
**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): **December 5, 2018**

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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 8.01 Other Events.

On December 5, 2018, Supernus Pharmaceuticals, Inc. (the “Company”) issued a press release announcing that the Company will report the results of its two pivotal Phase III studies of SPN-812 in children for the treatment of attention deficit hyperactivity disorder (“ADHD”) on Thursday, December 6, 2018. A copy of this press releases is furnished as Exhibit 99.1 hereto and is incorporated herein by reference.

On December 6, 2018, the Company issued a press release announcing positive topline results from its Phase III studies of SPN-812 in children for the treatment of ADHD. The trial was successful in meeting the primary endpoint, demonstrating that SPN-812 at daily doses of 100mg and 200mg in study P301 and 200mg and 400mg in study P303 achieved a statistically significant improvement in the symptoms of ADHD from baseline to end of study as measured by the ADHD Rating Scale-5. All SPN-812 doses tested in the trials were well tolerated. The Company expects to announce topline data from study P302, the first adolescent Phase III trial of SPN-812, by the end of December 2018. Topline data from the second adolescent Phase III trial, P304, are expected by the end of the first quarter of 2019. The Company expects to submit a New Drug Application for SPN-812 in the second half of 2019, and to launch it, pending U.S. Food and Drug Administration approval, in the second half of 2020. A copy of this press release is furnished as Exhibit 99.2 heretoand is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibit

The following document is furnished as an Exhibit pursuant to Item 8.01 hereof:

Exhibit 99.1 — Press Release Dated December 5, 2018.

Exhibit 99.2 — Press Release Dated December 6, 2018.

Exhibit 99.3 — Presentation Slides.

EXHIBIT INDEX

Number	Description	
99.1	Press Release Dated December 5, 2018.	Attached
99.2	Press Release Dated December 6, 2018.	Attached
99.3	Presentation Slides.	Attached

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: December 10, 2018

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



Supernus Schedules Conference Call to Present Topline Results of Two Phase III Studies for SPN-812 in Children with ADHD

ROCKVILLE, Md., December 5, 2018 — Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced that, on Thursday, December 6, 2018, at approximately 7:00 a.m. ET, it will issue a press release announcing the results of its two Phase III studies for SPN-812 in patients 6-11 years old, for the treatment of attention deficit hyperactivity disorder (ADHD).

Supernus will hold a conference call and webcast on Thursday, December 6, 2018, at 9:00 a.m. ET to discuss the topline results of the clinical trials. Presentation slides will be made available approximately 30 minutes prior to the call. The call will be hosted by Jack Khattar, President and Chief Executive Officer; Stefan Schwabe, Chief Medical Officer and Executive Vice President of Research & Development; and Greg Patrick, Vice President and Chief Financial Officer.

Conference Call Details

Presentation slides will be available via this webcast link approximately 30 minutes prior to the conference and webcast. 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.

Conference dial-in: (877) 288-1043

International dial-in: (970) 315-0267

Conference ID: 8685367

Conference Call Name: Supernus Pharmaceuticals SPN-812 Phase III 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 norepinephrine reuptake inhibitor with selective serotonin modulation activity 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 a well-differentiated ADHD treatment compared to 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.

Supernus Pharmaceuticals, Inc. is a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) diseases. The Company currently markets Trokendi XR[®] (extended-release topiramate) for the prophylaxis of migraine and the treatment of epilepsy, and Oxtellar XR[®] (extended-release oxcarbazepine) for the treatment of epilepsy. The Company is also developing several product candidates to address large market opportunities in the CNS market, including SPN-810 for the treatment of Impulsive Aggression in ADHD patients, SPN-812 for the treatment of ADHD and SPN-604 for the treatment of bipolar disorder.

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 filings with the Securities and Exchange Commission 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.
Tel: (301) 838-2591

Or

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Peter Vozzo
Westwicke Partners
Office: (443) 213-0505
Mobile: (443) 377-4767
Email: peter.vozzo@westwicke.com



Supernus Announces Positive Results from Two Phase III Studies For SPN-812 in Children with ADHD

- *Each study, P301 and P303, met primary endpoint with robust statistical significance*
- *Each study showed efficacy on both hyperactivity/impulsivity and inattention subscales with statistical significance*
- *P301 study showed statistically significant onset of action as early as week 1 on both treatment doses*
- *SPN-812 was well-tolerated with low incidence of adverse events and low discontinuation rates*
- *Conference call and webcast to discuss results at 9:00 a.m. ET today, December 6, 2018*

ROCKVILLE, Md., December 6, 2018 — Supernus Pharmaceuticals, Inc. (NASDAQ:SUPN), a pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system diseases, today announced positive topline results from each of two pivotal Phase III studies of SPN-812 in children for the treatment of attention deficit hyperactivity disorder (ADHD).

Both trials were successful in achieving the primary endpoint, with SPN-812, at daily doses of 100 mg and 200 mg in study P301 and 200 mg and 400 mg in study P303. Robust statistical significance in improvement in the symptoms of ADHD from baseline to end of study as measured by the ADHD Rating Scale-5 was achieved. Both active doses in each study were well tolerated.

The Company expects to announce topline data from study P302, the first adolescent Phase III trial of SPN-812, by the end of December 2018. Topline data from the second adolescent Phase III trial, P304, are expected by the end of the first quarter of 2019. The Company expects to submit a New Drug Application (NDA) for SPN-812 in the second half of 2019, and to launch it, pending U.S. Food and Drug Administration (FDA) approval, in the second half of 2020.

“These are very exciting data demonstrating the important role we believe SPN-812 can play in treating patients with ADHD,” stated Jack Khattar, President and Chief Executive Officer of

Supernus Pharmaceuticals. “We believe these data from the two pivotal Phase III studies, which are consistent with the Phase IIb data, demonstrate that SPN-812 is a well-differentiated novel non-stimulant treatment option for many children with ADHD.”

About the P301 and P303 Studies

Both studies are randomized, double-blind, placebo controlled, multicenter, parallel group clinical trials in children 6 to 11 years of age diagnosed with ADHD. Each treatment was administered orally once a day over five weeks in study P301 and seven weeks in study P302, after the titration phase.

A total of 477 patients were randomized in the P301 study across placebo and two doses of SPN-812 (100mg/200mg). A total of 313 patients were randomized in the P303 study across placebo and two doses of SPN-812 (200mg/400mg). The primary objective of both studies 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-5 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

P301 Study

At the end of the study, SPN-812 100 mg and 200 mg doses reached statistical significance compared to placebo in the primary endpoint. Patients receiving SPN-812 100 mg and 200 mg had a -16.6 point change ($p=0.0004$) and a -17.7 point change ($p<0.0001$) from baseline, respectively, in the primary endpoint vs. -10.9 for placebo at week 6.

This primary result based on Mixed Model Repeated Measures (MMRM) analysis in the Intent-To-Treat (ITT) population was confirmed by sensitivity analyses using Analysis of Covariance (ANCOVA) (100 mg, $p=0.0008$; 200 mg, $p<0.0001$). With respect to the effect size, patients receiving SPN-812 100 mg and 200 mg had an effect size of 0.54 and 0.57, respectively, within the range of 0.46 to 0.63 in the Phase IIb study results.

The study demonstrated fast onset of action, reaching statistical significance for 100 mg and 200 mg doses as early as week 1 with p - values of 0.0004 and 0.0244, respectively. Statistical significance was maintained on a weekly basis through the end of the trial at week 6.

In addition, at the end of the study, SPN-812 100 mg and 200 mg reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the ADHD-RS-5 scale with p - values ranging from <0.0001 to 0.0026.

Finally, SPN-812 100 mg and 200 mg met all secondary endpoints, including the important analysis of the Clinical Global Impression Improvement (CGI-I) secondary endpoint, with p - values of 0.002 and <0.0001 , respectively, compared to placebo.

P303 Study

At the end of the study, SPN-812 200 mg and 400 mg doses reached statistical significance compared to placebo in the primary endpoint. Patients receiving SPN-812 200 mg and 400 mg had a -17.6 point change ($p=0.0038$) and a -17.5 point change ($p=0.0063$) from baseline, respectively, in the primary endpoint vs. -11.7 for placebo at week 8.

This primary result based on Mixed Model Repeated Measures (MMRM) analysis in the ITT population was confirmed by sensitivity analyses using Analysis of Covariance (ANCOVA) (200 mg, $p=0.0058$; 400 mg, $p<0.0121$). With respect to the effect size, patients receiving 200 mg and 400 mg had an effect size of 0.46 and 0.49, respectively, within the range of 0.46 to 0.63 in the Phase IIb study results.

Onset of action for SPN-812 showed clear differences compared to placebo starting by week 1, reaching statistical significance at week 5, which was sustained through the rest of the trial.

Similar to the P301 study, at the end of the P303 study, SPN-812 200 mg and 400 mg reached statistical significance compared to placebo on the hyperactivity/impulsivity and inattention subscales of the ADHD-RS-5 scale with p - values ranging from 0.0020 to 0.0248.

In addition, SPN-812 200 mg and 400 mg met the CGI-I secondary endpoint with p - values of 0.0028 and 0.0099, respectively, compared to placebo.

Safety and tolerability

Overall, both trials exhibited favorable tolerability and safety profiles with low incidence of adverse events (AEs) across all doses. AEs were mild leading to low discontinuation rates due to AEs of 2.2% to 4.8%. Treatment related AEs that reported at more than or equal to 5% for SPN-812 were somnolence, headache, decreased appetite, fatigue, and upper abdominal pain.

“Considering the strong efficacy and robust statistical significance on the primary endpoint, and several other key measures, coupled with a fast onset of action and a favorable tolerability and safety profile, we believe the data from these two pediatric Phase III trials for SPN-812 point to a well-differentiated ADHD product,” stated Dr. Stefan Schwabe, Executive Vice President R&D, Chief Medical Officer of Supernus Pharmaceuticals.

Conference Call Details

The Company will hold a conference call and webcast today, December 6, 2018, at 9:00 a.m. ET to discuss these topline results. The call will be hosted by Jack Khattar, President and Chief Executive Officer, Dr. Stefan Schwabe, Executive Vice President R&D and Chief Medical Officer, and Greg Patrick, Vice President and Chief Financial Officer. Presentation slides will be available via this webcast link approximately 30 minutes prior to the call. A question and answer session with the Supernus management team will follow the Company’s remarks.

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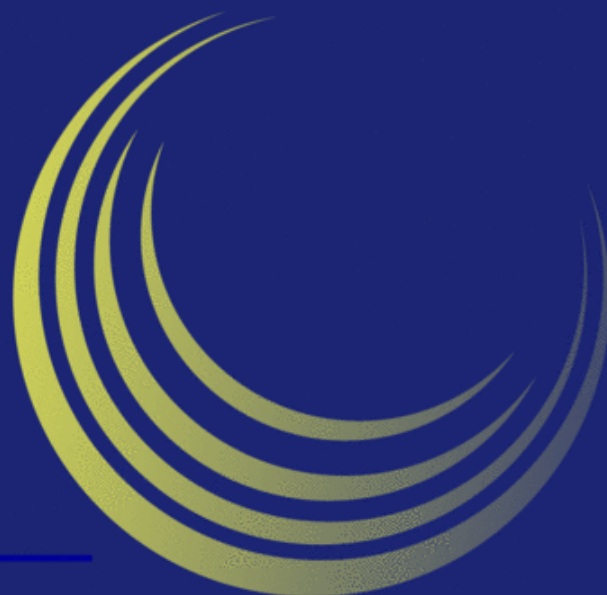
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Supernus Pharmaceuticals



SPN-812 Phase III Topline Data

Investor Webcast – December 2018

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 Candidate

- Viloxazine hydrochloride
 - Norepinephrine reuptake inhibitor, selective serotonin activity
 - New Chemical Entity (NCE) with five year market exclusivity
 - Previously marketed outside the U.S. as an antidepressant
- Building strong IP with expirations from 2029-2033
- Clinical data point to a well-differentiated ADHD product
- Targeted NDA filing 2H 2019, and if approved, launch 2H 2020

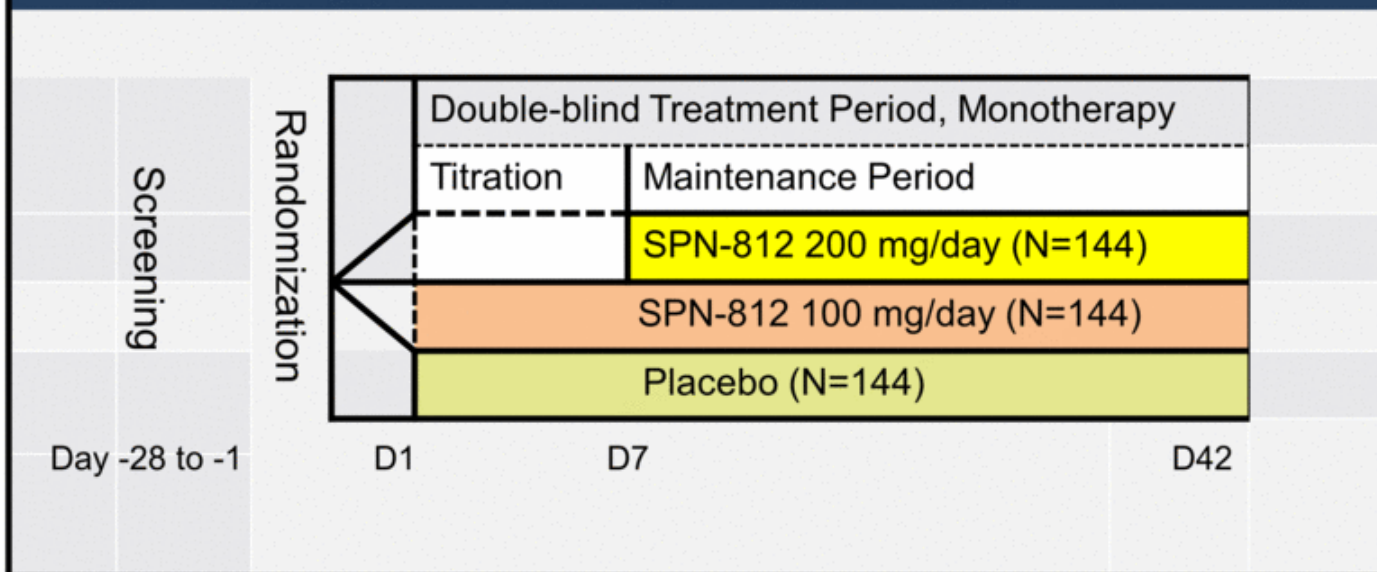
SPN-812

Phase III Studies Status

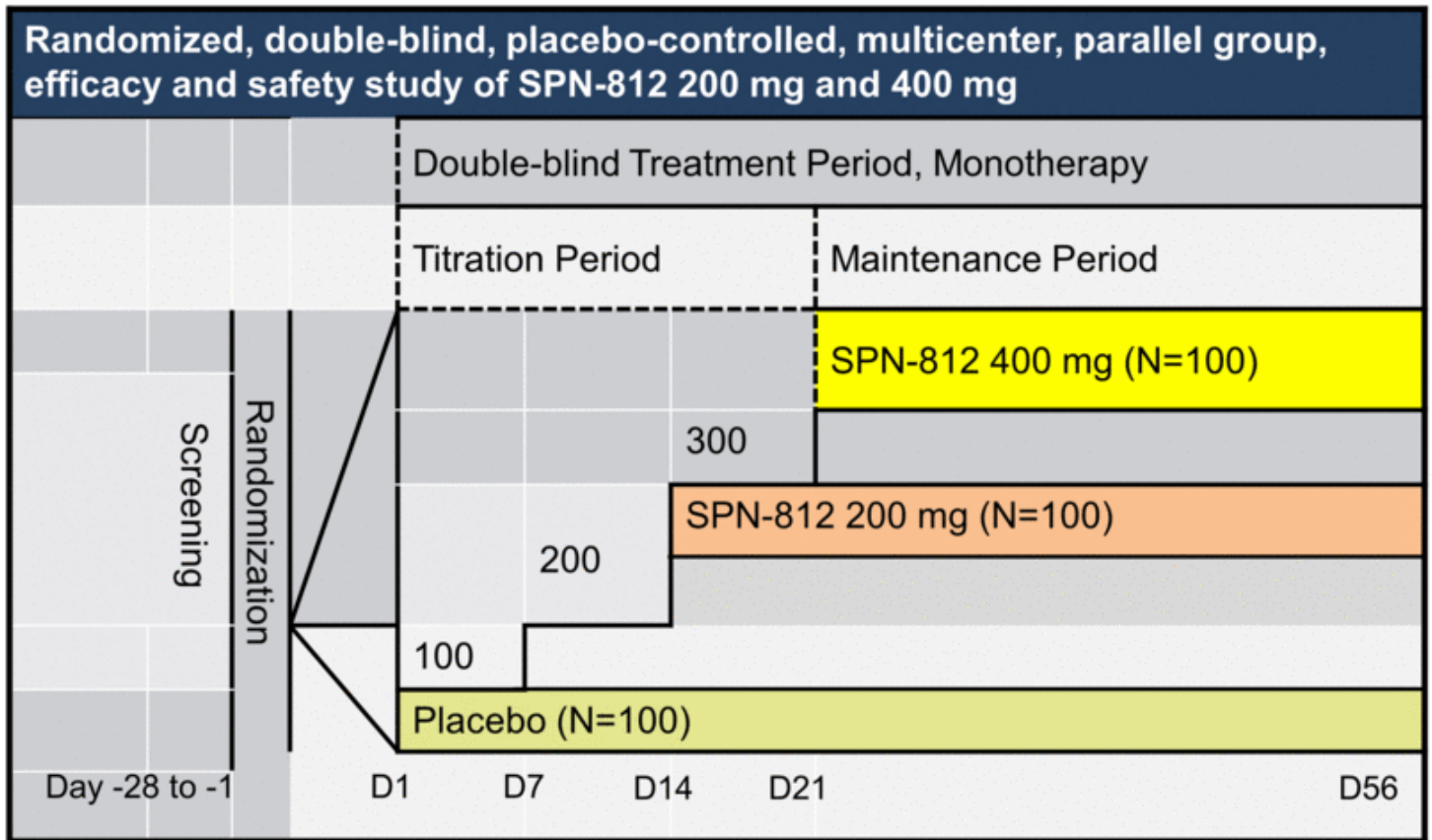
	P301 N = 477	P303 N = 313	P302 N = 300	P304 N = 300
ADHD Patients	6-11 years	6-11 years	12-17 years	12-17 years
Daily Doses	100mg 200mg	200mg 400mg	200mg 400mg	400mg 600mg
Status	Completed	Completed	Topline Data December 2018	Topline Data 1Q 2019

SPN-812 P301 Phase III Study Design

Randomized, double-blind, placebo-controlled, multicenter, parallel group, efficacy and safety study of SPN-812 100 mg and 200 mg



SPN-812 P303 Phase III Study Design



SPN-812 P301/303 Phase III Studies Design

- Primary Endpoint
 - Change from baseline on the ADHD-RS-5 scale compared to placebo
- Secondary Endpoints
 - Clinical Global Impression - Improvement (CGI-I) scale
 - Conners 3rd edition - parent, composite T-score
 - Weiss Functional Impairment Rating Scale - parent report (WFIRS-P)
- Evaluate safety & tolerability

SPN-812 P301/303 Topline Results

Executive Summary

- Two positive phase III trials in children 6-11 years old
 - Met primary endpoint with robust statistical significance
 - P-values ranging from <0.0001 to 0.0121
 - Sensitivity analysis confirms primary analysis
- Both trials showed strong efficacy on Hyperactivity and Inattention subscales
- Larger P301 study showed fast onset of action
 - Statistical significance as early as one week for 100mg and 200mg
 - Sustained statistical significance through the end of study (week 6)
 - P303 study shows a supportive trend

SPN-812 P301/303 Topline Results

Executive Summary

- P301 met all secondary endpoints
 - P303 met the CGI-I secondary endpoint
- Both trials showed favorable tolerability and safety profile
 - Low incidence of AE's across all doses (100mg, 200mg and 400mg)
- Overall, AE's are mild leading to very low discontinuation rates
 - Discontinuation rates due to AE's of 2.2% – 4.8%
 - Placebo-adjusted discontinuation rates of 0.9% - 1.9%



SPN-812 P301 Study Topline Results

SPN-812 P301: Met Primary Endpoint

Primary Analysis of ADHD-RS-5 based on MMRM (ITT Population)

Visit	Statistics	Placebo (N=155)	100 mg (N=147)	200 mg (N=158)
Baseline	Mean	43.6	45.0	44.0
Week 6 (EOS)	LS Mean	-10.9	-16.6	-17.7
	Effect Size		0.54	0.57
	p-value		0.0004	<.0001

MMRM = Mixed Model for Repeated Measure ITT = Intent to Treat
Effect size in Phase IIb study ranged from 0.46 to 0.63

EOS = End of study

SPN-812 P301: Met Primary Endpoint

Efficacy Starting in Week 1

Visit	Statistics	Placebo (N=155)	100 mg (N=147)	200 mg (N=158)
Baseline	Mean	43.6	45.0	44.0
Week 1	LS Mean	-5.8	-9.5	-8.1
	p-value		0.0004	0.0244
Week 2	LS Mean	-7.9	-12.6	-12.3
	p-value		<.0001	0.0001
Week 3	LS Mean	-9.9	-15.4	-15.7
	p-value		<.0001	<.0001
Week 4	LS Mean	-11.2	-17.0	-17.7
	p-value		<.0001	<.0001
Week 5	LS Mean	-11.9	-17.3	-18.4
	p-value		0.0006	<.0001
Week 6 (EOS)	LS Mean	-10.9	-16.6	-17.7
	p-value		0.0004	<.0001

MMRM = Mixed Model for Repeated Measure

ITT = Intent to Treat

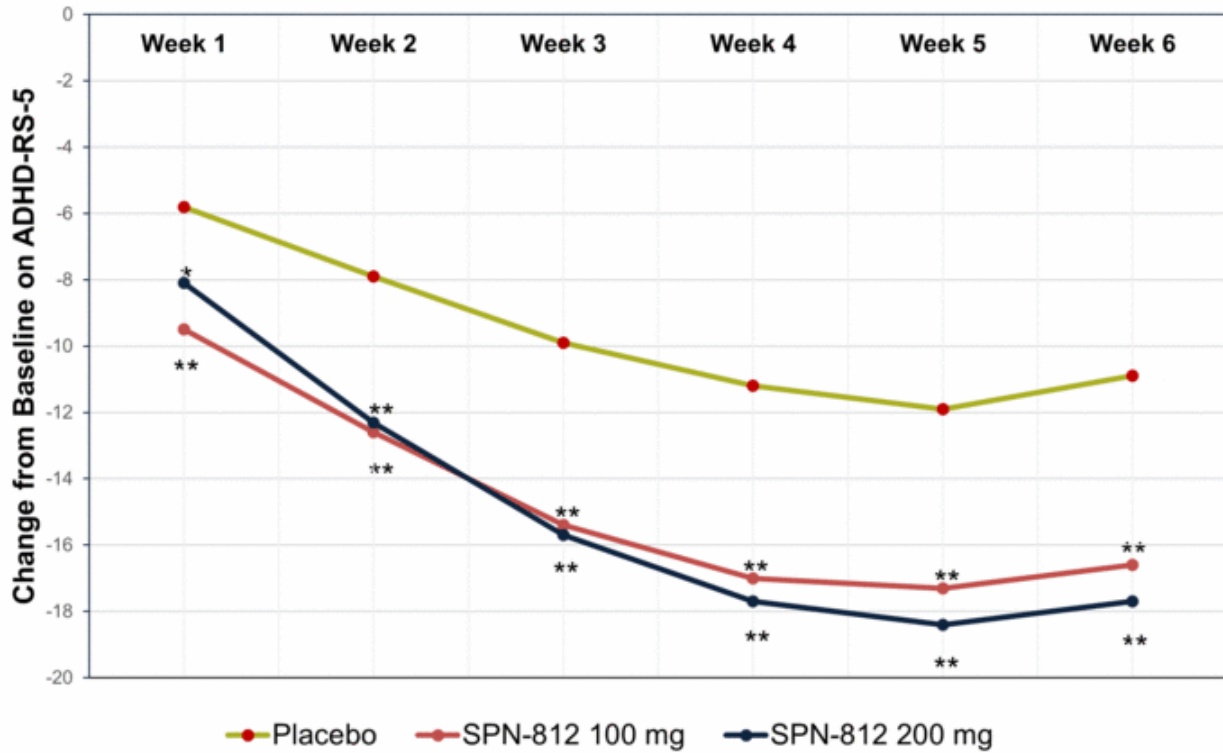
EOS = End of study



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SPN-812 P301 – Efficacy Starting in Week 1

LS Mean Change from Baseline over Time – MMRM (ITT Population)



* $p \leq 0.05$ ** $p \leq 0.01$ MMRM = Mixed Model for Repeated Measure ITT = Intent to Treat



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SPN-812 P301: Met Primary Endpoint

Sensitivity Analysis of ADHD-RS-5 based on ANCOVA at Week 6 (EOS) Confirms Primary Analysis (ITT Population)

Visit	Statistics	Placebo (N=155)	100 mg (N=147)	200 mg (N=158)
Baseline	Mean	43.6	45.0	44.0
Week 6 (EOS)	LS Mean	-11.1	-16.5	-17.8
	p-value		0.0008	<.0001

ANCOVA = Analysis of Covariance

ITT = Intent to Treat

EOS = End of study



SPN-812 P301: Met Secondary Endpoint

Analysis of Observed Global Improvement Score (CGI-I) at Week 6 (EOS)

Visit	Statistics	Placebo (N=155)	100 mg (N=147)	200 mg (N=158)
Baseline	Mean	4.8	4.8	4.8
Week 6 (EOS)	LS Mean	3.1	2.7	2.6
	p-value		0.0020	<.0001

EOS = End of study

SPN-812 P301: Met Secondary Endpoint

Analysis of Change from Baseline at Week 6 (EOS) in Composite T-score for Conners 3 - Parent Reported Scores

Visit	Statistics	Placebo (N=155)	100 mg (N=147)	200 mg (N=158)
Baseline	Mean	75.9	77.4	75.5
Week 6 (EOS)	LS Mean	-4.8	-9.1	-9.5
	p-value		0.0004	<.0001

EOS = End of study

SPN-812 P301: Met Secondary Endpoint

Analysis of Change from Baseline at Week 6 (EOS) in WFIRS-P

Visit	Statistics	Placebo (N=155)	100 mg (N=147)	200 mg (N=158)
Baseline	Mean	1.08	1.15	1.10
Week 6 (EOS)	LS Mean	-0.22	-0.36	-0.39
	p-value		0.0019	0.0002

EOS = End of study

WFIRS-P = Weiss Functional Impairment Rating Scale - Parent Report

SPN-812 P301

Significant Reduction in Hyperactivity and Inattention

Analysis in ADHD-RS-5 Inattention and Hyperactivity/Impulsivity Subscales

Visit	Statistics	Placebo (N=155)	100 mg (N=147)	200 mg (N=158)
ADHD-RS-5 Hyperactivity/Impulsivity				
Baseline	Mean	21.1	22.2	21.1
Week 6 (EOS)	LS Mean	-5.5	-8.0	-8.7
	p-value		0.0026	<.0001
ADHD-RS-5 Inattention				
Baseline	Mean	22.5	22.8	22.9
Week 6 (EOS)	LS Mean	-5.7	-8.6	-9.2
	p-value		0.0006	<.0001

EOS = End of study

SPN-812 P301

Well Tolerated

Number (%) of Patients Reporting Common AEs ($\geq 5\%$ and greater than placebo)

	Placebo (N=159)	100 mg (N=154)	200 mg (N=161)	Overall SPN-812 (N=315)
Somnolence	3 (1.9)	16 (10.4)	15 (9.3)	31 (9.8)
Headache	6 (3.8)	15 (9.7)	16 (9.9)	31 (9.8)
Decreased appetite	0	8 (5.2)	14 (8.7)	22 (7.0)
Sedation	0	3 (1.9)	9 (5.6)	12 (3.8)
Vomiting	3 (1.9)	7 (4.5)	8 (5.0)	15 (4.8)
Discontinuation Due to AE's	2 (1.3)	5 (3.2)	2 (1.2)	7 (2.2)

SPN-812 P301

Well Tolerated

Number (%) of Patients - Treatment Related AEs with $\geq 5\%$ incidence

	Placebo (N=159)	100 mg (N=154)	200 mg (N=161)	Overall SPN-812 (N=315)
Somnolence	3 (1.9)	14 (9.1)	14 (8.7)	28 (8.9)
Headache	3 (1.9)	7 (4.5)	10 (6.2)	17 (5.4)
Decreased appetite	0	7 (4.5)	12 (7.5)	19 (6.0)



SPN-812 P303 Study Topline Results

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SPN-812 P303: Met Primary Endpoint

Primary Analysis of ADHD-RS-5 Total Score based on MMRM (ITT Population)

Visit	Statistics	Placebo (N=97)	200 mg (N=107)	400 mg (N=97)
Baseline	Mean	43.5	43.8	45.0
Week 8 (EOS)	LS Mean	-11.7	-17.6	-17.5
	Effect Size		0.46	0.49
	p-value		0.0038	0.0063

MMRM = Mixed Model for Repeated Measure ITT = Intent to Treat EOS = End of study
Effect size in Phase IIb study ranged from 0.46 to 0.63

SPN-812 P303: Met Primary Endpoint

Efficacy Starting in Week 1 but not statistically significant

Primary Analysis of ADHD-RS-5 Total Score based on MMRM (ITT Population)

Visit	Statistics	Placebo (N=97)	200 mg (N=107)	400 mg (N=97)
Baseline	Mean	43.5	43.8	45.0
Week 1	LS Mean	-5.0	-7.9	-6.7
	p-value		0.0268*	0.2058
Week 2	LS Mean	-8.4	-11.6	-10.9
	p-value		0.0398*	0.1141
Week 3	LS Mean	-10.6	-13.7	-13.7
	p-value		0.0668	0.0742
Week 4	LS Mean	-11.8	-14.7	-15.3
	p-value		0.1182	0.0585

*Note: Though the "p-value" is 0.0268 for the 200 mg dose, the outcome is not statistically significant because the 400 mg dose was not statistically significant at the same time point



SPN-812 P303: Met Primary Endpoint

Efficacy Starting in Week 1 but not statistically significant

Primary Analysis of ADHD-RS-5 Total Score based on MMRM (ITT Population)

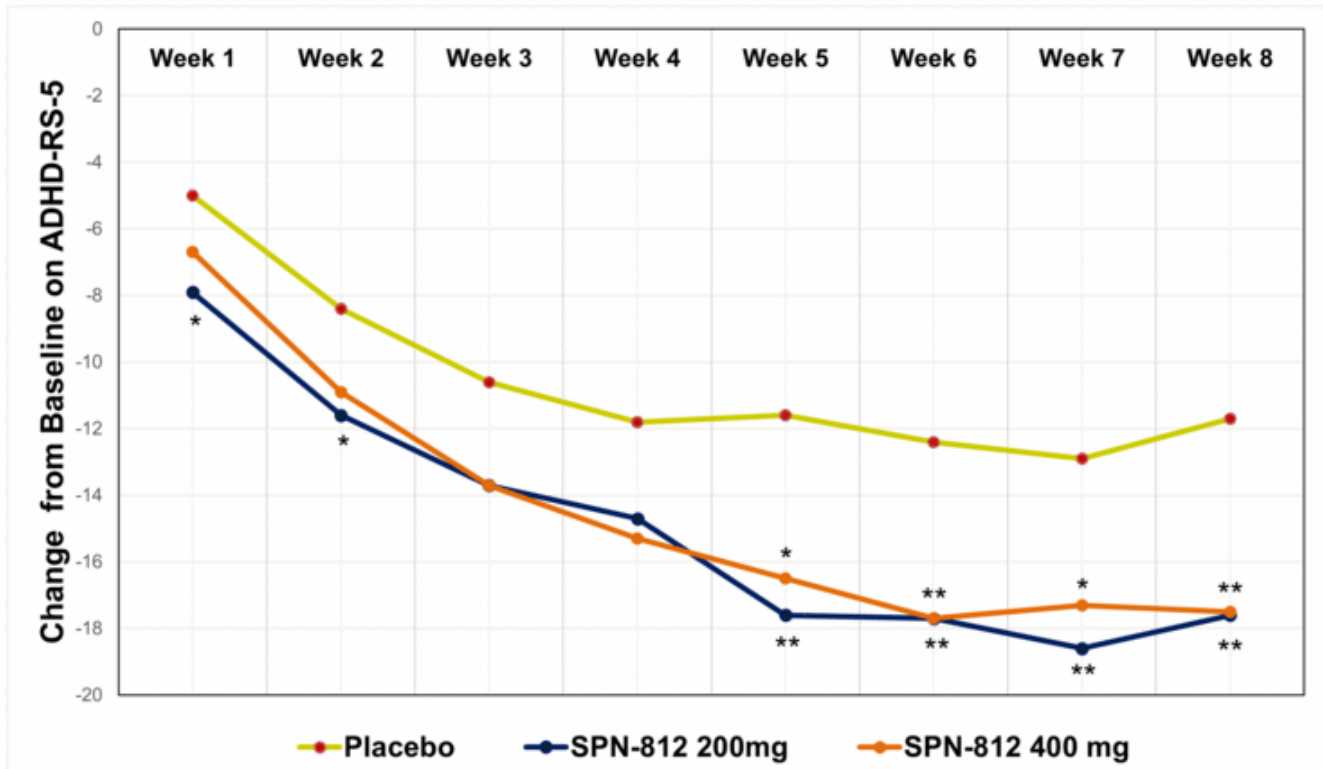
Visit	Statistics	Placebo (N=97)	200 mg (N=107)	400 mg (N=97)
Week 5	LS Mean	-11.6	-17.6	-16.5
	p-value		0.0015	0.0114
Week 6	LS Mean	-12.4	-17.7	-17.7
	p-value		0.0050	0.0057
Week 7	LS Mean	-12.9	-18.6	-17.3
	p-value		0.0045	0.0325
Week 8 (EOS)	LS Mean	-11.7	-17.6	-17.5
	p-value		0.0038	0.0063

EOS = End of study



SPN-812 P303 – Efficacy By Week

LS Mean Change from Baseline over Time – MMRM (ITT Population)



* $p \leq 0.05$; ** $p \leq 0.01$

MMRM = Mixed Model for Repeated Measure

ITT = Intent to Treat



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SPN-812 P303: Met Primary Endpoint

Sensitivity Analysis of ADHD-RS-5 based on ANCOVA at Week 8 (EOS) (ITT Population)

Visit	Statistics	Placebo (N=97)	200 mg (N=107)	400 mg (N=97)
Baseline	Mean	43.5	43.8	45.0
Week 8 (EOS)	LS Mean	-11.3	-17.0	-16.6
	p-value		0.0058	0.0121

ANCOVA = Analysis of Covariance
ITT = Intent to Treat EOS = End of study

SPN-812 P303: Met Secondary Endpoint

Analysis of Observed Global Improvement Score (CGI-I) at Week 8 (EOS)

Visit	Statistics	Placebo (N=97)	200 mg (N=107)	400 mg (N=97)
Baseline	Mean	4.8	4.8	4.8
Week 8 (EOS)	LS Mean	3.1	2.6	2.6
	p-value		0.0028	0.0099

EOS = End of study

SPN-812 P303

Significant Reduction in Hyperactivity and Inattention

Analysis in ADHD-RS-5 Inattention and Hyperactivity/Impulsivity Subscales

Visit	Statistics	Placebo (N=97)	200 mg (N=107)	400 mg (N=97)
ADHD-RS-5 Hyperactivity/Impulsivity				
Baseline	Mean	21.0	21.2	22.0
Week 8 (EOS)	LS Mean	-5.1	-8.4	-8.3
	p-value		0.0020	0.0039
ADHD-RS-5 Inattention				
Baseline	Mean	22.5	22.6	23.0
Week 8 (EOS)	LS Mean	-6.2	-8.9	-8.6
	p-value		0.0087	0.0248

EOS = End of study



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SPN-812 P303

Well Tolerated

Number (%) of Patients Reporting Common AEs ($\geq 5\%$ and greater than placebo)

	Placebo (N=103)	200 mg (N=107)	400 mg (N=100)	Overall SPN-812 (N=207)
Somnolence	2 (1.9)	16 (15.0)	14 (14.0)	30 (14.5)
Decreased appetite	0	10 (9.3)	9 (9.0)	19 (9.2)
Fatigue	5 (4.9)	10 (9.3)	9 (9.0)	19 (9.2)
Headache	5 (4.9)	13 (12.1)	6 (6.0)	19 (9.2)
Vomiting	1 (1.0)	1 (0.9)	7 (7.0)	8 (3.9)
Upper abdominal pain	3 (2.9)	6 (5.6)	6 (6.0)	12 (5.8)
Insomnia	1 (1.0)	7 (6.5)	3 (3.0)	10 (4.8)
Irritability	3 (2.9)	3 (2.8)	6 (6.0)	9 (4.3)
Cough	0	6 (5.6)	0	6 (2.9)
Discontinuation Due to AE's	3 (2.9)	6 (5.6)	4 (4.0)	10 (4.8)



SPN-812 P303

Well Tolerated

Number (%) of Patients - Treatment Related AEs with $\geq 5\%$ incidence

	Placebo (N=103)	200 mg (N=107)	400 mg (N=100)	Overall SPN-812 (N=207)
Somnolence	1 (1.0)	15 (14.0)	14 (14.0)	29 (14.0)
Decreased appetite	0	8 (7.5)	8 (8.0)	16 (7.7)
Fatigue	4 (3.9)	7 (6.5)	5 (5.0)	12 (5.8)
Headache	1 (1.0)	9 (8.4)	5 (5.0)	14 (6.8)
Upper abdominal pain	2 (1.9)	4 (3.7)	6 (6.0)	10 (4.8)

SPN-812 P301/303 Topline Results

Executive Summary

- Two positive phase III trials in children 6-11 years old
- Clinical data point to a well-differentiated ADHD product
 - Strong efficacy with robust statistical significance
 - Efficacy on both Hyperactivity and Inattention
 - Fast onset of action
 - Works as early as the first week
 - Very well tolerated
- Data on the P302 adolescent trial before year-end
- Data on the P304 adolescent trial in 1Q 2019
- Targeted NDA filing 2H 2019, and if approved, launch 2H 2020

Positioned For Continued Strong Growth



Growth Potential for Existing Products

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

Innovative Late Stage Portfolio in Psychiatry

SPN-812	Well Differentiated Novel Non-Stimulant
SPN-810	First Product to be Developed for Impulsive Aggression
SPN-604	Novel Product for Bipolar Disorder