

Sofdra Commercial Plan

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Authorized for release by:

Vince Ippolito
Executive Chairman

Botanix - accelerating towards commercialization of *Sofdra*TM

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)

TARGETING MID-24 FDA APPROVAL

Submitted final component required for approval (the “Instructions for Use”) in Q1 CY2024, targeting FDA approval in June 2024

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Corporate Overview

ASX: BOT TRADING INFORMATION

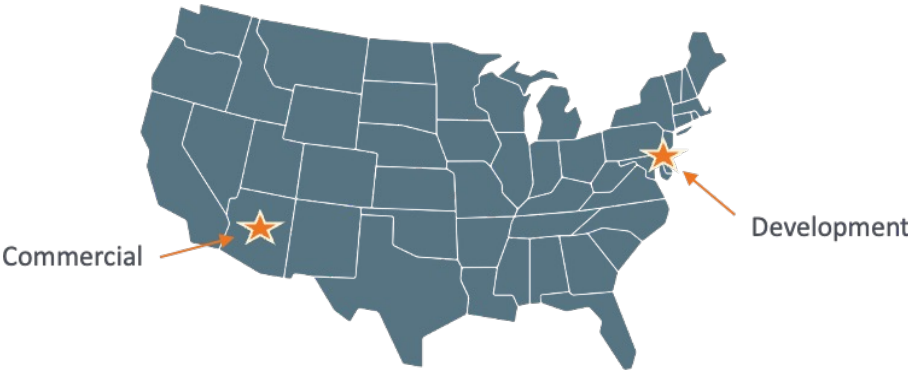
Share price	A\$0.275
6-month low / high	A\$0.12/0.275
Shares outstanding	1,563,437,373
Market Capitalization	A\$430m
Cash	A\$ 17.3m
Debt	Nil

SUBSTANTIAL SHAREHOLDERS

Shareholder	%
Antares Capital	9.0%
Board and Management	7.0%
Top 20	33%



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Highly experienced board and management team

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



VINCE IPPOLITO
Executive Chairman

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



HOWIE MCKIBBIN
Chief Executive Officer

- Former SVP Commercial of Dermavant, Anacor and Medicis
- 25+ 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 of 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
- Founder Botanix, Churchill Pharma, Orthocell, Dimerix



DR BILL BOSCH
Board Director

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



JOHN SCHOHL
VP Managed Markets

- Former SVP Commercial Operations Medicis
- 30+ years experience in pharma industry with 23+ years within dermatology



DAVID MORGAN
Head of Corporate Affairs

- 20+ years as ad agency principal
- Clients included Intel, Citibank, and Qwest (CenturyLink)
- Vice President responsible for the Medicis in-house ad agency



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 BORIS MEYERSON
Chief Business Officer

- Launched four pharma companies
- 20+ years in dermatology
- Proven expertise in commercial operations

Experience across multiple therapeutic areas

EFFEXOR XR[®] EXTENDED
RELEASE
CAPSULES

SOLODYN[®]
(MINOCYCLINE HCl, USP)
EXTENDED RELEASE TABLETS

Aldara[®]
Imiquimod Cream 5% w/w

Carac[®]
fluorouracil cream

PROTONIX[®] 40 mg
(pantoprazole sodium)

ZIANA[®]
(clindamycin phosphate 1.2%
and tretinoin 0.025%) Gel

ELIDEL[®]
(pimecrolimus) cream 1%

eucrisa[®]
crisaborole ointment 2%

ALTACE[®]
(ramipril) capsules

TRIAZ[®]
(benzoyl peroxide)

Winlevi[®]
(clascoterone)
cream 1%

LOPROX[®]
(ciclopirox)

TREANDA

Zyclara[®]
(imiquimod) Cream
3.75%

Kerydin[®]
(TAVABOROLE)
TOPICAL SOLUTION, 5%

MetroGel-Vaginal[®]
(metronidazole vaginal gel)
0.75% Vaginal Gel

RETIN-A MICRO[®]
(tretinoin gel) microsphere, 0.1%

PROVIGIL[®]
(MODAFINIL)[®]
Tablets

Efudex-40[™]
(fluorouracil)

Vanos[®]
(fluocinonide) Cream, 0.1%

NUVIGIL[®]
(ARMODAFINIL) Tablets



Sofdra™
(sofpironium bromide) gel, 15%

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Patient Burden

International Hyperhidrosis Society



LISA J PIERETTI, MBA

Executive Director & Founding Member

- Previously Director of Account Management at Medical Broadcasting Company, where she designed, developed, and executed integrated multi-channel strategic marketing programs for billion-dollar pharma brands
- Worked with SCIREX Corporation, a leader in CNS clinical research, as the Senior Director of Marketing and Communications
- At Merck & Co. she was a Market Analyst in the vaccine department



Listen

The podcast for anyone living with a sweat disorder or concerned or curious about issues of human perspiration -- including excessive sweating or hyperhidrosis (Hh.)



Learn

Sign up and get news alerts about hyperhidrosis research postings, treatment discoveries, and important developments in the universe of sweating.



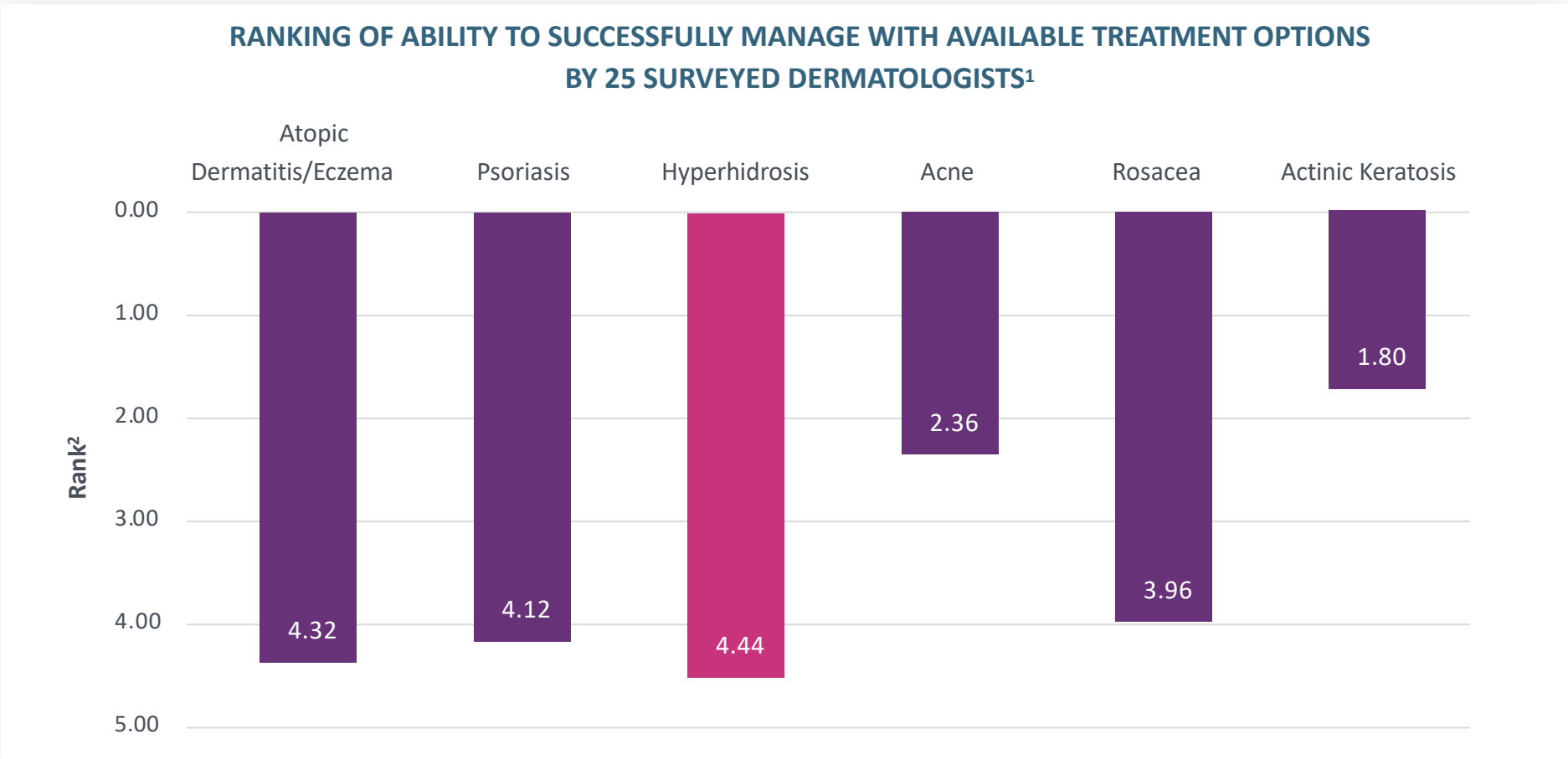
Watch

Watch videos of patient stories. Learn about Hyperhidrosis from top physicians treating this condition and see behind the scenes setup and treatment at our Master Class.

Top priorities include promoting awareness of hyperhidrosis, working to enable treatment access, and increased research into this medical condition

Hyperhidrosis: Significant unmet medical need

Clinicians ranked hyperhidrosis last in their ability to successfully manage with available treatments



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



SofdraTM
(sofpironium bromide) gel, 15%

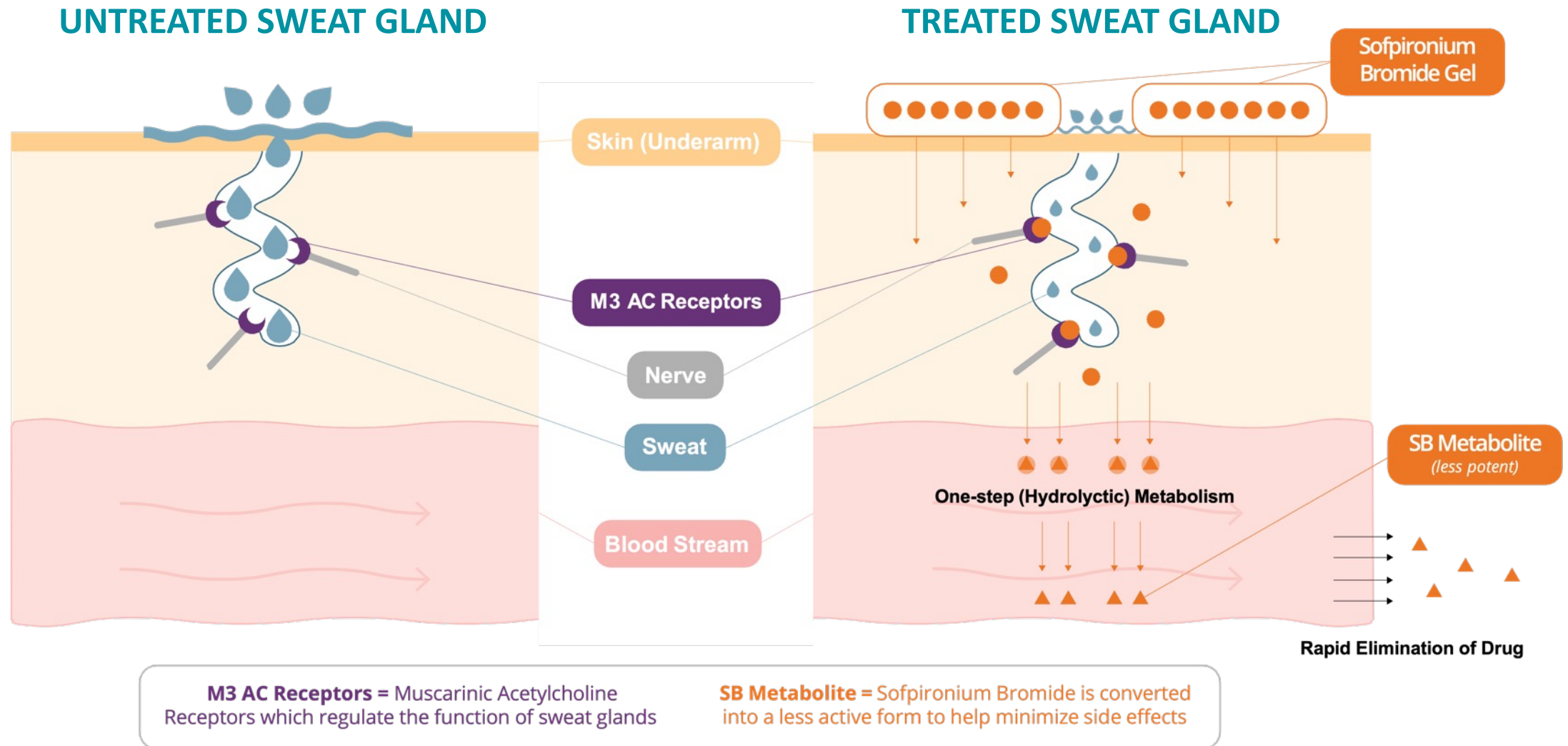
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SofdraTM Overview

Sofdra[™] has a targeted mechanism of action

Binds selectively to M3 AC receptors, thereby blocking acetylcholine to inhibit sweat production, and then rapidly degrades for excretion



Phase 3 pivotal program co-primary measures

Hyperhidrosis Disease Severity Measure-Axillary patient-reported outcome measure (HDSM-Ax)

- HDSM-Ax patient-reported outcome measure was used for a co-primary endpoint and all secondary endpoints
- HDSM-Ax is a validated patient-reported outcome measure of axillary hyperhidrosis severity
 - a 1-point change is clinically meaningful¹
- HDSM-Ax employs 7 questions on a 5-point scale
 - a similar children's version was used for children under age 12

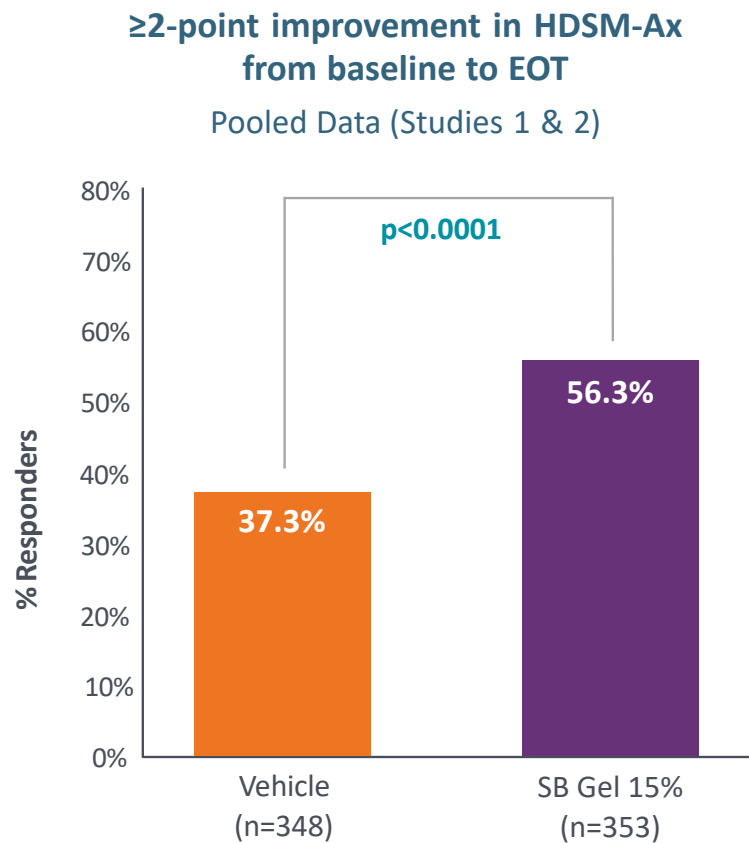
Gravimetric Sweat Production (GSP) measure

- GSP was used for a co-primary endpoint and in composite secondary endpoints
- Prior to measurements subjects remained in a semi-recumbent position for at least 30 minutes in a room with controlled humidity and temperature between 20°C and 25°C
- GSP was performed by standard methods
- A separate 5-minute continuous GSP weight measurement was done for each axilla

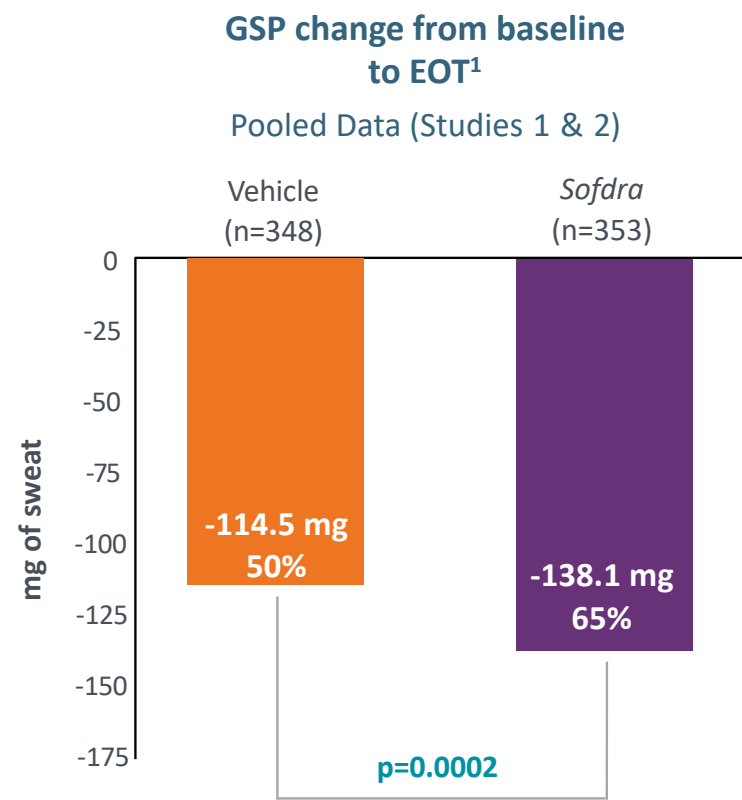
- HDSM-Ax measured improvement from baseline to end of treatment (Week 6)
- GSP measured the change in sweat production from baseline to End of Treatment

Source 1. Hobart J, Burke L, Kirsch B, Chadha D. Hyperhidrosis Disease Severity Measure-Axillary (HDSM-Ax): Evaluation of Measurement Performance. J Drugs Dermatol. 2021 Apr 1;20(4):410-418. doi: 10.36849/JDD.2021.5569.

In both Phase 3 studies, co-primary endpoints were observed to be highly statistically significant



HDSM-Ax scale measures patient reported severity of axillary (underarm) hyperhidrosis



GSP (Gravimetric Sweat Production) is an objective measurement of underarm sweat production (mg/ 5 min)
Baseline GSP: Vehicle 229.83 mg / SB Gel 15% 210.84 mg

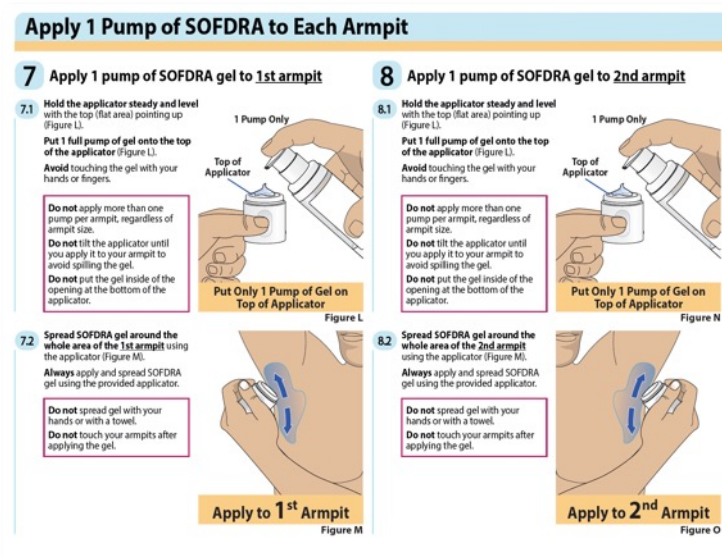
Notes: 1. Data are based on multiple imputations for missing values; 'n' represents number of subjects in the ITT population; EOT = end of treatment
Sources: BBI-4000-CL-301; BBI-4000-CL-302



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Regulatory and manufacturing

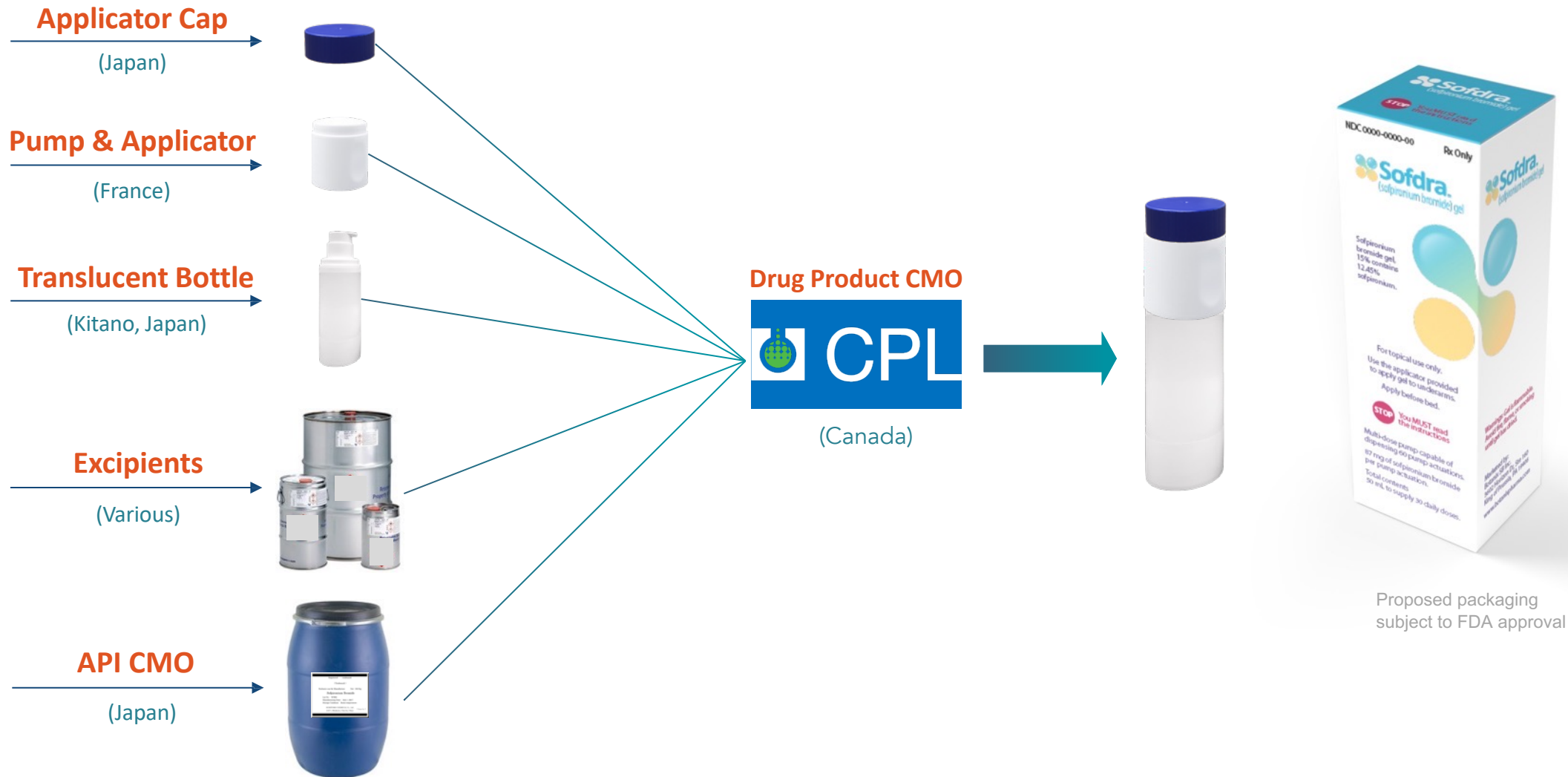
Instructions for Use revision - review being finalised with FDA



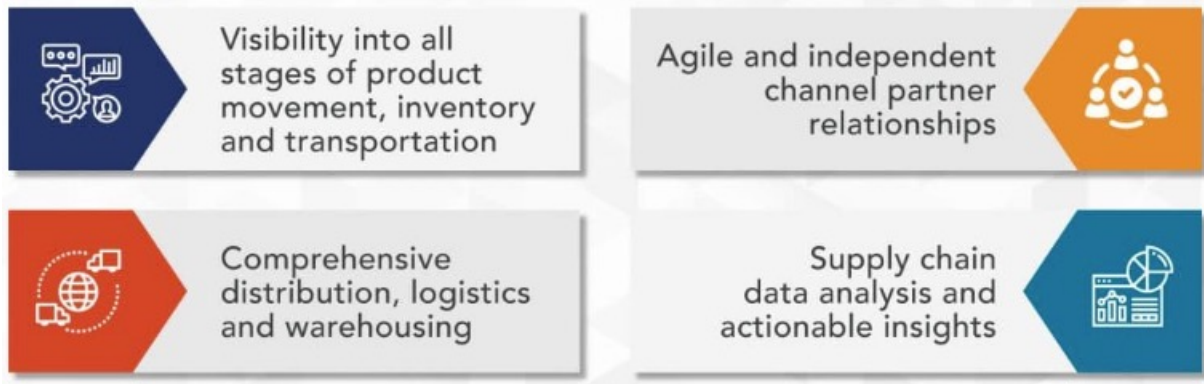
Instructions For Use

- ❖ 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 ✓
- ❖ Completed human factors *validation* studies to confirm revised Instructions for Use are reliably followed ✓
- ❖ Submitted to FDA and FDA communicated response was complete ✓

Manufacturing supplies and process settled



Eversana – our 3rd Party Logistics provider (3PL)



Our 3PL partner can fulfill efficiently and cost-effectively:

- ❖ managing inventory (including DSCSA¹)
- ❖ order-to-cash process (receiving POs from our customers, picking, packing and shipping product, invoicing, and collecting payments on Botanix's behalf)
- ❖ customer service (through its call center)

Using a 3PL cuts down time to market from a year to a few weeks and does not require capital spend



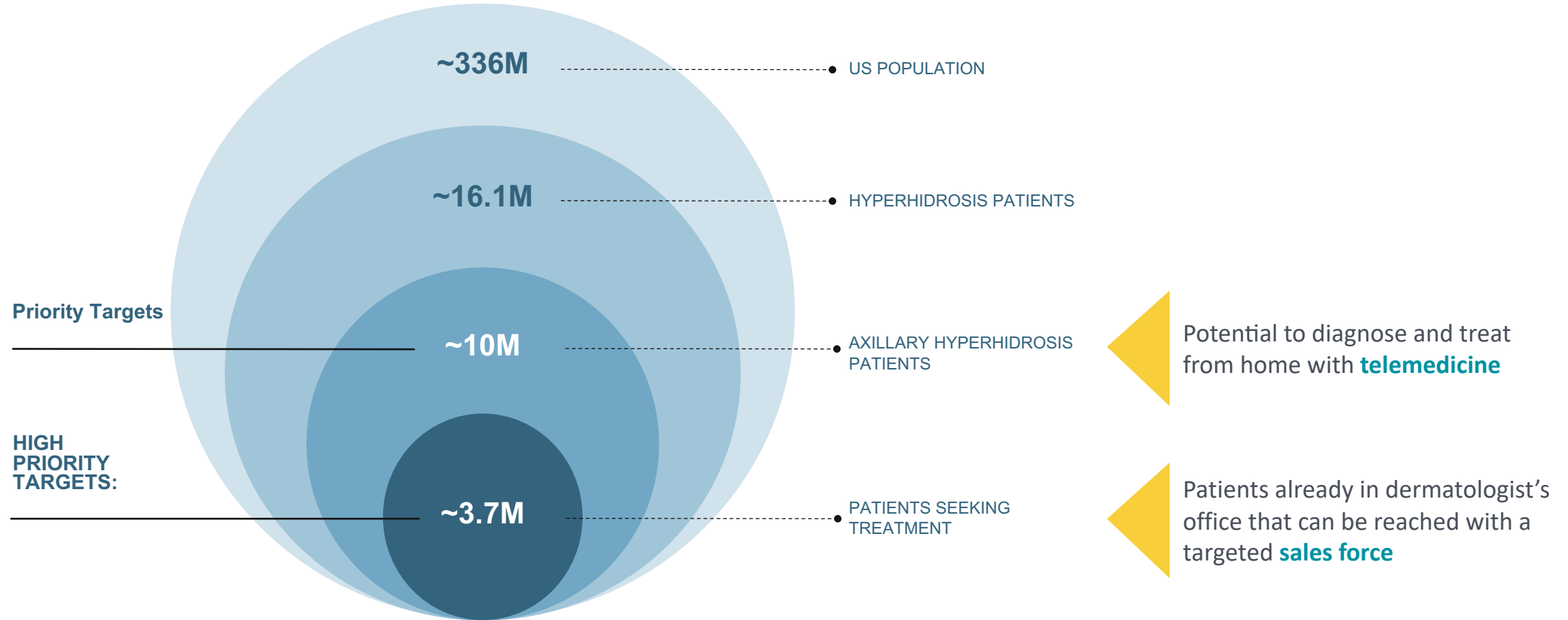
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Commercial Plan

 **Sofdra**TM
(sofpironium bromide) gel, 15%

~3.7M patients are accessible by targeting derms and an additional 6.3M are accessible via digital



Source: 1. International Hyperhidrosis Society, 2. Doolittle, et al, 2016, Hyperhidrosis: an update on prevalence and severity in the United States, Archives of Dermatology Research
Confidential. Internal use only.

85% of patients and dermatologists would use and prescribe *Sofdra gel*¹

Significant opportunity exists for a new topical product to address unmet needs

"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

UNMET NEED: ~6 OUT OF 7

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



PAYER

UNMET NEED: ~4 OUT OF 7

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

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



PATIENT

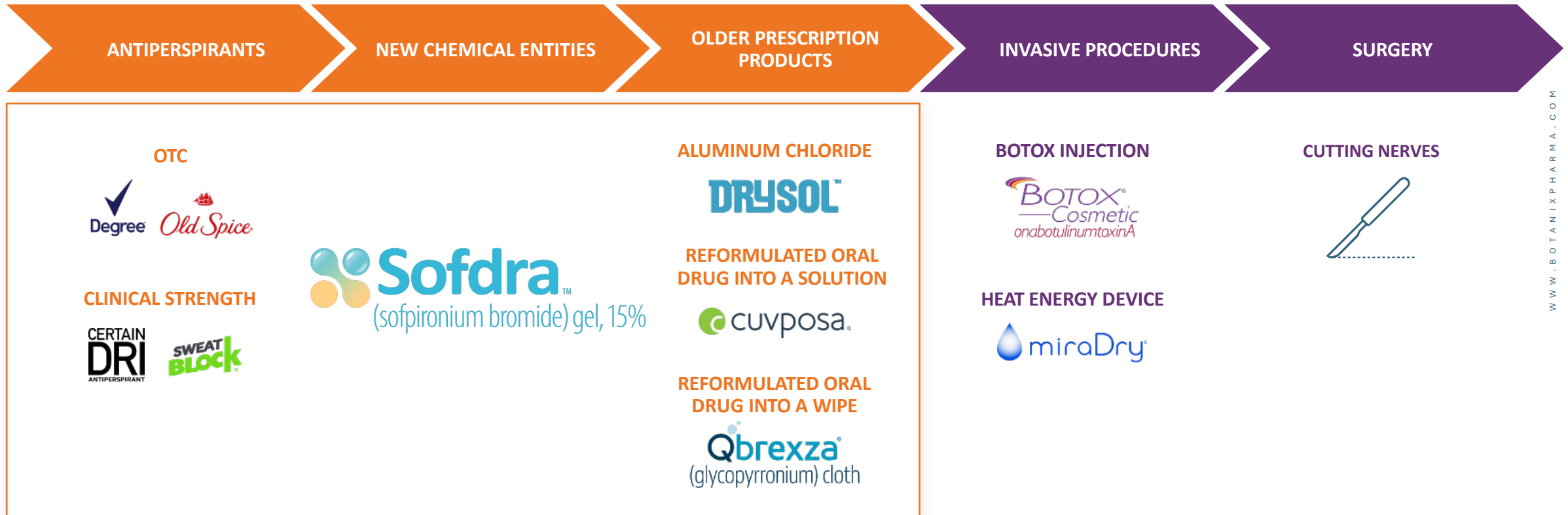
UNMET NEED: ~6 OUT OF 7

TOP 2
UNMET
NEEDS

- ① More efficacious treatments without access/cost concerns
- ② New treatment options (i.e., limited options)

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

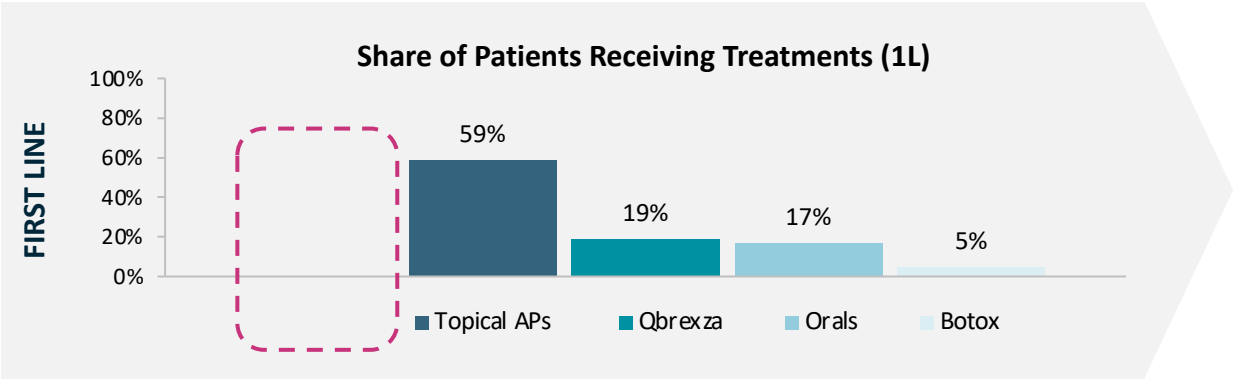
No new chemical entities were ever approved for hyperhidrosis



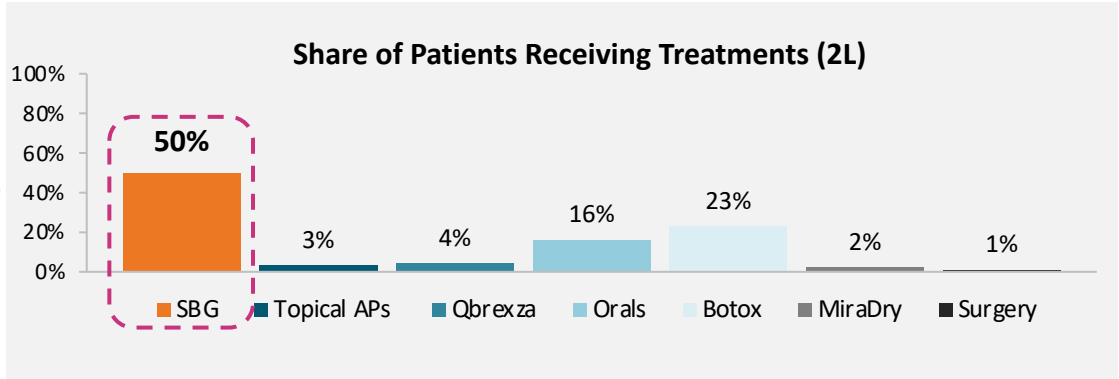
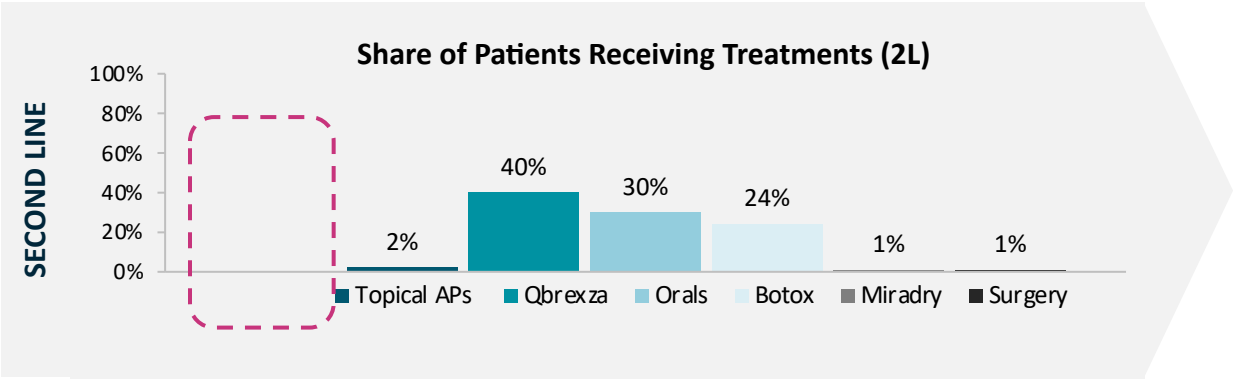
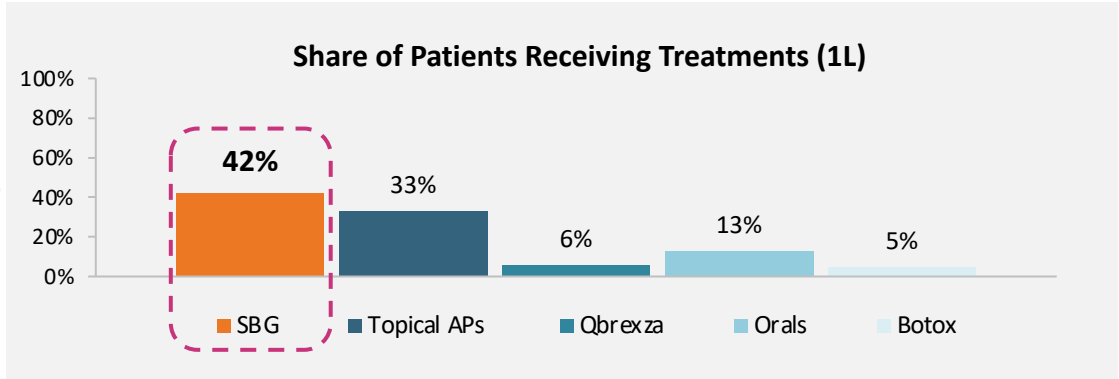
Due to its significant psychological impact, 54% of respondents suffering from hyperhidrosis say that they would pay anything for a treatment to stop their excessive sweating¹

Research indicates dermatologists would start new patients on *Sofdra* gel 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)

Sofdra gel launch strategy

Rapidly establish *Sofdra* gel as a safe and effective first-line therapy for treatment of primary axillary hyperhidrosis



Engage and motivate

patients to take control of their hyperhidrosis and see a telemedicine doctor for diagnosis and prescription



Maximize reimbursement and coverage

through strategic contracting



Provide patient access and eliminate friction

to provide immediate fulfillment and automatic refills



Drive Derm adoption

via comprehensive engagement around a compelling clinical story



Hire and train a highly effective **Sales Force** for immediate trial and adoption

 **Sofdra**[™]
(sofipirionium bromide) gel, 15%

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Engage and Motivate Patients

Drive impact across the patient experience and validate across channels

Turning Data Into Insights



Pathmatics

SimilarWeb

resonate

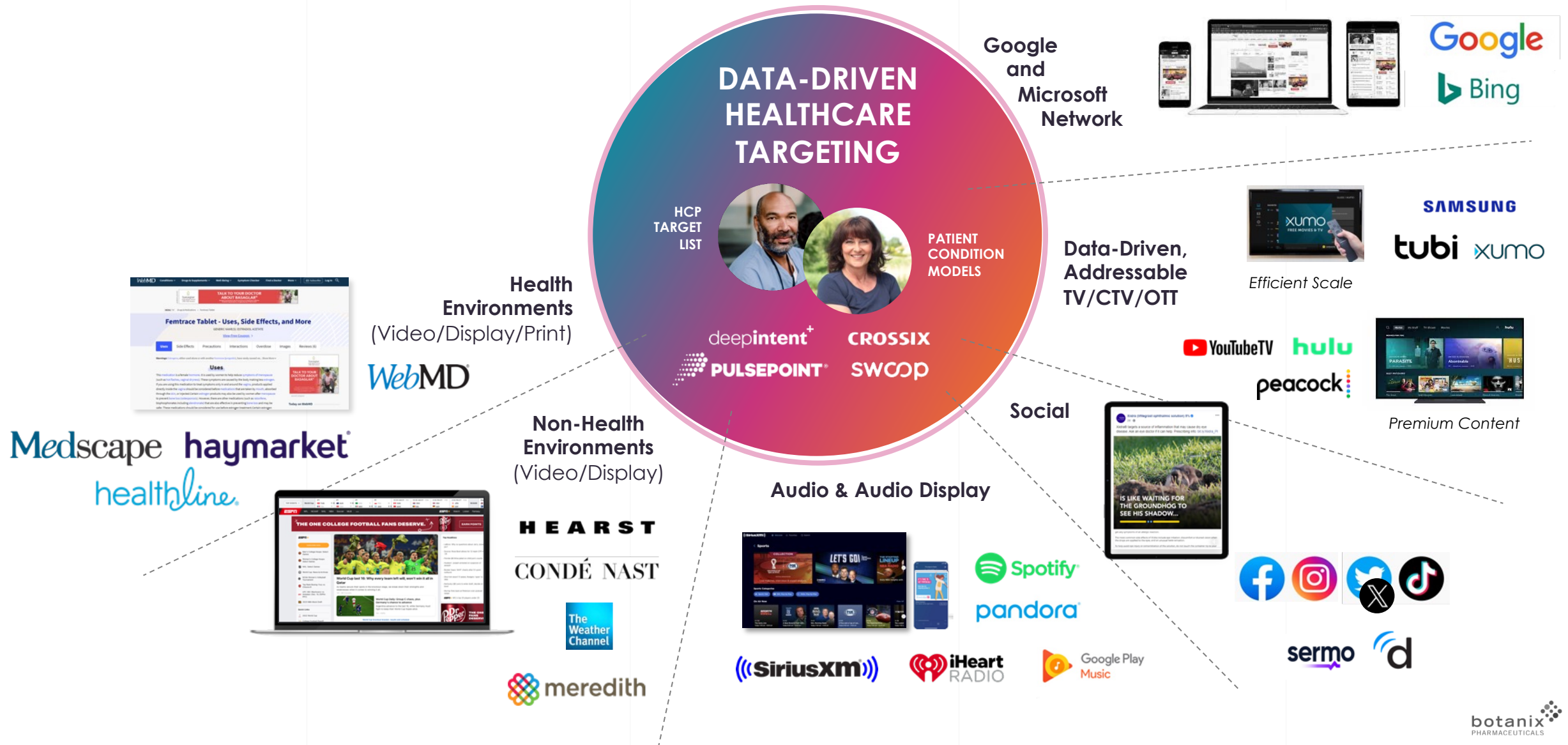
iSpot.tv

snowflake

datorama
A Salesforce Company

tableau

A data-centric approach allows us to activate our most valuable patient audiences cross-channel



AI content targeting tells us more about audiences who care and finds more like them

Social media as a cornerstone

HH Social Looks Different



37k highly active members on Reddit



Significant Twitch community



191.4 million lifetime views on hyperhidrosis-related TikToks



Medium-sized closed FB groups, with higher-than-average activity



Lower than average Instagram mentions and interaction

I didn't even realize a Dermatologist could treat this. I guess it makes sense because sweat comes from the skin.

- Chloe

[After Rx] I actually didn't fill it for months. I just was hoping it wasn't real.

- Sophie

After my diagnosis in college, I didn't even tell my family. I don't need them to know.

- Sabina

I guess I just stopped taking anything because it wasn't worth it. But honestly my sweat is still so bad. I'm probably going to have to get another soon – I wish something worked better.

- Patient

WHERE THEY ARE

of Gen Z



92%



85%



78%



74%



25%



17%



50%

of Gen Z is using social to search for more info about brands BEFORE search engines

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Hone in on actual patients during moments of sharing sweat stories with AI social sentiment targeting

Engage 396,464+ highly qualified hyperhidrosis patients per month while they are talking about their symptoms and personal journeys

1 SOCIAL POSTS/HASHTAGS



HASHTAG EXAMPLES:

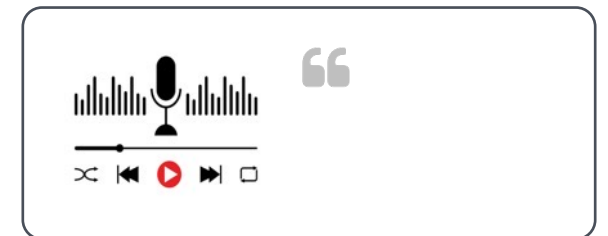
#hyperhidrosis
#sweatyfeet
#sweatfree
#excessivesweating
#sweatproblems
#sweatissues



2 IMAGES/VIDEOS



3 AUDIO RECOGNITION





Sofdra[™]
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Reimbursement and coverage

What is reimbursement?

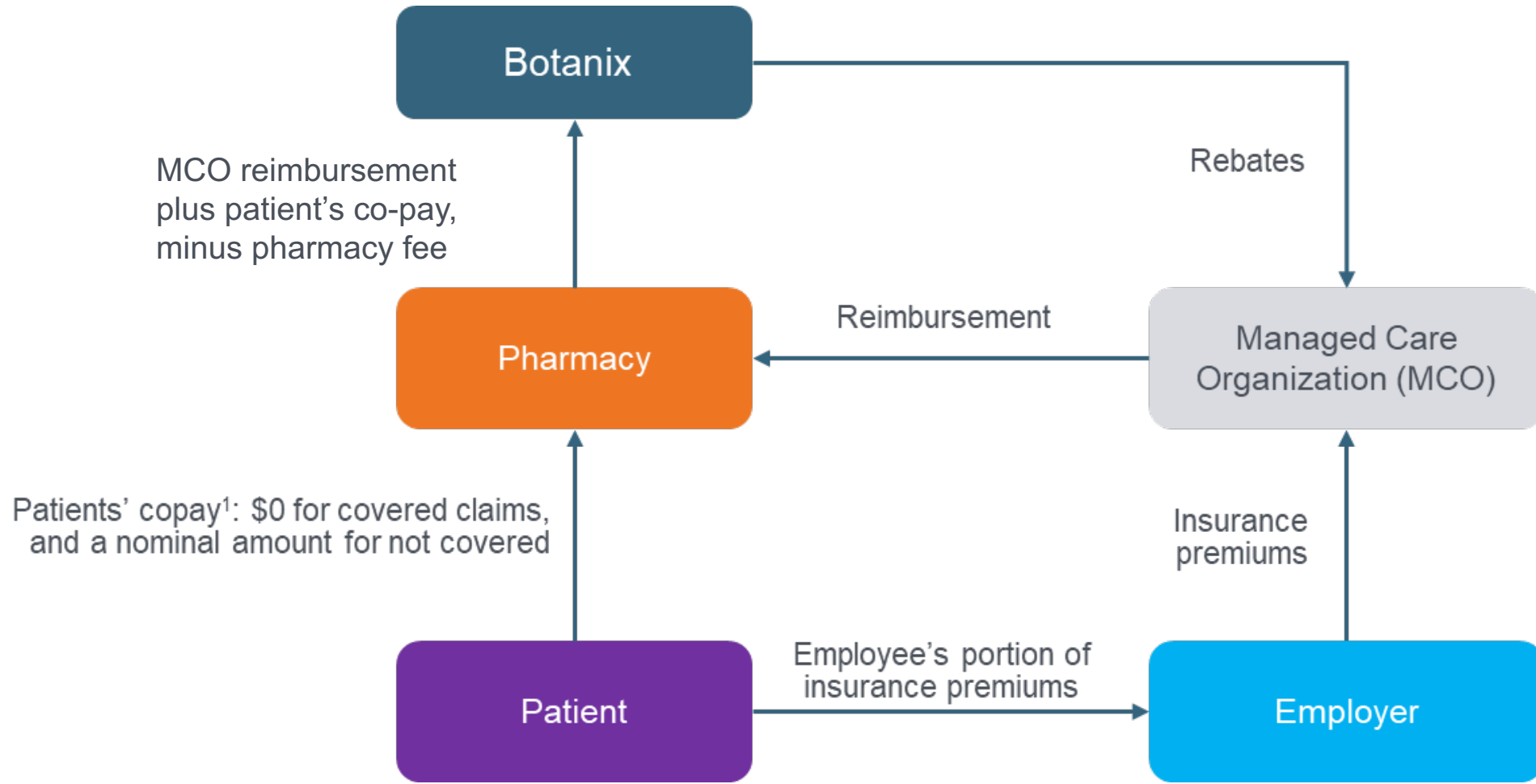
- ❖ In 2022 in the US¹: 92.1% of people, or 304 million individuals had health insurance (65.6% private + 36.1% government²)
- ❖ Health insurance comes with a “medical benefit” that largely covers medical treatments³ and a “pharmacy benefit” that covers all, or a part of the cost of drugs
- ❖ *Sofdra*, as a self-administered drug, will be covered under the pharmacy benefit and does not require a “code” for coverage
- ❖ HH is a recognized medical condition with existing coverage policies
- ❖ Engaged in discussions with payers to provide patients with frictionless access not only for the first fill but every refill

¹ [Health Insurance Coverage in the United States: 2022 \(census.gov\)](#), accessed 2024-05-01

² These statistics are based on having each insurance type at least once in the year, therefore leading to a total over 100% because of patients switching insurance types

³ When a drug is administered in the office, HCPs claim medical reimbursement via J-codes to cover the cost of the drug and CPT codes to cover the cost of their labor

***Sofdra* reimbursement as a part of the overall process**



Key payer account prioritization and engagement timing

Execute contracts with contracting PBMs and downstream clients in 2 phases

Phase 1 Accounts			Phase 2 Accounts					
--	Zinc Health	35.1M	CVS	Federal Employees Health Benefit	5.5M	Ascent	Premera	1.1M
--	Caremark PCS	2.1M	Zinc	Wellmark	950k	Ascent	Medical Mutual OH	560k
--	Ascent Health	22.6M	Zinc	CareFirst BCBS	1M	Emisar	Independence BC	1M
--	Express Scripts	1.2M	Zinc	BCBS MA	1.3M	Ascent	Emblem Health	400k
--	Emisar Health	27M	Zinc	Blue Shield CA	1.8M	Ascent	Kroger PBM	700k
--	OptumRx Government	750k	Emisar	BCBS SC	400k	Emisar	BCBS AZ	380k
--	Kaiser	8.1M	Ascent	HCSC Members	5.5M	Ascent	BCBS MN	735k
Emisar	United Healthcare	12.6M	Ascent	Horizon BCBS NJ	500k	Ascent	BCBS KS	294k
Zinc	Aetna Health	6M	Ascent	Florida Blue	1.2M	Emisar	BCBS Kansas City	376k
Ascent	Cigna	9M	Ascent	Regence / Cambia	1.1M	Emisar	BCBS Michigan	170k
Zinc	Elevance (Anthem)	6.1M	Ascent	BCBS NC	730k	Ascent	Elixir PBM	850k
Ascent	Prime Therapeutics	33.5M	Ascent	BCBS AL	1.2M	FLRx	Lifetime Healthcare	800k
			Ascent	BCBS LA	700k	--	Procare/MC21	560k
			Ascent	HMSA Hawaii	385k	--	Dividend Group/ MedImpact	1M
			Ascent	Humana Health	600k	Ascent	BCBS Highmark	190k

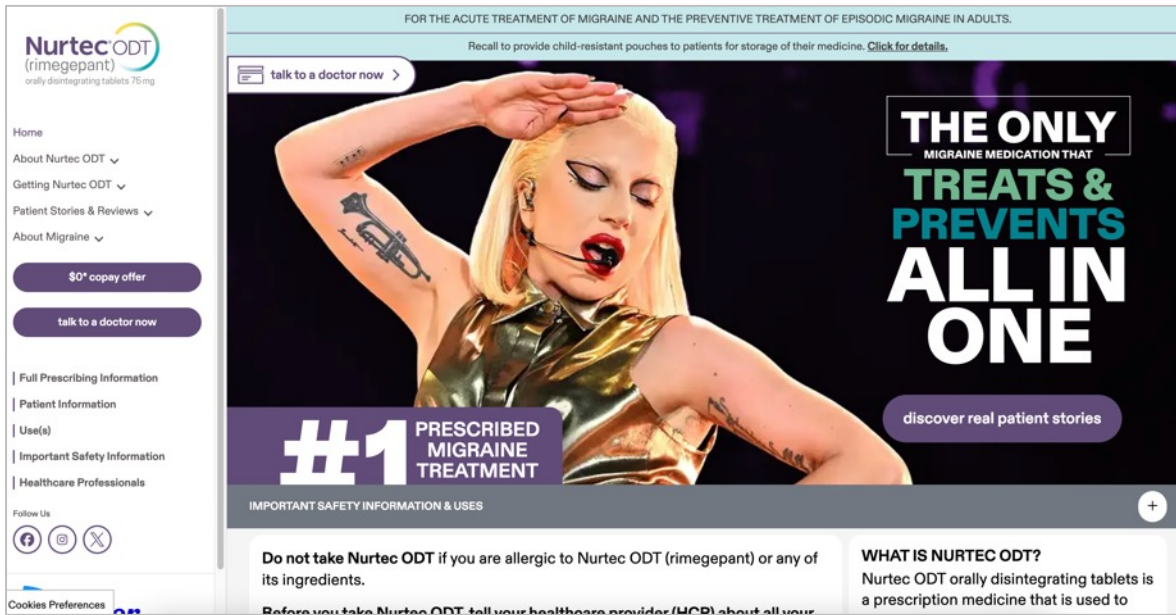
Key: Rx Contracting PBM Phase 1 Account Phase 2 Account Total Lives

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Frictionless Access with Telemedicine and Fulfillment

Telemedicine platforms are now a mainstream tool for many companies in a wide range of indications

Examples of Companies Partnering with Telemedicine Solutions



Pfizer: Nurtec ODT brand.com page, with link to the telehealth platform

Migraine



Psychiatry



Birth Control



Diabetes



Respiratory



Obesity

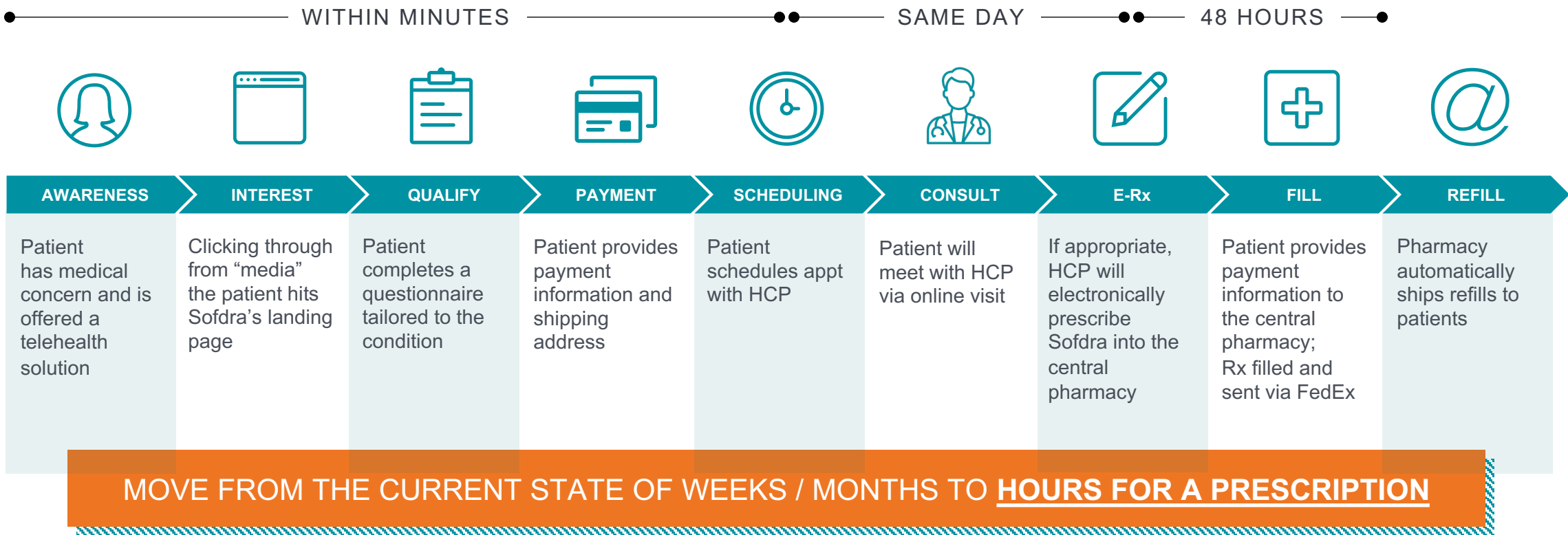


Gastroenterology



Telehealth is essential for new product commercialization

and significantly speeds time to therapy, especially with clinical diagnoses like HH¹



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¹ Clinical diagnoses are based on observation, interaction with the patient and medical knowledge. They do not require tests

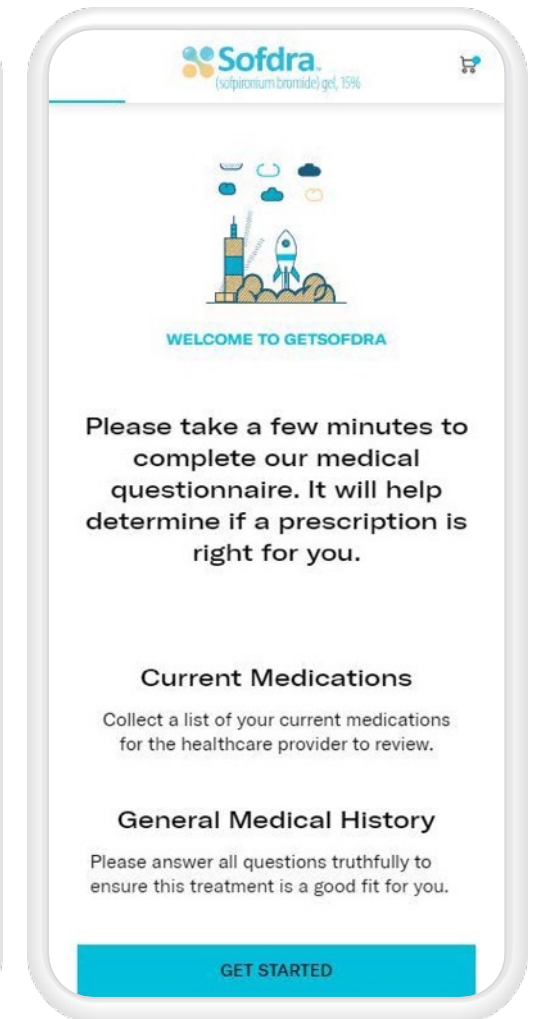
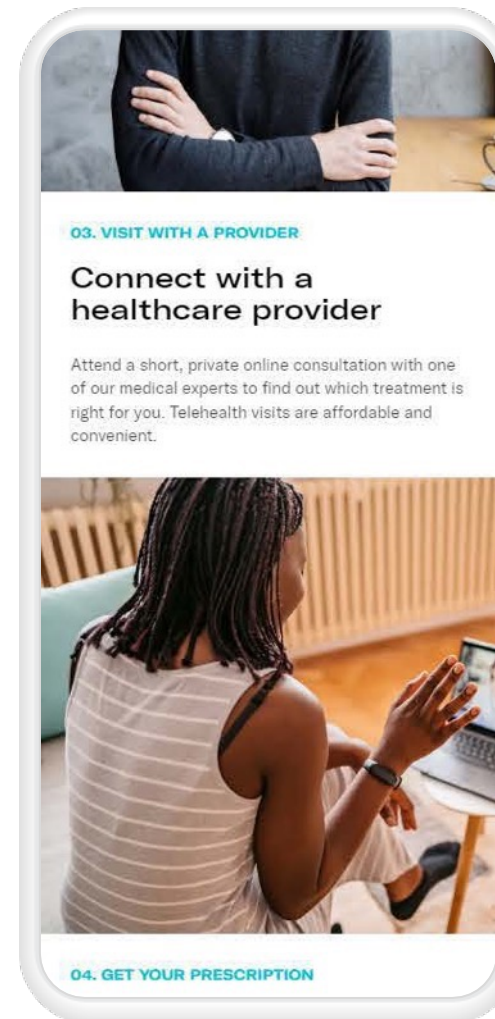
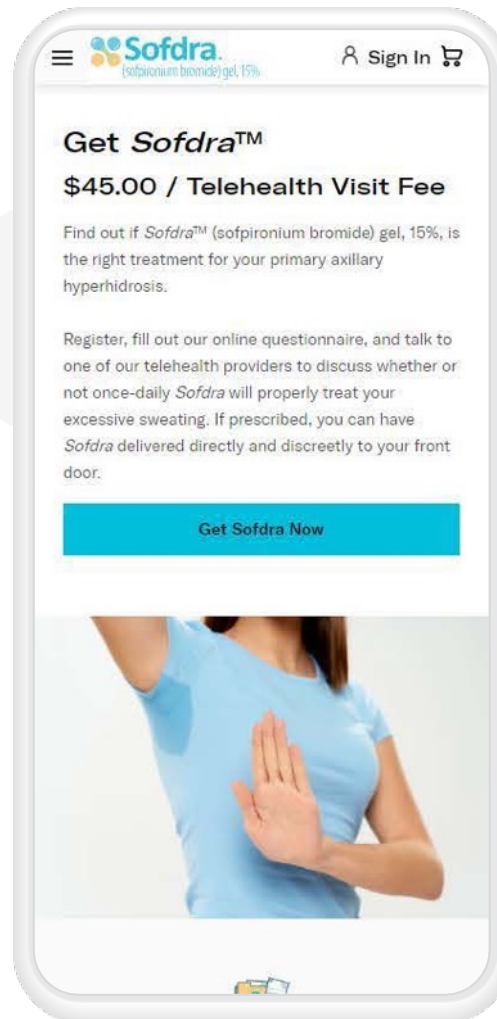
GetSofdra.com telehealth site powered by UpScript Health

Patients can reach GetSofdra.com via link from Sofdra.com or by organic search

Patients are prompted to register and provide contact information up front to allow email follow-up with the patient

The medical questionnaire was designed to collect information required to address possible Sofdra PAs

After scheduling with an HCP, reminder emails are sent including links to the start page



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(sofpironium bromide) gel, 15%

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Drive Dermatology Adoption

Field Force will be armed with Data

Comprehensive tools will enable sales force to effectively convey the *Sofdra* gel story and provide opportunity for demonstration

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Significant sweat reduction for the majority of patients. That's a Total SOFDRA Move.

Calculated GSP values at EOT for primary endpoint and selected secondary endpoint compared to controls in 11.68 hours.*

*Baseline GSP mg/5 min multiplied by 12 equals mg sweat per hour (211*12=2532 mg/hour). Time to mg sweat one ounce is mg per ounce divided by mg sweat per hour (29,573.5295625/2532=11.68 per hour) if sweating rate was constant. Dividing EOT (72.9/63.27) mg by Baseline (211) mg produced percentages (34.55%/29.99%) that were applied to one ounce for each EOT measure shown.

STUDY DESIGN

BASELINE
An average subject could fill this test tube

3 out of 5 (60%)
patients using SOFDRA achieved near normal sweat levels at 6 weeks

~1 out of 3 (32%)
patients using SOFDRA achieved ≥70% reduction in sweat levels at 6 weeks

One Ounce

Normal Controls

Sofdra
(sopipronium bromide) gel

INDICATION
Lorem ipsum dolor sit amet, consectetur adipiscing elit, nonummy nibh euismod ut laoreet dolore magna erat volutpat. Ut wisi enim minim veniam, quis

IMPORTANT SAFETY INFORMATION
Lorem ipsum dolor sit amet, consectetur adipiscing elit, nonummy nibh euismod ut laoreet dolore magna erat volutpat. Ut wisi enim minim veniam, quis

FULL IMPORTANT INFORMATION
REFERENCES

Bringing our data to life

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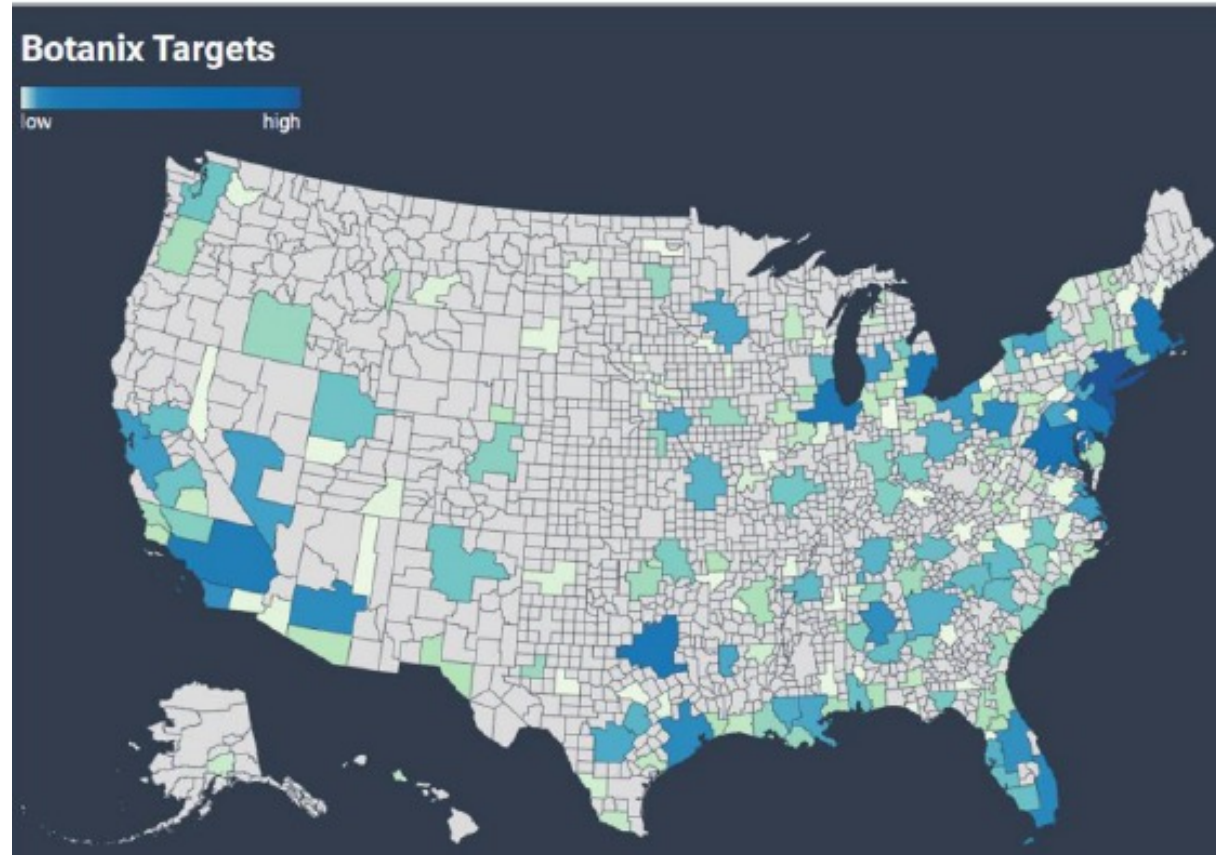
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Sales force and market opportunity

Target most productive prescribers and expand reach via digital channels

- ❖ Identify doctors with greatest potential for prescribing and reimbursement
- ❖ Expand doctor reach using search, media, PR, social, influencers, key opinion leaders
- ❖ Rapid scale-up of a 20-30 field sale reps to call on targeted high potential doctors



Sofpironium Bromide performance in Japan supports *Sofdra* commercial success



Mitigation of Commercial & Clinical Risk

- ❖ ~ 350,000 units of Ecclock sold by Kaken in the last 12 months
- ❖ The incidence and prevalence of hyperhidrosis in Japan and the USA is similar
- ❖ The population of Japan is ~ 1/3rd the size of the USA
- ❖ Kaken has been able to mobilize significant numbers of new patients even in the third year of launch

Approval Date	September 25, 2020, in Japan
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®

Source: Kaken Company Website, Kaken Press Release November 18, 2020, Kaken 2021 Corporate Report, FreshTracks Pharma (FKA Brickell Bio) Press Release June 24, 2021.



SofdraTM
(sofipironium bromide) gel, 15%

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In Summary

Botanix is rapidly preparing to launch *Sofdra* gel

Scale & Prepare the Organization

- ☒ Executive team
- ☒ Infrastructure
- ☒ Office staffing
- ☐ Field force
- ☐ Data warehouse

Product Availability

- ☒ Contract manufacturer
- ☒ Serialization vendor
- ☒ DP scale pre-validation
- ☒ DP quality agreements
- ☒ State licensing vendor
- ☒ 3PL vendor
- ☐ Final packaging & labeling

Product Access

- ☒ Payer strategy
- ☒ Managed care vendor
- ☒ Payer engagement
- ☒ Pricing established
- ☒ Telehealth vendor
- ☒ Central pharmacy

Medical & Regulatory

- ☒ MIS/AE vendor
- ☒ Human factors study
- ☐ PDUFA June 20, 2024

Sales & Marketing

- ☒ Ad Agency
- ☒ Brand positioning
- ☒ Core messaging
- ☒ HCP strategy
- ☒ Consumer strategy
- ☒ Sales force alignment
- ☒ Launch materials

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