28 February 2024

Botanix Pharmaceuticals Half Year Report

Key highlights

- **Successfully resubmitted the NDA for *Sofdra*™ in late December 2023, with FDA acceptance confirmed in January 2024 and planned approval on target for late June 2024**
- **Commercial launch preparation activities for Sofdra have been accelerated with pharmacy and telemedicine partners appointed, insurance discussions underway and sales force sizing and positioning now complete**
- **Strong cash position of $18.31 million at December 2023 year-end, not including planned proceeds from R&D tax return and the exercise of outstanding options**

Philadelphia PA and Phoenix AZ, 28 February 2024: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX:BOT, "Botanix" or "the Company"), is pleased to release its Half Year Report for the period ended 31 December 2023. The Company is well positioned, with a strong cash balance and momentum leading into the planned approval of Sofdra in late June 2024.

FDA is currently reviewing the resubmitted New Drug Application (NDA) for Sofdra and confirmed in January 2024, that the resubmission of the Sofdra NDA is a 'Class 2 response' (i.e., a 6-month review period from resubmission), with the result that approval remains on target for late June 2024. The resubmission was focused on the revised patient Instructions For Use (IFU) and the updated draft prescribing information, carton, and other product related information.

During 2H CY 2023, the Company accelerated its commercial launch preparation activities for Sofdra with the appointment of its pharmacy and telemedicine partners, as well as preparing patient and physician-focused launch marketing and sales materials, testing telemedicine and supply chain elements, and finalising sales force sizing and positioning.

In 1H CY24, the Company is continuing to invest in inventory, develop its sales and support infrastructure, undertake discussions with US insurers concerning contracting and pricing for the product and preparing systems for a strong launch of Sofdra, following targeted FDA approval in late June.

At the end of the half year, Botanix held A$18.31m in cash. The Company also expects to receive proceeds from the R&D tax return in the coming quarter, as well as some proceeds from the exercise of approximately 14.6 million outstanding A$0.09 options, which otherwise expire in March 2024. The combination of these sums gives us a strong balance sheet, that is sufficient to fund the Company's operations through planned approval for Sofdra in late June 2024.

Release authorised by

Vince Ippolito
Executive Chairman

About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is progressing its lead product Sofdra for the treatment of primary axillary hyperhidrosis through FDA approval. FDA accepted the resubmission of the NDA for Sofdra in January 2024 as a complete response and confirmed a target approval timing for late June 2024. Sofdra is positioned to be a leading first line and second line therapy and potentially represents a safe and effective new option for patients.

The Company also has a pipeline of other products in late-stage clinical development for range of other dermatology conditions. To learn more please visit: http://www.botanixpharma.com/

For more information, please contact:

General enquiries
Corporate Communications
Botanix Pharmaceuticals
P: +61 8 6555 2945
investors@botanixpharma.com

Investor enquiries
Hannah Howlett
WE Communications
P: +61 450 648 064
hhowlett@we-worldwide.com

Media enquiries
Haley Chartres
H^CK
P: +61 423 139 163
haley@hck.digital

Cautionary Note on Forward-Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, the Company's strategy, future operations, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the Company's ability to successfully develop its product candidates and timely complete its planned clinical programs, the Company's ability to obtain marketing approvals for is product candidates, the expected timing and/or results of regulatory approvals and the outcome and effects of Sofpironium Bromide and the market for Sofpironium Bromide. In addition, the forward-looking statements included in this press release represent the Company's views as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.