



DIVISION OF  
CORPORATION FINANCE

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

January 19, 2018

Tiziano Lazzaretti  
Chief Financial Officer  
Tiziana Life Sciences plc  
3rd Floor, 11-12 St. James's Square  
London SW1 4LB, United Kingdom

**Re: Tiziana Life Sciences plc**  
**Draft Registration Statement on Form 20-F**  
**Submitted December 22, 2017**  
**CIK No. 0001723069**

Dear Mr. Lazzaretti:

We have reviewed your draft registration statement and have the following comments. In some of our comments, we may ask you to provide us with information so we may better understand your disclosure.

Please respond to this letter by providing the requested information and either submitting an amended draft registration statement or publicly filing your registration statement on EDGAR. If you do not believe our comments apply to your facts and circumstances or do not believe an amendment is appropriate, please tell us why in your response.

After reviewing the information you provide in response to these comments and your amended draft registration statement or filed registration statement, we may have additional comments.

DRS Form 20-F submitted December 22, 2017

Item 4. Information on the Company

B. Business Overview

Overview, page 49

1. Please clarify the meaning of any scientific or technical terms the first time they are used in order to ensure that lay readers will understand the disclosure. For example, please briefly explain what you mean by “fully human monoclonal anti-CD3 mAB,” “cyclin-dependent kinases,” “microRNAs,” and “anti-IL6R mAB.” Please also explain briefly the significance of Foralumab being a “fully human” monoclonal antibody, as shown in the

graphic on page 52, the “Mayo Risk Score” referenced on page 54 and the “Fc portion of Foralumab” referenced on page 55.

2. Please revise your disclosure that states you acquired Milciclib from Nerviano Medical Sciences S.r.l. to clarify that you have in-licensed the intellectual property relating to the development of this product candidate.
3. The descriptions of our product candidates and the related clinical trials include numerous statements indicating that the candidates are safe and effective. Please remove all statements throughout your registration statement that present your conclusions regarding the safety or efficacy of your drug candidates as these determinations are within the authority of the U.S. Food and Drug Administration and comparable regulatory bodies. With respect to safety, we will not object to statements that your drug candidates were well-tolerated or that no serious adverse events were reported. With respect to statements that your clinical trials demonstrated efficacy, you may present a balanced summary of the data from the clinical trials but not your conclusions that the data demonstrates efficacy. Additionally, revise the descriptions of your clinical trials to describe the endpoints in terms of the objective data points you used to draw your conclusions.

Foralumab (TZLS-401 formerly known as NI-0401), page 51

4. Please revise your filing to disclose Professor Howard Weiner's and Prof. Kevan Herold's membership on your Scientific Advisory Board and any other material relationships they have with you.

Our Product Candidates, page 51

5. Please ensure that all graphs and charts are legible, including the chart on page 65 summarizing your intellectual property portfolio. Additionally, please provide us proofs of all graphics, visual or photographic information you will provide in the printed prospectus prior to its use, for example in a preliminary prospectus. Please note that we may have comments regarding this material.
6. Please remove Crohn's disease from the pipeline development chart since you have determined not to pursue this indication. Additionally, it appears from your disclosure that you are not presently in the position to commence Phase 3 clinical development of Miciclib for the treatment of thymic carcinoma/thymoma. Please revise the arrow for this indication so that it illustrates the current stage of development.

Milciclib (TZLS-201) , page 56

7. Please expand your disclosure on page 57 to explain what you mean that “a block in G1

phase of the cell cycle was observed” and the significance of Milciclib being able to “modulate the phosphorylation of the Retinoblastoma protein...as well as to reduce phosphorylation status of proteins of the TRKa signaling pathway in cells expressing the tyrosine kinase receptor.” Explain how “significant” anti-tumor activity and “consistent tumor growth inhibition” were measured. Additionally, explain the meaning of the statement in the chart on page 60 that references “encouraging clinical benefit in ~36% patients” and tell us why you report the number of patients on page 61 as approximate.

#### Phase I Development, page 58

8. Please revise your table to describe the clinical trial observations that you describe as "disease stabilization," "partial response," and patient benefit. Additionally, explain the meaning of Cmax, daily AUC, CR and PR.

#### Phase II Data in Thymoma and Thymic Carcinoma , page 62

9. Please provide support for your estimated PFS survival rate at three months of about 17% and explain the meaning of “clinically interesting” in this context.

#### Anti-IL6R Fully Human mAb TZLS-501 (formerly known as NI-1201), page 63

10. Please explain how TZLS-501 demonstrated a decreased potential for adverse events and the potential for overcoming the limitations of other IL-6 pathway drugs. Additionally, describe the limitations of other IL-6 pathway drugs.

#### Intellectual Property , page 64

11. Please revise the table on page 65 to identify the licenses related to your rights to each patent family.

#### Collaborations and License Agreements, page 66

12. Please provide your analysis of the Nerviano Option to repurchase shares. Include in this analysis a description of the terms, your determination of accounting treatment for the option, and the specific accounting guidance on which you relied. In addition, specifically tell us why you paid Nerviano £2.1 million for the subscription of 4.2 million of your ordinary shares issued to Nerviano as indicated in the third full paragraph on page 67 and how this is consistent with your disclosure in Note 16 on page F-18 regarding the issuance of these shares.

#### Item 5: Operating and Financial Review and Prospects

##### H. Critical Accounting Policies and Significant Judgments and Estimates

##### Income Taxes, page 90

13. Please tell us how your disclosed use of a valuation allowance against deferred tax assets and your two-step process to determine tax benefits to recognize for uncertain income tax positions complies with your stated policy in Note 2 on page F-8 and the guidance in IAS 12.

Item 9: The Offer and Listing

A. Offering and Listing Details, page 102

14. You indicate that the reported closing prices of your ordinary shares on the AIM is in pounds Sterling; however, the amounts presented in the table appear to be the amounts as reported on the exchange in pence. Please revise your disclosure to either move the decimal point in your table to appropriately reflect your closing prices in pounds Sterling or indicate that the presented amounts are in pence. In addition, please expand your disclosure to include the annual high and low market prices of your ordinary shares for fiscal years ended December 31, 2015 and 2014, and update your disclosure to provide the closing prices for the most recent six months. Refer to Item 9.A.4 of Form 20-F.

Consolidated Statements of Operations and Comprehensive Loss, page F-4

15. Please address the following regarding your presentation of other comprehensive loss and comprehensive loss (referencing, where appropriate, the specific accounting guidance on which you relied):
- Tell how your presentation complies with the guidance in paragraph 81A of IAS 1 to present total other comprehensive income in a single statement of profit or loss and other comprehensive income or two separate statements. In this regard, we note that:
    - you present translation income/loss in your consolidated statements of shareholders' equity that is in addition to that presented in this statement; and
    - therefore, total comprehensive loss presented in this statement differs from that presented in your equity statement.
  - Tell us how your consolidated statements of cash flows complies with the guidance in paragraph 18 of IAS 7. In this regard, although you indicate that those statements begin with net loss, the amounts presented appear to include the other comprehensive loss that is reported in your consolidated statements of operations and comprehensive loss.

Notes to Consolidated Financial Statements

2. ACCOUNTING POLICIES

Basis of preparation, page F-7

16. Please revise your footnote disclosure to specifically indicate that your financial statements are prepared in accordance with IFRS as issued by the International Accounting Standards Board consistent with your disclosure on page 4 and in your

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auditors' report. See Item 17(c) of Form 20-F.

Investments, page F-10

17. As your investments in subsidiary undertakings appear to be eliminated in consolidation, please tell us how your policy indicating that they are presented as non-current assets at cost less provision for any impairment is appropriate. Tell us the specific accounting guidance upon which you relied.

Share based payments, page F-11

18. Please tell us why it is appropriate to accelerate the vesting of share options that are cancelled. In this regard, tell us why vested share options on the cancellation date were not already recorded under paragraphs 15 and 20 of IFRS 2 and why compensation associated with unvested share options on the cancellation date is not reversed under paragraphs 19 and 20 of IFRS 2.

16. SHARE CAPITAL , page F-18

19. Please provide an analysis of the June 30, 2016 capital reduction exercise, including a description of the transaction, the amounts recorded as well as the financial statement line items impacted, and the accounting guidance on which you relied. In addition, tell us how you considered reporting the £41.3 million increase to retained earnings in a separate line item outside of retained earnings, given that this amount does not represent an accumulation of historical earnings.

You may contact Rolf Sundwall at (202) 551-3105 or Mark Brunhofer at (202) 551-3638 if you have questions regarding comments on the financial statements and related matters. Please contact Christine Westbrook at (202) 551-5019 or Suzanne Hayes at (202) 551-3675 with any other questions.

Division of Corporation Finance  
Office of Healthcare & Insurance

cc: Ed Lukins, Esq.