

8 November 2023

## Botanix Pharmaceuticals Limited Annual General Meeting Chairman's Address

Good morning everyone and thank you for attending the Botanix Pharmaceuticals Limited ("Botanix") AGM. I am sorry that CEO Dr Howie McKibbon and I cannot be there in person, as we spent all last week in Australia on an institutional roadshow, so you are in the capable hands of Directors Matt Callahan and Stewart Washer in person today in Perth.

Since our AGM last year, we have made substantial progress towards transforming Botanix into a commercial, revenue generating dermatology company and I'll talk briefly today about some of those achievements, our vision for the next 12 months and also the longer-term vision for what Botanix can be, and when approved, success from our first product launch, Sofdra™. First, however, I would like to acknowledge the work of our team led by our CEO, Dr Howie McKibbon, along with our development team with support from our board members and valued consultant team. Despite being a team of less than 10 people, we have been able to take a late-stage research asset and move it through the FDA process towards approval and preparation for launch. Without a doubt, we have an exceptional team.

Sofdra represents a significant opportunity for Botanix, as the only new chemical entity ever developed for the treatment of excessive underarm sweating (or hyperhidrosis). This is important, as most of the options for patients currently available are reformulations of old drugs that have challenges with off target effects, or application problems that mean that this patient population is very underserved. With the third largest patient population in dermatology, with ten million sufferers of the condition, many of them have given up due to the lack of effective solutions – we aim to provide a new option to this significant patient population.

The recent FDA feedback provides great confidence to us, that the safety and efficacy data we have developed for Sofdra represents a compelling package. FDA had no issues with our efficacy, safety, manufacturing, and other information presented in the NDA which was very pleasing. The FDA does require us to make some minor changes to the patient Instructions for Use and resubmit the NDA for approval, and we are on track to resubmit early in the new year, targeting FDA approval in mid-2024. So, from where we sit today, we are within a bit more than 6 months away from target approval and the commencement of revenue generation shortly thereafter.

The team is very well prepared and experienced in the launch of new dermatology products, having successfully done this with thirty products to date. Our discussions with payers or insurers in the US are well advanced and we have developed a novel telemedicine and distribution network that will improve profitability and accelerate Sofdra into the hands of

patients. With a highly focused small sales force, we can cover the large majority of regular prescribers of products for hyperhidrosis and our telemedicine platform will extend our reach beyond the dermatologists' door, to those any unserved patients around the US.

Finally, before I hand it over to the team to walk through a quick overview of our progress, I want to reiterate the timing for Sofdra and the opportunity that this novel product presents.

In mid-2024 we are planning for approval from the FDA for Sofdra and will follow that with a successful launch and revenue generation. With ten million patients in the US alone and only a few good solutions in the market, we have a substantial revenue opportunity to address, and we have the team and experience to do that effectively. It is an exciting time for Botanix, and we welcome the support of our existing and new investors as we execute on the vision for the company to build the leading independent dermatology company in the world.

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 is planning for a resubmission of the NDA for SOFDRA in 1Q CY2024 with approval targeted for mid-CY2024. Sofpironium Bromide 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 studies for the treatment of moderate to severe rosacea (successful Phase 1b/2 study in 4Q 2022), 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. To learn more please visit:  
<http://www.botanixpharma.com/>

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