

2 October 2019

Anjuli Sinniah  
Senior Adviser, Listings Compliance (Perth)  
Australian Securities Exchange Ltd

Email: ListingsCompliancePerth@asx.com.au.

Dear Ms Sinniah

In regards to your letter of 27 September 2019 in relation to Queries regarding Accounts, please find below our responses.

	Query	Response
1	<p>Is SUD able to confirm that in the Directors' Opinion the Full Year Accounts:</p> <p>(a) comply with the relevant Accounting Standards; and</p> <p>(b) give a true and fair view of SUD's financial performance and position?</p>	<p>SUD confirms that in the Directors' opinion, the full year accounts for the full year ended 30 June 2019 comply with the relevant Accounting Standards and give a true and fair view of SUD's financial performance and position.</p> <p>The Directors' declaration of 24 September 2019 contained in the full year accounts was resolved unanimously by SUD's board of directors (<b>Board</b>).</p>
2	<p>Given the qualified opinion relates to the recoverable amount of ArTiMist and that the Auditors were unable to obtain sufficient information to form an opinion as to the recoverability of that asset, please explain how the directors satisfied themselves that the carrying value of ArTiMist is \$5,338,148 and that the carrying values are appropriate and adheres to the current Australian Accounting Standards. In answering this question, reference should be made to the underlying assumptions used by the directors in coming to this conclusion, as well as any independent valuations and the validity of the assumptions upon which these valuations are based.</p>	<p>Accounting Standard AASB 136, Impairment of Assets, prescribes the procedures that an entity applies to ensure that its assets are carried at no more than their recoverable amount. The Accounting Standard requires an entity to assess at the end of each reporting period whether there is any indication that an asset may be impaired and test an intangible asset with an indefinite useful life or an intangible asset not yet available for use for impairment annually by comparing its carrying amount with its recoverable amount.</p> <p>The Directors determined the carrying value of ArTiMist as follows:</p> <ul style="list-style-type: none"> <li>An assessment of the likely sale value (being fair value less cost to sell) of ArTiMist was made based on discussions between the Chief Executive Officer and business development management of various pharmaceutical companies who had</li> </ul>

		<p>expressed an interest in the product. This process was informal and primarily evidenced by email exchanges and verbal discussions.</p> <ul style="list-style-type: none"> <li>The assessed likely sale value was then discounted to take into account the TGA's notice of denial for marketing approval of the product, and further discounted for the time value of money.</li> </ul> <p>An independent valuation of ArTiMist was obtained in 2012 and, whilst the performance of the product and the number of cases of malaria in sub-Saharan Africa had not materially declined, the Auditors were of the opinion that the independent valuation was not sufficiently current to be relied upon.</p> <p>The Directors consider they have taken a conservative approach determining the carrying value of ArTiMist as at 30 June 2019.</p>
3	<p>What steps has SUD taken since the release of the Annual Report to obtain an unqualified opinion with regards to its future financial statements?</p>	<p>The Directors note that the basis for the qualified opinion is limited to the recoverable amount of ArTiMist.</p> <p>SUD had submitted an appeal against the TGA decision to deny marketing approval of the product. SUD has recently received notification that its appeal has been dismissed (see SUD's release to the market on 1 October 2019).</p> <p>If a decision is made not to exercise SUD's further appeal rights, the Directors will carry out a full assessment of the viability of the product after taking advice from its advisers. One possible outcome of this assessment may be to fully impair the carrying value of ArTiMist.</p> <p>If a further appeal is made and SUD is ultimately successful, the Directors will consider obtaining a further independent valuation of the product to provide the Auditors with additional audit evidence of the product's carrying value.</p>
4	<p>What steps does SUD intend to take to obtain an unqualified audit opinion with regards to its future financial statements?</p>	<p>Please see SUD's response above.</p> <p>SUD's Risk and Audit Committee, which assists the Board to ensure compliance with SUD's financial reporting obligations, has ongoing discussions with the Auditors concerning SUD's compliance with the relevant Accounting Standards.</p>
5	<p>Does SUD consider that its level of operations is sufficient to warrant continued quotation of its securities on ASX as required under listing rule 12.1? In answering this question, please explain the basis for this conclusion. In answering this question,</p>	<p>The Directors note that the basis for the qualified opinion is limited to the recoverable amount of ArTiMist.</p> <p>SUD has ongoing discussions with the Auditors over this matter. No other aspect of SUD's financial</p>

	<p>please comment on the nature of the SUD's current business activities.</p>	<p>statements for the full year ended 30 June 2019 were queried by the Auditors.</p> <p>As outlined in the Annual Report, SUD has signed the following new agreements:</p> <ul style="list-style-type: none"> <li>• development and licence agreement with Strides, an Indian pharmaceutical company;</li> <li>• supply and licence agreement with Mitsubishi Tanabe Pharma Singapore for its ZolpiMist product;</li> <li>• feasibility study with Zeldia Therapeutics; and</li> <li>• binding term sheet with Cann Pharmaceutical Australia Ltd.</li> </ul> <p>In the prior year, SUD signed a supply and licence agreement with Teva Pharmaceutical Industries.</p> <p>The Directors firmly believe that the level of SUD's operations is sufficient to warrant continued quotation on ASX.</p>
6	<p>Does SUD consider that the financial condition of SUD is sufficient to warrant continued listing on ASX as required under Listing Rule 12.2? In answering this question, please also explain the basis for this conclusion.</p>	<p>The Directors have reviewed SUD's financial position and performance and consider SUD's financial condition is sufficient to warrant continued listing on ASX as required under Listing Rule 12.2.</p> <p>In making this determination, the Directors note that as at 30 June 2019:</p> <ul style="list-style-type: none"> <li>• SUD's cash position was \$4.3m following a successful capital raising in June 2019, which was oversubscribed;</li> <li>• Trade and other receivables totalled \$1.2m; and</li> <li>• Current liabilities totalled \$1.3m.</li> </ul>
7	<p>If the answer to questions 5 or 6 is "No", please explain what steps SUD has taken, or proposes to take, to warrant continued listing on ASX under the requirements of Listing Rules 12.1 and 12.2.</p>	<p>Not applicable.</p>
8	<p>In relation to the Annual Report did the Board receive the CFO and CEO declaration, as described in section 4.2 of SUD's Corporate Governance Disclosure, that in the opinion of the CFO and CEO, the financial records of SUD have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of SUD and that the opinion has been formed on the basis of a sound</p>	<p>As noted in the Directors' Declaration of 24 September 2019 contained in the full year accounts, these declarations were received by the Board.</p>

	system of risk management and internal control which is operating effectively?	
9	If the answer to Question 8 is 'no', why did the Board not receive the CEO and CFO declaration as described in section 4.2 of SUD's Corporate Governance Disclosure?	Not applicable.
10	What enquiries did the Board make of management to satisfy itself that the financial records of SUD have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of SUD?	<p>The primary objective of SUD's Risk and Audit Committee is to assist the Board in the discharge of its fiduciary and corporate governance responsibilities with regard to:</p> <ul style="list-style-type: none"> <li>independently verifying and safe-guarding the integrity and supporting controls of SUDA's financial reporting; and</li> <li>risk oversight.</li> </ul> <p>The Risk and Audit Committee met to discuss the full year accounts on 27 August and 17 September 2019.</p> <p>In relation to the qualified opinion, the chairman of the Risk and Audit Committee discussed the carrying value of ArTiMist with the Auditors and provided feedback to the Board.</p> <p>The Board met to discuss the full year accounts on 23 September 2019.</p> <p>Taking account of all of the above, the Board adopted the financial statements as giving a true and fair view of the financial position and performance of SUD.</p>
11	Commenting specifically on the qualified opinion, does the board consider that SUD has a sound system of risk management and internal control which is operating effectively?	<p>The Board considers that SUD has a sound system of risk management and internal control which is operating effectively. The systems of risk management are appropriate to an entity of SUD's size and nature.</p> <p>As noted above, the chairman of the Risk and Audit Committee discussed the carrying value of ArTiMist with the Auditors and provided feedback to the Board.</p> <p>It is the opinion of the Board, that after considering the required declarations, the carrying value of ArTiMist as at 30 June 2019 complies with the relevant Accounting Standards.</p> <p>It is of the opinion of the Board that the Risk and Audit Committee continues to satisfy its primary objectives.</p>
12	Please confirm that SUD is complying with the Listing Rules and, in particular, Listing Rule 3.1.	The Board confirms that SUD is complying with the Listing Rules and, in particular, Listing Rule 3.1.

13	Please confirm that SUD's responses to the questions above have been authorised and approved under its published continuous disclosure policy or otherwise by its board or an officer of SUD with delegated authority from the board to respond to ASX on disclosure matters.	SUD's responses to the questions above have been authorised and approved by the Board.
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**Joseph Ohayon**  
**Company Secretary**



27 September 2019

Reference: ODIN07764

Mr Joseph Ohayon  
Company Secretary

By email: johayon@sudapharma.com

Dear Mr Ohayon

**Suda Pharmaceuticals Limited ('SUD'): Queries regarding Accounts**

ASX refers to:

- A. SUD's full year accounts for the full year ended 30 June 2019 lodged with ASX Market Announcements Platform and released on 24 September 2019 ('Annual Report).
- B. ASX notes that the Independent Auditor's Report attached to the Annual Report ('Auditor's Report') contains a qualified opinion together with the Basis for qualified opinion]:

*Qualified opinion*

*We have audited the financial report of Suda Pharmaceuticals Limited ("the Company") and its controlled entities ("the Group"), which comprises the consolidated statement of financial position as at 30 June 2019, the consolidated statement of profit or loss and other comprehensive income, the consolidated statement of changes in equity and the consolidated statement of cash flows for the year then ended, and notes to the financial statements, including a summary of significant accounting policies, and the directors' declaration.*

*In our opinion, except for the effects of the matter described in the Basis for qualified opinion paragraph, the accompanying financial report of the Group is in accordance with the Corporations Act 2001, including:*

*a) giving a true and fair view of the Group's financial position as at 30 June 2019 and of its financial performance for the year then ended; and*

*b) complying with Australian Accounting Standards and the Corporations Regulations 2001.*

*Basis for qualified opinion*

*Included in the Group's intangible assets as at 30 June 2019 is the carrying value of ArTiMist of \$5,338,148. The directors of the Company have advised us that, in their opinion, this is the recoverable amount of ArTiMist. We were unable to obtain sufficient appropriate audit evidence regarding the recoverable amount of ArTiMist, in order to form an opinion as to the recoverability of that asset. Consequently, we are unable to determine whether any further adjustment to the carrying value is necessary.*

*We conducted our audit in accordance with Australian Auditing Standards. Our responsibilities under those standards are further described in the Auditor's Responsibilities for the Audit of the Financial Report section of our report. We are independent of the Group in accordance with the auditor*

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*independence requirements of the Corporations Act 2001 and the ethical requirements of the Accounting Professional and Ethical Standards Board's APES 110 Code of Ethics for Professional Accountants ("the Code") that are relevant to our audit of the financial report in Australia. We have also fulfilled our other ethical responsibilities in accordance with the Code.*

*We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our qualified opinion."*

- C. SUD's Corporate Governance Statement for 2019 lodged on the ASX Market Announcements Platform on 24 September 2019 which provides confirmation that SUD complies with recommendation 4.2 of the ASX Corporate Governance Principles and Recommendations which states:

*"The board of a listed entity should, before it approves the entity's financial statements for a financial period, receive from its CEO and CFO a declaration that, in their opinion, the financial records of the entity have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of the entity and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively."*

- D. Listing Rule 12.1 which states:

*12.1 The level of an entity's operations must, in ASX's opinion, be sufficient to warrant the continued +quotation of the entity's +securities and its continued listing.*

- E. Listing Rule 12.2 which states:

*12.2 An entity's financial condition (including operating results) must, in ASX's opinion, be adequate to warrant the continued +quotation of its +securities and its continued listing.*

- F. Listing Rule 19.11A which states:

*19.11A If a listing rule requires an entity to give ASX +accounts, the following rules apply.*

- (a) If the entity controls an entity within the meaning of section 50AA of the Corporations Act or is the holding company of an entity, required by any law, regulation, rule or accounting standard, or if ASX requires, the +accounts must be consolidated +accounts.*
- (b) The +accounts must be prepared to Australian accounting standards. If the entity is a +foreign entity the +accounts may be prepared to other standards agreed by ASX.*
- (c) If the listing rule requires audited +accounts, the audit must be conducted in accordance with Australian auditing standards by a registered company auditor. If the entity is a +foreign entity, the audit may be conducted in accordance with other standards agreed by ASX and may be conducted by an overseas equivalent of a registered company auditor.*
- (d) If the listing rule requires +accounts to be reviewed, the review must be conducted in accordance with Australian auditing standards. If the entity is a +foreign entity, the review may be conducted in accordance with other standards agreed by ASX. Unless the listing rule says an independent accountant may conduct the review, it must be conducted by a registered company auditor (or, if the entity is a +foreign entity, an overseas equivalent of a registered company auditor).*
- (e) If there is a +directors' declaration that relates to the +accounts, the +directors' declaration must be given to ASX with the +accounts.*

- (f) *If there is a +directors' report that relates to the period covered by the +accounts, the +directors' report must be given to ASX with the +accounts.*

### **Request for Information**

In light of the information contained in the Full Year Accounts and the Auditor's Report, and the application of the Listing Rules stated above, please respond to each of the following questions:

1. Is SUD able to confirm that in the Directors' Opinion the Full Year Accounts:
  - (a) comply with the relevant Accounting Standards; and
  - (b) give a true and fair view of SUD's financial performance and position?
2. Given the qualified opinion relates to the recoverable amount of ArtMist and that the Auditors were unable to obtain sufficient information to form an opinion as to the recoverability of that asset, please explain how the directors satisfied themselves that the carrying value of ArtMist is \$5,338,148 and that the carrying values are appropriate and adheres to the current Australian Accounting Standards. In answering this question, reference should be made to the underlying assumptions used by the directors in coming to this conclusion, as well as any independent valuations and the validity of the assumptions upon which these valuations are based.
3. What steps has SUD taken since the release of the Annual Report to obtain an unqualified opinion with regards to its future financial statements?
4. What steps does SUD intend to take to obtain an unqualified audit opinion with regards to its future financial statements?
5. Does SUD consider that its level of operations is sufficient to warrant continued quotation of its securities on ASX as required under listing rule 12.1? In answering this question, please explain the basis for this conclusion. In answering this question, please comment on the nature of the SUD's current business activities.
6. Does SUD consider that the financial condition of SUD is sufficient to warrant continued listing on ASX as required under Listing Rule 12.2? In answering this question, please also explain the basis for this conclusion.
7. If the answer to questions 5 or 6 is "No", please explain what steps SUD has taken, or proposes to take, to warrant continued listing on ASX under the requirements of Listing Rules 12.1 and 12.2.
8. In relation to the Annual Report did the Board receive the CFO and CEO declaration, as described in section 4.2 of SUD's Corporate Governance Disclosure, that in the opinion of the CFO and CEO, the financial records of SUD have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of SUD and that the opinion has been formed on the basis of a sound system of risk management and internal control which is operating effectively?
9. If the answer to Question 8 is 'no', why did the Board not receive the CEO and CFO declaration as described in section 4.2 of SUD's Corporate Governance Disclosure?
10. What enquiries did the Board make of management to satisfy itself that the financial records of SUD have been properly maintained and that the financial statements comply with the appropriate accounting standards and give a true and fair view of the financial position and performance of SUD?
11. Commenting specifically on the qualified opinion, does the board consider that SUD has a sound system of risk management and internal control which is operating effectively?
12. Please confirm that SUD is complying with the Listing Rules and, in particular, Listing Rule 3.1.

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18. Please confirm that SUD's responses to the questions above have been authorised and approved under its published continuous disclosure policy or otherwise by its board or an officer of SUD with delegated authority from the board to respond to ASX on disclosure matters.

**When and where to send your response**

Please note that ASX reserves its right under Listing Rule 18.7A to release this letter and SUD's response to the market. Accordingly, SUD's response should address each question separately and be in a format suitable for release to the market.

Unless the information is required immediately under Listing Rule 3.1, a response is requested as soon as possible and, in any event by no later than **3.00 pm AWST Wednesday, 2 October 2019**.

Any response should be sent to me by return email at [ListingsCompliancePerth@asx.com.au](mailto:ListingsCompliancePerth@asx.com.au). It should not be sent to the ASX Market Announcements Office.

**Enquiries**

If you have any queries regarding any of the above, please contact me.

Regards

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**Anjuli Sinniah**  
Senior Adviser, Listings Compliance (Perth)