

# Centered on CNS

A legacy of innovation, a portfolio of promise™



**Jefferies Global Healthcare Conference**

**Jack Khattar – President & CEO**

**June 2013**

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# Commercial Stage CNS Pharma

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**Two Product  
Launches**

**Robust  
Pipeline**

- Two epilepsy drugs in multi-billion dollar market
- Oxtellar XR™ launched in February 2013
- Trokendi XR™ planned launch in 3Q 2013
  
- SPN-810: Novel product for IA\* in ADHD
- SPN-812: Novel non-stimulant for ADHD
- Strong R&D with six technology platforms

\* Impulsive Aggression

# 23 Years of Successful Product Development

Former Division of Shire



# Non-Compliance – A Serious 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

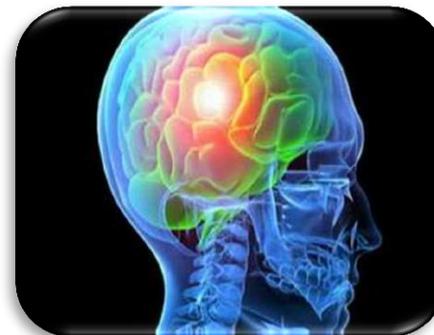


## Increased Healthcare Costs



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

## Worsening of Condition



# Extended-Release AEDs = Significant Patient Benefits

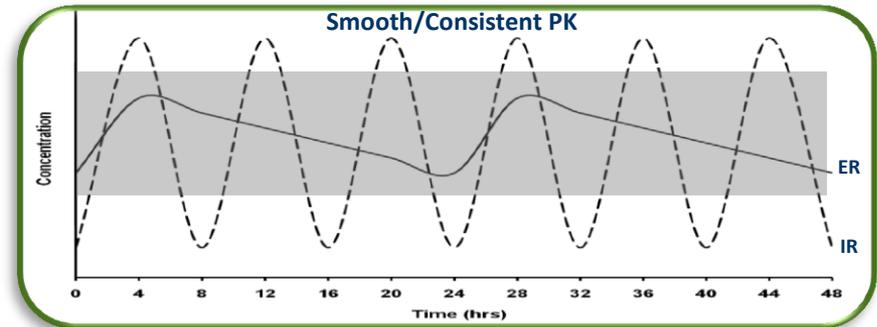
Reduced Dosing Frequency  
& Precise Timing



Compliance



Reduced Side Effects &  
Improved Tolerability



Higher Effective Doses



**Reduced Breakthrough Seizures & Reliable Seizure Control**

# Oxtellar XR™: Launched in February 2013

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- 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
  - Three year market exclusivity granted
  
- Phase III trial established efficacy and safety
  - Multicenter, randomized in refractory partial onset epilepsy
  - 366 adult patients randomized to 1200mg, 2400mg or placebo
  - Significant improvement in tolerability profile across many AEs

# Oxtellar XR™: Critical Improvement in AE Profile

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

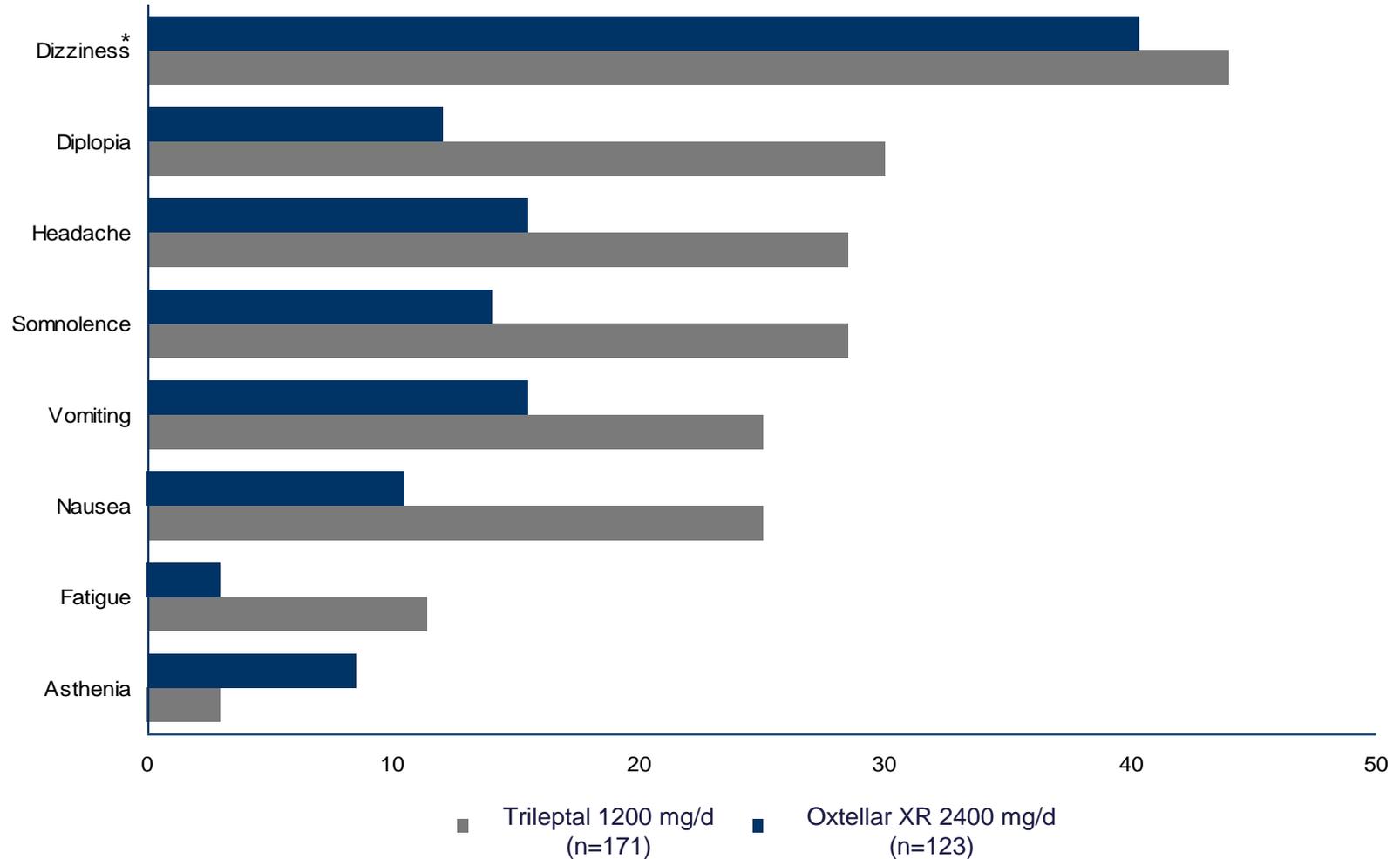
% of Patients With:	Oxtellar XR 2400 mg/d (n=123)	Oxtellar XR 1200 mg/d (n=122)	Placebo (n=121)
Any adverse event (AE)	69	57	55
Treatment-related AEs	58	43	39
AEs leading to discontinuation	<b>30</b>	16	12

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	<b>5</b>

# Oxtellar XR™: Can Enable Higher Dosing

## Improved AE Profile at Double the Dose of Trileptal®



Based on comparison of Oxtellar XR Study 301 vs. Trileptal PI (adjunctive therapy study in adults); differences in trial design exist between the two studies.

\*Dizziness includes vertigo in Trileptal group.

# Trokendi XR™: To Be Launched in 3Q 2013

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- Received Tentative Approval in June 2012
  - Based on bioequivalence strategy
  - J&J data exclusivity expires June 22, 2013
  - Filed “Request for Final Approval” in December 2012
    - If approved before June 22nd, will be a tentative approval
- Final Approval and launch expected in 3Q 2013
- Two issued U.S. patents with expiry no earlier than 2027

# Trokendi XR™: Switch Study to Establish Bioequivalence

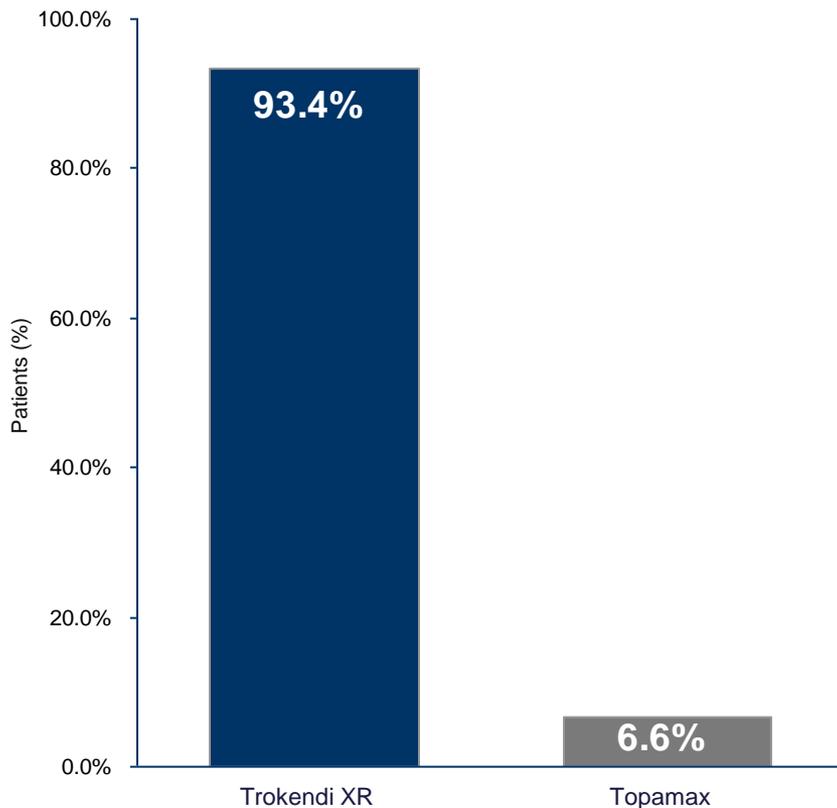
*Design mimics dose switching in actual clinical practice*



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

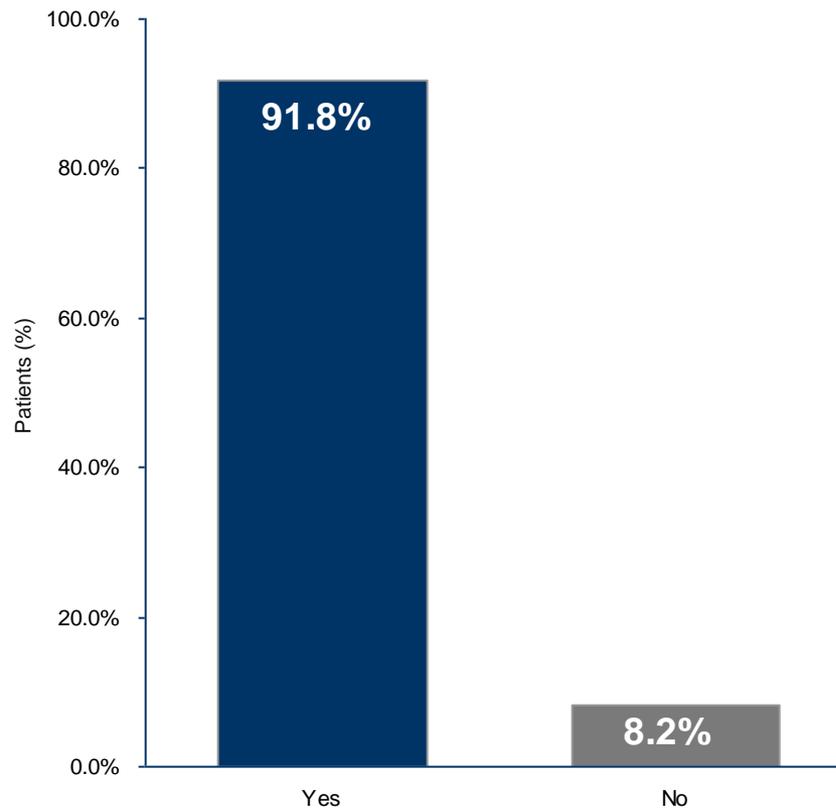
# Overwhelming Patient Preference for Trokendi XR™

Patient Preference (n=61)



**Over 90% of patients preferred once-daily Trokendi XR™ over twice-daily Topamax®**

Impact on Compliance (n=61)

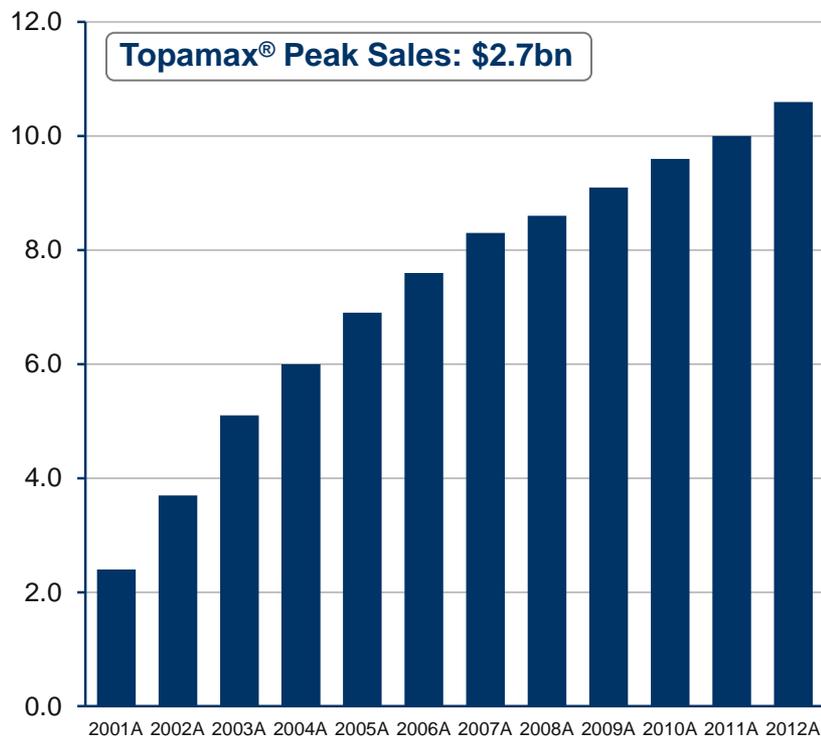


**Over 90% of patients agreed that once-daily Trokendi XR™ helps with compliance**

# Trokendi XR™ & Oxtellar XR™ Target Significant Markets

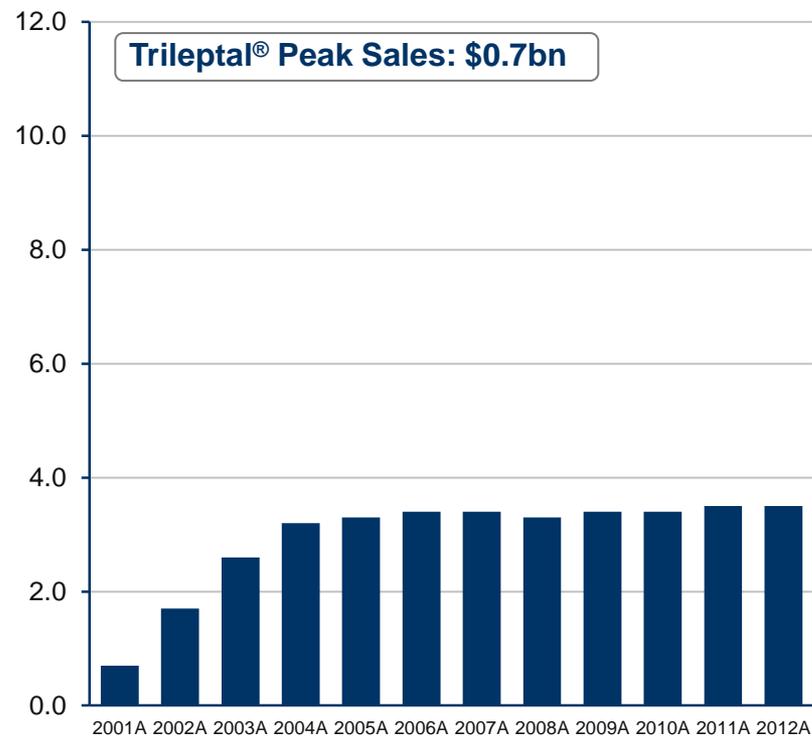
## Trokendi XR™

U.S. Topiramate Market



## Oxtellar XR™

U.S. Oxcarbazepine Market



(TRx's in millions)

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

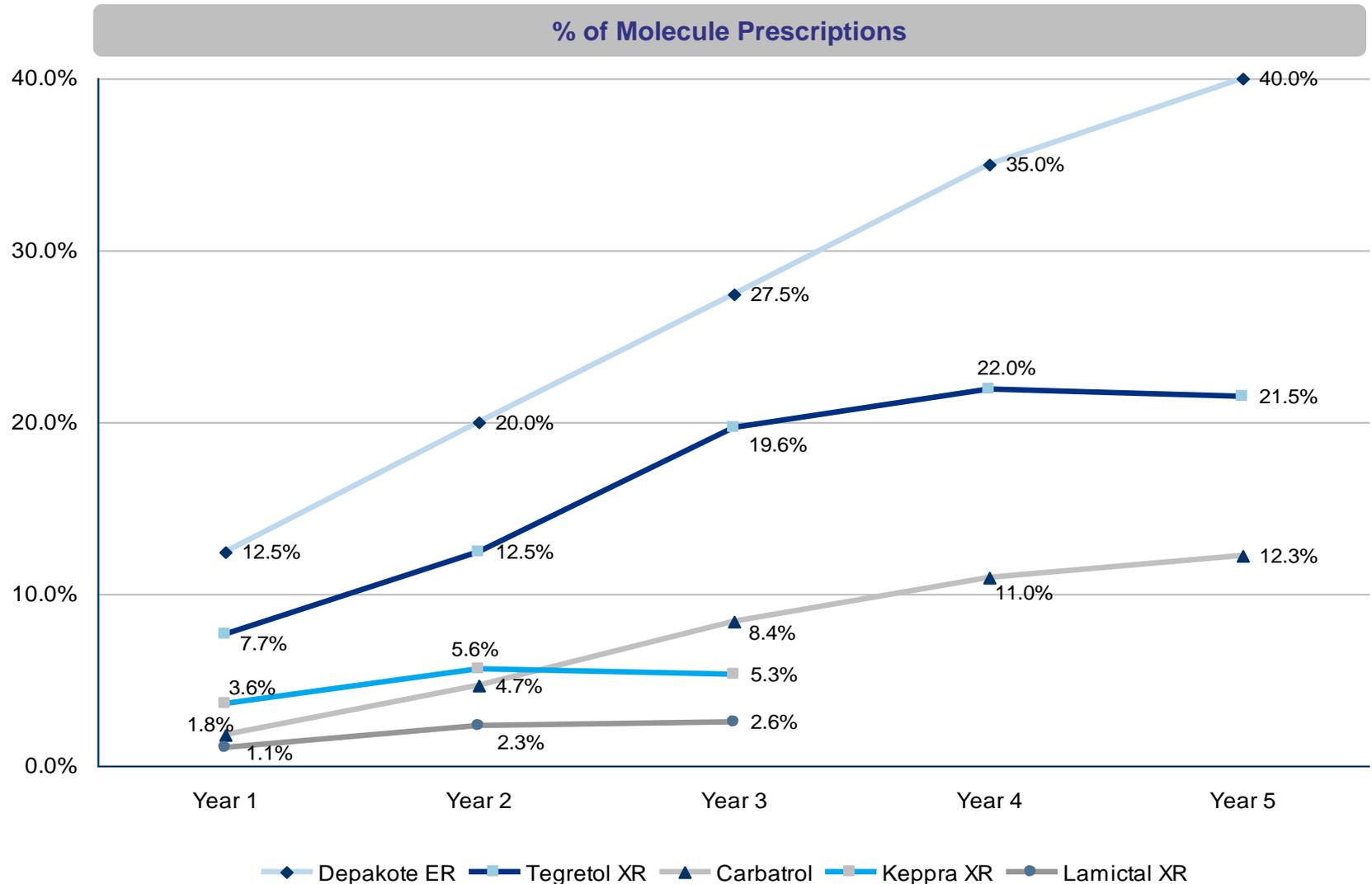
## Illustrative Example

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
<b>Potential Net Sales (\$MM)</b>	<b>27</b>	<b>82</b>	<b>120</b>	<b>150</b>	<b>196</b>	<b>229</b>	<b>285</b>	<b>356</b>	<b>426</b>	<b>465</b>

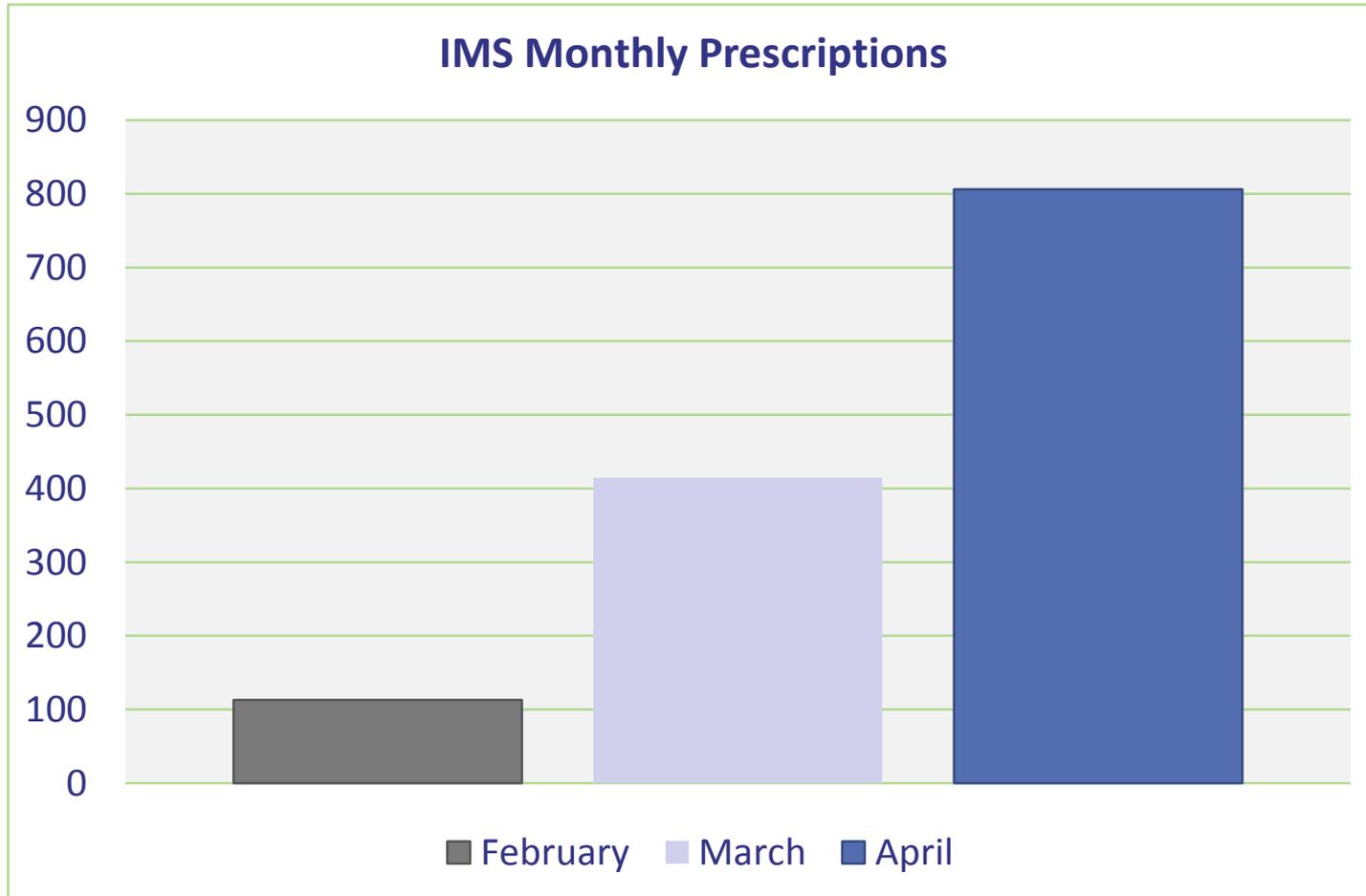
\* Assumes annual market growth of 4% and annual price increase of 5%

# XR Products Perform Well When Effectively Promoted

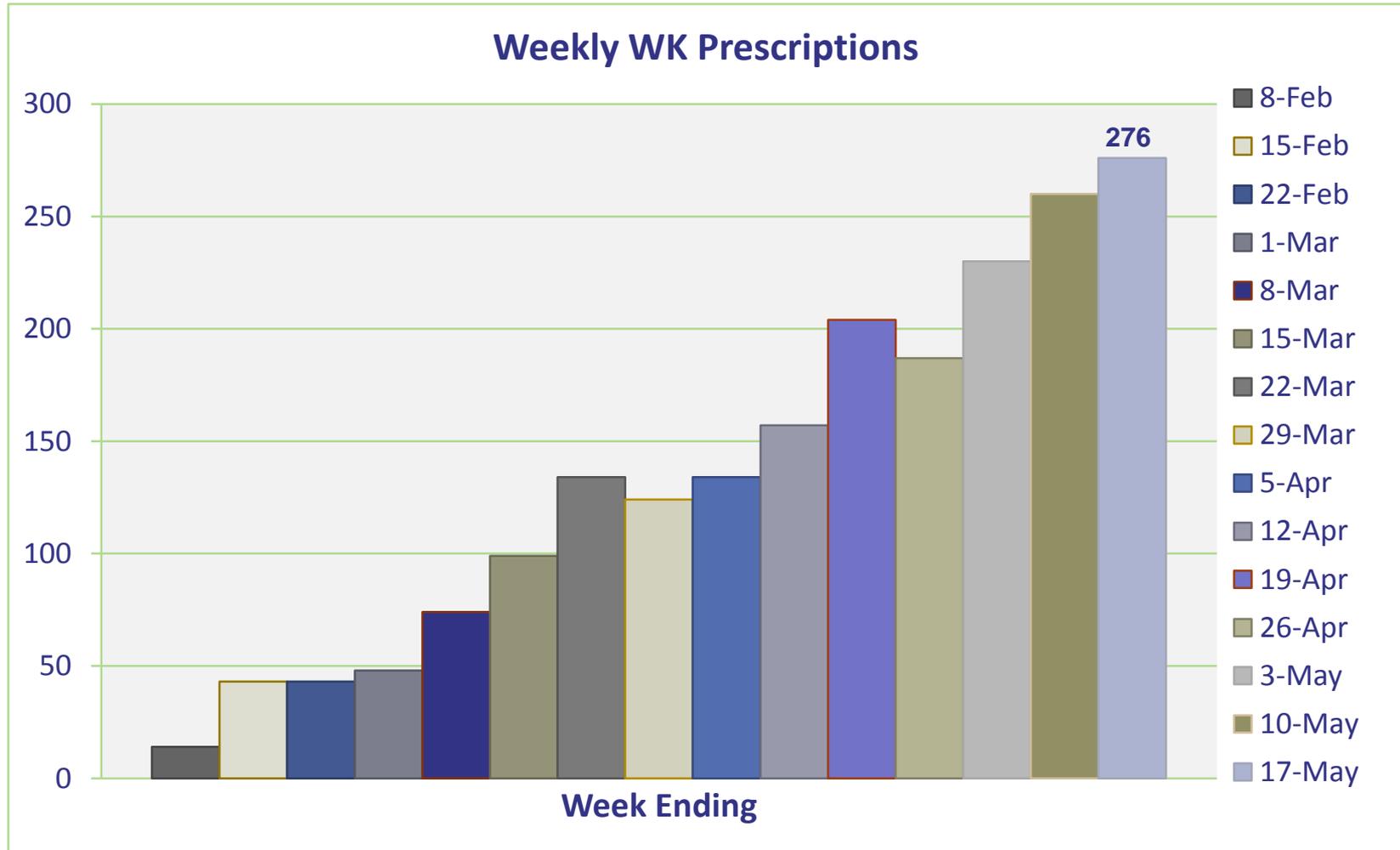


Note: Year 3 for Lamictal XR is based on 3 months of data (Jul-Sep 2011).

# Oxtellar XR™ Prescription Growth

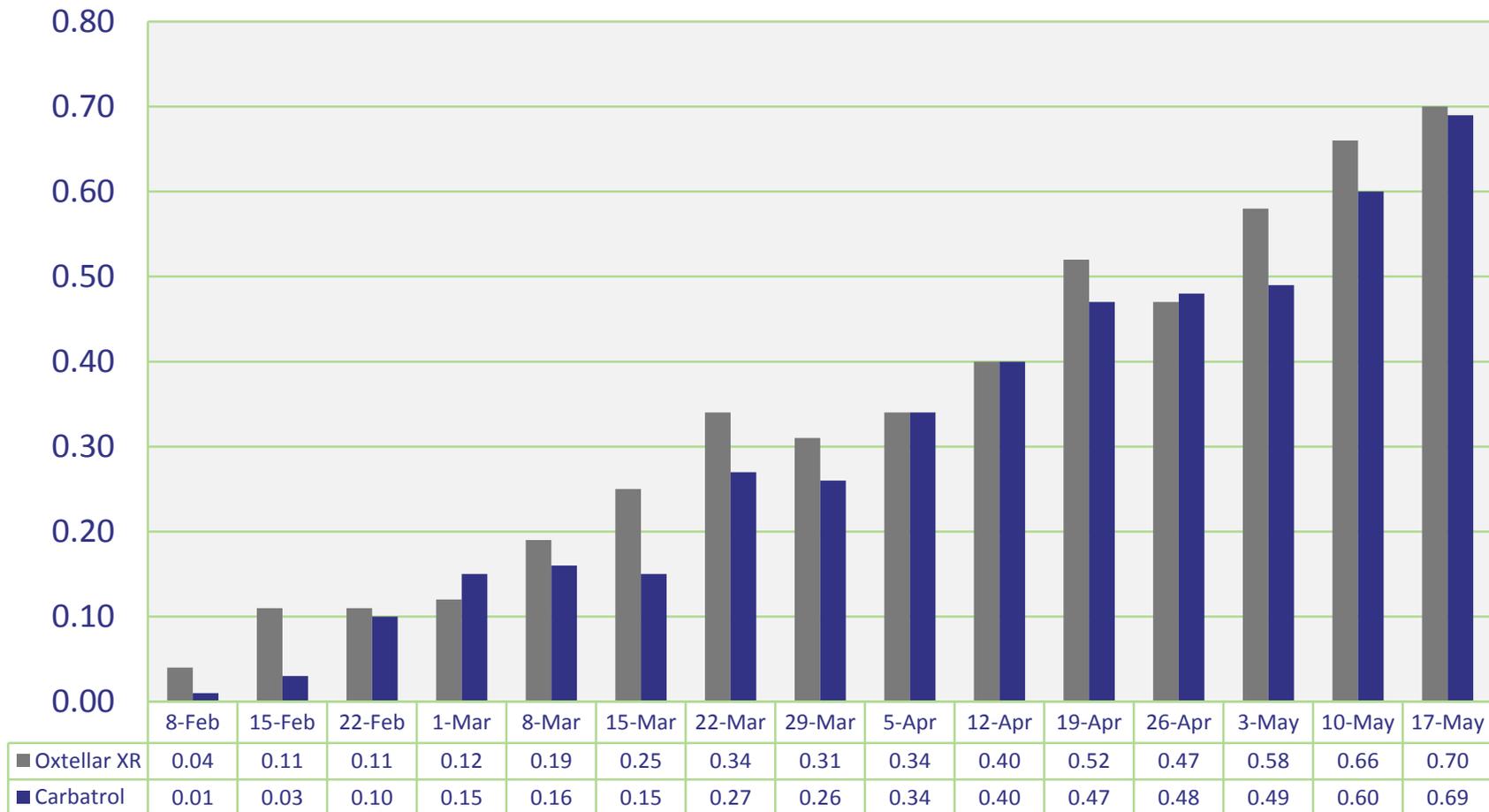


# Oxtellar XR™ Prescription Growth



# Oxtellar XR™ Conversion Share Growth

Weekly 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

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- Higher conversion share among:
  - Top ranking physicians, approx 1%
  - Physicians called on 6 times or more since launch, approx 2.5 – 3%
- Sales force focused on increasing call frequency
  - On average 600 calls per week in early weeks increased to 1300 calls in most recent week
- Qualitative research and reported patient cases showing:
  - High satisfaction with the product
  - Product is delivering on its differentiated profile
- To date, achieved managed care coverage for 135 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

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- Expected to have a better side effect 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

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- As of March 2013
  - Cash and marketable securities of \$69.9M
  - Venture debt of \$20.1M
- In May 2013, closed on a \$90M Convertible Senior Note
  - Retired venture debt
  - Net proceeds ~\$67M
- Expected 2013 annual cash burn of \$85M - \$95M
  - Lower than prior guidance of \$95M - \$105M, primarily due to retiring venture debt (11% coupon)
- Current cash sufficient to fund operations through end of 2014
  - Expect to be cash flow breakeven by then, based on revenue ramp of new products

# Summary

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**Emerging  
Leader  
in CNS**

**Multiple Value  
Drivers**

- Commercial stage CNS pharma with robust pipeline & 23 years of successful track record
- Strong execution since IPO
- Encouraging early launch metrics on Oxtellar XR
- Final approval & launch of Trokendi XR in 3Q 2013
- Continue to progress SPN-810 and SPN 812 in ADHD
- Cash position sufficient to cash flow breakeven