



Living Cell Technologies Limited

(the "Company")
Registered Office
Level 7
330 Collins Street
MELBOURNE VIC 3000

ASX Code: LCT

13 September 2019

Ms Lisa Bahn
Senior Advisor, Listings Compliance
Australian Securities Exchange
20 Bridge Street
SYDNEY NSW 2000

Dear Ms Bahn

Living Cell Technologies Limited ('LCT'): Aware Query

Thank you for your letter dated 10 September 2019. The response to the questions that you ask in your letter are as follows (your numbers referenced below):

1. No
2. The information was already known to the market (see below, the answer to question 3).
3. Information referred to in the "Living Insights Newsletter September 2019" (the 'Announcement') is consistent with data on NTCELL trial efficacy previously released to ASX immediately when 6 month, 12 month, 18 month and 24 month data were received by the Company.

Reference in the Announcement to the need for another trial is consistent with this conclusion being announced to ASX on 23 July 2019. "Although successful, the small numbers in the trial necessitate a confirmative larger phase III study. LCT with specialist input from its expert Medical Advisory Board is exploring the feasibility of a further study as it would require additional resources and clinical study design."

It is also consistent with the ASX release lodged on 29 August 2019 "Preliminary Final Report 30 June 2019" which includes a Directors' report that states on p.7 "the in-depth analysis of the entire Phase IIb study of NTCELL data by statisticians and other experts indicates to progress NTCELL towards a marketable product LCT would have to undertake a larger Phase III study which would require further resources and clinical study design. Strategies to achieve the above mission include: With expert opinion explore the feasibility of a confirmative larger Phase III study in NTCELL."

While the information was provided (for the first time) by Medsafe in their letter of 9 May 2019, it could not be considered as price sensitive because it was not clear that an application would not be successful notwithstanding the apparent regulatory position. Further analysis was required. This was undertaken and confirmed the position, following which the announcement of 23 July 2019 was made.

Explanation is as follows. As a continuum of discussions with New Zealand's regulatory agency Medsafe who advise the Minister of Health on the approval of medicines guided by the Medicines Act, the Company received a letter from Medsafe. The letter's intent was to help LCT decide on next steps in the development of NTCELL as a treatment for Parkinson's Disease.

The letter raised issues for the first time notably:

- a) What section of the Medicines Act guides Medsafe's recommendation to approval a xenotransplant product? and
- b) In assessing efficacy data they can comment but would have to seek input from an external agency with expertise (Note: their internal expert Dr Stewart Jessamine who helped design LCTs clinical trials died in early 2019).

In following up with Medsafe on these issues their comment was "it is complicated. They were seeking internal legal advice and would await input from their selected external agency on efficacy". Clearly work in progress at their end.

On 30 May 2019 Medsafe's letter together with several other inputs from expert neurologists, statisticians, regulatory professionals, and commercial consultants was presented and discussed at the LCT board meeting. More information particularly from statisticians and a neurology advisory board was requested by the board.

This was obtained and discussed by the board on 23 July 2019 and the ASX announcement of 23 July 2019 was approved and immediately made.

Each of the inputs including Medsafe's management's opinion if released alone could be misleading as the Board's work in progress remains to decide whether to submit a New Drug Application to Medsafe, undertake a further study to increase patient numbers or neither.

The overall description of our in depth analysis and work in progress was to inform shareholders in a newsletter and also as a directors' comment to the annual financial report.

This will allow more informed discussion at the LCT AGM in November.

LCT still has to decide if it will proceed with a regulatory submission to Medsafe or not, and as communicated is investigating the feasibility of another clinical trial.

4. Not applicable
5. Not applicable
6. I confirm that the Company is in compliance with ASX Listing Rules and in particular Listing Rule 3.1.
7. I confirm that the responses to the questions have been authorised and approved in accordance with the Company's Communication and Disclosure Policy.

We confirm that this response may be released to the market.

Yours sincerely,



Elizabeth McGregor
Company Secretary



10 September 2019

Reference: 06912

Ms Elizabeth McGregor
Company Secretary
Living Cell Technologies Limited

By email:

Dear Ms McGregor

Living Cell Technologies Limited ('LCT'): Aware Query

ASX refers to the following:

- A. LCT's announcement entitled "Living Insights Newsletter September 2019" lodged on the ASX Market Announcements Platform [and released at 03:15 PM] on 9 September 2019 (the 'Announcement'), disclosing the negative future prospects for NTCELL ('Information').
- B. The decline in LCT's share price from \$0.025 immediately prior to the Announcement, to a low of \$0.017 shortly after trading opened this morning, 10 September 2019.
- C. Listing Rule 3.1, which requires a listed entity to immediately give ASX any information concerning it that a reasonable person would expect to have a material effect on the price or value of the entity's securities.
- D. The definition of "aware" in Chapter 19 of the Listing Rules, which states that:

"an entity becomes aware of information if, and as soon as, an officer of the entity (or, in the case of a trust, an officer of the responsible entity) has, or ought reasonably to have, come into possession of the information in the course of the performance of their duties as an officer of that entity" and section 4.4 in Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B "When does an entity become aware of information."

- E. Listing Rule 3.1A, which sets out exceptions from the requirement to make immediate disclosure, provided that each of the following are satisfied.

"3.1A Listing rule 3.1 does not apply to particular information while each of the following is satisfied in relation to the information:

3.1A.1 One or more of the following applies:

- It would be a breach of a law to disclose the information;*
- The information concerns an incomplete proposal or negotiation;*
- The information comprises matters of supposition or is insufficiently definite to warrant disclosure;*
- The information is generated for the internal management purposes of the entity; or*
- The information is a trade secret; and*

3.1A.2 The information is confidential and ASX has not formed the view that the information has ceased to be confidential; and

3.1A.3 A reasonable person would not expect the information to be disclosed."

-
- F. ASX's policy position on the concept of "confidentiality", which is detailed in section 5.8 of Guidance Note 8 *Continuous Disclosure*: Listing Rules 3.1 – 3.1B. In particular, the Guidance Note states that:

"Whether information has the quality of being confidential is a question of fact, not one of the intention or desire of the listed entity. Accordingly, even though an entity may consider information to be confidential and its disclosure to be a breach of confidence, if it is in fact disclosed by those who know it, then it ceases to be confidential information for the purposes of this rule."

- G. Section 4.14 of Guidance Note 8 which says (in part) at the bottom of page 24:

"ASX has experienced difficulties in the past with announcements that have been given a fairly innocuous header (such as "Chairman's Address to AGM") but have had market sensitive material embedded in them. ASX would ask entities to ensure that the header to such an announcement clearly identifies the fact that it contains market sensitive information (eg, "Chairman's Address to AGM and Buyback Announcement") or, better still, that market sensitive announcements are made on a stand-alone basis and not embedded in other announcements that may not be market sensitive."

Request for Information

Having regard to the above, ASX asks LCT to respond separately to each of the following questions and requests for information:

1. Does LCT consider the Information to be information that a reasonable person would expect to have a material effect on the price or value of its securities?
2. If the answer to question 1 is "no", please advise the basis for that view.
3. When did LCT first become aware of the Information?
4. If the answer to question 1 is "yes" and LCT first became aware of the Information before the relevant date, did LCT make any announcement prior to the relevant date which disclosed the information? If so, please provide details. If not, please explain why this information was not released to the market at an earlier time, commenting specifically on when you believe LCT was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps LCT took to ensure that the information was released promptly and without delay.
5. If the answer to question 1 is "yes", why was the Information that contained market sensitive information embedded within the Announcement (newsletter) that may not be market sensitive, rather than disclosed in a separate stand-alone announcement?
6. Please confirm that LCT is complying with the Listing Rules and, in particular, Listing Rule 3.1.
7. Please confirm that LCT's responses to the questions above have been authorised and approved in accordance with its published continuous disclosure policy or otherwise by its board or an officer of LCT with delegated authority from the board to respond to ASX on disclosure matters.

When and where to send your response

This request is made under Listing Rule 18.7. Your response is required as soon as reasonably possible and, in any event, by no later than **9.30 AM AEST Monday, 16 September 2019**.

You should note that if the information requested by this letter is information required to be given to ASX under Listing Rule 3.1 and it does not fall within the exceptions mentioned in Listing Rule 3.1A, LCT's obligation is to disclose the information "immediately". This may require the information to be disclosed before the deadline set out in the previous paragraph and may require LCT to request a trading halt immediately.

If you wish to request a trading halt, you must tell us:

- the reasons for the trading halt;
- how long you want the trading halt to last;
- the event you expect to happen that will end the trading halt;
- that you are not aware of any reason why the trading halt should not be granted; and
- any other information necessary to inform the market about the trading halt, or that we ask for.

We require the request for a trading halt to be in writing. The trading halt cannot extend past the commencement of normal trading on the second day after the day on which it is granted.

You can find further information about trading halts in Guidance Note 16 *Trading Halts & Voluntary Suspensions*.

ASX reserves the right to release a copy of this letter and your response on the ASX Market Announcements Platform under Listing Rule 18.7A. Accordingly, your response should be in a form suitable for release to the market.

Your response should be sent to me by e-mail at ListingsComplianceSydney@asx.com.au. It should not be sent directly to the ASX Market Announcements Office. This is to allow me to review your response to confirm that it is in a form appropriate for release to the market, before it is published on the ASX Market Announcements Platform.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to LCT's obligations under Listing Rules 3.1 and 3.1A and also to Guidance Note 8 *Continuous Disclosure: Listing Rules 3.1 – 3.1B*. It should be noted that LCT's obligation to disclose information under Listing Rule 3.1 is not confined to, nor is it necessarily satisfied by, answering the questions set out in this letter.

Suspension

If you are unable to respond to this letter by the time specified above ASX will likely suspend trading in LCT's securities under Listing Rule 17.3.

Enquiries

If you have any queries or concerns about any of the above, please contact me immediately.

Regards

Lisa Banh
Senior Adviser, Listings Compliance (Sydney)