



Rodman & Renshaw Conference

Jack Khattar - President & CEO

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# **Commercial Stage CNS Specialty Pharma**

Two Marketed Products

Robust Pipeline





Two epilepsy drugs in multi-billion dollar market

- SPN-810: Novel product for IA\* in ADHD
- SPN-812: Novel non-stimulant for ADHD
- Strong R&D with six technology platforms



<sup>\*</sup> Impulsive Aggression

## 23 Years of Successful Product Development

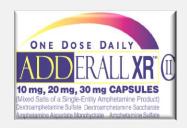
**Former Division of Shire** 



























# Non-Compliance – A <u>Serious</u> Problem in Epilepsy

71% of patients report missing a dose at least once/month 45% reporting seizures after a missed dose

#### **Serious Quality of Life Issues**





Non-compliance leads to breakthrough seizures that cost annually in excess of \$26,000 per patient

#### **Increased Healthcare Costs**



#### **Worsening of Condition**





# **Extended-Release AEDs = Significant Patient Benefits**

**Reduced Dosing Frequency Reduced Side Effects &** & Precise Timing **Improved Tolerability** Smooth/Consistent PK **Higher Effective Doses** Compliance

Reduced Breakthrough Seizures & Reliable Seizure Control



# **Two Epilepsy Products Launched in 2013**

- Oxtellar XR<sup>™</sup> The only once daily oxcarbazepine XR product in the U.S.
  - Adjunctive therapy in partial seizures in adults & children 6-17 years
  - Two U.S. patents issued with expiry no earlier than 2027
- Trokendi XR™ The only once daily topiramate XR product in the U.S.
  - Monotherapy in patients 10 years and older
    - Partial or primary generalized tonic-clonic seizures
  - Adjunctive therapy in patients 6 years and older
    - Partial or primary generalized tonic-clonic seizures
    - Lennox-Gastaut Syndrome
  - Two U.S. patents issued with expiry no earlier than 2027



### Oxtellar XR™: Phase III Study - Improvement in AE Profile

55% Reduction in AE-Related Discontinuation vs. Trileptal®

% of Patients With:	Oxtellar XR 2400 mg/d (n=123)	Oxtellar XR 1200 mg/d (n=122)	Placebo (n=121)
Any adverse event (AE)	69	57	55
Treatment-related AEs	58	43	39
AEs leading to discontinuation	30	16	12

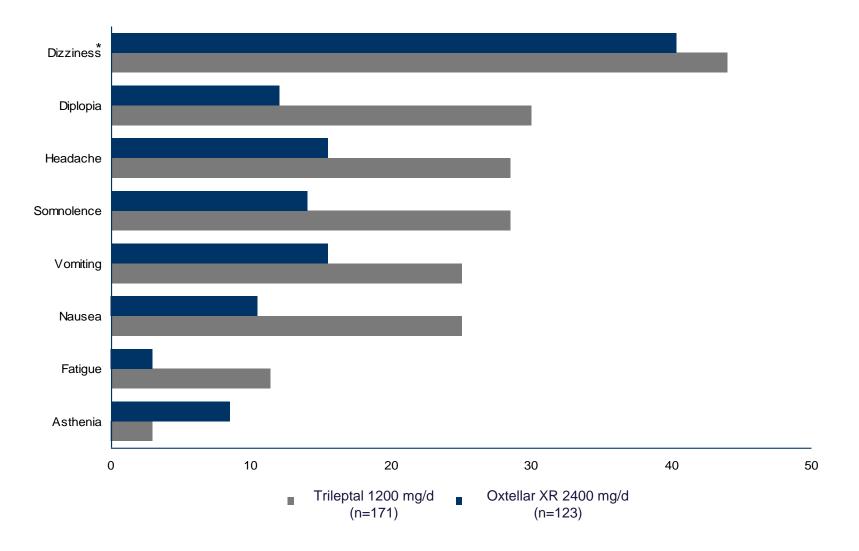
Discontinuations occurred on Trileptal® 2400 mg/d in **66.7%** of patients - Barcs G, et al study (*Epilepsia*. 2000;41[12]:1597-607).

% of Patients With:	Double Blind (16 weeks)	Open Label (1 year)		
	All Oxtellar XR (n=245)	All Oxtellar XR (n=214)		
AEs leading to discontinuation	23	5		



### Oxtellar XR™: Can Enable Higher Dosing

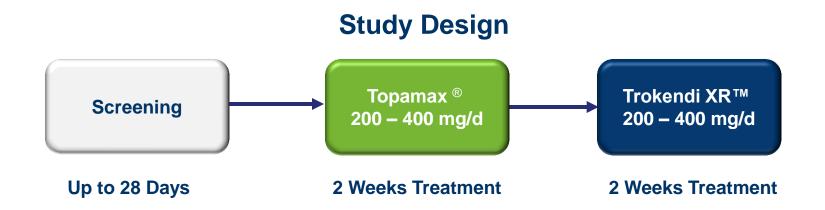
### Improved AE Profile at <u>Double</u> the Dose of Trileptal®





## Trokendi XR™: Switch Study to Establish Bioequivalence

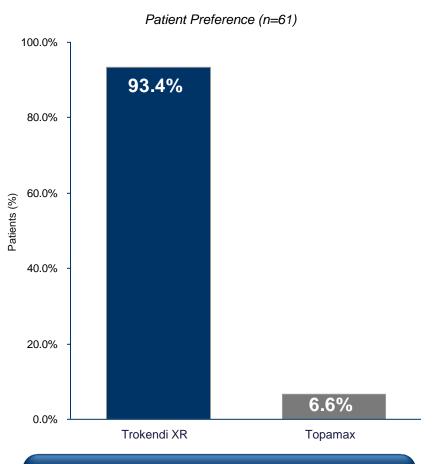
Design mimics dose switching in actual clinical practice



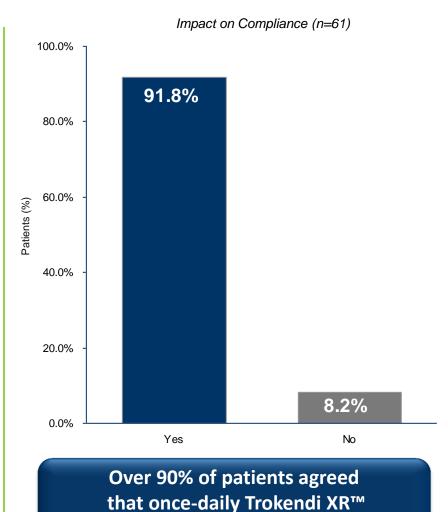
- Multicenter, open-label, 3-period switch study
- Patients on other AEDs
- Trokendi XR™ is bioequivalent to Topamax® at steady state



## Overwhelming Patient Preference for Trokendi XR™







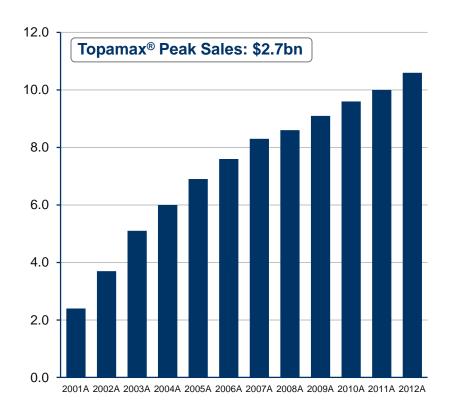
helps with compliance



## **Trokendi XR™ & Oxtellar XR™ Target Significant Markets**

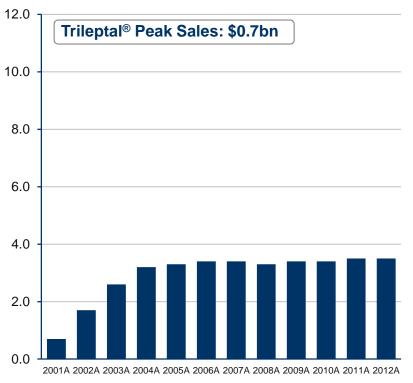
#### Trokendi XR™

### U.S. Topiramate Market



#### Oxtellar XR™

#### U.S. Oxcarbazepine Market



(TRx's in millions)



## Trokendi XR™ & Oxtellar XR™: A Significant Opportunity

### **Illustrative Example**

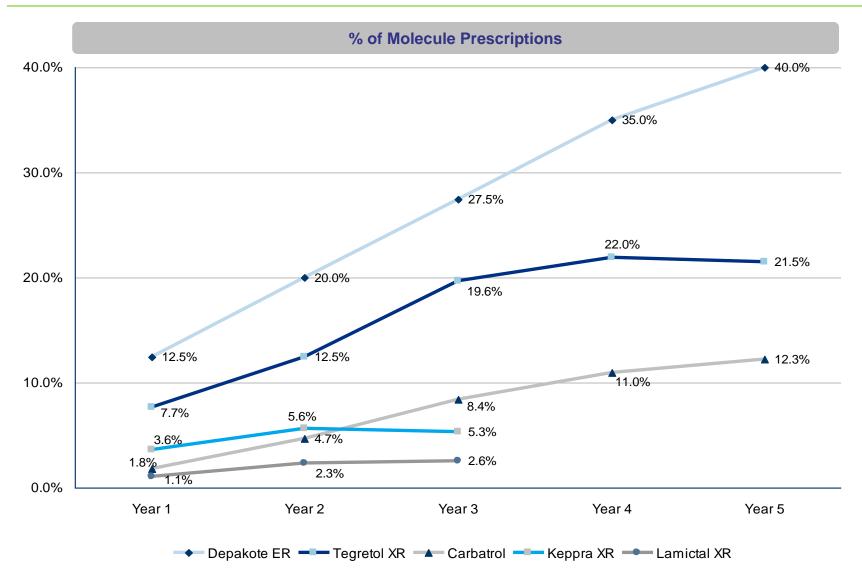
Assumes Total Market of 10 MM Prescriptions (TRx) for Topiramate + Oxcarbazepine

Period Post Launch	Year 1		Year 2		Year 3		Year 4		Year 5	
Total Market (MM TRx)*	10.0		10.4		10.8		11.2		11.6	
Conversion Rate (%)	1	3	4	5	6	7	8	10	11	12
Potential Prescriptions (k) Trokendi XR + Oxtellar XR	100	300	416	520	648	756	896	1120	1276	1392
Example of Average Net \$/ Rx*	275	275	289	289	303	303	318	318	334	334
Potential Net Sales (\$MM)	27	82	120	150	196	229	285	356	426	465

<sup>\*</sup> Assumes annual market growth of 4% and annual price increase of 5%

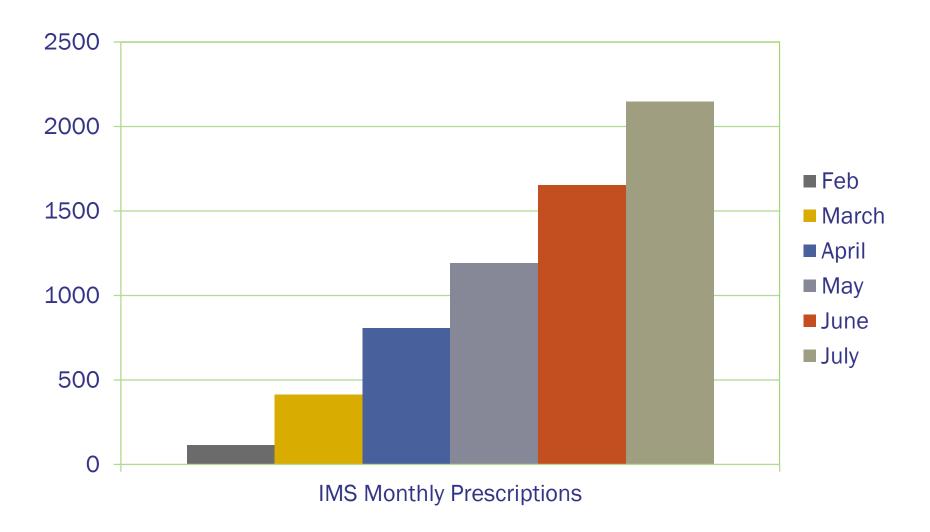


## **XR Products Perform Well When Effectively Promoted**



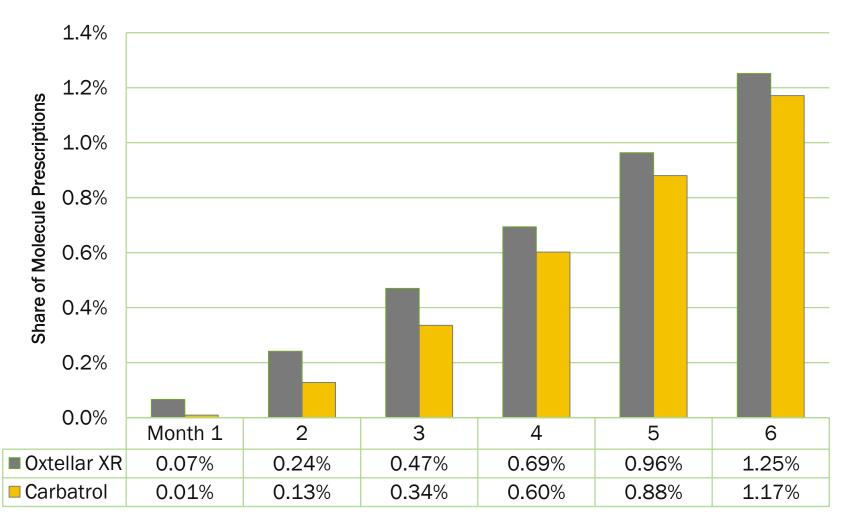


# Oxtellar XR™ Prescription Growth





### Oxtellar XR™ and Carbatrol® Conversion Share



Oxtellar XR launched in Feb 2013 (2.1 M addressable TRx market, WK), Carbatrol launched in April 1998 (7.6 M TRx market, IMS)



# Oxtellar XR™ Key Launch Metrics

- Higher conversion share among:
  - Top ranking physicians
  - Physicians called on 6 times or more since launch
- Sales force focused on increasing call frequency
- Qualitative research and reported patient cases showing:
  - High satisfaction with the product
  - Product is delivering on its differentiated profile
- To date, managed care coverage for 142 million lives
  - Majority of patients not paying more than \$15 with co-pay card



### SPN-810: Novel Product for Impulsive Aggression in ADHD



25% of children with ADHD have persistent conduct problems such as impulsive aggression

- Expected to be first product approved to treat this serious condition
  - Co-morbidity in ADHD, schizophrenia, autism and bipolar disorder
  - Molindone hydrochloride (D1&2, 5HT2A antagonist)
- Phase IIb in Impulsive Aggression (IA) in ADHD
  - Multicenter, placebo-controlled, randomized
  - ADHD children 6-12 yrs old with IA
    - N=118, three doses and placebo
  - Add-on to stimulant treatment
  - Established safety & tolerability
  - Established efficacy at low and medium doses



### **SPN-812: Novel Non-Stimulant for ADHD**

- Expected to have a better AE profile than current therapies
  - Norepinephrine reuptake inhibitor
  - NCE for U.S. market
- Positive Phase IIa trial showed:
  - Safety & tolerability in 52 adults
  - Efficacy with statistical significance vs. placebo\*
- Developing extended-release product

ADHD affects 6% to 9% of all school-age children and 3% to 5% of all adults



### **Financial Position**

- As of June 30, 2013
  - Cash, marketable securities, and financial instruments ~\$119M
  - In May 2013, closed on a \$90M Convertible Senior Note
  - Retired venture debt, net proceeds ~\$67M
- Expected 2013 annual cash burn of \$85M \$95M
  - \$39M six months YTD
- Anticipate being cash flow breakeven by 4Q 2014
  - Requires quarterly revenue run rate of \$30M \$35M
  - Current cash position sufficient to fund operations through 4Q 2014



# **Summary**

Emerging Growth in CNS

Multiple Value
Drivers

Two marketed products





- Robust pipeline
- 23 years of proven track record
- Strong execution since IPO
- Success on Oxtellar XR and Trokendi XR
- Progress of SPN 810 and SPN 812 in ADHD
- Cash position sufficient to cash flow breakeven

