

#### 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*™ 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

#### **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.





# **Investor Update**

October 2023

#### **Important Notice & Disclaimer**

#### 1. Summary information

This presentation has been prepared by Botanix Pharmaceuticals Ltd ("Botanix") and contains summary information about Botanix and the business conducted by it which is current as at the date of this presentation ("Presentation") (unless otherwise indicated).

The information in this Presentation is general in nature and does not purport to be accurate nor complete, nor does it contain all of the information that an investor may require in evaluating a possible investment in Botanix, nor does it contain all the information which would be required in a disclosure document or prospectus prepared in accordance with the requirements of the Corporations Act 2001 (Cth). It has been prepared by Botanix with due care but no representation or warranty, express or implied, is provided in relation to the accuracy, reliability, fairness or completeness of the information, opinions or conclusions in this Presentation by Botanix or any other party.

The information in this Presentation remains subject to change without notice. Reliance should not be placed on information or opinions contained in this Presentation, and Botanix does not have any obligation to finalize, correct or update the content of this Presentation. Certain data used in this Presentation has been obtained from research, surveys or studies conducted by third parties, including industry or general publications.

To the maximum extent permitted by law, Botanix is not responsible for updating, nor undertakes to update, this Presentation. It should be read in conjunction with Botanix's other periodic and continuous disclosure announcements lodged with the ASX, which are available at www2.asx.com, au or at https://botanixpharma.com/category/asx-releases/.

#### 2. Not an offer

Neither this Presentation nor any of its contents will form the basis of any understanding, proposal, offer, invitation, contract or commitment.

#### 3. Industry data

Certain market and industry data used in connection with or referenced in this Presentation has been obtained from public filings, research, surveys or studies made or conducted by third parties, including as published in industry-specific or general publications. Neither Botanix nor its advisers, or their respective representatives, have independently verified any such market or industry data.

#### 4. Financial data

-All dollar values are in United States dollars (\$ or US\$) unless otherwise stated. Amounts, totals and change percentages are calculated on whole numbers and not the rounded amounts presented.

#### 5. Forward-looking statements and forecasts

This Presentation contains certain "forward-looking statements" and comments about future matters. Forward-looking statements can generally be identified by the use of forward-looking words such as, "expect", "anticipate", "likely", "intend", "should", "could", "may", "predict", "plan", "propose", "will", "believe", "forecast", "estimate", "target" "outlook", "guidance" and other similar expressions and include, but are not limited to, plans and prospects for the Company, the Company's strategy, future operations, the expected timing and/or results of regulatory approvals and prospects of commercializing product candidates or research collaborations with its partners, including in Japan, the outcome and effects of Sofpironium Bromide and the market for Sofpironium Bromide. Indications of, and guidance or outlook on, future earnings or financial position or performance are also forward-looking statements. You are cautioned not to place undue reliance on forward-looking statements. Any such statements, opinions and estimates in this Presentation speak only as of the date hereof, are preliminary views and are based on assumptions and contingencies subject to change without notice, as are statements about market and industry trends, projections, guidance and estimates. Forward-looking statements are provided as a general guide only. The forward-looking statements contained in this Presentation are not indications, guarantees or predictions of future performance and involve known and unknown risks and uncertainties and other factors, many of which are beyond the control of Botanix, and may involve significant elements of subjective judgement and assumptions as to future events which may or may not be correct.

Any such forward looking statements are also based on assumptions and contingencies which are subject to change, and which may ultimately prove to be materially incorrect, as are statements about market and industry trends, which are based on interpretations of current market conditions. Investors should consider the forward-looking statements contained in this Presentation in light of those disclosures and not place undue reliance on such statements (particularly in light of the current economic climate and significant volatility, uncertainty and disruption caused by the COVID-19 pandemic). The forward-looking statements in this Presentation are not guarantees or predictions of future performance and may involve significant elements of subjective judgment, assumptions as to future events that may not be correct, known and unknown risks, uncertainties and other factors, many of which are outside the control of Botanix.

Except as required by law or regulation, Botanix undertakes no obligation to finalize, check, supplement, revise or update forward-looking statements or to publish prospective financial information in the future, regardless of whether new information, future events or results or other factors affect the information contained in this Presentation.

#### 6. No liability

The information contained in this document has been prepared in good faith by Botanix, Neither Botanix, nor any of its advisers or any of their respective affiliates, related bodies corporate, directors, officers, partners, advisers, employees and agents have authorised, permitted or caused the issue, lodgment, submission, dispatch or provision of this Presentation in a final form and none of them makes or purports to make any binding statement in this Presentation and there is no statement in this Presentation which is based on any statement by them.

To the maximum extent permitted by law. Botanix and its advisers, affiliates, related bodies corporate, directors, officers, partners, employees and agents:

expressly disclaims any and all liability, including, without limitation, any liability arising out of fault or negligence, for any loss arising from the use of or reliance on information contained in this document including representations or warranties or in relation to the accuracy or completeness of the information, statements, opinions, forecasts, reports or other matters, express or implied, contained in, arising out of or derived from, or for omissions from, this document including, without limitation, any estimates or projections and any other financial information derived therefrom, whether by way of negligence or otherwise; and

expressly exclude and disclaim all liabilities in respect of, make no representations regarding, any part of this Presentation and make no representation or warranty as to the currency, accuracy, adequacy, reliability or completeness or fairness of any statements, estimates, options, conclusions or other information contained in this Presentation.



## 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



**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



**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



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 BILL BOSCH
Board Director

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



**ANTHONY ROBINSON** 

**VP** of Development

- Recently Vice President R&D at Advicenne
- Senior leadership roles at Aquestive Therapeutics, Intrommune and Shire Pharmaceuticals



DR JACK HOBLITZELL

**SVP Pharmaceutical Development** 

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



**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

## **ASX: BOT TRADING INFORMATION**

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

## **SUBSTANTIAL SHAREHOLDERS**

%
9.0%
7.6%
34.3%



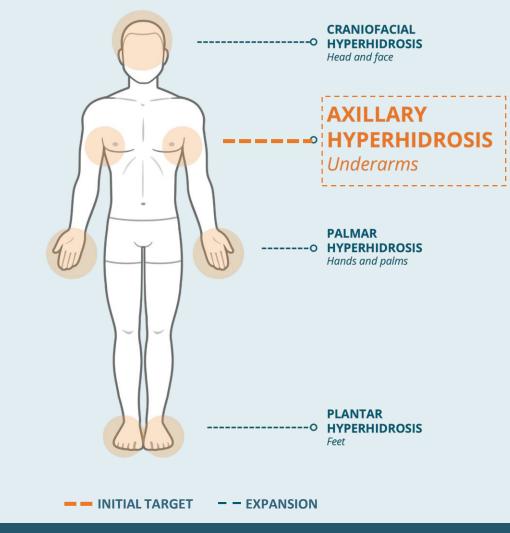




## **Hyperhidrosis**

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

- Hyperhidrosis affects ~16M people in the US¹
- 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 region¹.
- 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>











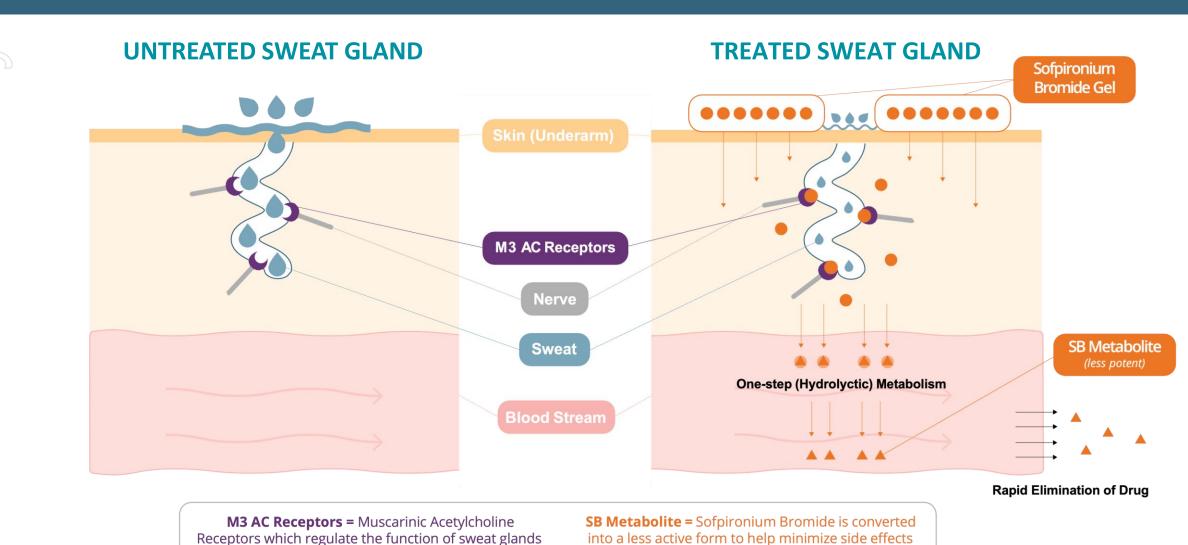
FREQUENTLY
CHANGE
CLOTHES

FRESHEN UP BY WIPING OR BATHING PLACE NAPKINS OR PADS UNDER THEIR ARMS OR THEIR POCKETS

HIDE UNDER DARK-COLOURED, BULKY CLOTHES

## Sofdra™ mechanism of action

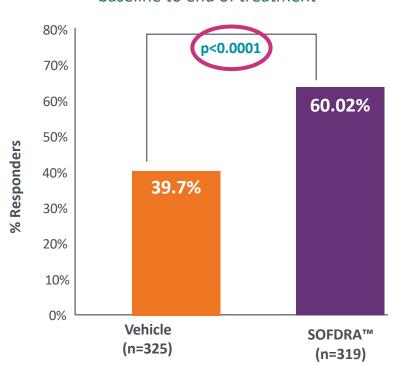
Blocks sweat gland receptors and rapidly degrades for excretion



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

### POOLED DATA (CARDIGAN I AND II)

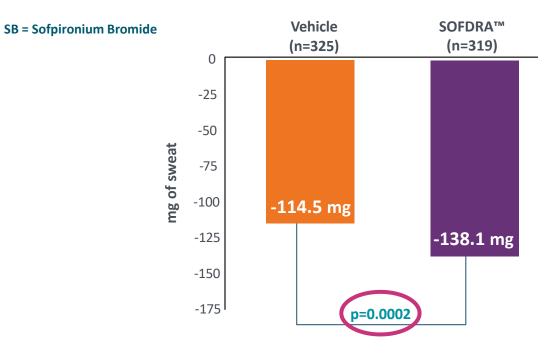
≥2-point improvement in HDSM-Ax-7 from baseline to end of treatment<sup>1</sup>



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)



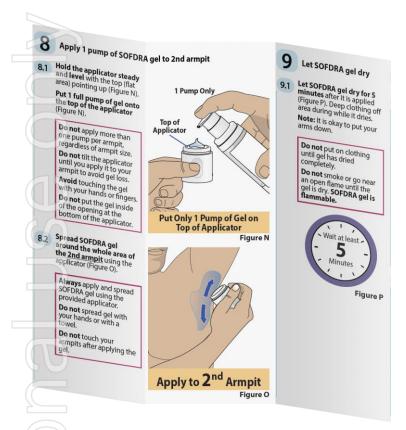
## **FDA Communication**

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





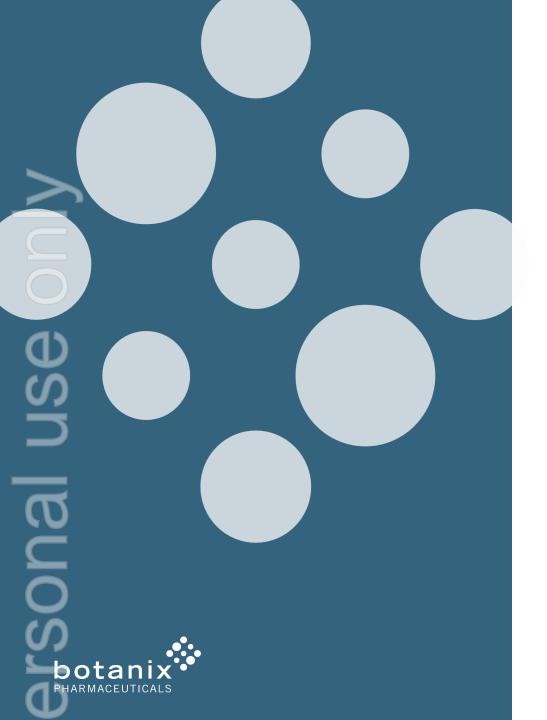






underway





# Commercial preparation for Sofdra™ 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

#### DRAFT HIGH-LEVEL STORY FLOW

New product for HH - New MOA

**Approved Efficacy** 

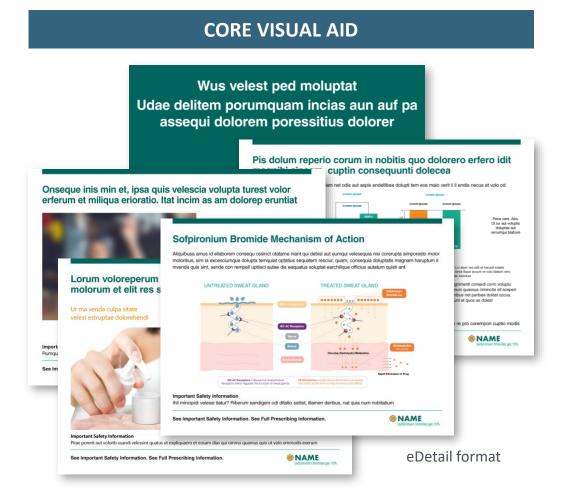
**Approved Safety** 

**Approved Use** 

**Long Term Safety** 

**Patient Preference for Use** 

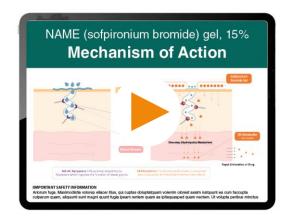
**Accessible to patients** 





# Sales force effectively convey story & provide opportunity for trial

#### **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



# Engagement with dermatologists supported by nonpersonal tactics

#### **CLINICAL RE-PRINT**

Arm field force with data



Article reprint with branded cover to facilitate early interactions with dermatologists

#### **WEBSITE**

**JOURNAL AD** 

**BANNER ADS** 

Support field force interactions through print/digital channels



Provide full information on including core data and other dermatology resources to increase brand awareness



Print and digital journal advertisements create and reinforce awareness among dermatologists



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



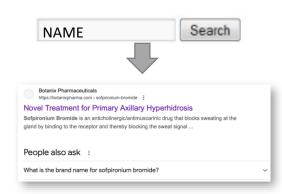
Drive positive and widespread discussion at FDA approval to establish a important new treatment option for primary axillary hyperhidrosis

## "Now Approved" website



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

## SEO, SEM



Support of branded keywords for physician and consumer focused ads served

## **Opt-Ins**

- Yes, tell me when NAME gel is available
- 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

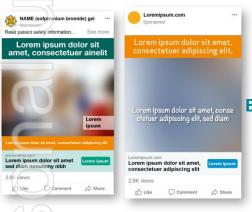
Launch integrated DTC campaign to drive targeted awareness and motivate patients to take action; drive rapid uptake of prescriptions

#### **DIGITAL**



Branded banner ads and updated website

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





# Branded/unbranded social media

Connect with patients and create a community

#### **TRADITIONAL**



## Branded campaign ads

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

PR









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-Approval 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**

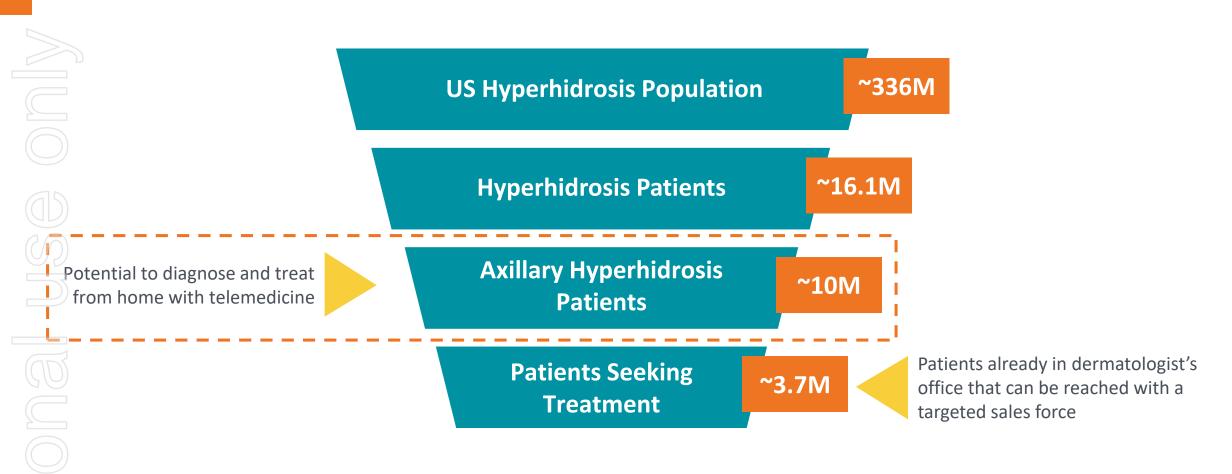
- Pricing and Product Fact Sheet
- Formulary kit
- Sales force training materials (Implementation Guides)
- Execute contracts with prioritized Payer accounts

# Contract for Favorable Coverage and Support Pull-Through

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

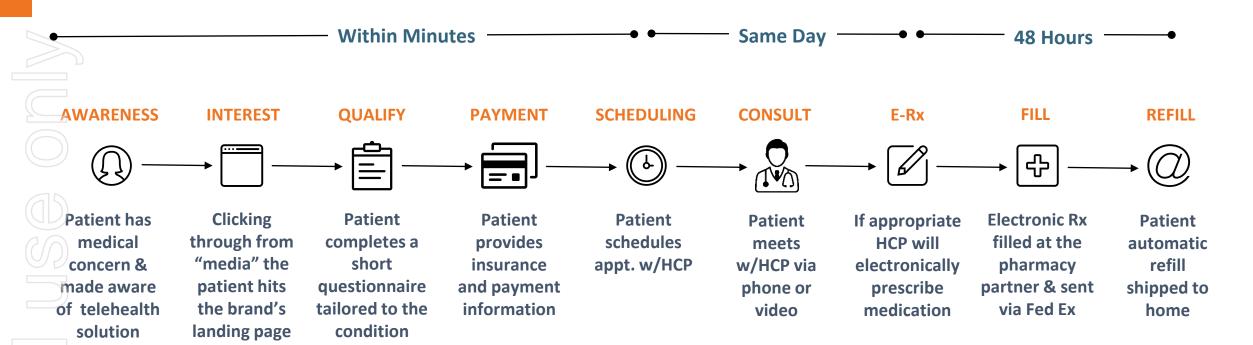


# Digital strategy—expands the addressable patient population





## Telehealth experience significantly speeds time to therapy

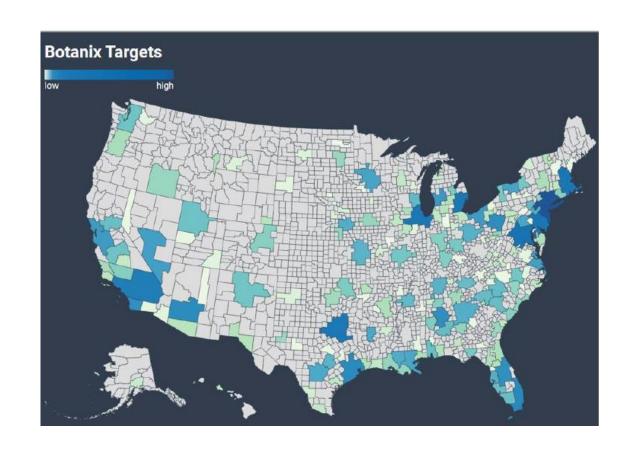


MOVE FROM THE CURRENT STATE OF WEEKS / MONTHS TO HOURS FOR A PRESCRIPTION



# Target most productive prescribers & expand reach via digital

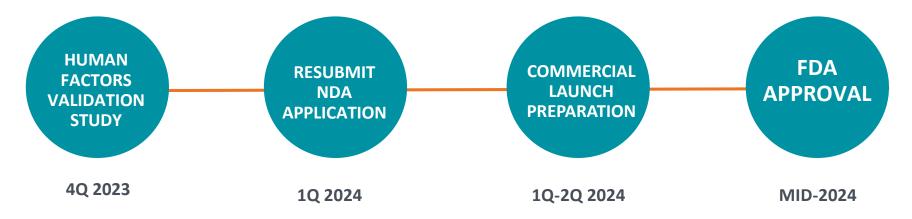
- Rapid scale-up of a new 20 30 rep field force to reach 4,500 high prescribing dermatologists
- Top sales professionals identified
- Recruiting ongoing for post approval start





## 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