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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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

**Date of Report (Date of earliest event reported): March 3, 2015**

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**Minerva Neurosciences, Inc.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36517**  
(Commission  
File Number)

**26-0784194**  
(I.R.S. Employer  
Identification No.)

**1601 Trapelo Road**  
**Suite 284**  
**Waltham, MA**  
(Address of principal executive offices)

**02451**  
(Zip Code)

(Registrant's telephone number, including area code): **(617) 600-7373**

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

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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:

- 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.**

Minerva Neurosciences, Inc. (the “Company”) is filing the investor presentation slides attached as Exhibit 99.1 to this Current Report on Form 8-K, which the Company may use from time to time in conversations with investors and analysts. The presentation will also be posted in the investor relations section of the Company’s website.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Investor Presentation dated March 2015.

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**SIGNATURE**

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.

**MINERVA NEUROSCIENCES, INC.**

By: /s/ Mark S. Levine

Name: Mark S. Levine

Title: Vice President, General Counsel and Secretary

Date: March 3, 2015

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**INDEX OF EXHIBITS**

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
99.1	Investor Presentation dated March 2015.



# Investor Presentation

March 2015

## Forward-Looking Statement Safe-Harbor

This presentation contains certain forward-looking statements about Minerva Neurosciences that are intended to be covered by the safe harbor for “forward-looking statements” provided by the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. Words such as “expect(s),” “feel(s),” “believe(s),” “will,” “may,” “anticipate(s)” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to: the benefits, efficacy and safety of the new once-a-day formulation of MIN-101; whether the results of the study of the analog of MIN-301 are applicable to MIN-301; the timing and results of future clinical milestones; the timing of future clinical trials and results of such clinical trials; statements regarding our ability to successfully develop and commercialize our therapeutic products; our ability to expand our long-term business opportunities; our expectations regarding approval for our products by the U.S. Food and Drug Administration or equivalent foreign regulatory agencies; estimates regarding the market potential for our products; financial projections and estimates and their underlying assumptions; and future performance. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the control of the Company, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. These risks and uncertainties include, but are not limited to: the benefits, efficacy and safety of the new once-a-day formulation of MIN-101; whether the analog of MIN-301 is a good predictor of clinical efficacy of MIN-301; the timing and results of future clinical milestones; the timing of future clinical trials and results of such clinical trials; whether any of our therapeutic candidates will advance further in the clinical trials process and whether and when, if at all, they will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether any of our therapeutic candidates will be successfully marketed if approved; whether our therapeutic product discovery and development efforts will be successful; our ability to achieve the results contemplated by our collaboration agreements; the strength and enforceability of our intellectual property rights; competition from pharmaceutical and biotechnology companies; the development of and our ability to take advantage of the market for our therapeutic products; our ability to raise additional capital to fund our operations on terms acceptable to us; general economic conditions; and the other risk factors contained in our periodic and interim reports filed with the Securities and Exchange Commission which are available on the SEC website at [www.sec.gov](http://www.sec.gov). Our audience is cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

**Portfolio of  
First in Class  
Neuropsychiatric  
Drugs**

- Focus on leadership in CNS clinical development
- Four clinical-stage compounds with transformative potential
- Validated MOAs differentiated by additional innovative receptor activities
- Multiple significant milestones over next 15 months

**Large Addressable  
Market**

- 88M patients covered under our commercial rights<sup>1</sup>
- Significant unmet medical need
- \$14B total addressable market<sup>2</sup>

**Management Team  
With Demonstrated  
Track Record**

- 8 FDA-approved neuropsychiatry drugs in the last 10 years
- Multiple successful exits for investors

**World Class  
Pharma Partners**



PHARMACEUTICAL COMPANIES  
OF *Johnson-Johnson*



Mitsubishi Tanabe Pharma

# Robust Pipeline of Transformative CNS Therapies

Next Generation of First in Class Neuropsychiatry Pharmaceuticals



Program	Primary Indication	Unique MOA	Preclinical	Phase 1	Phase 2	Prevalent Population	Existing Drug Sales <sup>1</sup>
<b>MIN-101</b>	Schizophrenia	<ul style="list-style-type: none"> <li>5-HT2A</li> <li>Sigma2</li> </ul>				4.3M US + EU5	\$4.5B
<b>MIN-117</b>	Major Depressive Disorder (MDD)	<ul style="list-style-type: none"> <li>5-HT1A</li> <li>5-HTT</li> <li>Alpha-1a,b</li> <li>Dopamine Transporter</li> <li>5-HT2A</li> </ul>				28M US + EU5	\$4.6B
<b>MIN-202</b>	Primary and Comorbid (Secondary) Insomnia	<ul style="list-style-type: none"> <li>Orexin-2 antagonist</li> </ul>				53M US + EU5 + Japan	\$2.8B
<b>MIN-301</b>	Parkinson's Disease	<ul style="list-style-type: none"> <li>ErbB4 activator</li> </ul>				2M US + EU5 + Japan	\$2.3B

\* Subject to additional financing



## Significant Progress Since IPO in 2014

### **MIN-101:**

- Once a day formulation with improved safety profile selected for Phase IIb study (IIa conducted with bid)
- Phase IIb protocol submitted to several European countries

### **MIN-202:**

- Two Phase 1 studies completed;
  - MAD study in healthy volunteers showing MIN-202 is well tolerated and appropriate PK/PD
  - Bioavailability study in healthy volunteers
- POC study in MDD patients with comorbid insomnia showing improvement in onset and maintenance

### **MIN-117:**

- Phase IIa protocol finalized

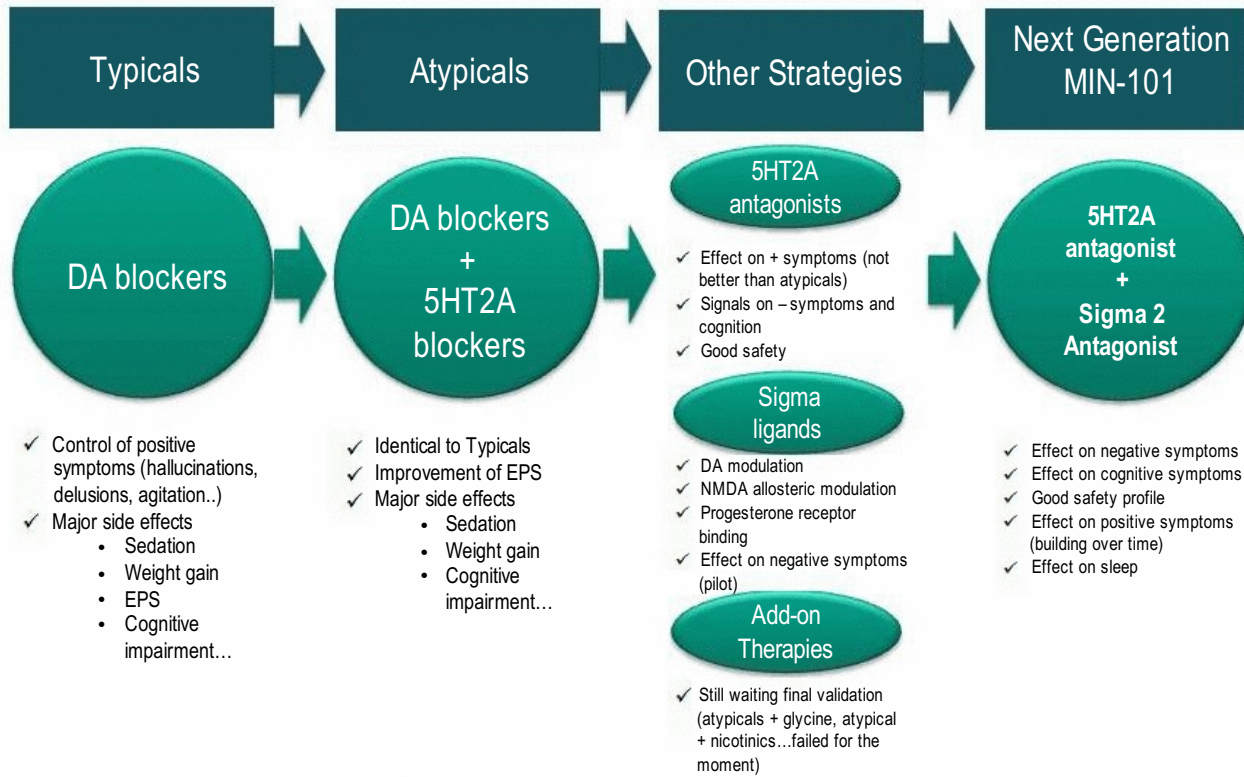
### **MIN-301:**

- Disease modifying potential as demonstrated in MPTP primate study on analog of MIN-301



## MIN-101

Our lead compound with a clear path through clinical development





## NIH Public Access

## Author Manuscript

*Nat Commun*. Author manuscript; available in PMC 2013 April 12.

Published in final edited form as:

*Nat Commun*. ; 2: 380. doi:10.1038/ncomms1386.

### Identification of the PGRMC1 protein complex as the putative sigma-2 receptor binding site

Jinbin Xu<sup>1</sup>, Chenbo Zeng<sup>1</sup>, Wenhua Chu<sup>1</sup>, Fenghui Pan<sup>1</sup>, Justin M. Rothfuss<sup>1</sup>, Fanjie Zhang<sup>1</sup>, Zhude Tu<sup>1</sup>, Dong Zhou<sup>1</sup>, Dexing Zeng<sup>1</sup>, Suwanna Vangveravong<sup>1</sup>, Fabian Johnston<sup>4</sup>, Dirk Spitzer<sup>4</sup>, Katherine C. Chang<sup>2</sup>, Richard S. Hotchkiss<sup>5</sup>, William G. Hawkins<sup>4</sup>, Kenneth T. Wheeler<sup>6</sup>, and Robert H. Mach<sup>1,2,3,4</sup>

<sup>1</sup>Department of Radiology, Washington University School of Medicine, 510 S. Kingshighway Blvd., St. Louis, MO 63110, USA

<sup>2</sup>Department of Cell Biology & Physiology, Washington University School of Medicine, 510 S. Kingshighway Blvd., St. Louis, MO 63110, USA

<sup>3</sup>Department of Biochemistry & Molecular Biophysics, Washington University School of Medicine, 510 S. Kingshighway Blvd., St. Louis, MO 63110, USA

<sup>4</sup>Department of Surgery, Washington University School of Medicine, 510 S. Kingshighway Blvd., St. Louis, MO 63110, USA

<sup>5</sup>Department of Anesthesiology, Washington University School of Medicine, 510 S. Kingshighway Blvd., St. Louis, MO 63110, USA

<sup>6</sup>Department of Radiology, Wake Forest University Health Science Center, Winston-Salem, NC 27157, USA

#### Abstract

The sigma-2 receptor, whose gene remains to be cloned, has been validated as a biomarker for tumor cell proliferation. Here we report the use of a novel photoaffinity probe, WC-21, to identify the sigma-2 receptor binding site. WC-21, a sigma-2 ligand containing both a photoactive moiety azide and a fluorescein isothiocyanate group, irreversibly labels sigma-2 receptors in rat liver; the membrane-bound protein was then identified as PGRMC1 (progesterone receptor membrane component-1). Immunocytochemistry reveals that both PGRMC1 and SW120, a fluorescent sigma-2 receptor ligand, colocalizes with molecular markers of the endoplasmic reticulum and mitochondria in HeLa cells. Overexpression and knockdown of the PGRMC1 protein results in an increase and a decrease in binding of a sigma-2 selective radioligand, respectively. The

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### **A Multi-center, Inpatient and ambulatory, Phase 2, Double-blind, Randomized, Placebo-controlled Proof of Concept Study of MIN-101 in 96 Patients with DSM-IV Schizophrenia (PANSS > 60)**

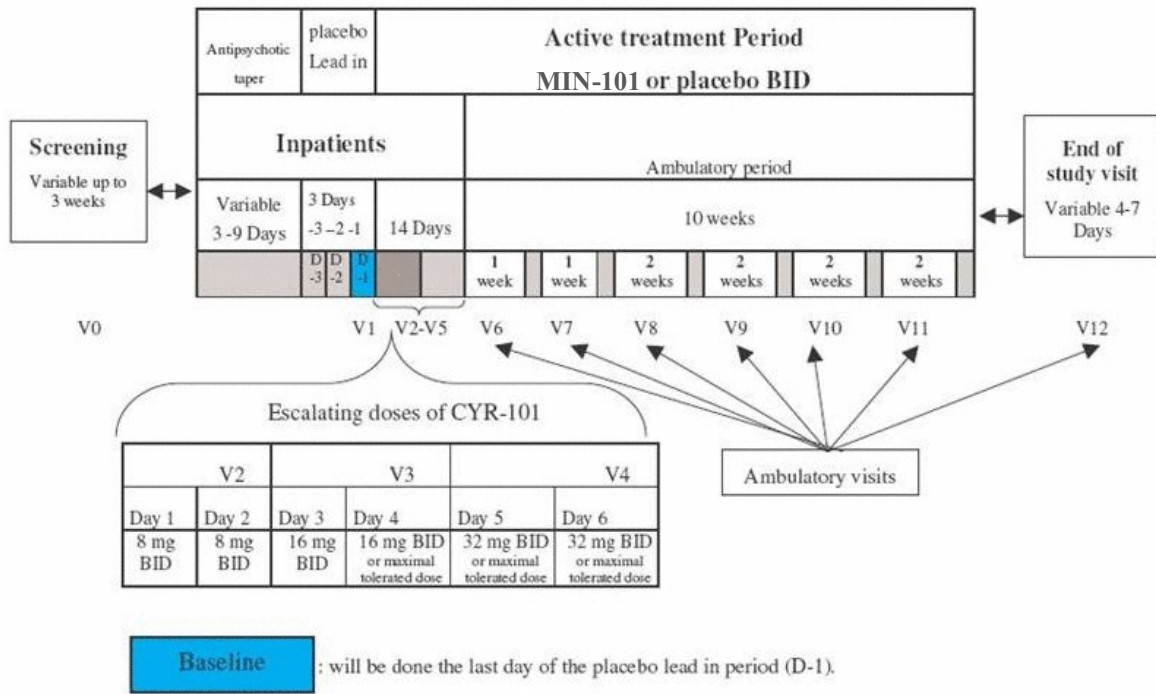
#### ▪ **Primary Endpoint:**

- Explore safety & tolerability of MIN-101 at a dose two or three times above the estimated therapeutic dose in order to:
  - Ensure safety of patients participating in future studies
  - Understand the PK/PD relationship of the QTc signal observed in non-clinical and Phase I studies
- Get first hints of therapeutic activity in schizophrenic patients

#### ▪ **Secondary Endpoints:**

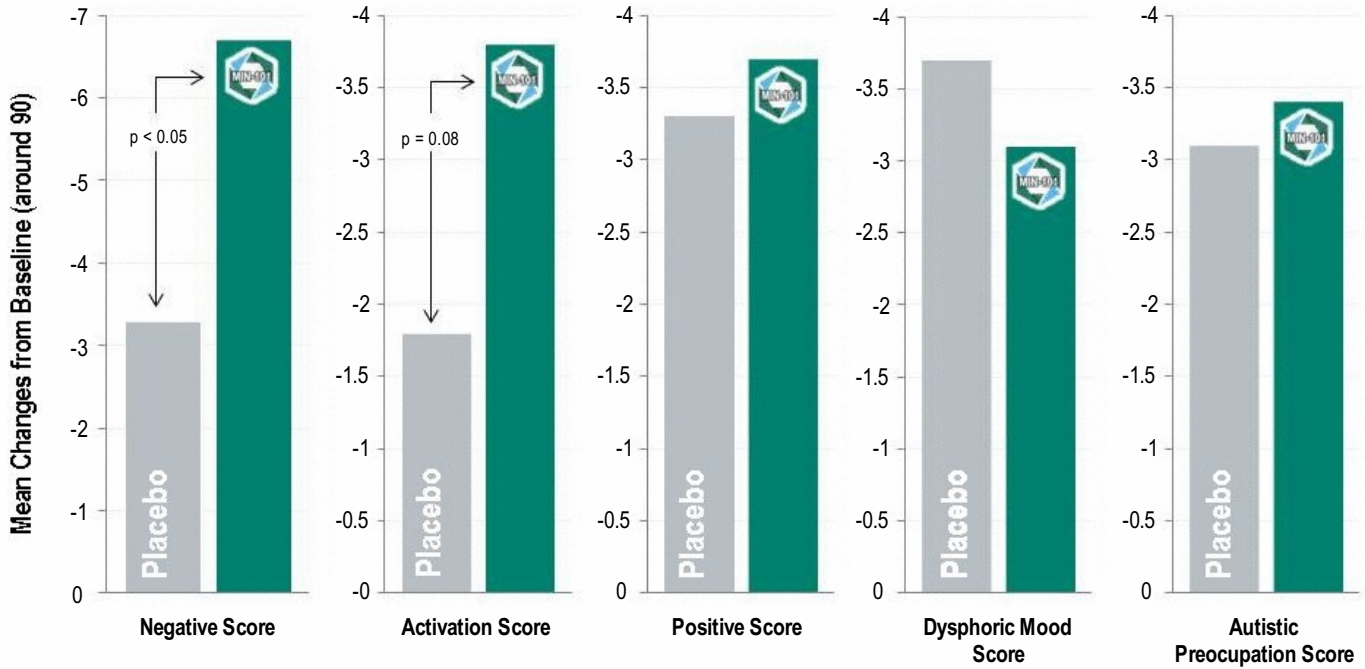
- Verify the safety and tolerability profile for three months in schizophrenic patients at a 32mg twice daily dose (> the estimated therapeutic dose)
- Verify the absence of the most predominant AEs associated with typical and/or atypical antipsychotics
- Measure effect size of CYR-101 on QTc at Tmax/Cmax after the morning administration
- Explore effects of the drug on overall schizophrenia psychopathology over 3 months to understand the time course in acutely relapsed patients (PANSS > 60), requiring hospitalization without adequately responding to prior treatment

# MIN-101 Phase IIa Study Design

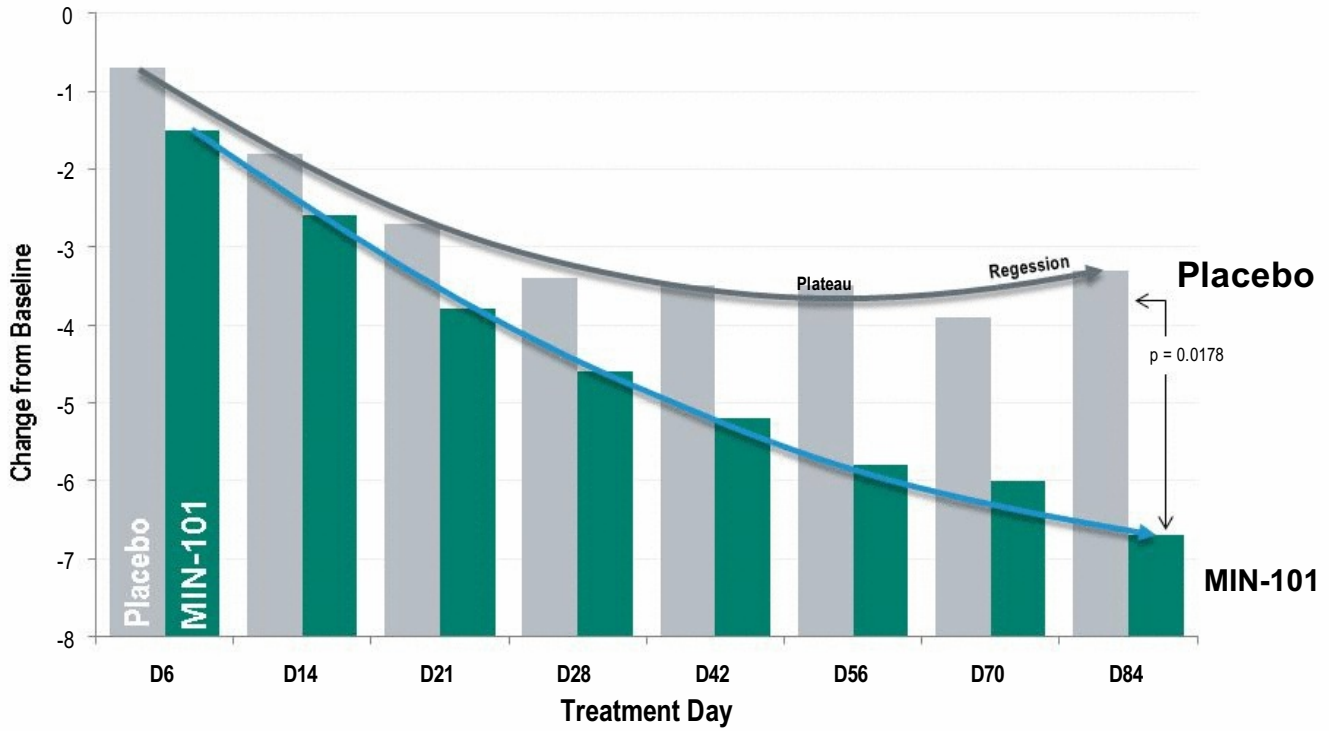


## Positive and Negative Syndrome Scale (PANSS) 5 Factors (PPC) After Three Months

Total Weighted Score Decrease: -24.1 for MIN-101 versus -17.9 Placebo

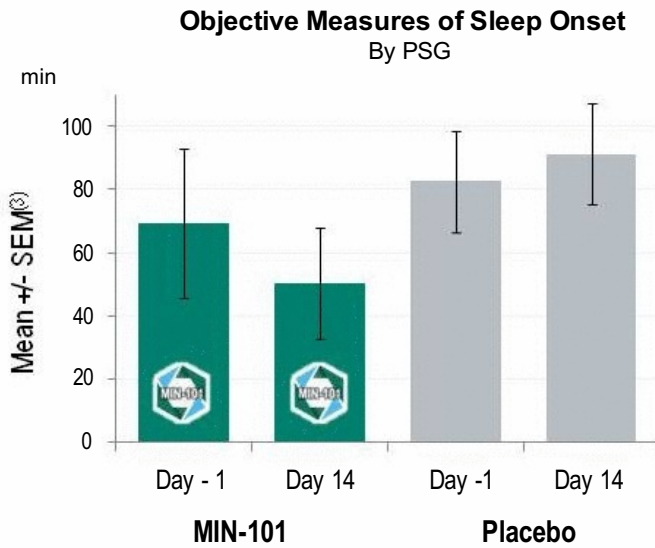


**MIN-101:** Phase IIa showed improvement in overall psychopathology of schizophrenia with outstanding efficacy on Negative Symptoms (32mg bid)

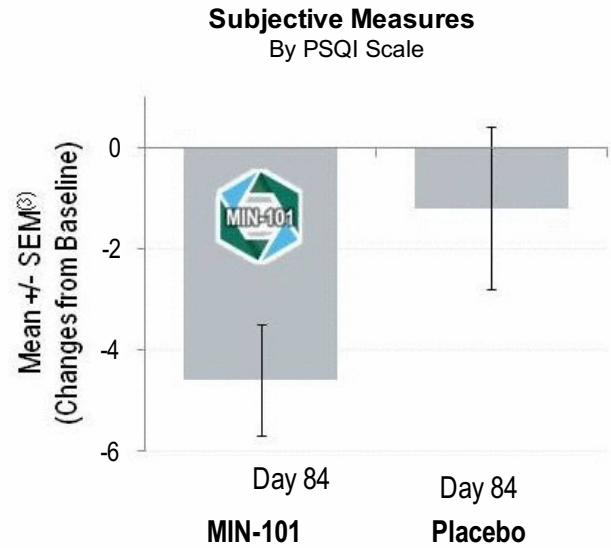




# MIN-101: Compelling Efficacy On Sleep Objective (PSG)<sup>1</sup> and Subjective (PSQI)<sup>2</sup> Measurements (Phase IIa)



- Quicker onset of sleep after 2 weeks of treatment with MIN-101 vs Placebo



- Improved sleep quality after 3 months of treatment with MIN-101 vs Placebo

Side Effect	Evaluation	Relative to Atypicals
AEs and SAEs	Limited and minor	Better
Weight gain, Waist Circumference	No increase on measurement	Better
Prolactin and Laboratory tests	No clinically significant effects	Better
Extra-pyramidal symptoms	No effect showed on Simpson Angus Scale (SAS)	Better
Sedation	No effect	Better
Vital signs – Cardiovascular	Minor QTc prolongation as expected with a supra-therapeutic dose	Comparable

## **MIN-101: Phase IIb**

**Reformulated compound with improved safety profile**

**A Phase IIb, Multi-centre, Randomized, Double-blind, Parallel-group, Placebo-controlled Study to Evaluate the Efficacy, Tolerability and Safety of MIN-101 in 234 patients with Negative Symptoms of Schizophrenia followed by a 24-week, Open-label extension**

# MIN-101CO3: Phase IIb Design in Patients with Schizophrenia

TITLE: A Phase IIb, Multi-centre, Randomized, Double-blind, Parallel-group, Placebo-controlled Study to Evaluate the Efficacy, Tolerability and Safety of MIN-101 in Patients with Negative Symptoms of Schizophrenia Followed by a 24-week, Open-label Extension

Screening	Wash Out Period	Baseline	Core Study Treatment Period (12 weeks): MIN-101 (64 or 32 mg) or PLACEBO						Extension 6-month: MIN-101 64 or 32 mg					
	Obligatory In patient Day -3 to day +2 afterwards up to the end of study at the discretion of the PI													
D-21	D-3 to D-1	Day-1	D1	D2	W2	W4	W8	W12	A	A	IN	A	IN	A
V1	V2	V3	V4	V5	V6	V7	V8	V9	W 14	W 18	W 24	W 30	W 36	W 37
	RANDOMIZATION & DOUBLE-BLIND						RANDOMIZATION & SINGLE-BLIND							

Core Study to include:

- 234 patients (78: 64mg, 78: 32mg, 78: placebo)
- 42 sites in 6 countries (Estonia, Russia, Ukraine, Romania, Latvia, Bulgaria)

## Primary Study Objectives

- To evaluate the efficacy of MIN-101 compared to placebo in improving the negative symptoms of schizophrenia as measured by the change from Baseline in the Positive and Negative Syndrome Scale (PANSS) negative subscale score of the pentagonal model over 12 weeks of treatment.

## Main Inclusion Criteria

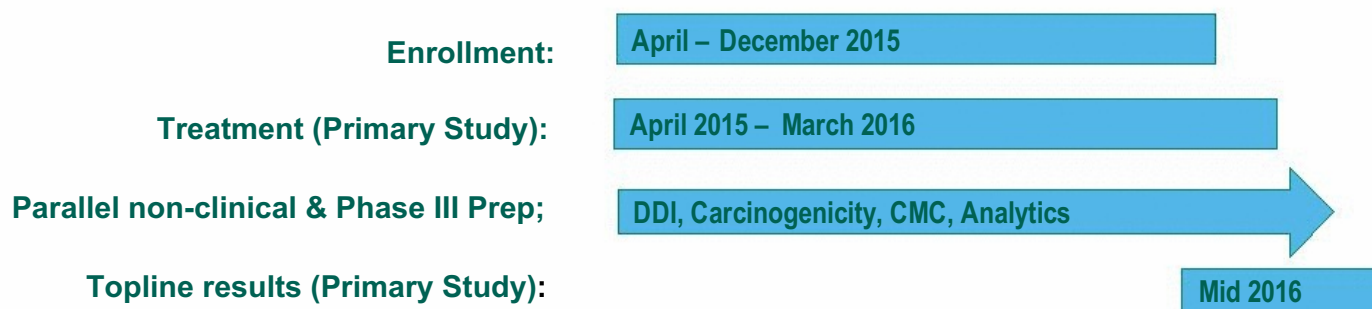
- Male or female patient, 18 to 60 years of age, inclusive.
- Patient meets the diagnostic criteria for schizophrenia as defined in DSM-V
- Patient being stable in terms of positive symptoms over the last three months
- Patient presenting with negative symptoms over the last three months
- **Patient with PANSS negative sub-score of at least 20.**
- **Patient with PANSS item score of <4 on: P4 Excitement, hyperactivity P7 Hostility P6 Suspiciousness G8 Uncooperativeness G14 Poor impulse control**
- No change in psychotropic medication during the last month
- Patient must be extensive metabolizers for P450 CYP2D6

## Efficacy Assessments

- Positive and Negative Symptoms Scale (PANSS)
  - **The study is powered to reach statistical significance on total score and negative score**
- Brief Negative Symptoms Scale (BNSS)
- Brief Assessment of Cognition in Schizophrenia (BACS)
- Personal and Social Performance (PSP): assess social functioning; clinician rated
- Sleep architecture and continuity

**Timelines**

<b>Country Submissions</b>	
<b>December 2014</b>	<b>January 2015</b>
Romania (16 sites) Russia (9 sites) Latvia (3 sites)	Estonia (3 sites) Bulgaria (3 sites) Ukraine (10 sites)

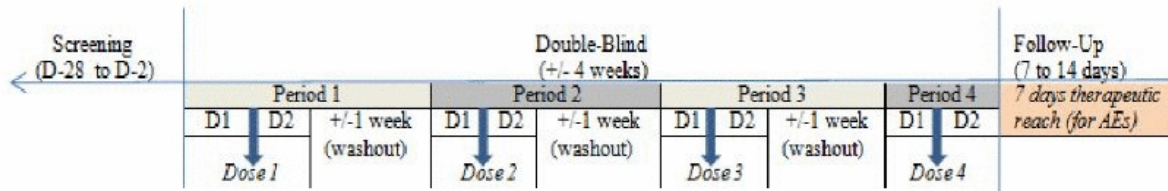




# MIN-202

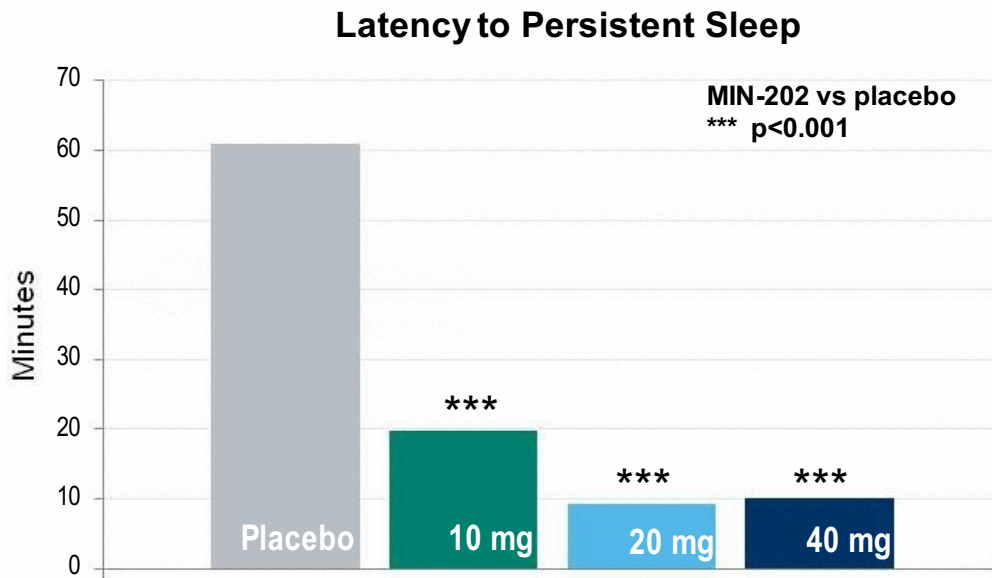
An Orexin2 antagonist for the treatment of primary and comorbid insomnia

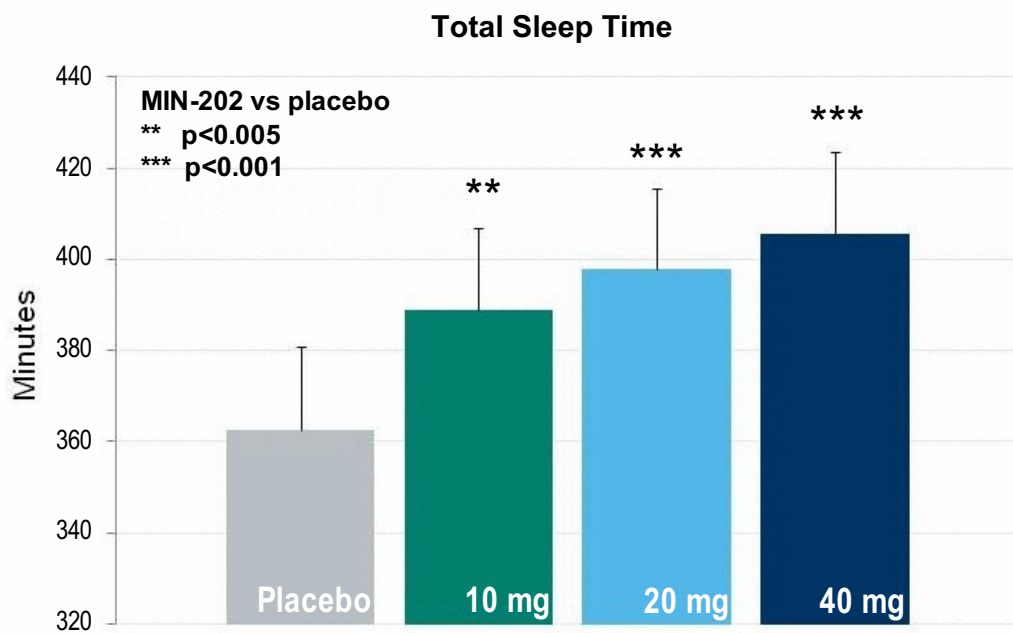
## MIN-202: Phase IB Study Design in MDD Patients



- Placebo controlled, cross-over, single dose study
- 3 doses (10mg, 20mg, 40mg)
- Washout period between periods of ~1 week
- 20 MDD patients treated with SSRI/SNRI having comorbid insomnia
- Diagnostic and drug effect evaluated with objective sleep measurements; PSG







- 5, 10, 20, 40 and 60 mg MAD ascending doses of 10 days treatment duration
- Young healthy volunteers
- 2 placebo subjects and 6 verum subjects per dose group; equally randomized between females and males
- Study objectives
  - Safety and tolerability
  - C-SSRS (Columbia Suicide Severity Rating Scale)
  - Pharmacodynamics:
    - CFF: Critical Flicker Fusion
    - Simple and multiple choice reaction time

1. Clear efficacy on sleep induction & sleep maintenance with all doses tested
2. REM sleep is preserved
3. Good safety and tolerability up to 60 mg/day after repeated administration
4. PK and PK/PD are adapted for the therapeutic indications pursued
5. First solid formulation “bio-equivalent” with the liquid formulation used in the 3 trials carried out in 2014
6. Clear path forward in terms of next steps development in both indications (i.e. primary and comorbid insomnia in MDD)

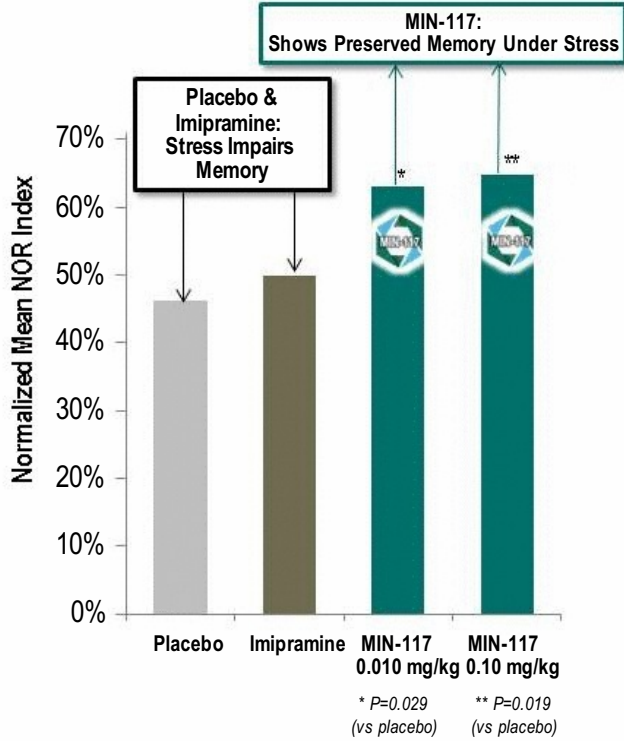


## MIN-117

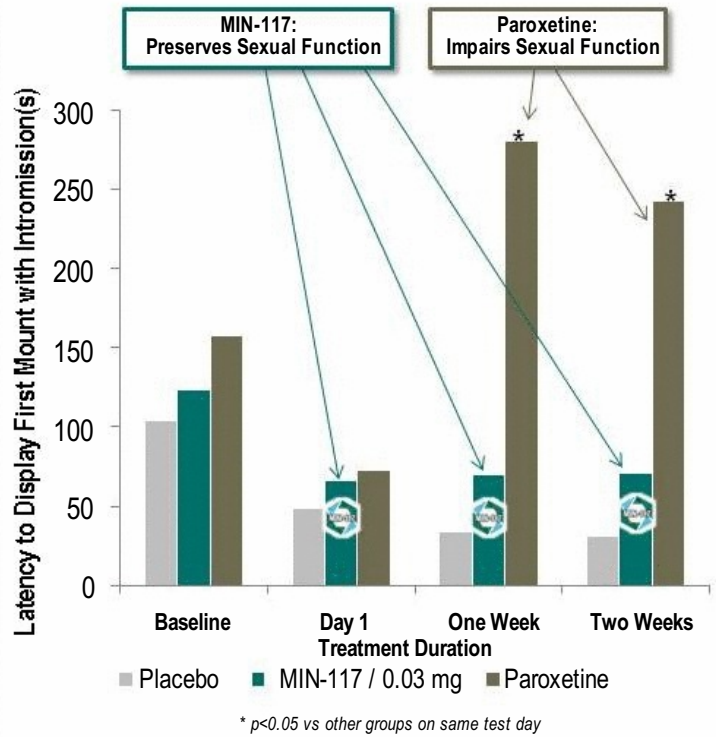
Potential for a more effective and safer treatment to address the unmet medical needs of Major Depressive Disorder patients

# MIN-117: Preserving cognition and sexual function

## Effects on Immediate Memory (a model of cognition)



## Effects on Sexual Function





# MIN-301

Potential for next generation of therapy for neurodegenerative diseases

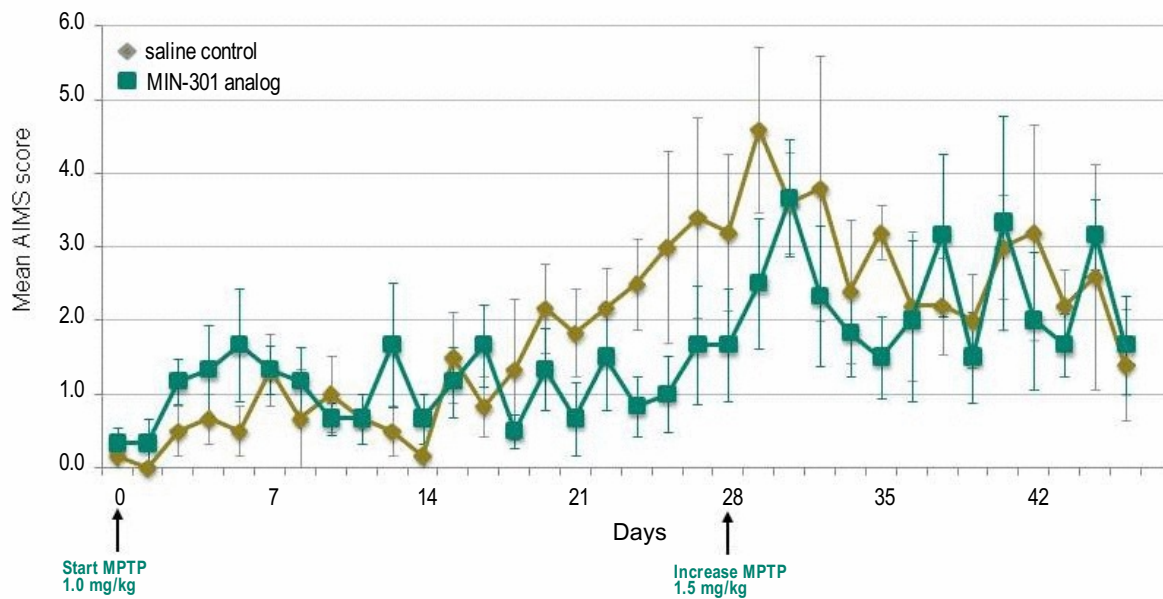
	Disease Progression >>>>							
Week -4 to 0	Week 1	Week 2	Week 3	Week 4	Week 5	Week 6	Week 7	Week 8
Habituation and establishment of baseline	←		MIN-301a or vehicle daily dosing		→			
								End
MPTP dosing	x	x	x	x	x	x	x	x

**Read-outs:**

- Daily clinical score (Parkinson signs) & body weight (twice weekly)
- Circadian rhythm: 24-h home cage activity (once / week)
- Sleep with EEG recording (once / week)
- Motor function (once / week)
- *Locomotor activity*
- *Righting reflex*
- Pathology of substantia nigra
- Immunology: profiling of cytokines involved in inflammation and/or neurodegeneration including IL1 $\alpha/\beta$ , MCP-1, MIP-1 $\alpha$ , TNF $\alpha$ , IL6, IFN- $\gamma$ , IL4, IL10, + inflammatory mediators (COX-2, NO-synthetase and leukotrienes), + trophic factors (GDNF, BDNF and TGF $\beta$ )



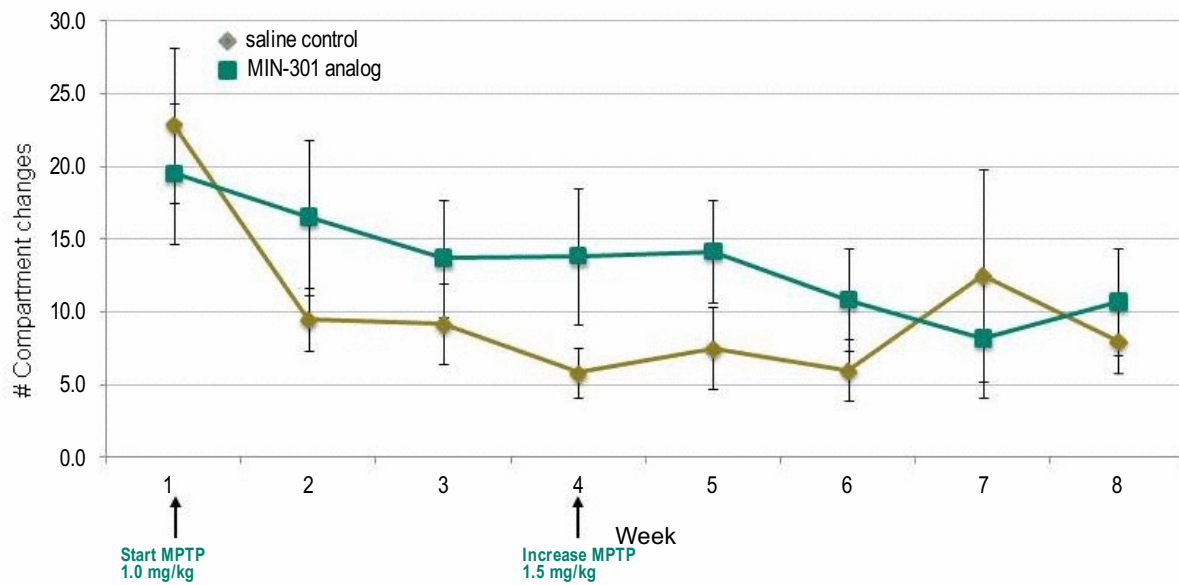
## Results: effect of treatment on abnormal involuntary movements scale (AIMS)



### Summary

- The MIN-301 analog group generally performed better than saline during the first 32 days.
- After increasing the dose of MPTP an increase of AIMS score was observed in the MIN-301 analog group. Thereafter, the AIMS scores of both groups were found to be overlapping.

## Results: effect of treatment on locomotor activity (bungalow test)



### Summary

- After the start of the MPTP treatment, the saline group showed a clear drop in performance. The MIN-301 analog treated group did not show this huge drop of activity.
- After increasing the MPTP dose, the activity of both groups gradually merged to a same performance level.



# Financial Overview

## Financial Summary

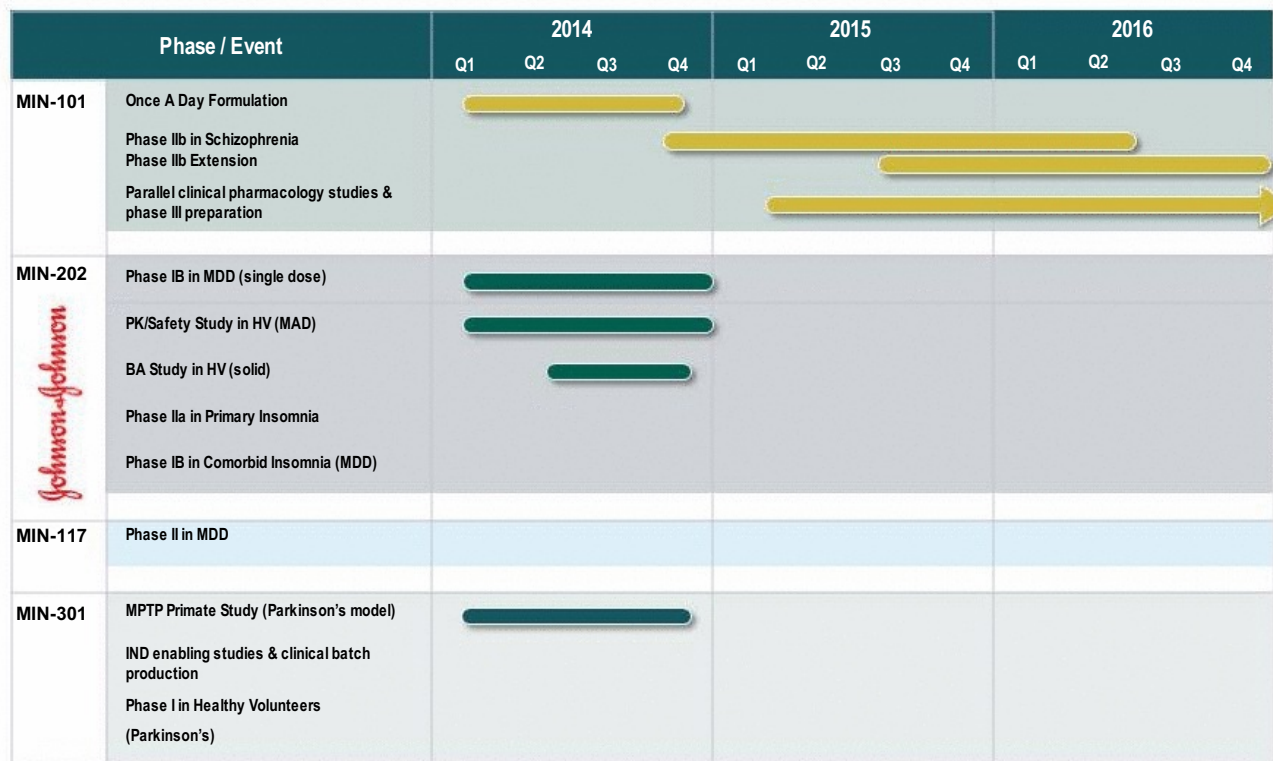
- At July 2014 IPO approximately 5.6M shares sold and a private placement of 0.7M shares at \$6/share resulting in net proceeds of \$29.9M
- Approximately 3.3M shares sold to Johnson & Johnson in a second private placement at \$6/share resulting in proceeds of \$19.7M
- Minerva paid a \$22M license fee to Janssen for certain rights to the MIN-202 program
  
- \$23.6M cash balance at 9/30/14
- \$15M credit facility with Oxford and SVB announced 1/20/15 (\$10m drawn down)
- Accumulated Net Operating Losses of \$67.3M as at 9/30/14
- 2014 IPO proceeds fund core MIN-101 & MIN-202 programs to end 2015
- MIN-117 & MIN-301 clinical initiation subject to additional funding
  
- 18,439,482 shares outstanding
- Approximately 2.1M options outstanding 9/30/14 (adjusted for cancellation of options in Nov 2014)
- 40,790 warrants issued in connection with the debt facility at exercise price of \$5.516

## Patent Protection

	Patent Jurisdiction	Type	U.S. Expiry	Term Extension	Regulatory Exclusivity
<b>MIN-101</b>	U.S., Europe, Canada, Australia, New Zealand, Russia and Israel	Composition of matter	<b>2021</b>	May be eligible for extension in the U.S. for up to 5 years	New Chemical Entity – 5 years in US Pediatric – 6 months in US Possible Orphan Drug – 7 years in US 10 years in Europe
	U.S., Brazil, Canada, China, Europe, Hong Kong, Indonesia, Japan, Korea, Taiwan and Russia	Methods of use / treatment	<b>2031 (Pending)</b>		
<b>MIN-117</b>	U.S., Germany, Spain, France, Italy, Netherlands, U.K. and Canada	Composition of matter	<b>2020</b>	May be eligible for extension in the U.S. for up to 5 years	New Chemical Entity – 5 years in US Pediatric – 6 months in US Possible Orphan Drug – 7 years in US 10 years in Europe
	U.S., To be filed in: Australia, Brazil, Canada, Chile, Colombia, Germany, Spain, France, Italy, Netherlands, U.K., Israel, Mexico, New Zealand, Peru, Russia, South Africa	Methods of use / treatment	<b>2034 (Pending)</b>		
<b>MIN-202</b>	European patent pending	Composition of matter	<b>Application in process; if granted, would expire no earlier than 2030</b>	–	10 years in Europe
<b>MIN-301</b>	U.S., Canada, Australia, Brazil, China, Japan, Mexico and Russia patents pending	Methods of use / treatment	<b>Application in process; if granted, would expire no earlier than 2028</b>	–	New Chemical Entity – 5 years in US Pediatric – 6 months in US Possible Orphan Drug – 7 years in US 10 years in Europe



# Multiple Significant Clinical Milestones Ahead



End of bar = expected availability of topline results



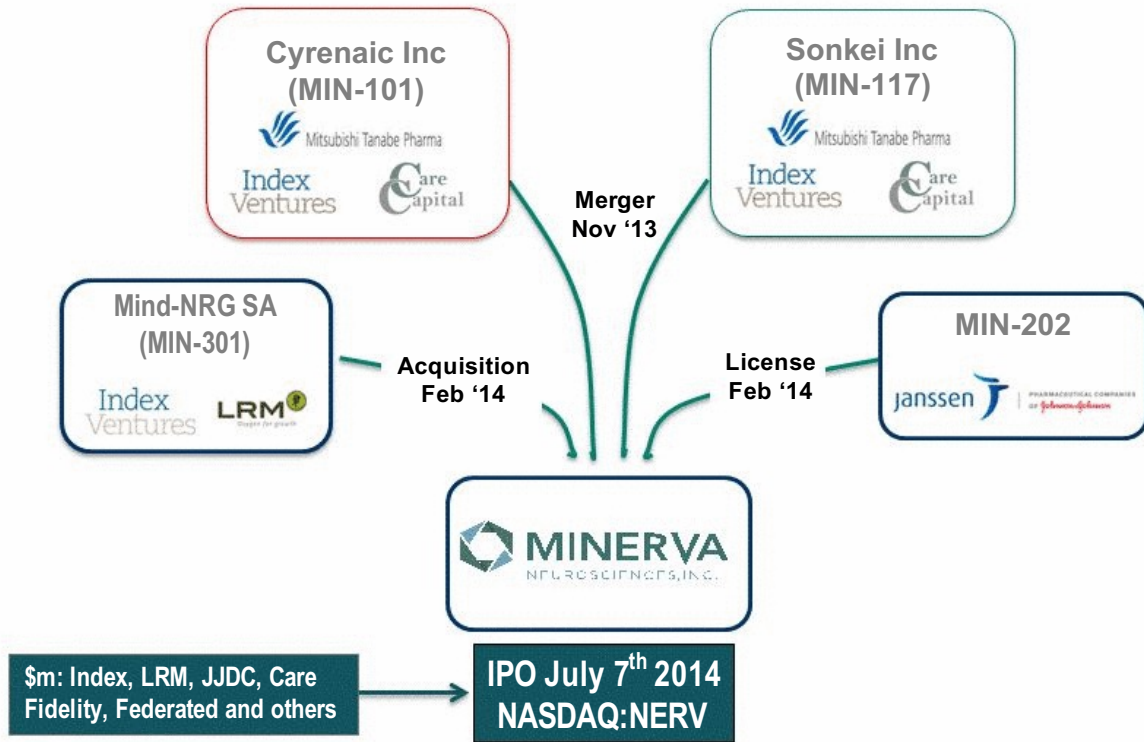
**Thank You**

Minerva Neurosciences, Inc.  
1601 Trapelo Road, Suite 284, Waltham, MA 02451

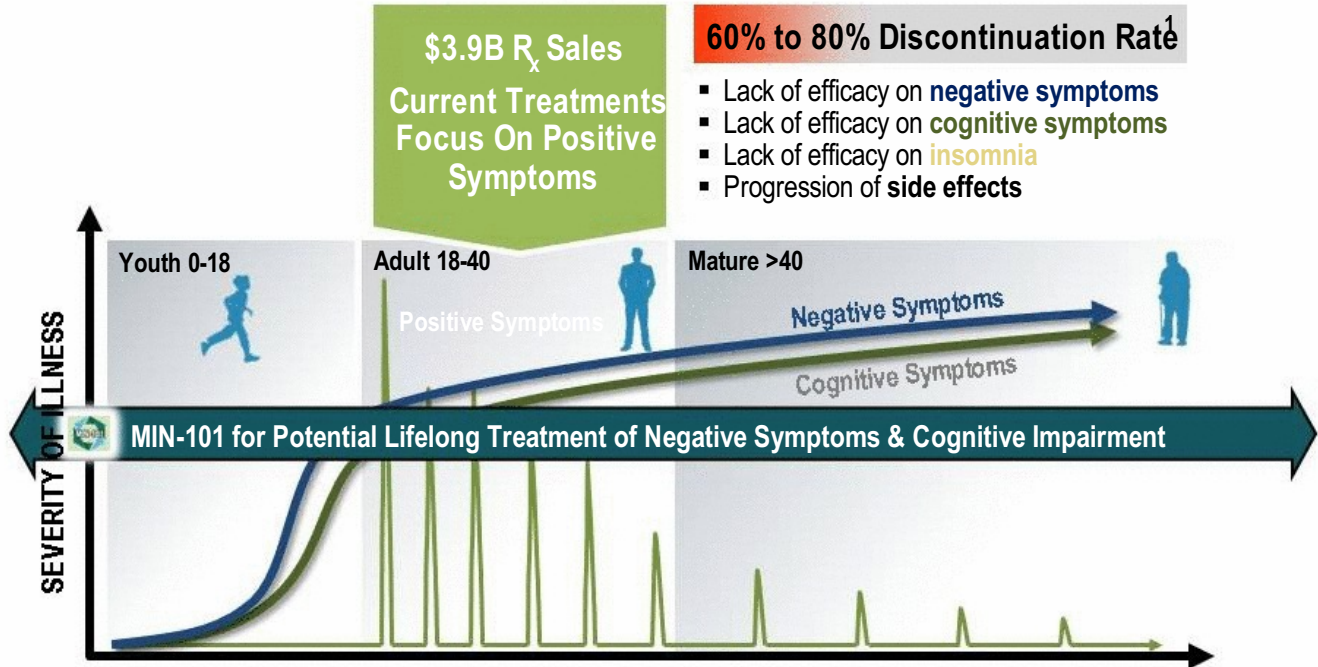
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**Back up**

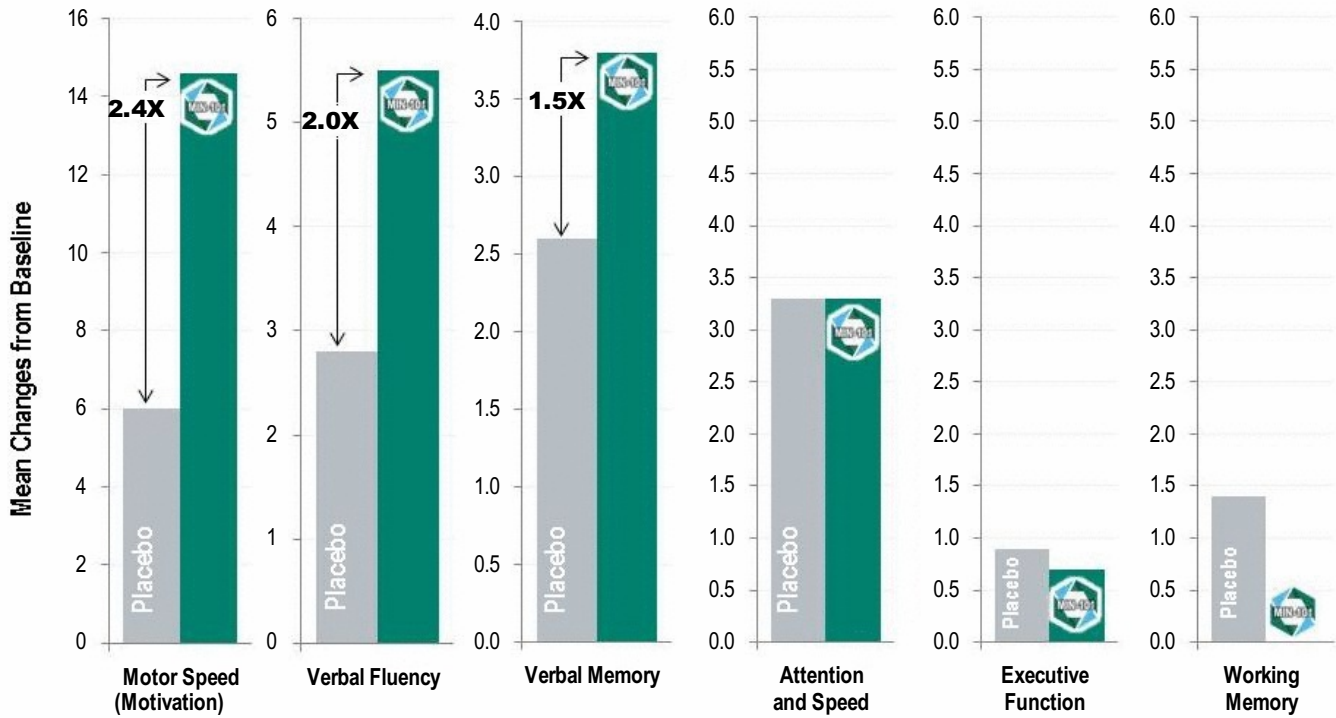




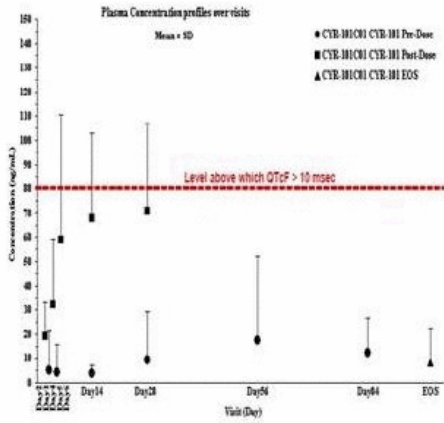
Schizophrenia:  
An Effective and Safe Lifelong Treatment Remains A Significant Unmet Need



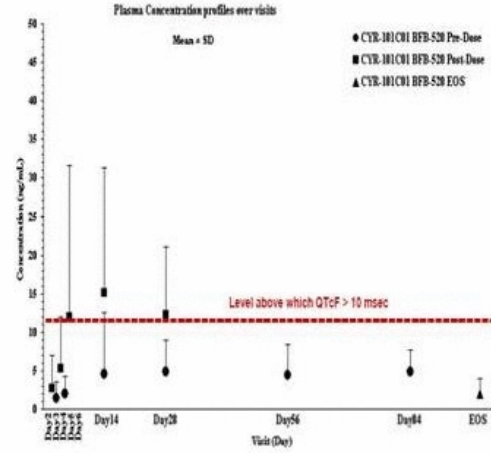
**Improves Several Cognitive Dimensions After Three Months <sup>(1)</sup>**

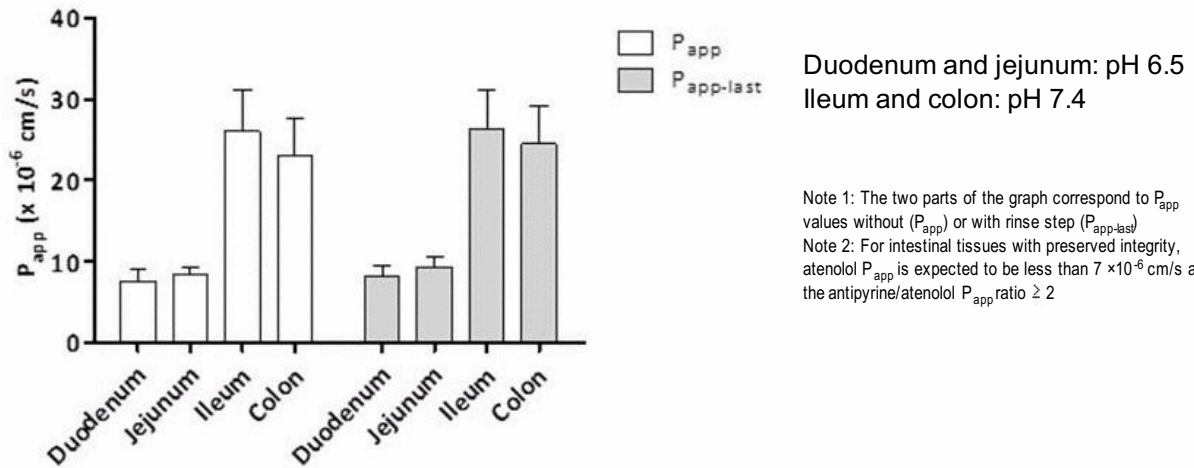


CYR-101



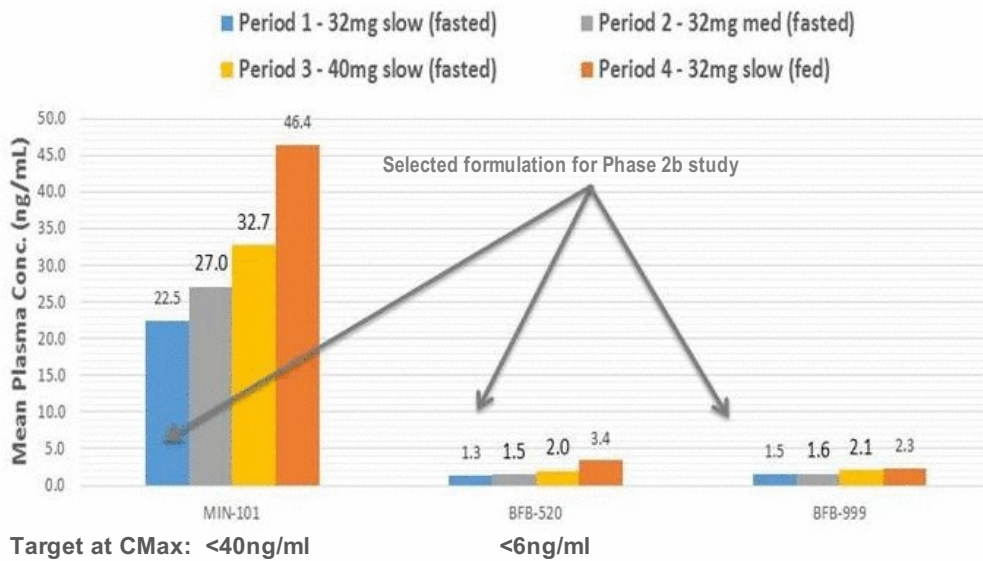
BFB-520





- In all intestinal segments, the permeability of MIN-101 is higher than that of atenolol (low permeability reference) and lower than that of antipyrine (high permeability reference) across the duodenum and jejunum, but similar across ileum and colon.

**MIN-101C02:** Once-A-Day Formulation Study  
 Cmax of MIN-101, BFB-520 and BFB-999 with the new formulation



- 32 mg and 64 mg slow will be the doses used in the Phase IIb study
- Cmax is linear to dose: 64mg is expected to give twice the levels of 32mg
- The observed Cmax levels are far below that inducing QTc increases
- Increased safety margin by at minimum 5 times

### **Exploratory Objectives**

- To evaluate the effects versus placebo of MIN-101 on depressive symptoms as measured by the Calgary Depression Scale for Schizophrenia (CDSS) over 12 weeks of double blind treatment.
- To evaluate the effects versus placebo of MIN-101 on social functioning by means of the Personal and Social Performance (PSP) over 12 weeks of double blind treatment.
- To assess the effects versus placebo of MIN-101 on sleep architecture and continuity as measured with the help of the V-Watch methodology over 12 weeks of double blind treatment.

### Sleep Assessment

- Sleep and circadian rhythm disruptions are reported in 30% to 80% of patients with schizophrenia.
- Patients with insomnia report
  - lower quality of life
  - greater symptom severity
  - worse adherence/compliance to treatment
- Sleep disturbances have also been associated with enhanced psychosis
- Sleep is important for memory consolidation, thus disturbances in sleep architecture, or circadian de-synchronization could also contribute to the cognitive impairment observed in schizophrenia.
- MIN-101 showed effects on sleep architecture in the previous Phase 2a study that could possibly be linked to the improvements observed on negative symptoms and cognition, thus they will be further investigated in the present study.
  - In a subgroup of patients (20) who underwent sleep recordings (PSG), sleep was evaluated at Baseline and Day 14. MIN-101 had an effect on
    - Slow Wave Sleep (SWS) distribution: it shifted SWS from the end to the beginning of the night: MIN-101 significantly increased SWS in the first third of the night and decreased it in the last third of the night.
    - Sleep initiation parameters (sleep onset latency, latency to persistent sleep).
  - Subjective sleep quality as measured by PSQI improved and this improvement was greater with MIN-101 than with placebo although not statistically significant.



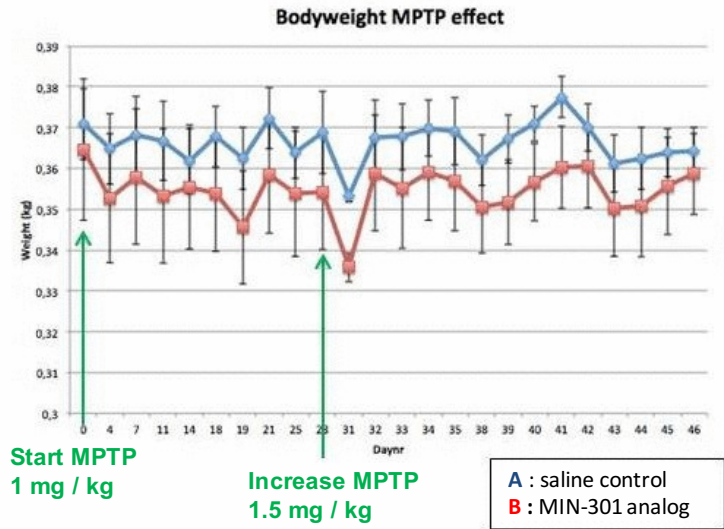
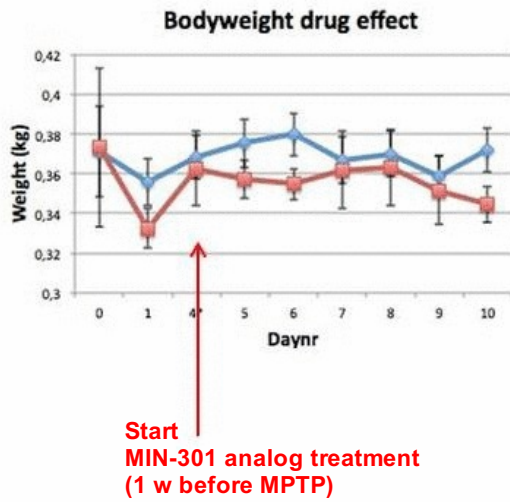
### Main Exclusion Criteria

- Current bipolar disorder, panic disorder, obsessive compulsive disorder, or evidence of mental retardation.
- Patient's condition is due to direct physiological effects of a substance (e.g., a drug of abuse, or medication) or a general medical condition.
- Significant risk of suicide or attempted suicide, or of danger to self or others.
- Patient who cannot be discontinued from psychotropics other than those allowed.
- Patient who received clozapine within 6 months of the Screening visit.
- Patient receiving treatment with depot antipsychotic medication can be enrolled in the study 4 weeks after the last injection.
- Patient with a history of significant other major or unstable neurological, neurosurgical (e.g., head trauma), metabolic, hepatic, renal, hematological, pulmonary, cardiovascular, metabolic, gastrointestinal, or urological disorder.
- Patient with a clinically significant electrocardiogram (ECG) abnormality that could be a safety issue in the study, including QT interval value corrected for heart rate using the Fridericia's formula (QTcF) > 430 msec for males and > 450 msec for females.



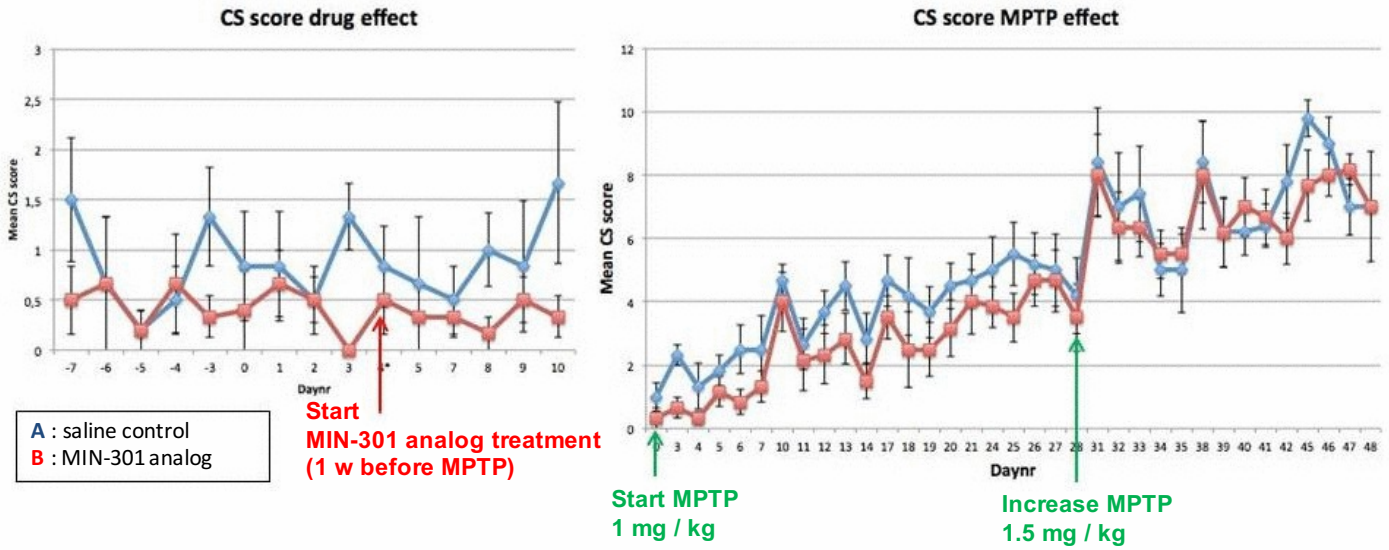
## **MIN-301: Summary/Key results**

### Effect Of Treatment On Body Weight



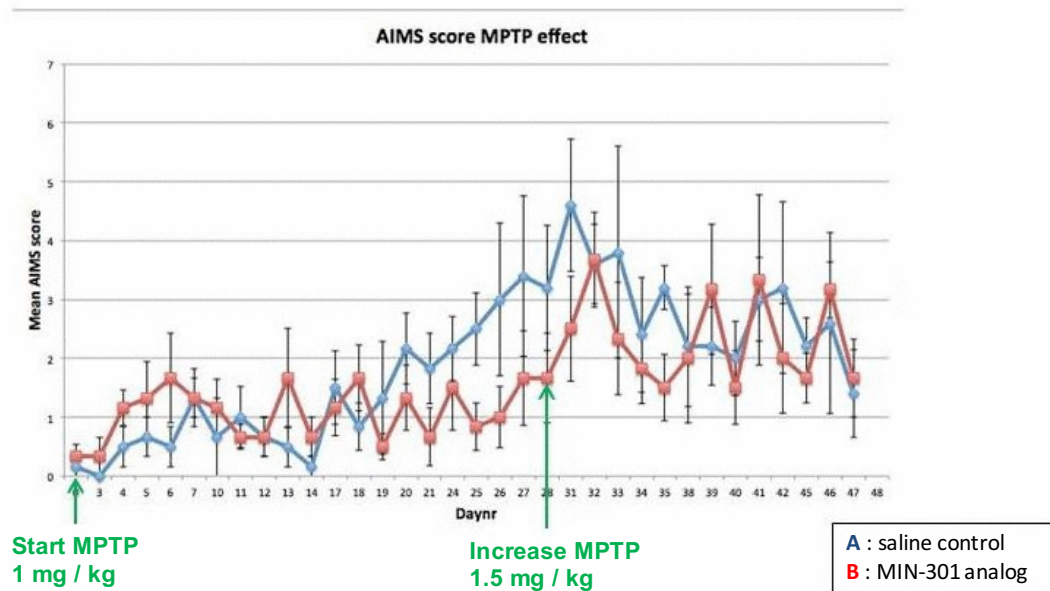
- Body weight during the complete study showed no remarkable effect in both groups

### Effect Of Treatment On Parkinsonian Clinical Signs



- MIN-301 analog alone did not affect the clinical score (CS).
- After start of MPTP treatment, the CS stayed very low (below 6) until day 28. During this period, the MIN-301 analog group did better compared to the vehicle group.
- After increase of MPTP dose to 1.5 mg/kg a huge increase of the CS in both groups was observed. The MPTP dose did lead to a saw-tooth pattern on the CS indicating direct MPTP toxic effects next to the Parkinson progression effects.

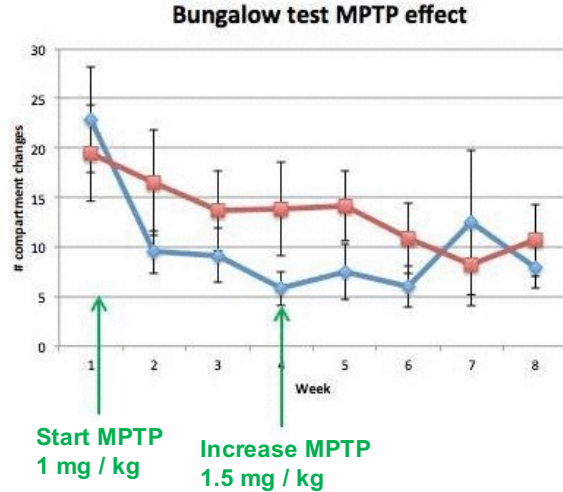
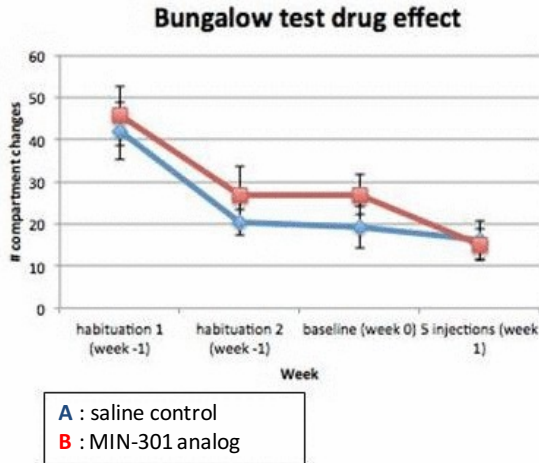
### Effect Of Treatment On Abnormal Involuntary Movements Scale (AIMS)



On AIMS:

- The MIN-301 analog group generally performed better than saline during the first 32 days.
- After increasing the dose of MPTP an increase of AIMS score was observed in the MIN-301 analog group. Thereafter, the AIMS scores of both groups were found to be equal.

### Effect of Treatment on Locomotor Activity (Bungalow Test)



- In the bungalow test there was a drop of activity after treatment of MIN-301 analog and placebo in healthy monkeys, measured by the number of compartment changes (from baseline week 0 to week 1).
- After the start of the MPTP treatment, the saline group showed a clear drop in performance.
- The MIN-301 analog treated group did not show this huge drop of activity.
- After increasing the MPTP dose, the activity of both groups gradually merged to a same performance level.