



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

Interim Results for the Six Months Ended 30 June 2019
Advancing pipeline of next generation therapeutics and diagnostics for oncology and immune diseases of high unmet need

London, 30 September 2019 – Tiziana Life Sciences plc ("Tiziana", AIM: TILS, NASDAQ: TLSA), the research and clinical stage biotechnology company focussing on proprietary drug candidates to treat cancer and autoimmune diseases, today announces its interim results for the six months ended 30 June 2019.

Highlights during the period:

RESEARCH & DEVELOPMENT

CLINICAL PROGRAMMES

Foralumab

TZLS-401

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.

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 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 was completed in September 2019 and Phase 1 clinical data demonstrated that nasally administered Foralumab, was well-tolerated at all doses. Importantly, the treatment showed significant positive effects on the biomarkers for activation of mucosal immunity, which is capable of inducing site-targeted immunomodulation to elicit anti-inflammatory effects.

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 third 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.

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 diarrhea, ascites, nausea, fatigue, asthenia, fever, ataxia, headache, and rash were manageable. No drug-related deaths were recorded.

As per the study protocol, data collection was limited to 6-months. Thus, clinical data were not collected from patients under compassionate use treatment. The clinical activity assessment in evaluable patients was based on the investigators' review using the modified Response Evaluation Criteria in Solid Tumors (mRECIST).

- 9 out of 14 patients (64.2%) were approved by their respective ethical committees to continue the treatment.
- 5 of the 9 patients on compassionate use had received Milciclib for a total of 9, 9, 11, 13 and 16 months.
- As of 1 September 2019, the remaining 4 patients continuing the treatment are in their 10th, 11th, 11th and 12th months.
- 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.
- 17 of 28 (60.7%) evaluable patients showed 'Stable Disease' (SD; met at least once in an 8-week interval).
- One patient (3.6%) showed 'Partial Response' (PR, unconfirmed).
- 18 of 28 (64.3%) evaluable patients showed 'Clinical Benefit Rate' defined as CBR=CR+PR+SD (with CR representing Complete Remission).

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.

PRE-CLINICAL PROGRAMMES

Anti IL-6R mAb

TZLS-501, formerly NI-1201

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.

FINANCIAL

- For the six months to 30 June 2019 the consolidated Group made a loss of £3.63m (six months to 30 June 2018: £3.94m).
- The Group ended the period with £0.4m cash as at 30 June 2019 (31 December 2018: £4.1m).

The Company continues to carefully manage its working capital position and continues the process, as referred to below, to seek to raise further funds through the issue of ADSs through a United States Offering as well as through private placements.

Highlights post period:

- On 22 July, 2019, the Group announced the preliminary topline clinical data from a Phase 2a trial of Milciclib as a monotherapy in patients with advanced hepatocellular carcinoma (HCC), the most common form of liver cancer. The primary endpoint of the study was overall safety. Under compassionate use, a few patients continued with total treatment for up to 16 months. Overall, treatment with Milciclib was well-tolerated and no drug-related deaths were recorded. Secondary endpoints of efficacy including progression-free survival (PFS) and time to progression (TTP) are currently being evaluated and will subsequently be reported.
- On 6 August 2019, the Company announced the commencement of an underwritten public offering in the United States of American Depositary Shares ("**ADSs**"), representing ordinary shares of nominal value £0.03 each in the capital of the Company ("**Ordinary Shares**") on the NASDAQ Global Market (the "**Offering**"). There can be no assurance as to whether or when the Offering may be completed, or as to the actual size or terms of the Offering. The price for the Offering has not yet been determined.
- On 4 September 2019 the Group announced additional positive Phase 2a clinical data exhibiting impressive clinical activity of Milciclib monotherapy in patients with advanced Sorafenib-resistant or -intolerant patients with unresectable or metastatic hepatocellular carcinoma (HCC).

- On 16 September 2019 the Group announced that the U.S. Food and Drug Administration (FDA) has allowed the initiation of a Phase I clinical trial in healthy volunteers using a novel oral enteric-coated capsule formulation of Foralumab, a fully human monoclonal antibody (mAb), in collaboration with the Brigham and Women's Hospital (BWH), Harvard Medical School, Boston, MA. This is the first clinical trial in which Foralumab will be administered orally to healthy subjects. The objective is to develop orally administered Foralumab for treatment of autoimmune and inflammatory diseases.

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About Tiziana Life Sciences

Tiziana Life Sciences plc 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, a molecule which blocks the action of specific enzymes called cyclin-dependent kinases (CDK) involved in cell division as well as a number of other protein kinases. Milciclib is currently completing phase II clinical trials for epithelial thymic carcinoma and/or thymoma in patients previously treated with chemotherapy and has filed an IND to enroll patients in an exploratory trial in Hepatocellular Carcinoma (HCC) in EU.

The Company is also in clinical development of foralumab. We believe foralumab is the only fully human anti-human CD3 antibody 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 drug candidate inhibiting specifically Bcl-3 is an innovative approach to suppress growth of metastases.

I am pleased to report on the Group's financial results for the six months ended 30 June 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 of small molecule New Chemical Entities.

The business employs a lean and virtual business model using highly experienced teams of experts for each business function to maximize value accretion and focus capital on the drug development and discovery processes.

In January 2017 the Company established its own R&D facilities at Doylestown Pennsylvania, employing resources with long standing and high qualified experience in the industry.

Financial summary

The Group has made a loss for the six months to 30 June 2019 of £3.63m (six months to 30 June 2018: £3.94m). The loss is detailed in the consolidated statement of comprehensive income.

The Group ended the period with £0.4m cash as at 30 June 2019 (31 Dec 2018: £4.1m).

Fund raising

During the six months to 30 June 2019, Tiziana has not engaged in any fundraising, but it signed an agreement with an underwriter on 25 June 2019 with a view to raise funds in the near future.

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.

Research & Development

On 4 September 2019, Tiziana Life Sciences announced additional positive Phase 2a clinical data exhibiting impressive clinical activity of Milciclib monotherapy in patients with advanced Sorafenib-resistant or intolerant patients with unresectable or metastatic hepatocellular carcinoma (HCC). This Phase 2a multi-center, single-arm, repeated-dose (100 mg once daily; 4 days on/3 days off for 4 weeks; defining each cycle) and 6-month duration study was conducted to evaluate the safety, tolerability and anti-tumor activity of Milciclib in Sorafenib-resistant patients with unresectable or metastatic advanced HCC. The trial enrolled 31 patients in Italy, Greece and Israel, of which 28 patients were evaluable. While the primary endpoint of this study was overall safety, secondary endpoints were also evaluated. As previously announced on 22 July 2019, the clinical data from the Phase 2a trial indicated that Milciclib was well tolerated with manageable toxicities and no recorded drug related deaths, thereby meeting the trial's primary endpoint. The Group expects to initiate a Phase 2b trial dosing Milciclib in combination with Sorafenib (the standard of care) in patients with HCC in the second half of 2019.

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 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 was completed in September 2019 and Phase 1 clinical data demonstrated that nasally administered Foralumab, was well-tolerated at all doses. Importantly, the treatment showed significant positive effects on the biomarkers for activation of mucosal immunity, which is capable of inducing site-targeted immunomodulation to elicit anti-inflammatory effects.

Outlook

It has been a busy six months for the Company as we continue to progress our pipeline of drugs to treat rare cancers and difficult to treat autoimmune inflammatory diseases.

Milciclib met the primary endpoint and secondary endpoints in two phase IIa multi-centered single arm, repeated dose clinical trials in thymic carcinoma (TC) and Thymoma (B3T) patients. Based on satisfying results from the completion of a 6 month trial with 14 sorafenib-resistant HCC patients, which demonstrated that toxicities of the milciclib treatment is manageable, 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. This is due to commence in the second half of 2019.

Following the approval of our Investigational New Drug ("IND") application to the U.S. Food and Drug Administration, phase 1 Clinical Trials with nasally administered Foralumab in healthy volunteers were successfully completed. The trials showed a positive trend in biomarkers of immunomodulation and anti inflammation. We expect to commence a phase 2 study in the forthcoming months.

The U.S. Food and Drug Administration (FDA) has allowed the initiation of a Phase I clinical trial in healthy volunteers using a novel oral enteric-coated capsule formulation of Foralumab, a fully human monoclonal antibody (mAb), in collaboration with the Brigham and Women's Hospital (BWH), Harvard Medical School, Boston, MA. This is the first clinical trial in which Foralumab will be administered orally to healthy subjects. Our objective is to develop orally administered Foralumab for treatment of autoimmune and inflammatory diseases.

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

for the six months ended 30 June 2019

		6 months to 30 June 2019 £'000 (unaudited)	6 months to 30 June 2018 £'000 (unaudited)	12 months to 31 Dec 2018 £'000
	Notes			
Research and development		(1,507)	(2,281)	(4,132)
Operating expenses		(2,202)	(1,575)	(3,313)
Operating loss		(3,709)	(3,856)	(7,445)
Financial income		--	--	--
Financial expense		(5)	(4)	(9)
Operating loss before taxation	5	(3,714)	(3,860)	(7,454)
Taxation		27	--	1,459
Operating loss after taxation		(3,687)	(3,860)	(5,995)
Net loss for the period attributable to equity owners		(3,687)	(3,860)	(5,995)
Other comprehensive income for the period		52	(77)	(113)
Total comprehensive loss attributable to equity owners		(3,635)	(3,937)	(6,108)
Basic and diluted loss per share (pence)				
Basic and diluted loss per share on continuing operations	6	(2.9p)	(3.1p)	(4.7p)
Total basic and diluted loss per share		(2.9p)	(3.1p)	(4.7p)

**Consolidated Statement of Financial Position
as at 30 June 2019**

		30 June 2019 £'000 (unaudited)	30 June 2018 £'000 (unaudited)	31 Dec 2018 £'000
Notes				
Assets				
Non-Current assets:				
	7	5	12	6
	4	358	--	--
		217	217	217
		<u>580</u>	<u>229</u>	<u>223</u>
Current assets:				
	8	245	53	248
		827	965	800
			66	4,165
		445		
		<u>1,517</u>	<u>1,084</u>	<u>5,213</u>
		<u>2,097</u>	<u>1,313</u>	<u>5,436</u>
Equity and liabilities				
Shareholders' equity				
		4,094	3,806	4,094
		25,896	20,271	25,894
	9	3,021	3,017	2,857
		612	485	548
		--	--	--
		--	--	--
		31,183	31,183	31,183
		(28,286)	(28,286)	(28,286)
		(61)	-	(113)
		(39,453)	(33,692)	(35,766)
		<u>(2,994)</u>	<u>(3,216)</u>	<u>411</u>
Current liabilities:				
	11	4,727	4,131	5,025
		87		
		<u>4,814</u>	<u>4,131</u>	<u>5,025</u>
Long term liabilities:				
		--	398	--
	4	277		
		<u>5,091</u>	<u>4,529</u>	<u>5,025</u>
		<u>2,097</u>	<u>1,313</u>	<u>5,436</u>

**Consolidated Statement of Cash Flows
for the 6 months ended 30 June 2019**

	6 months to 30 June 2019 £'000 (unaudited)	6 months to 30 June 2018 £'000 (unaudited)	12 months to 31 Dec 2018 £'000
Cash flows from operating activities			
Total comprehensive loss for the period before tax	(3,714)	(3,860)	(7,454)
Convertible loan interest accrued	--	--	9
Convertible loan interest paid as equity	5	4	16
Shares issued in lieu of fees	-	-	41
Share based payment – options	164	663	504
Cancellation of options	--	--	-
Share based payment – warrants	64	66	128
Net (increase) / decrease in operating assets			
-Trade / other receivables	3	590	(135)
Net increase / (decrease) in operating liabilities			
-Trade / other liabilities	(307)	617	1,592
Depreciation	1	6	12
Loss on foreign exchange	56	(144)	(222)
Lease adjustment	6	3	3
Net cash used in operating activities	(3,722)	(2,055)	(5,506)
Cash inflow from taxation	--	--	2,093
Net cash used in operating activities	--	--	(3,413)
Cash flow from financing activities			
Proceeds from issuance of ordinary shares	2	1,675	7,437
Proceeds from issuance of convertible loan notes	--	--	--
Proceeds from issuance of loans	--	398	1,132
Fundraising costs	--	--	(1,039)
Net cash generated from financing activities	2	2,073	7,530
Cash flows from investing activities			
Acquisition of property, plant and equipment	--	--	-
Acquisition of other investments	--	--	-
Net cash generated from investing activities	--	--	-
Net increase / (decrease) in cash and cash equivalents	(3,720)	18	4,117
Cash and cash equivalents at beginning of period	4,165	48	48
Cash and cash equivalents at end of period	445	66	4,165

**Consolidated Statement of Changes in Equity
for the six months ending 30 June 2019 and 30 June 2018**

(Unaudited)	Share Capital	Share Premium	Share Based Payment Reserve	Shares to Be Issued Reserve	Capital Reduction Reserve	Translation Reserve	Other Reserve	Retained Earnings	Total Equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Balance at 1 January 2019	4,094	25,894	2,857	548	31,183	(113)	(28,286)	(35,766)	411
<u>Transactions with owners</u>									
Issue of share capital	-	2	-	-	-	-	-	-	2
Share based payments (options)	-	-	662	-	-	-	-	-	662
Forfeiture of options	-	-	(498)	-	-	-	-	-	(498)
Share based payments (warrants)	-	-	-	64	-	-	-	-	64
Total transactions with owners	-	2	164	64	-	-	-	-	641
<u>Comprehensive income</u>									
Loss for the period	-	-	-	-	-	-	-	(3,687)	(3,687)
Foreign currency translation	-	-	-	-	-	52	-	-	52
Total comprehensive income	-	-	-	-	-	52	-	(3,687)	(3,635)
Balance at 30 June 2019	4,094	25,896	3,021	612	31,183	(61)	(28,286)	(39,453)	(2,994)
Balance at 1 January 2018	3,752	18,650	2,354	419	31,183	-	(28,286)	(29,755)	(1,683)
<u>Transactions with owners</u>									
Issue of share capital	54	1,621	-	-	-	-	-	-	1,675
Share based payments (options)	-	-	663	-	-	-	-	-	663
Share based payments (warrants)	-	-	-	66	-	-	-	-	66
Total transactions with owners	54	1,621	663	66	-	-	-	-	2,404
<u>Comprehensive income</u>									
Loss for the period	-	-	-	-	-	-	-	(3,860)	(3,860)
Foreign currency translation	-	-	-	-	-	-	-	(77)	(77)
Total comprehensive income	-	-	-	-	-	-	-	(3,937)	(3,937)
Balance at 30 June 2018	3,806	20,271	3,017	485	31,183	-	(28,286)	(33,692)	(3,216)

	Share Capital	Share Premium	Capital Reduction Reserve	Share Based Payment Reserve	Shares to Be Issued Reserve (warrants)	Convertible Loan Note Reserve	Other reserve	Translation reserve	Retained Earnings	Total Equity
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Balance as at 1 January 2018	3,752	18,650	31,183	2,354	419	-	(28,286)	-	(29,755)	(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)	-	-	-	-	129	-	-	-	-	129
Total transactions with owners	342	7,244	-	503	129	-	-	-	(16)	8,202
<u>Comprehensive income</u>										
Exchange differences on translating foreign operations	-	-	-	-	-	-	-	(113)	-	(113)
Loss for the year	-	-	-	-	-	-	-	-	(5,995)	(5,995)
Total comprehensive income	-	-	-	-	-	-	-	(113)	(5,995)	(6,108)
	-	-	-	-	-	-	-	-	-	-
Balance as at 31 December 2018	4,094	25,894	31,183	2,857	548	-	(28,286)	(113)	(35,766)	411

Notes to the Interim Financial Statements for the six month period to 30 June 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 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. ACCOUNTING POLICIES

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

Basis of preparation

These interim consolidated financial statements have been prepared using accounting policies based on International Financial Reporting Standards (IFRS and IFRIC Interpretations) issued by the International Accounting Standards Board ("IASB") as adopted for use in the EU. They do not include all disclosures that would otherwise be required in a complete set of financial statements and should be read in conjunction with the 31 December 2018 Annual Report and Financial Statements. The financial information has not been prepared (and is not required to be prepared) in accordance with IAS 34 Interim Financial Reporting. The annual consolidated financial statements of the group are prepared in accordance with IFRS as adopted by the European Union. The comparative financial information for the year ended 31 December 2018 included within this report does not constitute the full statutory Annual Report for that period.

The Group has applied the same accounting policies and methods of computation in its interim consolidated financial statements as in its 2018 annual financial statements, as set out in Note 2 of that document, except for the adoption of IFRS 16.

Going Concern

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

The Group is in the early stages of developing its business focusing on the discovery and development of novel molecules that treat human disease in oncology and immunology. The Directors expect the company to incur further losses and to require significant capital expenditure in continuing to develop clinical stage development therapeutic candidates in both oncology and immunology. The company has successfully funded clinical trials to date and is in the process of securing additional investment for purposes of continuing to fund their clinical trials moving forward.

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

However, until and unless the Group secures sufficient investment to fund their clinical trials, there is a material uncertainty about the Group's ability to continue as a going concern, and therefore about the applicability of the going concern basis of preparation. The financial statements do not include the adjustments that would be required if the going concern basis of preparation was considered inappropriate.

New and Revised Standards

Standards in effect in 2019

IFRS 16 'Leases' has come into effect from 1 January 2019 and has been adopted by the Group. The impact of the adoption of the leasing standard is disclosed in Note 4 below.

IFRS in issue but not applied in the current financial statements

The Directors do not expect that the adoption of new IFRS Standards, Interpretations and Amendments that have been issued but are not yet effective will have a material impact on the financial statements of the Group in future periods.

Beyond the information above, it is not practicable to provide a reasonable estimate of the effect of these standards until a detailed review has been completed.

A number of IFRS and IFRIC interpretations are also currently in issue which are not relevant for the Group's activities and which have not therefore been adopted in preparing these financial statements.

Basis of consolidation

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

Business combination

The consolidated position of the Group is as a result of the reverse acquisition of Alexander David Investments plc by Tiziana Pharma Ltd and the subsequent listing of the Company as Tiziana Life Sciences plc on 24 April 2014. Reverse acquisition for the business combination in the year as detailed below:

On 24 April 2014, the Company (Alexander David Investments plc, (ADI)) acquired via a share for share exchange the entire issued share capital of Tiziana Pharma Limited, whose principal activity is that of a clinical stage biotechnology company focussed on targeted drugs to treat diseases in oncology and immunology.

Due to the relative values of the companies, the former Tiziana Pharma Limited shareholders became majority shareholders with 96.1% of the enlarged share capital in ADI which was renamed Tiziana Life Sciences plc, and hence hold the majority of the voting rights. Furthermore, the executive management of Tiziana Pharma Limited became the executive management of Tiziana Life Sciences plc. A qualitative and quantitative analysis of these factors led the Directors to conclude that in this transaction Tiziana Pharma Limited has the controlling interest and should be treated as the accounting acquirer.

In determining the appropriate accounting treatment for the reverse acquisition, the Directors considered the Application Supplement to IFRS 3, Business combinations. However, they concluded that this transaction fell outside the scope of IFRS 3 since Tiziana Life Sciences plc, whose activity prior to the acquisition was purely the maintenance of the AIM listing, did not constitute a business. It was therefore determined that the transaction should be accounted for in a manner that was similar to the reverse acquisition accounting as described in IFRS 3, but without recognising goodwill.

The following accounting treatment has been applied in respect of the reverse acquisition;

- The assets and liabilities of the legal subsidiary, Tiziana Pharma Limited are recognised and measured in the consolidated financial statements at their pre-combination carrying amounts, without restatement to their fair value.
- The retained reserves recognised in the consolidated financial statements reflect the retained reserves of Tiziana Pharma Limited to the date of acquisition.
- In applying IFRS 3 by analogy, the equity structure appearing in the consolidated financial statements reflects the equity structure of the legal parent Tiziana Life Sciences plc, including the equity instruments issued under the share exchange to effect the business combination.

- A reverse acquisition reserve has been created to enable the presentation of a consolidated balance sheet which combines the equity structure of the legal parent with the non-statutory reserves of the legal subsidiary.
- Comparative numbers are based upon the consolidated financial statements of the legal subsidiary, Tiziana Pharma Limited for the year ended 31 December 2013 apart from the equity structure which reflects that of the parent.

Tiziana Pharma Limited was incorporated on 4 November 2013 and prepared its first set of financial statements to 31 December 2014. Therefore, the parent and subsidiary had the same reporting date but Tiziana Pharma Limited had a long period of account. No adjustment was made in the consolidated financial statements for the difference in length of reporting period because the only transaction in Tiziana Pharma Limited at 31 December 2013 was the issue of ordinary share capital of £1.

Inter-company transactions, balances and unrealised gains on transactions between group companies are eliminated upon consolidation. Unrealised losses are also eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the group.

Segment reporting

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

Taxation

The tax expense for the year represents the total of current taxation and deferred taxation. The charge in respect of current taxation is based on the estimated taxable profit for the year. Taxable profit for the year is based on the profit as shown in the income statement, as adjusted for items of income or expenditure which are not deductible or chargeable for tax purposes. The current tax liability for the year is calculated using tax rates which have either been enacted or substantively enacted at the balance sheet date.

Deferred tax is provided in full, using the liability method on temporary differences arising between the tax base of assets and liabilities and their carrying values in the financial statements. The deferred tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred tax is determined using tax rates which have been enacted or substantively enacted at the balance sheet date and are expected to apply when the related deferred tax asset is realised or the deferred income tax liability is settled.

Deferred tax assets are recognised to the extent that it is probable that future taxable profits will be available against which the temporary differences can be utilised.

Deferred tax is provided on temporary differences arising on investments in subsidiaries and associates, except where the timing of the reversal of the temporary difference is controlled by the group and it is probable that the temporary difference will not reverse in the foreseeable future.

Foreign currency translation

Foreign currency transactions are translated using the rate of exchange applicable at the date of the transaction. Foreign exchange gains and losses resulting from the settlement of such transactions and from the re-translation at the year end of monetary assets and liabilities denominated in foreign currencies are recognised in the income statement.

On consolidation, the assets and liabilities of foreign subsidiaries are translated into Pound Sterling at the rate of exchange prevailing at the reporting date and their statements of comprehensive income are translated at exchange rates prevailing at the dates of the transactions. The exchange differences arising on translation for consolidation are recognised in other comprehensive income. On disposal of a foreign subsidiary, the component of other comprehensive income relating to that particular foreign subsidiary is recognised in profit or loss.

Research and development

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

Financial instruments

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

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

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

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

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

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

Financial liabilities are classified as measured at amortized cost or FVTPL.

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

The Group's financial liabilities include trade and other payables.

Share capital

Ordinary shares of the company are classified as equity.

Property, plant and equipment

(i) Recognition and measurement

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset. Purchased software that is integral to the functionality of the related equipment is capitalised as part of that equipment.

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

Gains and losses on disposal of an item of property, plant and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, plant and equipment, and are recognised in profit or loss. When revalued assets are sold, the amounts included in the revaluation reserve are transferred to retained earnings.

(ii) Depreciation

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

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

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

IT and equipment	3 years
Fixtures and fittings	5 years

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

Impairment

Impairment of financial assets measured at amortised cost

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

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

General approach

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

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

Simplified approach

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

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

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

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

Leases

IFRS 16 Leases was issued in January 2016 and was implemented by the Group from 1 January 2019. The Standard replaces IAS 17 and requires lease liabilities and 'right of use' assets to be recognised on the balance sheet for almost all leases. The adoption methodology of IFRS 16 is the cumulative catch-up method, and the impact of adoption was to recognise a right of use asset of £435k and a lease liability of £435k on 1 January, 2019.

Fair Value Measurement

Management have assessed the categorisation of the fair value measurements using the IFRS 13 fair value hierarchy. Categorisation within the hierarchy has been determined on the basis of the lowest level of input that is significant to the fair value measurement of the relevant asset as follows;

Level 1 - valued using quoted prices in active markets for identical assets

Level 2 - valued by reference to valuation techniques using observable inputs other than quoted prices included within Level 1

Level 3 - valued by reference to valuation techniques using inputs that are not based on observable market data.

Share based payments

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

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

In accordance with IFRS 2, a charge is made to the Statement of Comprehensive Income for all share-based payments including share options based upon the fair value of the instrument used. A corresponding credit is made to a Share Based Payment Reserve, in the case of options / warrants awarded to employees, directors or advisers, and Shares To Be Issued Reserve in the case of warrants issued in association with the issue of Convertible Loan Notes, net of deferred tax where applicable.

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

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

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

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

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

Other non-current assets

Other current assets are currently measured at cost less accumulated impairment. The asset is not yet being amortised since it is not yet in the condition necessary for it to be capable of operating in the manner intended by management.

Convertible loan notes

Under IAS 32 the liability and equity components of convertible loan notes must be presented separately on the Statement of Financial Position. The Group has examined the terms of each issue of convertible loan notes and determined their accounting treatment accordingly. Convertible loan notes are treated differently depending upon a number of factors.

Where there is no option to repay as cash and the interest rate is fixed

The Group considers these to be Convertible Equity Instruments and records the principal of the loan note as an equity in a Convertible loan note reserve. The accrued interest on the principal amount is also recorded in the Convertible loan note reserve. Upon redemption of the instrument and the issue of share capital, the amount is reclassified from the convertible loan note reserve to share capital and share premium.

Where there is no option to repay as cash and the interest rate is variable

The Group considers these to be Convertible Debt Instruments and records the principal of the loan note as a debt liability in the liabilities section of the balance sheet. The accrued interest on the principal amount is recorded in the income statement and as an increase in the debt liability. Upon redemption of the instrument and the issue of share capital, the amount is reclassified from the debt liability to share capital and share premium.

3. CRITICAL ACCOUNTING ESTIMATES AND JUDGEMENTS

The preparation of financial information in accordance with generally accepted accounting practice, in the case of the Group being International Financial Reporting Standards ('IFRS') as adopted by the European Union, requires the Directors to make estimates and judgements that affect the reported amount of assets, liabilities, income and expenditure and the disclosures made in the financial statements. Such estimates and judgements must be continually evaluated based on historical experience and other factors, including expectations of future events.

When entering into agreements with third parties which provide the rights to conduct research into specific biological processes the group account for these agreements as an expense if the agreements are 'milestone' in nature and relate to the Group's own research and development costs. Such agreements involve periodic payments and are evaluated as representing payments made to fund research.

The only other critical accounting estimates and judgements in the preparation of the financial statements were fair value estimates used in the calculation of share based payments and warrants which have been detailed above in note 2, accounting policies, and note 8, share based payments, to the accounts.

4. CHANGES IN ACCOUNTING POLICIES

The group has adopted IFRS 16 retrospectively from 1 January 2019, but has not restated comparatives for the 2018 reporting period, as permitted under the specific transitional provisions in the standard. The reclassifications and the adjustments arising from the new leasing rules are therefore recognised in the opening balance sheet on 1 January 2019.

On adoption of IFRS 16, the group recognised lease liabilities in relation to leases which had previously been classified as 'operating leases' under the principles of IAS 17 Leases. These liabilities were measured at the present value of the remaining lease payments, discounted using the lessee's incremental borrowing rate as of 1 January 2019. The weighted average lessee's incremental borrowing rate applied to the lease liabilities on 1 January 2019 was 3.35%.

The Group assesses whether a contract is or contains a lease at inception of the contract. The Group recognises a right-of-use assets and corresponding lease liabilities at the lease commencement date, except for short term leases and leases of low value. For these leases, the lease payments are recognised as an operating expense on a straight-line basis over the term of term of the lease.

The right-of-use asset is initially measured at cost, which comprises the initial amount of the lease liabilities adjusted for any lease payments made at or before the commencement date, plus any initial costs incurred. The right-of-use assets are subsequently measured at cost less accumulated depreciation and impairment losses. The right-of-use assets are from the commencement date depreciated over the shorter period of lease term and useful life of the underlying asset. The estimated useful lives of right-of-use assets are determined on the same basis as those of property and equipment. In addition, the right-of-use assets are periodically reduced by impairment losses, if any, and adjusted for certain remeasurements of the lease liabilities, e.g. revised discount rate, change in the lease term or change in future lease payments resulting from a change in an index.

The lease liabilities are initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate determined by the Group's borrowing rate.

	2019 £000
Operating lease commitments disclosed under IAS17 as at 31 December 2018	835

Less low value and short term leases recognised in a straight-line basis as an expense	(42)
Remaining lease commitments discounted using the Group's incremental borrowing rate as at the date of initial application	435
Lease Liability recognised ad at 1 January 2019	435
Of which:	
Current lease liabilities	87
Non-current lease liabilities	277

The associated right-of-use assets for all leases were measured at the amount equal to the lease liability.

The recognised right-of-use assets relate to the following types of assets:

	30 June 2019	1 January 2019
	£000	£000
Properties	358	435
Total right-of-use assets	358	435

5. OPERATING LOSS

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

	6 months to 30 June 2019	6 months to 30 June 2018	12 months to 31 Dec 2018
	(Unaudited) £'000	(Unaudited) £'000	£'000
License Fees	-	176	781
Depreciation	1	6	12
Foreign exchange losses	(136)	(136)	(222)

6. Earnings per share

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

	6 months to 30 June 2019	6 months to 30 June 2018	12 months to 31 Dec 2018
	(unaudited)	(unaudited)	
Total comprehensive loss for the period (£'000)	(3,634)	(3,937)	(6,108)
Basic and diluted weighted average number of shares	126,049,229	126,049,229	127,553,866
Basic and diluted loss per share - pence	(2.9)	(3.1)	(4.7)

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

7. PROPERTY, PLANT AND EQUIPMENT

Details of the Groups property, plant and equipment are as follows:

	Furniture and fixtures £'000	IT equipment £'000	Total £'000
Cost			
At 1 January 2019	12	25	37
Additions	-	-	-
Disposals	-	-	-
At 30 June 2019	12	25	37
Depreciation			
At 1 January 2019	7	24	31
Charge in period	1	-	1
At 30 June 2019	8	24	32
Net book value as at 30 June 2019	4	1	5
Net book value as at 30 June 2018	8	4	12
Net book value as at 31 December 2018	5	1	6

8. Trade and other receivables

	(unaudited) 30 June 2019 £'000	(unaudited) 30 June 2018 £'000	31 Dec 2018 £'000
Trade and other receivables	84	33	195
Related party receivable	150	--	20
Prepayments	11	20	33
	245	53	248

9. Share based payments

Options

The Group operates share-based payment arrangements to remunerate Directors and key employees in the form of a share option scheme. The exercise price of the option is normally equal to the market price of an ordinary share in the Company at the date of grant.

	30 June 2019 (unaudited)		31 December 2018	
	Weighted Average exercise price (pence)	Options (‘000)	Weighted Average exercise price (pence)	Options (‘000)
Outstanding at 1 January	84	18,617	93	10,717
Granted	-	-	82	9,500
Cancelled	-	-	-	-
Forfeited	(46)	(1,480)	(172)	(1,600)

Outstanding at period end	<u>88</u>	<u>17,137</u>	<u>84</u>	<u>18,617</u>
Exercisable at period end	<u>39</u>	<u>3,831</u>	<u>39</u>	<u>5,236</u>

No options were exercised during the period to 30 June 2019.

The total outstanding fair value of the share option instruments is deemed to be approximately £4,483,621 as at 30 June 2019. (2018: £6,486,110).

The Company has used the Black-Scholes option pricing model to estimate the fair value of the options applying the assumptions below.

Historical volatility relies in part on the historical volatility of a group of peer companies that management believes is generally comparable to the Company.

The Company has not paid any dividends on common stock since its inception and does not anticipate paying dividends on its common stock in the foreseeable future.

The Company has estimated a forfeiture rate of zero.

For the options issued with a market condition attached, the Directors have used the Monte Carlo simulation to estimate the fair value of these options, the Company uses the following methods to determine its underlying assumptions:

- expected volatilities are based on the historical volatilities of the market;
- the expected term of the awards is based on managements' assessment of when the market condition is likely to be achieved of 15 years; and
- a range of fair value's per share were produced and management have determined the most appropriate value based on their knowledge of the market and vesting conditions being fulfilled.

Warrants

On 2 March 2015, warrants were granted over 600,000 shares at an exercise price of £0.50 per share in lieu of the issue of options. The warrants are exercisable in 25% portions until 22 January 2016, 22 January 2017, 22 January 2018, and 22 January 2019.

On 31 May 2015, warrants were granted over 292,500 shares at an exercise price of £0.66 per share in lieu of fundraising fees. The warrants are exercisable until 31 May 2022.

On 11 November 2017, warrants were granted over 100,000 shares at an exercise price of £1.60 per share in lieu of fundraising fees. The warrants are exercisable until 20 November 2022.

On 11 December 2017, warrants were granted over 183,333 shares at an exercise price of £1.60 per share in lieu of fundraising fees. The warrants are exercisable until 11 December 2023.

On 15 December 2017, warrants were granted over 196,667 shares at an exercise price of £1.60 per share in lieu of fundraising fees. The warrants are exercisable until 15 December 2023.

On 15 January 2018, warrants were granted over 163,334 shares at an exercise price of £1.60 per share in lieu of fundraising fees. The warrants are exercisable until 15 January 2024.

On 22 January 2018, warrants were granted over 80,000 shares at an exercise price of £1.60 per share in lieu of fundraising fees. The warrants are exercisable until 22 January 2024.

On 5 March 2018, warrants were granted over 78,000 shares at an exercise price of £1.60 per share in lieu of fundraising fees. The warrants are exercisable until 5 March 2024.

On 19 April 2018, warrants were granted over 51,563 shares at an exercise price of £0.8 per share in lieu of fundraising fees. The warrants are exercisable until 19 April 2024.

The Directors have estimated the fair value of the warrants in services provided using an appropriate valuation model. The remaining fair value of the warrant instruments is deemed to be approximately £638,000. For each set of warrants, the charge has been expensed over the vesting period. A share based payment charge for the six months to June 30, 2019 of £63k (six months to June 2018: £66k) has been expensed in the statement of comprehensive income.

10. Convertible loan notes

Planwise Convertible Loan Notes 2016

From the date of the reverse acquisition a convertible loan note of £200,000 was in existence as detailed in the Admission Document dated 31 March 2014. Proceeds of the subscriptions for the notes are to be used exclusively to finance the Group's ongoing working capital requirements. The terms of the loan note are that the loan notes, plus accrued interest at a rate of 4 per cent above Bank of England base rate per annum, will convert into ordinary shares in the Company at a price of £0.10 per share at the election of Planwise any time after the second anniversary of the re-admission to AIM on 24 April 2014.

Accounting for the convertible debt instrument

The net proceeds received from the issue of the Planwise Convertible Loan Note 2016 has been recorded as a debt liability in the Statement of financial position and the accrued interest charged to the Statement of comprehensive income and the debt liability. The liability for the convertible debt instrument at 30 June 2019 is;

	Planwise Convertible Loan Note 2019 £000
Convertible loan notes issued	200
Accrued interest	47
	<u>247</u>

11. Trade and other payables

	(unaudited) 30 June 2019 £'000	(unaudited) 30 June 2018 £'000	12 months to 31 Dec 2018 £'000
Convertible loan note liability	247	238	243
Trade and other payables	3,286	3,400	2,859
Accruals	795	493	1,813
Related party payable	399	--	110
Other creditors	--	--	--
	<u>4,727</u>	<u>4,131</u>	<u>5,025</u>

12. Post balance sheet events

On 22 July 2019, the Group announced the preliminary topline clinical data from a Phase 2a trial of Milciclib as a monotherapy in patients with advanced hepatocellular carcinoma (HCC), the most common form of liver cancer. The primary endpoint of the study was overall safety. Under compassionate use, a few patients continued with total treatment for up to 16 months. Overall, treatment with Milciclib was well-tolerated and no drug-related deaths were recorded. Secondary endpoints of efficacy including progression-free survival (PFS) and time to progression (TTP) are currently being evaluated and will subsequently be reported.

On 6 August 2019, the Group announced the commencement of an underwritten public offering in the United States of American Depositary Shares, representing ordinary shares of nominal value £0.03 each in the capital of the Company on the NASDAQ Global Market. There can be no assurance as to whether or when the Offering may be completed, or as to the actual size or terms of the Offering. The price for the Offering has not yet been determined.

On 4 September 2019, the Group announced additional positive Phase 2a clinical data exhibiting impressive clinical activity of Milciclib monotherapy in patients with advanced Sorafenib-resistant or -intolerant patients with unresectable or metastatic hepatocellular carcinoma (HCC).

On 1 September 2019, the Group reported its Phase 1 clinical data demonstrating that nasally administered Foralumab, was well-tolerated at all doses. Importantly, the treatment showed significant positive effects on the biomarkers for activation of mucosal immunity, which is capable of inducing site-targeted immunomodulation to elicit anti-inflammatory effects.

On 16 September 2019, the Group announced that the U.S. Food and Drug Administration (FDA) has allowed the initiation of a Phase I clinical trial in healthy volunteers using a novel oral enteric-coated capsule formulation of Foralumab, a fully human monoclonal antibody (mAb), in collaboration with the Brigham and Women's Hospital (BWH), Harvard Medical School, Boston, MA. This is the first clinical trial in which Foralumab will be administered orally to healthy subjects. The objective is to develop orally administered Foralumab for treatment of autoimmune and inflammatory diseases.