

20 July 2020

The Manager
Australian Securities Exchange
152-158 St Georges Terrace
PERTH WA 6000

Attention: Sean Maloney

Via email

Dear Sir,

General - Aware Query

With reference to your letter of 17 July 2020 Botanix Pharmaceuticals Limited (**Botanix**) provides the following responses:

1. Yes
2. Not applicable
3. Botanix held an End of Phase 2 (EOP2) Meeting with FDA on Thursday 2 July 2020. Draft minutes of that meeting were provided by FDA, as an attachment to a letter from FDA to its regulatory advisers on Tuesday July 7, 2020, which included the usual requirement to notify FDA of any suggested changes that may be required by Botanix to those minutes before finalization. Botanix engaged Intertek, a regulatory consulting firm, to review the minutes and provide suggestions for amendments or corrections of those minutes on Wednesday July 8, 2020. A meeting between Botanix and its regulatory advisers was held on Tuesday July 14, 2020, to discuss potential amendments to the minutes. A further phone call was held with regulatory advisers on Thursday July 16, 2020 where a strategic decision was made not to pursue any amendments to the minutes, given that FDA had confirmed in the minutes that Botanix would have an opportunity to submit a later application for a Special Protocol Assessment (which process could be used to clarify any outstanding questions Botanix may have around the Phase 3 design). Botanix's decision not to seek changes to the minutes on Thursday July 16 meant that the minutes of the meeting would therefore remain unchanged and could be considered final without any further communication with FDA. Botanix proceeded to announce the results of those minutes promptly the next day on Friday July 17, 2020.
4. Botanix did not previously release the information in relation to the FDA meeting. Only 4 board directors (Messrs Ippolito and Callahan and Drs Thurn and Bosch) were aware of the meeting minutes information, along with Botanix's regulatory advisers and 2 key opinion leaders who attended the telephonic meeting. When the minutes were finalized to Botanix's satisfaction and communicated to FDA on Thursday July 16, the "information" was then "sufficiently definite to warrant disclosure".

5. Confirmed

6. Confirmed

Yours sincerely

A handwritten signature in black ink that reads "Simon Robertson". The signature is written in a cursive style with a trailing flourish.

Simon Robertson
Company Secretary



17 July 2020

Reference: 20650

Mr Simon Robertson
Company Secretary
Botanix Pharmaceuticals Ltd

By email: simon@slrconsulting.com.au

Dear Mr Robertson

Botanix Pharmaceuticals Ltd ('BOT'): General – Aware Query

ASX refers to the following:

- A. BOT's announcement entitled "BTX 1503 End of Phase 2 Milestone with FDA" lodged on the ASX Market Announcements Platform today, 17 July 2020 ('Relevant Date') ('Announcement'), disclosing the following, among other things:
- (i) BOT achieved an important drug development milestone through completion of a successful End of Phase 2 meeting for BTX 1503 with the U.S. Food and Drug Administration;
 - (ii) BOT has now confirmed a drug development plan to support registration of BTX 1503 for the treatment of moderate and severe acne; and
 - (iii) Planning is now underway for Phase 3 clinical studies with the final outcomes informed by the completion of the BTX 1702 (rosacea) Phase 2 study and lifting of COVID-19 restrictions, (together 'Information').
- B. The change in the price of BOT's securities from a low of \$0.046 to an intraday high of \$0.056 on 16 July 2020.
- C. The significant increase in the volume of BOT's securities traded from 15 July 2020 to 16 July 2020.
- D. 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.
- E. 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."*
- F. 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;*

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- *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.”*

- G. 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 BOT to respond separately to each of the following questions and requests for information:

1. Does BOT 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 BOT first become aware of the Information?
4. If the answer to question 1 is “yes” and BOT first became aware of the Information before the Relevant Date, did BOT 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 BOT was obliged to release the information under Listing Rules 3.1 and 3.1A and what steps BOT took to ensure that the information was released promptly and without delay.
5. Please confirm that BOT is complying with the Listing Rules and, in particular, Listing Rule 3.1.
6. Please confirm that BOT’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 BOT 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 **4:00 PM AWST Wednesday, 22 July 2020**. 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, BOT’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 BOT to request a trading halt immediately.

Your response should be sent to me by e-mail at ListingsCompliancePerth@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.

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 BOT'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 BOT's securities under Listing Rule 17.3.

Listing Rules 3.1 and 3.1A

In responding to this letter, you should have regard to BOT'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 BOT'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

We reserve the right to release a copy of this letter, your reply and any other related correspondence between us to the market under listing rule 18.7A.

Questions

If you have any questions in relation to the above, please do not hesitate to contact me.

Yours sincerely

Sean Maloney
Adviser, Listings Compliance (Perth)