

21 June 2024

## Botanix secures commitments for \$70 million via institutional placement to fund launch of *Sofdra*<sup>™</sup>

*Not for release to US wire services or distribution in the United States*

### Key highlights

- Botanix has received firm commitments for \$70 million capital raising via an institutional placement
- Proceeds will be used to fund sales and marketing, manufacturing and support costs for *Sofdra*<sup>™</sup> (sofpironium) gel, 12.45%, as well as working capital and costs of the Placement
- A significant number of new leading Australian and international institutional investors have committed under the placement, alongside key existing institutional shareholders
- Funds raised are expected to fully fund the launch of *Sofdra*<sup>™</sup> and first revenues are expected in Q4 CY 2024
- The institutional Placement follows the approval of *Sofdra*<sup>™</sup> by the FDA for the treatment of primary axillary hyperhidrosis (excessive underarm sweating), in adults and children 9 years of age and older

**Philadelphia PA and Phoenix AZ, 21 June 2024:** Clinical dermatology company, Botanix Pharmaceuticals Ltd (ASX: BOT, “**Botanix**” or “the **Company**”), is pleased to announce that it has received firm commitments from a significant number of new leading Australian and international institutional investors, alongside key existing institutional and sophisticated investors for 233,333,334 new fully paid ordinary shares (“**New Shares**”) at A\$0.30 per New Share to raise \$70 million in gross proceeds (“**Placement**”).

The issue price of A\$0.30 represents a 2.8% premium to the 30-day VWAP and 10.4% discount to the Company’s last traded price before the trading halt on Wednesday, 19 June 2024. The Placement is not underwritten.

The proceeds from the Placement will be applied towards funding the launch of *Sofdra*<sup>™</sup> in the United States. Specifically, the Placement will fund sales force and marketing infrastructure as well as digital marketing costs and the telemedicine platform (‘sales and marketing costs’), manufacturing costs, as well as new quality assurance, pharmacovigilance and support services (‘support costs’), working capital and costs of the Placement.<sup>1</sup>

**Botanix Executive Chairman, Vince Ippolito, commented:** *“We are extremely pleased to announce this significant Placement, following on from the successful approval of Sofdra<sup>™</sup> by the FDA yesterday.”*

*“We are grateful to our loyal base of shareholders for supporting us through the approval of Sofdra and we welcome our new institutional investors, as we enter this exciting commercial phase.”*

<sup>1</sup> The use of funds is a statement of current intentions as at the date of this announcement. As with any budget, intervening events and new circumstances have the potential to affect the manner in which the funds are ultimately applied. The Board of Botanix reserves the right to alter the way in which the funds are applied on this basis

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## About Sofdra™

The Placement follows the approval yesterday by the US Food and Drug Administration (“FDA”) of *Sofdra*™, a prescription medicine used to treat primary axillary hyperhidrosis (excessive underarm sweating) in adults and children 9 years and older. *Sofdra*™ is the first and only new chemical entity approved by the FDA to treat primary axillary hyperhidrosis (“hyperhidrosis”) and presents a novel safe and effective solution for patients who have lacked treatment options for this socially challenging medical condition.

Hyperhidrosis is a condition characterised by abnormally increased sweating, beyond that required to regulate body temperature.<sup>2</sup> The disproportionate sweat production that characterises hyperhidrosis, results in a disabling medical condition with profound effects on the patient’s quality of life. Hyperhidrosis affects work productivity, daily routine activities, emotional well-being and personal relationships.<sup>3</sup> Hyperhidrosis is the third largest dermatology condition (after acne and atopic dermatitis), with approximately 10 million patients in the US with primary axillary hyperhidrosis.<sup>4</sup>

An early patient experience program is planned to be launched by the Company in Q3 CY2024 to enable highly qualified patients to gain early access to *Sofdra*™. These patients will be guided through the telemedicine and payer reimbursement process to be the first commercial users of the product. Broader launch of *Sofdra*™ is expected to follow in early Q4 CY2024 and Botanix expects to receive first revenues from sales in Q4 CY2024.

## Details of the Placement

Up to 233,333,334 New Shares (for gross proceeds of up to \$70 million) will be issued pursuant to Botanix’s placement capacity under ASX Listing Rule 7.1 and is expected to settle on Thursday, 27 June 2024. New Shares issued under the Placement will rank pari passu with existing Botanix fully paid ordinary shares from their date of issue.

Euroz Hartleys Limited acted as Sole Lead Manager and E&P Corporate Advisory Pty Ltd acted as Co-Lead Manager to the Placement and are entitled to the fees as set out in the Appendix 3B lodged today.

## Indicative timetable\*

Event	Date
Trading halt	Wednesday, 19 June 2024
Announcement of completion of Placement, trading halt lifted	Friday, 21 June 2024
Settlement of the Placement	Thursday, 27 June 2024
Allotment and expected trading of New Shares issued under the Placement	Friday, 28 June 2024

\* This timetable is indicative only and Botanix may, at its discretion, vary any of the above dates, subject to the ASX Listing Rules and the Corporations Act 2001 (Cth) and other applicable laws. The commencement of trading and quotation of New Shares is subject to ASX confirmation.

<sup>2</sup> Oshima Y, Tamada Y. Classification of systemic and localized sweating disorders. In: Yokozeki H, Murota H, Katayama I, editors. Perspiration research. Current problems in dermatology, vol 51. Basel: Karger; 2016. p. 7–10

<sup>3</sup> Hamm H, Naumann MK, Kowalski JW, Kutt S, Kozma C, Teale C. Primary focal hyperhidrosis: disease characteristics and functional impairment. *Dermatology*. 2006;212(4):343–353. doi: 10.1159/000092285

<sup>4</sup> Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, *Archives of Dermatology Research*

Additional information in relation to the Placement and Botanix can be found in the investor presentation released to the ASX simultaneously with this announcement, which contains important information including a breakdown of sources and uses of funds, key risks and foreign selling restrictions with respect to the Placement.

Botanix also takes the opportunity to clarify a statement published in The West Australian newspaper yesterday in relation to the timing of availability of *Sofdra*<sup>™</sup> in US pharmacies. Manufacturing and labeling of *Sofdra*<sup>™</sup> will likely take approximately 4-5 weeks to complete before product is shipped to Botanix's warehouse, for distribution to US pharmacies to support the early patient experience program.

This ASX announcement is authorised for release by the Board.

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### About Botanix Pharmaceuticals

Botanix Pharmaceuticals Ltd (ASX:BOT) is a dermatology company based in Philadelphia and Phoenix (US) which has received FDA approval for its lead product *Sofdra*<sup>™</sup> for the treatment of primary axillary hyperhidrosis. *Sofdra*<sup>™</sup> is the first and only new chemical entity approved by FDA to treat primary axillary hyperhidrosis and presents a novel safe and effective solution for patients who have lacked treatment options for this socially challenging medical condition

To learn more please visit: <http://www.botanixpharma.com/>

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## **Sofdra Important Safety Information & Indication**

### **Indication**

*Sofdra* (sofipironium) topical gel, 12.45% is a prescription anticholinergic medicine used on the skin (topical) to treat excessive underarm sweating (primary axillary hyperhidrosis) in adults and children 9 years of age and older.

### **IMPORTANT SAFETY INFORMATION**

***Sofdra* is for use on the skin in the underarm area only. Wash your hands right away after you apply *Sofdra*. Do not touch your underarms after applying *Sofdra*. *Sofdra* is flammable. Avoid heat and flame while applying *Sofdra*.**

### **Who should not use *Sofdra*?**

Do not use *Sofdra* if you have certain medical conditions that can be made worse by taking an anticholinergic medicine such as glaucoma, severe ulcerative colitis (UC) or certain other serious bowel problems associated with severe UC, myasthenia gravis, and Sjogren's syndrome.

### **What should I tell my healthcare provider before using *Sofdra*?**

- **Tell your healthcare provider about all of your medical conditions**, including bladder or kidney problems, problems passing urine, if you are pregnant or breastfeeding, or plan to become pregnant or breastfeed. It is not known if *Sofdra* will harm your unborn baby or pass into your breast milk.
- **Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, especially any anticholinergic medicines.

### **What are possible side effects of *Sofdra*?**

#### **Serious side effects may include:**

- **Blurred vision.** Stop using *Sofdra*, call your healthcare provider right away, and do not drive or operate machinery or do hazardous work until your vision is clear.
- **New or worsened urinary retention.** Stop using *Sofdra* and call your healthcare provider right away if you experience difficulty urinating, urinating frequently, urination in a weak stream or drips, full bladder or difficulty emptying your bladder.

**The most common side effects of *Sofdra* include** dry mouth; blurred vision; pain, redness, swelling, itching, and irritation in the underarm area; dilation of the pupils of your eyes (mydriasis); and problems with urination. These are not all of the possible side effects of *Sofdra*. Call your doctor for medical advice about side effects.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088. You may also report side effects to Botanix at 1-866-763-6337.

**Keep *Sofdra* and all medicines out of the reach of children.**



JUNE 2024

WWW.BOTANIXPHARMA.COM

# Botanix Pharmaceuticals Ltd

ABN 70 009 109 755

**FDA Approval and Capital Raising**  
**June 2024**

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Authorised for release by the Board of Directors of Botanix

# **Sofdra™ now approved and key launch activities underway**



*Sofdra* now approved by the FDA for the treatment of primary axillary hyperhidrosis in adults and children 9 years of age and older

- ❖ Botanix has a well developed and clear path to commercialisation, informed by management’s extensive experience and new digital tools
- ❖ Hyperhidrosis is a condition that is already recognized and reimbursed by insurers. Data and patient surveys demonstrate a significant unmet need
- ❖ Early patient experience program to launch in Q3 CY2024 with first revenue expected in Q4 CY2024
- ❖ Up to approximately A\$70 million (before costs) capital raising to be undertaken by way of institutional placement to fund its launch and commercialisation – see ‘Capital raising details’ section

# Botanix overview

## DERMATOLOGY FOCUS

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

## WORLD CLASS TEAM

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

## NEW PRODUCT “SOFDRA”

*Sofdra* is the first and only new chemical entity for primary axillary hyperhidrosis (5% product already approved in Japan with solid sales)

## NOW FDA APPROVED

Approved by FDA for the topical treatment of primary axillary hyperhidrosis in adults and children 9 years of age and older

## EXPECTED TO BE WELL CAPITALISED

Up to approximately A\$70 million (before costs) capital raise to ensure Botanix is well funded through commercial launch

FDA approval represents a transformational event in the Company’s history

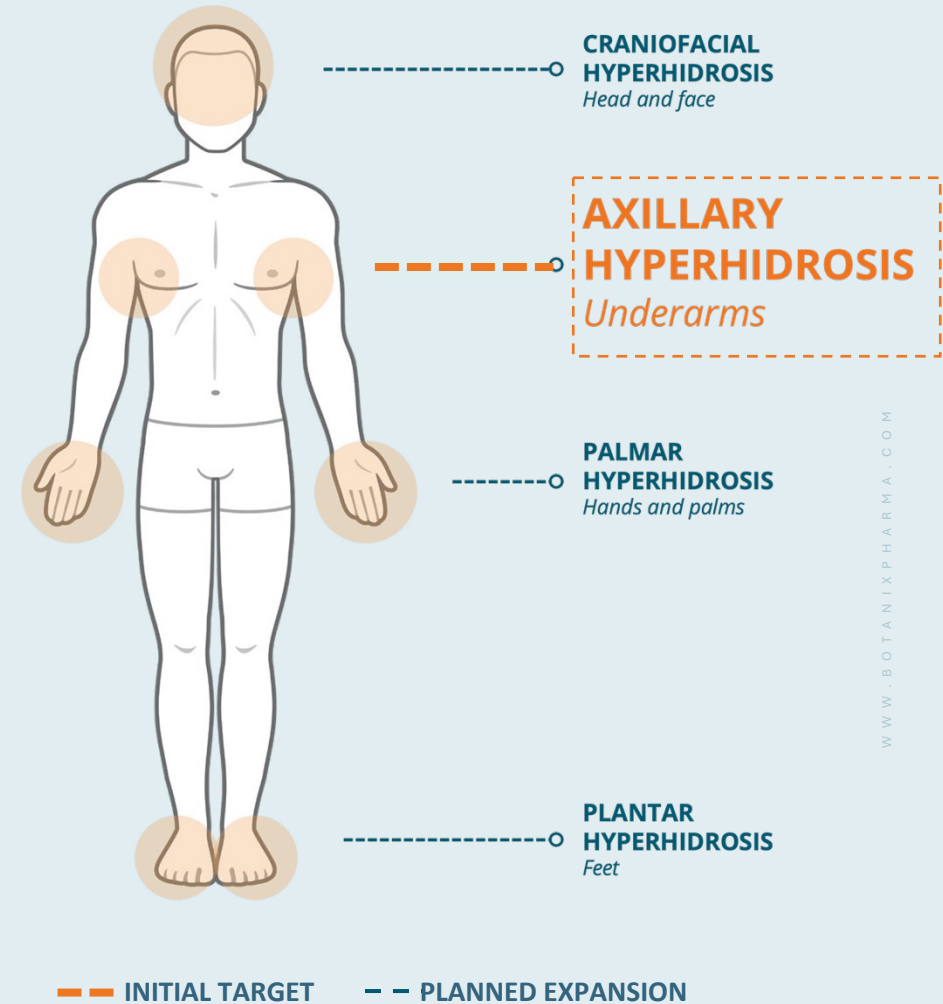


# Hyperhidrosis

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

- ❖ 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>

Source: 1. Doolittle, J. et al. Arch Dermatol Res, 2016. 2. Hamm H. et al. Dermatology. 2006.



FREQUENTLY  
CHANGE  
CLOTHES



FRESHEN UP  
BY WIPING OR  
BATHING

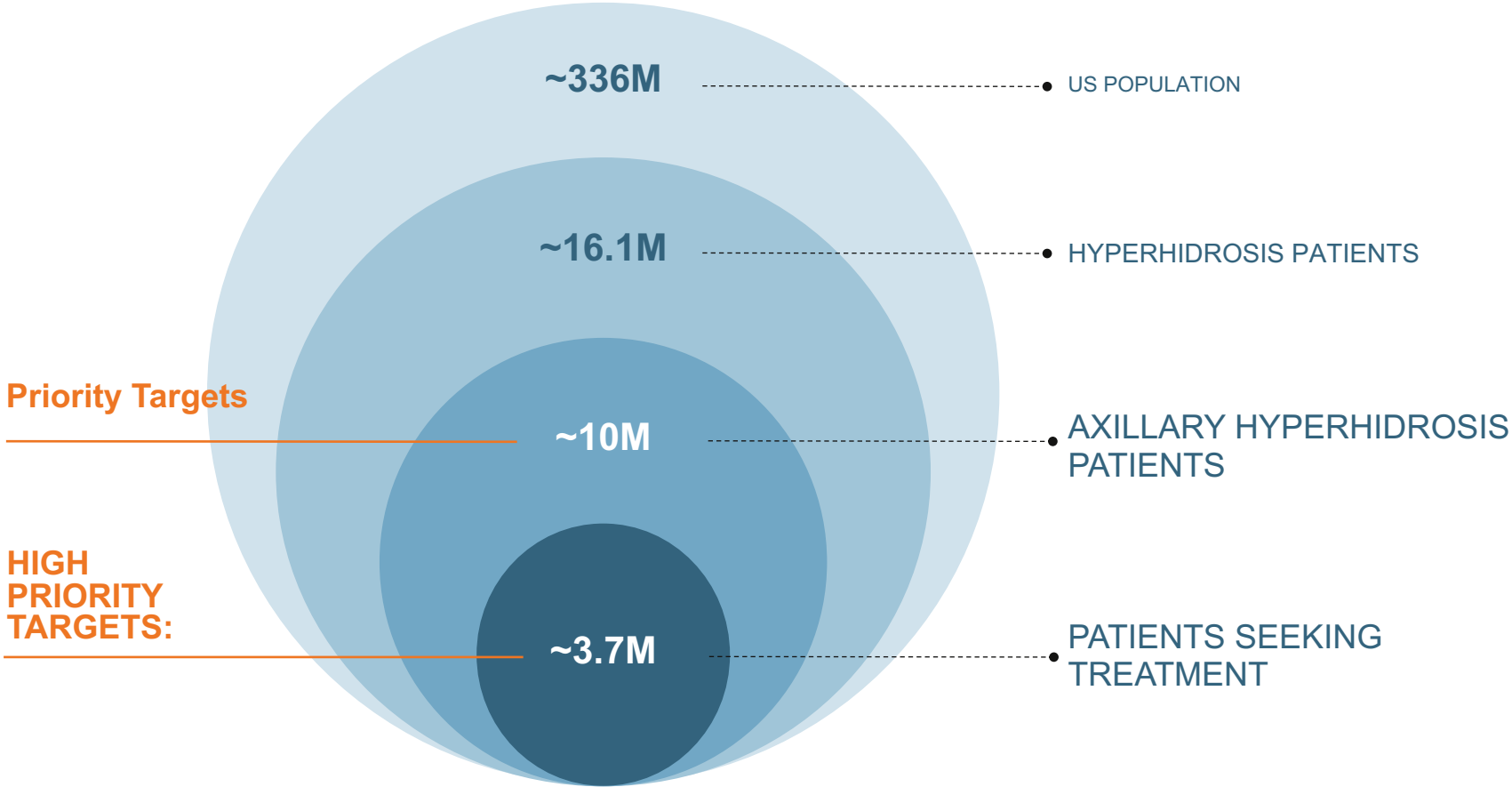


PLACE NAPKINS OR  
PADS UNDER THEIR  
ARMS OR THEIR  
POCKETS



HIDE UNDER  
DARK-COLOURED,  
BULKY CLOTHES

# ~10M patients with ~3.7M patients visiting a doctor and ~6.3M patients still searching



Source: 1. International Hyperhidrosis Society, 2. Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology Research

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 **Sofdra**<sup>TM</sup>  
(sofpironium) topical gel, 12.45%

**botanix**<sup>®</sup>  
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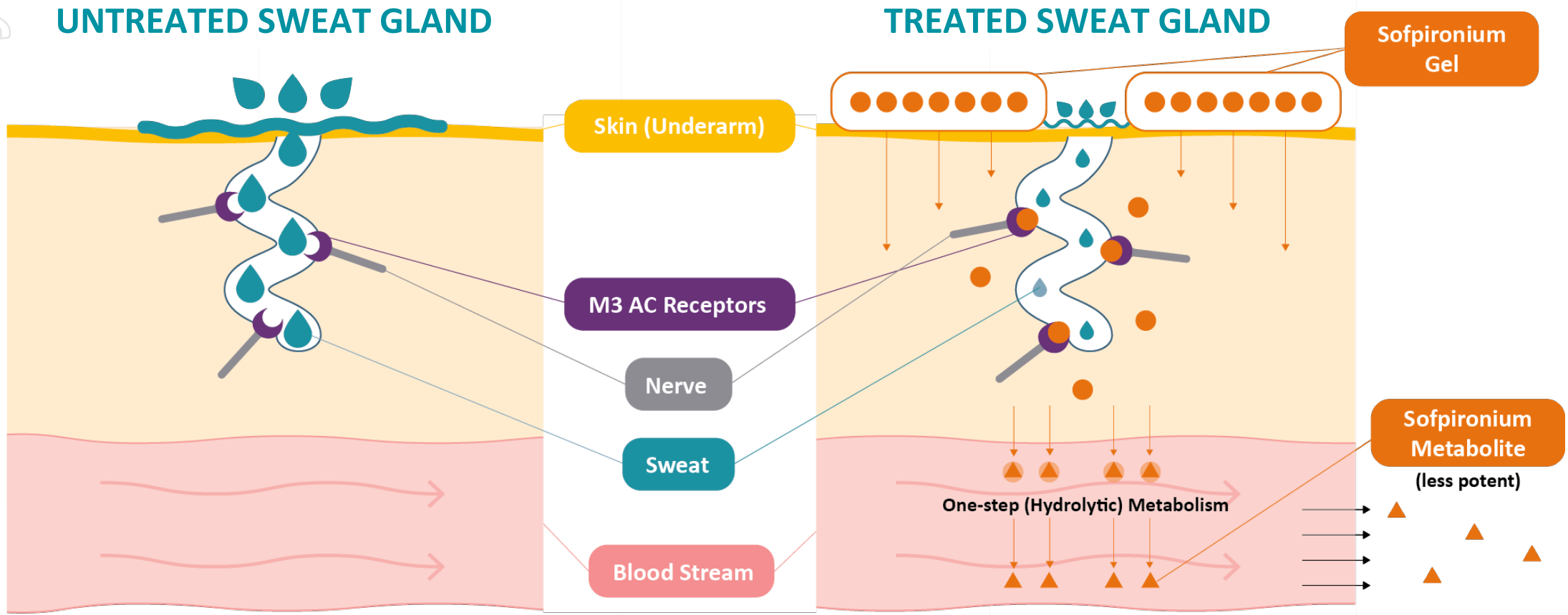
**Sofdra**<sup>TM</sup>

Sofdra<sup>TM</sup>



# Sofdra mechanism of action

Binds selectively to the M3-AC receptors in the sweat gland, blocks acetylcholine to inhibit sweat and is rapidly metabolized



**M3 AC Receptors** = Muscarinic Acetylcholine Receptors which regulate the function of sweat glands

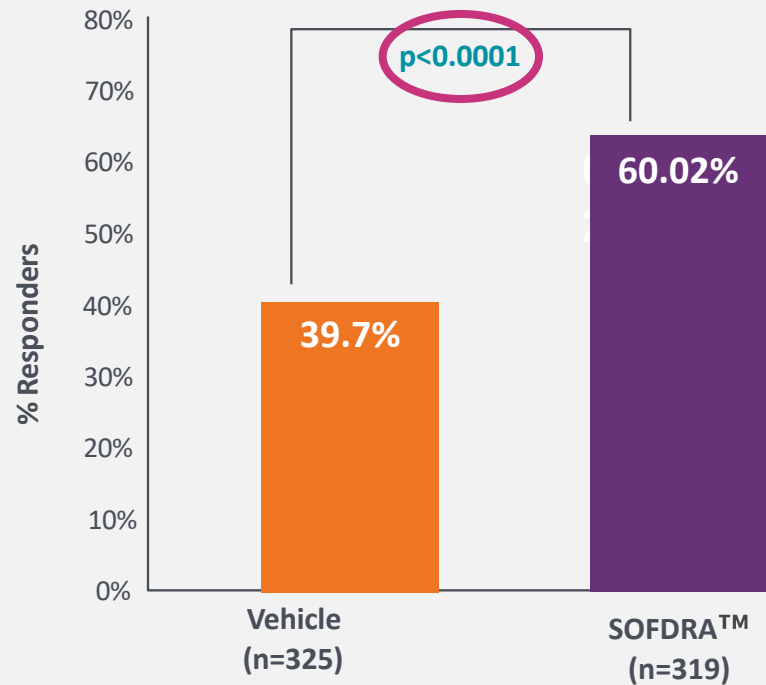
**Sofpironium Metabolite** = Sofpironium is converted into a less active form to help minimize side effects

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# Both Phase 3 clinical study co-primary endpoints were highly statistically significant

## POOLED DATA (CARDIGAN I AND II)

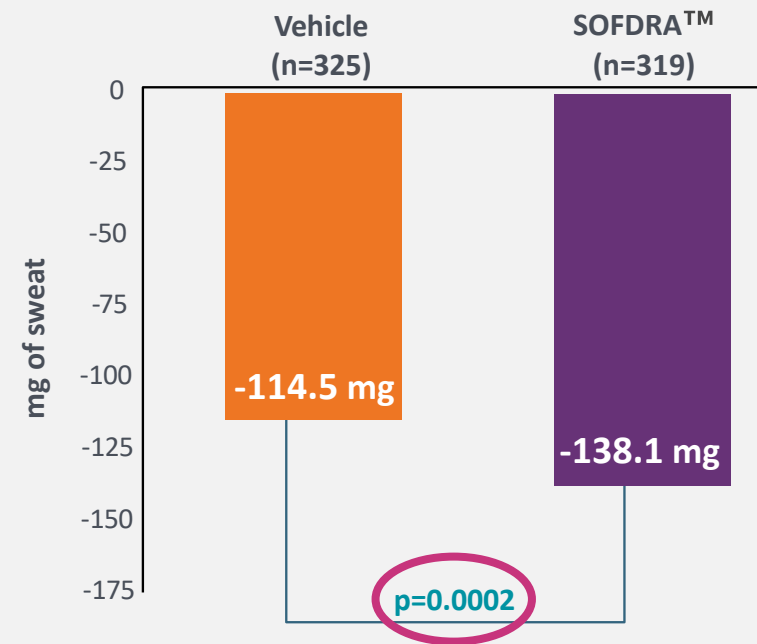
≥2-point improvement in HDSM-Ax-7 from baseline to end of treatment<sup>1</sup>



HDSM-Ax-7 scale measures patient reported severity of axillary (underarm) hyperhidrosis

## POOLED DATA (CARDIGAN I AND II)

GSP change from baseline to end of treatment<sup>1</sup>

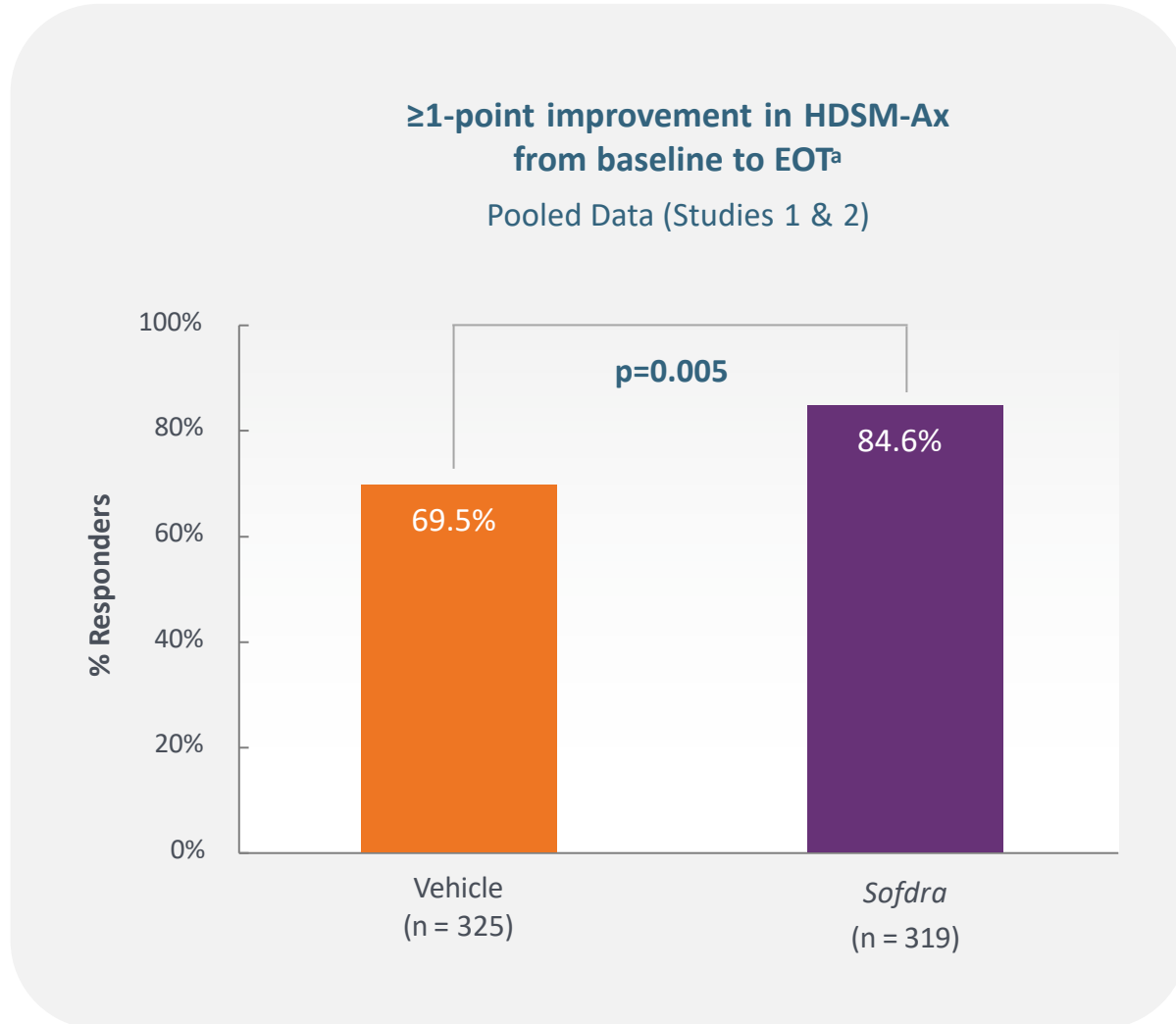


GSP (Gravimetric Sweat Production) is an objective measurement of underarm sweat production (mg/ 5 min)

Source: 1. Data on File.

SB = Sofpironium Bromide

# In both Phase 3 studies, all *secondary* endpoints were also highly statistically significant



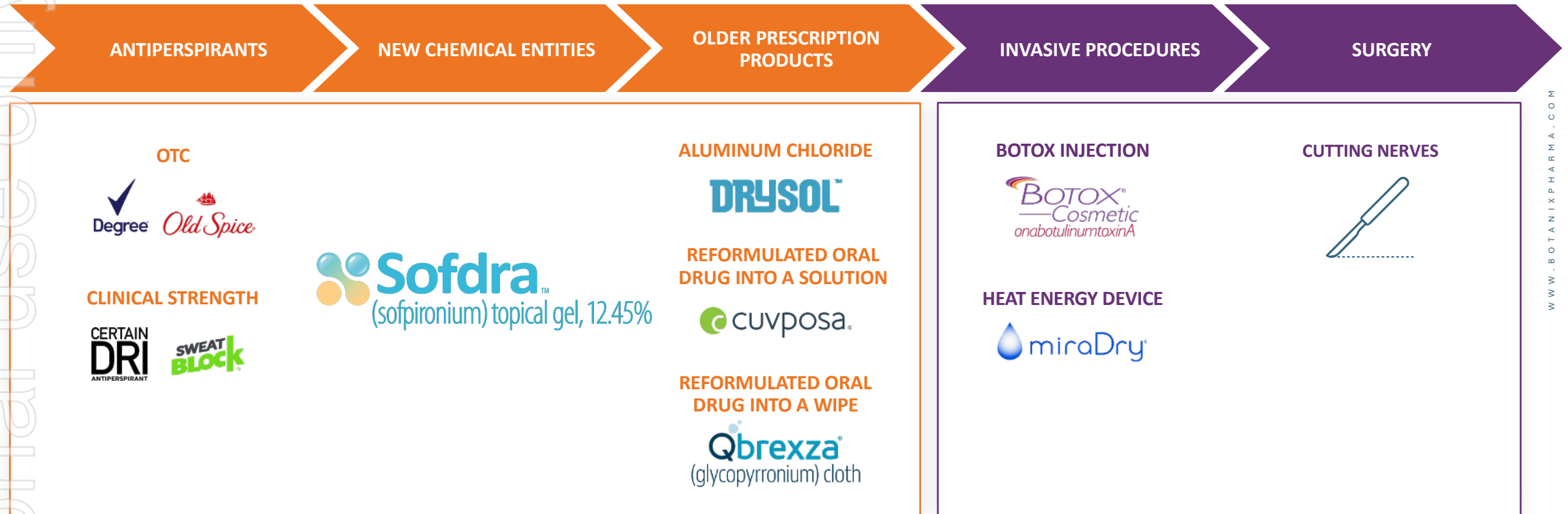
Almost 9 in 10 patients had a clinically meaningful result from using *Sofdra*

**Notes:** a. Data are based on multiple imputations for missing values. 'n' represents number of subjects in the ITT population; EOT = end of treatment (6 weeks)

**Sources:** 1. Hobart J, Burke L, Kirsch B, Chadha D. Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax): Evaluation of Measurement Performance. J Drugs Dermatol. 2021 Apr 1;20(4):410-418. doi: 10.36849/JDD.2021.5569. BBI-4000-CL-301; BBI-4000-CL-302

# Sofdra has a significant opportunity as a new treatment option for hyperhidrosis patients

No new chemical entities have ever been approved for hyperhidrosis



Due to its significant psychological impact, 54% of respondents suffering from hyperhidrosis say that they would pay anything for a treatment to stop their excessive sweating<sup>1</sup>



 **Sofdra**<sup>™</sup>  
(sofpironium) topical gel, 12.45%

 **botanix**  
PHARMACEUTICALS

# Commercialisation Plan

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Commercialisation Plan

# ***Sofdra* gel launch strategy**

Clear and targeted path to market, informed by previous launch experience and new digital tools

Rapidly establish *Sofdra* gel as a safe and effective first-line therapy for treatment of primary axillary hyperhidrosis

**Engage and motivate patients**

**Provide patient access and remove friction**

**Maximize reimbursement and coverage**

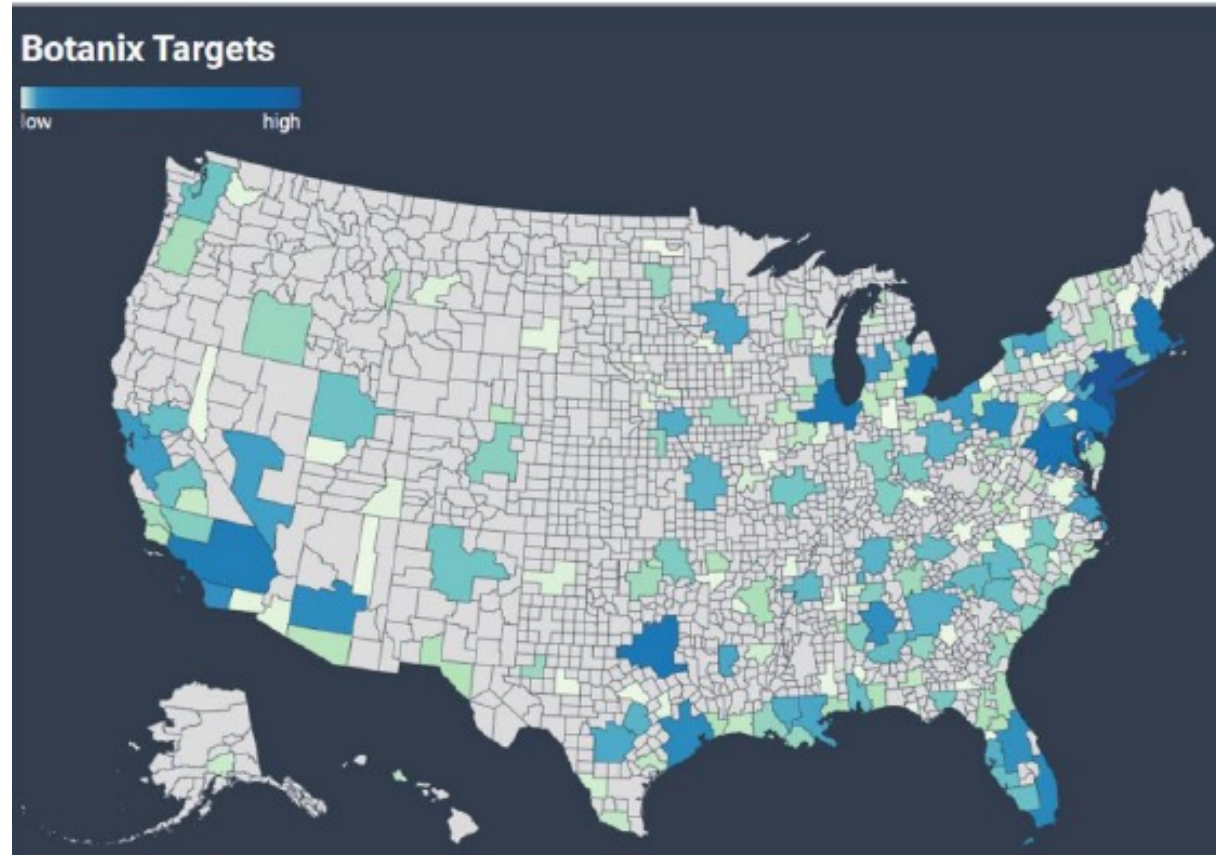
**Drive dermatologist adoption**

**Hire and train a highly effective sales force**

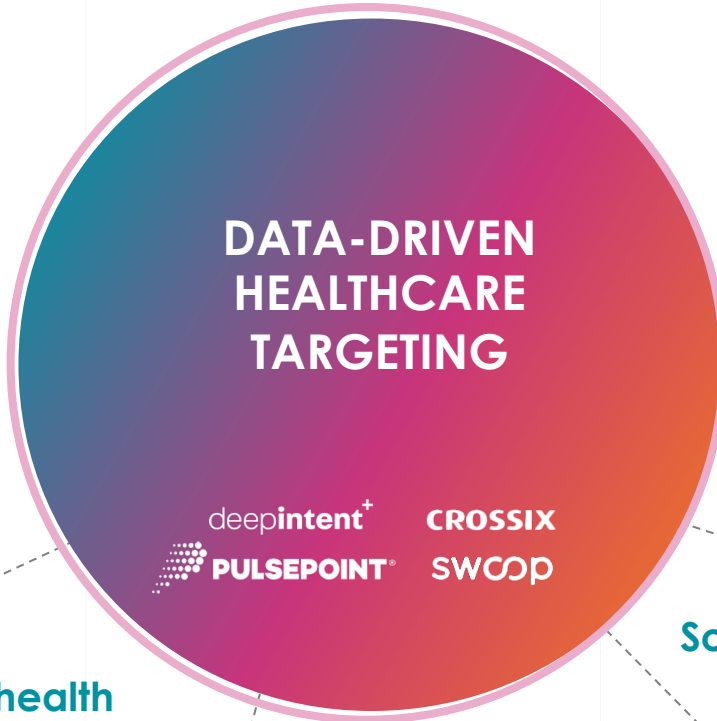


# Target the most productive prescribers and expand reach via digital channels

- ❖ Identify doctors with greatest potential for prescribing and reimbursement
- ❖ Expand doctor reach using search, media, PR, social, influencers, key opinion leaders
- ❖ Rapid scale-up of 20–30 field sales reps to call on targeted high potential doctors



# Data allows us to activate our most valuable patient audiences across carefully indexed channels



Google and search engines



Data-driven addressable TV

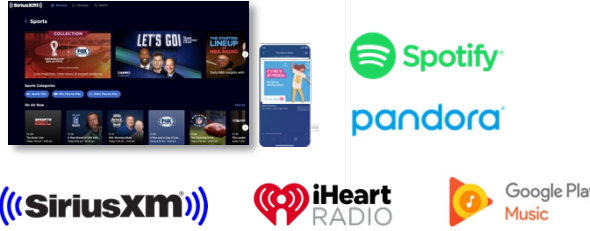


Premium Content

Social



Audio & audio display



Health environments



WebMD

Medscape haymarket healthline

Non-health environments



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# Hone in on actual patients while sharing sweat stories with AI social sentiment targeting

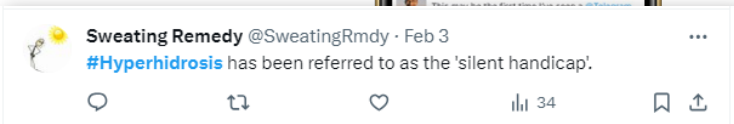
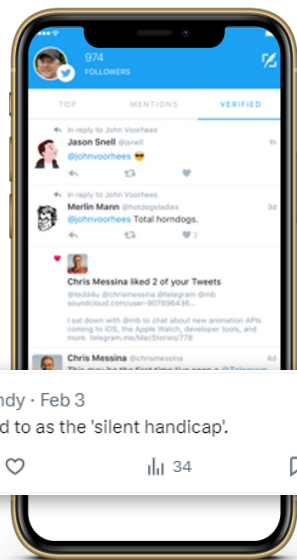
There were 396,464+ highly qualified hyperhidrosis patients talking about their symptoms and personal journeys last month<sup>1</sup>

## 1 SOCIAL POSTS/HASHTAGS



### HASHTAG EXAMPLES:

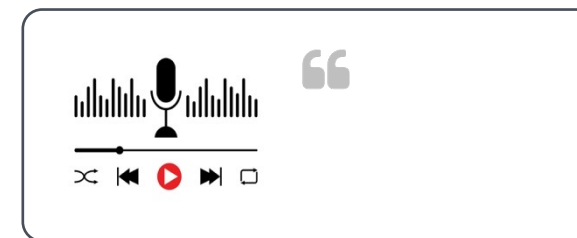
- #hyperhidrosis
- #sweatypits
- #sweatfree
- #excessivesweating
- #sweatproblems
- #sweatissues



## 2 IMAGES/VIDEOS



## 3 AUDIO RECOGNITION



1. Klick Health social listening survey May 2024 – data on file

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(sofpironium) topical gel, 12.45%

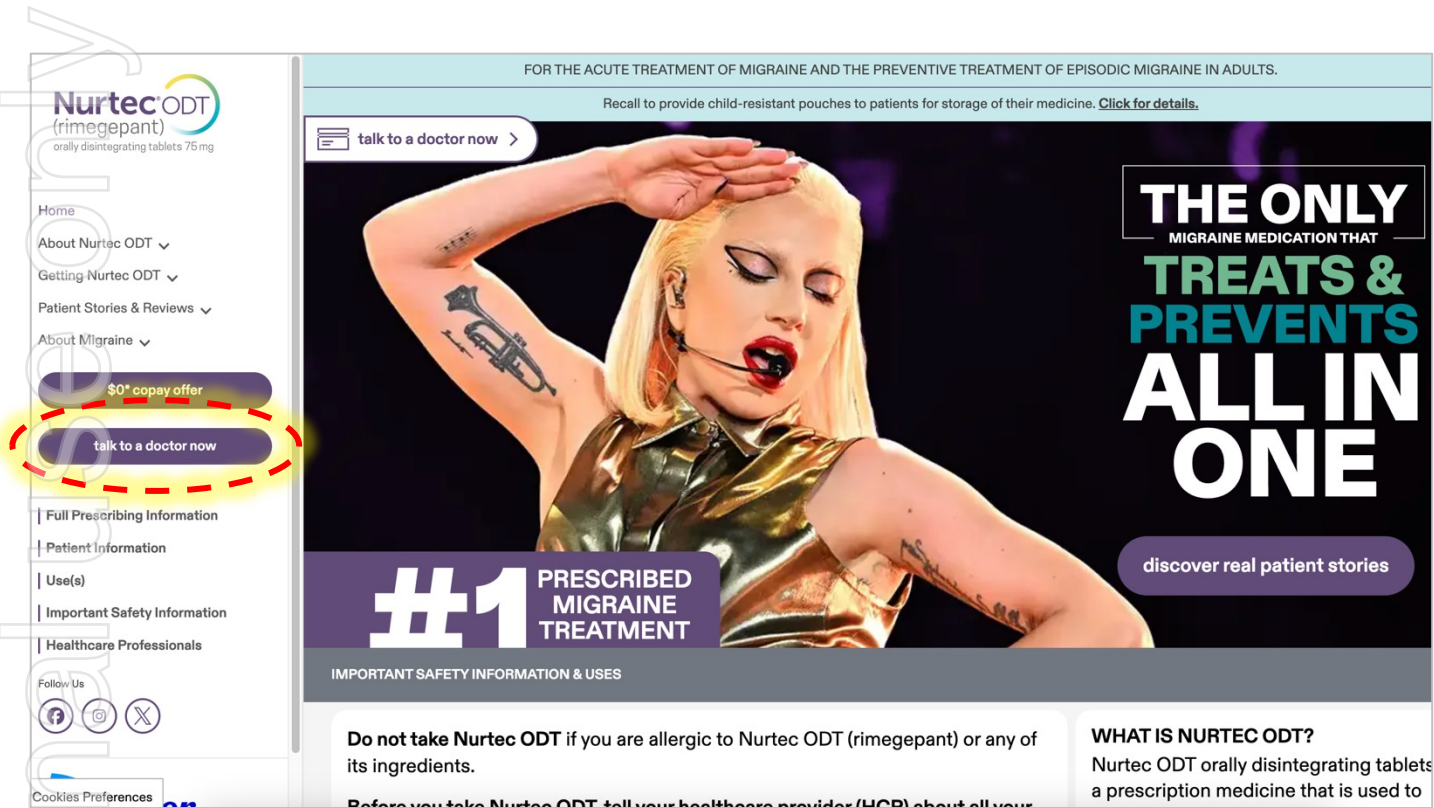
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**Frictionless  
access with  
telemedicine**

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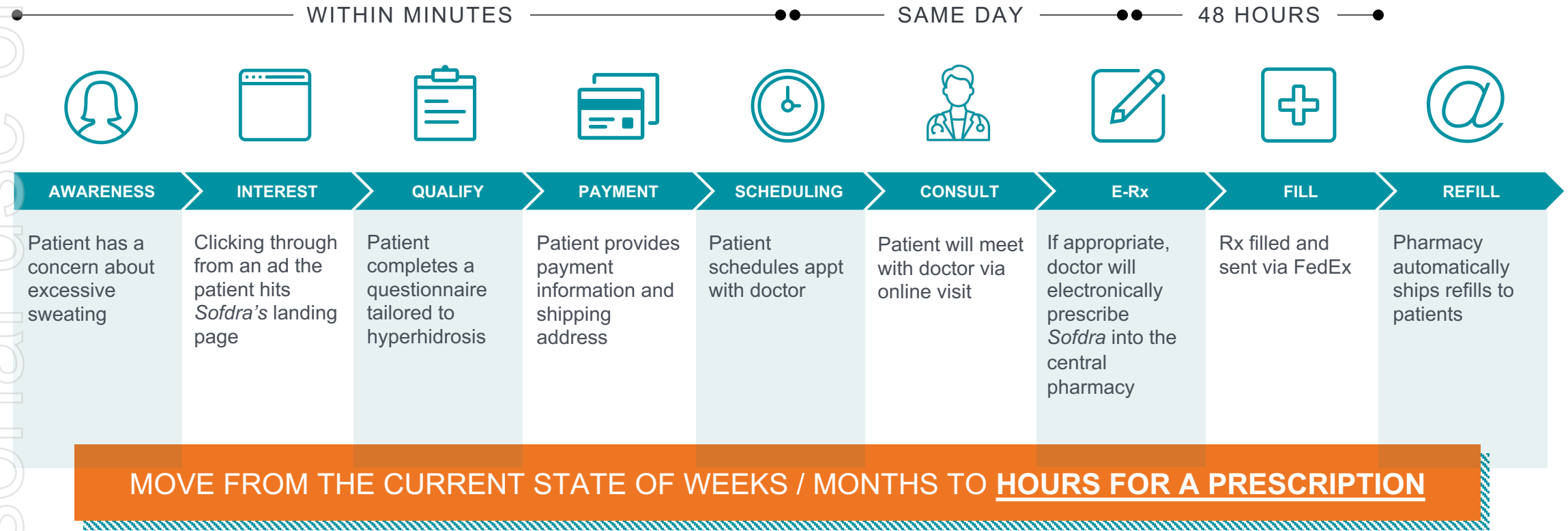
# Telemedicine platforms are now a mainstream tool for many companies in a wide range of indications



Pfizer: Nurtec ODT brand.com page, with link to the telehealth platform

Migraine	
Psychiatry	Birth Control
Diabetes	Respiratory
Obesity	Gastroenterology

# Telemedicine is particularly well suited to embarrassing and easily diagnosed conditions and significantly shortens time to therapy<sup>1</sup>



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<sup>1</sup> Clinical diagnoses are based on observation, interaction with the patient and medical knowledge. They do not require tests

# Sofdra reimbursement well advanced



Insurers



PBMS



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❖ Hyperhidrosis is an established medical condition and treatments are already reimbursed by insurers

❖ Some insurers may require a rebate off the *Sofdra* list price and confirmation of diagnosis, or that the patient has already tried Drysol

❖ Commercially insured patients will pay \$0 as their co-pay amount, once insurance is cleared



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# Sofdra opportunity

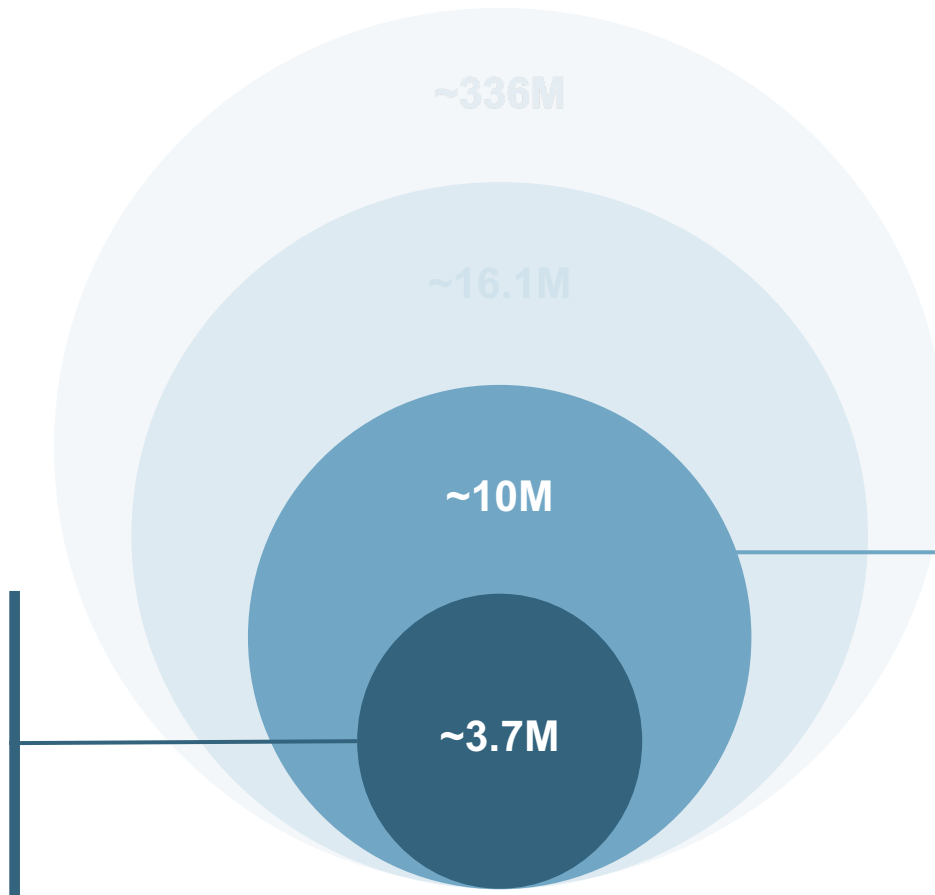
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# ~10M patients with ~3.7M patients visiting a doctor and ~6.3M patients still searching

Sales Force Target



3.7 million people visited a doctor for axillary hyperhidrosis in the last 12 months



Digital Target



6.3 million people with axillary hyperhidrosis – either previously or not yet diagnosed

Source: 1. International Hyperhidrosis Society, 2. Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology Research

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# Sofdra opportunity supported by Japanese licensee experience



Product

Sofpironium topical gel (5%)

Approval Date

September 25, 2020

Launch Date

November 26, 2020

Name

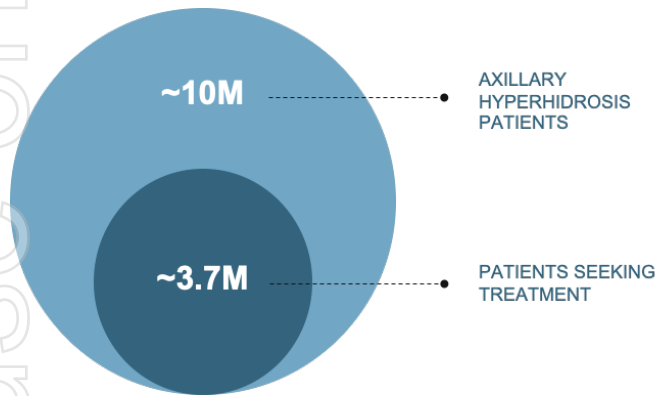
Ecclock®

- ❖ ~350,000 units of Ecclock® have been sold by Botanix's licensee in Japan in the last 12 months
- ❖ The incidence and prevalence of hyperhidrosis in Japan and the USA is similar
- ❖ The population of Japan is ~1/3<sup>rd</sup> the size of the USA
- ❖ Kaken has been able to attract significant numbers of new patients – even in the third year of launch



# Sofdra success is built on 3 pillars

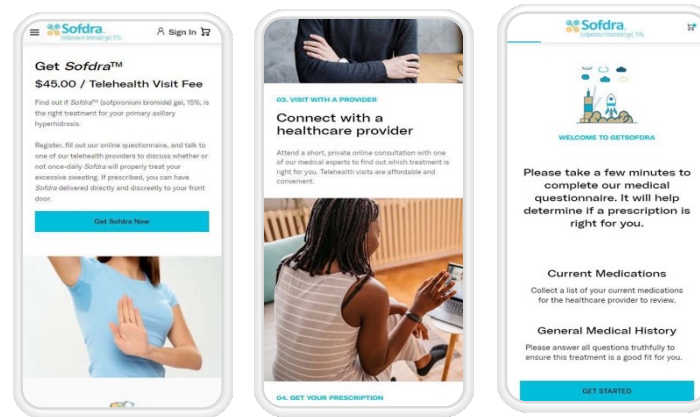
## 1 LARGE MARKET AND ENGAGED POPULATION



❖ Convert a percentage of the 3.7M existing patients seeking treatment

❖ Activate a percentage of the other 6.3M patients who have hyperhidrosis, utilizing digital tools

## 2 FRICTIONLESS ACCESS WITH TELEMEDICINE



- ❖ Provide immediate and comfortable access to online diagnosis
- ❖ Rapidly move from diagnosis to prescription utilizing the telemedicine platform






## 3 PRODUCT SPEED TO PATIENT AND ENSURING REFILLS



- ❖ Avoid distributor fees by using direct fulfilment
- ❖ Ensure that the patient gets every refill to drive positive patient outcomes and profitability

# Indicative launch milestones

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	Manufacturing, labeling and packaging	Manufacturing and labeling with FDA approved wording and packaging	Q3 CY24
	Patient experience program	Early user program with highly qualified patients from database sources	Q3 CY24
	First sales of Sofdra	First sales of reimbursed Sofdra and broader launch into patient market	Q4 CY24
	Telemedicine platform launch	Engaging patients digitally and diagnosing them, with first prescriptions and refills mailed direct to the patient	Q4 CY24
	Sales force deployment	Dermatologist focused sales force of 25 deployed into key target geographies	Q1 CY25

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# Capital raising details

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# Capital raising summary

Offer structure and size	A single tranche placement to sophisticated and institutional investors <sup>1</sup> to raise up to approximately A\$70.0 million (before costs) (“Placement”) via the issue of up to approximately 233 million new fully paid ordinary shares (“New Shares”) utilising the Company’s available placement capacity under Listing Rule 7.1
Offer Price	The Placement conducted at A\$0.30 per New Share, representing a: <ul style="list-style-type: none"><li>• 10.4% discount to the last traded price of A\$0.33 on Tuesday 18 June 2024</li><li>• 6.4% discount to the 5-day VWAP</li><li>• 2.8% premium to the 30-day VWAP</li></ul>
Use of Proceeds	The proceeds from the Placement will be applied towards funding the launch of <i>Sofdra</i> <sup>TM</sup> in the United States. Specifically, the Placement will fund sales force and marketing infrastructure as well as digital marketing costs and the telemedicine platform (‘sales and marketing costs’), manufacturing costs, as well as new quality assurance, pharmacovigilance and support services (‘support costs’), working capital and costs of the Placement – see next slide
Ranking	Each New Share issued under the Placement will rank equally with existing fully paid ordinary shares on issue
Syndicate	Euroz Hartleys Limited as Sole Lead Manager and E&P Corporate Advisory Pty Ltd as Co-Lead Manager

1. The Company has determined to extend the Placement to sophisticated and institutional investors in selected jurisdictions, subject to the International Offer Jurisdictions in this Presentation.



# Use of funds

Uses	A\$m
Sales force and marketing infrastructure	~\$17.5 million
Digital marketing costs and telemedicine platform	~\$17.5 million
Manufacturing and logistics	~\$6 million
Quality assurance, pharmacovigilance and support services	~\$6 million
Operating expenses	~\$18.8 million
Costs of the Placement <sup>1</sup>	~\$4.2 million
<b>Total use of funds</b>	<b>~\$70 million</b>

Note: The above table is a statement of current intentions as at the date of this Presentation. As with any budget, intervening events and new circumstances have the potential to affect the manner in which the funds are ultimately applied. The Board of Botanix reserves the right to alter the way in which the funds are applied on this basis.

1. Placement costs are an estimate

# Capital raising indicative timetable

Event	Date
Trading Halt	19 June 2024
Capital raising results announced and Trading Halt lifted	21 June 2024
Settlement of Placement	27 June 2024
Allotment of New Shares under the Placement	28 June 2024
Commencement of trading of New Shares under the Placement	28 June 2024

Note: This timetable is indicative only and the Company reserves the right to withdraw the Placement or vary the timetable for the Placement at any time before the issue of the relevant securities without notice, subject to the ASX Listing Rules and the Corporations Act and other applicable laws. The commencement of trading and quotation of New Shares is subject to ASX confirmation. The Company gives no assurance that such quotation will be granted.

# International offer restrictions

This Presentation does not constitute an offer of New Shares of the Company in any jurisdiction in which it would be unlawful. In particular, this Presentation may not be distributed to any person, and the New Shares may not be offered or sold, in any country outside Australia except to the extent permitted below.

## Hong Kong

**WARNING:** This Presentation has not been, and will not be, registered as a prospectus under the Companies (Winding Up and Miscellaneous Provisions) Ordinance (Cap. 32) of Hong Kong, nor has it been authorised by the Securities and Futures Commission in Hong Kong pursuant to the Securities and Futures Ordinance (Cap. 571) of the Laws of Hong Kong (the “SFO”). Accordingly, this Presentation may not be distributed, and the New Shares may not be offered or sold, in Hong Kong other than to “professional investors” (as defined in the SFO and any rules made under that ordinance).

No advertisement, invitation or document relating to the New Shares has been or will be issued, or has been or will be in the possession of any person for the purpose of issue, in Hong Kong or elsewhere that is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to New Shares that are or are intended to be disposed of only to persons outside Hong Kong or only to professional investors. No person allotted New Shares may sell, or offer to sell, such securities in circumstances that amount to an offer to the public in Hong Kong within six months following the date of issue of such securities.

The contents of this Presentation have not been reviewed by any Hong Kong regulatory authority. You are advised to exercise caution in relation to the offer. If you are in doubt about any contents of this Presentation, you should obtain independent professional advice.

## New Zealand

This Presentation has not been registered, filed with or approved by any New Zealand regulatory authority under the Financial Markets Conduct Act 2013 (the “FMC Act”).

The New Shares are not being offered or sold in New Zealand (or allotted with a view to being offered for sale in New Zealand) other than to a person who:

- is an investment business within the meaning of clause 37 of Schedule 1 of the FMC Act;
- meets the investment activity criteria specified in clause 38 of Schedule 1 of the FMC Act;
- is large within the meaning of clause 39 of Schedule 1 of the FMC Act;
- is a government agency within the meaning of clause 40 of Schedule 1 of the FMC Act; or
- is an eligible investor within the meaning of clause 41 of Schedule 1 of the FMC Act.

## United Kingdom

Neither this Presentation nor any other document relating to the offer has been delivered for approval to the Financial Conduct Authority in the United Kingdom and no prospectus (within the meaning of section 85 of the Financial Services and Markets Act 2000, as amended (“FSMA”)) has been published or is intended to be published in respect of the New Shares.

The New Shares may not be offered or sold in the United Kingdom by means of this Presentation or any other document, except in circumstances that do not require the publication of a prospectus under section 86(1) of the FSMA. This Presentation is issued on a confidential basis in the United Kingdom to “qualified investors” within the meaning of Article 2(e) of the UK Prospectus Regulation. This Presentation may not be distributed or reproduced, in whole or in part, nor may its contents be disclosed by recipients, to any other person in the United Kingdom.

Any invitation or inducement to engage in investment activity (within the meaning of section 21 of the FSMA) received in connection with the issue or sale of the New Shares has only been communicated or caused to be communicated and will only be communicated or caused to be communicated in the United Kingdom in circumstances in which section 21(1) of the FSMA does not apply to the Company.

In the United Kingdom, this Presentation is being distributed only to, and is directed at, persons (i) who have professional experience in matters relating to investments falling within Article 19(5) (investment professionals) of the Financial Services and Markets Act 2000 (Financial Promotions) Order 2005 (“FPO”), (ii) who fall within the categories of persons referred to in Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the FPO or (iii) to whom it may otherwise be lawfully communicated (“relevant persons”). The investment to which this Presentation relates is available only to relevant persons. Any person who is not a relevant person should not act or rely on this Presentation.

## Singapore

This Presentation and any other materials relating to the New Shares have not been, and will not be, lodged or registered as a prospectus in Singapore with the Monetary Authority of Singapore. Accordingly, this Presentation and any other document or materials in connection with the offer or sale, or invitation for subscription or purchase, of New Shares, may not be issued, circulated or distributed, nor may the New Shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore except pursuant to and in accordance with exemptions in Subdivision (4) Division 1, Part 13 of the Securities and Futures Act 2001 of Singapore (the “SFA”) or another exemption under the SFA.

This Presentation has been given to you on the basis that you are an “institutional investor” or an “accredited investor” (as such terms are defined in the SFA). If you are not such an investor, please return this Presentation immediately. You may not forward or circulate this Presentation to any other person in Singapore.

Any offer is not made to you with a view to the New Shares being subsequently offered for sale to any other party in Singapore. On-sale restrictions in Singapore may be applicable to investors who acquire New Shares. As such, investors are advised to acquaint themselves with the SFA provisions relating to resale restrictions in Singapore and comply accordingly.



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# Key Risks

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# Key Risks

## Commercial

- **Pricing:** There is no guarantee that the Company's products will obtain anticipated selling prices or reimbursement levels, which may impact profitability and marketability of the products.
- **Competition:** Botanix's industry is highly competitive. The development of pharmaceuticals is very difficult and demanding; even more so if this competition is against competitors who may have larger resources than Botanix. A number of companies, both in Australia and overseas, may be developing products that target similar markets that Botanix is targeting. Botanix may face competition from companies with superior technologies or greater resources.
- **Supply Chain:** Botanix depends on third parties for the supply of critical materials for the manufacture of products, highly-specialised manufacturing of products, and the distribution of products once manufactured. Botanix may experience disruptions to its supply chain, such as: a shortage of raw materials; lack of capacity by Botanix's key manufacturers to provide the required services during appropriate timeframes; manufacturing quality risks; disruptions associated with distribution and logistics; labour shortages; and an inability to pass on increased costs of any of the above.
- **Launch:** there is no guarantee that the proposed launch and commercialisation plan for *Sofdra<sup>TM</sup>* will be successful in the indicative timeframe or at all. The current plan is based on current information, estimates and assumptions, including as to time and cost. Given the impact of matters beyond the control of the Company, there may be unforeseen delays to these timeframes and to the overall launch and commercialisation of *Sofdra<sup>TM</sup>*.

## Corporate

- **Financial:** The Placement is not underwritten and there is no guarantee that the amount sought will be raised. Even if the Company does raise the amount sought, proceeds from the Placement may be insufficient for the Company to reach financial self-sustainability if sales are lower than anticipated, costs are higher than anticipated or there are other delays to sales over the long term. As a result, Botanix may need to raise further capital through equity financing or other means. There is no guarantee that Botanix will be able to raise such additional capital when it is required, or on terms satisfactory to Botanix. If Botanix is unsuccessful in obtaining funding when required, this may have a material adverse effect on Botanix's business and financial condition and performance and Botanix may need to delay, scale down or cease its operations. Further, any additional capital raised via equity may dilute shareholders' interests in Botanix.
- **Key Person(s):** Botanix's ability to execute its business plan is highly dependent upon the efforts and abilities of a number of key staff, including the ability to recruit an appropriately experienced and effective sale teams. Botanix seeks to recruit individuals and maintain high retention rates through the establishment of a high-quality working environment, competitive salary packages including STI / LTI components and performance benchmarking, however, this may not be sufficient to attract and maintain the required skilled workforce. There can be no assurance given that there will be no detrimental impact on Botanix if one or more of these employees cease their employment.
- **Foreign Exchange:** The Group conducts certain clinical and regulatory activities internationally, and accordingly has foreign currency liabilities in United States Dollars (USD), giving rise to a currency and foreign exchange risk. The Group maintains foreign currency bank accounts denominated in USD in order to minimise this risk.
- **Insurance:** Botanix insures its business and operations. However, Botanix's insurance may not be of a nature or level to provide adequate insurance cover to insure against the occurrence of all events that may impact on the operations of Botanix. The occurrence of an event that is not covered or fully covered by insurance could have a material adverse effect on the business, financial conditions and results of Botanix.

## Clinical and Regulatory

- **Regulatory Approvals:** The Company will need to maintain approvals from the US FDA to commercialise and market future products, as well as equivalent regulatory authorities in other foreign jurisdictions to commercialise in those regions. The Company may not receive the necessary regulatory approvals for any given product.
- **Regulatory Compliance:** Botanix is required to comply with a broad range of legal and regulatory requirements (including competition law, anti-bribery, GDPR and privacy laws). Botanix has implemented a commercial compliance system to ensure its regulatory compliance. However, global regulation is multi-disciplinary and complex and there is a risk that Botanix may breach or fail to meet one or more of its compliance and regulatory obligations.

## IP / Licensing

- **Licensors:** Botanix's *Sofdra* product is under license. Botanix may encounter potential challenges if a licensor attempts to terminate a licence or enters insolvency.
- **Intellectual Property:** The Company's success will depend partly on its ability to obtain and maintain commercially useful patent claims for its products. The prospect of attaining patent protection for products such as those Botanix proposes to develop is highly uncertain and involves complex and continually evolving factual and legal questions. Botanix may incur significant costs in prosecuting or defending its intellectual property rights. Botanix seeks to utilise effective advisory, in-house IP management resources and an internal technical team to effectively manage its product IP, however, any failings with this system may have a detrimental impact on the Company.

## Operations

- **Quality Assurance:** Botanix operates in a complex, highly regulated environment relating to the manufacture and supply of medical treatments for humans. Botanix has implemented a Quality Management System (QMS) which is paramount to ensuring patient safety, however, for issued product that is not in line with Botanix and global specifications, Botanix may incur liabilities such as product recall obligations.
- **IT and Infrastructure:** Botanix remains open to threats of cyber-attack, data theft and data loss.