Shackelford™ Pharma

An Opportunity to Improve the Lives of People with Epilepsy

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FEB 2023

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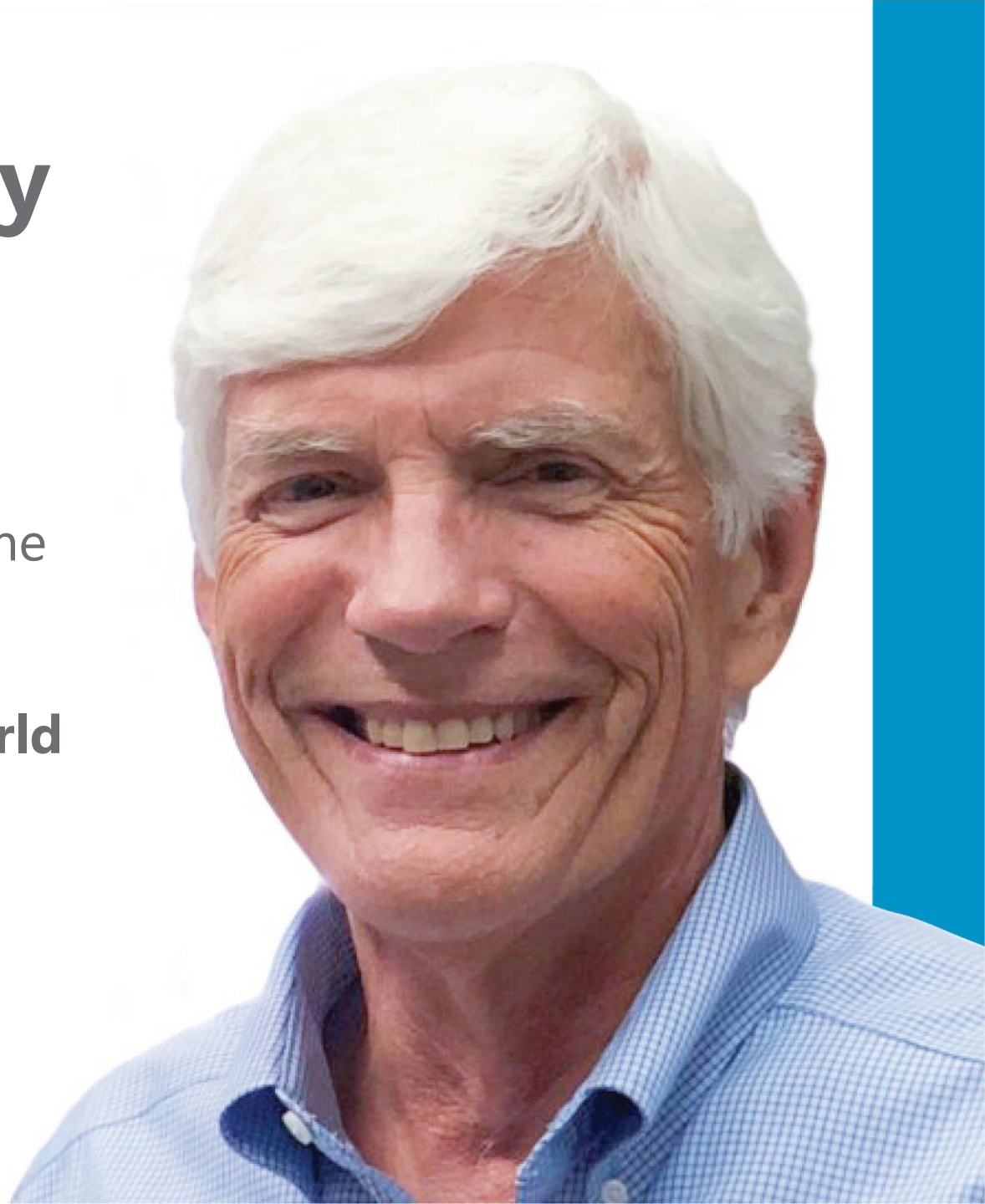
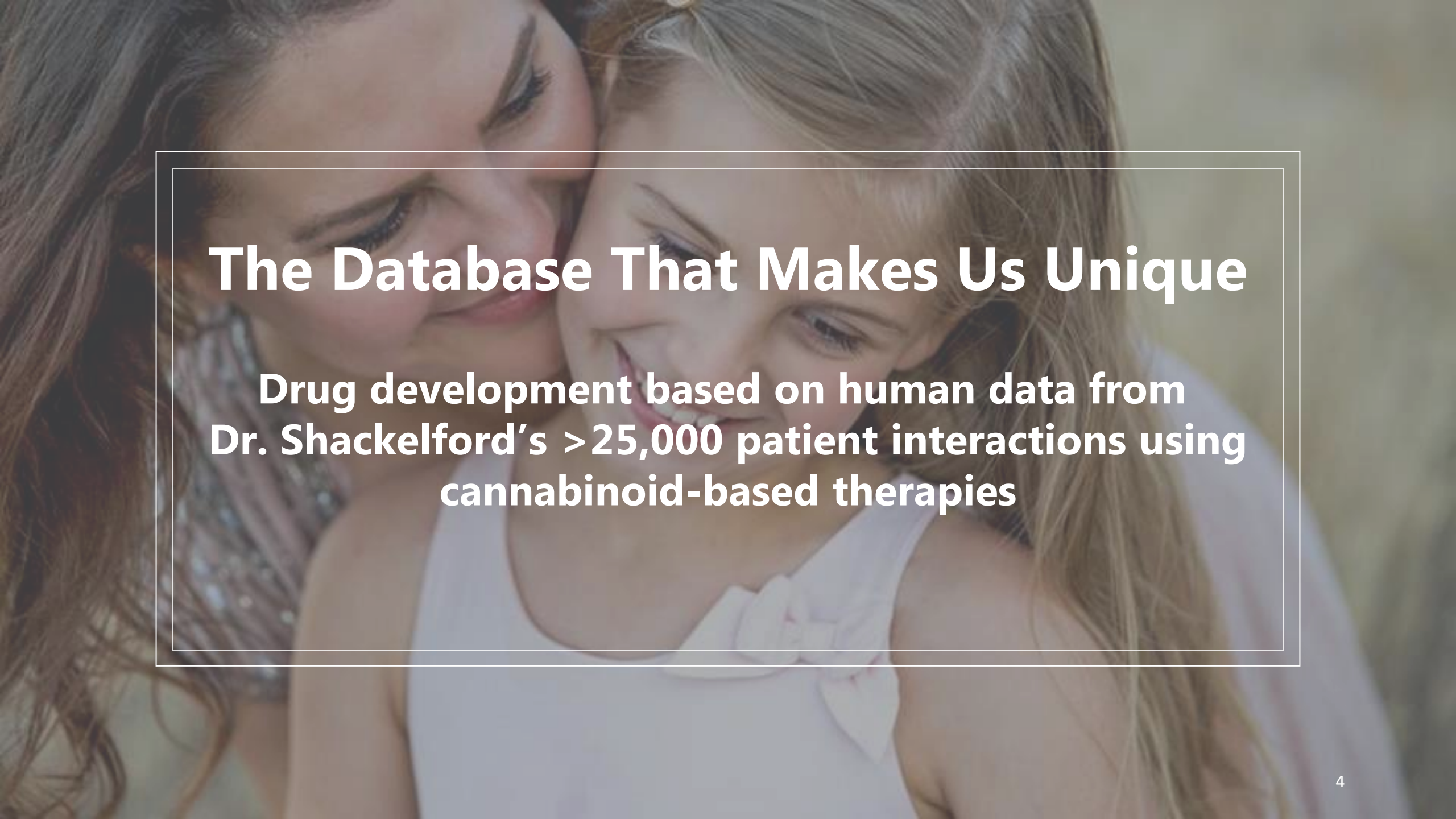
A History in Epilepsy

Dr. Alan Shackelford gained national attention for his **breakthrough treatment** of a young Dravet Syndrome patient with cannabinoids.

Based upon Dr. Shackelford's **real-world experience**, Shackelford Pharma, Inc., was formed to develop medicines for neurological diseases with significant unmet patient needs.





The Database That Makes Us Unique

Drug development based on human data from Dr. Shackelford's >25,000 patient interactions using cannabinoid-based therapies

Exceptional Team

- **>320** years experience
- Individuals on our team were directly responsible for **43** FDA Drug Approvals
  - ✓ **7** drugs >$1B annual sales each
  - ✓ **6** FDA approved epilepsy drugs
- Renown Scientific Advisory Board
- Accomplished Corporate Team

Epilepsy: The Unmet Need

Despite ~28 anti-epileptic drugs (AEDs) on the market[1], ~36% of patients with epilepsy still have uncontrolled seizure activity[2].

- For many epilepsy patients, the suffering they endure goes well beyond seizures. They struggle with depression, impaired cognition, impaired brain development or even reversal of development progress in children.
- Frequent seizures that don't respond to currently available medications can cause brain damage. Some patients with intractable epilepsy even have brain tissue surgically removed to treat their seizures.
- Estimated direct costs of epilepsy are approximately $28 billion per year, a significant portion of which can be attributed to increases in all-cause costs related to uncontrolled epilepsy.[2]

1. Epilepsy Currents. Summary of Antiepileptic Drugs Available in the United States. July-August 2018.
2. AJMC. Examining the Economic Impact and Implications of Epilepsy. February 2020.

SP1707: Lead Drug Candidate

- Contains **active ingredient used by Dr. Shackelford** in this specific epilepsy population
- **Real world evidence from large cohort of patients** with seizures or seizure disorders representing hundreds of patient treatment years of real-world data.
- **Probability of demonstrating efficacy** in controlled clinical trials **projected to be higher** due to this real-world experience
- **No safety or tolerability issues identified**
- **Unique Mechanism of Action** – positive for drug development & complimentary to existing anti-seizure medications
- **Adjunct and Monotherapy** use cases
- **Large Unmet Medical Need:** ~1.3M patients (USA, EU5, CAN, AUS)

Dr. Shackelford's Real-World Experience Compared With Published Data from Jazz Pharmaceuticals

	SP1707	SP1707	EPIDIOLEX®	EPIDIOLEX®
	Adult	Pediatric	Ped. RCTs	EAP
Demographics				
Number of Patients	82	13	61-76 per indication	892
Male/Female	47/35	8/5	N/A	464/428
SZ/Epilepsy Duration Prior to SP1707 Treatment	Mean= 15.55; Up to 46 yrs	Mean=6.6; Up to 16 YRS	<18 YRS	N/A (age range 0-75, median 12 YRS)
Duration of Follow-Up (years)	307	49	~14-20	1755
Disease Outcomes: Benefit				
Indication	Undisclosed	Undisclosed	DS, LGS, TSC	TRE
Responder Rate (>/=50% reduction in seizure frequency over 1 year period)	71% (24/34)	60% (6/10)	~45% @ 14 WKS	53% @48 WKS
1 YR Seizure Remission Rate (in patients with 1+ seizures in prior year with at least 1 year follow up post SP1707 treatment initiation)	44% (15/34)	40% (4/10)	6-7% @14 WKS	11% @48 WKS
Expected 1 YR Seizure Remission Rate	4-5%	4-5%	4-5%	4-5%
Increase in 1 YR Seizure Remission Rate over expected	~9X	~9X	~1.5X	~2X
Disease Outcomes: Safety				
Adverse Events	2% (2/82)	0% (0/13)	Up to 12%	7%

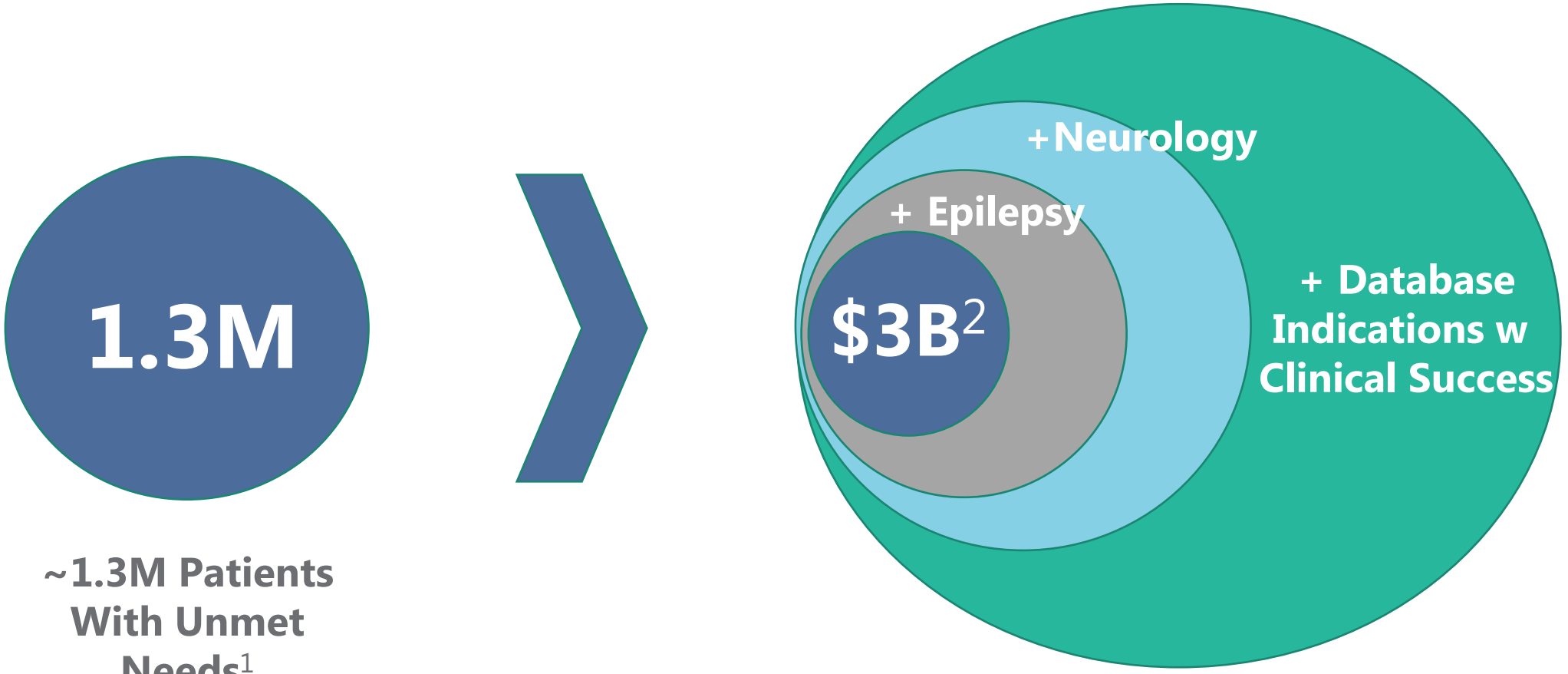
Retrospective Data

Efficacy in Primary Indication
(same seizure type vs EPIDIOLEX®)
=34 adults & 10 pediatric patients

Safety: SP1707 total patients on active ingredient
=82 adults & 13 pediatric patients

RCT = randomized controlled trial
EAP = expanded access program
N/A = not available
SZ = seizures
DS = Dravet Syndrome
LGS = Lennox-Gastaut Syndrome
TSC = Tuberous Sclerosis Complex
TRE = Treatment-Resistant Epilepsy

SP1707: Lead Candidate & Beyond



1. WJM. "Seizure Disorders: Part 1. Classification and Diagnosis". (USA, EU5, CAN, & AUS). 2. Internal Forecast

Current Status

- **Provisional Patent application filed** related to the use of Shackelford's drug candidate for the treatment of seizure disorders, either alone or as adjunctive therapy. This application included **both** supportive preclinical data and real-world experience.
- **Pre-IND Meeting and response from FDA:** Complete
- **IND Submission:** planned H2 2023
- **Start of Phase 2:** planned H2 2023
- **CMC/Formulation Development:** underway to develop a proprietary sustained-release final formulation

Summary

Real World Experience

- Unique to Pharma Industry
- De-risks Drug Development
- Directs Pipeline Development

Right People

- World-Class Team with Proven Track Record
- Strong Scientific Advisory Board

SP1707 Opportunity

- Freedom to Operate Opinion
- Significant Unmet Medical Need
- Commercial Opportunity
- Robust Real-World Data (>350 patient treatment years)

Strong Pipeline Potential

- Large Underserved Markets
- Near Term Additions Identified
- Opportunities Outside of Neurology

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THANK YOU

www.shackelfordpharma.com