

11 March 2024

## Botanix to Present at Euroz Hartleys Institutional Conference

### Key highlights

- Botanix Pharmaceuticals will participate in the annual Euroz Hartleys Institutional Conference being held March 12–14 on Rottnest Island
- Botanix CEO Dr Howie McKibbon will be among the featured presenters tomorrow at the renowned “Rotto” Conference
- Botanix Executive Chairman Vince Ippolito will also take part in a panel discussion with Australia-based life science companies
- The Conference brings together institutional and sophisticated investors from around Australia and internationally, to showcase small to mid-cap companies with a Western Australian focus
- Botanix will provide an update on progress towards commercialisation of *Sofdra*<sup>™</sup>, which remains on track for FDA approval in late June 2024, as launch readiness activities accelerate

**Philadelphia and Phoenix US, 11 March 2024:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX:BOT, “Botanix” or “the Company”), is pleased to announce the Company’s participation in the annual Euroz Hartleys Institutional Conference being held March 12–14 on Rottnest Island. Botanix CEO Dr Howie McKibbon is among the featured presenters tomorrow at the Conference and Executive Chairman Vince Ippolito will also take part in a panel discussion with Australia-based life science companies.

The Conference brings together institutional and sophisticated investors around Australia and internationally to showcase small to mid-cap companies with a Western Australian focus. Botanix will provide an update on progress towards commercialisation of *Sofdra*<sup>™</sup>, which remains on track for FDA approval in late June 2024, as launch readiness activities accelerate.

A copy of the presentation being given by the Company is attached to this press release.

This ASX announcement is authorised for release by the Board.

### 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/>

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# Euroz Hartleys Rottnest Island Institutional Conference

March 2024

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# Botanix – accelerating towards commercialization of Sofdra™

## DERMATOLOGY FOCUS

New treatments for underserved common skin diseases, with an initial focus on excessive sweating (“primary axillary hyperhidrosis”)

## TOPICALLY DRIVEN

Targeting key indications with topical (gel) treatments that are designed for safety, tolerability, and clinical efficacy

## EXPERIENCED TEAM

US-based team that has been responsible for successful development and commercial launches of more than 30 dermatology drugs

## NEW PRODUCT “SOFDRA”

Sofpironium Bromide (*Sofdra*)<sup>1</sup> is the first and only new chemical entity developed for primary axillary hyperhidrosis (5% strength approved in Japan with solid sales)<sup>2</sup>

## TARGETING MID-24 FDA APPROVAL

Resubmission of NDA for approval was completed in late December 2023; targeting FDA approval in late June 2024

# Corporate Overview

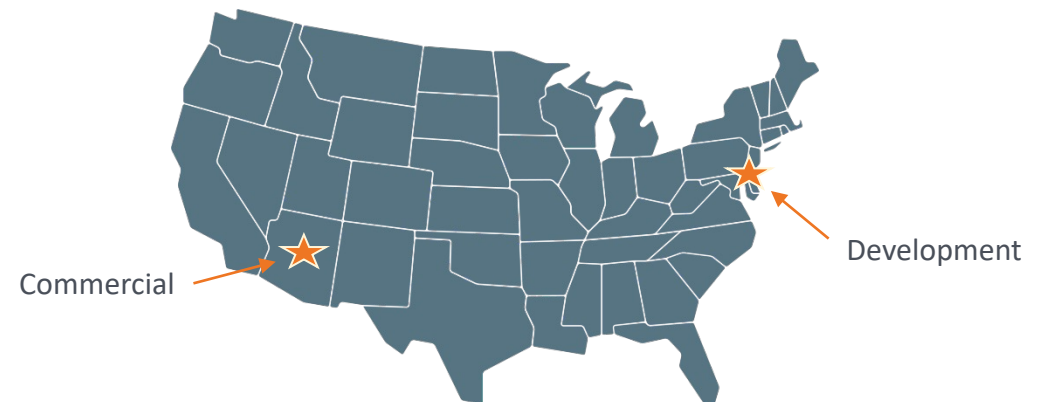
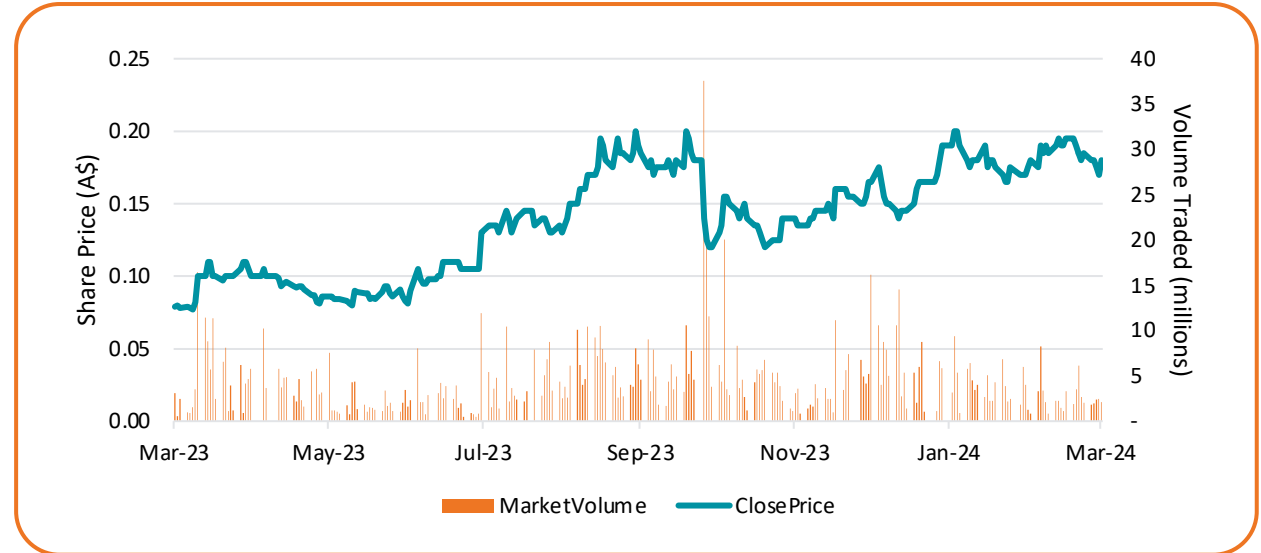
Well-funded to FDA approval, supported by leading life science institutional investors

## ASX: BOT TRADING INFORMATION

Share price	A\$0.185
6-month low / high	A\$0.12/0.20
Shares outstanding	1,563,437,373
<b>Market Capitalization</b>	<b>A\$275m</b>
Cash	A\$ 18.3m
Debt	Nil

## SUBSTANTIAL SHAREHOLDERS

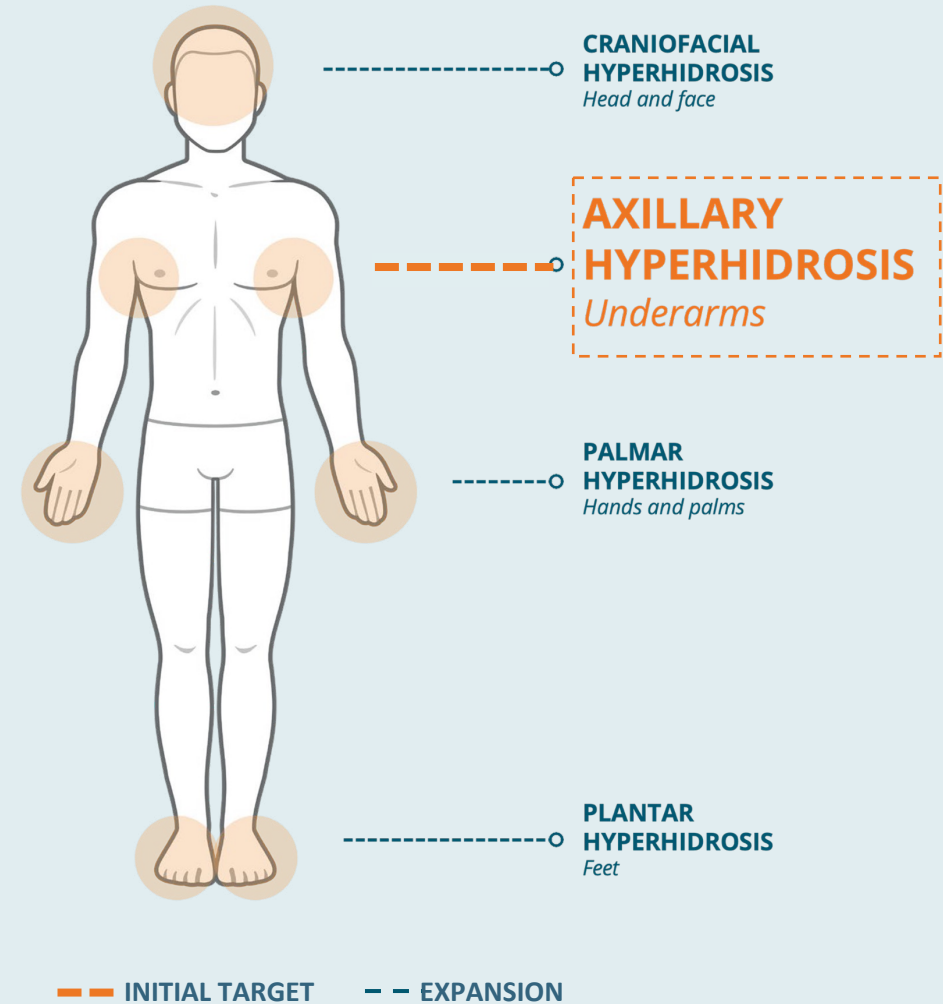
Shareholder	%
Antares Capital	9.0%
Board and Management	7.0%
Top 20	33%



# Hyperhidrosis

A medical condition where excessive sweating occurs beyond what is needed to maintain normal body temperature

- ❖ Hyperhidrosis affects ~16M people in the US<sup>1</sup>
- ❖ Results from overstimulation of the nervous system (a physiological not psychological condition)<sup>1</sup>
- ❖ 90% of axillary (underarm) patients also have it in a second region<sup>1</sup>
- ❖ The most common age of onset for axillary hyperhidrosis patients is 12–17<sup>2</sup>
- ❖ **Market for treatments is ~\$US1.6B per annum—projected to grow to \$US2.8B by 2030<sup>2</sup>**



FREQUENTLY  
CHANGE  
CLOTHES



FRESHEN UP  
BY WIPING OR  
BATHING



PLACE NAPKINS OR  
PADS UNDER THEIR  
ARMS OR THEIR  
POCKETS



HIDE UNDER  
DARK-COLOURED,  
BULKY CLOTHES

# Our lead asset: Sofpironium Bromide (*Sofdra*)<sup>1</sup>

The only new chemical entity developed specifically for the treatment of primary axillary hyperhidrosis

- ❖ Met both co-primary endpoints in two Phase 3 trials<sup>2</sup>
  - 60% of subjects had  $\geq 2$ -point improvement in HDSM-Ax
  - 65% had a significant reduction in GSP sweat production
- ❖ Met all secondary endpoints including clinically meaningful effect on 85% of patients
  - $\geq 1$ -point improvement in HDSM-Ax
  - Statistically significant improvement
- ❖ Favorable tolerability and safety profile<sup>3</sup>
  - Well-tolerated with adverse events that were mostly mild or moderate, and events were transient



Proposed packaging subject to FDA approval

1. Sofdra (sofpironium bromide gel, 15%) is an investigational drug and is not FDA approved. The Sofdra brand name is under review by FDA  
2. Two identical randomized, double-blinded, vehicle-controlled Phase 3 trials for primary axillary hyperhidrosis (pooled; sofpironium bromide gel, 15% n=353; vehicle n=348)  
3. Dry mouth and blurred vision were the predominant treatment-emergent adverse events at 14.4% and 8.5%, respectively, and are common among anticholinergic drugs

# Innovative launch strategy to accelerate adoption following approval

Rapidly establish *Sofdra* as a safe and effective first line treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older

- Drive Derm adoption through comprehensive engagement around a compelling clinical story
- Engage and motivate patients to take control of their hyperhidrosis by visiting a telemedicine doctor for a diagnosis and prescription
- Maximize favorable coverage
- Provide patient access and immediate fulfillment through telemedicine and pharmacy network with mail-order fulfillment to drive trial while ensuring compliance
- Hire and train a highly effective Sales Force



# Planned launch activities targeting high prescribers of HH products

In-office rep activities will include video, animation, and printed leave behinds

Digital advertising to drive targeted prescribers to SofdraHCP.com



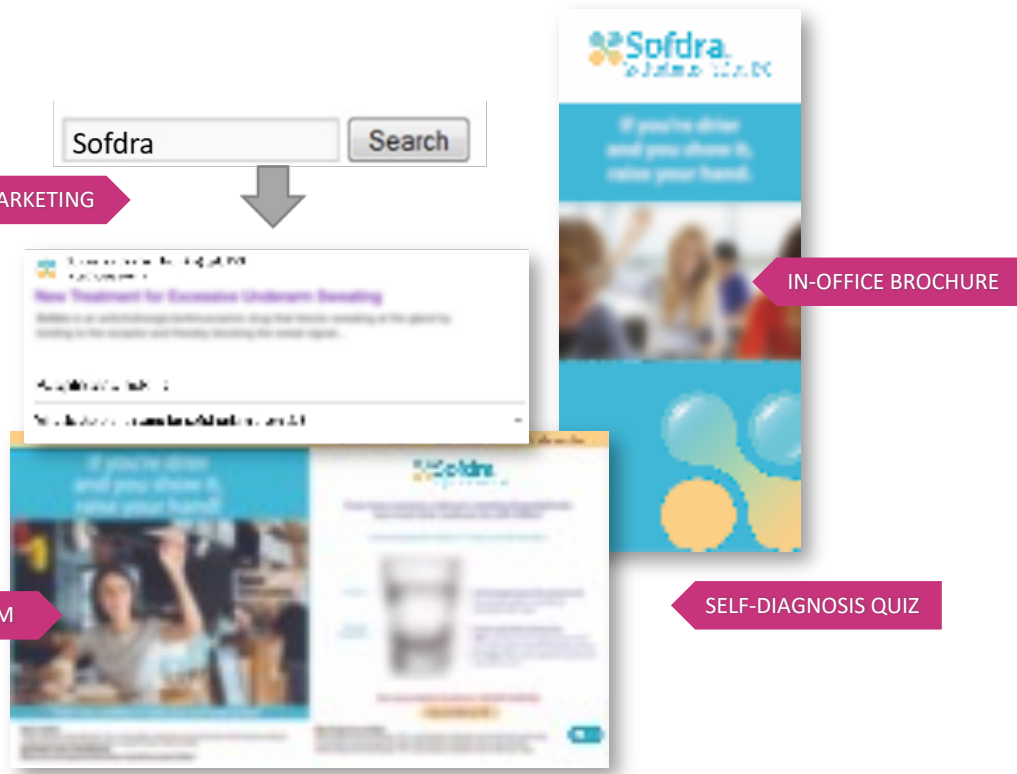
Images of marketing materials are for representative purposes only

# Patient launch activities to target active HH information seekers

Planned search engine optimization/marketing and all materials will drive patients to Sofdra.com

Planned social media and digital advertising will drive patients to quiz on Sofdra.com

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# Proactive, pre-approval engagement with Payors with >200K lives

Optimize access ahead of planned launch

Rx Con PBM	Account	Lives	Rnk	Clin Pres
CVS	CVS Caremark - Advanced Control, Performance Standard Control, Value	1,845,000	1	Yes
EXPRESS	Express Scripts - High Performance, Basic	1,718,678	1	Yes
Rx Con PBM	Account	Lives	Rnk	Clin Pres
EMISAR				
ASCENT				
ASCENT	ZINC CVS Caremark - Advanced Control, Performance Standard Control, Value	30,650,000	1	Yes
N/A	ASCENT Express Scripts - National Preferred Formulary	26,709,534	1	Yes
ZINC	EMISAR OptumRX Premium Standard, Value, Select Standard	15,435,000	1	Yes
PROCARE	ZINC Anthem Essential HMO, PPO, National, Traditional	12,833,835	2	Yes
PRIME	EMISAR United Healthcare- Access, Advantage, Choice, Essential, Flex	12,658,000	2	Yes
ASCENT	ASCENT Cigna- Advantage, National Preferred, Performance	8,760,900	2	No
EMISAR	KAISER Kaiser Permanente	8,303,484	1	Yes
EMISAR	TRICARE TriCare	7,214,213	2	Yes
EMISAR	ZINC AETNA- Open, Standard, Fully Insured	5,958,336	2	Yes
DIVIDEND	CVS (FEHBP)- Basic, Focus, Standard	5,330,051	1	Yes
NAVITUS	DoD DEPARTMENT OF VETERANS AFFAIRS	4,701,838	2	Yes
	PRIME BCBS IL/ Tx/NM/MT (HCSC)- HMO or PPO Enhanced, Performance, Multi Tier	4,575,000	2	No
	ASCENT Prime Therapeutics	2,460,000	2	Yes
	PRIME BCBS FL- HMO, PPO Multi Tier	2,125,000	2	No

- ❖ Completed Payor profiles and engagement plan
- ❖ Engaged target Payors around unmet need in primary axillary hyperhidrosis and *Sofdra* value proposition
- ❖ Confirmed hyperhidrosis reimbursement status as medical condition
- ❖ Commenced initial discussions with target Payors responsible for 80% of covered lives

# Docs will e-prescribe directly to our national pharmacy network

- ❖ Instructions are provided to patient in doctor's office when prescription is written
- ❖ Strong value and convenience messaging includes capping patient's out-of-pocket cost
- ❖ QR code to enter instantly into digital space and begin interaction with our pharmacy network
- ❖ Pharmacy mails *Sofdra* the same day that the patient completes their intake form

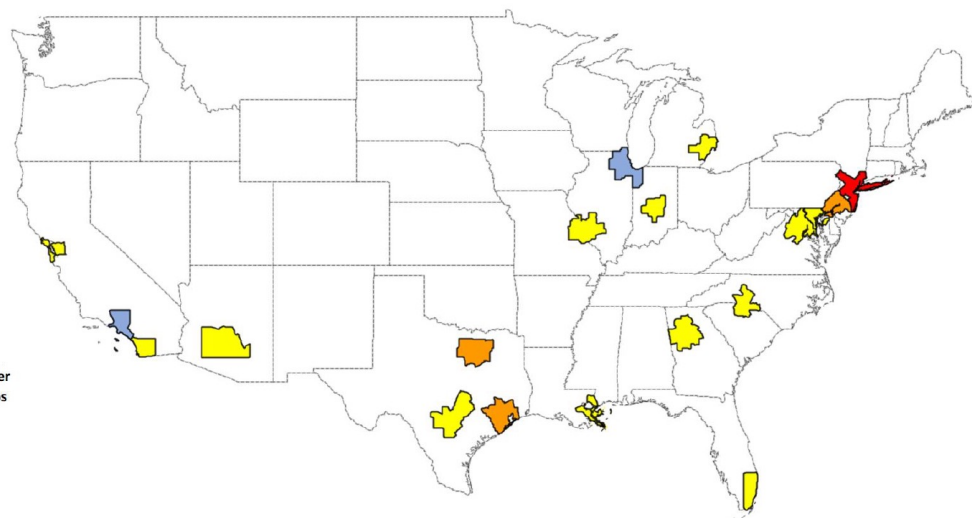


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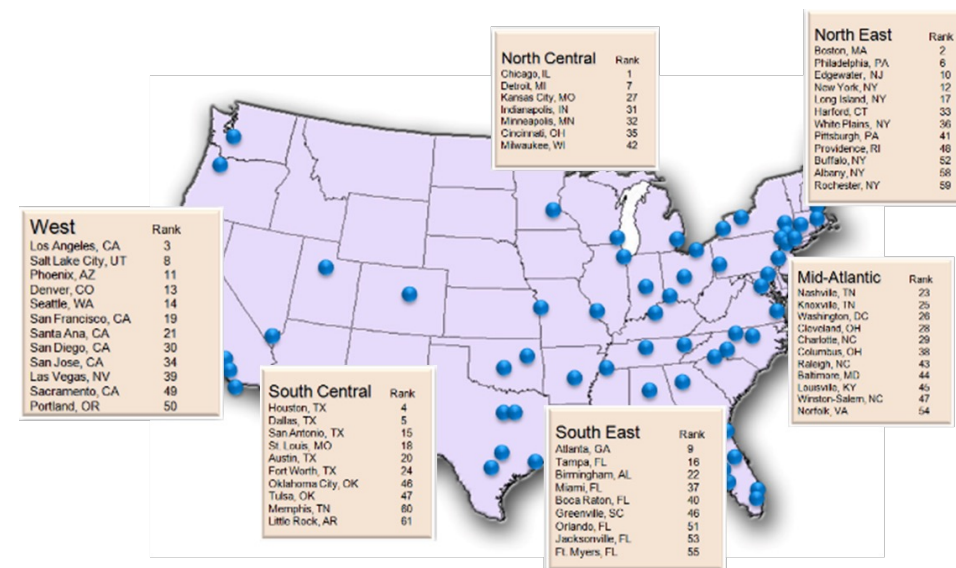
# Territories created based on prescriptions and HH diagnosis data

National programs focused on educating physicians and office staff

Territories aligned with  
prescriber and HH Data



Targeted cities based on  
prescriber and HH data



# Focused pre-launch period ahead

- ❖ FDA approval targeted for late June 2024
- ❖ The issue being considered by the FDA is related to patient Instructions For Use—no efficacy, safety or manufacturing issues remain
- ❖ Commercial preparation is accelerating in anticipation of FDA approval
- ❖ Company is funded through approval and has multiple commercialization options



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Authorised for release by Vince Ippolito, Executive Chairman