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**2 September 2022**

# Botanix completes successful A$7.5m placement to Australian and international institutions and sophisticated investors

## Key highlights

- **Botanix has received firm commitments to raise up to $7.5 million from new and existing institutional and sophisticated investors**
- **Directors of the Company have subscribed for $0.5 million as part of the raising, which is subject to shareholder approval**
- **Funds raised will be used towards the costs associated with the filing for FDA approval for Sofpironium Bromide, preparation for commercial launch in the US, enhancing quality and manufacturing capabilities for Sofpironium Bromide and for general working capital purposes**
- **Sofpironium Bromide NDA filing with FDA remains on track for submission in 3Q CY 2022 with an expected 12-month review process for approval**
- **Botanix's transition to a commercial revenue generating dermatology company accelerating, with its valuable lead asset and pipeline**

**Philadelphia and Phoenix US, 2 September 2022**: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to announce that the Company has received firm commitments from new and existing institutional and sophisticated investors for the placement of 113,636,364 fully paid ordinary shares ("New Shares") at A$0.066 per New Share to raise up to $7.5m in gross proceeds in an oversubscribed placement ("Placement").

Commitments for A$7.5 million worth of New Shares were received from investors who will also receive a free-attaching unlisted option for every two New Shares issued to them under the Placement ("New Options"). Each New Option will have an exercise price of $0.09 and expire 18 months from their date of issue. The New Options are not transferable without the Company's prior written approval, and may only be exercised in the first two weeks of every quarter and the last month prior to their expiry. All other terms will be customary in nature.

All Botanix directors committed to participate in the Placement, with the Directors subscribing for a total of $0.5 million of Ordinary Shares as part of the Placement, which is subject to shareholder approval. Directors are not being issued New Options as part of their participation in the Placement.

The proceeds from the Placement will be used to progress Botanix's lead development program, Sofpironium Bromide gel (15%), including costs associated with filing for FDA approval, preparing for commercial launch in the United States, enhancing quality and manufacturing capabilities, as well as general working capital purposes.

Euroz Hartleys were the sole lead manager and book runner for the Placement.

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**Botanix President and Executive Chair Vince Ippolito said***: "We are delighted by the response of our investors in supporting our plans to file for FDA approval this quarter and commercialise Sofpironium Bromide, for the treatment of axillary hyperhidrosis.*

*With positive Phase 3 data in hand and a multi-billion market opportunity for Sofpironium Bromide, Botanix is in a strong position to transform itself from a small research and development focused company into a leading commercial dermatology company in the US."*

## Sofprionium Bromide filing for FDA approval on target for 3Q CY 2022

Sofpironium Bromide is a topically applied gel which has successfully completed Phase 3 studies with very high statistical significance for the treatment of primary axillary hyperhidrosis (a medical condition which causes excessive underarm sweating). The Company is in the final stages of preparing a New Drug Application ("NDA") which is expected to be filed with the FDA this quarter, with an anticipated approval in 2023 (assuming the usual 12-month review process).

Positive results from Phase 3 clinical studies demonstrated that 60% of patients had a greater than 2-point improvement on the 4-point Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax) scale and greater than 138mg reduction of sweat on average. In addition, secondary endpoints showed that approximately 85% of patients using the gel, experienced a clinically meaningful improvement in their condition. More than 700 patients were enrolled in the two Phase 3 studies and approximately 300 patients participated in a separate 48-week safety study of Sofpironium Bromide. There were no treatment related serious adverse events in any of the studies and adverse events were transient and mild to moderate in nature.

Based on these studies, the Company believes that Sofpironium Bromide has the potential to be the best-in-class treatment for axillary hyperhidrosis, as existing therapies are less than ideal, either because of the lack of sweat control, an unfavourable side effect profile, or pain from invasive injection procedures or severing of the nerves through surgery.

Sofpironium Bromide is a de-risked asset as the drug has already been approved in Japan by the Japanese equivalent of the FDA and was recently launched by Botanix's partner, Kaken Pharmaceutical Co., Ltd (Ecclock® Sofpironium Bromide 5%). Kaken's most recent reported quarterly sales show a significant increase in prescriptions and revenue quarter-on-quarter, and provide a significant indication of the unmet need for new treatments for hyperhidrosis and the potential for the products commercialisation in the US and other international markets.

In the US alone, there are approximately 16 million subjects who suffer from hyperhidrosis, with approximately 7.3 million severe axillary subjects, which is the patient population in which the successful Phase 3 studies were conducted. Of the severe axillary patient population, approximately 3.7 million subjects are actively seeking treatment.[1]

[1] Source. 1.Reports and Data, "Hyperhidrosis Treatment Market By Treatment Type, By Disease Type, By End-User, By Regional Outlook, and Segment Forecasts, 2022.

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## Botanix broader pipeline continues to develop

The Company's product pipeline continues to develop with dermatology and antimicrobial programs which leverage the Company's novel skin delivery technology (Permetrex™), along with the unique anti-inflammatory and antimicrobial properties of synthetic cannabidiol (CBD). The rosacea (BTX 1702) Phase 1b/2 clinical study is now fully enrolled and on track for completion in Q3 CY2022. The study is investigating the safety and tolerability of two different concentrations of BTX 1702 against a vehicle (placebo) in 120 adults over an eight-week treatment period at 16 dermatology sites across Australia and New Zealand. Data readout will follow the completion of the study in 3Q CY2022.

The Company's canine dermatitis (BTX 1204A) pilot study is now also fully enrolled and on track for completion in Q3 CY2022. Given the similarity in disease between humans and canines, further positive outcomes of this study will support progress towards a late-stage Phase 2b clinical study in humans. Finally, Botanix is preparing to initiate a Phase 2 study for its BTX 1801 antimicrobial product which is designed to help reduce the incidence of bloodstream infections suffered by patients undergoing haemodialysis, by killing (or "decolonising") the bacteria that reside in patients' noses. The Company has submitted an application for ethics approval for the planned Phase 2 study and plans to initiate the study in 2H CY2022.

## Transition to commercial dermatology company accelerating

With the upcoming FDA filing of the Sofpironium Bromide NDA, Botanix is accelerating its transition to a commercial dermatology company that can be revenue generating following FDA approval, which is expected to be received 12 months after filing. To support this transition, Botanix has begun building its commercial capability led by its Chief Commercial Officer Howie McKibbon, and will be preparing for the important mid-cycle review from FDA which occurs 6 months after filing of the NDA. The Company will continue to look for other opportunities to bolster its pipeline with additional late stage or revenue producing dermatology products, that can be acquired for modest cost and which contribute to profitability and value.

## Placement details

The Offer Price of A$0.066 per share represented a 17.5% discount to the last traded price on 30 August 2022 (A$0.08) and a 18.7% discount to the 15-day VWAP (A$0.0812) prior to the trading halt.

The New Options and 8,137,218 of the New Shares to be issued under the Placement will be issued in accordance with the Company's available 15% placement capacity pursuant to ASX Listing Rule 7.1. The remaining 97,923,388 New Shares will be issued under the Company's available 10% ASX Listing Rule 7.1A capacity given the issue price for the New Shares is not less than 75% of the 15-day VWAP for the Company's shares. The New Shares the subject of the Directors' commitments do not take up capacity as they are subject to shareholder approval under ASX Listing Rule 10.11.

New Shares issued under the Placement will rank equally with the Company's existing shares on issue. Any shares issued on exercise of the New Options will rank equally with the Company's fully paid ordinary shares then on issue.

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## Indicative Timetable*

| Event | Date |
|---|---|
| Trading halt lifted | Friday. 2 September 2022 |
| Settlement under Placement (other than Directors) | Friday, 9 September 2022 |
| Allotment of New Shares and New Options (other than Directors) | Monday, 12 September 2022 |
| New Shares (other than Directors) expected to commence trading | Monday, 12 September 2022 |
| Annual General Meeting (including for approval of issue of New Shares to Directors) | Friday, 21 October 2022 |
| Expected date of allotment of New Shares to Directors (subject to shareholder approval) | Monday, 24 October 2022 |

** These dates are indicative only and are subject to change at Botanix's discretion, subject to compliance with applicable laws and the ASX Listing Rules.*

Release authorised by

**Vince Ippolito**
President and Executive Chairman

## About Botanix Pharmaceuticals

Botanix Pharmaceuticals Limited (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which is committed to the development of novel treatments for a range of common skin diseases. The Company has a mature dermatology pipeline with its first product, Sofpironium Bromide, for the treatment of primary axillary hyperhidrosis, planned to be filed for FDA in Q3 CY2022. The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea, dermatitis and acne respectively. Botanix is also developing a topical antimicrobial product for the eradication of bacteria on the skin surface, initially in patients who are undergoing hemodialysis.

Botanix leverages its proprietary drug delivery system (Permetrex™) for direct skin delivery of active pharmaceuticals in all skin diseases, which is utilised in its existing development programs and is being explored with a view to being utilized in a number of other product opportunities. To learn more please visit: http://www.botanixpharma.com/

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## 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.

## Not an offer in the United States

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