

### 7 June 2023

### **Investor Webinar Presentation**

**Philadelphia and Phoenix US, 7 June 2023**: Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, "Botanix" or "the Company"), is pleased to provide a copy of its investor presentation as attached to this release.

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 Sofpironium Bromide for the treatment of primary axillary hyperhidrosis, through FDA approval. A mid-cycle review for the product has been successfully completed by FDA in 1Q 2023, which subject to other information that may be required by FDA, remains on track for approval for Q3 2023. Sofpironium Bromide is positioned to be a leading first line and second line therapy and represents a safe and effective new option for patients.

The Company also has a pipeline of other products in late-stage clinical studies for the treatment of moderate to severe rosacea (successful Phase 1b/2 study in 4Q 2022), dermatitis and acne respectively. Botanix is also developing a topical antimicrobial product for the eradication of bacteria on the skin surface, initially in patients who are undergoing hemodialysis. To learn more please visit: http://www.botanixpharma.com/

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## **Investor Webinar**

June 2023

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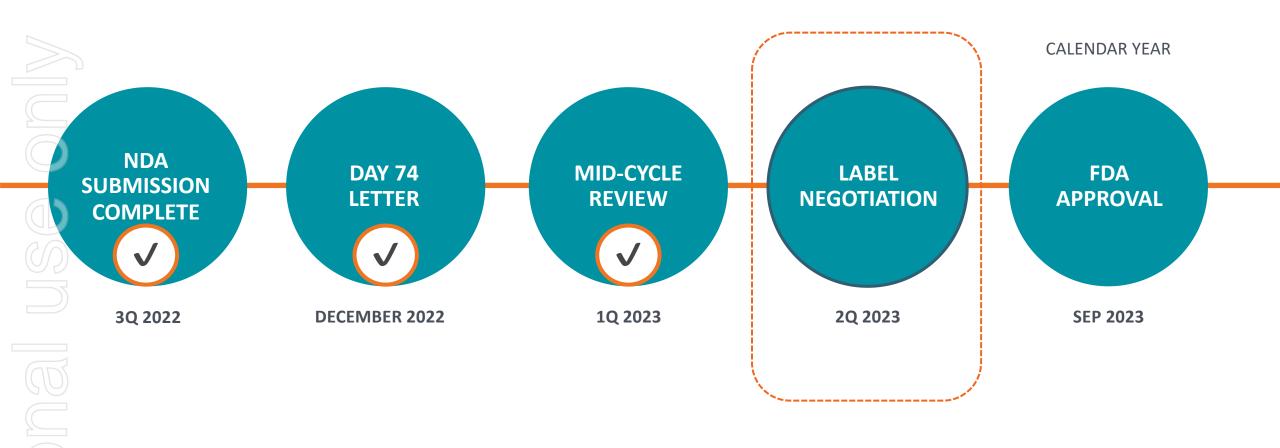
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#### Authorised for release by Vince Ippolito, Executive Chairman

# **Executing on planned commercial and regulatory milestones**



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# **Activities leading up to FDA approval**

Initiation of label negotiations accelerates Botanix's commercial activities ready for launch

### LABEL NEGOTIATIONS

COMMERCIAL MANUFACTURING & PACKAGING

### **COMMERCIAL LAUNCH STRATEGY**

- Planned to commence late Q2 2023 to be finalized before anticipated approval in Q3 2023
- Finalizing the branded packaging and timing manufacturing to coincide with launch
- Rapidly establish SB Gel as a safe and effective first line treatment for hyperhidrosis

# Label negotiations

Towards the end of the NDA review process, FDA and Botanix negotiate the drug's final package label

### EFFICACY AND SAFETY DATA

### **DOSING AND ADMINISTRATION**

### **INDICATION AND CLAIMS**

### FINAL STEP IN THE APPROVAL PROCESS

- The label will reflect the efficacy and safety data that FDA and the Sponsor (Botanix) agrees needs to be included
- The label provides instructions for the dermatologist and patient about how SB Gel should be applied, how often and when
- Based on the age groups tested (in SB Gel's case, down to age 9), the label will specify those populations and target application area (ie underarm or axillary)
- Once the label is agreed, no further reviews are required before FDA approval anticipated in September 2023

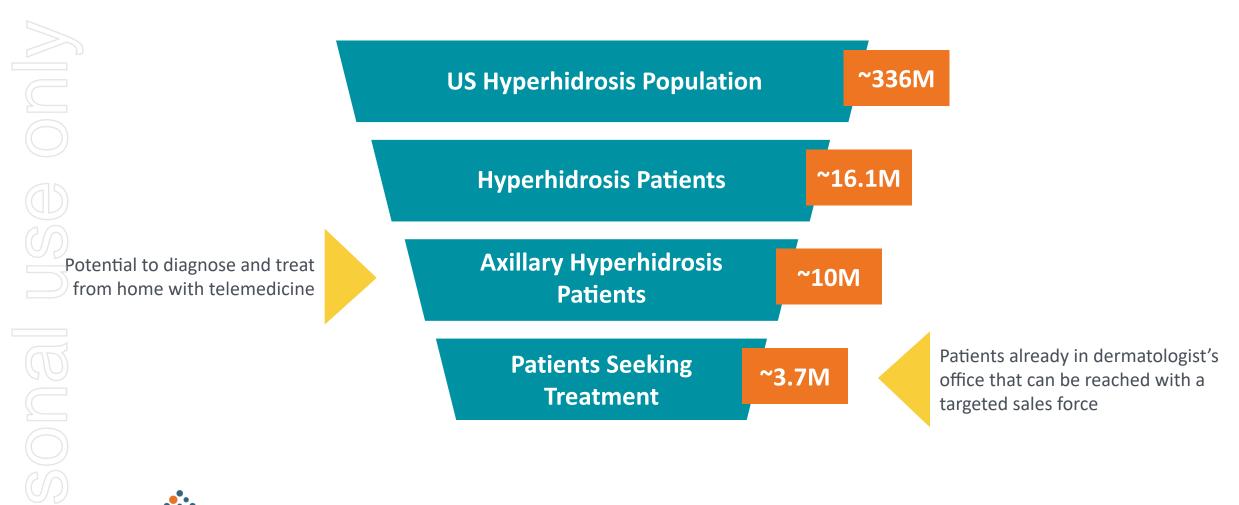
# **Commercial manufacturing and packaging**

Utilizing same site as Phase 3 studies and at same scale and equipment

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	DRUG SUBSTANCE (API)	<ul> <li>Well-characterised synthetic process - room temperature stability &gt;36 months</li> <li>Manufactured by same company as for our partner Kaken in Japan (at 450 kg scale)</li> </ul>
	DRUG PRODUCT (Gel)	<ul> <li>Process includes filling, capping and secondary packaging (cartons)</li> <li>Commercial contract manufacturer for US already appointed and manufactured 4x registration &amp; 2x qualification batches at 200 kg scale</li> </ul>
5	CONTAINER (Dispenser)	<ul> <li>Proprietary applicator to limit direct patient contact to the drug product during application</li> <li>Patents covering the container-closure system already submitted in key markets</li> </ul>
30	PACKAGING (Label and IFU)	<ul> <li>Branded carton with trade name and logo</li> <li>Label and patient instructions for use included in final packaging</li> </ul>
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# Efficient dermatologist targeting <u>plus</u> digital strategy—expands the addressable patient population



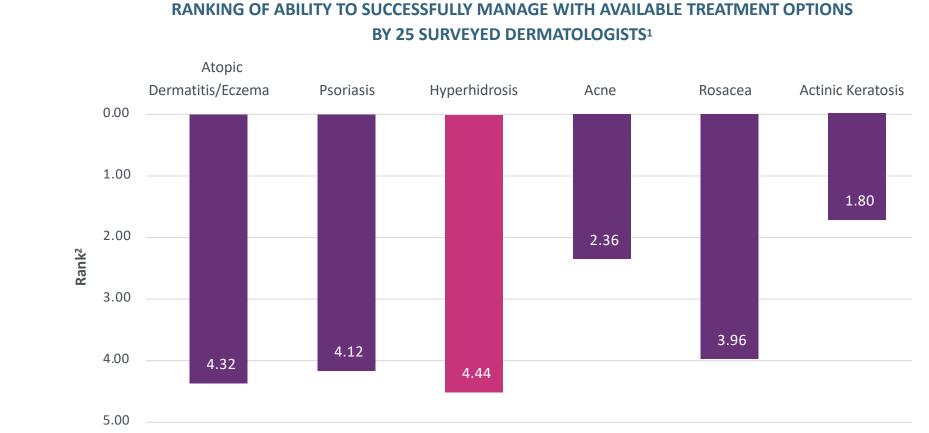
Source: 1. International Hyperhidrosis Society, 2. Dolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology

Research

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# **Hyperhidrosis: Significant Unmet Medical Need**

When provided with a selection of key dermatologic indications, surveyed clinicians ranked hyperhidrosis last in their ability to successfully manage with available treatment options





Source: 1. Adapted from Cowen and Company Analyst Report dated February 27, 2019; survey executed by ExpertConnect. 2. 1 = most able to successfully manage; 6 =least able to successfully manage

# **SB Gel launch strategy**

Rapidly establish SB Gel 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 telemedicine doctor for appropriate diagnosis and prescription



Maximize favorable coverage through strategic contracting with insurance companies



Provide patient access and immediate fulfillment through telemedicine and a pharmacy network, to drive trial and usage while optimizing profitability ('gross to net')



Hire and train a highly effective sales force and target accordingly

# Create tools to drive early adoption

Targeted at dermatologists and patients



- Placebo demonstration video
  - Mechanism of action video

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- Sales force leave behind
- Sales force objection handler
- Sales force generated emails
- Journal advertisement
- ✤ Clinical reprint
- HCP website
- HCP banner advertisements
- Congress booth & materials
- PR plan
- ✤ HCP SEO/SEM





# Create consumer collateral to engage and motivate patients

Targeted at dermatologists and patients

Consumer creative

- Consumer messaging
- Branded banners ads
- Consumer website

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- Consumer print ad
   Consumer social media ads
   Consumer in-office materials
- Consumer digital video

- Patient advocacy plan
- Public relations plan
- Consumer medical plan
  - SEO/SEM
  - Social media
  - Print
  - Digital video
  - Banner ad placement



# **Implement insurance (payer) plans**

	PAYER VALUE PROPOSITION & KEY COMMUNICATIONS
0 1)	PRICING & CONTRACTING
	PAYER ENGAGEMENT
10	PULL-THROUGH

- Compelling payer value proposition, leveraging market research/internal expertise
- Tools and resources to effectively communicate value proposition ٠.
- Communicate key product info to payers and channel at approval to expedite reimbursement and enable fulfillment \*
- Supporting data to justify desired price point for SB Gel \*
- Contracting strategy supported by robust research and analysis \*
- Understanding of payers' intent and ability to manage hyperhidrosis category and SB Gel through market research/ \* internal feedback
- Payer profiles and engagement plan to maximize access at FDA approval \*

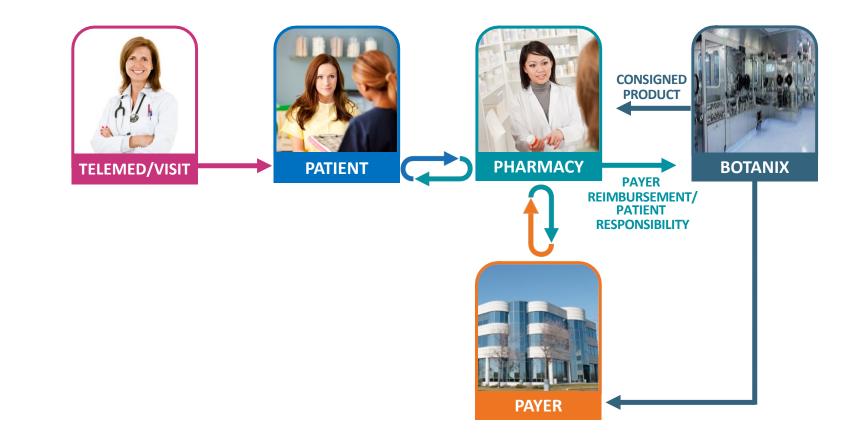
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Resources to ensure dermatologists' confidence in the availability and affordability of SB Gel \*

# Create a pharmacy network that is directly connected to a telemedicine provider, that will facilitate prescribing of SB Gel

**PROPOSED PROGRAM DESIGN** 

Remove barriers to use by providing doctors with the ability to prescribe SB Gel at launch



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**PROVIDE ACCESS** 

### Finalize contracts with partners that meet key criteria Discussions underway

### **Telemedicine Partner**

- History of experience
- ✤ Prescribing in all 50 states
- Exceeds industry standard for patient experience
- Provides end to end closed loop solution
- Supports a "digital first" approach
  - Allows for asynchronous diagnosis and prescribing
  - Experience with Dermatology & Consumer spaces

### **Pharmacy Partner**

- Fulfillment in all 50 states
- Coordinates central filling to optimize data
- Provides weekly data refresh
- Average shipment time less than 3 days
- Enough space to allow for growth of program
- Patient interactions provided by licensed HCPs



# Rapid scale up of sales force after FDA approval

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- Rapid scale-up of a 20–30 rep field force
- Efficient & effective onboarding and initial training
- Targeted deployment in high value areas only

**Comprehensive, pressure-tested, onboarding and training plan** anchored to the key field activities that we initially target

Key live Sales meetings to provide training and certification to enable compliant and effective physician engagement

### SALES FORCE ONBOARDING & TRAINING PLAN

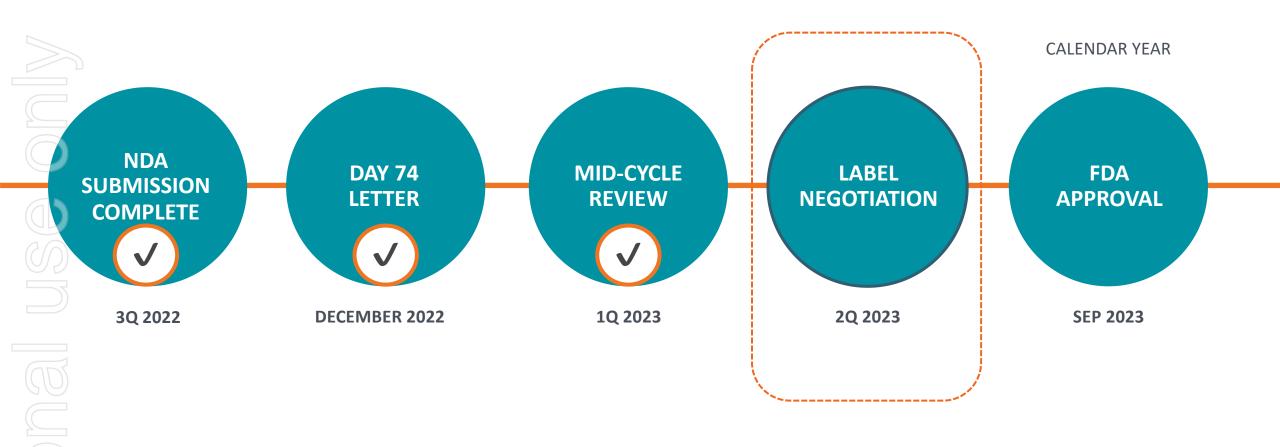


# Why we're excited about the Sofpironium Bromide opportunity

$\geq$	Significant Market Opportunity	Potential Best-in-Class		Robust Clinical Data		Launched in Japan		Global IP Protection
	mpacts >16M peoplespecifically designed axillary hyperhidron U.Saxillary HHMultiple ways to differentiate (efficient)	differentiate (efficacy, safety, formulation,	*	Positive and statistically significant results in U.S. and Japan P3 pivotal programs Completed U.S. and	*	SB gel, 5% (ECCLOCK <sup>®</sup> ) approved & launched in Japan for primary axillary HH by Kaken Pharmaceutical ~300k units sold in	*	Comprehensive IP in U.S. and other countries Patent protection extends through 2040
	Broad reimbursement already in place (no need to get a code or new category)	device) First-to-market outside U.S.	*	Japanese P3 long-term safety studies Exposure in >1,600 HH patients for U.S. NDA; submission expected mid-2022		second year of launch	unch	
Resea	re: 1. International Hyperhidrosis Society, 2. D Irch	olittle, et al, 2016, Hyperhidrosis: an update	on prev		Archive	es of Dermatology		

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