

# A significant milestone in mental health research

Completing a phase IIb clinical trial in COMP360 psilocybin therapy for treatment-resistant depression



**Psilocybin therapy:** one of the most promising innovations in psychiatry today

## COMP360

COMPASS's synthetic psilocybin is administered in conjunction with psychological support from specially trained therapists

COMP360 has been designated a Breakthrough Therapy by the US FDA

**Treatment-resistant depression (TRD):** significant unmet medical need

## 100 million people

suffer with depression which is not helped by existing treatments

Associated with longer depressive episodes, higher risk of suicide, lower productivity at work, greater financial burden

## Clinical development programme

### Phase I

Completed **2019**

**89** healthy participants

### Phase IIb

#### Dose-finding study

COMP360 psilocybin therapy administration completed

**July 2021**

**World's largest** psilocybin therapy study

Topline data announced in **November 2021**

### Phase III

To follow in **2022**

Large-scale pivotal trials, prior to application for marketing approval

**22 sites**

**10 countries**



**233 TRD patients**

(exceeding target recruitment of 216)

**>300** people involved in the trial

including:



Principal and sub-investigators



Study co-ordinators



Study nurses



Therapists



Pharmacists



Raters



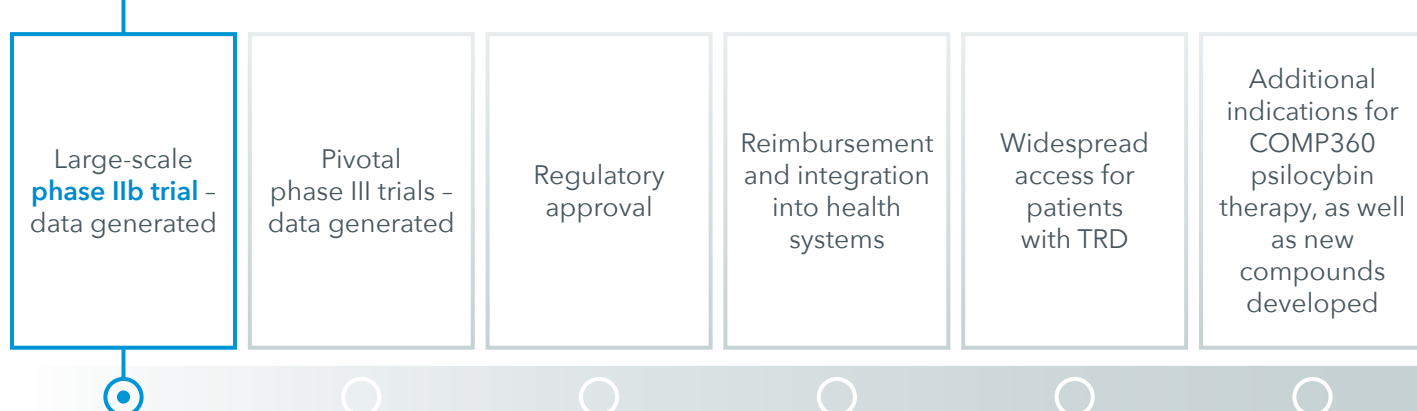
Clinical research organisation partners and suppliers

Randomised, controlled, double-blinded study

Dose-finding study **comparing 25mg and 10mg with 1mg of COMP360**, administered with psychological support

Patients followed up for **12 weeks**

**Making COMP360 psilocybin therapy accessible to patients with serious mental health illnesses**



**“This has been an amazing effort by the whole team and is a huge step forward towards our goal of getting psilocybin therapy to patients in need”**

*George Goldsmith, CEO and Co-founder, COMPASS Pathways*