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From Unmet Need to Reality

Roluperidone is potentially the first treatment for negative symptoms of schizophrenia

Corporate deck I November 2026

Updated: 2026.11.16

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De-risked path to first approved therapy for negative symptoms of schizophrenia

Unmet Need	Negative symptoms drive profound, lifelong disability and remain untreated, with no FDA-approved therapies and clinical practice focused primarily on positive symptoms.
Only Therapy of its Kind	Roluperidone is only late-stage drug in development targeting primary negative symptoms of schizophrenia.
Clinical Evidence	Roluperidone monotherapy had a meaningful improvement in negative symptoms while supporting stable positive symptoms with a low relapse rate in two registrational trials (C03 & C07 studies).
De-risked Execution	Confirmatory Phase 3 trial design (C19 study) established following extensive FDA engagement; topline 12-week efficacy data expected in 2H 2027.
Financial Strength & Large Opportunity	$200 million financing in October 2025 provides funding through C19 Study data, NDA resubmission and preparation for negative symptoms of schizophrenia commercialization.* Roluperidone MOA provides label expansion opportunities for negative symptoms beyond schizophrenia.

*Led by Vivo Capital LLC, with participation from new and existing investors including Janus Henderson, Federated Hermes Kaufmann Funds, Farallon Capital, Coastlands Capital, Balyasny Asset Mgmt, Logos Capital, BSQUARED Capital, Trails Edge Capital Partners, Ally Bridge Group, Foresite Capital and Spruce Street Capital as well as several healthcare-focused funds, with Jefferies LLC acting as sole placement agent; $200 million consists of (i) $80 million up front, (ii) up to an additional $80 million subject to the full exercise of Tranche A warrants and (iii) a further $40 million that may be received in connection with cash exercise of Tranche B warrants contingent upon achievement of milestone event.

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Negative symptoms of schizophrenia drive lifelong disability and remain untreated

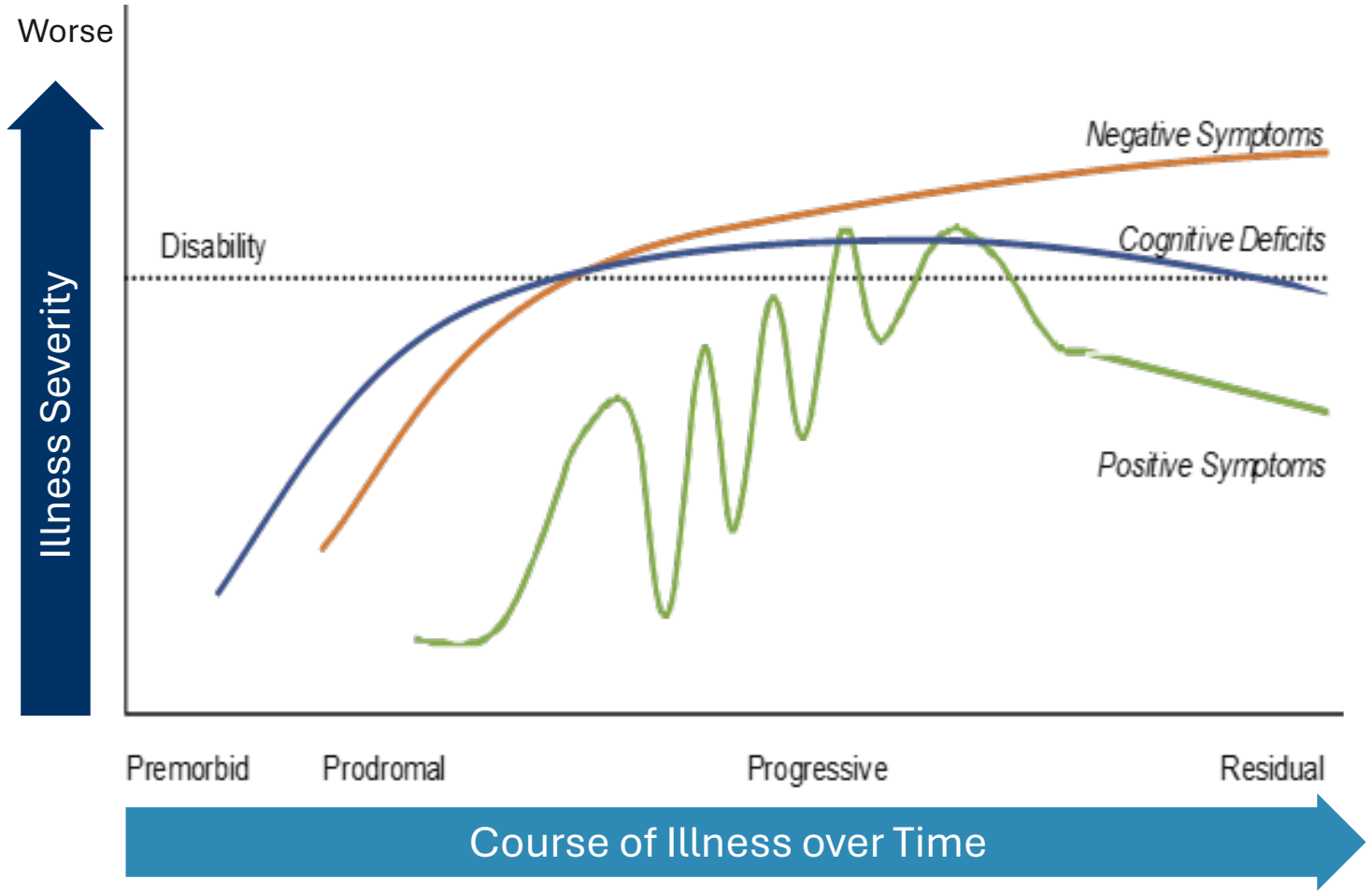
Current treatment options improve positive symptoms, but negative symptoms remain untreated and drive long-term disability

Schizophrenia has three symptom domains

1) **Positive Symptoms** - delusions, hallucinations, disorganized behavior

2) **Negative Symptoms** - diminution or absence of normal behaviors related to motivation and interest

3) **Cognitive Deficits**



Source: Correll and Schooler, 2020

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Negative symptoms, not positive symptoms, are the primary drivers of disability in schizophrenia

> *"While positive symptoms are often the most recognized features of schizophrenia due to their external observation of distorted normal function,* ***negative symptoms*** *are the lack of normal functions that* ***differentially affect schizophrenia treatment and prognosis****."* [1]

Negative Symptoms

- Associated with lower functioning
- Associated with lower Health-Related Quality of Life (HRQoL)

Improved functioning associated with improved HRQoL[1]

80%–90% of people with schizophrenia are **unemployed**[2,3,4,5]

vs. ~4–5% in the general population

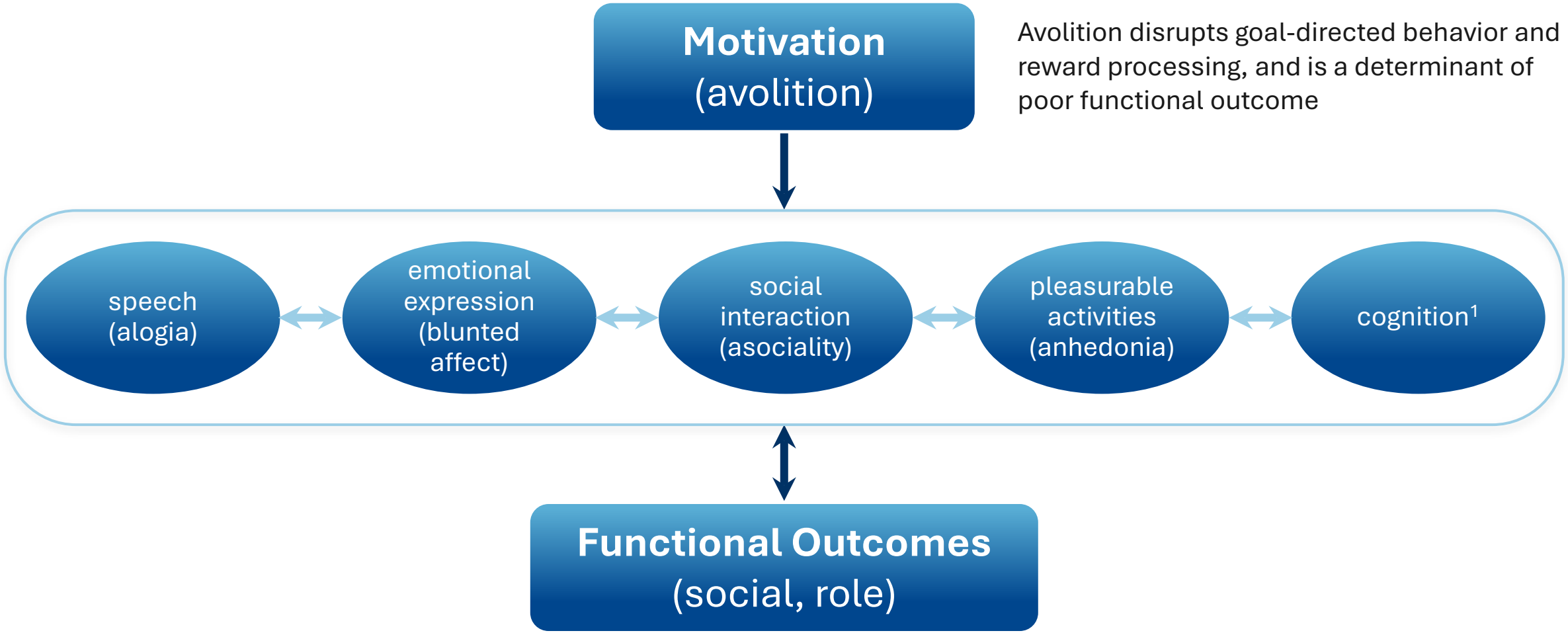
Negative symptoms; not positive symptoms drive disability in schizophrenia[6]

Consistent finding across >25 studies; yet no approved treatment targets negative symptoms

[1] Chan A et al., Assoc between negative symptoms and HRQoL and functional outcomes in persons with schizophrenia. *Schizophrenia Research* (2026); [2] Evensen S et al. Prevalence, Employment Rate, and Cost of Schizophrenia in a High-Income Welfare Society. *Schizophr Bull.* 2016;42(2):476–483; [3] Holm M et al. Employment among people with schizophrenia or bipolar disorder. *Acta Psychiatr Scand.* (2021); [4] Rosenheck R et al. Barriers to Employment for People With Schizophrenia. *Am J Psychiatry.* (2006); [5] Davidson M et al. Nation-Wide Study on Percentage of Schizophrenia and Bipolar Disorder Patients Who Earn Minimum Wage or Above. *Schizophr Bull.* (2015); [6] Rabinowitz, J et al. Negative symptoms have greater impact on functioning than positive symptoms in schizophrenia: Analysis of CATIE data. *Schizophrenia Research* (2012).

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Targeting avolition improves entire constellation of negative symptoms & functional outcomes



Avolition disrupts goal-directed behavior and reward processing, and is a determinant of poor functional outcome

[1] Keefe, R et al. Cognitive Effects of MIN-101 in Patients with Schizophrenia and Negative Symptoms. *J.Clin.Psychiatry* (2018).

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Roluperidone for negative symptoms of schizophrenia

Clinical data that matters

C03 & C07 Studies: similar designs and similar results – guiding C19 confirmatory trial

	C03 Study 244 patients	C07 Study 515 patients
Negative symptoms (NSFS)*	**p ≤ 0.001** Statistically significant (64 mg)	**p ≤ 0.043** Nominally significant (64 mg)**†
Function (PSP total score)	**p ≤ 0.002** Statistically significant (64 mg)	**p ≤ 0.016** Statistically significant (64 mg)†

Avoids side effects of antipsychotics, like

- ❑ Metabolic syndrome
- ❑ Sedation
- ❑ Motor symptoms (extra pyramidal symptoms (EPS))
- ❑ Prolactin elevation
- ❑ Nausea

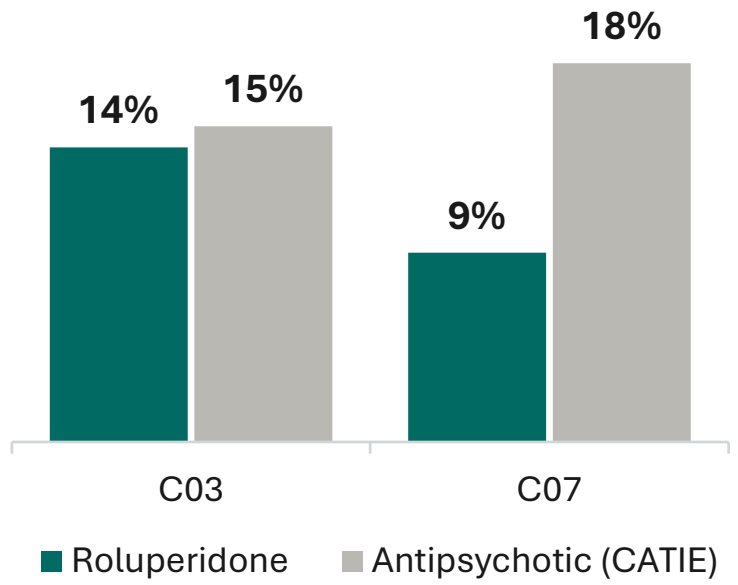
C03 & C07 Studies: 12-week DB efficacy, then OL extension (24 weeks in C03, 40 weeks in C07)

Relapse rate, psychotic symptoms

C03: after 12-week DB + 24-week OL

C07: after 12-week DB + 40-week OL

Roluperidone Studies vs. CATIE[1,2] ††



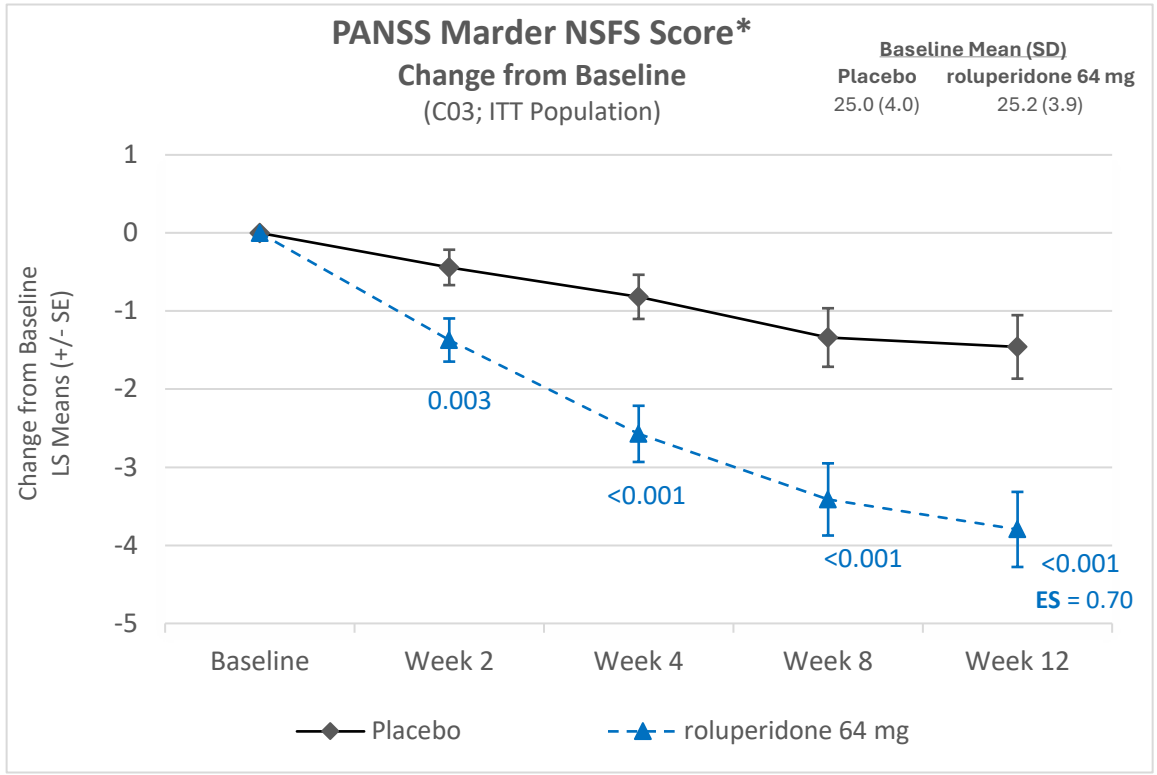
*NSFS was not primary endpoint of C03 Study but is shown because it is primary endpoint agreed with FDA for ongoing C19 Study (primary endpoint of C03 Study was PANSS Pentagonal-NFS, which also showed statistically significant improvement (0.004 for 64 mg); **C07 Study's primary endpoint met only on nominal basis (p ≤ 0.043) due to statistical plan's use of Hochberg Type 1 error correction; †mITT population (excludes 1 site for reasons of implausible data). ††Historical comparison data from CATIE study in patients meeting inclusion-exclusion criteria of Minerva's C03 and C07 studies. [1]Lieberman JA et al. Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. *NEJM* (2005); [2]Speyer H, et al. Moderate to severe negative symptoms predict low risk of symptoms worsening in schizophrenia patients in CATIE. *Schizophr Res.* (2026). Other source: Minerva Neurosciences.

DB: double-blind. **OL:** open-label extension. **NSFS:** PANSS Marder Negative Symptoms Factor Score. **PSP:** Personal and Social Performance scale.

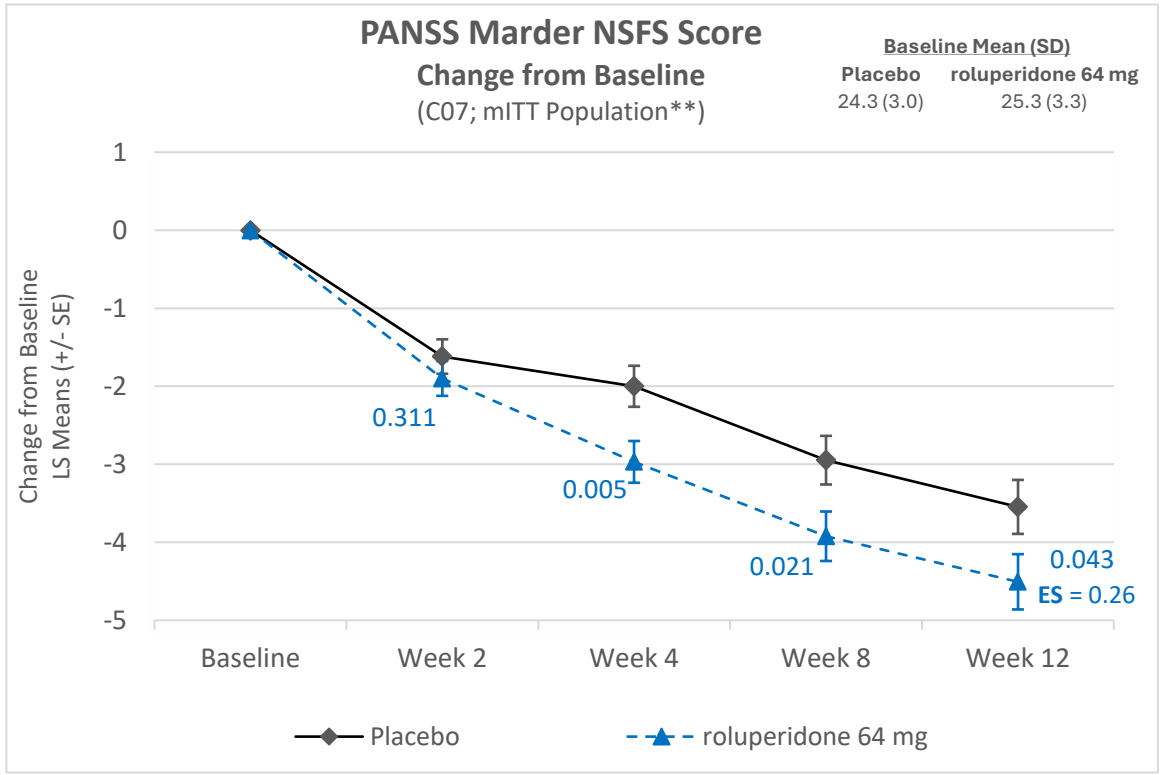
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C03 & C07 Studies: Negative Symptom Factor Score

C03 Study



C07 Study



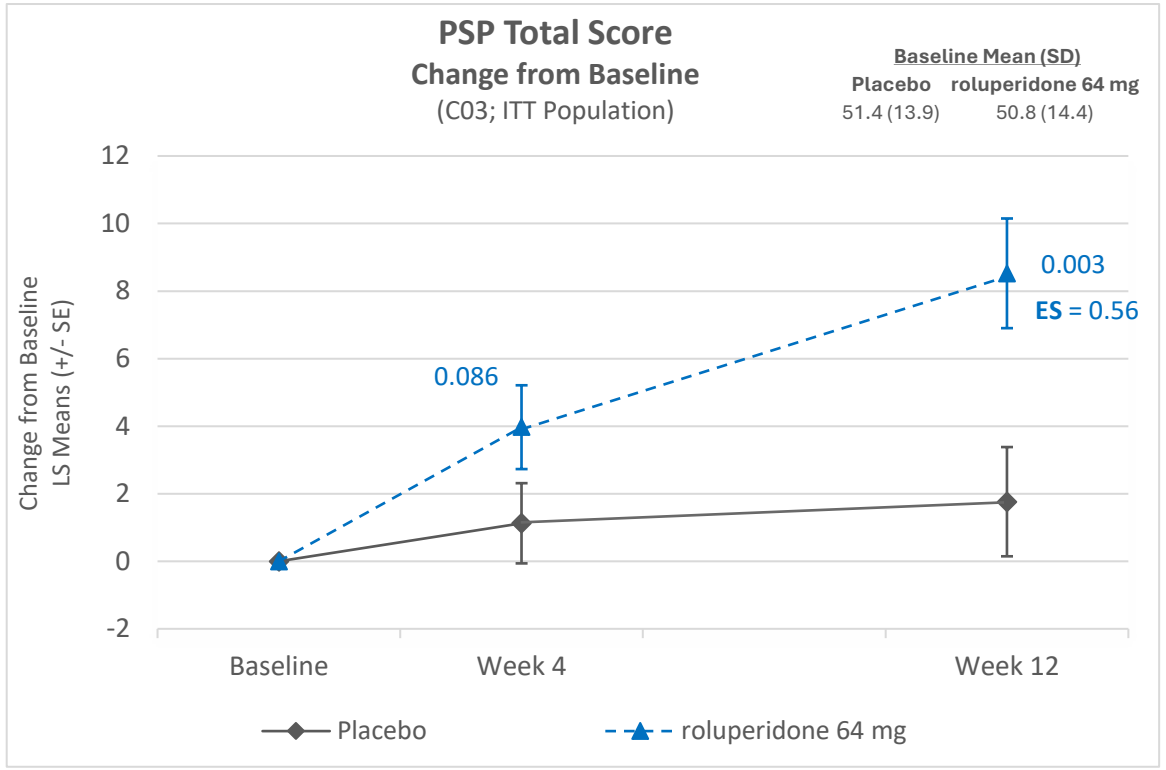
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* NSFS: Negative Symptom Factor Score calculated from PANSS scale (Marder et al., 1997)

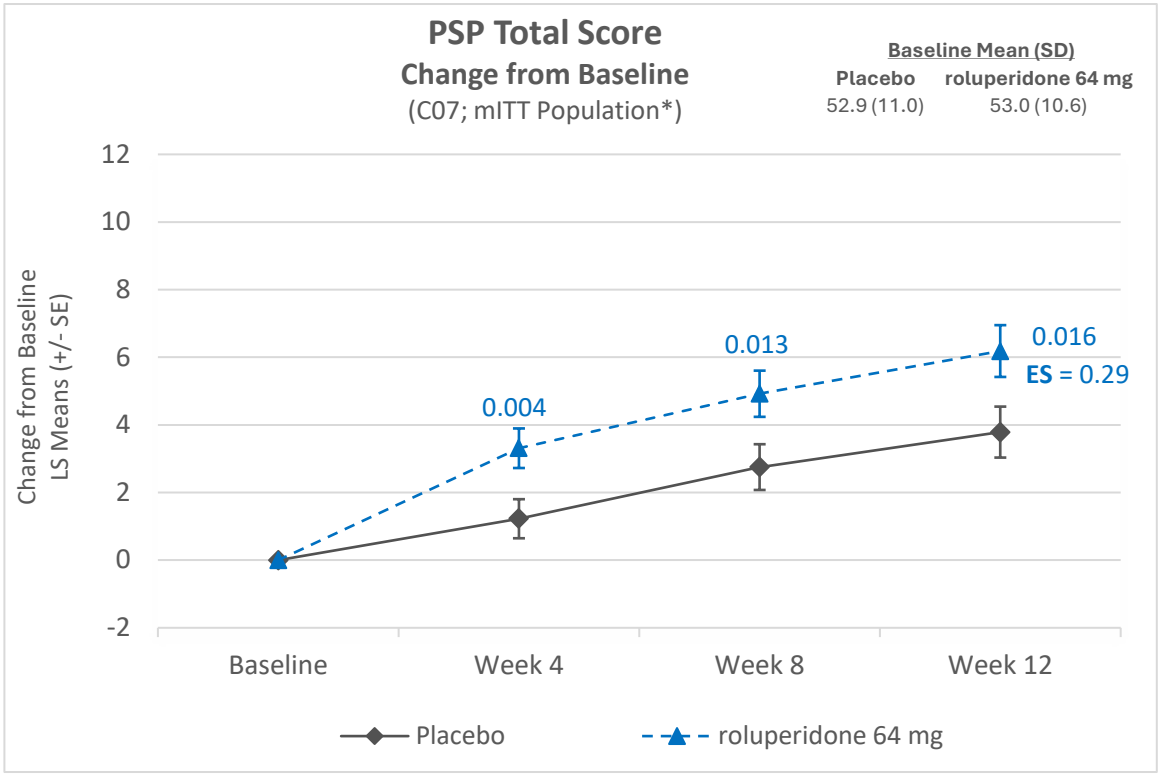
** mITT population (excludes 1 site for reasons of implausible data)

C03 & C07 Studies: Personal and Social Performance (PSP) Score

C03 Study



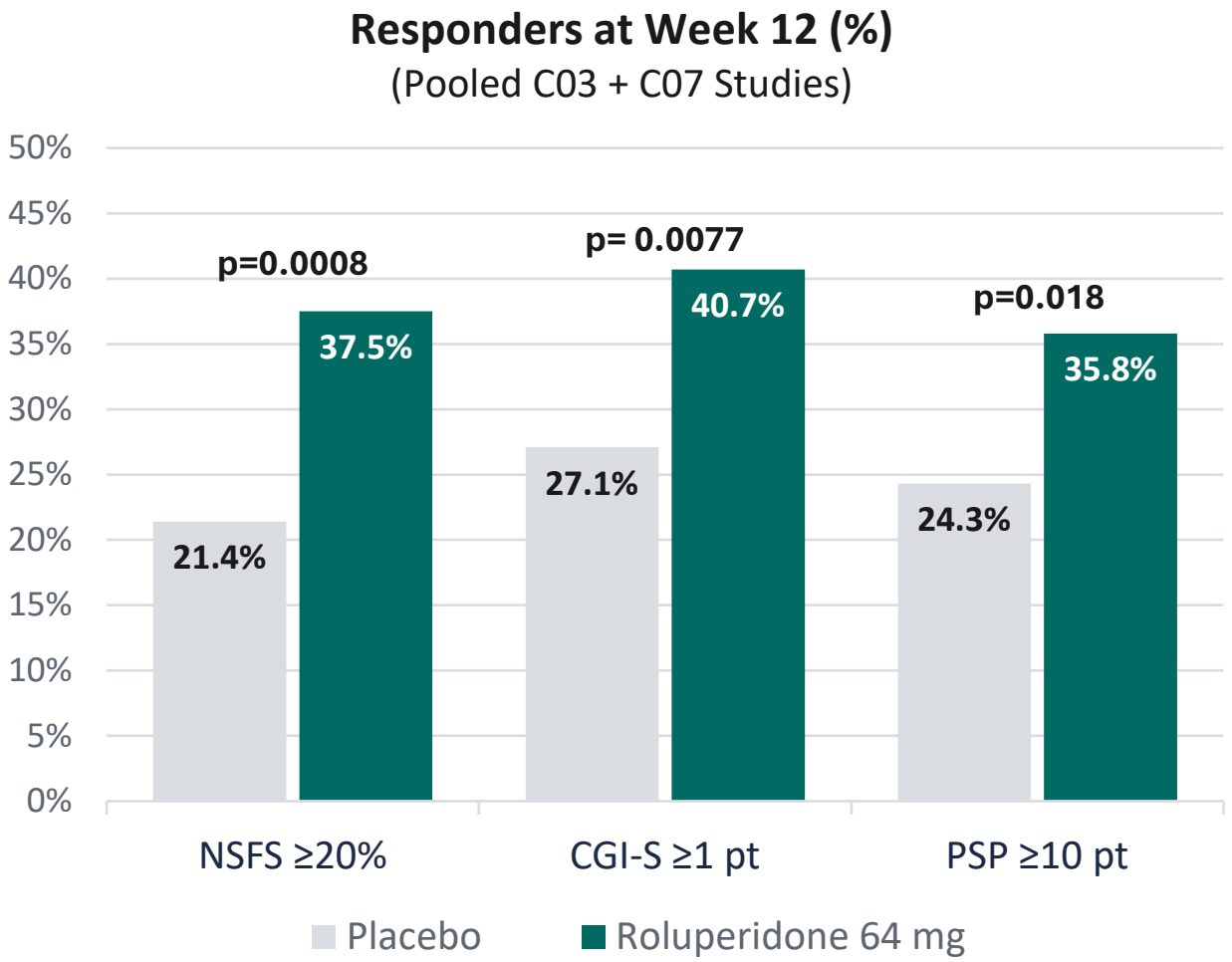
C07 Study



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* mITT population (excludes 1 site for reasons of implausible data)

Responder Analysis: meaningful across three independent anchors



NUMBER NEEDED TO TREAT

7	8	9
NSFS ≥20%	CGI-S ≥1 pt	PSP ≥10 pt

Higher responder rates than placebo on symptoms (**NSFS**), clinician global (**CGI-S**), and functioning (**PSP**) (RR 1.47–1.75).

NNTs of 7–9 fall within the range of approved antipsychotics (NNT 5) and antidepressants (NNT 8); comparisons are indirect.

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Pooled analysis of C03 + C07 studies, roluperidone 64 mg vs placebo,12-week completers. **NSFS:** Marder Negative Symptoms Factor Score; **CGI-S**: Clinical Global Impression - Severity of illness; **PSP:** Personal and Social Performance scale. Source: Minerva Neurosciences. Source: Minerva Neurosciences.

Conclusions from C03 and C07 Studies

Roluperidone demonstrated clear statistical significance on multiple efficacy endpoints:

- ✓ Improves primary negative symptoms (i.e., NSFS)
- ✓ Improves functioning (i.e., PSP)
- ✓ Improves avolition
- ✓ Stable positive symptoms, with a low relapse rate

Roluperidone avoids well-known troubling sides effects seen with atypical antipsychotics:

- ✓ Metabolic syndrome
- ✓ Sedation
- ✓ Motor symptoms (extra pyramidal symptoms (EPS))
- ✓ Prolactin elevation
- ✓ Nausea (for muscarinic antipsychotics)

Unique pharmacological profile that drives the differentiated clinical benefits in previous clinical trials

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De-risked, execution-focused confirmatory C19 trial design

FDA Alignment on C19, confirmatory trial design: ***actively enrolling NCT07565428***

Alignment reached on design of a confirmatory Phase 3 study following extensive collaborative discussions with FDA throughout 2023-2024 and the findings of an FDA Public Meeting in August 2024:

Evaluating the Negative Symptoms of Schizophrenia in Clinical Trials[1]

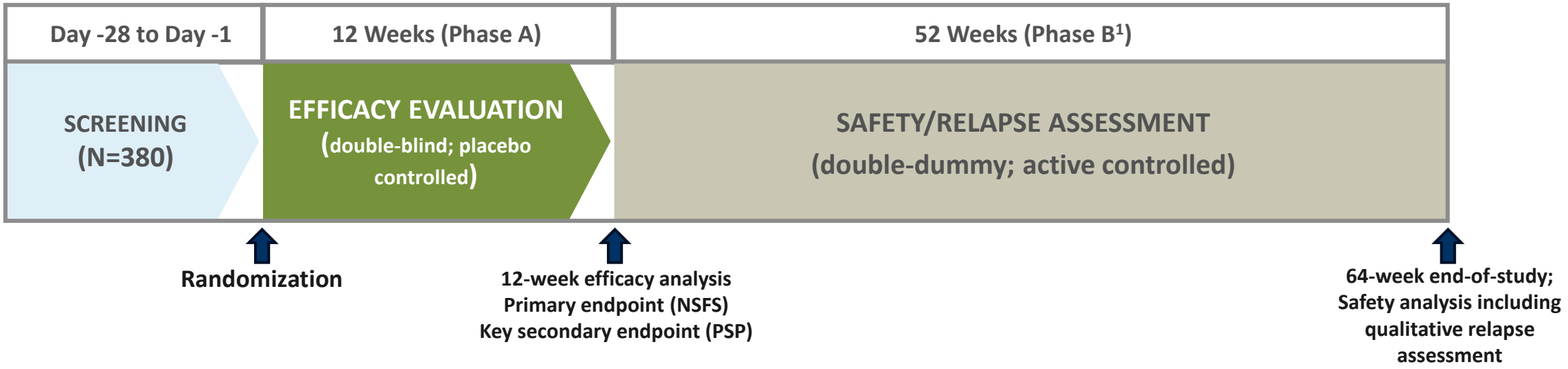
Excerpts from FDA Meeting Minutes

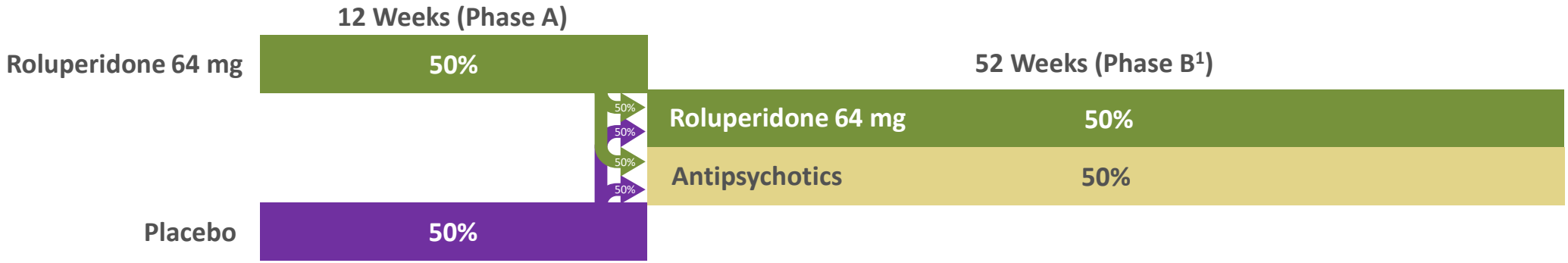
- ***FDA acknowledges Minerva's position*** *that a population of people with schizophrenia can be identified* ***with high negative symptoms and a low risk of relapses*** *who can safely be withdrawn from antipsychotic treatment.*
- *The Division is willing to discuss an additional study that provides robust, controlled data about the efficacy and safety of long-term* ***monotherapy*** *with roluperidone in* ***subjects with negative symptoms of schizophrenia****.*
- *The Division agreed that it would consider a resubmission that included a double-blind, placebo- or active-controlled trial of roluperidone with a duration of at least 52 weeks.*
- *The Division does not object to a 12-week primary endpoint for negative symptom.*
- *To support a* ***monotherapy indication,*** *a comparison of relapse rates between patients on roluperidone monotherapy and similar patients maintained on antipsychotics would be important for regulatory decision making.*
- *[The approach]* ***would represent a new treatment paradigm.***

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[1]: *FDA Meeting August 16, 2024*

C19 Study: ***actively enrolling***





[1] Patients re-randomized to either one of three atypical antipsychotics or roluperidone.

Execution-focused trial maximizes probability of a clean, interpretable C19 Study outcome

Trial Design Improvements

- **64 mg of roluperidone** in treatment arm, the dose which showed greater symptom improve in C03 and C07 trials
- Single active dose (64 mg) versus placebo **eliminates need for Type I error correction** applied in C03 and C07 trials
- Single active dose (64 mg) versus placebo **reduces treatment expectation bias**, which inflates placebo response
- Fewer patient assessment visits to **limit the "nursing effect,"** which inflates placebo response in CNS trials
- Rigorous, systematized **inclusion and exclusion criteria** to ensure enrollment of appropriate patients

Scale, Monitoring and Data Quality Controls

- ~380 patients across ~40 sites in the U.S. (25–30%) and four European countries
- **Focused site footprint** reduces variability and supports statistical integrity; and selection accounts for **prior site performance** in C03 and C07 trials
- **Standardized training** in PANSS ratings; and **oversight to support patient selection consensus** between investigators and sponsor
- Independent expert **oversight of rating quality** with real-time monitoring
- **Centralized data collection** using electronic tablets with built-in prompts to reduce rater error

Market opportunity in negative symptoms of schizophrenia & beyond

~900,000 US adults fit the roluperidone target profile amid massive need for negative symptoms treatments

~3.4M

Adults with schizophrenia, U.S.

1.17% age-adjusted prevalence[1]

~2.2M

Diagnosed schizophrenia prevalence, U.S.[2]

Estimated to increase to ~2.5M by 2035[2]

~1.3M

Clinically relevant, impairing negative symptoms

~60% of treated patients[3]

~900k

Stable patients: target patients for roluperidone

~68.9% of diagnosed patients have stable positive symptoms[4]

~$7.1B

US schizophrenia drugs market, 2025

Growing at ~4.5% CAGR[2]

$0

Approved treatments for negative symptoms in the US

>$2B

Roluperidone peak annual US net sales potential as the first approved negative-symptoms therapy[5]

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[1]Krasa et al., National and State Societal Costs of Schizophrenia in US in 2024. *JAMA Psychiatry* (2026); [2]Clarivate Schizophrenia Disease Landscape & Forecast (Major Markets) (2026); [3]Correll CU, Schooler NR. Negative Symptoms in Schizophrenia: A Review and Clinical Guide for Recognition, Assessment, and Treatment. *Neuropsychiatr Dis Treat.* (2020); [4] Starzer M et al., 20-year trajectories of positive and negative symptoms after the first psychotic episode in patients with schizophrenia spectrum disorder: results from the OPUS study. World Psychiatry (2023); [5]Based on estimates including Minerva Neurosciences estimates of TAM, market share, pricing and adoption including input from 2024 Payer survey conducted by Lumanity Inc.

Pipeline of label expansion opportunities with roluperidone

Negative symptoms occur in 19 DSM-5 disorders[1]

Adjacent Psychiatry & Mood Disorders

Schizoaffective & Related Schizophrenia-Spectrum Disorders

Mechanistically aligned

Major Depressive Disorder (MDD) residual symptoms

Anhedonia and low motivation; possible adjunct to antidepressants

Apathy in Neurodegenerative Disorders

Alzheimer's Disease apathy

No approved therapy; established apathy endpoints

Parkinson's Disease apathy

Under-treated; distinct from motor symptoms

Apathy in Other Neurologic Disorders

Traumatic Brain Injury (TBI) · Multiple sclerosis

Apathy and reduced initiative after injury or in MS

Autism Spectrum Disorder · Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) · Long COVID

Areas of high unmet need involving social withdrawal or reduced ability to engage in goal directed behavior

Cognitive Impairment

Cognitive Impairment in Schizophrenia (CIAS)[2]

Cognitive Impairment in Alzheimer's Disease

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[1]Strauss, GP & Cohen, AS. A transdiagnostic review of negative symptom phenomenology and etiology. *Schizophrenia bulletin* (2017); [2]Keefe, R et al. Cognitive Effects of MIN-101 in Patients with Schizophrenia and Negative Symptoms. *J.Clin.Psychiatry* (2018).

Summary: The Minerva Confluence

Right pharmacology and MOA

- **Only drug to date** to show a significant, clinically relevant improvement
- Specific to **primary negative symptoms** of schizophrenia
- **Label expansion** opportunity for multiple indications beyond schizophrenia

Right patient profile

- Clinically relevant population with predominant and **impairing negative symptoms**
- Moderate to severe negative symptom patients, as shown in C03, C07, and several other studies, have a relatively **low risk of relapse**

Right phase 3 trial design

- **Previous experience** with two statistically significant (one nominally) trials
- **FDA alignment** on ongoing Phase 3 trial
- **Ongoing 'high touch'** confirmatory Phase 3 trial increases probability of success

Right moment

- **Growing awareness** of unmet need in psychiatry community
- Backed by **world-class investors**
- Near-term opportunity to be the first treatment for negative symptoms of schizophrenia

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