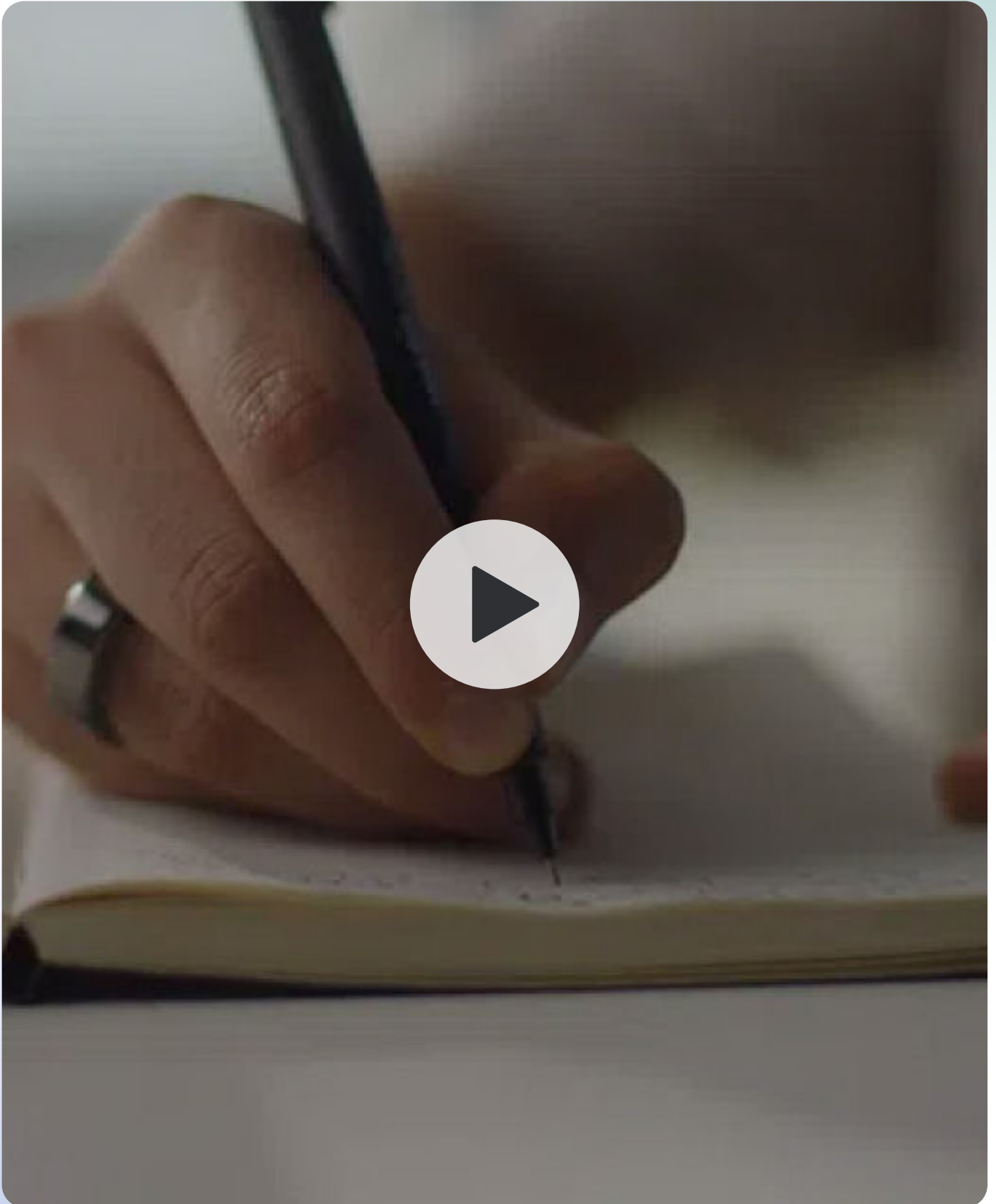


# Welcome to our Annual Review 2023



# Our purpose

Watch our video to learn about our purpose



# Letter from our CEO

## Hear from our CEO, Kabir Nath, on our highlights from 2023 and our plans for the year ahead

Dear Friends of Compass Pathways,

### Urgent need

A year ago, I noted how privileged I felt to join Compass at such a crucial juncture; my enthusiasm for our mission has only deepened since then.

Our dedication to innovation in mental health care is more vital than ever, as millions continue to grapple with mental health challenges—we all know someone affected, including many of us personally.

### Momentum increasing

The pressing need for improved care options continues to spur momentum for psychedelic treatments.

We've witnessed significant strides in the regulatory landscape, signalling a shift towards increasing acceptance. Notable developments include the US Food and Drug Administration (FDA) issuing draft guidance for the clinical investigation of psychedelic drugs and the European Medicines Agency updating guidelines to incorporate psychedelic therapy for depression.

These regulatory advancements reflect a growing acknowledgment of the therapeutic potential of psychedelics.

We also welcome Lykos Therapeutics' submission of a landmark New Drug Application for their post-traumatic stress disorder (PTSD) therapy to the FDA, a noteworthy milestone in mental health care. More broadly, we saw continued public interest in the potential of psychedelics which underscores the urgency and importance of our work.

In August, our success in securing up to \$285 million in funding was a highly significant achievement. Not only did this bolster our financial position, but it also attracted sophisticated healthcare and biotech investors who recognise the promise of our rigorous efforts. We view this new investment as validation of our evidence-based approach to developing psychedelic medicines.

### Evidence pursued

The establishment of the Centre for Mental Health Research and Innovation in collaboration with King's College London (KCL) and the South London and Maudsley NHS Foundation Trust in November marked a tangible milestone in our journey, at the same time initiating our phase 3 trials in the UK. This unique partnership serves as a focal point for COMP360 research, offering a space for psilocybin treatment sessions, therapist training, and the development of digital technologies to support personalised care.

Our global phase 3 programme, the largest ever study of psilocybin treatment, continues to progress. To facilitate the conduct of our studies, we've introduced three new digital products aimed at streamlining workflows and enhancing data collection. Additionally, comprehensive therapist training ensures that our clinical trial execution remains rigorous.





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### Evidence generated

The publication of further data from our phase 2b study in the Journal of Affective Disorders and the study of COMP360 psilocybin treatment alongside SSRI antidepressants in the prestigious journal Neuropsychopharmacology underscores our commitment to advancing the field. Beyond treatment-resistant depression (TRD), our research extends to other mental health disorders, and we were pleased to see promising data published from investigator-initiated studies in cancer-related depression (May), anorexia nervosa (July), and bipolar type II depression (December).

### Access

As we await study results, we've begun preparations for potential regulatory approval and subsequent commercialisation.

In 2023 we published papers focusing on optimising psilocybin treatment outcomes and addressing current terminology limitations. Additionally, we published several papers exploring the application of generative AI and large-language models to analyse psychological support sessions, aiming to enhance care provision.

Embracing digital innovation is pivotal in our journey towards precision medicine in mental health and underscores our commitment to improving outcomes. Expanding digital tools and partnerships remains essential as we progress towards commercialisation.

We're proud to have worked with Lykos Therapeutics to establish a new CPT III code with the American Medical Association, for in-person monitoring and intervention services during administration of psychedelic treatments. This is a vital step to enable reimbursement from payers in the US, which is critical to ensuring broad and equitable access.

Partnerships finalised in late 2023 and announced in early 2024 with healthcare providers like Greenbrook TMS and Hackensack Meridian Health aim to optimise care delivery and ensure broad access to COMP360, if approved.

The strengthening of our leadership team with the appointments of Teri Loxam as Chief Financial Officer and Daphne Karydas to our Board of Directors brings invaluable expertise to our organisation. Their extensive experience in the pharmaceutical and biotechnology sectors will be instrumental as we navigate the complexities of drug development and commercialisation.

The establishment of our Diversity, Equity, and Inclusion (DEI) Council reflects our commitment to fostering a more diverse and inclusive workplace. By focusing on various workstreams, including digital accessibility, therapist diversity, and patient engagement, the council has helped accelerate our progress towards a more equitable organisation and a treatment model that is more diverse, inclusive, and equitable.



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## Looking to the future

2024 will be a critical year for Compass as we anticipate our first pivotal data announcement. We look forward to primary endpoint data from our first phase 3 study in TRD and results from our phase 2 open-label study in PTSD.

Strong phase 3 data would keep us on a path to seek regulatory approval of COMP360 psilocybin treatment, potentially transforming mental health care for those failed by current standards.

Amidst these developments, our unwavering commitment to addressing the urgent need for improved mental health care remains paramount and drives us forward.

Sincerely,

**Kabir Nath**

*Read more, including important cautionary statements about forward-looking information, here in our [Annual Report on Form 10-K](#)*

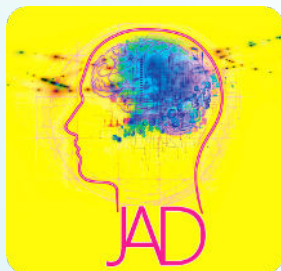


This video was recorded in January 2024 and the information contained in the video speaks only as of January 2024.



# 2023 Timeline highlights

## February



Further data from Compass's phase 2b study published in the Journal of Affective Disorders

## March



DEI Council launched

## May



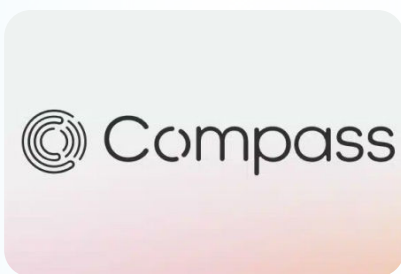
AMA accepted first new code for psychedelic therapies

## May



ISS data demonstrating long-term improvement in depression in cancer patients following single dose of COMP360 psilocybin therapy presented at ASCO 2023

## June



Compass Pathways announced key patents upheld by the US Patent and Trademark Office

## July



Compass announced its term loan facility with Hercules Capital for up to \$50 million

## July



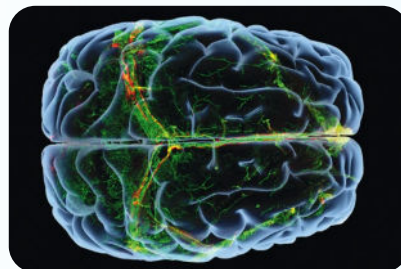
AMA released language of first new CPT code for psychedelic therapies

## July



Opinion paper calling for clarity on the definition of "psychedelic-assisted therapy" published in the American Journal of Psychiatry

## July



Positive data from treatment-resistant depression phase 2 clinical trial of COMP360 psilocybin alongside antidepressants published in Nature journal, Neuropsychopharmacology

# 2023 Timeline highlights

## July



First clinical study results of psilocybin treatment in anorexia nervosa published in Nature Medicine

## August



Compass announced up to \$285 million private placement financing

## September



First study evaluating potential of AI model to predict outcomes COMP360 psilocybin treatment in treatment-resistant depression published in Psychopharmacology

## November



Compass initiated UK component of phase 3 programme and opened Centre for Mental Health Research and Innovation

## December



Study results of psilocybin treatment in bipolar II depression published in JAMA Psychiatry

## December



Teri Loxam appointed as Chief Financial Officer

## December



Compass announced investigational COMP360 psilocybin treatment was well-tolerated in phase 2 study of post-traumatic stress disorder

# Spotlight series

## Evidence: Update on our research



### **Dr Guy Goodwin, Chief Medical Officer at Compass, gives an overview of Compass's research**

In 2023, we progressed our phase 3 programme in treatment-resistant depression (TRD), including initiating the study in the UK. Expected to enrol over 800 patients, our phase 3 programme is the largest clinical study of psilocybin ever conducted. It is comprised of two trials evaluating the safety and efficacy of investigational COMP360 psilocybin in TRD, one against placebo and one with a fixed repeat dose using three arms: 25mg, 10mg, and 1mg. We expect to announce primary endpoint data from one of our two phase 3 studies this year.

*This video was recorded in January 2024 and the information contained in the video speaks only as of January 2024.*

We also continued to make progress in our phase 2 clinical trials in post-traumatic stress disorder (PTSD) and anorexia nervosa, two difficult-to-treat conditions. We announced initial safety findings at 24 hours from our study in PTSD in December 2023, which showed that COMP360 psilocybin treatment was well-tolerated. We plan to announce the full results this year.

Further data from Compass's phase 2b study was published in the Journal of Affective Disorders in February, and in July we saw our study of COMP360 psilocybin treatment alongside SSRI antidepressants published in the Nature journal Neuropsychopharmacology. Finally, we were also pleased to see the publication of encouraging data from investigator-initiated studies in cancer-related depression (May), anorexia nervosa (July) and bipolar type II depression (December).



# Spotlight series

## Pioneer: Opening the Centre for Mental Health Research and Innovation



Opening the Centre for Mental Health Research and Innovation at the Maudsley Hospital in South London in November was a proud moment for Compass.

The Centre is an important research site for our phase 3 programme. Established as part of a pioneering long-term strategic partnership between Compass, South London and Maudsley NHS Foundation Trust, and the Institute of Psychiatry, Psychology & Neuroscience at King's College London, it will accelerate psychedelic research and develop new models of care for mental health in the UK, helping to integrate COMP360 psilocybin treatment into health systems, if approved. This will include evaluating real-world evidence,

researching and developing digital technologies that may help to deliver personalised, predictive and preventative care models, and conducting therapist training.

Thank you to King's College London and the South London and Maudsley NHS Foundation Trust for joining us in this important partnership.

# Spotlight series

## Access: Preparing for commercialisation



### CPT III code

In 2023, the American Medical Association accepted a new Current Procedural Terminology (CPT) III code for Continuous In-Person Monitoring and Intervention During Psychedelic Medication Therapy, which became effective on 1 January 2024. The CPT III code provides a mechanism to track and report the delivery of psychedelic treatments and will help to ensure broad and equitable access to psychedelic therapies, if approved.

The approval of a CPT III code was a critical milestone for Compass as we look towards commercialisation, and we were pleased to partner on the effort with Lykos Therapeutics (formerly MAPS PBC).

### Research collaborations

We also formed important research collaborations last year with Greenbrook TMS and Hackensack Meridian Health. These research collaborations will investigate and inform the delivery model design for COMP360 psilocybin treatment, if FDA-approved. This is an essential step before commercial launch.

# Thank you

For more information, please see our Annual Review on Form 10-K for the year ended 31 December 2023, which has been filed with the U.S. Securities and Exchange Commission and is available on our [investor website](#).

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