

Investor Update

**Positive results from FDA mid-cycle  
review of Sofpironium Bromide**

April 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—as well as life-threatening bacterial infections



## 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 and approval timeline on track for September 2023

Preparing for  
FDA approval of  
first product in a  
US\$1.6 billion  
market

# 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 Operating 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, Intromune 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

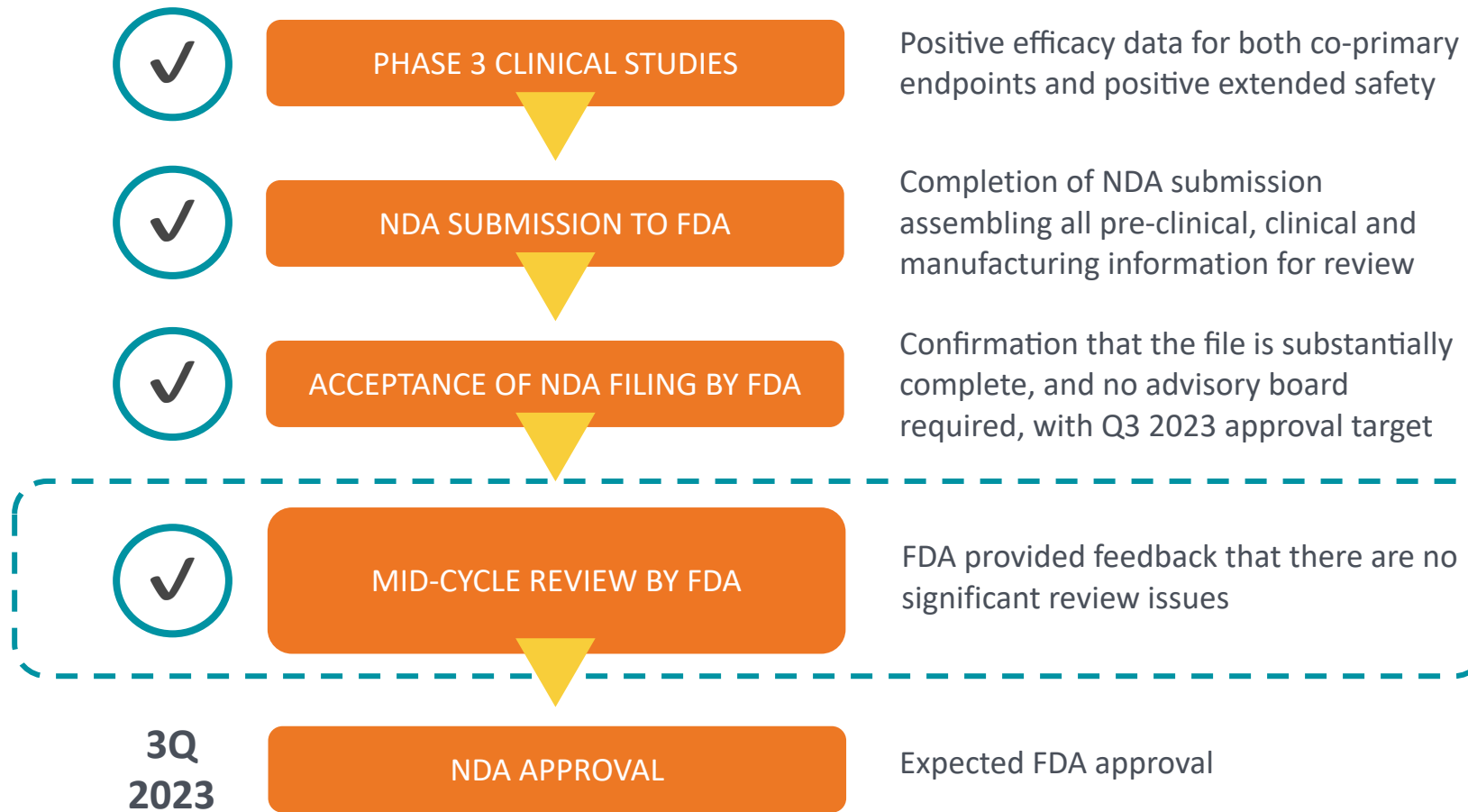


**DR IRA LAWRENCE**  
Clinical and Regulatory Adviser

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

# Value inflection points accrue as FDA review progresses

Successful mid-cycle review now completed



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# Mid-cycle review meeting successfully completed with FDA

FDA's review of the NDA with each of its internal functional groups (manufacturing, pre-clinical, clinical etc.) provides preliminary notice of issues to the sponsor (Botanix)

**NO SIGNIFICANT ISSUES**

- ❖ No significant issues have been identified by FDA as a result of its review of product quality, non-clinical or clinical

**NO SAFETY OR RISK ISSUES**

- ❖ No major safety issues, no risk management or advisory board requirements

**DISCUSSIONS ON FINAL ISSUES**

- ❖ FDA will continue its discussions with Botanix and focus on labeling, clinical outcome assessments, patient instructions and brand name

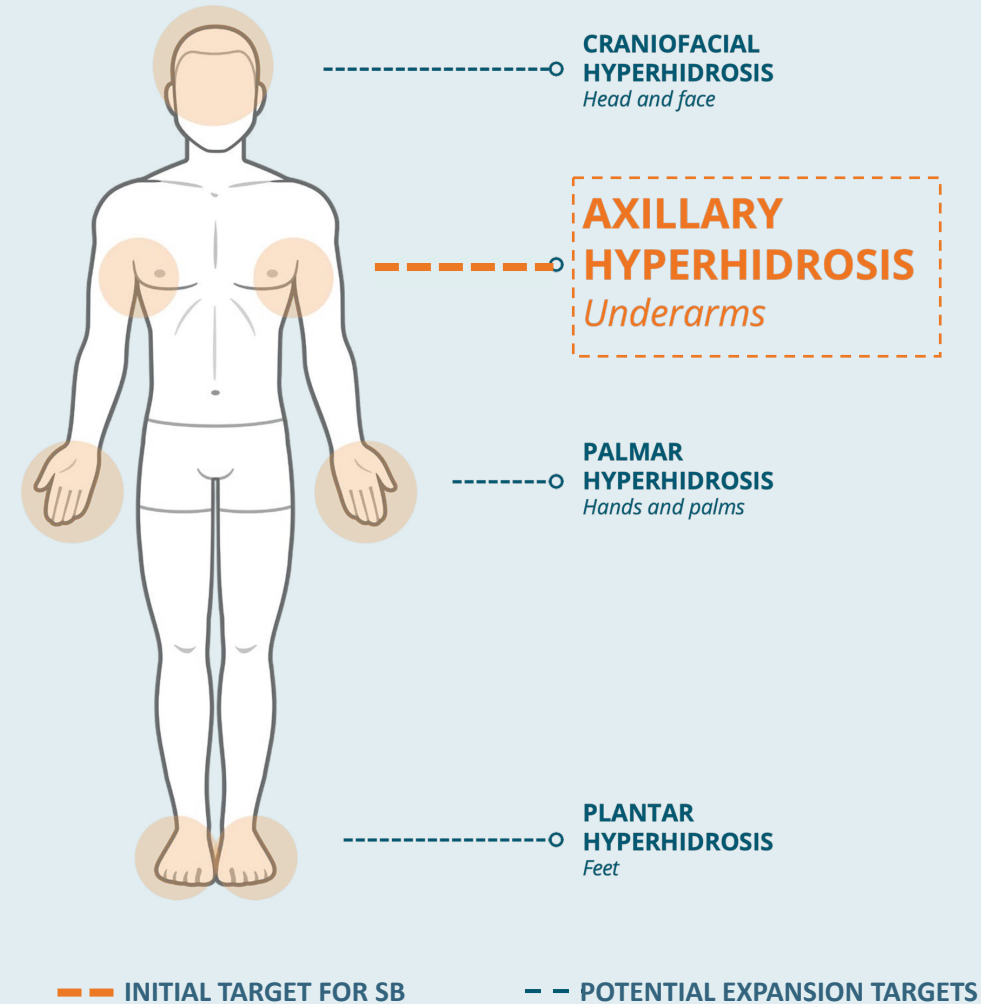
**INSPECTIONS AND RESPONSES**

- ❖ Working with FDA to respond to usual information requests, review further comments and facilitate planned inspections

# 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 ~US\$1.6B per annum—projected to grow to US\$2.8B by 2030<sup>3</sup>



FREQUENTLY  
CHANGE  
CLOTHES



FRESHEN UP  
BY WIPING OR  
BATHING



PLACE NAPKINS OR  
PADS UNDER THEIR  
ARMS OR THEIR  
POCKETS

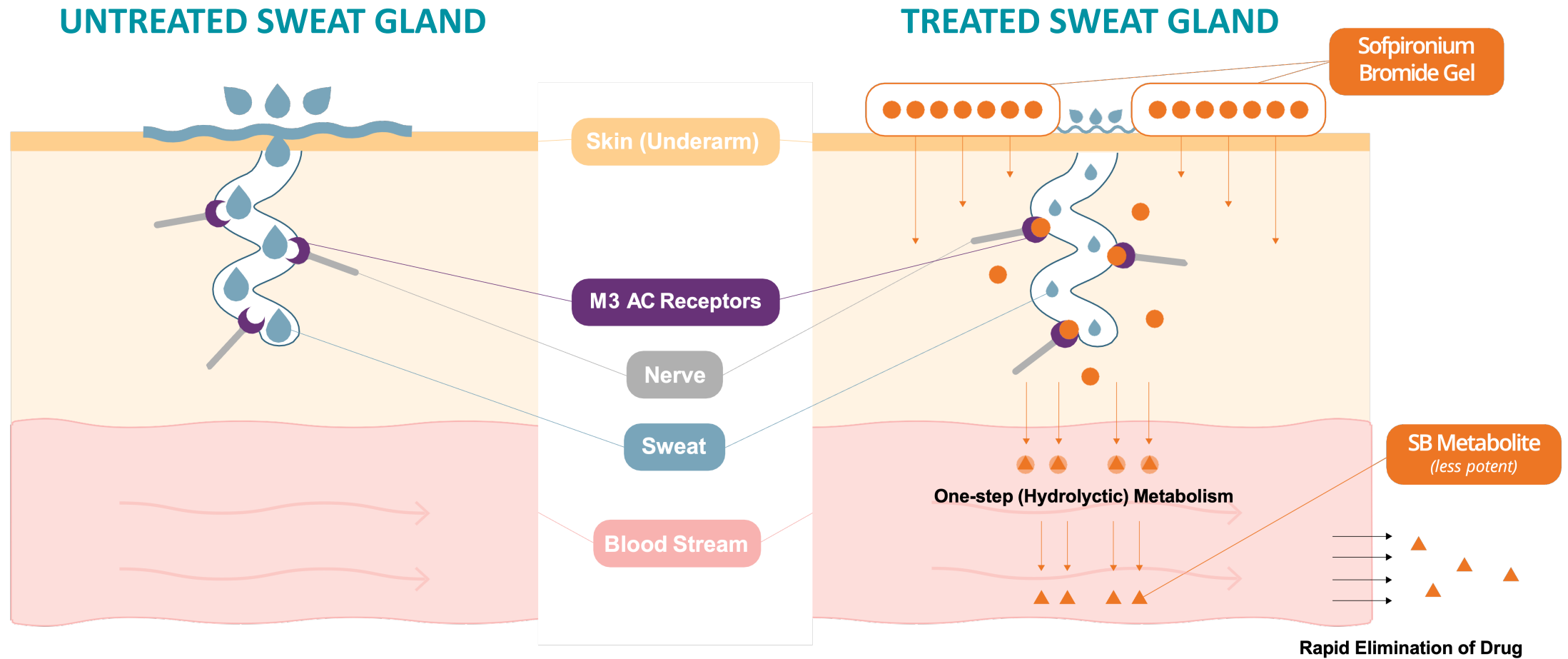


HIDE UNDER  
DARK-COLOURED,  
BULKY CLOTHES



# Sofpironium Bromide mechanism of action

Blocks sweat gland receptors and rapidly degrades for excretion



**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

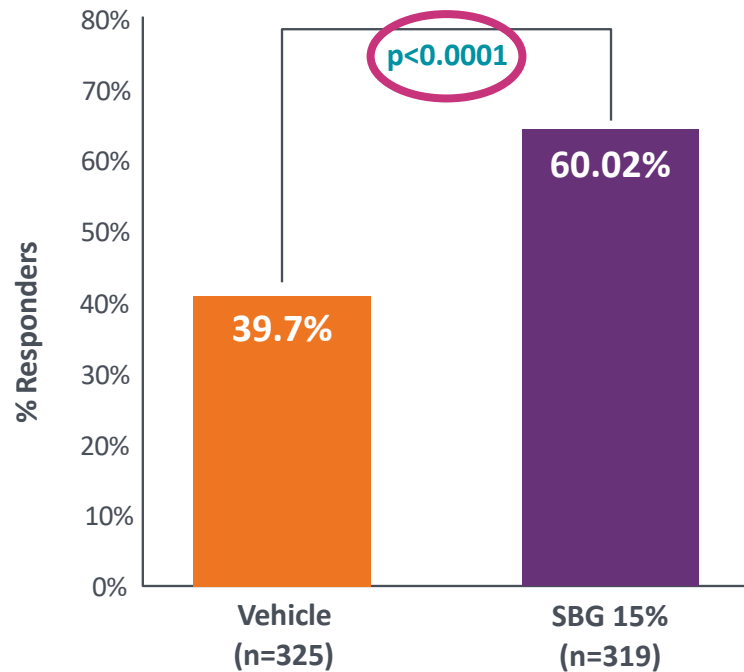
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# Both Phase 3 clinical study co-primary endpoints were highly statistically significant

## POOLED DATA (CARDIGAN I AND II)

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

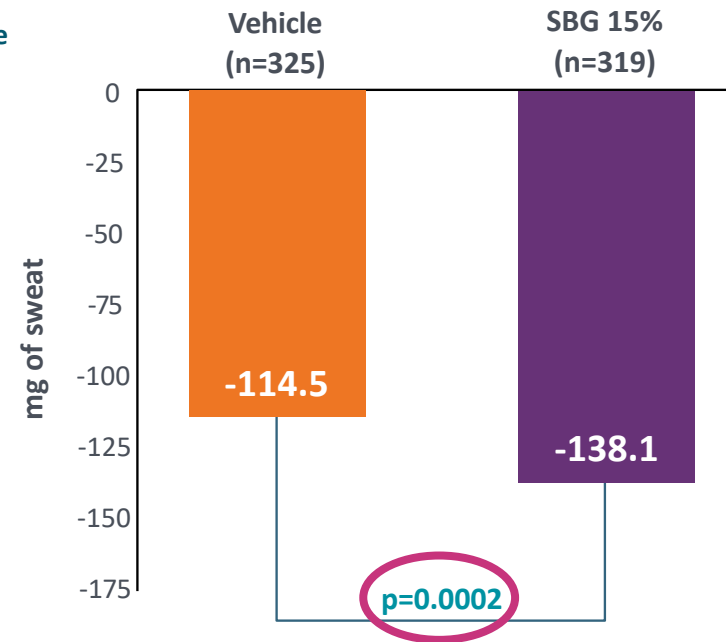


SB = Sofpironium Bromide

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>

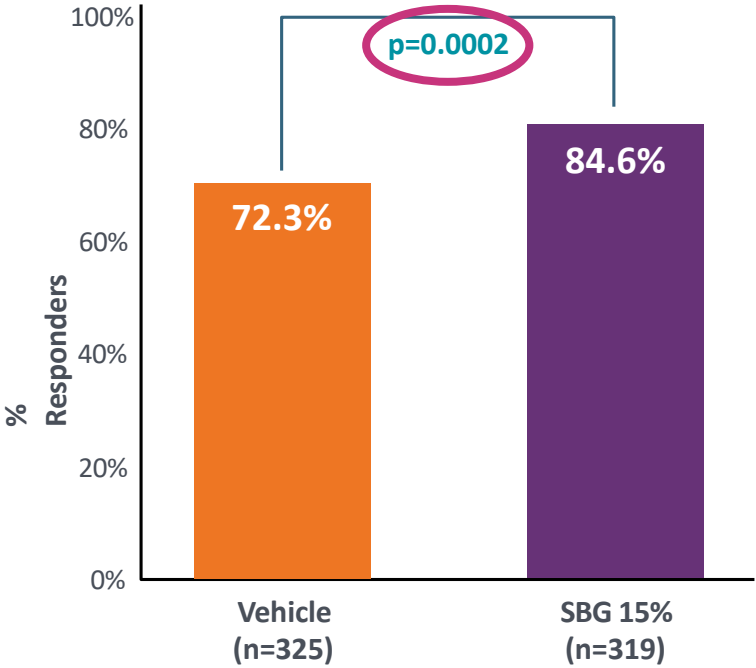


GSP (Gravimetric Sweat Production) is an objective measurement of underarm sweat production over 5 minutes

# Secondary Efficacy Endpoint

## Pooled Data (Cardigan I and II)

HDSM-Ax-7 reduction ( $\geq 1$ -point improvement) from baseline to end of treatment<sup>1</sup>



SB= Sofpironium Bromide

Almost **85%** of patients experienced a *statistically significant and clinically meaningful response*

# 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>

# Independent research shows 85% of patients and dermatologists would use and prescribe Sofpironium Bromide<sup>1</sup>

With ~13M hyperhidrosis patients in the US, a significant opportunity exists for a new topical product to address an unmet need if it is effective, convenient, and not priced prohibitively<sup>2</sup>



UNMET NEED: ~6 OUT OF 7

"I can count on one hand my total armory for treating hyperhidrosis. I need **more tools in my toolbox** and a **convenient product** for my patients."

– DERMATOLOGIST



*A rating of 4 out of 7 is high based on our experience with payers across therapeutic areas*

UNMET NEED: ~4 OUT OF 7

"We are always looking for more **efficacious** therapies that are **easier to take**."

– PAYER



UNMET NEED: ~6 OUT OF 7

"The treatments that we have are **not very convenient** and are **pretty costly**. I just feel like there are **not enough options**"

– PATIENT

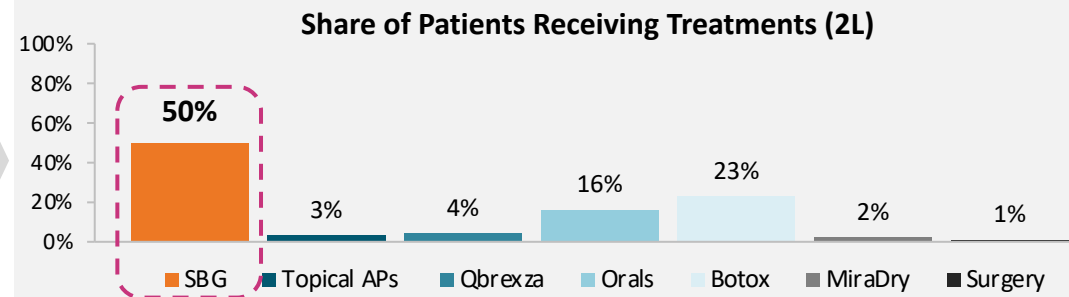
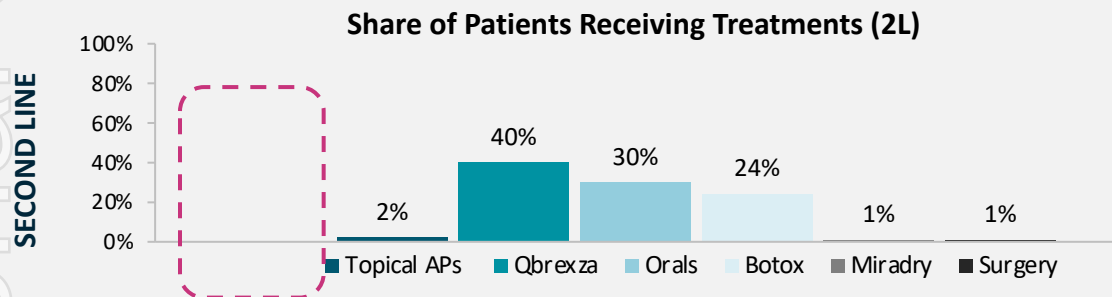
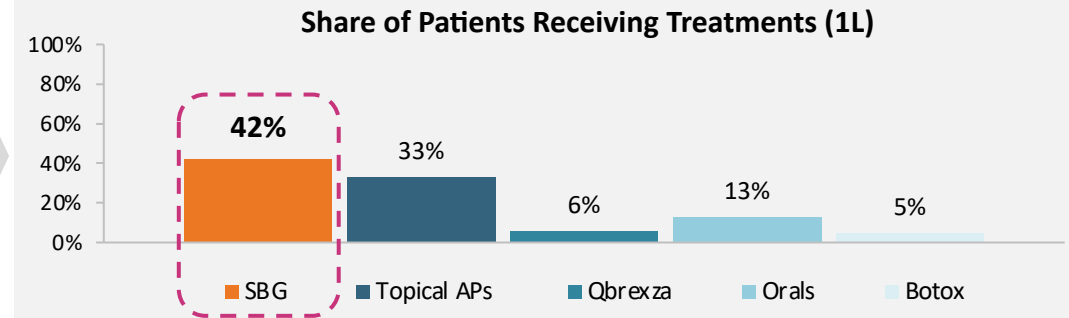
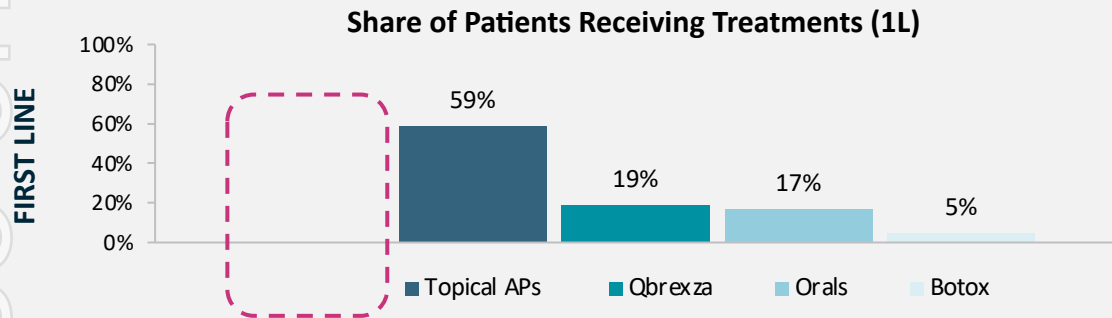
## TOP TWO UNMET NEEDS

- New treatment options (i.e., limited options)
- More efficacious treatments without access/cost concerns

# Research indicates dermatologists would start *new* patients on Sofpironium Bromide in addition to moving *existing* patients

## CURRENT PRESCRIPTION PREFERENCES

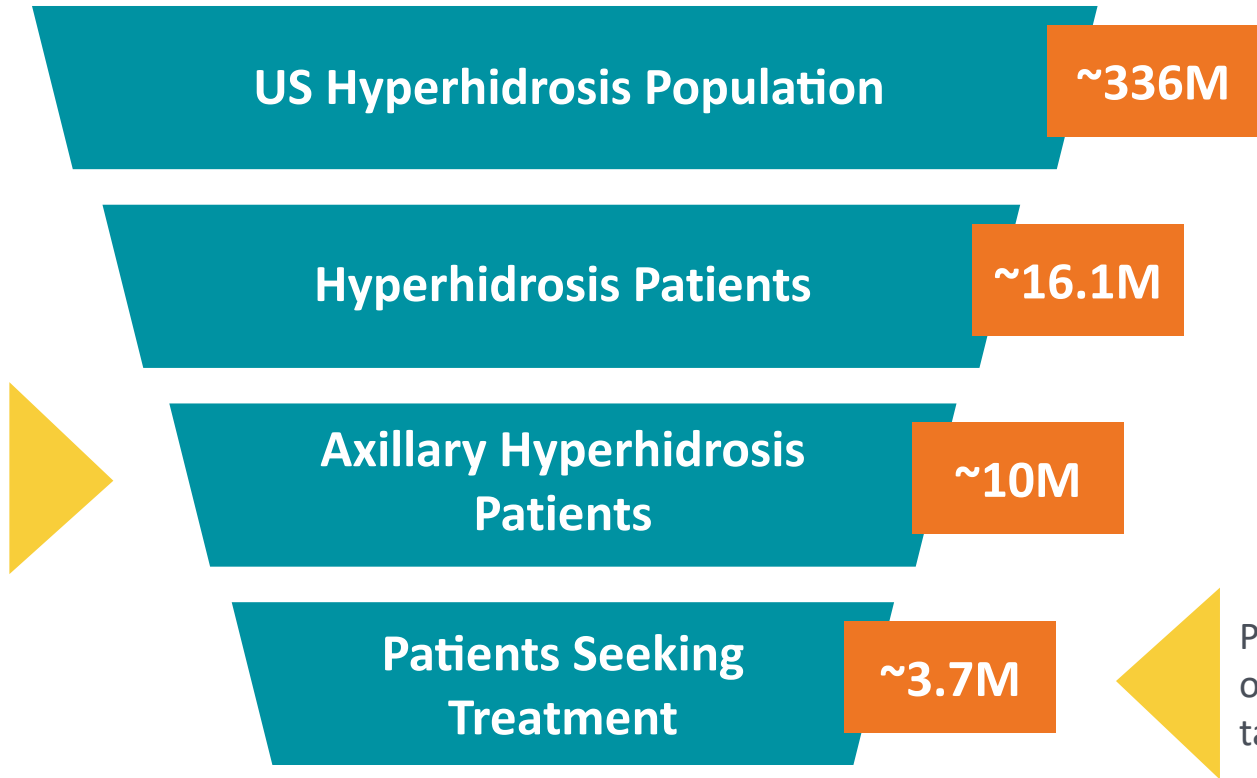
## PROSPECTIVE PRESCRIPTION PREFERENCES



\*Share of patients by treatment type shows a weighted average across severities

Source: 1. Triangle Insights conducted interviews with US dermatologists (n=20), US payers (n=10), US patients (n=20)

# Limited dermatologist targeting plus digital strategy—expands the addressable patient population



Potential to diagnose and treat from home with telemedicine

Patients already in dermatologist's office that can be reached with a targeted sales force

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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

# Sofpironium Bromide has already been approved in Japan which helps de-risk FDA approval and supports commercial success



Approval Date	September 25, 2020, in Japan <sup>1</sup>
Indication	Primary axillary hyperhidrosis
Launch Date	November 26, 2020
Application	An applicator allows for drug application without the need for the patient to touch the product
Name	Ecclock®

## Mitigation of Commercial & Clinical Risk

### Clinical & Regulatory

- ❖ Japanese approval paired with strong Phase 3 clinical trial results in the US help to support safety and efficacy and de-risk SB from a regulatory standpoint

### Commercial

- ❖ Inclusion on the National Health Insurance drug reimbursement price list supports the perceived need for the product from payers and suggests receptivity to Ecclock's (SBG) value proposition<sup>2</sup>
- ❖ **Initial performance in the Japanese market is promising, with year 2 sales reaching ~300K units<sup>1</sup>**
- ❖ Japan's population is 1/3<sup>rd</sup> the size of the USA (with prevalence similar for hyperhidrosis)<sup>3</sup> – so if this volume of sales is replicated in the USA, a substantial opportunity exists for Sofpironium Bromide



# Sofpironium Bromide intellectual property summary

Sofpironium bromide is protected by strong IP in the US and other major global markets with potential significant commercial exclusivity

## COMPOSITION OF MATTER

- ❖ US patent issued with claims covering compounds, compositions, and methods of use (expires 2027, excluding patent term extension targeted for 2033)
- ❖ US non-provisional and national stage applications filed covering crystalline forms and manufacturing process of SB; issued in Japan (expiry not before 2040)

## METHOD OF DOSING

- ❖ US patent issued with claims covering uses of SBG for treatment of HH (expires 2034)
- ❖ National stage filings pending or allowed (Granted in EP, JP & CA)

## FORMULATION

- ❖ US patents issued with claims covering novel topical compositions and uses for treatment of HH (expires 2034)
- ❖ PCT filed (national stages pending and available) covering Japan commercial formulation

## APPLICATOR SYSTEM

- ❖ US provisional utility application filed for the novel applicator system (expires 2039)
- ❖ Design application filed in US (and other key jurisdictions) covering the applicator and container system (expiration not before 2034)

# Executing on planned commercial and regulatory milestones

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NDA  
SUBMISSION  
COMPLETE



3Q 2022



DAY 74  
LETTER



4Q 2022



MID-CYCLE  
REVIEW



1Q 2023



FDA  
APPROVAL

3Q 2023

CALENDAR YEAR

# Offer Summary

## Botanix Institutional Placement of up to A\$10 million

<b>Offer Structure and Size</b>	<ul style="list-style-type: none"><li>▪ Botanix is undertaking an institutional placement to raise up to \$10 million</li><li>▪ The Placement is being undertaken in a single tranche utilising the Company’s existing 10% Placement capacity under ASX Listing Rule 7.1</li><li>▪ Up to approximately 111 million New Shares will be issued under the Placement (representing ~9.3% of current shares on issue)</li><li>▪ Use of funds – preparation for commercial launch of SB, payment of milestones, manufacturing scale-up, regulatory costs and costs of the offer.</li><li>▪ Firm commitments received from new and existing institutional investors with extensive experience investing in life sciences</li></ul>
<b>Offer Price</b>	<ul style="list-style-type: none"><li>▪ The Placement will be conducted at an offer price of \$0.09 per New Share (“<b>Offer Price</b>”) represented a:<ul style="list-style-type: none"><li>– 10% discount to the last close price on Friday, 31 March 2023 before the trading halt; and</li><li>– 5.9% discount to the 30-day volume weighted average price on Friday, 31 March 2023 before the trading halt</li></ul></li></ul>
<b>Ranking</b>	<ul style="list-style-type: none"><li>▪ New Shares issued under the Placement will rank pari passu with existing Shares from their issue date</li></ul>
<b>Joint Lead Managers</b>	<ul style="list-style-type: none"><li>▪ Jefferies (Australia) Pty Ltd and Euroz Hartleys Limited acted as Joint Lead Managers and Bookrunners to the Placement</li></ul>

# Indicative Timetable

## Placement timetable

Event	Date (Sydney, Australia time)
Trading halt	Monday, 3 April 2023
Announcement of completion of Placement, 3B, trading halt lifted	Wednesday, 5 April 2023
Settlement of the Placement	Wednesday, 12 April 2023
Allotment and normal trading of New Shares issued under the Placement	Thursday, 13 April 2023

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The research, development, manufacture and sale of Botanix's products is subject to a number of regulations prescribed by government authorities in Australia and overseas.

Generally, there is a high rate of failure for drug candidates proceeding through pre-clinical and clinical trials. Further, even if Botanix views the results of a trial to be positive, the FDA or other regulatory authorities may disagree with Botanix's interpretation of the data. Thus, any product deploying Botanix's technology may be shown to be unsafe, non-efficacious, difficult or impossible to manufacture on a large scale, uneconomical to market, compete with superior products marketed by third parties, fail to secure meaningful reimbursement approval, or not be as attractive as alternative treatments.

Likewise, comments from the FDA do not reflect a final decision on the information reviewed as part of any NDA submission and should not be construed to do so. These comments are preliminary and may be subject to change as FDA finalizes its review of any NDA and FDA may also identify other information that must be provided before any application can be approved. If FDA do not provide approval in a timely fashion, then the primary asset for Botanix may be reduced in value.

## INNOVATIVE TECHNOLOGICAL DEVELOPMENTS

Botanix's product range includes candidates that are in pre-clinical development and need to be further tested before they can progress to human clinical trials. Pre-clinical and clinical development of Botanix's product candidates could take several years to complete, and might fail for a number of reasons including but not limited to lack of efficacy, failure to obtain regulatory approval, difficulty or failure to manufacture Botanix's products on a large scale, or toxicity. There is no guarantee that Botanix's products will be, or continue to be, commercially successful.

## DEPENDENCE ON SERVICE PROVIDERS AND THIRD-PARTY COLLABORATORS

Botanix relies upon independent third-party service providers and third party collaborators including academic institutions to complete the development and commercialisation of its products. Botanix therefore is exposed to the risk that any of these parties can experience problems related to operations, financial strength or other issues, which in turn could negatively impact the progress or success of Botanix's product development efforts.

## INTELLECTUAL PROPERTY

Botanix's ability to leverage its innovation and expertise depends upon its ability to protect its intellectual property including maintaining patent protection for its product candidates and their respective targets. Botanix owns or has licensed, issued and pending patent applications covering a range of potential drug candidates.

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.

## Risk Factors cont.

### COMPETITION RISK

The pharmaceutical sectors are highly competitive and subject to rapid and significant change. 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.

### CURRENCY RISK

Revenue and expenditure in overseas jurisdictions are subject to the risk of fluctuations in foreign exchange markets. Botanix main business is carried on outside of Australia. Accordingly, revenues and payments will be made in those countries' currencies and may deviate from budgeted expectations if there are adverse currency fluctuations against the Australian dollar.

### REQUIREMENT TO RAISE ADDITIONAL FUNDING

Botanix may be required to raise additional funds in the future. 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 may dilute shareholders' interests in Botanix.

### RISK OF DELAY AND CONTINUITY OF OPERATIONS

Botanix may experience delays in achieving some or all of its milestones, including but not limited to product development, completion of trials, obtaining regulatory approvals manufacturing delays, or delays in sales or out licensing. Botanix is also dependent on amongst other things its technology, key personnel and IT systems. Botanix is also dependent on third party suppliers, which may encounter delays which can impact Botanix. Any disruption or delay to any key inputs could impact adversely on Botanix.



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Executive Chairman

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### 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.

### MARKET CONDITIONS

The price at which Botanix's securities are quoted on ASX may increase or decrease due to a number of factors outside Botanix's control and which are not explained by the fundamental operations and activities of Botanix, including unpredictable influences on the market for securities in general and pharmaceutical stocks in particular. These factors may cause Botanix's securities to trade at prices above or below the price at which Botanix's securities were initially acquired. Some of the factors which may affect the price of the securities include:

- fluctuations in the domestic and international market for listed stocks;
- general economic conditions in both Australia and internationally, including interest rates, inflation rates, exchange rates, commodity prices, inclusion in or removal from market indices;
- changes to government fiscal, monetary or regulatory policy, legislation or regulation; and
- the nature of competition in the markets and industries in which Botanix operates.

### FORCE MAJEURE

Events may occur within or outside Australia that could affect investor sentiment or impact upon the global and Australian economies, the operations of Botanix and the price of its securities. These events include acts of terrorism, an outbreak of international hostilities, fires, floods, earthquakes, labour strikes, civil wars, natural disasters, outbreaks of disease or other man-made or natural events. These events can have an adverse effect on the demand for Botanix's products and its ability to conduct business. Botanix has only a limited ability to insure against some of these risks.

**Operations:**

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Risk Factors cont.

#### RELIANCE ON KEY PERSONNEL

The responsibility of overseeing the day-to-day operations and the strategic management of Botanix depends substantially on its senior management and its key personnel. 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.

#### COVID-19

The current COVID-19 pandemic has been having, and is likely to continue to have, a significant impact on global capital markets, commodity prices and foreign exchange rates. The COVID-19 pandemic creates particular risks and challenges for Botanix, which outsources both research and manufacturing activities, as operational progress may be slowed or arrested as jurisdictions and suppliers respond to differing conditions. While to date COVID-19 has not had a material impact on Botanix, it could have an adverse impact on Botanix's operations, financial position and prospects in the future in addition to impacting on the ability of Botanix personnel to travel and execute the planned activities and studies.

#### LITIGATION RISK

There is a risk that Botanix may in the future be the subject of or require to commence litigation, mediation or arbitration. The impact of such actions may have a material adverse impact on Botanix.

#### INSOLVENCY RISK

The Directors are unable to predict the risk of insolvency or managerial failure by any of the contractors used (or to be used in the future) by Botanix in any of its activities or the insolvency or other managerial failures by any of the other service providers used (or to be used by Botanix in the future) for any activity.

#### CHANGE TO LAW

Botanix may be affected by changes to laws, regulations and policy (in Australia and other countries in which Botanix operates) concerning pharmaceuticals, superannuation, taxation, trade practices and competition, government grants, incentive schemes, accounting standards and other matters. Such changes may have adverse impacts on Botanix from a financial and operational perspective.



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