



19 December 2023

ASX Listing Compliance

525 Collins St
Rialto, North Tower Level 4
Melbourne VIC 3000

Dear Mr Bisset,

Response to ASX Aware Query - Reference: ODIN86234

LTR Pharma Limited (ASX: LTP) refers to your letter dated 15 December 2023 regarding a General - Aware Query and responds to your questions as follows:

1. Does LTP consider the information contained in the Preliminary Report to be information that a reasonable person would expect to have a material effect on the price or value of its securities?

LTP response: No.

2. If the answer to question 1 is “no”, please advise the basis for that view.

LTP response: The Preliminary Report is a preliminary expression of opinion and generally not binding or final. In summary, no patents are granted under the Patent Corporation Treaty (**PCT**), but rather PCT applications facilitate subsequent national and regional phase applications upon which substantive examination occurs and on which a patent may grant. Receipt of a preliminary report containing objections with respect to an application is not unusual and, generally speaking, not definitive or final – the application process continues after the issue of such reports and, as noted earlier, in most cases substantive examination occurs at the national and regional phase applications after further claims have been modified and/or arguments put forth.

LTP considers issuance of the Preliminary Report (or any similar preliminary reports), as a typical part of the patent process and the applicant has numerous opportunities to file arguments or amendments addressing opinions in the Preliminary Report (if the same or similar opinions are also raised by the national/regional examiners during substantive examination).

For the time being, the relevant applications continue to be prosecuted and there is no change as to the status of the patent applications as a result of the issuance of the Preliminary Report.

LTP is also aware of the ASX's *Code of Best Practice for Reporting by Life Science Companies* (**Code**). In the Code, ASX has expressed, in summary, that the fact that a patent application has been filed is seldom material, and that disclosures in relation to patents should be generally made after a patent right becomes a material asset. LTP contends, in line with the policy of the Code, that general information relating to patent filings or progress on patent applications should generally not be disclosed unless the information is balanced and informative and does not otherwise give investors a



misleading impression of the breadth of protection afforded by a patent, the likelihood of grant of a patent or the ability of the company to enforce its patent rights.

In light of the above, LTP does not consider that a reasonable person would expect information in relation to the Preliminary Report to have a material effect on the price or value of its securities.

3. When did LTP first become aware of the Preliminary Report?

LTP response: 13 December 2023. Strategic Drug Solutions Inc. (**SDS**) is currently responsible for the management and prosecution of the patent applications. Receipt of the Preliminary Report was not reported by SDS to LTP (at the time the Preliminary Report was issued), noting LTP does not expect SDS to report on any matters relating to the patent applications where there is no effective change as to the status of the patent applications.

4. If the answer to question 1 is “yes”, has LTP made an announcement which discloses the Preliminary Report, or the information contained in the Preliminary Report? If so, please provide details. If not, please explain why this information has not been released to the market, commenting specifically on when you believe LTP was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps LTP took to ensure that the information was released promptly and without delay.

LTP response: Not applicable.

5. Please confirm that LTP is complying with the Listing Rules and, in particular, Listing Rule 3.1.

LTP response: Yes.

6. Please confirm that LTP’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 LTP with delegated authority from the board to respond to ASX on disclosure matters.

LTP response: Yes.

Yours faithfully,

Belinda Cleminson
Company Secretary



15 December 2023

Reference: ODIN86234

Ms Belinda Cleminson
Company Secretary
LTR Pharma Limited
9/204 Alice Street
Brisbane, QLD, 4000

By email: belinda.cleminson@automicgroup.com.au

Dear Ms Cleminson

LTR Pharma Limited ('LTP'): General – Aware Query

ASX refers to the following:

- A. The International Preliminary Report on Patentability by the International Preliminary Examining Authority dated 16 October 2023 in respect of international patent application no. PCT/US2021/061488 (the 'Patent Application', and such report, the 'Preliminary Report').¹
- B. Statements in the Preliminary Report that, in respect of 38 claims in the Patent Application:
- 'claims 1-10 lack an inventive step under PCT Article 33(3) as being obvious over US 8,911,751 B2 to Touitou et al.';
 - '[c]laims 1-3, 6-7, and (9-10)/7 lack an inventive step under PCT Article 33(3) as being obvious over US 6,740,306 82 to Semo et al.'; and
 - claims 11-38 are 'so unclear that no meaningful opinion could be formed [because] [c]laims 11-38 are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)'.
- C. LTP's replacement prospectus dated 9 November 2023 and published on the ASX Market Announcements Platform on 7 December 2023 (the 'Prospectus').
- D. Statements in the Prospectus that LTP has licenced from Strategic Drug Solutions, Inc. ('SDS') certain intellectual property from which LTP's lead product SDS-089 is derived, that SDS has lodged various patent applications relating to the SDS-089 formulation (including the Patent Application), and that if the patent applications (including the Patent Application) are granted and SDS receives certain milestone payments from LTP, SDS is required to assign to LTP those patents (including the patent underlying the Patent Application).
- E. 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.
- F. 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*

¹ The Preliminary Report is accessible at: https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2022250731&_cid=P22-LQ4H3U-74855-1#detailMainForm:MyTabViewId:PCTDOCUMENTS.

in Guidance Note 8 Continuous Disclosure: Listing Rules 3.1 – 3.1B “When does an entity become aware of information.”

- G. 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.”

- H. 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.”

Request for information

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

1. Does LTP consider the information contained in the Preliminary Report 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 LTP first become aware of the Preliminary Report?
4. If the answer to question 1 is “yes”, has LTP made an announcement which discloses the Preliminary Report or the information contained in the Preliminary Report? If so, please provide details. If not, please explain why this information has not been released to the market, commenting specifically on when you believe LTP was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps LTP took to ensure that the information was released promptly and without delay.
5. Please confirm that LTP is complying with the Listing Rules and, in particular, Listing Rule 3.1.
6. Please confirm that LTP’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 LTP 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 **9:00AM AEDT Wednesday, 20 December 2023**. 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, LTP'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 LTP to request a trading halt immediately.

Your response should be sent by e-mail to **ListingsComplianceMelbourne@asx.com.au**. It should not be sent directly to the ASX Market Announcements Office. This is to allow us 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.

Trading halt

If you are unable to respond to this letter by the time specified above, you should discuss with us whether it is appropriate to request a trading halt in LTP's securities under Listing Rule 17.1. If you wish 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*.

Suspension

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

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to LTP'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 LTP'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.

Release of correspondence between ASX and entity

ASX reserves the right to release all or any part of this letter, your reply and any other related correspondence between us to the market under Listing Rule 18.7A.

Yours sincerely

ASX Compliance