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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): January 8, 2018**

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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 286  
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))

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).

Emerging growth company

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.

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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 available 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	<a href="#">Investor Presentation dated January 2018.</a>

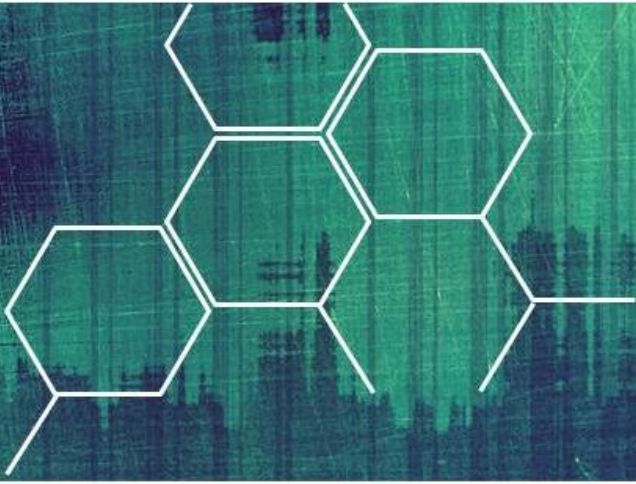
**SIGNATURE**

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/ Geoffrey Race  
Name: Geoffrey Race  
Title: Executive Vice President, Chief Financial Officer and Chief  
Business Officer

Date: January 8, 2018



**MINERVA**  
NEUROSCIENCES, INC.

## CORPORATE PRESENTATION

San Francisco  
January 2018

# Forward-Looking Statement Safe-Harbor

This presentation contains forward-looking statements about Minerva Neurosciences which are subject to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts, reflect management's expectations as of the date of this presentation, and involve certain risks and uncertainties. Forward-looking statements include, but are not limited to: the benefits, efficacy and safety of our new formulations; whether studies performed on analogs or backups of our compounds are a good predictor of the clinical efficacy of our compounds; statements with respect to the timing and results of future clinical milestones with MIN-101, seltorexant (MIN-202), MIN-117 and MIN-301, including the Phase 3 trial of MIN-101; the potential for a single Phase 3 trial with supportive Phase 2b results to support the basis for an NDA for MIN-101; the Phase 2b trials of seltorexant; the planned Phase 2b trial of MIN-117; 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 forward-looking statements are based on our current expectations and may differ materially from actual results due to a variety of factors including, without limitation, whether any of our therapeutic products 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 the results of future clinical trials of MIN-101, seltorexant, MIN-117 and MIN-301, if any, will be consistent with the results of past clinical trials; whether MIN-101, seltorexant, MIN-117 and MIN-301 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 co-development 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; and general economic conditions. These and other potential risks and uncertainties that could cause actual results to differ from the results predicted are more fully detailed under the caption "Risk Factors" in our filings with the Securities and Exchange Commission, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed with the Securities and Exchange Commission on November 6, 2017. Copies of reports filed with the SEC are posted on our website at [www.minervaneurosciences.com](http://www.minervaneurosciences.com). Our audience is cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we disclaim any obligation to update any forward-looking statements, except as required by law.

## Focus: to address the debilitating unmet needs of millions of patients afflicted by neuropsychiatric illnesses

### Differentiated assets

- Targeting clearly recognized unmet needs
- Innovative mechanisms of action

### Advanced clinical development

- Lead product in pivotal Phase 3 trial
- Three Phase 2b studies ongoing, one planned to begin in 2018



### Commercially attractive CNS markets

- Negative symptoms in schizophrenia & beyond
- Major depressive and anxiety disorders
- Insomnia with and without comorbid psychiatric symptoms
- Parkinson's disease & other neurodegenerative disorders

### Funded beyond multiple significant data read-outs in 2019

- \$143.3 million cash balance at 9/30/17

## Innovative pipeline of four compounds and multiple indications in the CNS space

Program	Primary Indications	MoA	Pre-clinical	Phase 1	Phase 2	Phase 3
<b>MIN-101</b>	Negative symptoms in Schizophrenia	<ul style="list-style-type: none"> <li>• 5-HT<sub>2A</sub> antagonist</li> <li>• Sigma <sub>2</sub> antagonist</li> </ul>				Phase 3 initiated Dec 2017 (MIN-101-C07)
<b>Seltorexant MIN-202</b>	Primary Insomnia  Major Depressive Disorder as adjunctive therapy	<ul style="list-style-type: none"> <li>• Selective Orexin2 antagonist</li> </ul>			Phase 2b initiated Dec 2017 (ISM2005) Phase 2b initiated Sep 2017 (MDD2001) Phase 2b initiated Dec 2017 (MDD2002)	
<b>MIN-117</b>	Major Depressive Disorder in monotherapy	<ul style="list-style-type: none"> <li>• 5-HT<sub>1A</sub></li> <li>• 5HT transporter</li> <li>• Alpha-1a, b</li> <li>• Dopamine transporter</li> <li>• 5-HT<sub>2A</sub> antagonist</li> </ul>				Phase 2b planned H1 2018 (MIN-117-C03)
<b>MIN-301</b>	Parkinson's Disease	<ul style="list-style-type: none"> <li>• Neuregulin 1<math>\beta</math>1 activating ErbB4</li> </ul>	Pre-clinical			

## Five clinical trials anticipated to read out in 2019

- **Lead program MIN-101:** Negative symptoms in schizophrenia, monotherapy
  - MIN-101C07 Phase 3 ongoing (~500 patients worldwide)
- **Seltorexant (MIN-202):** Primary insomnia and major depressive disorder (MDD)
  - MDD2001 Phase 2b ongoing in adjunctive MDD & placebo (~280 patients worldwide)
  - MDD2002 Phase 2b ongoing in adjunctive MDD & comparator (~100 patients U.S.)
  - ISM2005 Phase 2b ongoing in insomnia monotherapy (~360 patients worldwide)
- **MIN-117:** MDD with prominent anxiety in monotherapy
  - MIN-117C03 Phase 2b expected to begin in early 2018 (~325 patients worldwide)



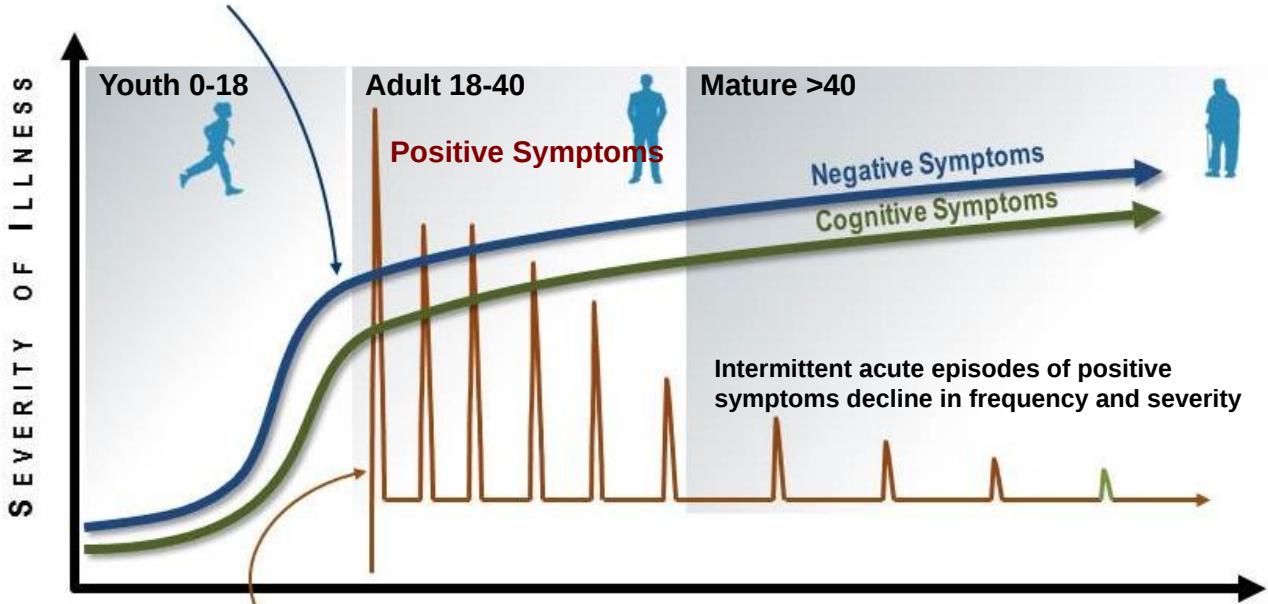


# MIN-101

A new paradigm for the treatment of schizophrenia

Schizophrenia has three symptom domains: positive symptoms fluctuate over time while negative & cognitive symptoms persist and cause lifelong disability

Negative symptoms and cognitive impairment are evident at onset of illness and are lifelong debilitating symptoms

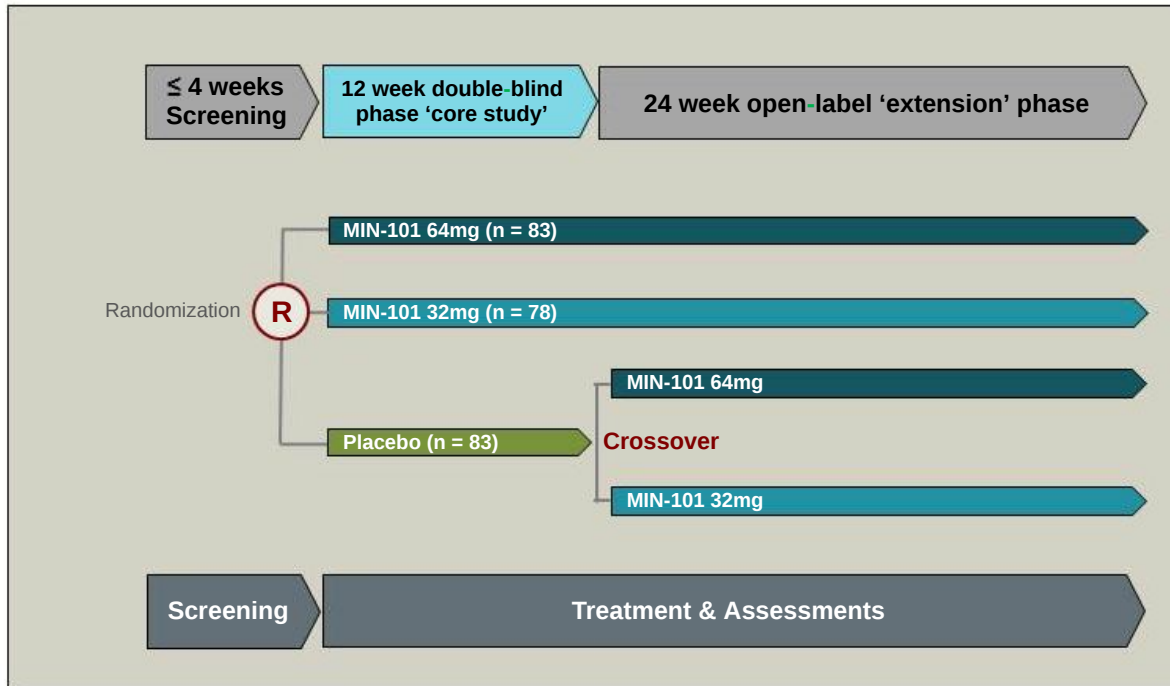


All antipsychotics directly target dopamine (DA) receptors and have only shown efficacy against positive symptoms; none are indicated for negative symptoms or cognitive impairment

## MIN-101 has a unique MoA with the potential to be the first to address negative symptoms and shift the treatment paradigm of schizophrenia

- A unique MOA: 5-HT<sub>2A</sub> antagonist + Sigma<sub>2</sub> antagonist
- No direct dopamine blocking, unlike most available antipsychotics
- Avoids antipsychotic side-effects
- Exclusive worldwide rights outside of Asia
- Granted formulation patent and method of use exclusivity until at least 2035
- Major commercial opportunity as potential first therapy in indication

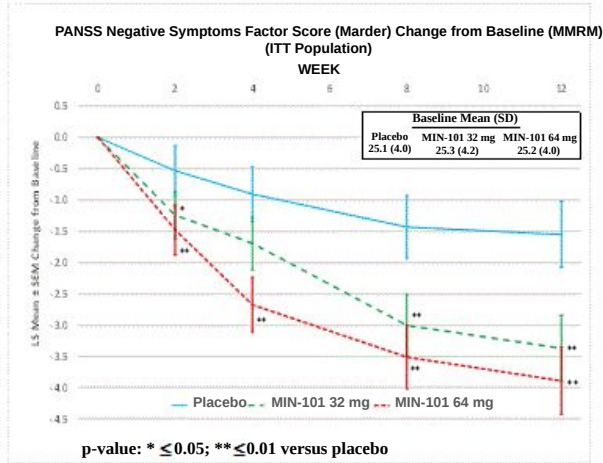
# MIN-101: Phase 2b study design: monotherapy, double-blind, placebo-controlled in schizophrenic patients with confirmed negative symptoms



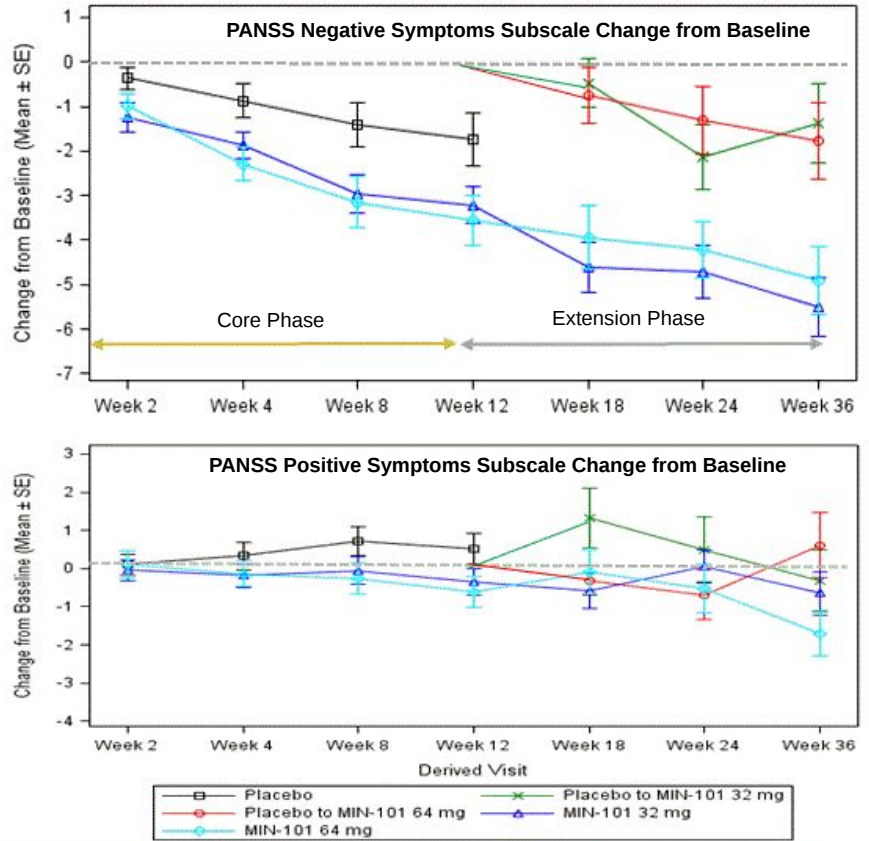
Specific effects on negative symptoms can only be determined in a placebo-controlled study

# Phase 2b study showed specific improvements in negative symptoms over 12 weeks and 36 weeks in both doses and stable positive symptoms

Statistically significant improvements in the primary endpoint



## Extension



## Efficacy and Safety of MIN-101: A 12-Week Randomized, Double-Blind, Placebo-Controlled Trial of a New Drug in Development for the Treatment of Negative Symptoms in Schizophrenia

Michael Davidson, M.D., Jay Saoud, Ph.D., Corinne Staner, M.D., Nadine Noel, Ph.D., Elisabeth Luthringer, R.N., Sandra Werner, Ph.D., Joseph Reilly, M.S., Jean-Yves Schaffhauser, Pharm.D., Jonathan Rabinowitz, Ph.D., Mark Weiser, M.D., Remy Luthringer, Ph.D.

**Objective:** The authors assessed the efficacy, safety, and tolerability of MIN-101, a compound with affinities for sigma-2 and 5-HT<sub>2A</sub> receptors and no direct dopamine affinities, in comparison with placebo in treating negative symptoms in stabilized patients with schizophrenia.

**Method:** The trial enrolled 244 patients who had been symptomatically stable for at least 3 months and had scores of at least 20 on the negative subscale of the Positive and Negative Syndrome Scale (PANSS). After at least 5 days' withdrawal from all antipsychotic medication, patients were randomly assigned to receive placebo or 32 mg/day or 64 mg/day of MIN-101 for 12 weeks. The primary outcome measure was the PANSS negative factor score (pentagonal structure model). Secondary outcome measures were PANSS total score and scores on the Clinical Global Impressions Scale (CGI), the Brief Negative Symptom Scale, the Brief Assessment of Cognition in Schizophrenia, and the Calgary Depression Scale for Schizophrenia.

**Results:** A statistically significant difference in PANSS negative factor score was observed, with lower scores for the MIN-101 32 mg/day and 64 mg/day groups compared with the placebo group (effect sizes,  $d=0.45$  and  $d=0.57$ , respectively). Supporting these findings were similar effects on several of the secondary outcome measures, such as the PANSS negative symptom, total, and activation factor scores, the CGI severity item, and the Brief Negative Symptom Scale. There were no statistically significant differences in PANSS positive scale score between the MIN-101 and placebo groups. No clinically significant changes were observed in vital signs, routine laboratory values, weight, metabolic indices, and Abnormal Involuntary Movement Scale score.

**Conclusions:** MIN-101 demonstrated statistically significant efficacy in reducing negative symptoms and good tolerability in stable schizophrenia patients.

*Am J Psychiatry* 2017; 00:1-8; doi: 10.1176/appi.ajp.2017.17010122

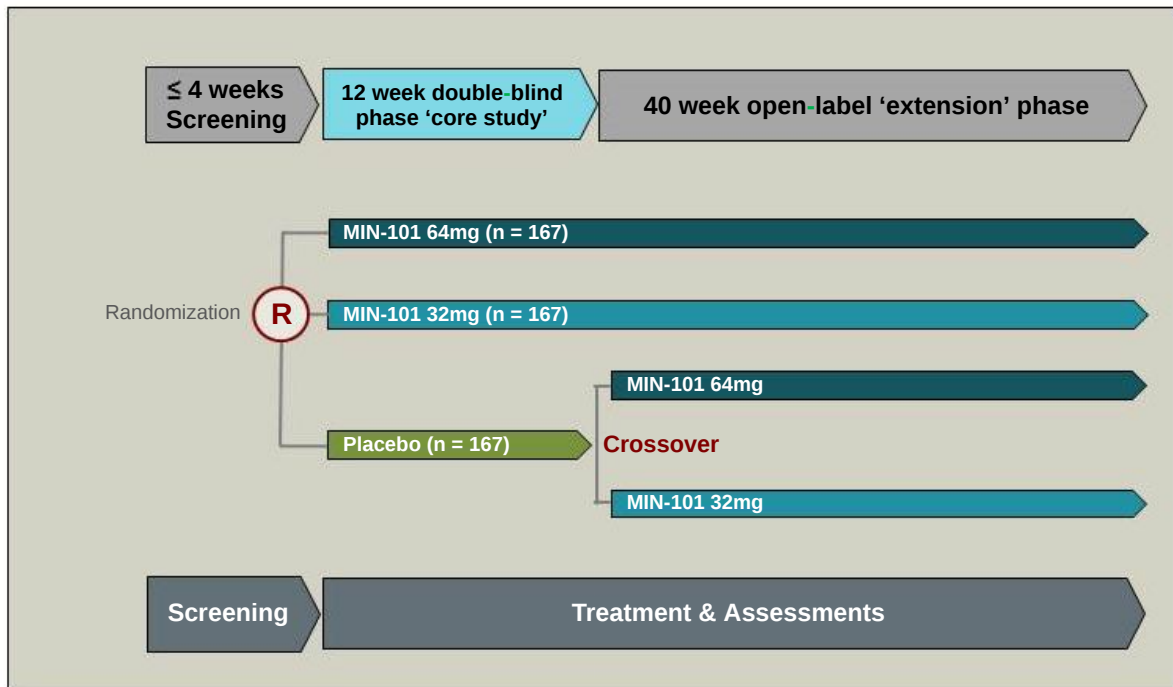
## MIN-101: Phase 3 initiated December 2017

## Phase 3 efficacy study: confirmatory study design guided by insights from Phase 2b and dialogue with FDA

- **Primary endpoint:** PANSS Negative Symptoms Factor Score (NSFS) according to Marder after 12 weeks administration
- Secondary endpoints: Clinical Global Impression of Severity (CGI-S) and Personal and Social Performance scale (PSP)
- 40 weeks (9 months) open-label extension
- 501 patients randomized 1:1:1 to 32mg & 64mg doses of MIN-101 vs placebo
  - Symptomatically stable patients for several months with moderate to severe negative symptoms (>20 PANSS NSFS) and stable positive symptoms
- If patients are on antipsychotic medication, switch to MIN-101 without long wash-out periods so as to mimic clinical practice
- Study carried out in US (approx 30% of patients) and Europe



## MIN-101 Phase 3 study design: monotherapy, double-blind, placebo-controlled in schizophrenic patients with negative symptoms



Phase 3 compared to Phase 2b: same patient population; same double-blind duration; same doses; PANSS negative score primary endpoint; CGI & PSP secondary endpoints; 40 weeks extension allows 1 year safety coverage

## MIN-101: Route to the schizophrenia market

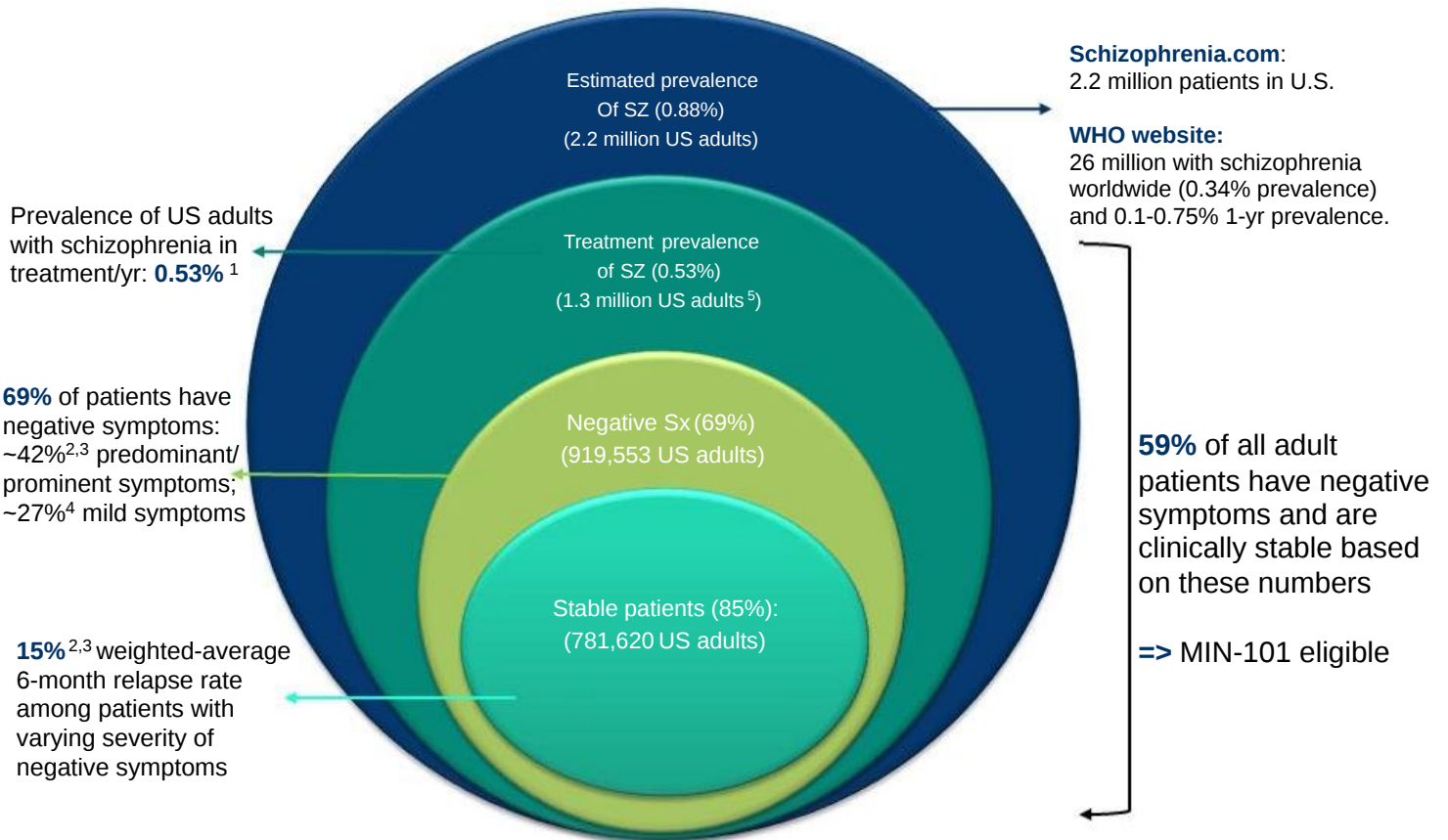
# MIN-101 is unique in the late-stage schizophrenia pipeline: a monotherapy targeting negative symptoms in maintenance phase

Indications	Acute studies	Maintenance & Sub-population studies	
		Negative Symptoms, Residual positive symptoms, and Niche populations	Long-Acting Injectables or Patch
	<p><b>Alkermes</b> <b>ALKS 3831</b> (Mu-opioid antagonist + olanzapine)</p> <p><b>Intra-Cellular Therapies</b> <b>ITI-007 (lumateperone)</b> (5-HT<sub>2A</sub> antagonist, D<sub>2</sub>/D<sub>3</sub> modulator, SSRI)</p> <p><b>Reviva</b> <b>RP 5063</b> (D<sub>2,3,4</sub> &amp; 5-HT<sub>1A+2A</sub> partial agonist + 5-HT<sub>2B,6,7</sub> antagonist)</p>	<p><b>MINERVA</b> <b>MIN-101</b> (5-HT<sub>2A</sub> &amp; σ<sub>2R</sub> antagonist) <b>Negative symptoms monotherapy</b> in stable patients with switch study</p> <p><b>Lu AF35700</b> (D<sub>1</sub>, 5-HT<sub>2A</sub> &amp; 5-HT<sub>6</sub> antagonist) Tx-resistant monotherapy with switch study vs. RIS and OLA (2ry EP negative symptoms)</p> <p><b>ACADIA Pharmaceuticals</b> <b>ACP-103 (pimavanserin)</b> (5-HT<sub>2A</sub> inverse agonist) 2 indications: -Residual positive symptoms as add-on -<b>Negative symptoms as add-on</b></p> <p><b>SyneuRx</b> <b>NaBen sodium benzoate</b> (D-amino acid oxidase inhibitor) 3 indications: -Residual positive symptoms as add-on Orphan designations: -Adolescent monotherapy -Clozapine refractory add-on</p>	<p><b>INDIVIOR</b> <b>RBP-7000</b> (once-monthly, SR risperidone)</p> <p><b>Risperidone implant</b> (6 monthly, nonbiodegradable risperidone drug-eluting stent)</p> <p><b>HP 3070</b> (transdermal patch of asenapine)</p> <p><b>Risperidone ISM</b> (once-monthly IM risperidone)</p>



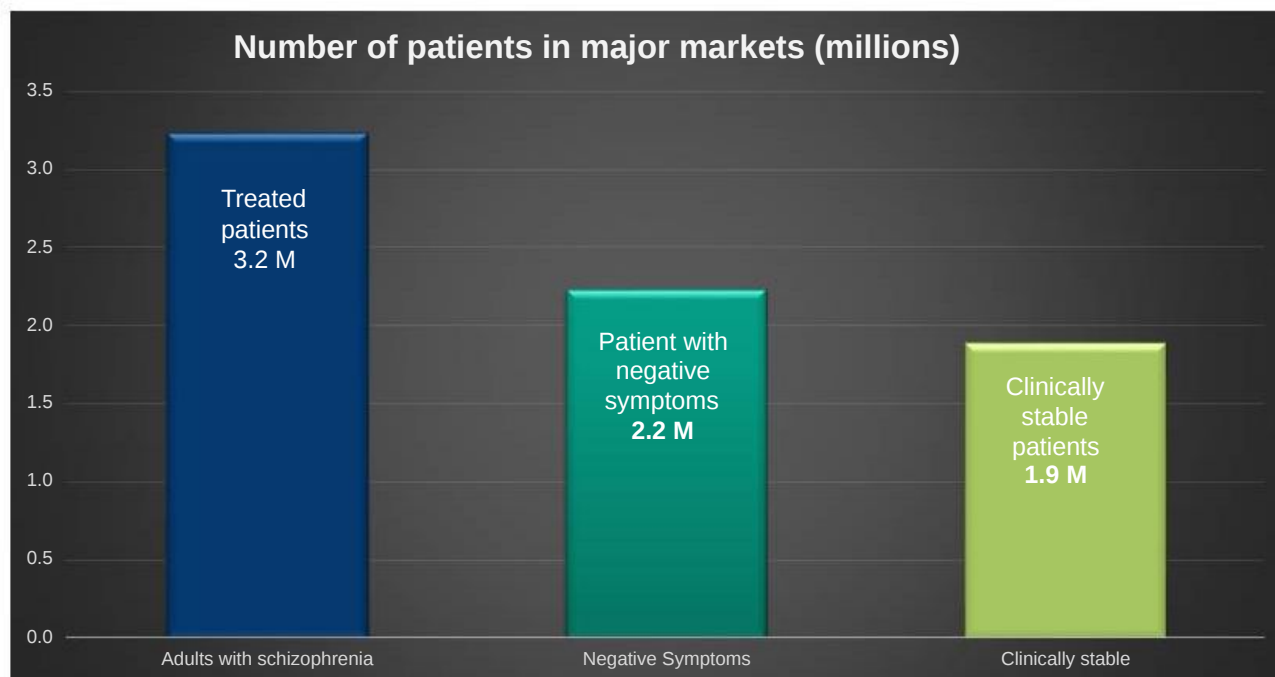
Source: Dec 2017; Cambridge Healthcare Research (CHR) Limited. UK

**Studies show 69% of adult patients with schizophrenia have negative symptoms and 85% are clinically stable, U.S. 2016 patient estimates below**



1. Wu 2006; 2. Toumi 2017; 3. Haro 2015; 4. Nordstroem 2017; 5. [www.census.gov/quickfacts](http://www.census.gov/quickfacts) (July 1, 2016 adult population)

Approximately 2.2 million patients with schizophrenia in major markets (US, EU5, Japan) have negative symptoms and nearly 2 million are stable and may be eligible for MIN-101 monotherapy



Population estimates: [www.census.gov/quickfacts/](http://www.census.gov/quickfacts/), [www.ons.gov.uk/peoplepopulationandcommunity/](http://www.ons.gov.uk/peoplepopulationandcommunity/), [www.insee.fr/en/statistiques/](http://www.insee.fr/en/statistiques/), [www.istat.it/en/](http://www.istat.it/en/), [www.ine.es/dyngs/INEbase/en/](http://www.ine.es/dyngs/INEbase/en/), [www.destatis.de/EN/www.stat.go.jp/english/data/jinsui/tsuki/](http://www.destatis.de/EN/www.stat.go.jp/english/data/jinsui/tsuki/), [en.wikipedia.org](http://en.wikipedia.org) (populations of IT, DE, ES), [populationpyramid.net](http://populationpyramid.net) (for % adults in IT, DE, ES)  
Schizophrenia treatment prevalence estimate, proportion of patients with negative symptoms and % clinically stable (same as prior slide, same references).



# Seltorexant

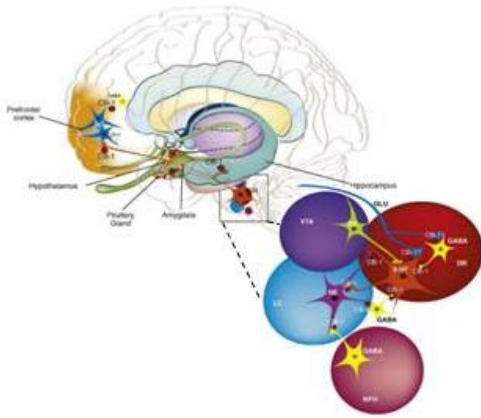
MIN-202 / JNJ42847922

**A drug to treat insomnia & major depressive disorder by restoring physiological sleep**

A co-development/co-commercialization program with:



# Orexin system: neurobiology targets circuits that mediate sleep and mood symptoms



Depressive Symptom	Orexinergic Domain
Depression/Irritability	Emotion/Arousal
Low Self View/Guilt	Emotion
Loss of Interest & Pleasure	Reward/Motivation
Suicide/Death Ideation	Reward/Motivation
Sleep Disturbance	Sleep-Wake
Agitation, Restlessness	Arousal/Energy Balance

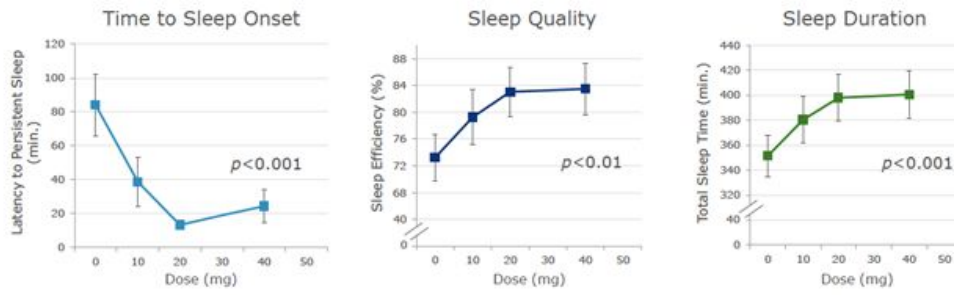
## Name

## MoA

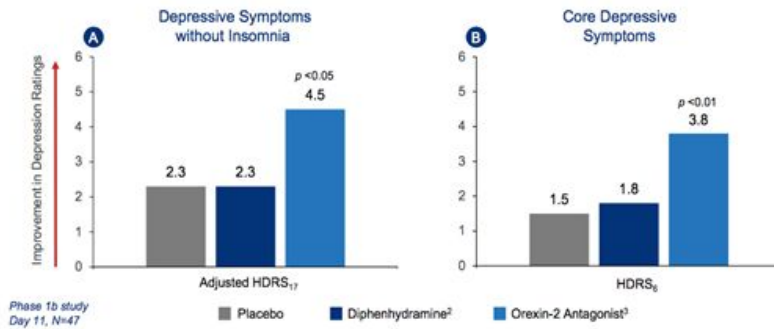
## PK/PD profile

Seltorexant	Selective Orexin-2 Antagonist	<ul style="list-style-type: none"> <li>Highly selective for Orexin-2 (relative to Orexin-1)</li> <li>Short Tmax (30 minutes) - produces rapid onset of effect</li> <li>Short half-life (2 hours) - minimizes daytime "hangover"</li> </ul>
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# Seltorexant studies in MDD with comorbid insomnia shows improvements of insomnia and depressive symptoms



Reference: Internal data, study 42847922ED1002, disclosed by Minerva Neurosciences, Q1 2015.



1. ACP, 2016. [ClinicalTrials.gov NCT02479058](https://clinicaltrials.gov/ct2/show/study/NCT02479058)  
2. Diphenhydramine (Benadryl), included as a placebo  
3. JNJ-7922

HDRS<sub>17</sub> = 17-item Hamilton Depression Rating Scale  
Adjusted HDRS<sub>17</sub> = HDRS with the 3 items related to sleep subtracted  
HDRS<sub>5</sub> = 5-item subscale encompassing the core symptoms of depression





## Seltorexant Phase 2b program: two trials in MDD and one in Insomnia ongoing

### First MDD trial initiated Sep 2017 (clinicaltrials.gov: NCT03227224)

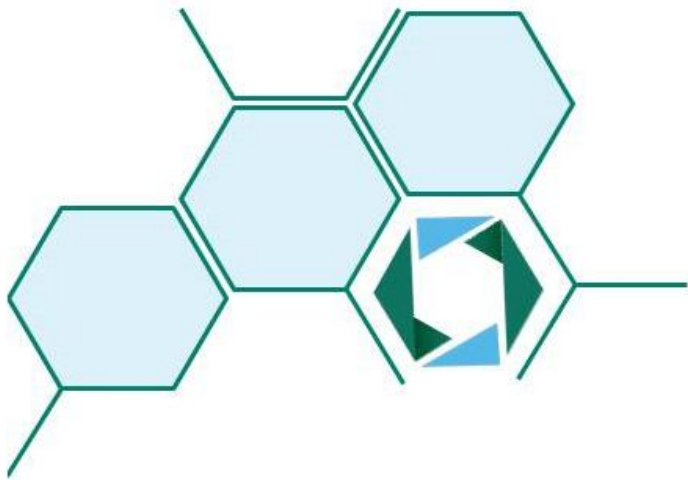
- Double-blind, randomized, parallel-group, placebo-controlled adaptive-dose finding study
- 4-week screening, 6-week double-blind treatment and 2-week follow-up
- ~ 280 patients planned to be enrolled at >85 clinical sites in the U.S., Europe, Russia and Japan
  - safety & tolerability and dose response and efficacy in up to 3 doses of seltorexant

### Second MDD trial initiated Dec 2017 (clinicaltrials.gov: NCT03321526)

- Double-blind, randomized, flexible-dose parallel-group study
- 4-week screening, 6-month double-blind treatment and 2-week follow-up
- ~ 100 patients planned to be enrolled at ~34 clinical sites in the U.S.
  - assess the efficacy of flexibly dosed seltorexant compared to flexibly dosed quetiapine as adjunctive therapy to baseline antidepressant therapy (either an SSRI or SNRI) in delaying time to all-cause discontinuation of study drug over a 6-month treatment period

### Insomnia trial initiated Dec 2017 (clinicaltrials.gov: NCT03375203)

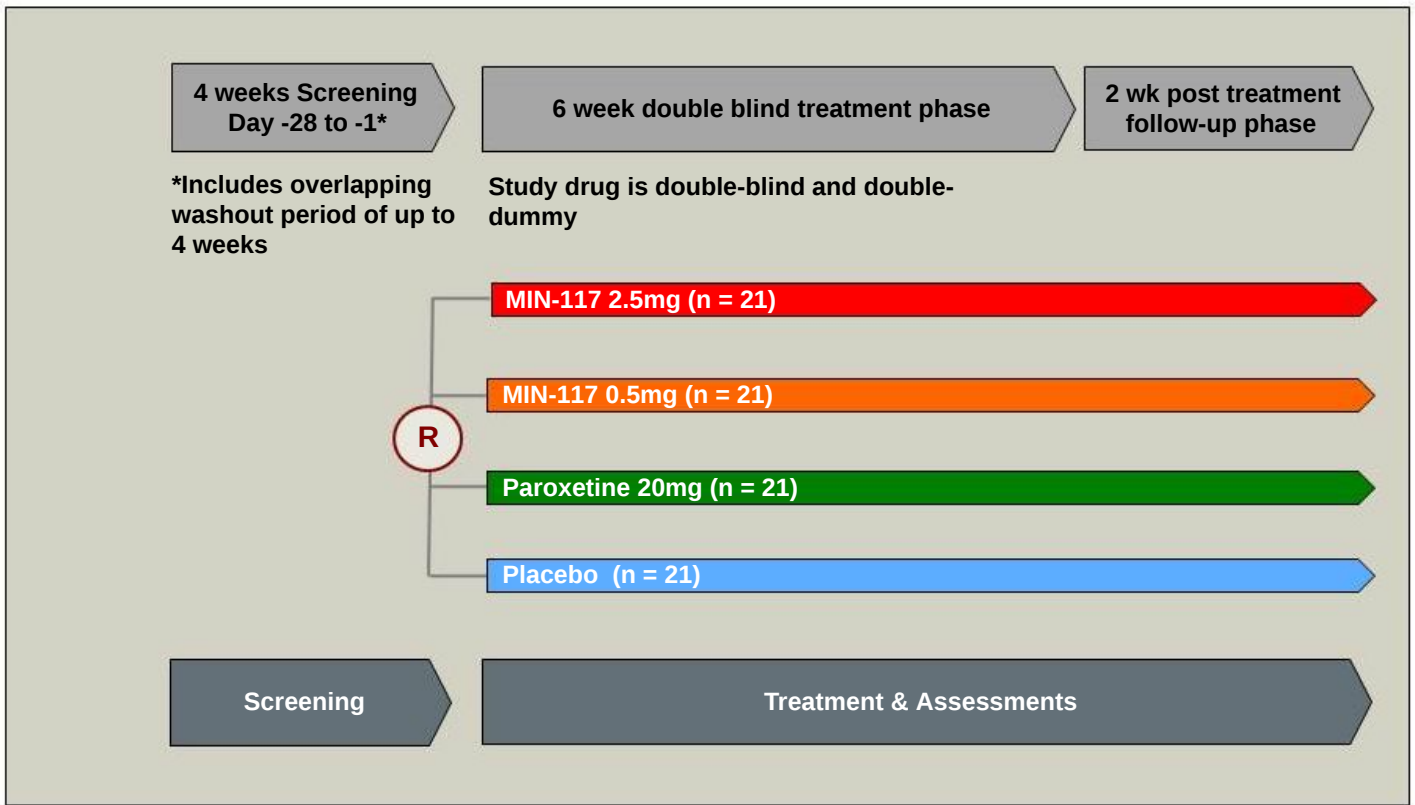
- Double-blind, randomized, parallel-group, active- and placebo-controlled dose finding study
- Up to 61-day duration, including screening and follow-up
- ~ 360 patients planned to be enrolled at clinical sites in the U.S., Europe and Japan
  - assess the dose-response of three doses of seltorexant compared to placebo on sleep onset as measured by latency to persistent sleep (LPS) using polysomnography (PSG)
  - assess the dose-response of these doses compared to placebo on wake after sleep onset (WASO) over the first six hours using PSG
  - compare the effects of seltorexant on sleep and cognition to those effects of zolpidem



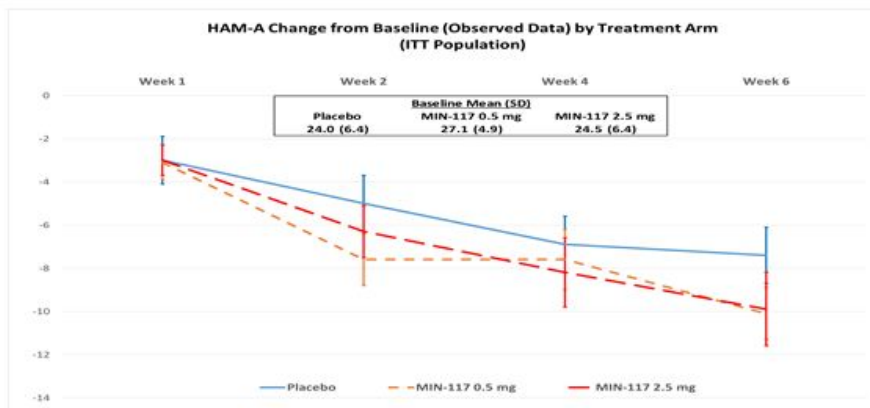
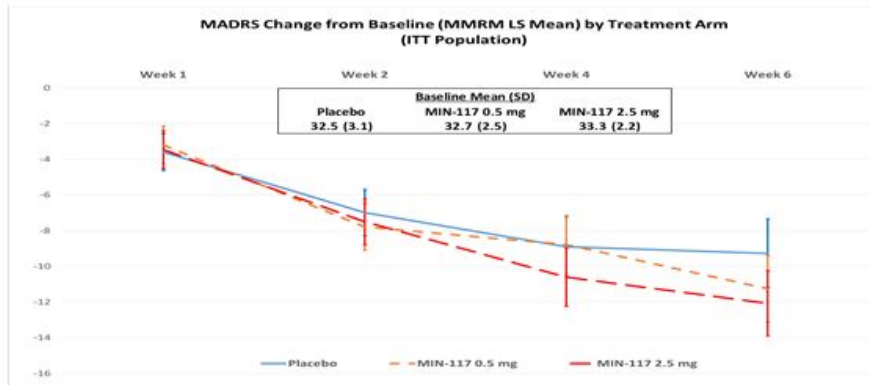
# MIN-117

Addressing the unmet medical needs of patients with Major Depressive Disorder and anxiety symptoms

# Phase 2a study designed to explore unmet needs in patients with MDD



## The Phase 2a results show effect on primary endpoint in depression as well as noted effect on anxiety



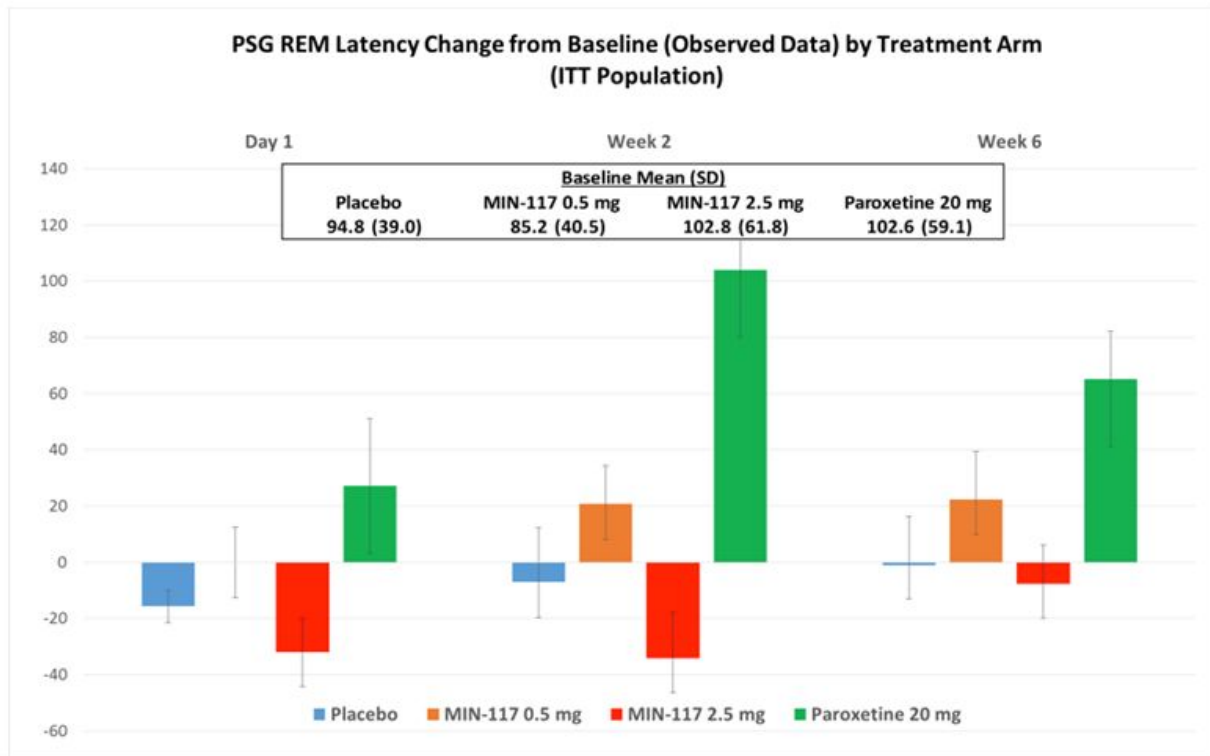
Exploratory study for dose finding, safety and efficacy – not statistically powered:

Results:

- ✓ Efficacy on depressive symptoms
- ✓ Onset evident as early as 2 weeks
- ✓ Efficacy on anxiety symptoms
- ✓ Both doses of MIN-117 are well tolerated, no sexual s/e, cognitive benefits

Assay sensitivity confirmed by positive separation of Paroxetine from placebo

**Sleep polysomnography shows intact REM latency resulting in preservation of sleep architecture and continuity of sleep, an important product differentiator**

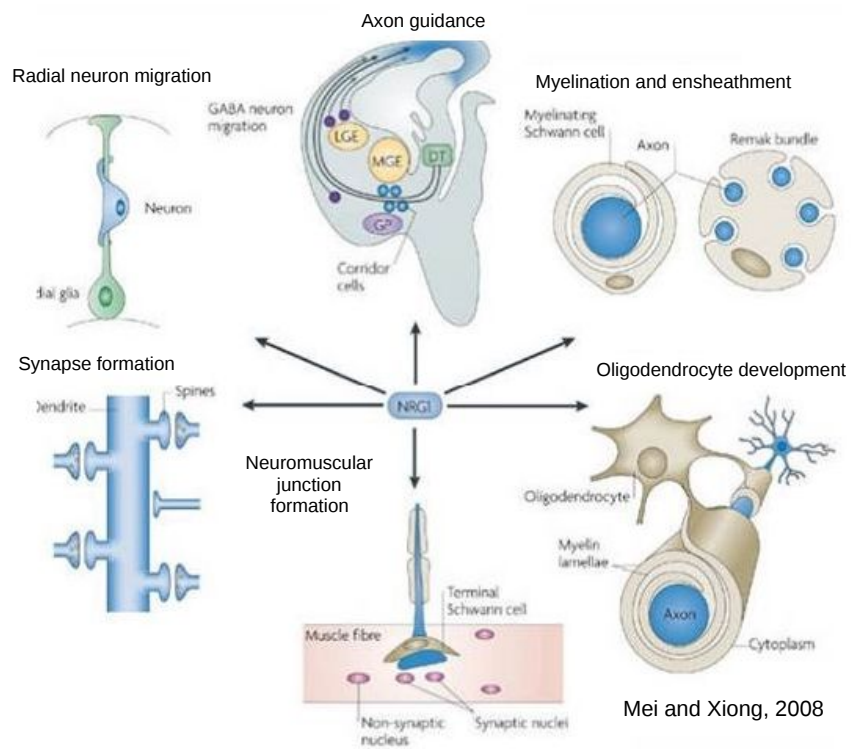




# MIN-301

A protein drug with disease modifying potential for the treatment of unmet medical needs in Parkinson's Disease and other major CNS indications

# Neuregulin-1 (NGR1) has multiple roles in neuronal development offering potential for neuronal repair in several CNS indications

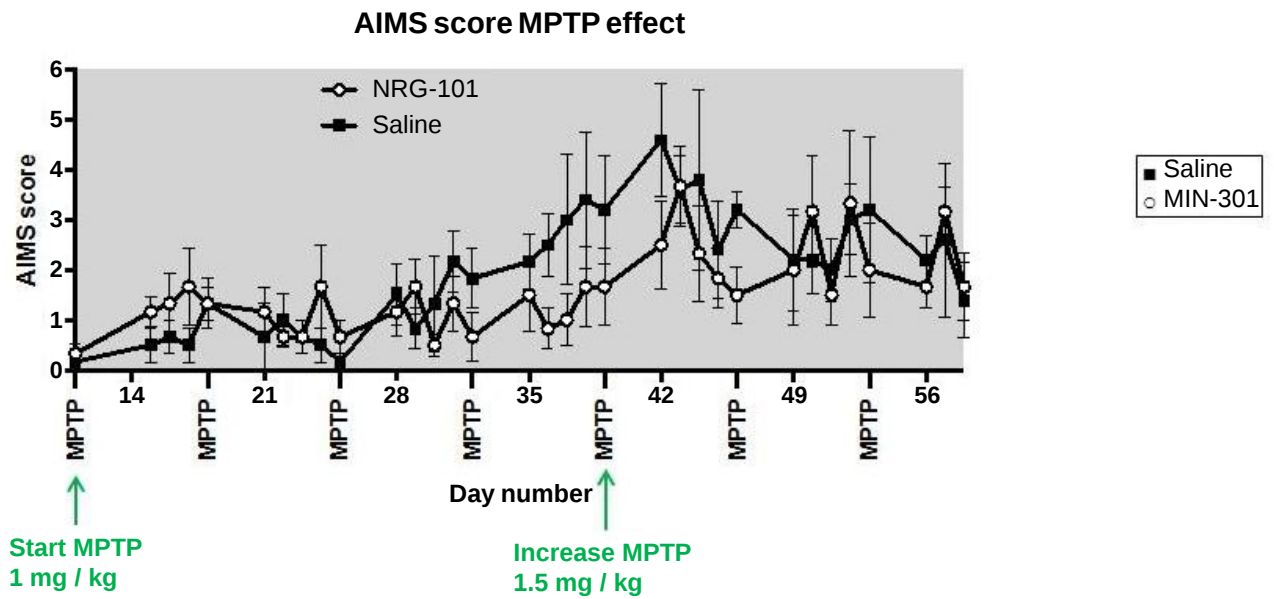


NRG1 controls key neuronal development pathways

Initial clinical focus will be on treatment of Parkinson's Disease based on preclinical models.

## Animal models (non-human primates):

Effect of treatment on abnormal involuntary movements scale (AIMS)



- Clear MPTP-induced increase in AIMS scores
- Scores in MIN-301-treated animals lower during low MPTP (< 1 mg/kg) induction as compared to placebo



## Financial position

- ~\$143.3 million cash balance (cash, cash equivalents and marketable securities) at September 30, 2017
- Q3 2017 cash inflow
  - Public offering July 5, 2017 net proceeds ~ \$41.6 M
  - \$30 M received from J&J in connection with renegotiation of collaboration in August 29, 2017
- Shares outstanding October 31, 2017: ~38.7 M (~42.9 M fully diluted)

## Innovative pipeline of four compounds and multiple indications in the CNS space

Program	Primary Indications	MoA	Pre-clinical	Phase 1	Phase 2	Phase 3
<b>MIN-101</b>	Negative symptoms in Schizophrenia	<ul style="list-style-type: none"> <li>• 5-HT<sub>2A</sub> antagonist</li> <li>• Sigma<sub>2</sub> antagonist</li> </ul>	Phase 3 initiated Dec 2017 (MIN-101-C07)			
<b>Seltorexant MIN-202</b>	Primary Insomnia  Major Depressive Disorder as adjunctive therapy	<ul style="list-style-type: none"> <li>• Selective Orexin<sub>2</sub> antagonist</li> </ul>	Phase 2b initiated Dec 2017 (ISM2005) Phase 2b initiated Sep 2017 (MDD2001) Phase 2b initiated Dec 2017 (MDD2002)			
<b>MIN-117</b>	Major Depressive Disorder in monotherapy	<ul style="list-style-type: none"> <li>• 5-HT<sub>1A</sub></li> <li>• 5HT transporter</li> <li>• Alpha-1a, b</li> <li>• Dopamine transporter</li> <li>• 5-HT<sub>2A</sub> antagonist</li> </ul>	Phase 2b planned H1 2018 (MIN-117-C03)			
<b>MIN-301</b>	Parkinson's Disease	<ul style="list-style-type: none"> <li>• Neuregulin 1<math>\beta</math>1 activating ErbB4</li> </ul>	Pre-clinical			