
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **October 10, 2016**

Supernus Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
Incorporation)

001-35518

(Commission File Number)

20-2590184

(IRS Employer Identification No.)

1550 East Gude Drive, Rockville MD

(Address of principal executive offices)

20850

(Zip Code)

Registrant's telephone number, including area code: **(301) 838-2500**

Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 8.01 Other Events

On October 10, 2016, Supernus Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the Company will report the results of its Phase IIb dose-ranging clinical trial of SPN-812 in children for the treatment of attention deficit hyperactivity disorder (ADHD) on Tuesday, October 11, 2016. A copy of this press release is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

On October 11, 2016 the Company announced positive topline results from its Phase IIb dose-ranging clinical trial of SPN-812 in children for the treatment of attention deficit hyperactivity disorder (ADHD). The trial was successful in meeting the primary endpoint, demonstrating that SPN-812 at daily doses of 400 mg, 300 mg and 200 mg achieved a statistically significant improvement in the symptoms of ADHD from baseline to end of study as measured by the ADHD Rating Scale-IV. All SPN-812 doses tested in the trial were well tolerated. Based on these positive results in children with ADHD and the positive Phase IIa results in adults with ADHD, the Company plans to have an end-of-Phase II meeting with the U.S. Food and Drug Administration after which it will initiate Phase III clinical testing. A copy of this press release is furnished as Exhibit 99.2 hereto and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following documents are furnished as Exhibits pursuant to Item 8.01 hereof:

Exhibit 99.1 — Press Release Dated October 10, 2016.

Exhibit 99.2 — Press Release Dated October 11, 2016.

Exhibit 99.3 — Presentation Slides.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SUPERNUS PHARMACEUTICALS, INC.

DATED: October 14, 2016

By: /s/ Gregory S. Patrick
Gregory S. Patrick
Vice-President and Chief Financial Officer

EXHIBIT INDEX

Number	Description	
99.1	Press Release Dated October 10, 2016.	Attached
99.2	Press Release Dated October 11, 2016.	Attached
99.3	Presentation Slides.	Attached



**Supernus Schedules Conference Call to Present Results of
Phase IIb Clinical Trial of SPN-812 in Children with ADHD**

ROCKVILLE, Md., October 10, 2016 — Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced that, on Tuesday, October 11, 2016, prior to the market open, it will report the results of its Phase IIb dose-ranging clinical trial of SPN-812 in children for the treatment of attention deficit hyperactivity disorder (ADHD).

Supernus will hold a conference call with slides on Tuesday, October 11, 2016, at 9:00 a.m. ET to discuss the topline results of the clinical trial. The call will be hosted by Jack Khattar, President and Chief Executive Officer, and Greg Patrick, Vice President and Chief Financial Officer.

Conference Call Details

Presentation slides will be available via this [webcast link](#). A question and answer session with the Supernus management team will follow the company's remarks.

Please refer to the information below for conference call dial-in information and webcast registration. Callers should dial in approximately 10 minutes prior to the start of the call.

Date and time:	Tuesday, October 11, 2016, 9:00 a.m. ET
Conference dial-in:	(877) 288-1043
International dial-in:	(970) 315-0267
Conference ID:	93788624
Conference Call Name:	Supernus Pharmaceuticals SPN-812 Phase IIb Topline Results
Webcast link:	Click here

Following the live call, a replay will be available on the company's website, www.supernus.com, under 'Investors'.

About SPN-812

SPN-812 is a selective norepinephrine reuptake inhibitor that Supernus is developing as a novel non-stimulant for the treatment of ADHD. The active ingredient in SPN-812, viloxazine

hydrochloride, has an extensive safety record in Europe, where it was previously marketed for many years as an antidepressant.

About Supernus Pharmaceuticals, Inc.

Supernus Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases. The Company has two marketed products for epilepsy, Oxtellar XR[®] (extended-release oxcarbazepine) and Trokendi XR[®] (extended-release topiramate). The Company is also developing several product candidates to address large market opportunities in psychiatry, including SPN-810 for the treatment of Impulsive Aggression in ADHD patients and SPN-812 for the treatment of ADHD.

Forward-Looking Statements:

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements do not convey historical information, but relate to predicted or potential future events that are based upon management's current expectations. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. In addition to the factors mentioned in this press release, such risks and uncertainties include, but are not limited to, the Company's ability to sustain and increase its profitability; the Company's ability to raise sufficient capital to fully implement its corporate strategy; the implementation of the Company's corporate strategy; the Company's future financial performance and projected expenditures; the Company's ability to increase the number of prescriptions written for each of its products; the Company's ability to increase its net revenue; the Company's ability to enter into future collaborations with pharmaceutical companies and academic institutions or to obtain funding from government agencies; the Company's product research and development activities, including the timing and progress of the Company's clinical trials, and projected expenditures; the Company's ability to receive, and the timing of any receipt of, regulatory approvals to develop and commercialize the Company's product candidates; the Company's ability to protect its intellectual property and operate its business without infringing upon the intellectual property rights of others; the Company's expectations regarding federal, state and foreign regulatory requirements; the therapeutic benefits, effectiveness and safety of the Company's product candidates; the accuracy of the Company's estimates of the size and characteristics of the markets that may be addressed by its product candidates; the Company's ability to increase its manufacturing capabilities for its products and product candidates; the Company's projected markets and growth in markets; the Company's product formulations and patient needs and potential funding sources; the Company's staffing needs; and other risk factors set forth from time to time in the Company's SEC filings made pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. The Company undertakes no obligation to update the information in this press release to reflect events or circumstances after the date hereof or to reflect the occurrence of anticipated or unanticipated events.

CONTACT:

Jack A. Khattar, President and CEO
Gregory S. Patrick, Vice President and CFO
Supernus Pharmaceuticals, Inc.
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Or

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Westwicke Partners
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Email: peter.vozzo@westwicke.com



**Supernus Announces Positive Results from Phase IIb Clinical Trial
For SPN-812 in Children with ADHD**

- *Study confirms efficacy of SPN-812, a novel non-stimulant product, in children, showing statistically significant reduction in ADHD symptoms*
- *SPN-812 was well-tolerated*
- *Conference call and webcast to discuss results at 9:00 a.m. ET, October 11, 2016*

ROCKVILLE, Md., October 11, 2016 — Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced positive topline results from its Phase IIb dose-ranging clinical trial of SPN-812 in children for the treatment of attention deficit hyperactivity disorder (ADHD).

The trial was successful in achieving the primary endpoint, demonstrating that SPN-812 at daily doses of 400 mg, 300 mg and 200 mg achieved a statistically significant improvement in the symptoms of ADHD from baseline to end of study as measured by the ADHD Rating Scale-IV. All four active doses were well tolerated. Based on these positive results in children with ADHD and the positive Phase IIa results in adults with ADHD, Supernus plans to have an end-of-Phase II meeting with the U.S. Food and Drug Administration (FDA) after which it will initiate Phase III clinical testing.

“We are very excited about these results and that SPN-812 met the objectives of the study with an encouraging and strong clinical profile,” stated Jack Khattar, President and Chief Executive Officer of Supernus Pharmaceuticals. “We believe SPN-812 has the potential of being a well differentiated treatment for ADHD that sets itself apart from current treatment options.”

Phase IIb Study Design

The study was a randomized, double-blind, placebo controlled, multicenter, dose-ranging clinical trial in children 6 to 12 years of age diagnosed with ADHD. Each treatment was administered orally once a day over five weeks, after a three week titration phase. A total of 222 patients were randomized in the study across placebo and four doses of SPN-812 (100/200/300/400mg). The primary objective of the study was to assess the effect of SPN-812

in reducing the symptoms of ADHD in children. The primary outcome measure was the change from baseline to the end of the study in the ADHD-RS-IV total score. Safety and tolerability of SPN-812 were assessed by the monitoring of adverse events, clinical laboratory tests, vital signs, ECGs, suicidality and physical examinations. Patients who completed the study were offered the opportunity to continue into an open-label phase that is currently on-going.

Topline Results

At the end of the study, SPN-812 400 mg, 300 mg and 200 mg doses were statistically significant compared to placebo in the primary endpoint. Patients receiving SPN-812 400 mg, 300 mg and 200 mg had a -19.0 point change ($p=0.021$), -18.6 point change ($p=0.027$) and a -18.4 point change ($p=0.031$) from baseline, respectively, in the primary endpoint vs. -10.5 for placebo.

This primary analysis using the Intent-To-Treat (ITT) population and last observation carried forward (LOCF) was confirmed with sensitivity analyses using the Per Protocol population and Mixed Model Repeated Measures (MMRM).

With respect to the effect size, patients receiving SPN-812 400 mg, 300 mg and 200 mg had a median effect size of 0.63, 0.60 and 0.55, respectively. Patients receiving SPN-812 100 mg had a -16.7 point change from baseline in the primary endpoint and a median effect size of 0.46, which did not quite reach statistical significance ($p=0.089$) in this relatively low number of patients.

In addition, SPN-812 400 mg, 300 mg and 200 mg met the Clinical Global Impression Severity (CGI-S) secondary endpoint with p -values of 0.014, 0.015 and 0.031, respectively, compared to placebo.

“These results exhibit a strong clinical efficacy profile with effect sizes that are typically not seen with non-stimulants. In addition, of the 160 patients who completed the trial, 87% or 139 patients chose to enter the open-label phase showing a high level of confidence in SPN-812,” stated Dr. Stefan Schwabe, Executive Vice President R&D, Chief Medical Officer of Supernus Pharmaceuticals.

SPN-812 was well tolerated in the study. All four active doses were well tolerated, with adverse events almost entirely mild or moderate in severity. Two subjects experienced three adverse events that were classified as severe and related to the medication; one on 400 mg with easy tearfulness and intermittent irritability and another on 200 mg with decreased appetite. There were no serious adverse events or deaths in the study. The most frequent adverse events across all the active doses were primarily somnolence, headache, decreased appetite, fatigue, vomiting and nausea. The percentage of patients discontinuing the study due to adverse events for all active doses of SPN-812 was low at 6.7%.

“We believe this side effect profile compares very well with existing treatments in the market,” added Dr. Schwabe.

Product Pipeline

SPN-812 is the company's second psychiatry product in development. Supernus is also developing SPN-810 (molindone hydrochloride), a novel treatment for impulsive aggression in patients with ADHD. SPN-810 is currently in clinical development with two Phase III trials in children with ADHD.

"We are excited about our psychiatry pipeline, with two late-stage novel product candidates with positive Phase II clinical results. With SPN-812 now proceeding towards Phase III clinical testing, Supernus expects to have two product candidates in Phase III testing in 2017. We believe these two product candidates represent a significant platform for future growth for Supernus in multi-billion dollar markets," added Jack Khattar.

Conference Call Details

The Company will hold a conference call and webcast today, October 11, 2016, at 9:00 a.m. ET to discuss these topline results. The call will be hosted by Jack Khattar, President and Chief Executive Officer, and Greg Patrick, Vice President and Chief Financial Officer. Presentation slides will be available via this webcast link. A question and answer session with the Supernus management team will follow the company's remarks.

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Conference dial-in: (877) 288-1043
International dial-in: (970) 315-0267
Conference ID: 93788624
Conference Call Name: Supernus Pharmaceuticals SPN-812 Phase IIb Topline Results
Webcast link: [Click here](#)

Following the live call, a replay will be available on the company's website, www.supernus.com, under 'Investors'.

About SPN-812

SPN-812 is a selective norepinephrine reuptake inhibitor that Supernus is developing as a novel non-stimulant for the treatment of ADHD. Based on data generated to date, the Company believes SPN-812 could be more effective and have a better side effect profile than other non-stimulant treatments for ADHD due to its different pharmacological and pharmacokinetic profile. The active ingredient in SPN-812, viloxazine hydrochloride, has an extensive safety record in Europe, where it was previously marketed for many years as an antidepressant.

About Supernus Pharmaceuticals, Inc.

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Forward-Looking Statements:

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CONTACT:

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Supernus Pharmaceuticals



SPN-812 Phase IIb Topline Data

Investor Webcast – October 11, 2016

Safe Harbor Statement

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.

Supernus has filed with the U.S. Securities and Exchange Commission (SEC) reports and other documents required by Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended. Before you purchase any Supernus securities, you should read such reports and other documents to obtain more complete information about the company's operations and business and the risks and uncertainties that it faces in implementing its business plan. You may get these documents for free by visiting EDGAR on the SEC website at <http://www.sec.gov>.

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
 - API, formulation, novel use
- 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 of SPN-812 ER in reducing symptoms of ADHD in children aged 6-12 years
- Evaluate safety and tolerability of SPN-812 ER in children with ADHD

● Primary Endpoint:

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

● Secondary Endpoints:

- Assess effect of SPN-812 ER on:
 - Clinical Global Impression – Improvement Scale (CGI-I) and
 - Clinical Global Impression – Severity Scale (CGI-S)

SPN-812 Phase IIb Design

● Design:

- Double-blind, placebo-controlled, multicenter
- Dose-ranging study; 5-arm, parallel-group
- Monotherapy

● Randomization:

- Randomized in a ratio of 1:2 of placebo to each of the active treatment arms (100/200/300/400 mg)
- 222 subjects randomized

● Study Duration:

- 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)

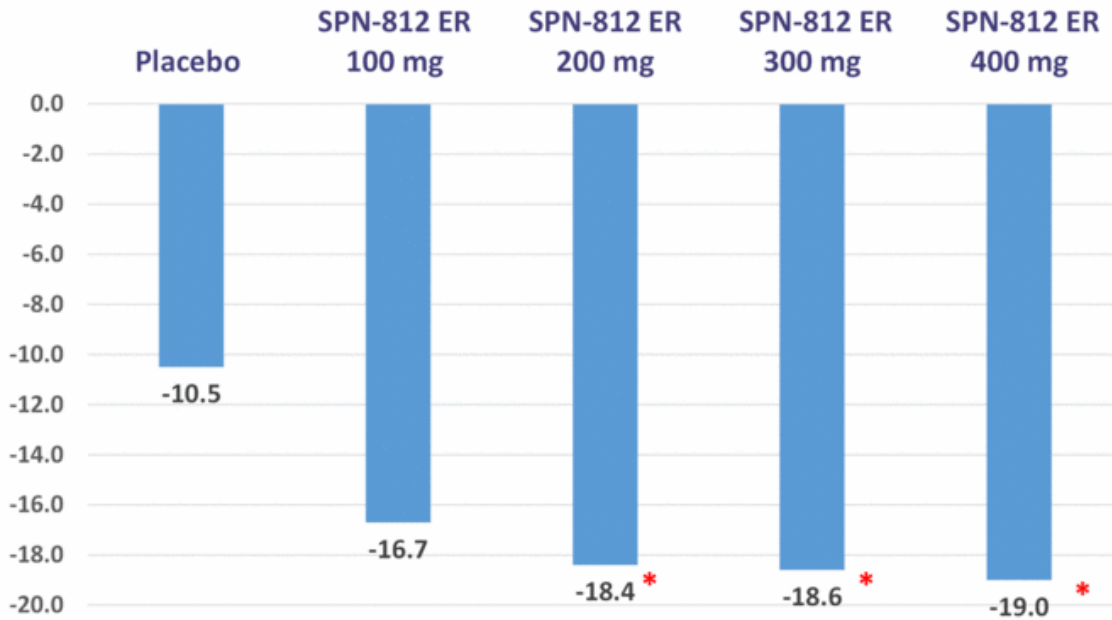
Statistics	400 mg N=44	300 mg N=47	200 mg N=46	100 mg N=45	Placebo N=24	
LS Mean	-19.0	-18.6	-18.4	-16.7	-10.5	End of Study
Effect Size	0.63	0.60	0.55	0.46		
P-value	0.021*	0.027*	0.031*	0.089		
* At end of study all SPN-812 doses except the 100 mg dose are statistically significant compared to placebo at $\alpha = 0.05$ level.						

ITT = Intent To Treat
LOCF = Last Observation Carried Forward



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LS Means of Change from Baseline in ADHD-RS-IV Score



*P-value <0.05

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All SPN-812 Doses Met Primary Endpoint

Sensitivity Analysis Change from baseline in ADHD-RS-IV Total Score (PP Population)

Statistics	400 mg N=32	300 mg N=34	200 mg N=29	100 mg N=35	Placebo N=19	
LS Mean	-23.3	-19.2	-20.7	-18.3	-9.4	End of Study
P-value	0.001*	0.017*	0.008*	0.028*		

* At end of study, all SPN-812 doses are statistically significant compared to placebo at $\alpha = 0.05$ level.

PP = Per Protocol

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Three SPN-812 Doses Met CGI-S Secondary Endpoint

Analysis of Secondary Endpoints, CGI-I and CGI-S (ITT Population with LOCF)

Statistics	400 mg N=44	300 mg N=47	200 mg N=46	100 mg N=45	Placebo N=24
Change from baseline to End of Study in CGI-S					
LS Mean	-1.7	-1.6	-1.5	-1.4	-0.8
P-value	0.014*	0.015*	0.031*	0.071	

Observed CGI-I at End of Study					
LS Mean	2.4	2.2	2.6	2.6	3.0
P-value	0.055	0.009*	0.138	0.131	

ITT = Intent To Treat
 LOCF = Last Observation Carried Forward
 CGI-I = Clinical Global Impression Improvement
 CGI-S = Clinical Global Impression Severity
 *Statistical significance at $\alpha = 0.05$ level.

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SPN-812 Was Well Tolerated

Adverse Event (AE)	Percentage of Patients with Related AEs, >5%				
	Placebo N=24	SPN-812 ER			
		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

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SPN-812: Novel Non-Stimulant ADHD Product



Market Opportunity
\$2.5B

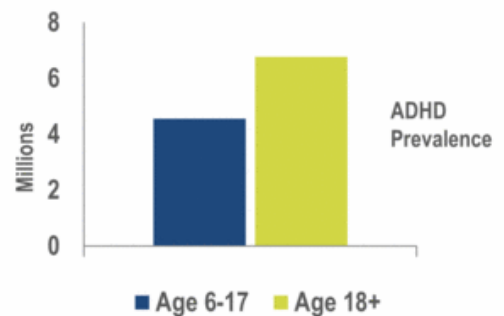
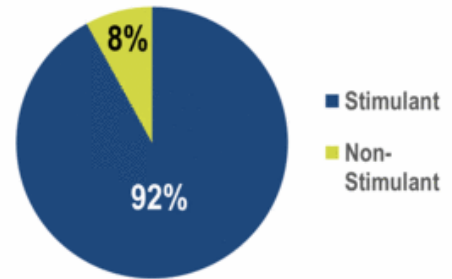


Completed Phase IIa and
Phase IIb studies in ADHD

Demonstrated safety and
efficacy in adults and
children

2017 Phase III studies

Total ADHD Prescriptions

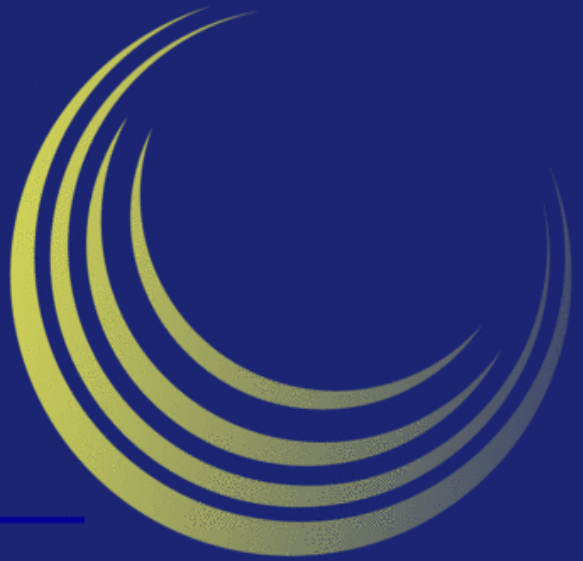


ADHD Prescriptions per SHA TRx data, December 2014
Centers for Disease Control "Trends in the Parent-Report of Health Care Provider-Diagnosed and Medicated ADHD:
United States, 2003–2011; WebMD; Datamonitor

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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