Transforming mental health care

COMPASS Pathways plc
September 2022

Navigating Mental Health Pathways
Disclaimer

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Everyone has a STORY
We are a mental health care company

Dedicated to accelerating patient access to evidence-based innovation in mental health care

- Significant unmet need: 100m people¹ with treatment-resistant depression (TRD)
- Committed to transforming the patient experience in mental health care
- Expansion into PTSD and additional indications

COMP360 psilocybin therapy for TRD to phase III

- COMP360 purified psilocybin formulation designated a FDA Breakthrough Therapy for TRD
- Completed phase I – largest healthy volunteers trial
- Completed phase IIb – largest psilocybin therapy clinical trial
- Completed COMP360 psilocybin therapy as adjunct to SSRI in open-label study

Driven by science and rigour

- COMP360 mechanism of action, activating the 5HT₂A receptor²
- Signals from academic studies and evidence from our own research have shown that psilocybin therapy can improve outcomes for patients
- IP strategy combining patent protection with regulatory and market exclusivity

Source: 1. Depression and Other Common Mental Disorders: Global Health Estimates and Cleare, A. et al - 2015: Evidence-based guidelines for treating depressive disorders with antidepressants: A revision of the 2008 British Association for Psychopharmacology guidelines. These sources state that 1/3 of those suffering with major depressive disorder (MDD) are estimated to be TRD. Therefore, we approximated 100 million from 320 million people with MDD.
2. Halberstadt and Geyer – 2011
Developing a personalized, predictive and preventative model of care

Our vision
A world of mental wellbeing

FDA Breakthrough Therapy designation for COMP360 in TRD; New indications and compounds in development

Health systems and payer partnerships
Value-based models, real-world evidence

Innovative care delivery models
Centres of Excellence, digital technologies
Pipeline overview

**COMPASS development programmes**
COMPASS-owned and sponsored

**Investigator-initiated studies**
Signal-generating exploratory studies looking at indications in areas of unmet need with COMP360
- COMPASS owns or has a license to new IP generated around COMP360 psilocybin
- Studies may provide signals that we can explore further and bring into our development pipeline

### Programme
<table>
<thead>
<tr>
<th>Programme</th>
<th>Discovery</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Approved</th>
</tr>
</thead>
<tbody>
<tr>
<td>COMP360 for TRD</td>
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<tr>
<td>COMP360 for PTSD</td>
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<tr>
<td>Prodrug programme</td>
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<tr>
<td>Discovery Center</td>
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</tr>
</tbody>
</table>

### Indication
<table>
<thead>
<tr>
<th>Indication</th>
<th>Institution</th>
<th>CMPS financed</th>
</tr>
</thead>
<tbody>
<tr>
<td>MDD in cancer patients</td>
<td>Aquilino Cancer Center</td>
<td>✓ Complete</td>
</tr>
<tr>
<td>MDD</td>
<td>University of Zurich</td>
<td></td>
</tr>
<tr>
<td>Chronic cluster headache</td>
<td>University of Copenhagen</td>
<td></td>
</tr>
<tr>
<td>Severe TRD</td>
<td>Sheppard Pratt</td>
<td>✓</td>
</tr>
<tr>
<td>Bipolar disorder II</td>
<td>Sheppard Pratt</td>
<td>✓</td>
</tr>
<tr>
<td>Body dysmorphic disorder</td>
<td>Columbia University</td>
<td>✓</td>
</tr>
<tr>
<td>Anorexia nervosa</td>
<td>UC San Diego</td>
<td>✓</td>
</tr>
<tr>
<td>Suicidal ideation</td>
<td>Sheppard Pratt</td>
<td>✓</td>
</tr>
<tr>
<td>Autism</td>
<td>King’s College London</td>
<td>✓</td>
</tr>
</tbody>
</table>
Psilocybin mechanism of action

1. Stimulation of 5-HT$_{2A}$ receptors\(^1\) results in downstream cascades via G-protein signalling\(^2\)

2. Altered extracellular release of dopamine\(^3,4\) and leading to enhanced positive mood

3. Downregulation of the default mode network, or DMN\(^5\), and de-synchronisation of cortical activity as well as the emergence of new patterns of functional connectivity across the brain\(^6\)

4. Sustained cellular changes leading to neuroplasticity\(^7\) and “window of opportunity” for therapy

**Note:** understood mechanism of action based on studies of psilocybin (not COMP360); \(^*5\)-HT$_{2A}$ = 5-hydroxytryptamine 2A; DMN = default mode network; mPFC = medial prefrontal cortex

Brain network alterations may indicate the emergence of novel patterns of connectivity, following downregulation of the DMN.

Note: Figure adapted from Petri et al., 2014; study analysed fMRI (functional magnetic resonance imaging) data from healthy volunteers to compare resting-state functional brain connectivity after intravenous infusion of placebo and psilocybin (not using COMP360).

Our COMP360 psilocybin therapy

COMP360 (GMP drug substance and drug product)

- Synthetic, high-purity, polymorphic crystalline psilocybin formulation
- 1mg, 5mg and 25mg oral capsule formulation (25 mg for phase III and commercialisation)
- Stability testing in place with adequate shelf life for clinical trials/commercialisation
- UK CMO manufacturing at commercial scale

COMP360 psilocybin therapy: clinical status

- FDA Breakthrough Therapy designation for TRD in 2018
- Preclinical genotoxicity and cardiotoxicity studies completed
- Phase I trial completed: COMP360 generally well-tolerated in healthy participants (n=89)
- Phase IIb trial in TRD completed
- Phase II study in PTSD launched
- Additional IISs in new areas of high unmet need

Psychological support

COMP360 is combined with psychological support from specially trained therapists

Psilocybin session is preceded by preparation and followed up with integration

Therapists are supported with digital learning platform

Note: COMP360 Psilocybin therapy is under evaluation for the treatment of TRD; GMP = Good Manufacturing Practice; CMO = Contract manufacturing organisation; MHRA = UK Medical and Healthcare products Regulatory Agency; CMC = chemistry, manufacturing and control
# TRD treatment pathway: significant unmet need for 100 million patients

<table>
<thead>
<tr>
<th>Treatment pathway stage</th>
<th>New onset depression Major depressive disorder (MDD)</th>
<th>Persistent depression Major depressive disorder (MDD)</th>
<th>Treatment-resistant depression (TRD)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Line of therapy</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First line</td>
<td></td>
<td></td>
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<tr>
<td>Second line</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Third line +</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Estimated no of patients (worldwide)</strong></td>
<td>320 million</td>
<td>200 million</td>
<td>100 million (~1 in 3 of total) US healthcare cost approx $17-25k per patient/year</td>
</tr>
<tr>
<td><strong>Available treatments</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Antidepressants</td>
<td>• Antidepressants</td>
<td>• Antidepressants</td>
<td>• Antidepressants</td>
</tr>
<tr>
<td>• Psychological interventions, eg CBT*</td>
<td>• Antidepressant combinations</td>
<td>• Psychological interventions</td>
<td>• Augmentation therapy (antidepressants, mood stabilisers, anticonvulsants, atypical antipsychotics, esketamine)</td>
</tr>
<tr>
<td>• Antidepressants</td>
<td>• Antidepressant combinations</td>
<td>• Psychological interventions</td>
<td>• Ketamine</td>
</tr>
<tr>
<td>• Psychological interventions, eg CBT*</td>
<td>• Psychological interventions</td>
<td>• Psychological interventions</td>
<td>• Somatic therapy (rTMS*, tDCS*, ECT*, DBS*)</td>
</tr>
<tr>
<td>% relapse</td>
<td>60-70%</td>
<td>50-75%</td>
<td>80-90%</td>
</tr>
</tbody>
</table>

**Note:** *CBT* = cognitive behavioural therapy; *rTMS* = repetitive transcranial magnetic stimulation; *tDCS* = transcranial direct current stimulation; *ECT* = electroconvulsive therapy; *DBS* = deep brain stimulation

**Source:** Hasler et al, 2004 - Acute psychological and physiological effects of psilocybin in healthy humans: a double-blind, placebo-controlled dose effect study
Our clinical development programme for COMP360 psilocybin therapy in TRD
Preparing for phase III

Phase I
- Safety and feasibility
  - 89 healthy volunteers

Phase II
- Safety and efficacy (phase IIb)
  - Primary endpoint: change in MADRS
  - 233 patients, 22 sites in EU, US, Canada

- Psilocybin as adjunct to SSRI
  - (small, exploratory study)

Phase III
- Status
  - Completed Dec 2019
  - Completed Topline data Nov 2021
  - Completed Topline data Dec 2021
  - Ongoing

Note: SSRI = Selective serotonin reuptake inhibitors; TRD = treatment-resistant depression
Primary endpoint (to determine appropriate phase III dose)
Reduction of symptoms of depression as measured by change in MADRS total score from baseline to week 3

Note: MADRS = Montgomery-Åsberg Depression Rating Scale; EOS = end of study; TRD = treatment-resistant depression; D = day; V = visit
Primary endpoint – change from baseline in MADRS total score

Statistically significant primary endpoint (p<0.001) at week 3 (25mg vs 1mg). There was a rapid onset of action and durable effects with treatment differences between the 25mg vs 1mg group apparent from the day after COMP360 psilocybin administration.

Baseline mean (SD): 25mg (n=79) = 31.9 (5.41); 10mg (n=75) = 33.0 (6.31); 1mg (n=79) = 32.7 (6.24)

Note: MADRS = Montgomery-Åsberg Depression Rating Scale; n = number observed; SE: Standard error; SD = standard deviation; LS = least squares; * = statistically significant treatment difference vs 1mg at visit; $p$ = $p$-value
MADRS sustained responders at week 12

Higher proportion of sustained responders found in the 25mg vs 1mg arm

Sustained responder – patients meeting the MADRS response criteria at any visit up to and including week 3 and also at week 12 and at least one visit out of week 6 and week 9, and who did not start any new treatments for depression

Note: MADRS = Montgomery-Åsberg Depression Rating Scale; number of sustained responders stated in bar
Statistical significance cannot be claimed on secondary endpoints due to hierarchical testing being broken for the 10mg vs 1mg dose on the primary endpoint
Participants who started new treatment for depression were assumed to be a non-responder hence decreasing numbers reflecting antidepressant use over time
Key secondary endpoints: sustained responders and sustained non-responders for COMP360 25mg

Sustained responders were found to have clinically meaningful reductions on the QIDS-SR-16 from baseline at week 1 through to week 12 with mean scores moving from the moderate/severe range at baseline to subthreshold at week 1 onwards.

Sustained responders were found to have clinically meaningful increases in quality of life from baseline at week 3 and week 12 with scores in the normal range after treatment.

Sustained responders were found to have clinically meaningful increases in positive affect from baseline at day 2 and week 3.

Baseline mean (SD): Sustained responders 25mg (n=19) = 0.49 (0.249); sustained non-responders 25mg (n=21) = 0.49 (0.223)

Baseline mean (SD): Sustained responders 25mg (n=19) = 20.1 (7.53); sustained non-responders 25mg (n=21) = 18.2 (4.77)

Baseline mean (SD): Sustained responders 25mg (n=19) = 15.9 (3.48); sustained non-responders 25mg (n=21) = 16.0 (4.77)

Baseline mean (SD): Sustained responders 25mg (n=19) = 0.49 (0.249); sustained non-responders 25mg (n=21) = 0.49 (0.223)

Baseline mean (SD): Sustained responder 25mg (n=19) = 20.1 (7.53); Sustained non-responder 25mg (n=21) = 18.2 (4.77)

Note: QIDS-SR-16= 16-item Quick Inventory of Depressive Symptomatology – Self Report; n = number observed; EQ-5D-3L= EuroQoL 5-Dimensions 3-Levels; PANAS= Positive and Negative Affect Schedule; n = number observed; SD = standard deviation. 12 sustained non-responders in 25mg arm took treatment for depression at some point in the study. Sustained responders are defined as participants who responded (≥50% change in MADRS total score from baseline) at weeks 3 and 12, and at least one visit at week 6 or 9 who did not start new treatments for depression. Sustained non-responders are defined as participants who did not respond (<25% change in MADRS total score from baseline) at weeks 3 and 12, and at least one visit at week 6 or 9.
Safety

- **COMP360 was generally well tolerated, with more than 90% of treatment-emergent adverse events (TEAEs) being mild or moderate in severity**
  
  - Further analysis showed that there were no concerns with vital signs, ECG or clinical laboratory data in any of the treatment groups
  
  - The majority of treatment-emergent adverse events (TEAEs) occurring on the day of COMP360 administration resolved on the same day or the day after (77.4%); most were mild or moderate in nature, eg headache, nausea, fatigue
  
  - All TEAEs involving hallucination (which only occurred in the 25mg and 10mg groups) and illusion (which occurred in all groups) started on the day of administration and resolved on the same day. No events of this nature continued past the administration day
  
  - TEAEs of suicidal ideation, suicidal behaviour and intentional self-injury were seen in all groups, as is regularly observed in a TRD population
  
  - Two thirds of the patients had previous thoughts of wishing to be dead, as assessed by a suicidality scale completed during patient screening; this included all patients reporting one of these adverse events, so all patients who experienced these events during the trial had said in patient screening that they had had suicidal thoughts prior to the trial
  
  - Case-by-case analysis of safety data found no evidence to suggest, at this time, a causal relationship between these reported adverse events and administration of COMP360. The events occurred in all treatment groups and at a range of onset times and durations; the majority occurred more than a week after the psilocybin session
Most frequent TEAEs ordered by the 25mg arm ` (at least 5% in any treatment group)

<table>
<thead>
<tr>
<th>MedDRA TEAE preferred term</th>
<th>COMP360 25mg</th>
<th>COMP360 10mg</th>
<th>COMP360 1mg</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=79</td>
<td>N=75</td>
<td>N=79</td>
<td>N=233</td>
<td></td>
</tr>
<tr>
<td>n (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>27 (34.2)</td>
<td>16 (21.3)</td>
<td>20 (25.3)</td>
<td>63 (27.0)</td>
</tr>
<tr>
<td>Nausea</td>
<td>18 (22.8)</td>
<td>7 (9.3)</td>
<td>4 (5.1)</td>
<td>29 (12.4)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>12 (15.2)</td>
<td>5 (6.7)</td>
<td>7 (8.9)</td>
<td>24 (10.3)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>8 (10.1)</td>
<td>11 (14.7)</td>
<td>14 (17.7)</td>
<td>33 (14.2)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>7 (8.9)</td>
<td>13 (17.3)</td>
<td>3 (3.8)</td>
<td>23 (9.9)</td>
</tr>
<tr>
<td>Mood altered</td>
<td>7 (8.9)</td>
<td>3 (4.0)</td>
<td>1 (1.3)</td>
<td>11 (4.7)</td>
</tr>
<tr>
<td>Back pain</td>
<td>6 (7.6)</td>
<td>0</td>
<td>3 (3.8)</td>
<td>9 (3.9)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>6 (7.6)</td>
<td>1 (1.3)</td>
<td>1 (1.3)</td>
<td>8 (3.4)</td>
</tr>
<tr>
<td>Suicidal ideation</td>
<td>5 (6.3)</td>
<td>5 (6.7)</td>
<td>4 (5.1)</td>
<td>14 (6.0)</td>
</tr>
<tr>
<td>Myalgia</td>
<td>5 (6.3)</td>
<td>2 (2.7)</td>
<td>1 (1.3)</td>
<td>8 (3.4)</td>
</tr>
<tr>
<td>Euphoric mood</td>
<td>4 (5.1)</td>
<td>5 (6.7)</td>
<td>4 (5.1)</td>
<td>13 (5.6)</td>
</tr>
<tr>
<td>Depression</td>
<td>4 (5.1)</td>
<td>6 (8.0)</td>
<td>5 (6.3)</td>
<td>15 (6.4)</td>
</tr>
<tr>
<td>Abdominal pain upper</td>
<td>4 (5.1)</td>
<td>2 (2.7)</td>
<td>1 (1.3)</td>
<td>7 (3.0)</td>
</tr>
<tr>
<td>Irritability</td>
<td>4 (5.1)</td>
<td>2 (2.7)</td>
<td>1 (1.3)</td>
<td>7 (3.0)</td>
</tr>
<tr>
<td>Panic reaction</td>
<td>4 (5.1)</td>
<td>1 (1.3)</td>
<td>1 (1.3)</td>
<td>6 (2.6)</td>
</tr>
<tr>
<td>Depressed mood</td>
<td>3 (3.8)</td>
<td>5 (6.7)</td>
<td>4 (5.1)</td>
<td>12 (5.2)</td>
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<tr>
<td>Paraesthesia</td>
<td>3 (3.8)</td>
<td>4 (5.3)</td>
<td>1 (1.3)</td>
<td>8 (3.4)</td>
</tr>
<tr>
<td>Thinking abnormal</td>
<td>0</td>
<td>4 (5.3)</td>
<td>0</td>
<td>4 (1.7)</td>
</tr>
</tbody>
</table>

Note: MedDRA = Medical Dictionary for Regulatory Activities; TEAE = treatment emergent adverse event; N = number of participants in the population; n = number observed

TEAE incidence is higher in the 25mg group overall

Key mood-related TEAEs (euphoric mood, depression, depressed mood, suicidal ideation) do not have a higher incidence in the 25mg arm
Achieving broad, safe and equitable access under a medical model

Our goal: for COMP360 psilocybin therapy to be approved by regulators, reimbursed by payers, lawfully prescribed and administered to well-defined patients suffering with serious mental illness (starting with TRD) by licensed and adequately trained HCPs in a safe environment.

Our current development model anticipates the following activities:

- Conducting a rigorous Phase III clinical trial to evaluate the safety and efficacy of the drug product delivered with psychological support
- Engaging with FDA and DEA and state-level on rescheduling the drug product in the US
- Conducting payer-relevant clinical trials and pharmacoeconomic studies (durability, quality of life, healthcare resource utilisation, budget impact, etc.)
- Developing a comprehensive reimbursement and coding strategy for both the drug product and therapeutic support
- Identifying and engaging with multiple established treatment centres and PE/VC backed clinic networks with the requisite capabilities of delivering therapeutic treatment
- Establishing distribution channels via specialty pharmacies
- Certifying treatment centers with capabilities to safely store and administer drug product and provide for its safe and effective administration and patient support to optimize patient outcomes
- Developing enabling services and solutions (training, site activation, digital solutions) to support treatment centers
- Engaging and training prescribers and therapists. 50k HCPs who can prescribe COMP360 (psychiatrists, PMHNPs, physician assistants) and >500k HCPs who can be trained to deliver COMP360 psilocybin therapy (including psychologists, master-level accredited therapists/counsellors)


Source: APA, AMA, Datausa, other
COMPASS is developing integrated technology solutions

- Developing a closed loop quality oversight system utilising natural language processing
- Evolving capability to analyze digital biomarker collection with the goal of predicting disease course, preventing relapse and personalizing therapy delivery
- Developing additional technologies to augment or complement our therapies
- Led by a world-class internal technology team
COMP360 commercial exclusivity strategy

COMP360 can be registered as NCE*/NAS*

- Possibility of full patent and regulatory exclusivity
- Data protection, up to
  - 8-11 years (EU)
  - 5-7.5 years (US)

Reschedule COMP360 psilocybin

- Upon approval by FDA, COMP360 psilocybin would be rescheduled by DEA

Breakthrough Therapy designation by FDA

Five US patents granted

- 1st US patent (Dec 2019): includes claims to methods of treating drug-resistant depression with high-purity polymorphic crystalline psilocybin formulations
  - Petition for Post Grant Review was dismissed on merits in August 2020
- 2nd US patent (Mar 2021): includes claims to oral dosage forms of psilocybin and methods of treating major depressive disorder (MDD) with those forms
- 3rd US patent (Mar 2021): includes claims to high-purity crystalline psilocybin (including the form used in COMP360), formulations of psilocybin and methods of treating MDD with psilocybin
- 4th US patent (Oct 2021), composition claims to an alternative crystalline psilocybin
- 5th US patent (Nov 2021): covers methods of treating treatment-resistant depression (TRD) with crystalline psilocybin as well as with oral dosage forms of crystalline psilocybin with an excipient

Five European and Asian patents granted/registered

- German utility model (March 2020): includes claims to forms of crystalline psilocybin, use in medicine and methods of synthesis
- First UK patent (May 2020): includes claims to manufacturing methods, product-by-process and formulations
- Second UK patent (July 2020): includes claims covering crystalline psilocybin, pharmaceutical formulations, medical uses and manufacturing methods
- Two Hong Kong patents granted (Feb 2021) covering crystalline psilocybin compositions, formulations and manufacturing methods (corresponds to above UK patents)

Multiple related applications pending

- Pursue additional claim scope and extend coverage in over 20 additional countries/regions

Three PCT applications and Taiwanese application pending

- Additional formulations, methods of administration, therapeutic and digital supports, combination treatments, methods of treatment for a variety of additional indications

Note: *NCE = new chemical entity; NAS = new active substance; ADHD = attention deficit hyperactivity disorder; ALS = amyotrophic lateral sclerosis

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Working in partnership

COMPASS’s first Center of Excellence, at Sheppard Pratt, Baltimore, US

COMPASS’s second Centre of Excellence in partnership with South London & Maudsley NHS Trust & Institute of Psychiatry, Psychology & Neurosciences

COMPASS Discovery Center with University of the Sciences, Philadelphia, UC San Diego, School of Medicine, and Medical College of Wisconsin (MCW)

IP portfolio of novel psychedelic compounds and prodrugs developed together with inventor Matthias Grill PhD, who is working with COMPASS on an exclusive research project to develop new product candidates

COMP360 psilocybin therapy study of MDD in cancer, at the Aquilino Cancer Center, Rockville, Maryland, US

IIS signal-generating studies in new indications for psilocybin therapy using COMP360

Note: MDD = major depressive disorder; IIS = investigator-initiated study
COMPASS’s broad expertise
Financial overview

Cash and cash equivalents at 30 June 2022
• $207.2 million

Issued shares
• 42 million

Covering analysts
• Berenberg
• Robert (Bert) Hazlett, BTIG
• Sumant Kulkarni, Canaccord Genuity
• Charles Duncan, Cantor Fitzgerald
• Neena Bitritto-Garg, CITI
• Ritu Baral, Cowen
• Josh Schimmer, EvercoreISI
• Patrick Trucchio, HC Wainwright & Co
• Jason McCarthy, Maxim Group
• Francois Brisebois, Oppenheimer
• Elemer Piros, ROTH

Notes:
1. As at Aug 2022
2022 anticipated milestones

✓ Hold end-of-phase II meeting with FDA and other regulators
✓ Commence phase III clinical program in TRD
✓ Data published/presented from PIIb trial
✓ PIIb long-term follow up data
✓ Launch additional COMP360 clinical development programs
✓ Data published from IISs using COMP360
✓ Expand current IP portfolio with additional patent grants
✓ Further strategic partnerships and collaborations
✓ Expand Centres of Excellence
✓ Develop pipeline of future compounds through our Discovery Center and other partnerships
✓ Continue to evolve data and technology strategy
✓ Develop scalable therapist training platform
✓ Advance COMP360 payer partnerships in anticipation of commercial launch

Note: TRD = treatment-resistant depression
“I feel like I’m living again. I feel this is one of the greatest gifts that I have been given.”

Quote from a patient in the COMPASS Pathways phase IIb clinical trial of COMP360 psilocybin therapy for treatment-resistant depression. The patient was one of 29 in the 25mg group (n=79) of the trial who had a response to treatment at week 3. The image is representative and not of a patient.
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