
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): September 24, 2015

Minerva Neurosciences, Inc.

(Exact name of registrant as specified in its charter)

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)

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 7.01 Regulation FD Disclosure

On September 24, 2015, Minerva Neurosciences, Inc. (the “Company”) issued a press release announcing an update on two ongoing clinical trials with the Company’s MIN-202 (JNJ-42847922) product candidate, a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV.

A copy of the above referenced press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and a copy of the Company’s updated corporate presentation that includes supporting data for the press release is furnished as Exhibit 99.2 to this Current Report on Form 8-K. This information, including the information contained in the press release furnished as Exhibit 99.1 and the presentation furnished as Exhibit 99.2, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any of the Company’s filings, whether made before or after the date hereof, regardless of any general incorporation language in any such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of the Company dated September 24, 2015
99.2	Presentation of the Company dated September 24, 2015

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: Senior Vice President, General Counsel and Secretary

Date: September 24, 2015

INDEX OF EXHIBITS

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Contact:

William B. Boni
VP, Investor Relations/
Corp. Communications
Minerva Neurosciences, Inc.
(617) 600-7376

FOR IMMEDIATE RELEASE**MINERVA NEUROSCIENCES PROVIDES UPDATE ON CLINICAL DEVELOPMENT
PROGRAM WITH MIN-202, SELECTIVE OREXIN-2 RECEPTOR ANTAGONIST****Patient recruitment ongoing in trials in insomnia disorder and
adjunctive major depressive disorder**

Waltham, MA, September 24, 2015 – Minerva Neurosciences, Inc. (NASDAQ: NERV), a clinical-stage biopharmaceutical company focused on the development of innovative therapies to treat central nervous system (CNS) disorders, today provided an update on two ongoing clinical trials with MIN-202 (JNJ-42847922), a selective orexin-2 receptor antagonist under joint development with Janssen Pharmaceutica NV. Patient recruitment is ongoing in both trials, which include a Phase 2a trial in insomnia disorder and a Phase 1b trial in adjunctive major depressive disorder (MDD).

“We are pleased with the progress that is being made in the development of MIN-202 in insomnia and adjunctive MDD,” said Dr. Remy Luthringer, president and chief executive officer of Minerva. “The ongoing trials in these indications are designed to provide assessments of the effects of this compound in sleep and major depressive disorder. We believe that MIN-202 has the potential to physiologically regulate biological rhythm and control of the wake drive based on its unique mechanism of action as a selective orexin-2 receptor antagonist.”

Insomnia trial (clinicaltrials.gov identifier: NCT02464046):

The Phase 2a trial in insomnia disorder is a randomized, placebo-controlled double-blind study to evaluate treatment with MIN-202 in subjects with insomnia disorder without psychiatric co-morbidity. It is estimated that 26 patients will be enrolled. Half of these patients will receive MIN-202 for five days, followed by a washout period and then placebo for five days. The other half will receive placebo first, followed by a washout period and then MIN-202 under the same schedule.

The primary endpoint of this trial is sleep efficiency as measured by polysomnography, and secondary endpoints include additional assessments of sleep, mood and cognition, as well as safety. The trial is being conducted at clinical sites in the U.S. and Europe, and the data readout is expected in the first half of 2016.

Adjunctive MDD trial (clinicaltrials.gov identifier: NCT02476058):

The Phase 1b trial in adjunctive MDD is a randomized, diphenhydramine- and placebo-controlled double-blind study to evaluate treatment with MIN-202 in subjects with MDD. It is estimated that 48 patients will be enrolled in three groups, which will be treated with MIN-202, diphenhydramine and placebo, respectively, while maintained on their antidepressant regimens.

The primary endpoint of this trial is safety, and secondary endpoints include assessments of depressive symptomology, cognition and sleep. The trial is being conducted at clinical sites in Europe, and the data readout is expected in the first half of 2016.

About Minerva Neurosciences

Minerva Neurosciences, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of a portfolio of products to treat CNS diseases. Minerva's proprietary compounds include: MIN-101, in development for the treatment of schizophrenia; MIN-202 (JNJ-42847922), in development for the treatment of insomnia; MIN-117 in development for the treatment of major depressive disorder; and MIN-301 in development for the treatment of Parkinson's disease. Minerva's common stock is listed on the NASDAQ Global Market under the symbol "NERV." For more information, please visit www.minervaneurosciences.com.

Forward-Looking Safe Harbor Statement

This press release contains forward-looking statements 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 press release, and involve certain risks and uncertainties. Forward-looking statements include statements herein with respect to the timing and results of future clinical milestones regarding MIN-202; the timing of future clinical trials and results of clinical trials regarding MIN-202; the clinical and therapeutic potential of MIN-202; our ability to successfully develop and commercialize MIN-202; the sufficiency of our current cash position to fund our operations; and management's ability to successfully achieve its goals. These forward-looking statements are only predictions and may differ materially from actual results due to a variety of factors including, without limitation, whether MIN-202 will advance further in the clinical trials process and whether and when, if at all, it will receive final approval from the U.S. Food and Drug Administration or equivalent foreign regulatory agencies and for which indications; whether MIN-202 will be successfully marketed if approved; whether our therapeutic product discovery and development efforts will be successful for MIN-202; our ability to achieve the results contemplated by our co-development agreements; management's ability to successfully achieve its goals; 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 June 30, 2015, filed with the Securities and Exchange Commission on August 5, 2015. Copies of reports filed with the SEC are posted on our website at www.minervaneurosciences.com. The forward-looking statements in this press release are based on information available to us as of the date hereof, and we disclaim any obligation to update any forward-looking statements, except as required by law.



MINERVA
NEUROSCIENCES, INC.

*Innovative Mechanisms With Transformative Potential
in Central Nervous System (CNS) Diseases*

September 24, 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. 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.

Minerva: Unique presence in CNS

- Extensive management leadership and expertise in CNS
 - Experience in more than 750 clinical trials includes multiple products approved by the FDA
- Harnessing innovative mechanisms of action
 - Biological insights and unmet needs drive development of differentiated products
- Platform approach based on science
 - Potential cross-indication synergy based on prevalent target pathologies and symptomologies
- Portfolio provides multiple opportunities for value creation
 - Four first-in-class compounds with several clinical milestones expected by mid-2016

Pipeline of potentially transformative CNS therapies

Program	Primary Indication	Preclinical	Phase I	Phase II	Milestones
MIN-101	Schizophrenia	Phase IIa completed, Phase IIbongoing			Topline IIb data expected Q2 2016
MIN-117	Major Depressive Disorder	Phase Ib completed, Phase IIaongoing			Topline IIa data expected H1 2016
MIN-202	Primary Insomnia	Phase IIa ongoing			Data expected from both trials H1 2016
	Comorbid Insomnia	Phase Ib ongoing (MDD)			
MIN-301	Parkinson's Disease	Preclinical			IND or IMPD in 2016; Phase I expected to initiate thereafter

Schizophrenia: a devastating chronic disease

High burden for patients, families and society

- Affects ~30 million people worldwide ¹
- Often starts in late teens or early adulthood ²
- 75% patients are non-adherent to existing therapies within 2 years of being discharged from hospital ³
- The largest unmet medical needs in schizophrenia are negative symptoms, cognitive impairment: no treatment is approved to treat those symptoms ⁴

1. *Global Prevalence of Schizophrenia PLOS Medicine, 2005*

2. *NIMH*

3. *Weiden PJ et al. Psychiatr Serv, 1995; 46:1049-1054*

4. *Rabinowitz J et al. (2013) Schizophrenia Research*



What do we need?

Treatments that:

- Improve negative symptoms and cognitive impairment
- Free patients from debilitating side-effects
- Improve sleep

Mechanism of action

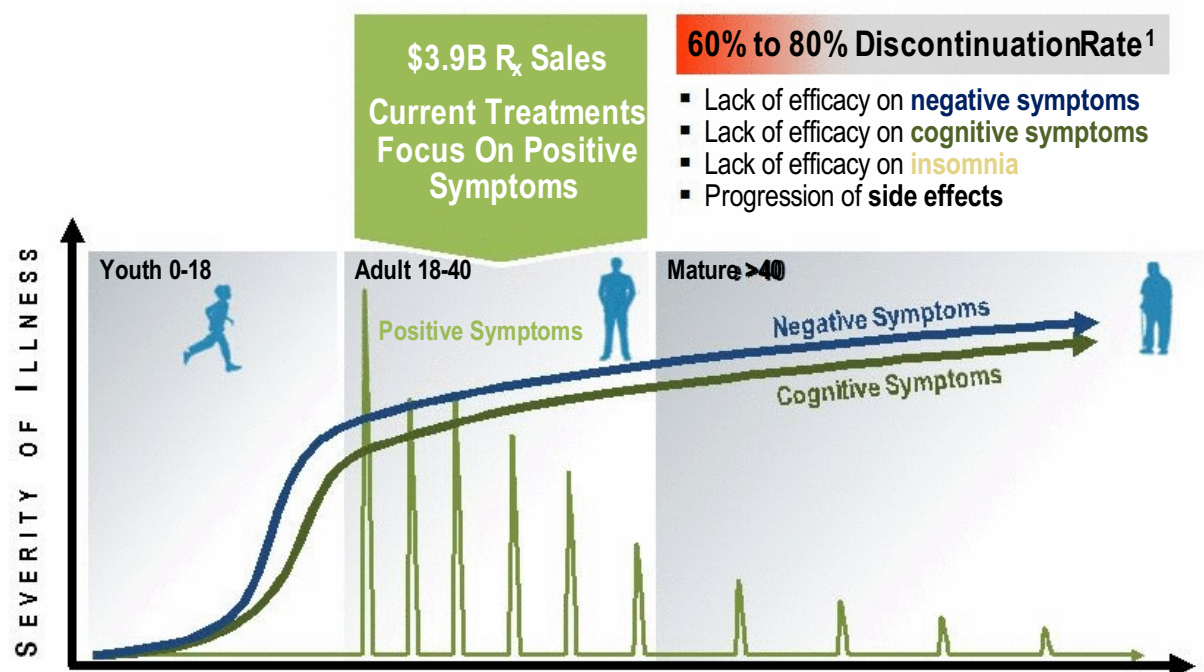
5-HT_{2A} antagonist

Sigma₂ antagonist

Potential benefits / differentiation

Address negative
symptoms, cognition
and sleep disorders,
in addition to
positive symptoms

An effective and safe lifelong treatment for schizophrenia remains a significant unmet need



A Multi-center, Inpatient and Ambulatory, Phase IIa, 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_Δ signal observed in non-clinical and Phase I studies
- Get first hints of therapeutic activity in schizophrenic patients

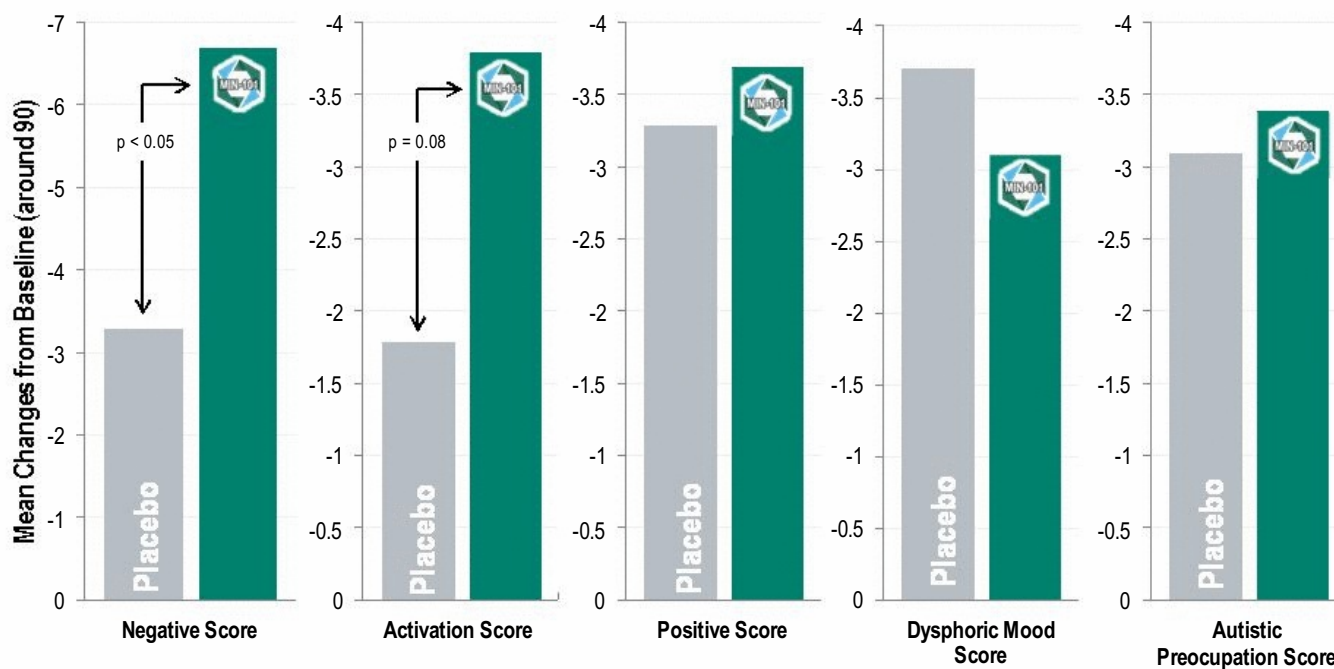
▪ Secondary Endpoints:

- 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 MIN-101 on QTc_Δ at T_{max}/C_{max} 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

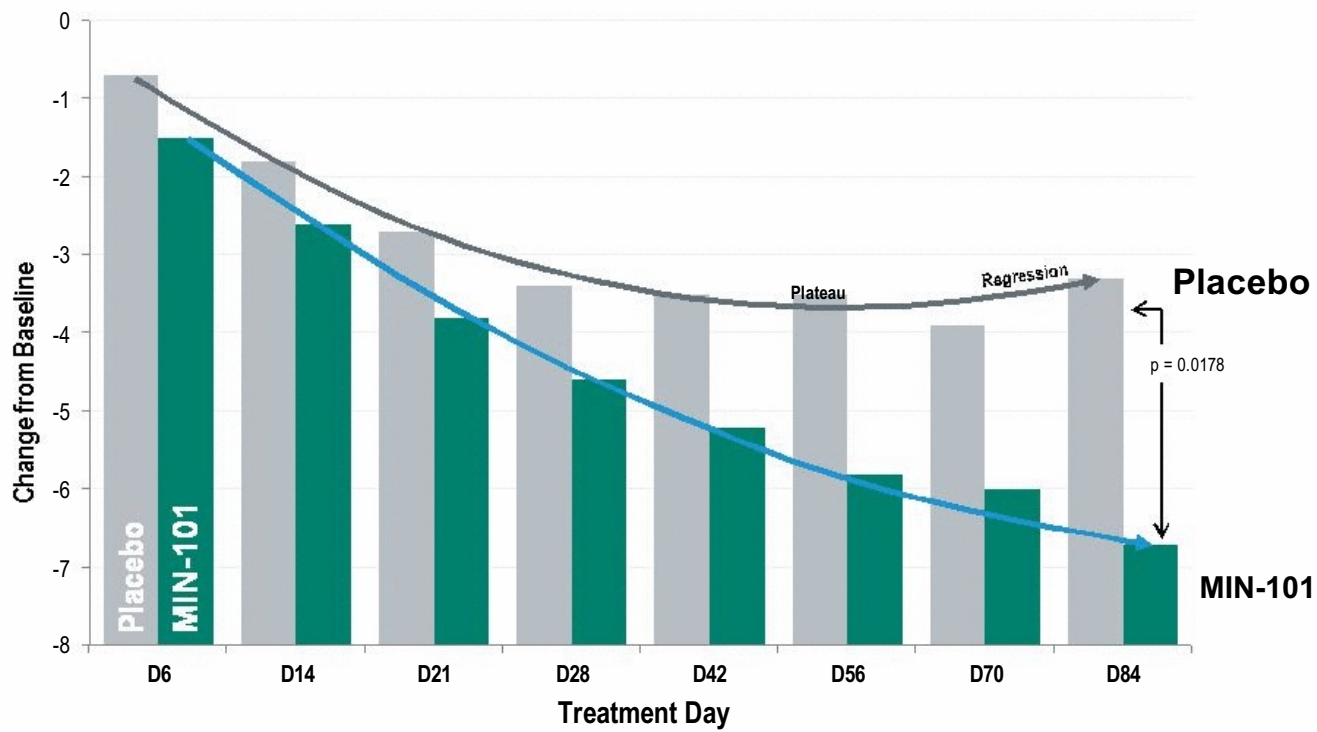
MIN-101: Phase IIa compelling efficacy on spectrum of symptoms

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

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

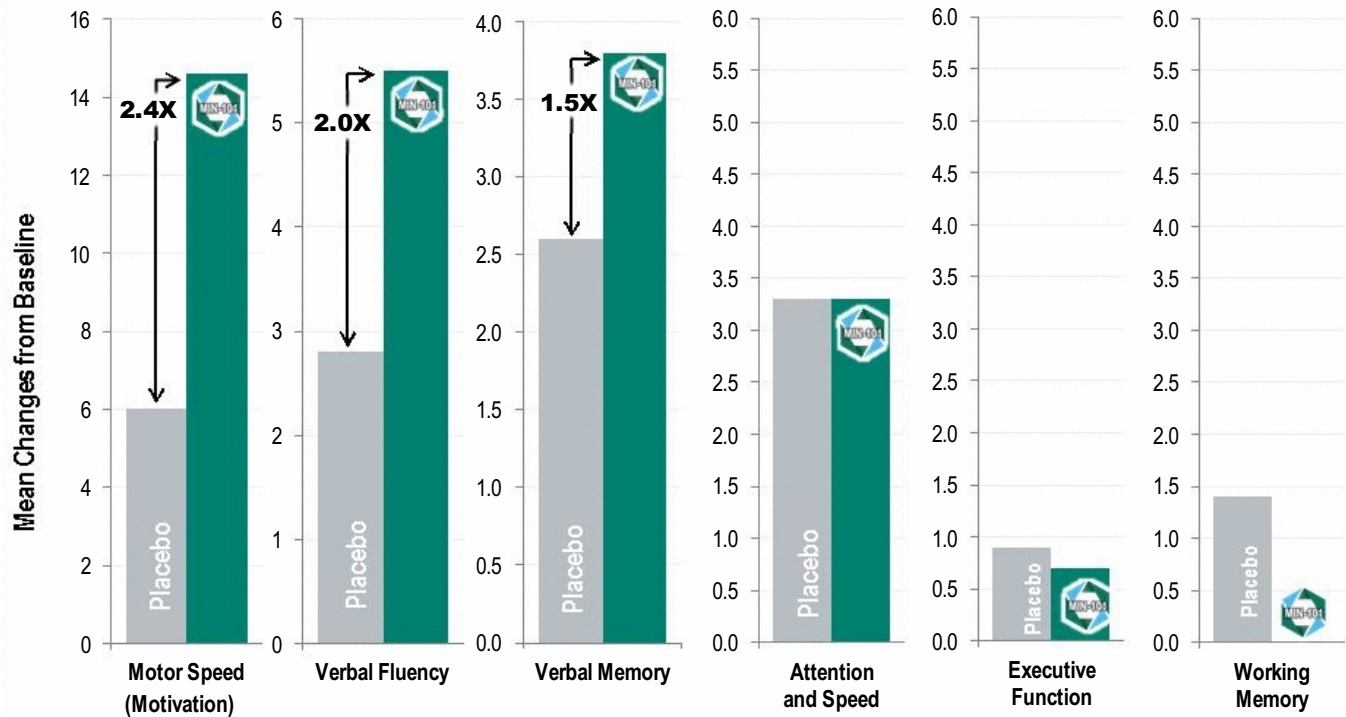


MIN-101: Phase IIa showed improvement in overall psychopathology of schizophrenia with outstanding efficacy on negative symptoms (32mg bid)

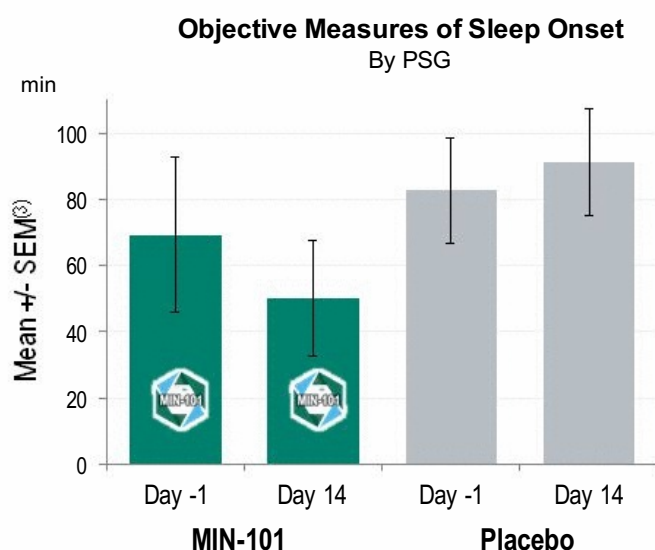


MIN-101: Compelling efficacy on cognition (Phase IIa)

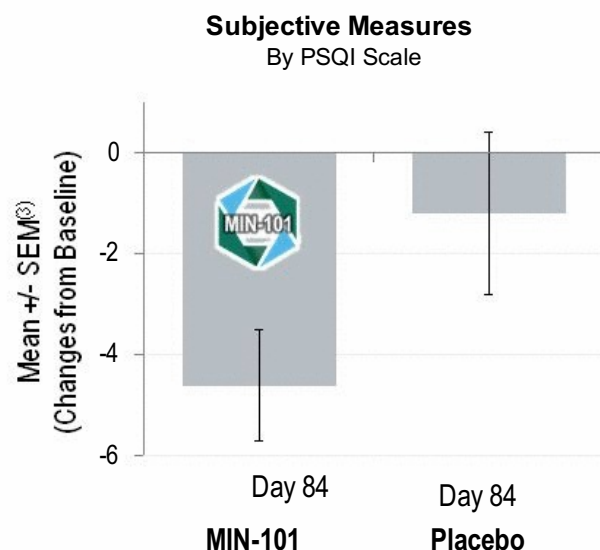
Improves Several Cognitive Dimensions After Three Months⁽¹⁾



MIN-101: Compelling efficacy on sleep objective (PSG)¹ and subjective (PSQI)² 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

MIN-101: Phase IIa safety evaluation

Side Effect	Evaluation	Relative to Atypical Antipsychotics
AEs and SAEs	Limited and comparable to placebo	Improved
Weight Gain, Waist Circumference	No increase	Improved
Prolactin and Laboratory Tests	No increase	Improved
Extra-pyramidal Symptoms	No effect on Simpson Angus Scale	Improved
Vigilance	No sedation	Improved
Vital Signs – Cardiovascular	Minor QTc prolongation with the supra-therapeutic dose used in phase IIa (as expected)	Comparable

MIN-101CO3: Phase IIb currently recruiting

A Phase IIb, Multi-Centre, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled 12 Week 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									A	A	IN	A	IN	A
D-21	D-3 to D-1	Day-1	D1	D2	W2	W4	W8	W12		W 14	W 18	W 24	W 30	W 36	W 37
V1	V2	V3	V4	V5	V6	V7	V8	V9		V 10	V 11	V 12	V 13	V 14	V 15
RANDOMIZATION & DOUBLE-BLIND									RANDOMIZATION & SINGLE-BLIND						

234 patients (78: 64mg, 78: 32mg, 78: placebo)

MIN-101CO3: Primary Objective

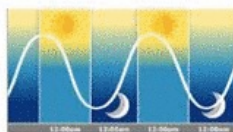
To evaluate the efficacy of MIN-101 compared to placebo in improving the negative symptoms of schizophrenia as measured by the change from Baseline in the Positive and Negative Syndrome Scale (PANSS) negative subscale score of the pentagonal model over 12 weeks of treatment.

MIN-101CO3: Secondary Objectives

- To evaluate the efficacy of MIN-101 compared to placebo in improving other symptoms of schizophrenia as measured by the change from Baseline in the PANSS total score, positive symptoms score, dysphoric mood, activation, and autistic preoccupation sub-scores of the pentagonal model over 12 weeks of double-blind treatment.
- To evaluate the efficacy of MIN-101 compared to placebo in improving symptoms of schizophrenia as measured by changes from Baseline in the PANSS total score and sub-scores according to the 3 factors analysis over 12 weeks of double-blind treatment.
- To evaluate the efficacy of MIN-101 compared to placebo in improving negative symptoms of schizophrenia as measured by the change from Baseline in the Brief Negative Symptoms Scale (BNSS) total score over 12 weeks of double-blind treatment.
- To assess the effects of MIN-101 compared to placebo on the Clinical Global Impression of Severity (CGI-S) and Clinical Global Impression of Improvement (CGI-I) over 12 weeks of double-blind treatment.
- To assess the effects versus placebo of MIN-101 on cognitive function as measured by the Brief Assessment of Cognition in Schizophrenia (BACS) battery over 12 weeks of double-blind treatment.
- To evaluate the safety and tolerability of MIN-101 compared to placebo.
- To assess the pharmacokinetics (PK) profile of MIN-101 and its metabolites using population PK models.
- To assess the persistence of efficacy, and the safety and tolerability of MIN-101 during the 24-week, open-label extension phase.

Insomnia affects about 10% of adults and the majority of people with depression

- ~85% of patients with major depressive disorder have symptoms of insomnia, which often persists despite treatment with currently available sleep medications
 - ~13.6 million Americans have major depression and insomnia
- Most existing treatments “force” sleep, rather than physiologically attenuating the “wake drive”
- The Orexin system regulates the wake drive



Circadian Rhythm

CNS Spectr. 2010 Jun;15(6):394-404.
Insomnia in patients with depression: a STAR*D report.
NIMH



What Do We Need?

Therapies that provide:

- A more physiological approach to treat insomnia
- Rapid onset of action
- Preservation of deep, restful sleep
- Minimal residual daytime sleepiness or cognitive impairment

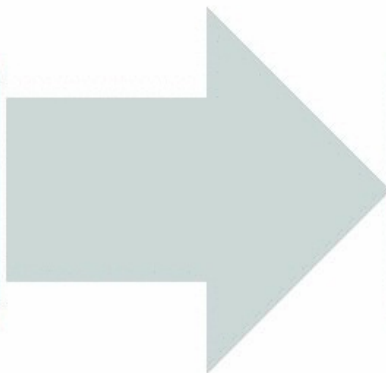
MIN-202 (JNJ-42847922) for Insomnia (primary and co-morbid)

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janssen
PHARMACEUTICAL COMPANIES
of Johnson & Johnson

Mechanism of action

Selective Orexin2
antagonist

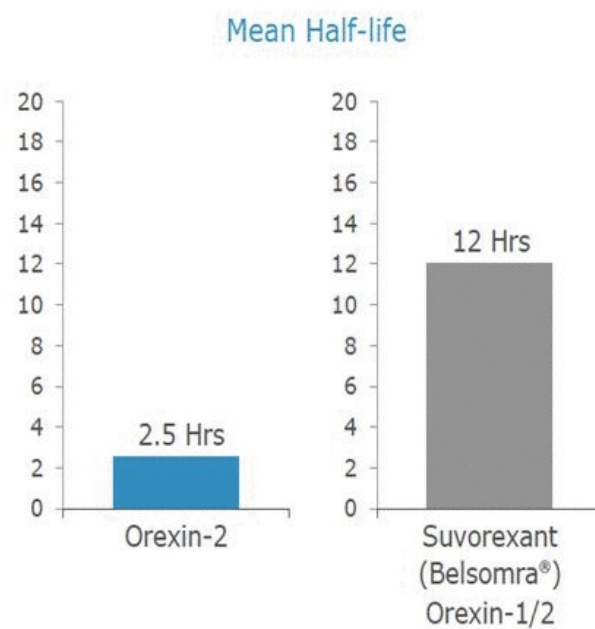


Potential benefits /
differentiation

Physiological
regulation of
biological rhythm
and control of
wake drive

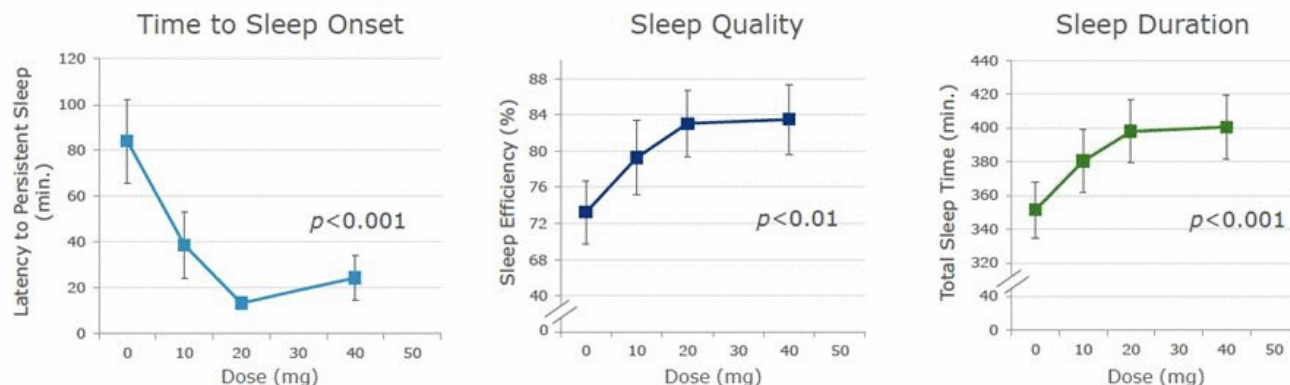
Potential differentiation based on selectivity for the Orexin-2 receptor and half-life

	OREXIN-2R	OREXIN-1R/2R
Sleep Induction (LPS)		
Sleep Maintenance (TST)		
Normal REM/NREM		
Cataplexy Risk		



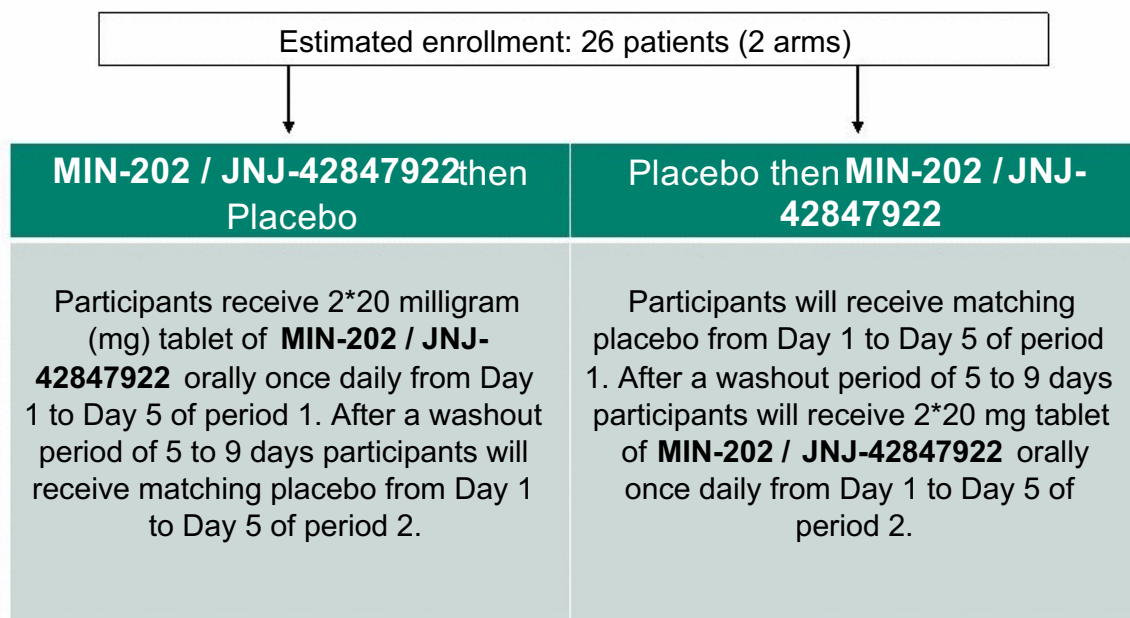
MIN-202 (JNJ-42847922): Selective Orexin-2 antagonist A promising new approach to treat primary insomnia and comorbid insomnia in MDD patients (adjunctive MDD)

Exploratory Phase 1a Study in Patients with Major Depressive Disorder and Insomnia (n=20)



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

A Randomized, Placebo-controlled, 2-way Crossover, Double-Blind Study to Evaluate the Efficacy, Safety and Tolerability of JNJ-42847922 in Subjects With Insomnia Disorder Without Psychiatric Comorbidity



- **Primary outcome measure**
 - Sleep efficiency by polysomnography
- **Secondary outcome measures**
 - Total sleep time by polysomnography
 - Wake time after sleep onset by polysomnography
 - Number of awakenings after persistent sleep by polysomnography
 - Total time spent in deep sleep by polysomnography
 - Mean latency to persistent sleep by polysomnography
 - Leeds sleep evaluation questionnaire (LSEQ) score
 - Subjective assessment of sleep by questionnaire
 - Next morning residual effects by Bond and Lader Visual Analogue Scale
 - Next morning residual effects by cognitive test battery
 - Next morning residual effects by Karolinska Sleepiness Scale
 - Number of participants with adverse events (AEs) and serious AEs

An Exploratory Multicenter, Double-Blind, Diphenhydramine and Placebo-controlled Safety, Efficacy and Biomarker Study With JNJ-42847922 in Subjects With Major Depressive Disorder

Estimated enrollment: 48 patients (3 arms); participants are either antidepressant naïve or being treated with a maximum of two concurrent antidepressants

MIN-202 / JNJ-42847922	Diphenhydramine	Placebo
20 mg capsule, orally, once daily, at bedtime for 10 days in women of childbearing potential or for 4 weeks in all other participants	25 mg capsule, orally, once daily, at bedtime for 10 days in women of childbearing potential or for 4 weeks in all other participants	Matching placebo, orally, once daily, at bedtime for 10 days in women of childbearing potential or for 4 weeks in all other participants

- **Primary outcome measure**
 - Number of participants with AEs or SAEs
- **Secondary outcome measures**
 - Inventory of Depressive Symptomatology-clinician Rated 30 (IDSC30) Score and Structured Interview Guide for Hamilton Depression Scale (SIGH-D) (as combined SIGHD-IDS)
 - Quick Inventory of Depressive Symptoms-16 (QIDS-SR16) Score
 - Ruminative Response Scale (RRS) Score
 - Changes in Major Depressive Disorder (MDD)-related Biomarkers
 - Participants Leeds Sleep Evaluation Questionnaire (LSEQ) Score
 - Computerized cognitive test battery: ISLT (Verbal Learning and Memory) Test
 - Computerized cognitive test battery: Detection (DET) Test
 - Computerized cognitive test battery: Identification (IDN) Test
 - Computerized cognitive test battery: One Back (OBK) Test
 - Computerized cognitive test battery: Groton Maze Learning Test (GMLT)
 - Polysomnography (PSG) objective assessment of latency to persistent sleep
 - Subjective assessment of latency to persistent sleep
 - PSG objective assessment of total sleep time
 - Subjective assessment of total sleep time
 - PSG objective assessment of Wake Time After Sleep Onset (WASO)
 - Subjective assessment of WASO
 - Plasma concentrations for JNJ-42847922

Major Depressive Disorders

Treatments with faster onset and better response, without side effects, are critically needed

- Major depression: primary cause of disability worldwide by 2030 ¹
- ~6 million patients in US with treatment-resistant depression ²
- Only ~30% of patients achieve remission using current treatments ³
- Current therapies have slow onset of effect; typically 4 – 8 weeks



What do we need?

Treatments that:

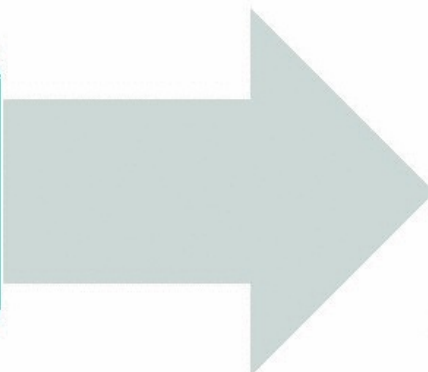
- Act rapidly
- Are effective in patients who do not respond to or receive only partial benefit from existing medicines
- Do not impair cognition or sexual function
- Free patients from debilitating side-effects
- Improve sleep

1. World Health Organisation, "Global Burden of Mental Disorders," 2011
2. IMS and Truven Health
3. Cleveland Clinic Journal of Medicine Volume 75. Number 1 January 2008

MIN-117 for Major Depressive Disorder

Mechanism of action

5-HT1A
5HT Transporter
Alpha-1a,b
Dopamine Transporter
5-HT2A antagonist



Potential benefits / differentiation

Faster onset
Preserve cognition
and sexual function
Treat partial and non-
responders

MIN-117: New generation of treatment for MDD

Acts through multiple mechanisms on several receptors associated with the control of mood

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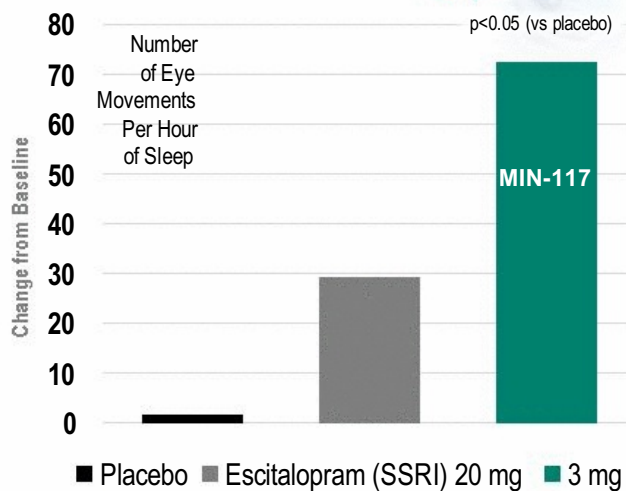
Rapid Onset Potential

- Antagonist on 5-HT_{1A} receptor
- Dopamine reuptake inhibitor

Potential to Manage Partial and Non-Responders

- Serotonin reuptake inhibitor
- Dopamine reuptake inhibitor
- Alpha 1A & B adrenergic receptors

After Two Weeks of Treatment (Phase I):

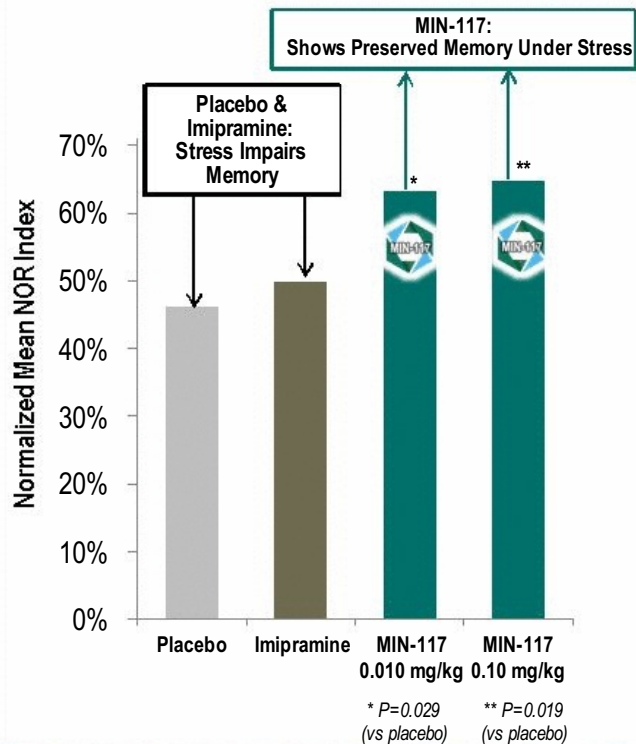


Effects of MIN-117 on REM Density In Healthy Subjects Using PSG

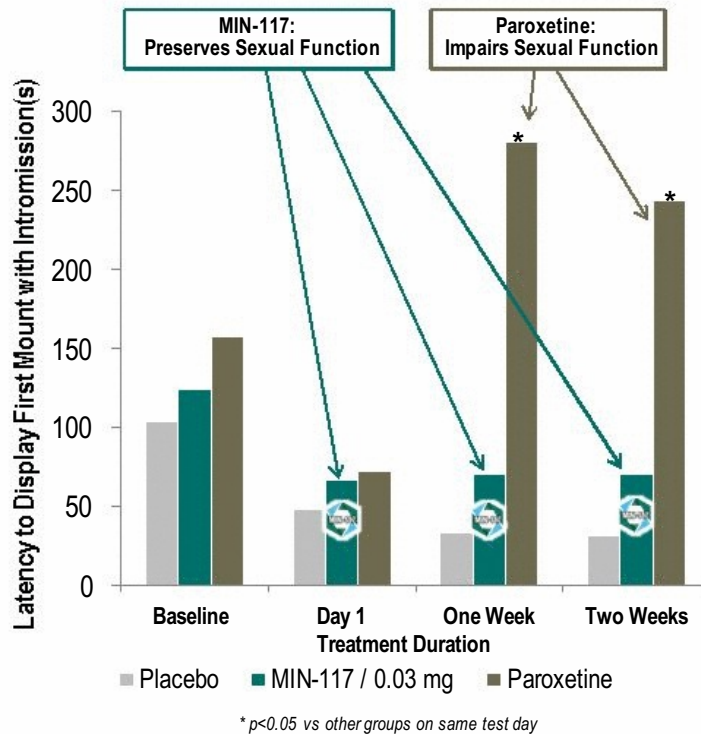
REM sleep improvement as a marker of early onset of therapeutic benefit in humans.

MIN-117: Preserving cognition and sexual function based on results of preclinical studies

Effects on Immediate Memory (a model of cognition)



Effects on Sexual Function



MIN-117: Phase II currently recruiting

A Randomized, Double-Blind, Parallel-Group, Placebo- and Active-Controlled Study to Evaluate the Efficacy and Safety of 2 Doses of MIN-117 in Adult Subjects with Major Depressive Disorder

Study Phase	4-Week Pre-Treatment Phase		6-Week Double-Blind Treatment Phase					2-Week Post-Treatment Follow-up
	Screening & washout Period	Baseline						
Study Day/Week	Day -28 to Day - 3	Day -2 & Day - 1	Day 1	Week 1 Day 8	Week 2 Day 15	Week 4 Day 29	Week 6 Day 43	Week 8 Day 57 (EOS)
Visit Number	1	2a	2b	3	4	5	6	7

RANDOMISATION

80 patients (20: 0.5mg, 20: 2.5mg, 20: paroxetine 20mg, 20 placebo)

MIN-117C01: Primary Objective

To evaluate the efficacy of MIN-117 0.5 and 2.5 mg compared to placebo in reducing the symptoms of a major depressive episode as measured by the change from Baseline in the Montgomery- Asberg Depression Rating Scale (MADRS) total score over 6 weeks of treatment.

MIN-117C01: Secondary Objectives

- To evaluate the efficacy of MIN-117 0.5 and 2.5 mg compared to placebo in onset of antidepressant response as measured by the change from Baseline in the MADRS total score over 6 weeks of treatment.
- To assess the effects of MIN-117 compared to placebo on severity of illness and improvement using the Clinical Global Impression of Severity (CGI-S) and Clinical Global Impression of Improvement (CGI-I) over 6 weeks of treatment.
- To assess the effect of MIN-117 compared to placebo on sexual functioning using the Arizona Sexual Experiences Scale (A-SEX).
- To assess the effect of MIN-117 compared to placebo on executive function and working memory using Digit-Symbol Substitution Test (DSST), Towers of London Test, and Digit Span Backwards task.
- To evaluate the safety and tolerability of MIN-117 compared to placebo over 6 weeks of treatment.

Parkinson's Disease: Large and growing prevalence with huge burden to patients, families and society

Caused by a cascade of events leading to the death of dopamine-generating cells

- Progressive and incurable
 - Leads to lower quality of life, disability
 - Loss of speech, mobility, cognitive abilities
 - Lower life expectancy
- A chronic, degenerative neurological disorder that affects one in 100 people over age 60¹
 - Average age at onset is 60¹
 - No objective test or biomarker
 - Estimates of the number of people living with the disease vary but recent research indicates that at least one million people in the US and an estimated 7-10 million worldwide have the disease¹



What do we need?

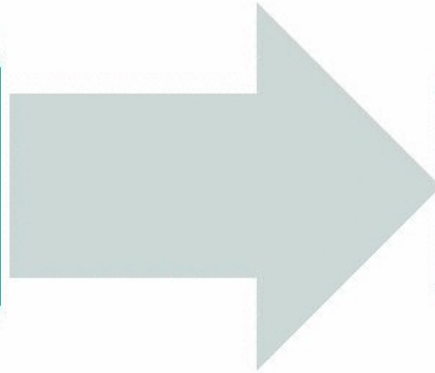
Treatments that:

- Are disease modifying
- Have less side effects
- Treat all symptoms particularly cognitive decline and not just the motor impairment

1. Parkinson's Disease Foundation, Statistics on Parkinson's, www.pdf.org/en/parkinson_statistics
2. The Michael J. Fox Foundation for Parkinson's Research, Parkinson's Diagnosis Question <https://www.michaeljfox.org/understanding-parkinsons/i-have-got-what.php>

Mechanism of action

Neuregulin 1 β 1
activating ErbB4

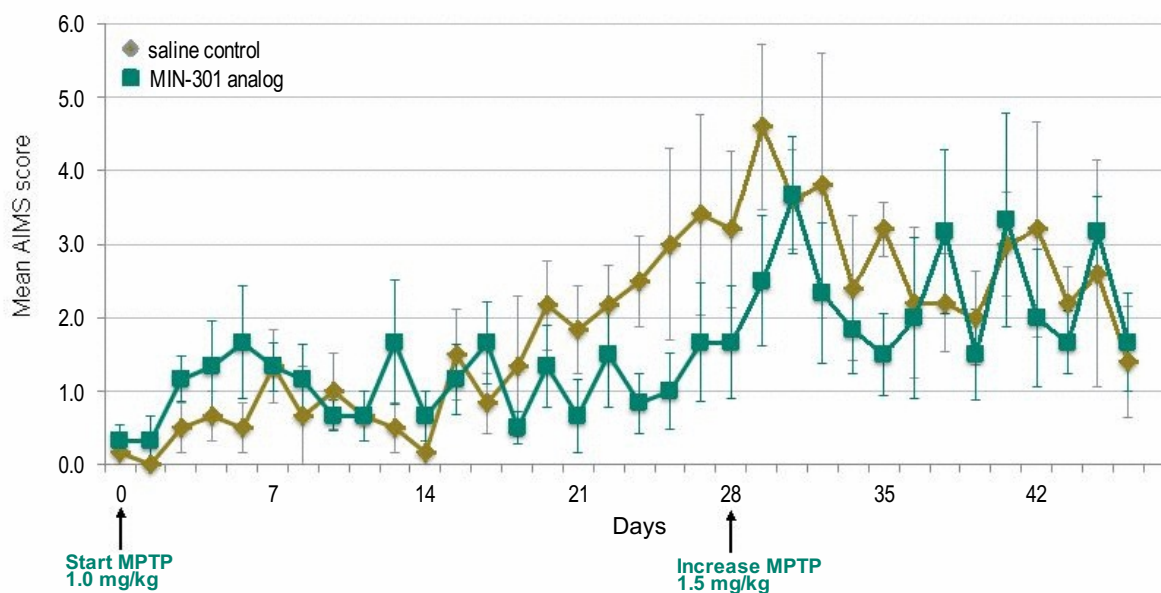


Potential benefits /
differentiation

Cognitive
improvement and
neuroprotective/
neurorestorative
effects

MIN-301 Analog: PRIMOMED Study

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.

Financial Summary

- ~\$44.8M cash balance at 6/30/15
- \$15M credit facility with Oxford and SVB entered into January 2015 (\$10m drawn down)
 - 40,790 warrants issued in connection with the debt facility at exercise price of \$5.516
- ~\$31M PIPE completed in March 2015
 - 6,281,661 shares sold at \$4.81/share
 - 6,281,661 warrants issued at \$0.125 for exercise at \$5.772
- 24,721,143 shares outstanding 6/30/15
- Approximately 2.9M options outstanding 6/30/15

2016 Expected Milestones

Program	Primary Indication	Milestone
MIN-101	Schizophrenia	Topline Phase IIb data expected Q2 2016
MIN-117	Major Depressive Disorder (MDD)	Topline IIa data expected H1 2016
MIN-202	Primary and Comorbid (Secondary) Insomnia	Data expected from Phase IIa and Phase Ib trials H1 2016
MIN-303	Parkinson's Disease	IND or IMPD in 2016, with Phase I expected to initiate thereafter



Thank You

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