
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 6-K

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

April 2019

Commission File Number: 0001723069

Tiziana Life Sciences plc

(Exact Name of Registrant as Specified in Its Charter)

**3rd Floor,
11-12 St James's Square
London SW1Y 4LB
United Kingdom**

(Address of registrant's principal executive office)

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):

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):

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On April 4, 2019, Tiziana Life Sciences plc (the “Company”) issued a regulatory news service announcement, announcing its Annual Report and Accounts for the year ended December 31, 2018 (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.

TIZIANA LIFE SCIENCES PLC

Date: April 4, 2019

By: /s/ Kunwar Shailubhai

Name: Kunwar Shailubhai

Title: Chief Executive Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Regulatory News Service Announcement, dated April 4, 2019

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

Financial Results for the Year Ended 31 December 2018

London, 4 April 2019 – Tiziana Life Sciences plc (AIM: TILS), the clinical stage biotechnology company focused on targeted drugs to treat diseases in oncology and immunology, today announces its financial results for the year ended 31 December 2018.

Highlights of the period:

RESEARCH & DEVELOPMENT

- Foralumab
 - Following the exclusive licence agreement entered into with The Brigham and Women's Hospital, Inc. relating to a novel formulation of Foralumab in a medical device for nasal administration, the Company filed an investigational new drug application (IND) for the first-in-human evaluation of the nasal administration of Foralumab.
 - Initiated Phase 1 trial to evaluate biomarkers of immunomodulation of clinical responses of the nasal administration of Foralumab in healthy volunteers.
 - Completed cGMP manufacturing of clinical trial materials for a Phase 1 study in preparation of an IND for the first-in-human evaluation of the oral administration of Foralumab.
- Milciclib
 - 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. Top-line data is expected in the second quarter of 2019.
 - Expects to initiate a Phase 2b trial (TZLS (201)-125a-011) dosing Milciclib in combination with Sorafenib (the standard of care) in patients with HCC in 2019.
- TZLS-501 (Anti-IL6R)
 - In preclinical studies, TZLS-501 demonstrated the potential to overcome limitations of other IL-6 blocking pathway drugs
 - TZLS-501 also demonstrated the potential to block or reduce IL-6 signaling in mouse models of inflammation.

LEADERSHIP

- On 4th April 2018, the Group announced the addition of Mr Leopoldo Zambeletti as a non-executive director with responsibility for strategic development. Mr Zambeletti will also chair the Nomination Committee.
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FINANCIAL

- In the period January to October 2018, the Company raised a total of £2,811,363 through issue of new ordinary shares.
- In November 2018, the Company announced pricing of its initial public offering of American Depositary Shares (“ADSs”) raising gross proceeds of £3.42 million.
- On 20 November 2018, in addition to the £3.42 million raised in the US IPO, the Company announced the issue of 607,500 Ordinary Shares totalling £1.09 million.
- On 20 November 2018, the Company also announced the issue of 2,137,625 Ordinary Shares at a price of 60p each to certain persons who had made loans to the Company on terms that the loans would be converted (without interest) into Ordinary Shares in the Company completing a qualifying public offering on Nasdaq, equating to the extinguishment of £1.39 million.

POST PERIOD

- On 7 February 2019, the Company announced that Riccardo Dalla-Favera MD had resigned from his role as Non-Executive Director of the Company.
- On 20 March 2019, the Company announced that it had submitted an IND to the U.S. Food and Drug Administration (FDA) to initiate a Phase 1 clinical trial of enteric-coated capsules of Foralumab in healthy volunteers. This single-site clinical study is expected to enrol 36 subjects and it will be conducted at the Brigham and Women’s Hospital (BWH), Harvard Medical School.

Contacts:

Tiziana Life Sciences plc

Gabriele Cerrone, Chairman and founder

+44 (0)20 7493 2853

Cairn Financial Advisers LLP (Nominated adviser)

Liam Murray / Jo Turner / Richard Nash

+44 (0)20 7213 0880

About Tiziana

Tiziana is a UK biotechnology company that focuses on the discovery and development of novel molecules that treat human disease in oncology and immunology. The Company is focused on its lead compound milciclib. The Company is also in clinical development of foralumab. Foralumab is the only fully human engineered human anti-CD3 antibody in clinical development. This phase II compound has potential application in a wide range of autoimmune and inflammatory diseases, such as nonalcoholic steatohepatitis (NASH), primary biliary cholangitis (PBS), ulcerative colitis, multiple sclerosis, 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>

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

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 2018.

Background

Tiziana Life Sciences plc is a publicly-listed (NASDAQ: TLISA; 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 of small molecule New Chemical Entities.

Clinical Programmes

The Group is focused on targeting large markets with a high unmet medical need. Driven by an obesity and diabetes epidemic, non-alcoholic fatty liver disease (NAFLD) has become the most common liver disease, affecting one-third of the Western world. Between 3% and 5% of NAFLD patients progress to a more severe form of inflammatory disease, known as NASH (non-alcoholic steatohepatitis), a progressive disease associated with chronic inflammation, fibrosis and cirrhosis in the liver. Based on data from US adult Liver Transplant (LT) databases, since 2004 the number of adults with NASH awaiting LTs has almost tripled. In 2013, NASH became the second-leading disease among liver transplant waiting list registrants, after the Hepatitis C virus. It is predicted that NASH may become the leading cause of liver transplantation in the United States by 2020.

The market for NASH therapies is estimated to reach £16.2 billion by 2025 (10.7% CAGR from 2015 to 2025). This anticipated growth has resulted in several high-profile M&A transactions, including four announced deals in 2016 totalling more than £2.3 billion in value. Around 20% of NASH patients progress further to cirrhosis of the liver, which may ultimately develop into fatal HCC, the primary cause of obesity-related cancer death in middle-aged men in the U.S. Liver transplants are the only effective option for end-stage patients, including HCC patients. More effective therapeutic agents to treat Hepatocellular Carcinoma (“HCC”) are needed. Currently approved therapeutic agents are marginally effective and have significant safety issues.

Tiziana Life Sciences is focused on developing novel drugs for treatment of liver diseases with a pipeline of two clinical-stage drug candidates, Foralumab and Milciclib:

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 April 16, 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 was filed in the second quarter of 2018, and a Phase 1 trial to evaluate biomarkers of immunomodulation of clinical responses was initiated in November 2018. The study is expected to be completed by May 2019.

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.

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 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. 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. Top-line data is expected in the second quarter of 2019. This trial is conducted in Sorafenib-resistant HCC patients. 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. It is important to emphasize that 4 out of the 11 patients on treatment, completed 6 months in the trial and then requested continued treatment on a compassionate use basis. Subsequently, 3 patients were approved under the compassionate use program by the respective ethical committees. Among these three patients, one patient completed 9 months, and another completed 13 months of treatment with no apparent signs of toxicity. The third patient continued to receive the treatment and recently reached 16 months of treatment.

Preclinical data presented at the AASLD meeting in November 2018, demonstrated significant tumour reduction in an orthotopic mouse model of HCC following five weeks of treatment with Milciclib (-20% reduction, 30mg/kg/day), Sorafenib (-20% reduction, 20 mg/kg/day) and the combination of Milciclib and Sorafenib (-38% reduction) relative to vehicle control.

Based on the expected synergistic anti-tumour effect of Milciclib and Sorafenib, the Group expects to initiate a Phase 2b trial (TZLS (201)-125a-011) dosing Milciclib in combination with Sorafenib (the standard of care) in patients with HCC in 2019.

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 signalling 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 transsignalling via the agonistic soluble IL-6 receptor in human diseases". *Biochimica et Biophysica Acta*. 1592 (3): 323–343.).

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 £6,108k (2017: £6,770k). The loss is detailed in the consolidated statement of comprehensive income on page 31.

Consolidated Statement of Financial Position

At the end of the year the Group cash balance amounted to £4,165k (2017: £48k) and the total assets of the Group amounted to £5,436k (2017: £1,831k).

Fund raising

In the period, the Group successfully raised funds to further progress its on-going clinical trials and give the Group the resources to expand its presence internationally.

On 16 January 2018, the Company announced that it had raised £150,000 in cash by the issue of 100,000 new ordinary shares at a price of 150p per share, each new ordinary share having a warrant attached entitling the holder to subscribe for one new ordinary share at a price of 160p per share, exercisable until 15 January 2024. Fees in connection with the placing were satisfied through the issue of an additional 63,334 warrants on the same terms.

On 22 January 2018, the Company announced that it had raised £100,000 in cash by the issue of 66,667 new ordinary shares at a price of 150p per share, each new ordinary share having a warrant attached entitling the holder to subscribe for one new ordinary share at a price of 160p per share, exercisable until 22 January 2024. Fees in connection with the placing were satisfied through the issue of an additional 13,333 warrants on the same terms.

On 5 March 2018, the Company announced that it had raised £600,000 in cash by the issue of 600,000 new ordinary shares at a price of 100p per share. Fees in connection with the placing were satisfied through the issue of 78,000 warrants each exercisable at a price of £1.00 each at any time up to 5 March 2023.

On 19 April 2018, the Company announced that it had raised £825,000 in cash by the issue of 1,301,250 new ordinary shares at a price of 80p per share. In addition, the Company issued 51,563 new ordinary shares credited as fully paid and 51,563 warrants exercisable at a price of 80p per share to intermediaries in lieu of commissions on the funds raised.

On 26 October 2018, the Company announced that it had raised £1,136,363 in cash by the issue of 1,515,150 new ordinary shares at a price of 75p per share.

In November 2018, the Company announced pricing of its initial public offering of American Depositary Shares (“ADSs”) representing ordinary shares of nominal value £0.03 each on the Nasdaq Global Market. The United States Securities and Exchange Commission declared it effective with a registration statement relating to such securities on 19 November 2018 and the ADSs were listed for trading on such market under the symbol “TLSA” on 20 November 2018. The Company raised gross proceeds of £3.42 million (or \$4.39 million at a GBP1: US\$1.2839 exchange rate), by offering 442,910 ADS’s at \$9.90.

On 20 November 2018, in addition to the £3.42 million raised in the US IPO, the Company also announced the issue of 607,500 Ordinary Shares at a price of 75p each and 793,144 Ordinary Shares at a price of 80p each to certain persons who had agreed to exercise warrants to acquire Ordinary Shares at a revised exercise price, the proceeds of which were £1.09 million.

On 20 November 2018, the Company also announced the issue of 2,137,625 Ordinary Shares at a price of 60p each to certain persons who had made loans to the Company on terms that the loans would be converted (without interest) into Ordinary Shares in the Company completing a qualifying public offering on Nasdaq, equating to the extinguishment of £1.39 million.

On 11 December 2018, the Company announced that further to its announcement regarding a temporary reduction to exercise prices of outstanding warrants issued on 20 November 2018, it had received a notification from warrant holders to exercise warrants over 54,000 ordinary shares of nominal value 3p each in the capital of the Company at an exercise price between 75p and 80p per share, providing the Company with gross proceeds of £41,567.

Funds raised by the Company were 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 licence agreements, and for general working capital purposes.

Appointments

Non-Executive Director

On 4 April, 2018, the Group announced the addition of Mr Leopoldo Zambelletti as a non-executive director with responsibility for strategic development. Mr Zambelletti will also chair the Nomination Committee.

During a 19 year career as an investment banker, Mr Zambelletti led the European Healthcare Investment Banking team at J.P. Morgan for eight years before taking up the same position at Credit Suisse for a further five years. Since 2013 he has been an independent strategic advisor to life science companies on merger and acquisitions, out-licensing deals and financing strategy. He is a non-executive director of, Qardio Inc., Summit Therapeutics plc, Nogra Pharma Limited, Faron Pharmaceuticals OY and DS Biopharma Limited. Mr. Zambelletti started his career at KPMG as an auditor. Mr. Zambelletti received a B.A. in Business from Bocconi University in Milan, Italy. He serves as a trustee to Barts and the London Charity, which helps to fund the hospitals of the Barts NHS Trust including St Bartholomew, the Royal London and the London Chest Hospitals. He is the founder of the cultural initiative 5x5 Italy.

Resignations

Non-Executive Director

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

Outlook

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

We have outlined our clinical development plan for Foralumab with initial plans to evaluate orally-dosed Foralumab in two clinical indications: NASH and Crohn's disease. The IND for nasal administration for neurodegenerative diseases was submitted in November 2018 and the trial is ongoing smoothly. The IND for oral administration is anticipated to be submitted by March 15, 2019.

For Milciclib, two Phase 2 clinical trials for thymic carcinoma (thymoma) in patients previously treated with chemotherapy were completed. A Phase 2 monotherapy trial using Milciclib to treat patients with hepatocellular carcinoma (HCC) is ongoing and the topline data from this trial is anticipated to be available by July 2019. We expect to commence a Phase 2b combination therapy trial dosing HCC patients with Milciclib and the standard of care, Sorafenib, in the second quarter of 2019.

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

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME FOR THE YEAR ENDED 31 DECEMBER 2018

	<u>2018</u> £'000	<u>2017</u> £'000
Continuing Operations		
Research and development costs	(4,132)	(4,672)
Operating expenses	<u>(3,313)</u>	<u>(3,574)</u>
Operating loss	(7,445)	(8,246)
Finance costs	<u>(9)</u>	<u>(9)</u>
Loss before taxation	(7,454)	(8,255)
Taxation	<u>1,459</u>	<u>1,485</u>
Loss for the year attributable to equity owners	<u>(5,995)</u>	<u>(6,770)</u>
Other comprehensive income that may be classified to profit and loss in subsequent periods		
Exchange differences on translation of foreign operations	<u>(113)</u>	<u>-</u>
Total comprehensive loss for the year attributable to equity owners	<u>(6,108)</u>	<u>(6,770)</u>
Loss per share		
Basic and diluted (loss) per share on continuing operations	<u>(4.7p)</u>	<u>(6.4p)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION FOR THE YEAR ENDED 31 DECEMBER 2018

	<u>2018</u>	<u>2017</u>
	£'000	£'000
ASSETS		
Non-Current assets		
Property, plant and equipment	6	18
Total non-current assets	<u>6</u>	<u>18</u>
Current assets		
Other receivables	1,048	1,548
Other current assets	217	217
Cash and cash equivalents	4,165	48
Total current assets	<u>5,430</u>	<u>1,813</u>
TOTAL ASSETS	<u><u>5,436</u></u>	<u><u>1,831</u></u>
EQUITY AND LIABILITIES		
Equity		
Capital and reserves attributable to equity holders of the company		
Called up share capital	4,094	3,752
Share premium	25,894	18,650
Capital reduction reserve	31,183	31,183
Share based payment reserve (options)	2,857	2,354
Share based payment reserve (warrants)	548	419
Other reserve	(28,286)	(28,286)
Translation reserve	(113)	-
Retained earnings	(35,766)	(29,755)
Total equity	411	(1,683)
Liabilities		
Current liabilities		
Trade and other payables	5,025	3,514
	<u>5,025</u>	<u>3,514</u>
TOTAL EQUITY AND LIABILITIES	<u><u>5,436</u></u>	<u><u>1,831</u></u>

CONSOLIDATED STATEMENT OF CASH FLOWS FOR THE YEAR ENDED 31 DECEMBER 2018

	<u>2018</u>	<u>2017</u>
	£'000	£'000
Cash flows from operating activities		
Loss for the year before taxation	(7,454)	(8,255)
Adjustments for:		
Convertible loan interest accrued	9	9
Loan interest paid as equity	16	-
Shares issued in lieu of fees	41	-
Share based payment – options	504	419
Cancellation of options	-	(105)
Share based payment – warrants	128	228
Net (increase)/decrease in other receivables	(135)	40
Net increase in trade and other payables	1,592	1,790
Depreciation	12	11
(Gain)/Loss on foreign exchange	(222)	35
Lease adjustment	3	(24)
CASH USED IN OPERATING ACTIVITIES	<u>(5,506)</u>	<u>(5,852)</u>
Cash inflow from taxation	2,093	-
NET CASH USED IN OPERATING ACTIVITIES	<u>(3,413)</u>	<u>(5,852)</u>
Cash flows from financing activities		
Proceeds from issuance of ordinary shares	7,437	1,198
Proceeds from issuance of warrants	1,132	-
Fundraising costs	(1,039)	-
NET CASH GENERATED FROM FINANCING ACTIVITIES	7,530	1,198
Cash flows from investing activities		
Acquisition of property, plant and equipment	-	(1)
Acquisition of other investments	-	-
NET CASH GENERATED FROM INVESTING ACTIVITIES	-	(1)
NET INCREASE/ (DECREASE) IN CASH AND CASH EQUIVALENTS	4,117	(4,655)
Cash and cash equivalents at beginning of year	48	4,703
CASH AND CASH EQUIVALENTS AT END OF YEAR	<u>4,165</u>	<u>48</u>

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 31 DECEMBER 2018

	Share Capital	Share Premium	Capital Reduction Reserve	Share Based Payment Reserve	Shares To Be Issued Reserve (warrants)	Convertible Loan Note Reserve	Other Reserve	Retained Earnings	Total Equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Balance at 1									
January 2017	2,832	2,071	31,183	1,935	191	13,535	(28,286)	(20,147)	3,314
Transactions with owners									
Issue of share capital under share-based payment scheme	66	1,131	-	-	-	-	-	-	1,197
Share based payment (options)	-	-	-	980	-	-	-	-	980
Share based payment (warrants)	-	-	-	-	228	-	-	-	228
Options forfeited/cancelled in the year	-	-	-	(561)	-	-	-	(105)	(666)
Convertible loan note interest	-	-	-	-	-	2,767	-	(2,767)	-
Convertible loan note conversion	854	15,448	-	-	-	(16,302)	-	-	-
Prior year adjustments	-	-	-	-	-	-	-	34	34
Total transactions with owners	920	16,579	-	419	228	(13,535)	-	(2,838)	1,773
Comprehensive income									
Comprehensive loss for the year	-	-	-	-	-	-	-	(6,770)	(6,770)
Total comprehensive income	-	-	-	-	-	-	-	(6,770)	(6,770)
Balance as at 31									
December 2017	3,752	18,650	31,183	2,354	419	-	(28,286)	(29,755)	(1,683)
Transactions with owners									
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)	-	-	-	-	129	-	-	-	129
Total transactions with owners	342	7,244	-	503	129	-	-	(16)	8,202
Comprehensive income									
Exchange differences on the	-	-	-	-	-	-	-	(113)	(113)

translating foreign
operations

Comprehensive loss for the year	-	-	-	-	-	-	-	(5,995)	(5,995)
Total comprehensive income	-	-	-	-	-	-	-	(6,108)	(6,108)
Balance as at 31 December 2018	4,094	25,894	31,183	2,857	548	-	(28,286)	(35,879)	411

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

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 (£'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.

	<u>2018</u>	<u>2017</u>
(Loss) attributable to equity holders of the Company (£)	(5,995,153)	(6,769,365)
Weighted average number of ordinary shares in issue	<u>127,553,866</u>	<u>106,403,903</u>
	<u>(4.7)</u>	<u>(6.4)</u>

Basic loss per share (pence per share)

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. Availability of Report and Accounts and Notice of Annual General Meeting

The Company has posted its audited Report and Accounts to 31 December 2018 and Notice of AGM to shareholders. The AGM will be held at the offices of Cooley (UK) LLP, Dashwood, 69 Old Broad Street, London EC2M 1QS. A copy of the Report and Accounts and Notice of AGM are available to be downloaded from the Company's website at www.tizianalifesciences.com.

4. Audit Opinion

The audit opinion contains an emphasis of matter paragraph in relation to material uncertainty related to going concern of the Company regarding the net asset position; the full audit report is below:

Independent Auditor's Report to the members of Tiziana Life Sciences PLC

Opinion

We have audited the financial statements of Tiziana Life Sciences Plc (the 'Parent Company') and its subsidiaries (the 'Group') for the year ended 31 December 2018 which comprise the Consolidated Statement Of Comprehensive Income; the Consolidated and Company Statements Of Financial Position; the Consolidated and Company Statements Of Cash Flows; the Consolidated and Company Statements Of Changes In Equity and notes to the financial statements, including a summary of significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and International Financial Reporting Standards (IFRSs) as adopted by the European Union and, as regards the Parent Company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the Parent Company's affairs as at 31 December 2018 and of the Group's loss for the year then ended;
- the Group's financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union;
- the Parent Company financial statements have been properly prepared in accordance with IFRSs as adopted by the European Union and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard, as applied to SME listed entities and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

The impact on our audit of uncertainties due to Britain exiting the European Union ('Brexit')

The directors' view on the impact of Brexit is disclosed on page 16.

The terms on which the United Kingdom may withdraw from the European Union are not clear and it is therefore not currently possible to evaluate all the potential implications for the Group's and Parent Company's trade, customers, and suppliers, and to the wider economy.

We considered the impact of Brexit on the Group and Parent Company as part of our audit procedures, applying a standard firm wide approach in response to the uncertainty associated with the Group's and Parent Company's future prospects and performance. However, no audit should be expected to predict unknowable factors or all possible implications for the Group and Parent Company, and this is particularly the case in relation to Brexit.

Material uncertainty related to going concern

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 in the early stages of development and its business model requires significant ongoing expenditure on research and development. At 31 December 2018, the Group had net assets of £411,000 and cash and cash equivalents of £4,165,000. In Note 2, the directors explain that to date they have successfully raised funds to finance clinical trials but further funding will be required within the foreseeable future to continue their development programmes and to meet other 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. However, until the Group secures sufficient investment to fund their clinical trials and ongoing working capital requirements, these events or 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.

Our opinion is not modified in respect of this matter.

Key audit matters

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team.

In addition to the matter described in the "Material uncertainty related to going concern" section, we have determined the matter described below to be the key audit matter to be communicated in our report. This matter was addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on this matter. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

Key Audit Matter 1 - Valuation and accounting of options, warrants, and convertible loan notes (Parent Company)

The Group's accounting policy in respect of "share based payments and convertible loan notes" are set out in the accounting policy notes on pages 42 and 43.

The Parent Company operates share-based payments arrangements to remunerate directors and employees in the form of a share options. Additionally, warrants were granted in lieu of fundraising fees in 2015 which are exercisable over four year period.

With regards to the convertible loan notes, IAS 32 requires liability and equity components to be presented separately on the Statement of Financial Position. As a result, particular attention is required when reviewing the contractual obligations of the notes in order to conclude as to their accounting as debt or equity classified.

Due to the complexity in calculation and judgement involved in underlying assumptions for the valuation of share options and warrants, there is a risk that these instruments are not accounted for correctly.

Our response:

Our audit procedures over options, warrants, and convertible loan notes included but were not restricted to:

- We obtained management's valuation of options and warrants based on an appropriate Model and reviewed for completeness and accuracy of information used;
- We reviewed the mechanics of the options and warrants calculations, and validated the inputs to the model;
- We obtained and reviewed the option and warrant agreements for all current year issuances and determined whether or not they were to be accounted for under IFRS 2 Share-Base Payments;
- We examined the contractual obligations of the convertible loan note to ensure that management's accounting for the aforementioned notes under IAS 32 Financial Instruments as debt classified was appropriate;
- We reviewed the calculation for convertible debt instrument and ensured the principal of loan note and accrued interest are recorded appropriately on the financial statements;
- We reviewed Regulatory News Service (RNS) announcements per the London Stock Exchange website for purposes of concluding the completeness and accuracy of current year equity instrument issuances and/or other equity related transactions and conversion of convertible loan notes; and
- We reviewed the disclosure in the financial statements to ensure disclosure is sufficient and appropriate.

Our findings:

Based on our procedures performed, the options, warrants and convertible loan notes were all appropriately accounted for under relevant accounting standards. Management's assumptions were deemed to be reasonable.

Our application of materiality

The scope of our audit was influenced by our application of materiality. We set certain quantitative thresholds for materiality. These, together with qualitative considerations, helped us to determine the scope of our audit and the nature, timing and extent of our audit procedures on the individual financial statement line items and disclosures and in evaluating the effect of misstatements, both individually and on the financial statements as a whole. Based on our professional judgement, we determined materiality for the financial statements as a whole as follows:

Group and Parent Company materiality	Group - £424,000 Parent Company - £250,000
How we determined materiality In determining our materiality, we considered financial metrics which we believed to be relevant. We believe that the benchmark of losses is most appropriate for both Group & Parent Company as the users of the accounts were likely to be most concerned with the annual and accumulated losses of the Group and Parent Company and the Group and Parent Company's ability to continue as a going concern.	
Rationale for benchmark applied Having considered factors such as the Group and Parent Company's AIM and (NASDAQ) listing, we determined materiality at 6.0% of Group and Parent Company's losses for the year.	
Performance materiality – Group and Parent Company We performed our audit procedures using a lower level of materiality – termed 'performance materiality' – which is set to reduce to an appropriate level the probability that the aggregate of uncorrected and undetected misstatements in the financial statements exceeds materiality for the financial statements as a whole. Having considered factors such as the Group's control environment, we set performance materiality at 65% of overall materiality.	Group - £275,000 Parent Company - £162,500
Reporting threshold – Group and Parent Company We agreed with the Audit Committee that we would report to that committee all identified corrected and uncorrected audit differences in excess of this level, together with differences below that level that, in our view, warranted reporting on qualitative grounds.	Group - £12,737 Parent Company £7,500
Component performance materiality range All components have been audited by the group engagement team. Materiality is allocated to components based on size and risk.	£133,904 - £149,500

An overview of the scope of our audit

As part of designing our audit, we determined materiality and assessed the risk of material misstatement in the financial statements. In particular, we looked at where the directors made subjective judgements such as making assumptions on significant accounting estimates.

We gained an understanding of the legal and regulatory framework applicable to the Group and Parent Company, the structure of the Group and the Parent Company and the industry in which it operates. We considered the risk of acts that could be considered to be contrary to applicable laws and regulations, including fraud. We designed our audit procedures to respond to those identified risks, including non-compliance with laws and regulations (irregularities) that are material to the financial statements.

We focused on laws and regulations that could give rise to a material misstatement in the financial statements, including, but not limited to, the Companies Act 2006. We tailored the scope of our Group audit to ensure that we performed sufficient work to be able to give an opinion on the financial statements as a whole. We used the outputs of a risk assessment, our understanding of the Parent Company and Group's accounting processes and controls and its environment and considered qualitative factors in order to ensure that we obtained sufficient coverage across all financial statement line items.

Our tests included, but were not limited to, obtaining evidence about the amounts and disclosures in the financial statements sufficient to give reasonable assurance that the financial statements are free from material misstatement, whether caused by irregularities including fraud, review of minutes of directors' meetings in the year and enquiries of management. As a result of our procedures, we did not identify any Key Audit Matters relating to irregularities, including fraud.

The risks of material misstatement that had the greatest effect on our audit, including the allocation of our resources and effort, are discussed under “Key audit matters” within this report.

Our Group audit scope included an audit of the Group and Parent Company financial statements. Based on our risk assessment, each of the Group’s key subsidiaries (Tiziana Life Sciences Plc & Tiziana Pharma Limited) considered to be a significant component of the Group were subject to a full scope audit by the Group engagement team and other Group entities not considered to be significant components (Tiziana Therapeutics Inc & Longevia Srl), were subject to analytical review and limited audit procedures.

At the Parent Company level we also tested the consolidation process and carried out overall analytical procedures to confirm our conclusion that there were no material misstatements in the aggregated financial information.

Other information

The directors are responsible for the other information. The other information comprises the information included in the Annual Report other than the financial statements and our auditor’s report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement in the financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

Opinions on other matters prescribed by the Companies Act 2006

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the Strategic Report and the Directors’ Report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Strategic Report and the Directors’ Report have been prepared in accordance with applicable legal requirements.

Matters on which we are required to report by exception

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

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

- adequate accounting records have not been kept by the Parent Company, or returns adequate for our audit have not been received from branches not visited by us; or

- the Parent Company financial statements and the parts of the Directors' Remuneration Report to be audited are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

Responsibilities of directors

As explained more fully in the Directors' Responsibilities Statement set out on pages 15 and 16, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view.

In preparing the financial statements, the directors are responsible for assessing the Group's and the Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the Group or the Parent Company or to cease operations, or have no realistic alternative but to do so.

Auditor's responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

Use of the audit report

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

Robert Neate (Senior Statutory Auditor)
for and on behalf of Mazars LLP
Chartered Accountants and Statutory Auditor

Tower Bridge House
St Katharine's Way
London
E1W 1DD