

### 31 October 2023

## **Investor Presentation and Investor Meetings**

**Philadelphia and Phoenix US, 31 October 2023**: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to provide a copy of its updated investor presentation as attached to this release.

Senior leadership from the Company will be meeting with investors in Australia this week, to update them on the progress of *Sofdra*<sup>™</sup> towards resubmission of the NDA and planned approval in mid-CY 2024.

The investor presentation highlights the significant activity undertaken by the Botanix team in the last month, since the FDA provided feedback regarding the Instructions for Use for *Sofdra* and minor updates required for resubmission of the NDA. The presentation also outlines the activities being undertaken to prepare for launch, following the recent engagement of our telehealth partner UpScript Health.

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 CY 2024 with approval targeted for mid-CY 2024. 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/



### 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

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## **Investor Update**

October 2023

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**Operations:** 3602 Horizon Drive, Suite 160 King of Prussia PA 19406 **Corporate Office:** Level 1, 50 Angove Street North Perth W. Australia 6006

Authorized for release by: Vince Ippolito Executive Chairman

# Botanix – Accelerating towards commercialization of SOFDRA™

DERMATOLOGY FOCUS	New treatments for underserved common skin diseases, with a first focus on excessive sweating ("primary axillary hyperhidrosis")
TOPICALLY DRIVEN	Targeting key indications with topical (gel) treatments that are safe, well tolerated and validated with clinical efficacy
WORLD CLASS TEAM	US-based team that have been responsible for successful development and commercial launches of more than 30 dermatology 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) <sup>1</sup>
TARGETING MID-24 FDA APPROVAL	Submission of final component required for approval (the 'Instructions for Use') on target for Q1 CY2024, targeting FDA approval in mid-CY2024



# World class board and management team

Developed, secured approval for and commercialised over 30 successful dermatology products



VINCE IPPOLITO Executive Chairman

- COO of Anacor and Medicis; former President Dermavant; more than 17 years at Novartis
- More than 35 years experience in pharma with 20+ years within dermatology



DR BILL BOSCH Board Director

- 30+ years experience in pharma industry
- Co-inventor of SoluMatrix<sup>™</sup> drug delivery technology and NanoCrystal<sup>®</sup> Technology



### HOWIE MCKIBBON Chief Executive Officer

- Former SVP Commercial of Dermavant, Anacor and Medicis
- 20+ years working in dermatology—launched more than 15 brands and managed over 35 dermatology products

**ANTHONY ROBINSON** 

**VP of Development** 

Recently Vice President R&D at Advicenne

• Senior leadership roles at Aquestive

Pharmaceuticals

Therapeutics, Intrommune and Shire



### DR PATRICIA WALKER Chief Medical Adviser

- Former President and head R&D Brickell Biotech
- Former CMO/CSO at Kythera, Inamed and Allergan Medical responsible for multiple products including Botox and Tazorac



## **DR JACK HOBLITZELL** SVP Pharmaceutical Development

- 30+ years leading world-class technical operations
- Senior leadership roles at Assertio Therapeutics, Pfizer, King, Ivax and Teva



### MATT CALLAHAN Board Executive Director

- Serial founder and ex-investment director of two venture capital firms in life sciences
- Developed four products through FDA approval and launch



### DR IRA LAWRENCE Clinical and Regulatory Adviser

- 30+ years of senior level leadership experience within the global pharmaceutical and medical device industries
- Former SVP R&D Medicis, Astellas and Fujisawa

## **Corporate Overview**

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

Share price	A\$0.14	
6-month low / high	A\$0.052/0.21	
Shares outstanding	1,421,196,813	
Market Capitalization	A\$199m	
Cash (30 Sep 2022)	A\$ 6.8m	
Debt (30 Sep 2022)	Nil	

**ASX: BOT TRADING INFORMATION** 



## SUBSTANTIAL SHAREHOLDERS

Shareholder	%
Antares Capital	9.0%
Board and Management	7.6%
Тор 20	34.3%

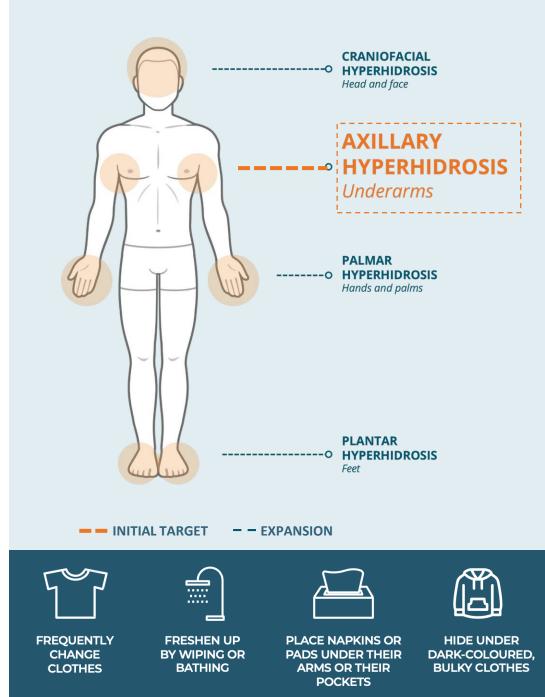




# Hyperhidrosis

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

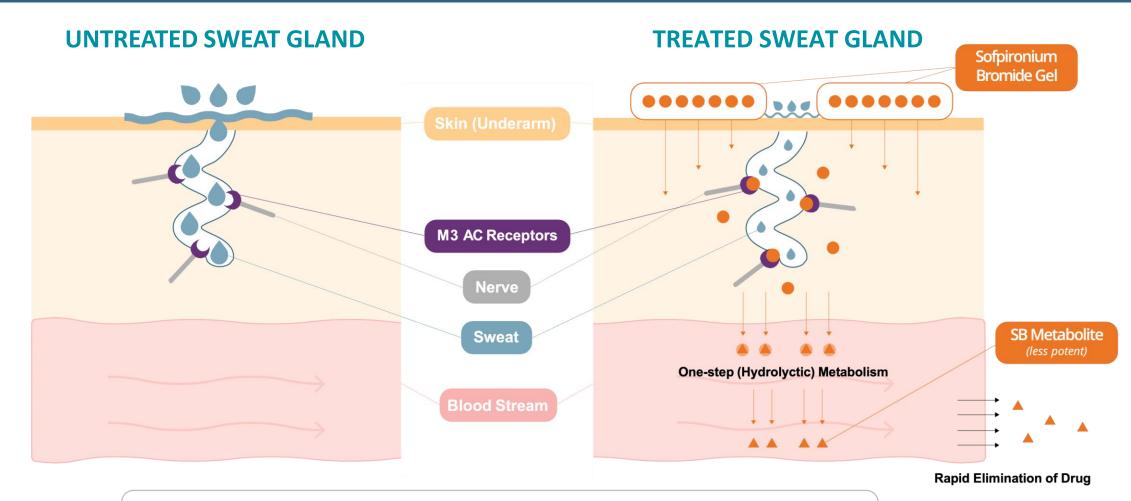
- Hyperhidrosis affects ~16M people in the US<sup>1</sup>
- Results from overstimulation of the nervous system (a physiological not psychological condition)<sup>1</sup>
- ✤ 90% of axillary (underarm) patients also have it in a second region<sup>1</sup>
- The most common age of onset for axillary hyperhidrosis 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>





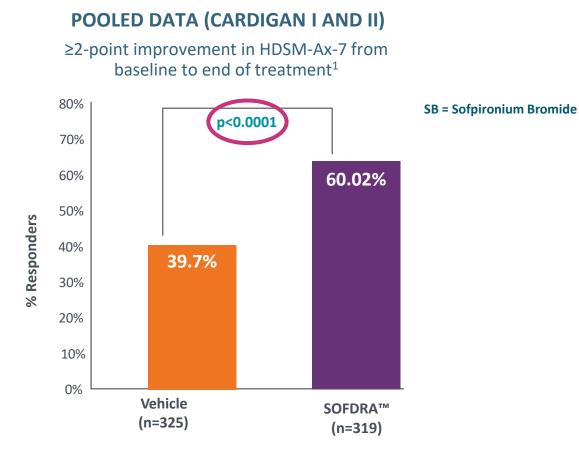
## Sofdra<sup>™</sup> mechanism of action

Blocks sweat gland receptors and rapidly degrades for excretion



**M3 AC Receptors =** Muscarinic Acetylcholine Receptors which regulate the function of sweat glands **SB Metabolite =** Sofpironium Bromide is converted into a less active form to help minimize side effects

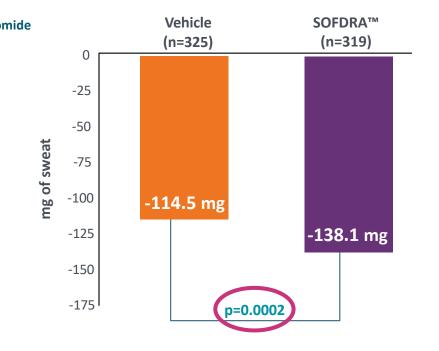
## **Both Phase 3 clinical study co-primary endpoints were highly** statistically significant



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)



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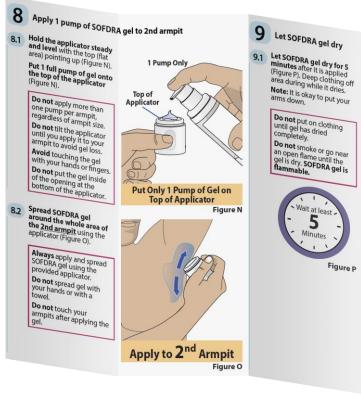
# **FDA Communication**

Efficacy, safety and manufacturing all acceptable, one issue to address - patient use instructions

- The only area identified by FDA was related to the patient *Instructions for Use*
- No efficacy, safety, or manufacturing issues were raised, and no additional clinical studies are required by FDA to support NDA approval
- No new review issues are anticipated as part of the resubmission review and the requested activities can be quickly addressed
- Botanix will meet with FDA in November/December to confirm resubmission guidance
- On track to resubmit the NDA by early Q1 CY2024, with a target approval of mid-CY2024
- Anticipated delay in launch from 1Q CY2024 of 3-6 months, with no change in large market opportunity



# Instructions for Use revision – well advanced and on target



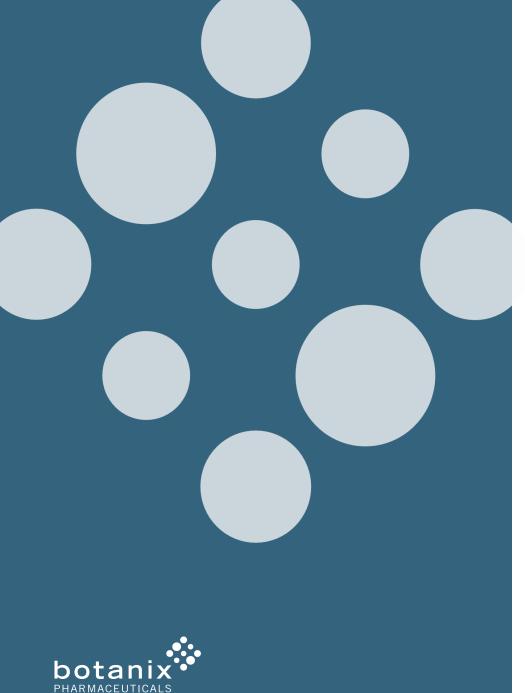
Instructions For Use



- Revised the Instructions For Use to further simplify the guidance for application
- Updated bottle label and carton to prominently display "wash hands with soap and water immediately after use"
- Conducted a *pilot* human factors study to demonstrate the revised Instructions For Use are reliably followed
- Filed an end-of-review meeting request with FDA to be held end of November/start of December CY 2023
- Preparing to commence human factors validation study to confirm revised Instructions for Use are reliably followed
- Preparing resubmission to FDA once completed study results are available targeted for early Q1 CY2024

underway

underway



# Commercial preparation for Sofdra<sup>™</sup> launch

# Sofdra<sup>™</sup> launch strategy

Rapidly establish Sofdra as a safe and effective first-line topical treatment of primary axillary hyperhidrosis, in patients 9 years of age and older

- Drive dermatology adoption through comprehensive engagement around a compelling clinical story
- Engage and motivate patients to take control of their hyperhidrosis and visit a physician for appropriate diagnosis and prescription

Ensure favorable coverage with payers



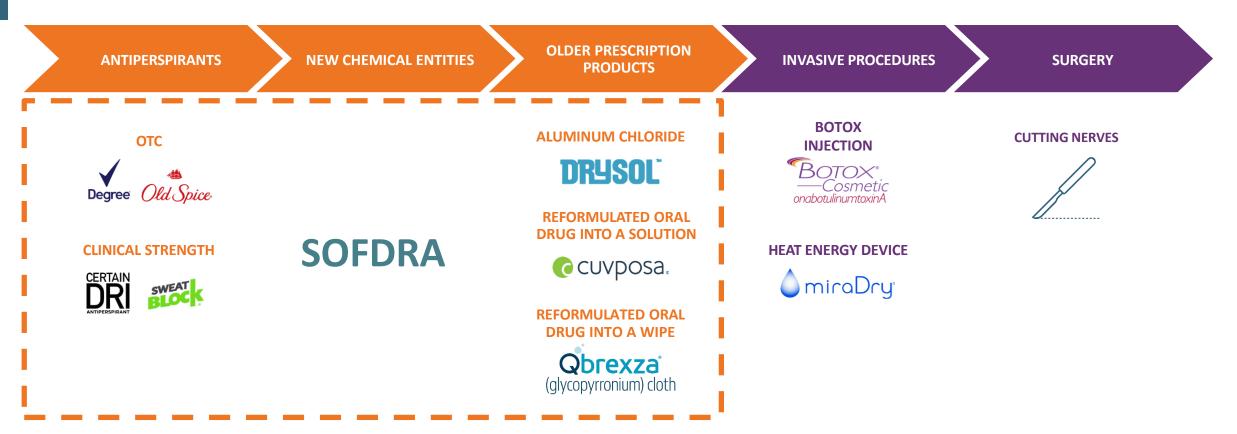
Provide patient access and immediate fulfillment through telemedicine and a dedicated pharmacy network, to drive trial and usage



Hire and train a highly effective sales force and target accordingly



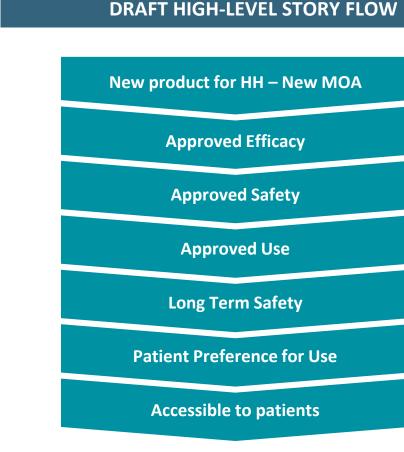
# Significant opportunity for a new topical agent with class leading efficacy and safety

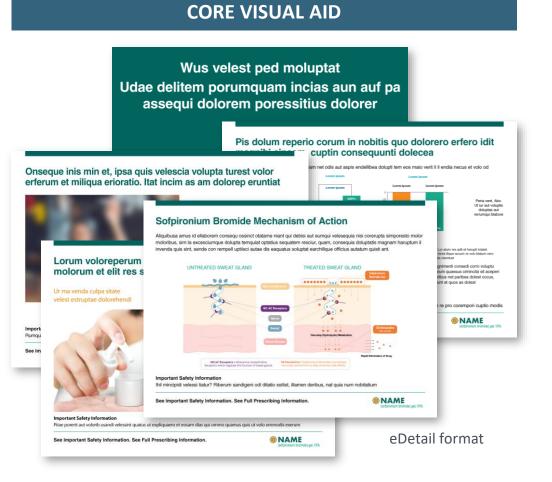


Due to its significant psychological impact, 54% of respondents suffering from hyperhidrosis say that they would <u>pay anything</u> for a treatment to stop their excessive sweating<sup>1</sup>



# **Tactics grounded on tested product position and messages**



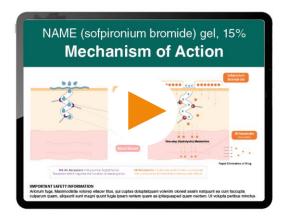




# Sales force effectively convey story & provide opportunity for trial

PHARMACEUTICALS

## **eDETAIL WITH MOA ANIMATION**



Digital platform to contain approved information to facilitate field force communication with physicians

## PLACEBO DEMO AND VIDEO DEMO



Aim to provide placebo product for every sales representative to demonstrate ease of use and provide video demo at launch



## LEAVE-BEHIND

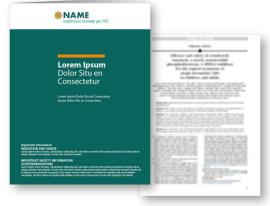
Consolidated Sales Aid style brochure that effectively conveys the story

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# **Engagement with dermatologists supported by nonpersonal tactics**



**CLINICAL RE-PRINT** 



Article reprint with branded cover to facilitate early interactions with dermatologists Provide full information on including core data and other dermatology resources to increase brand awareness

**WEBSITE** 

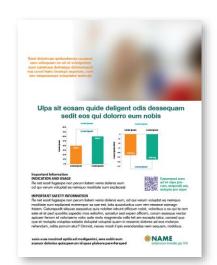
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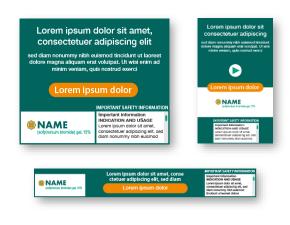
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JOURNAL AD

Support field force interactions through print/digital channels

Print and digital journal advertisements create and reinforce awareness among dermatologists



**BANNER ADS** 

Strategically placed banner ads, to drive physicians to branded website

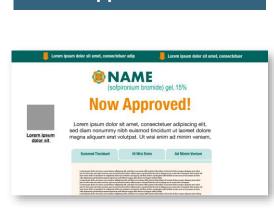


# **Tactics will provide information across multiple platforms**

Drive awareness of approval and provide resources to patients seeking further information

OR IMMEDIATE RELEASE onth 00, 2024	Media Contact: Haley Chartres 123-234-3466 hchartres@abcxyz.com
otanix Announces FDA Approval o	of Sofpironium Bromide Gel
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PR



"Now Approved" website

W important new treatment option for primary axillary hyperhidrosis

Responsive website compatible across desktop and mobile, including prescribing information, press release, important safety information, and communications opt-in

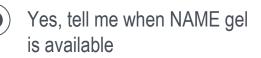


### People also ask

What is the brand name for sofpironium bromide?

Support of branded keywords for physician and consumer focused ads served

## **Opt-Ins**





Let me know when I can use telemedicine

Send me product updates

Build awareness and motivate patients to sign up to be receive updates



# Engage consumers where they are already active

Launch integrated DTC campaign to drive targeted awareness and motivate patients to take action; drive rapid uptake of prescriptions

<section-header>

Branded banner ads and updated website Customized branded banner ads that drive target to website and online self-test





Branded campaign ads Advertisements designed for direct response placed in strategically targeted print/digital publications



Drive positive discussion and coverage in consumer media. Strengthen relationships with community influencers. Establish Botanix as a leader and partner to the HH community



# Ensuring favorable Payer coverage leading up to and post launch

## Maximize coverage through strategic contracting

Pre-A	pprova	l Period

PDUFA–Launch Period

## Post-Launch Period

## Confirm anticipated Payer management

- Confirm current management approach for HH therapies
- Identify potential contracting opportunities
- Clinical presentations as requested

## **Execute contracts**

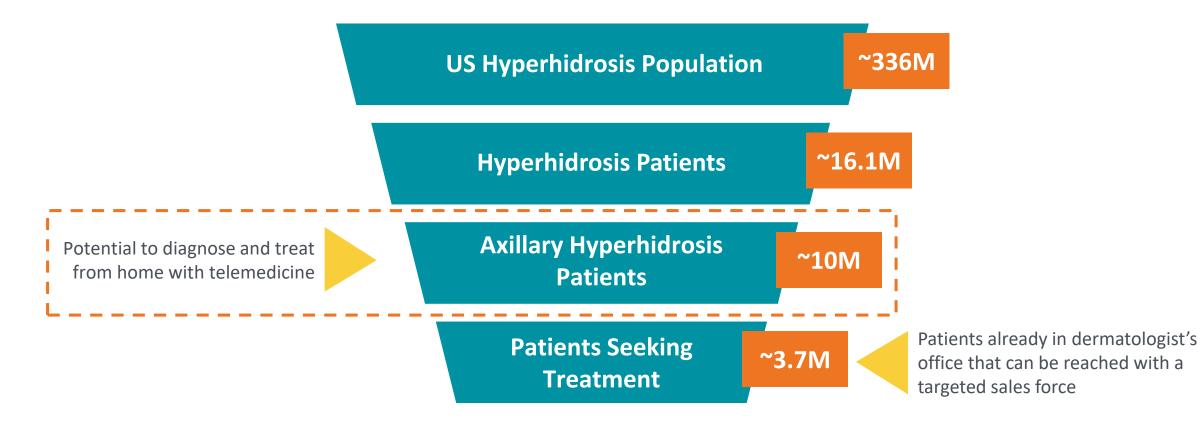
- Pricing and Product Fact Sheet
- Formulary kit
- Sales force training materials (Implementation Guides)
- Execute contracts with prioritized Payer accounts

## Contract for Favorable Coverage and Support Pull-Through

- Capitalize on formulary "wins" with sales force
- Continue discussions and execute contracts with prioritized accounts



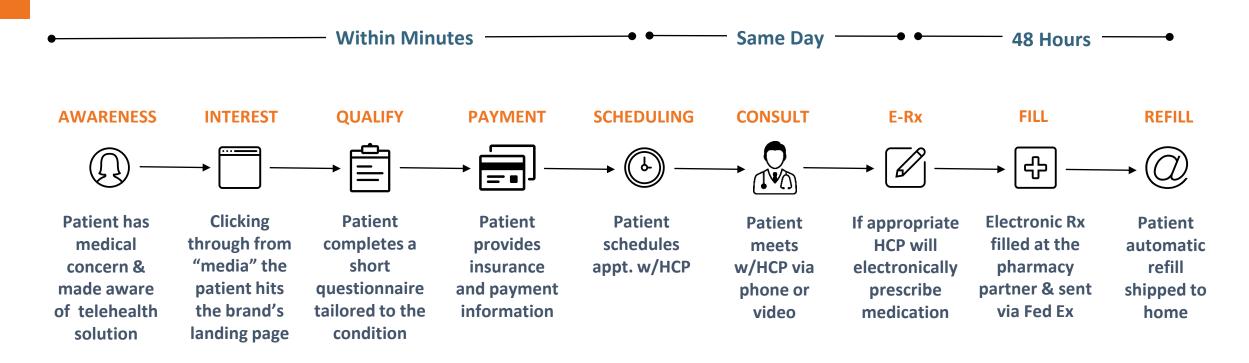
# **Digital strategy—expands the addressable patient population**





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

# Telehealth experience significantly speeds time to therapy

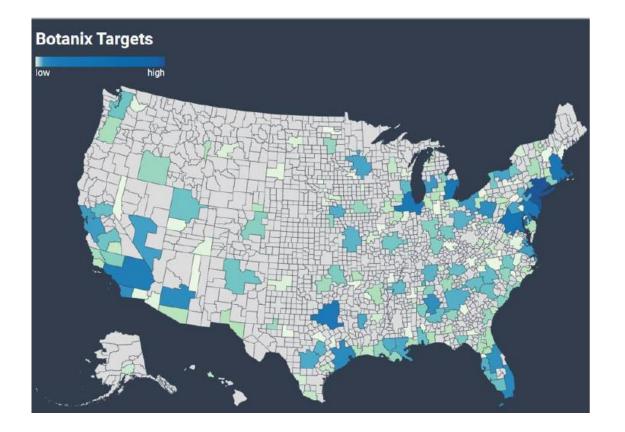


MOVE FROM THE CURRENT STATE OF WEEKS / MONTHS TO HOURS FOR A PRESCRIPTION



# Target most productive prescribers & expand reach via digital

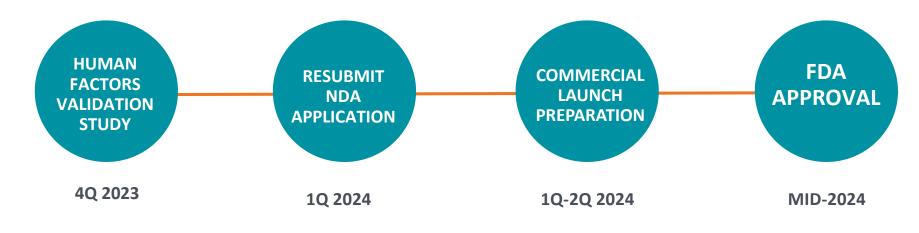
- Rapid scale-up of a new 20 30 rep field force to reach 4,500 high prescribing dermatologists
- Top sales professionals identified
- Recruiting ongoing for post approval start





## Focused pre-launch period ahead

- FDA submission on track for 1Q CY2024, with approval targeted for mid-CY2024
- Only remaining issue to be addressed for FDA approval relates to patient Instructions for Use – no efficacy, safety or manufacturing issues
- Commercial preparation accelerating, given de-risking of FDA approval
- Company is funded to approval and has multiple commercialization options







## **Investor Update**

October 2023