eight completed and ongoing Phase 1 and 2 clinical trials in 316 patients. In these trials, Milciclib was observed to be well-tolerated and showed initial signals of anti-tumour action. Prior to in-licensing, Milciclib was granted orphan designation by the European Commission and by the U.S. Food and Drug Administration ("FDA") for the treatment of malignant thymoma and an aggressive form of thymic carcinoma in patients previously treated with chemotherapy. In two Phase 2a trials, CDKO-125a-006 and CDKO125a-007, Milciclib showed signs of slowing disease progression and acceptable safety.

The Group initiated a Phase 2a trial (CDKO-125a-010) of Milciclib safety and tolerability as a single therapy in Sorafenib-resistant patients with HCC in the first half of 2017. Typically, this population of patients have an advanced form of the disease with poor prognosis and an average overall survival expectancy of 3-5 months In May 2018, the Independent Data Monitor committee (IDMC) completed an interim analysis of tolerability data from the first eleven treated patients and recommended expansion of the initial cohort to an additional 20 patients to complete the trial enrolment, which was completed in December 2018.

In March 2019, the Independent Monitoring Committee, or 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 diarrhea, ascites, nausea, fatigue, asthenia, fever, ataxia, headache, and rash were manageable. No drug-related deaths were recorded.

The clinical activity assessment in evaluable patients was based on the independent radiological review using the modified Response Evaluation Criteria in Solid Tumors (mRECIST).

- 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).

The Phase 2a trial was completed in June 2019 with clinical safety and efficacy result reported in July 2019.

Since overexpression of 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 refractory to gemcitabine. We plan to explore a combination approach in patients with HCC.

#### **Pre-Clinical Programmes**

In pre-clinical development, the Group has two programmes:

Anti-IL6R (TZLS-501)

TZLS-501 is a fully human engineered mAb targeting the interleukin-6 receptor (IL-6R). Tiziana Life Sciences licensed the intellectual property from Novimmune in January 2017. This fully human mAb has a unique mechanism of action that binds to both the membrane-bound and soluble forms of the IL-6R resulting in lowering of circulating levels of IL-6 in the blood. Excessive production of IL-6 is regarded as a key driver of chronic inflammation, associated with autoimmune diseases such as multiple myeloma, oncology indications and rheumatoid arthritis, and the Group believes that TZLS-501 may have potential therapeutic value for these indications.

In preclinical studies, TZLS-501 demonstrated the potential to overcome limitations of other IL-6 blocking pathway drugs. Compared to Tocilizumab and Sarilumab, while binding to the membrane-bound IL-6R complex TZLS-501 has shown a higher affinity for the soluble IL-6 receptor as seen from the antibody binding studies conducted in cell culture. TZLS-501 also demonstrated the potential to block or reduce IL-6 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.

#### 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.

#### **Financial summary**

Consolidated Statement of Comprehensive Income

The Group has made a loss for the year of £7,178k (2018 restated: £6,063k). The loss is detailed in the consolidated statement of comprehensive income on page 32.

Research and development costs were £2.9 million for the year ended December 31, 2019 as compared to £4.1 million for the year ended December 31, 2018, a decrease of £1.2 million. The decrease in cost is a result of the completion of the Miciclib Phase 2a of clinical trials during the first half of 2019.

Consolidated Statement of Financial Position

At the end of the year the Group cash balance amounted to £153k (2018: £4,165k) and the total assets of the Group amounted to £1,808k (2018: £5,436k). To bolster our cash reserves, the Group raised \$10m via a public offering of American Depositary Shares ("ADSs") on the NASDAQ Global Market in March 2020

#### **Fund raising**

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

On 1 November 2019, the Company announced that it had raised £1,434,000 cash by issue of convertible unsecured loan notes, with warrants attached. The Loan Notes are expected to be short term instruments and carry a coupon of 16% per annum and are convertible (together with all accrued interest) into ordinary shares of nominal value £0.03 each in the capital of the Company at a conversion price of 42p. The warrants issued in connection with the Loan Notes entitle the holders to subscribe for one additional share per conversion share at the same price of 42p. The warrants may be exercised for a period of up to 5 years from their issue.

#### Resignations

Non-Executive Directors

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

On 20 November 2019, the Group announced the resignation of Mr Leopoldo Zambeletti as a non-executive director, noting the significant business interests of Mr Zambeletti in a wide range of life sciences companies.

#### 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 its ongoing "At the Market" or "ATM" Sales Agreement with Think Equity (a division of Fordham Financial Management, Inc.) to raise up to US\$20m from the sale of ADSs.

We are also aware of the responsibility we have as a member of the global healthcare community we have developed investigational new technology 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 have developed 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 handheld inhaler or nebulizer. Preclinical studies are ongoing and we hope to commence a trial investigating the direct delivery of an anti-IL-6 mAb to the lungs using a portable inhaler.

We have outlined our clinical development plan for Foralumab and anticipate to commence Phase 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.

We are continuing development of StemPrint ER diagnostic tester. Recently, StemPrintER results were announced, from a poster selected for discussion session at the American Society of Clinical Oncology (ASCO) Virtual Conference, demonstrating the superiority of StemPrintER stem cell based genomic prognostic tool versus the market leader, Oncotype DX, in predicting recurrence in ER+/HER2- postmenopausal breast cancer patients. Looking ahead, Tiziana is confident that it is well positioned to advance these programs to their next respective value inflection points.

We would like to thank the staff and Board members for all their contributions and shareholders for their continued support during a successful year.

#### **Gabriele Cerrone**

Executive Chairman

June 17, 2020

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2019

Continuing Operations	<b>2019</b> £'000	2018 £'000 (Restated)
Community Operations		
Research and development costs	(2,910)	(4,132)
Operating expenses	(4,864)	(3,268)
Operating loss	(7,774)	(7,400)
Finance costs	(72)	<u>(9)</u>
Loss before taxation	(7,846)	(7,409)
Taxation	540	1,459
Loss for the year attributable to equity owners	(7,306)	(5,950)
Other comprehensive income that may be classified to profit and loss in subsequent periods		
Exchange differences on translation of foreign operations	129	(113)
Total comprehensive loss for the year attributable to equity owners	(7,177)	(6,063)
Loss per share		
Basic and diluted (loss) per share on continuing operations	(5.4p)	(4.7P)

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION AS AT 31 DECEMBER 2019

	2010	2010	1 January
	2019	2018	2018
	£'000	£'000 (Restated)	£'000 (Restated)
ASSETS		(Residied)	(Nestateu)
Non-Current assets			
Property, plant and equipment	5	6	18
Finance lease receivable	113	-	-
Right of use asset	329	-	-
Other non-current assets	217	217	217
Total non-current assets	664	223	235
Current assets			
Finance lease receivable	109	-	-
Related party receivable	245	20	20
Other receivables	124	228	94
Taxation receivable	513	800	1,434
Cash and cash equivalents	153	4,165	48
Total current assets	1,144	5,213	1,596
TOTAL ASSETS	1,808	5,436	1,831
	1,000	3,430	1,031
EQUITY AND LIABILITIES			
Equity			
Capital and reserves attributable to equity holders of the company			
Called up share capital	4,099	4,094	3,752
Share premium	25,194	25,117	18,113
Capital reduction reserve	31,183	31,183	31,183
Shares to be issued reserve (convertible notes)	1,099		
Share based payment reserve (options)	3,850	2,857	2,354
Share based payment reserve (warrants)	1,812	1,399	1,075
Other reserve	(28,286)	(28,286)	(28,286)
Translation reserve	15	(113)	-
Retained earnings	(43,146)	(35,840)	(29,874)
Total equity	(4,180)	411	(1,683)
Liabilities			
Non-Current liabilities			
Lease Liability	411	-	_
Current liabilities			
Trade and other payables	4,851	4,673	3,270
Lease liability	212	-	-
Related party payable	451	352	244
Other liabilities	63	-	_
Total current and non-current liabilities	5,988	5,025	3,514
TOTAL EQUITY AND LIABILITIES	1,808	5,436	1,831

# CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 31 DECEMBER 2019

000	£'000
0.46)	(7.400)
,846)	(7,409)
39	9
-	16
82	41
992	504
-	45
(225)	-
342	108
125	(135)
(17)	1,483
4	12
194	-
129	(222)
-	3
56	-
50	
,125)	(5,544)
	(6,5 1.1)
800	2,093
	2,000
,325)	(3,451)
	(0,102)
_	7,437
,473	1,132
(157)	1,102
	(1,001)
	(1,001)
,316	7,568
.510	7,300
(3)	_
(3)	
(3)	
(3)	_
012)	4,117
012)	7,117
165	48
105	<del></del>
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199	4,165
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# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 31 DECEMBER 2019

				Share Based	Share Based					
			Capital	Payment	Payment	Convertible				
	Share Capital	Share Premium	Reduction Reserve	Reserve (options)	Reserve (warrants)	Loan Note Reserve	Other Reserve	Translation Reserve		Total Equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Balance at 1 January 2018	3,752	18,650	31,183	2,354	419	-	(28,286)	-	(29,755)	(1,683)
Prior period adjustment	-	(537)	_	-	656	-	-	-	(119)	-
Balance at 1 January 2018										
(restated)	3,752	18,113	31,183	2,354	1,075		(28,286)	-	(29,874)	(1,683)
<u>Transactions with owners</u>										
Issue of share capital (private										
placement and IPO)	232	4,864	-	-	-	-	-	-	-	5,096
Issue of share capital (warrants)	44	1,085	-	-	-	-	-	-	-	1,129
Issue of share capital (loan										
conversion)	64	1,240	-	-	-	-	-	-	-	1,304
Share based payment (options)	-	-	-	503	-	-	-	-	-	503
Issue of share capital in lieu of fees	1	40	-	-	-	-	-	-	-	41
Convertible loan note interest	1	15	-	-	-	-	-	-	(16)	-
Share based payment (warrants)	-	(240)	-	-	324	-	-	-	-	84
Total transactions with owners	342	7,004	_	503	324				(16)	8,158
Comprehensive income										
Exchange differences on translating										
foreign operations	-	-	-	_	-	-	-	(113)	-	(113)
Comprehensive loss for the year	-	-	-	-	-	-	_	` -	(5,950)	(5,950)
Total comprehensive income								(113)		(6,063)
•								(===)	(0,000)	(0,000)
Balance as at 31 December 2018										
(Restated)	4,094	25,117	31,183	2,857	1,399	_	(28,286)	(113)	(35,840)	411
Transactions with owners	.,	,	0 =,=00	_,==.	_,		(==,===)	(===)	(55,515)	
Issue of share capital (in lieu of fees)	5	77	_	_	-	-	_	_	_	82
Convertible loan notes issued	_	_	-	_	_	1,473	-	-	-	1.473
Convertible loan note interest	_	_	_	_	-	39	_	-	-	39
Share based payment (options)	-	-	-	993	-	-	-	_	-	993
Issuance of warrants	_	_	_	_	413	(413)	_	_	_	_
Total transactions with owners	5	77	-	993	413	1,099	-	-	-	2,587
Comprehensive income										
Exchange differences on translating										
foreign operations	-	-	-	-	-	-	-	128	-	128
Comprehensive loss for the year									(7,306)	(7,306)
Total comprehensive income		-		-			-	128	(7,306)	(7,178)
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)

### NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED 31 DECEMBER 2019

#### 1. GENERAL INFORMATION

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

These financial statements are presented in thousands of pounds sterling ( $\mathfrak{E}$ '000) which is the functional currency of the primary economic environment in which the Company operates.

The ultimate parent of the group is Planwise Group Limited, incorporated in the British Virgin Islands. Gabriele Cerrone is the ultimate beneficial owner of the entire issued share capital of Planwise Group Limited.

#### 2. 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.

	2019	2018 (restated)
(Loss) attributable to equity holders of the Company (£)	(7,306,423)	(5,950,061)
Weighted average number of ordinary shares in issue	136,482,627	127,553,866
Basic loss per share (pence per share)	(5.4)	(4.7)

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.

#### 3. Audit Opinion

The audit opinion notes a material uncertainty relating to going concern as set out in the paragraph below. The audit opinion has not been modified in respect of this matter.

"We draw attention to Note 2 in the financial statements concerning the applicability of the going concern basis of preparation. As detailed in the financial statements and the Strategic Report, the Group and Parent Company are pre revenue and its business model requires significant ongoing expenditure on research and development. In the period to 31 December 2019 the Group incurred losses after taxation of £7,306,000. At 31 December 2019, the Group and the Company had net liabilities of £4,180,000 and £1,705,000, and cash and cash equivalents of £153,000 and £116,000 respectively. In Note 2, the directors explain that to date they have successfully raised funds to finance clinical trials. Since the year end the Group has raised approximately \$12m in new equity. However, further significant funding will be required to continue their development programmes and to meet liabilities as they fall due. As the directors are confident that the Group will raise the additional funding they have prepared the accounts on the going concern basis. The Group needs to secure sufficient investment to fund their clinical trials in full and ongoing working capital requirements. These conditions indicate that a material uncertainty exists that may cast significant doubt on the Group's and Parent Company's ability to continue as a going concern."