

24 July 2023

## Botanix Bioshares Biotech Summit Presentation

### Key highlights

- **Botanix is presenting at the Bioshares Biotech Summit being held this week in Hobart, Tasmania**
- **The Conference attracts attendees from around Australia and the region, and features presentations by and business development discussions with biotechnology companies and investors**
- **Botanix will be highlighting the significant commercial potential of Sofpironium Bromide which remains on track for FDA approval in late September 2023, as well as the recent acquisition of royalty and milestone payment obligations from its partner Fresh Tracks Therapeutics Inc**

**Philadelphia and Phoenix US, 23 July 2023:** Clinical dermatology company, Botanix Pharmaceuticals Limited (ASX: BOT, “Botanix” or “the Company”), is pleased to advise that it is presenting at the Bioshares Biotech Summit being held in Hobart, Tasmania this week.

The Conference brings together biotech companies and investors from around Australia and the region for company presentations, investor discussions and industry engagement. Botanix will be presenting the significant commercial potential of Sofpironium Bromide and sharing some of the reasons behind its recently announced buyout of royalty and milestone payment obligations from its partner Fresh Track Therapeutics Inc and associated capital raising.

With commercial activities ramping up for the planned launch of Sofpironium Bromide and increasing interest from potential partners, the product remains on target for FDA approval in late September 2023.

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

Release authorised by

**Vince Ippolito**  
Executive Chairman

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## 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 targeted for the end of September 2023. 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/>

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# Bioshares Conference 2023

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# Botanix: A leader in topical drug development



## DERMATOLOGY FOCUS

New treatments for common skin diseases—such as excessive sweating (hyperhidrosis), rosacea and acne



## 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 more than 30 dermatology drug developments and launches



## SOFPIRONIUM BROMIDE GEL (“SB”)

First and only new drug for “primary axillary hyperhidrosis” (medical condition which results in excessive underarm sweating) already approved in Japan and sales ramping up with partner<sup>1</sup>



## MID-CYCLE REVIEW POSITIVE

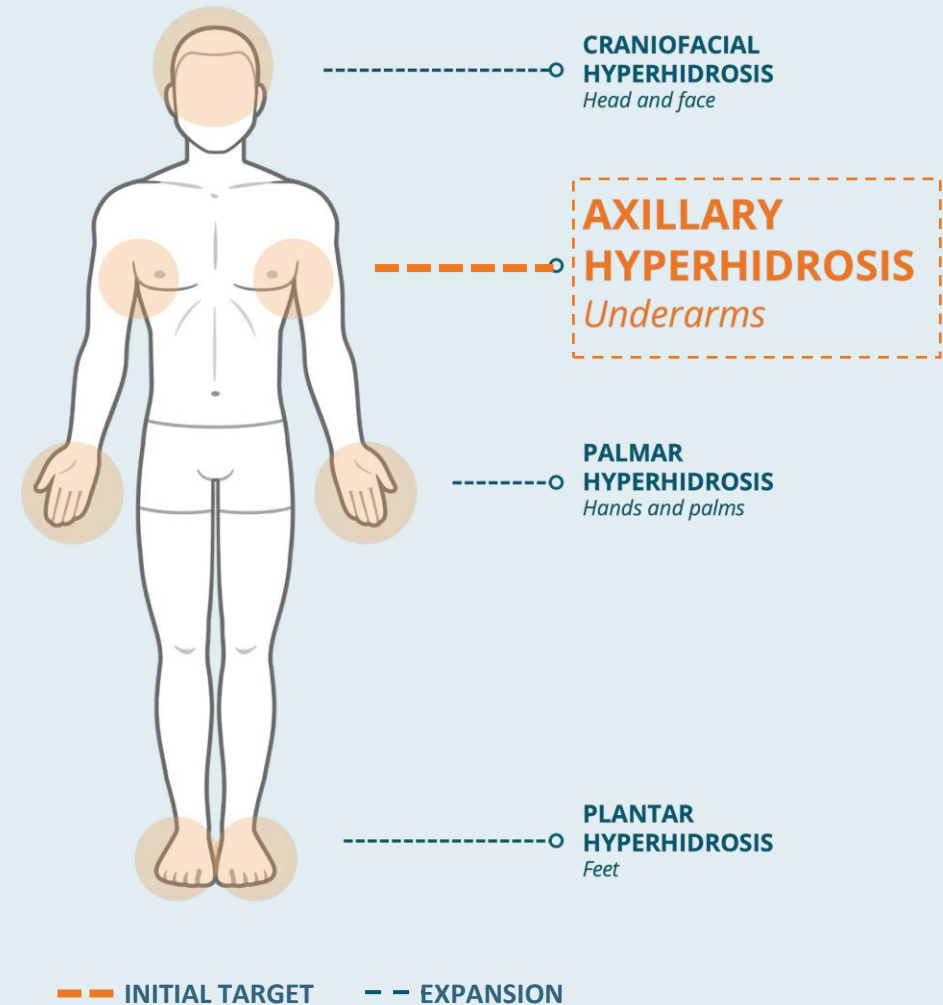
FDA mid-cycle review of SB confirmed that no significant issues have been identified. Approval timeline on track for September 2023

Preparing for  
FDA approval  
of first product  
in a \$US1.6  
billion market

# Hyperhidrosis

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

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



FREQUENTLY  
CHANGE  
CLOTHES



FRESHEN UP  
BY WIPING OR  
BATHING



PLACE NAPKINS OR  
PADS UNDER THEIR  
ARMS OR THEIR  
POCKETS

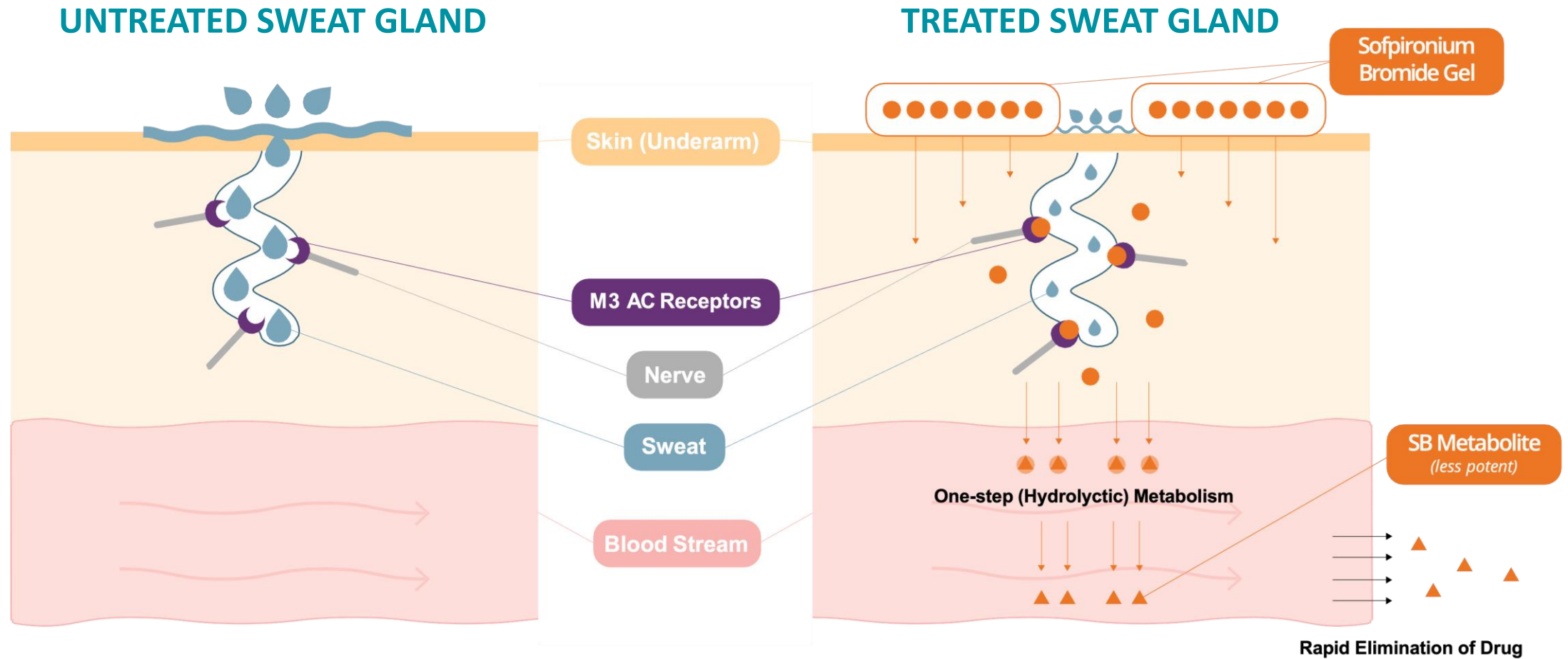


HIDE UNDER  
DARK-COLOURED,  
BULKY CLOTHES

# Sofpironium Bromide mechanism of action

Blocks sweat gland receptors and rapidly degrades for excretion

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**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

# Label negotiations

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

EFFICACY AND SAFETY DATA

- ❖ The label will reflect the efficacy and safety data that FDA and the Sponsor (Botanix) agrees needs to be included

DOSING AND ADMINISTRATION

- ❖ The label provides instructions for the dermatologist and patient about how SB Gel should be applied, how often and when

INDICATION AND CLAIMS

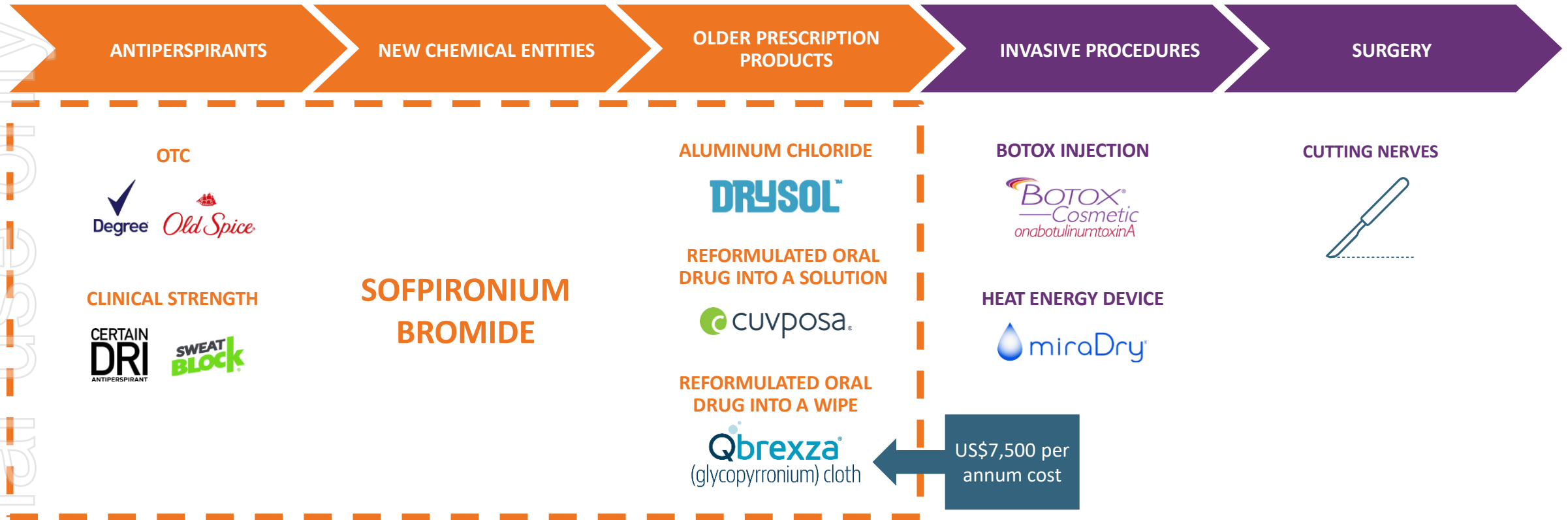
- ❖ Based on the age groups tested (in SB Gel's case, down to age 9), the label will specify those populations and target application area (ie underarm or axillary)

FINAL STEP IN THE APPROVAL PROCESS

- ❖ **Once the label is agreed, no further reviews are required before FDA approval anticipated in September 2023**

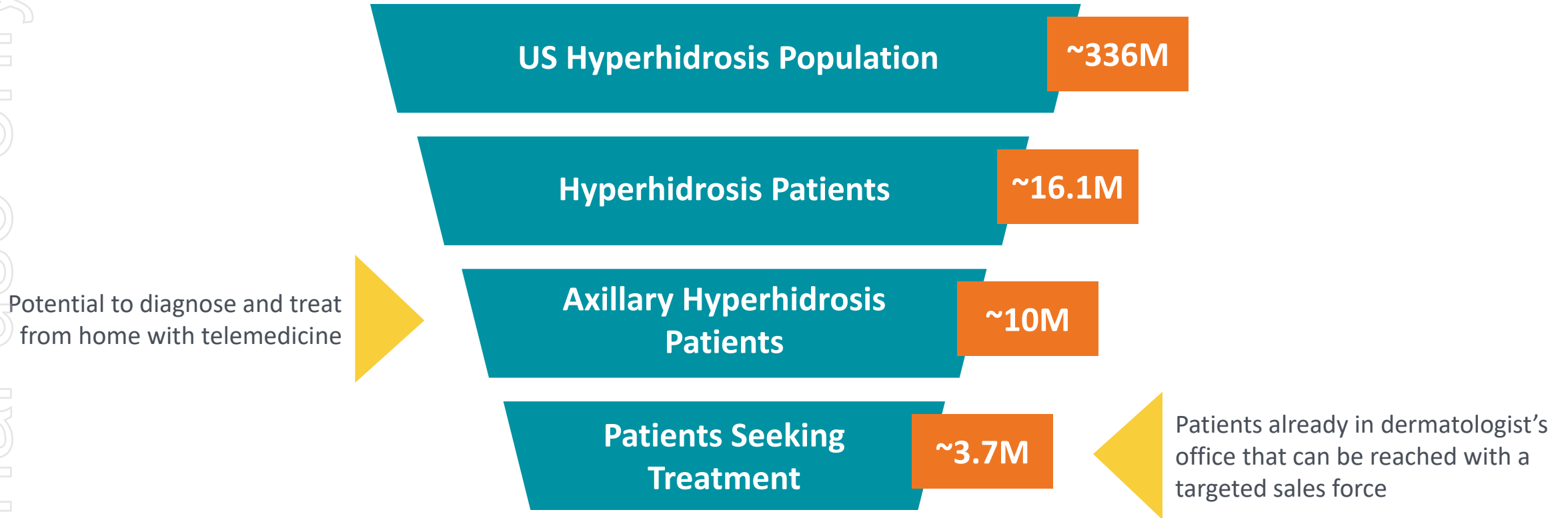


# Significant opportunity for a new topical agent with class leading efficacy and safety



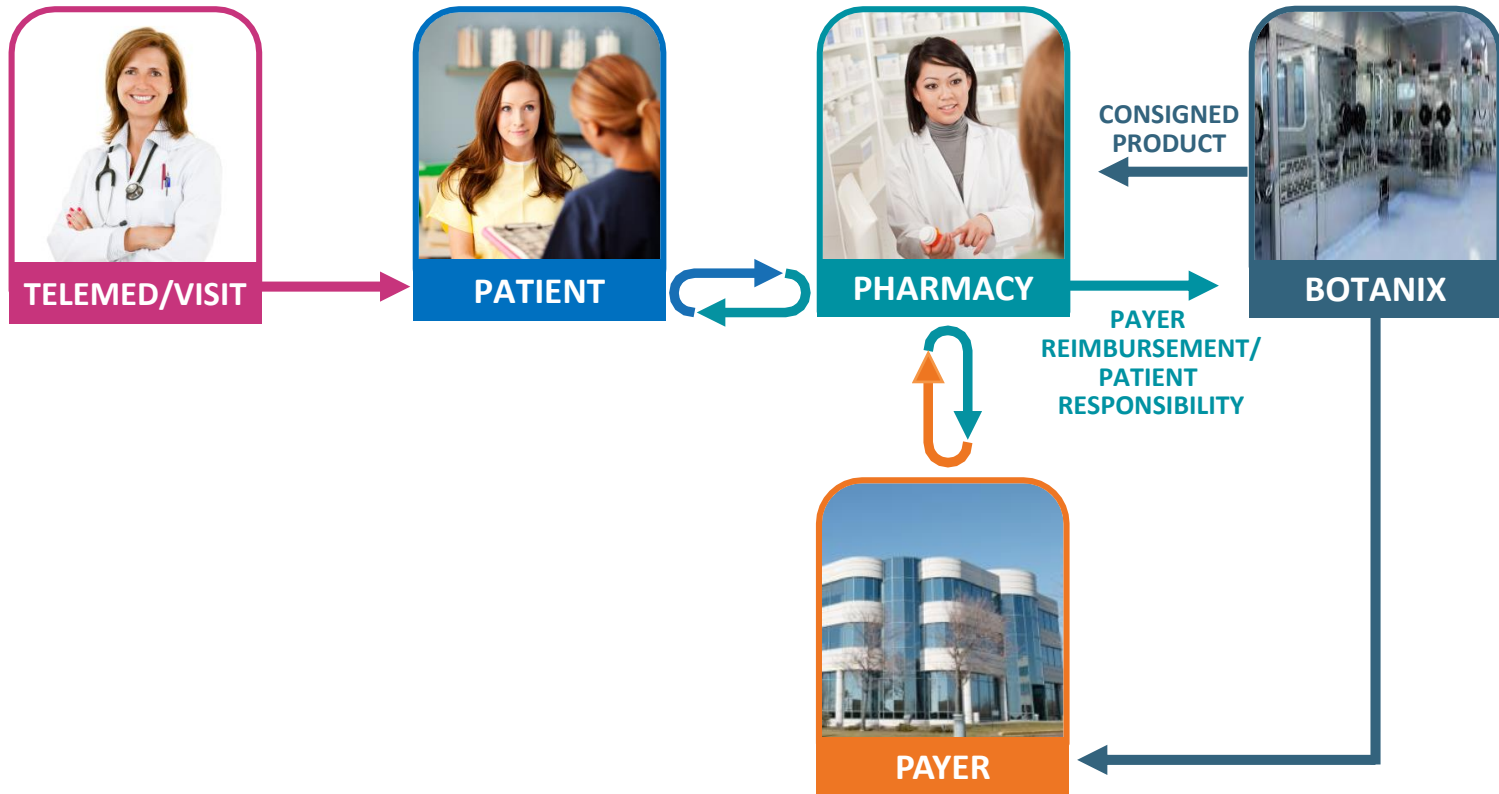
Due to its significant psychological impact, 54% of respondents suffering from hyperhidrosis say that they would pay anything for a treatment to stop their excessive sweating<sup>1</sup>

# Digital strategy—expands the addressable patient population



# 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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# Royalty and Milestone buyout transaction benefits

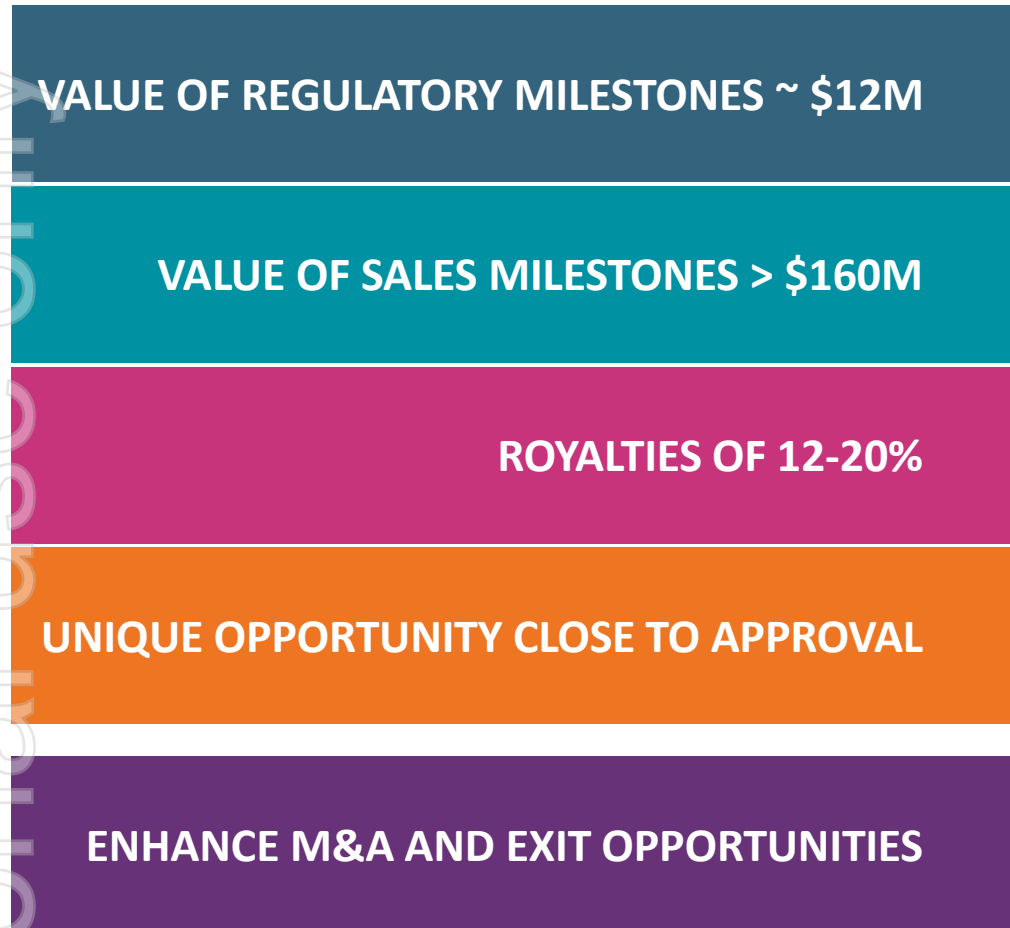
Opportunity to remove milestones payments and double-digit royalties payable to Fresh Tracks (the company Botanix acquired the SB asset from)

Financial Obligations to Fresh Tracks	Current Commitment to Fresh Tracks (USD)	After Royalty Buyout Transaction (USD)
Upfront payment to buyout future milestone and royalty payments		\$8.25m
FDA Approval for SB (target September)	\$4m	Nil
Marketing approval for SB in EU or UK	\$4m	Nil
Approval of SB in another indication	\$4m	Nil
Sales Milestones (once Net Sales exceed \$75m - up to \$1.8 billion p.a)	~\$160m	Nil
Royalties on Net Sales	12-20%	Nil*

\*Note – Botanix will retain an obligation to the head licensor, Bodor Laboratories, to pay a 5% royalty on Net Sales made by Botanix

# Why buy out the royalties and milestones now?

Compelling and unique opportunity to add significant value to Botanix, as we approach planned FDA approval



- ❖ Avoids September \$4M “FDA approval and potential “EU/UK approval” and “other indication” (e.g hyperhidrosis on hands) milestones
- ❖ Avoids all sales milestones which impact Botanix future profitability
- ❖ Avoids all royalties due to Fresh Tracks which impacts Botanix future profitability
- ❖ Fresh Tracks are in the midst of a strategic review and potential change of business direction. Botanix is unlikely to have this opportunity again
- ❖ With no royalties or milestones due to Fresh Tracks, the Sofpironium Bromide asset (and Botanix) are more attractive for M&A and exit opportunities

# Executing on planned commercial and regulatory milestones

