# **Supernus Pharmaceuticals**



**Investor Presentation** 

March 2017



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This presentation and other matters discussed today or answers that may be given to questions asked include forward-looking statements within the meaning of the federal securities laws. These statements, among other things, relate to Supernus' business strategy, goals and expectations concerning its product candidates, future operations, prospects, plans and objectives of management. The words "anticipate", "believe", "could", "estimate", "expect", "intend", "may", "plan", "predict", "project", "will", and similar terms and phrases are used to identify forward-looking statements in this presentation. Supernus' operations involve risks and uncertainties, many of which are outside its control, and any one of which, or a combination of which, could materially affect its results of operations and whether the forward-looking statements ultimately prove to be correct. Supernus assumes no obligation to update any forward-looking statements except as required by applicable law.

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### **Proven Execution**

#### **Nine Marketed Products Using Our Technologies**

				La	aunch Year	
				2013	2014	2017*
Supern	US® ticals			Trokendi XR®  Oxtellar XR®		
<b>Shire</b>	Carbatrol® Adderall XR® E	Equetro®	Intuniv®			SHP 465
GALDERMA &	Oracea <sup>®</sup>					
<b>ALLERGAN</b>	Sanctura XR®					
United Therapeutics of the post of the pos	cs				Orenitram®	

<sup>\*</sup> As publically disclosed by Shire All trademarks are the property of their respective owners.



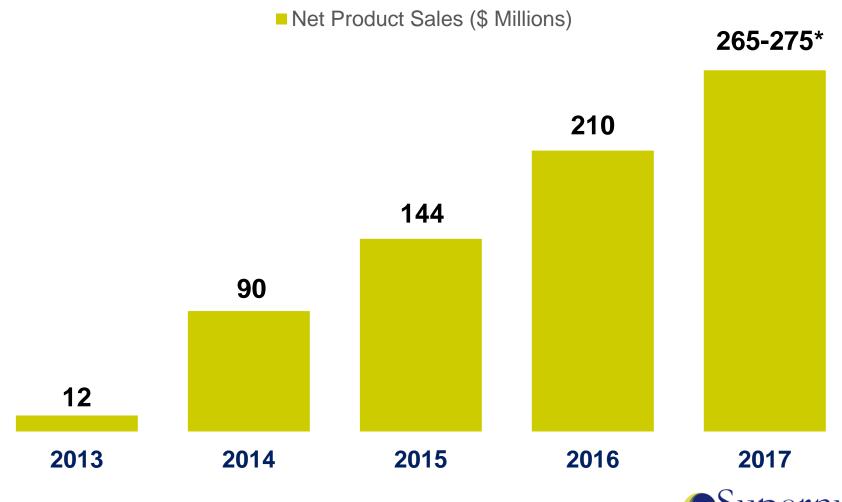


## **Robust Portfolio of CNS Products**

Product	Indication	Development	NDA	Launch
Oxtellar XR®	Epilepsy			February 2013
Trokendi XR®	Epilepsy			August 2013
Trokendi XR®	Migraine	Tentative	e Approval Aug 2016	
SPN-810	Impulsive Aggression		Phase III	
SPN-812	ADHD		Phase IIb Complete	
SPN-809	Depression		IND/Phase II Ready	



# **Strong Net Product Sales Growth**

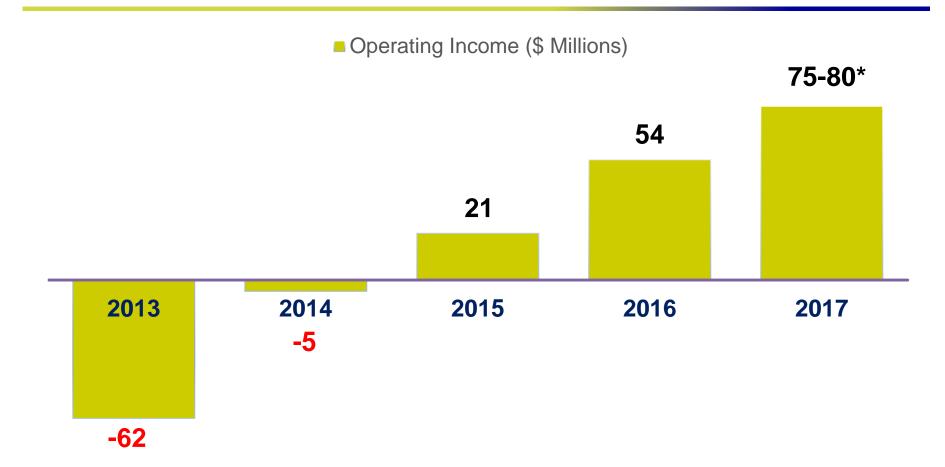


<sup>\*</sup> Guidance provided on February 28, 2017 which has not been updated

5

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# **Growing Operating Income**

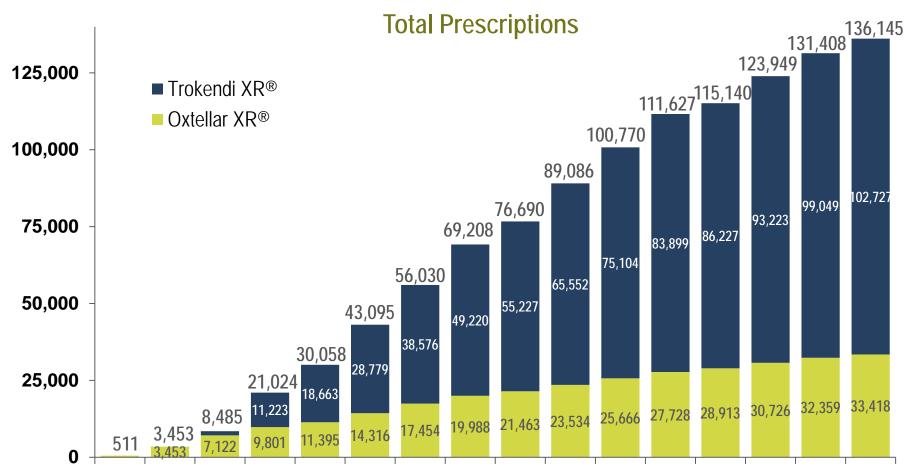


<sup>\*</sup> Guidance provided on February 28, 2017 which has not been updated





# **Solid Prescription Growth Since Launch**



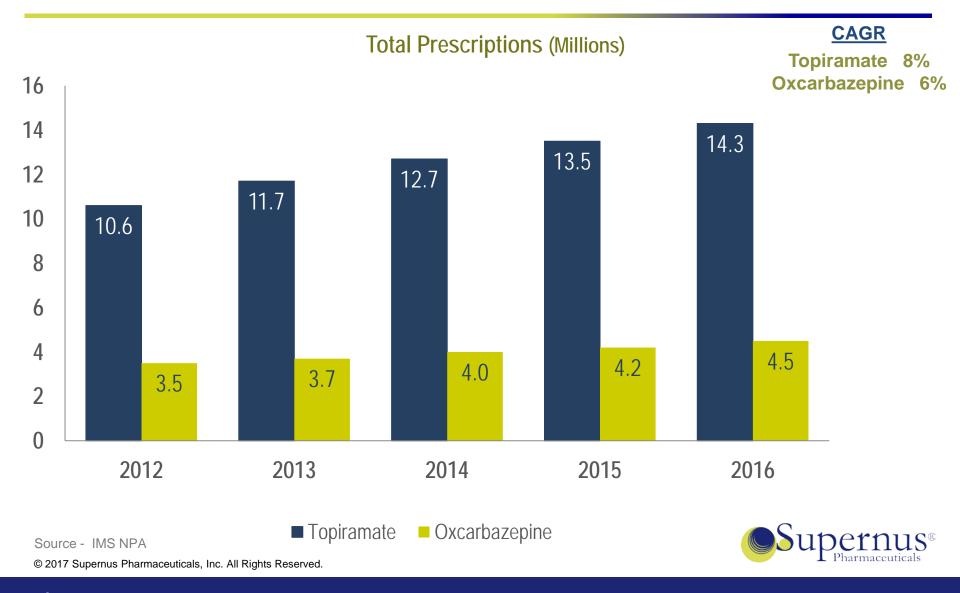
1Q13 2Q13 3Q13 4Q13 1Q14 2Q14 3Q14 4Q14 1Q15 2Q15 3Q15 4Q15 1Q16 2Q16 3Q16 4Q16

Source: IMS Monthly Prescriptions

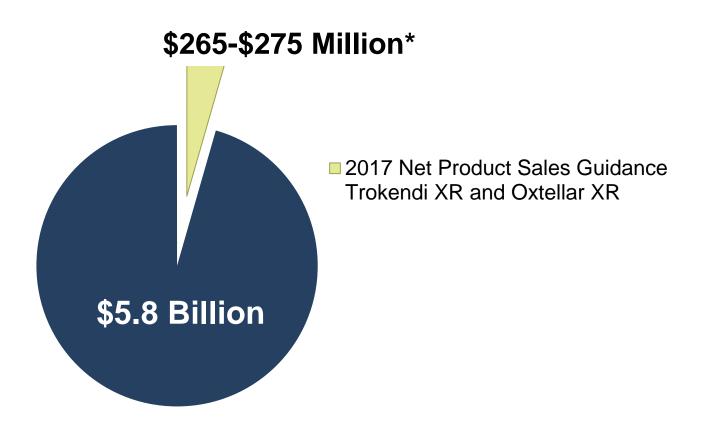
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# **Continued Growth in Target Markets**



# Combined Target Markets Potential of \$5.8 Billion

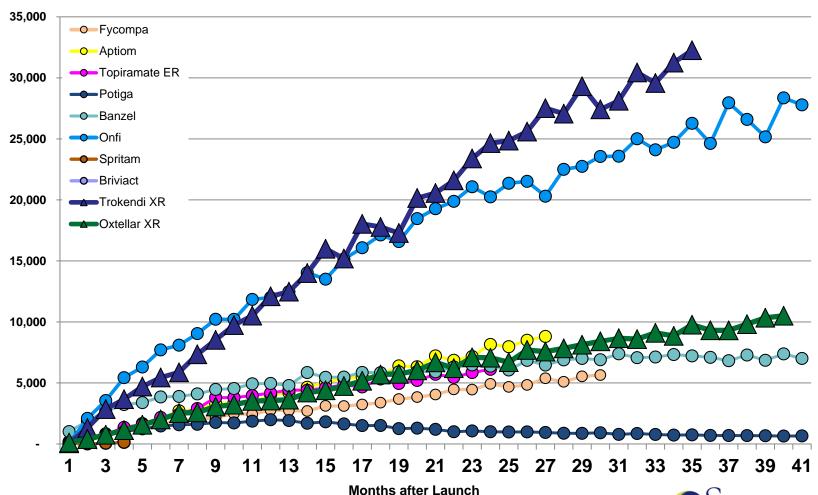




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### Trokendi XR®

#### The Most Successful Anti-Epileptic Drug Launch Since 2010



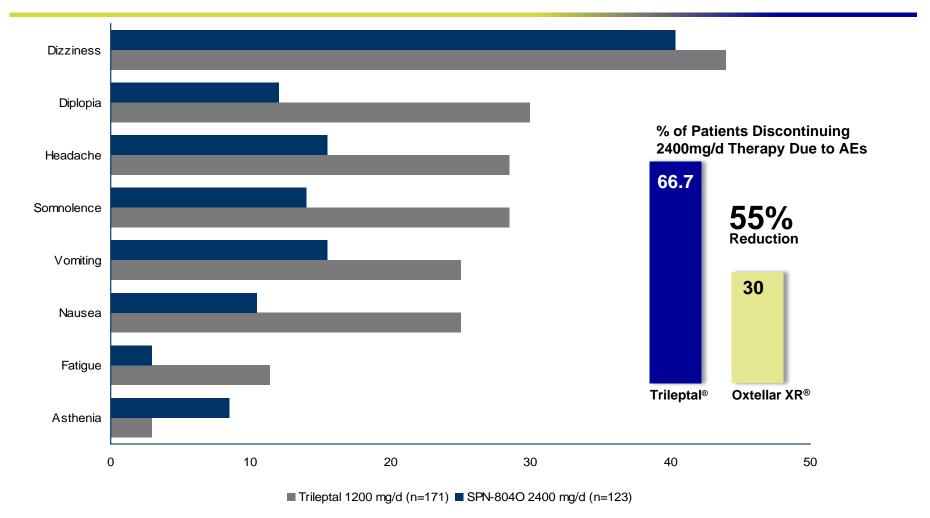
Source: IMS NPA

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Launch Dates – Trokendi XR 8/13; Potiga 5/12, Fycompa 1/14, Aptiom 4/14, Oxtellar XR 2/13, Topiramate ER 7/14, Banzel 1/09, Onfi 12/11, Vimpat 6/09

#### Oxtellar XR®

#### Improved Adverse Event Profile at Double the Dose of Trileptal®



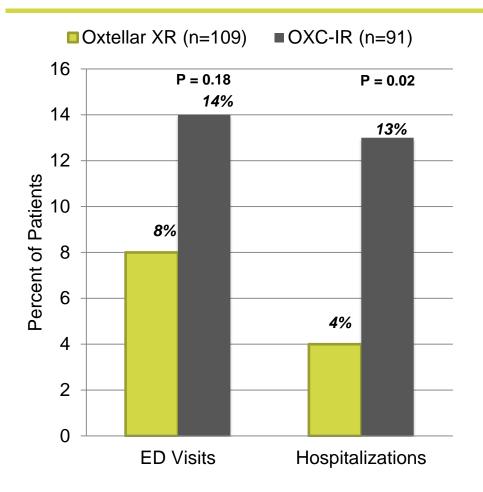
Based on comparison of Oxtellar XR (SPN-804O) Phase III vs. Trileptal PI (adjunctive therapy study in adults); differences in trial design exist between the two studies. Dizziness includes vertigo in Trileptal group because of change in the MedDRA system

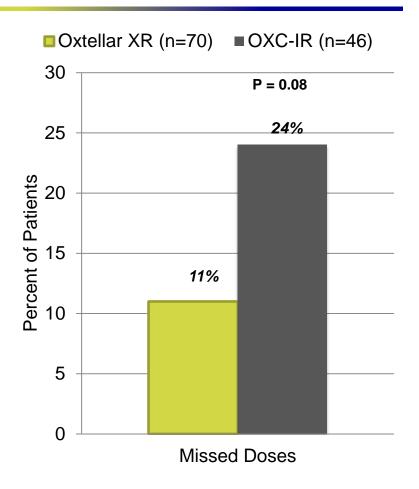


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## Oxtellar XR®

#### More Favorable Clinical Outcomes & Greater Adherence Compared to OXC-IR<sup>1</sup>





<sup>1</sup>O'Neal W, et al., Adherence and Resource Utilization with Extended-Release Oxtellar XR® or Immediate-Release Oxcarbazepine (OXC-IR) Treatment in Clinical Practice: A Standardized Case Record Review. Neurology 2015;84 (P1.244)



# Psychiatry Pipeline SPN-810 & SPN-812



#### **Innovative Late Stage Portfolio**

SPN-810: The First Treatment for Impulsive Aggression

SPN-812: Highly Effective and Well Tolerated Non-Stimulant

**Multi-Billion Dollar Products** 



# **Understanding Impulsive Aggression (IA)**

- IA is a subtype of Maladaptive Aggression
- Impulsivity can be defined neurobiologically
  - Short fuse that causes impairment in self-control
- IA occurs across multiple disorders including
  - ADHD, autism, bipolar disorder, schizophrenia, Alzheimer's,
     PTSD and disorders of traumatic stress



#### **SPN-810: Novel Product for IA**

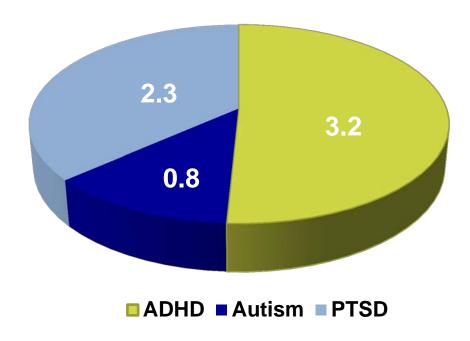


**Granted Fast Track Development Designation** 

Market Opportunity +\$6.3B

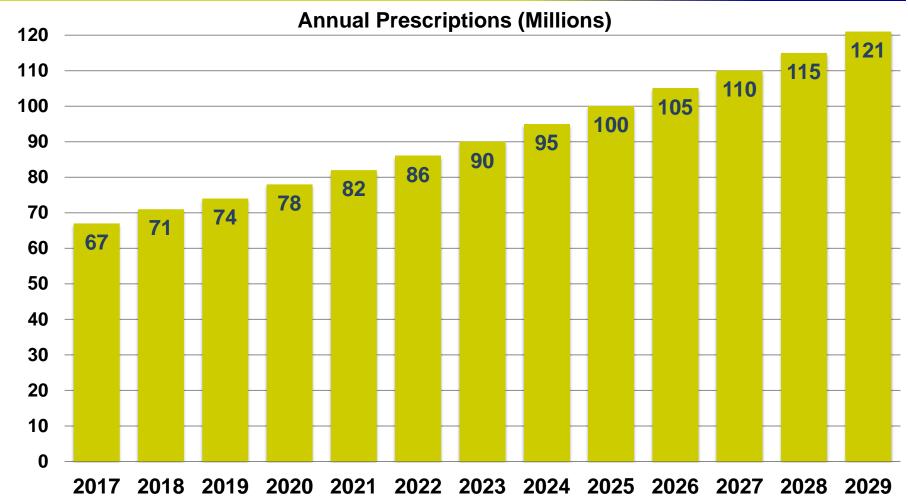
1st Expected to be First Product Approved to Treat IA

2017 Two Ongoing Phase III





# **ADHD Market Opportunity in the U.S**



Source - IMS NPA and Company Estimates

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# **SPN-810 Market Opportunity for IA in ADHD**

	Percent	Prescriptions in Peak Year
ADHD Market Prescriptions		95 - 110 Million
Child and Adolescent ADHD Prescriptions Child Psychiatrists, Child Neurologists, Psychiatrists, and Top Pediatrician Deciles		24 - 28 Million
Prevalence of Impulsive Aggression	22.5 - 32%	5.4 - 9.0 Million
	Peak Market Share	SPN-810 Potential Prescriptions
SPN-810 Peak Demand	16 - 20%	0.9 - 1.8 Million

SPN-810 Market Sizing and Demand Study (April 2015); Assumes prevalence and demand from quantitative research are applicable to high ADHD pediatrician prescribers, and peak market share at 3–5 years post launch



# SPN-810: A Billion Dollar Product for Supernus

#### **Potential Gross Revenue**

ADHD

Autism and PTSD

Total at Peak

\$515 - \$1,050 Million

\$590 - \$720 Million

\$1,105 - \$1,770 Million



#### **Other Impulsive Aggression Opportunities:**

Schizophrenia, Bipolar, Alzheimer's, Oppositional Defiant Disorder, etc.



# SPN-810 Phase IIb Study

#### **Demonstrated Proof of Concept in IA in ADHD Patients**

- Extended release molindone
- Randomized, double-blind, placebo-controlled, multicenter
- 6–12 year old patients with IA co-morbid with ADHD
- Primary endpoint: change from baseline to endpoint (Visit 10) in R-MOAS\* ratings.
- Optional six-month open-label extension

	Children < 30 kg (mg/day)	Children ≥ 30 kg (mg/day)
Low Dose	12	18
<b>Medium Dose</b>	24	36
High Dose	36	54

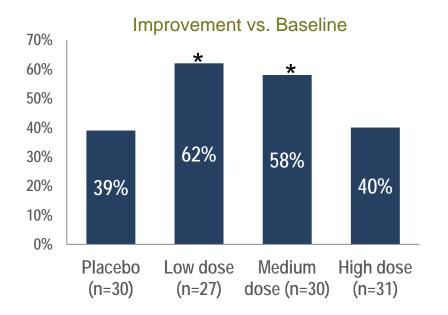
<sup>\*</sup> Retrospective modified overt aggression scale





# **SPN-810 Phase IIb Demonstrated Efficacy**

Primary Endpoint: Change from Baseline at Visit 10 in R-MOAS# Score<sup>1</sup> LOCF, ITT Population



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#### Improved Remission Rate at End of Study<sup>2</sup>

R-MOAS	Placebo (n=30)	Low Dose (n=27)	Medium Dose (n=30)	High Dose (n=31)
Subjects Remitted	6 (20%)	14 (52%)	12 (40%)	10 (32%)
P-value for Remission Rate		0.009	0.043	0.276

Remission: RMOAS≤10, P significant at p< 0.05



<sup>\*</sup> P<0.05 vs. placebo

<sup>#</sup> Retrospective modified overt aggression scale

<sup>&</sup>lt;sup>1</sup> Primary Endpoint based on FDA input

<sup>&</sup>lt;sup>2</sup> Primary Endpoint before FDA input

### **SPN-810 Was Well-Tolerated**

Most Common Adverse Events* (Reported by ≥ 5% of Subjects in one or more treatment groups)	Placebo (n=31) N (%)	All Treatment (n=90) N (%)
Headache	4 (13%)	9 (10%)
Sedation	2 (7%)	8 (9%)
Somnolence	1 (3%)	2 (2%)
Abdominal Pain	1 (3%)	5 (6%)
Increased Appetite	1 (3%)	7 (8%)
Decreased Appetite	0	5 (6%)
Fatigue	0	3(3%)
Abnormal Weight Gain	0	1 (1%)
Extrapyramidal Symptoms (EPS)		
Dystonia	0 (0)	2 (2%) [Severe]
Akathisia	1 (3.2%) [Mild]	0 (0)
Dyskinesia	0 (0)	1 (1%) [Moderate]

<sup>\*</sup>There is no statistically significant difference in the rate of incidence of AEs between the placebo arm and all active treatment groups combined



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# SPN-810 Phase III Study Design

Study	Population	Primary Objective*	Study Duration	Treatment Duration	Dose Range	No. of Subjects	Status
810P301	Pediatric (6-12 years)	Efficacy	10 weeks	6 weeks	Placebo 18mg 36mg	291 (randomized)	Enrolling
810P302	Pediatric (6-12 years)	Efficacy	10 weeks	6 weeks	Placebo 18mg 36mg	291 (randomized)	Enrolling

<sup>\*</sup>Primary Endpoint : Change in IA behavior frequency



#### SPN-812: Novel Non-Stimulant ADHD Product

- Viloxazine hydrochloride
  - Norepinephrine reuptake inhibitor
- Once-daily oral extended-release product
- New Chemical Entity (NCE)
  - Five year market exclusivity
  - Previously marketed outside the US as an antidepressant
- Building strong IP portfolio with expirations from 2029-2033
- Emerging clinical profile points to a well differentiated ADHD product
  - A highly effective non-stimulant with a tolerable side effect profile



# SPN-812 Phase IIb Design

#### Objectives:

- Assess effect in reducing symptoms of ADHD in children aged 6-12 years
- Evaluate safety and tolerability

#### Primary Endpoint:

Change from baseline to End of Study in the ADHD-RS-IV total score

#### Design:

- Double-blind, placebo-controlled, multicenter, dose-ranging study
  - Placebo, 100/200/300/400mg
- Monotherapy
- 222 subjects randomized
- 3 weeks titration (100mg/week), 5 weeks treatment
- Rollover to Open-Label Extension Study



# **Three SPN-812 Doses Met Primary Endpoint**

Primary Analysis
Change from baseline in ADHD-RS-IV Total Score (ITT Population with LOCF)

Statistics	400 mg N=44	300 mg N=47	200 mg N=46	100 mg N=45	Placebo N=24	
LS Mean	-19.0	-18.6	-18.4	-16.7	-10.5	
Effect Size	0.63	0.60	0.55	0.46		End of Study
P-value	0.021*	0.027*	0.031*	0.089		2 23.6.7

<sup>\*</sup> At end of study all SPN-812 doses except the 100 mg dose are statistically significant compared to placebo at  $\alpha$  = 0.05 level.

ITT = Intent To Treat LOCF = Last Observation Carried Forward



# **SPN-812 Was Well Tolerated**

Percentage of Patients with Related AEs, >5%			SPN-812 ER			
Adverse Event (AE)	Placebo N=24	100 mg N=48	200 mg N=48	300 mg N=48	400 mg N=49	
Somnolence	0	14.6	20.8	20.8	24.5	
Decreased appetite	8.3	10.4	12.5	8.3	16.3	
Headache	0	4.2	10.4	6.3	12.2	
Insomnia	0	6.3	4.2	6.3	6.3	
Nausea	0	4.2	2.1	8.3	4.1	
Fatigue	0	4.2	4.2	2.1	10.2	
Irritability	0	2.1	8.3	4.2	2.0	
Weight decreased	0	0	0	0	8.3	
Discontinuations Due to AEs	0	8.3	6.3	2.1	10.2	



# SPN-812: A Billion Dollar Product for Supernus

	Percent	Prescriptions in Peak Year
ADHD Market Prescriptions		90 - 100 Million
	Peak Market Share	SPN-812 Potential Prescriptions
SPN-812 Peak Demand	3 - 5%	2.7 - 5.0 Million
SPN-812 Peak Gross Revenue		\$1.6 - 3.0 Billion

Source - IMS NPA, Company Research and Estimates – Assumes peak at 3-5 years post launch



# **Financial Summary**

#### 2016 Full Year Results

- Net product sales of \$210 million, up 46% over 2015
- Operating income of \$54 million, up 160% over 2015
- As of December 31,2016, cash, cash equivalents, marketable securities and long term marketable securities were \$165.5 million
  - \$117.2 million at December 31, 2015
- Exceeded original 2016 net product sales and operating income guidance



# **Financial Summary**

#### 2017 Full Year Financial Guidance<sup>1</sup>

- Net product sales: \$265 million \$275 million
- Operating income: \$75 million to \$80 million
- R&D expenses: approximately \$55 million



<sup>\*</sup> Guidance provided on February 28, 2017 which has not been updated

# Positioned For Continued Strong Growth



#### **Strong Portfolio in Neurology**

Potential Peak Sales for Oxtellar XR® and Trokendi XR® >\$500M

#### Innovative Late Stage Portfolio in Psychiatry

SPN-812: Highly Effective and Well Tolerated Non-Stimulant

SPN-810: The First Treatment for Impulsive Aggression

