

Welcome to our Annual Review 2022



COMPASSION
Navigating Mental Health Pathways

At **COMPASS**, we're
building the future of
mental health care.

[Learn about our work](#)



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Letter from our CEO

Hear from our CEO, Kabir Nath, on our highlights from 2022 and our plans for the year ahead

[Listen to Kabir talk about our achievements in 2022](#)

Dear friends of COMPASS Pathways,

For years I watched COMPASS with interest and excitement as it took its first bold steps. Like many others, I saw a young company with obvious passion and – best of all – a novel and exciting approach to answer the urgent need for better mental health care worldwide.

In 2022, I was delighted to become COMPASS's CEO, and joined a team every bit as dynamic, driven and optimistic as I had expected. It's my privilege to continue the pioneering journey of our co-founders, George Goldsmith and Ekaterina Malievskaia, and I'm delighted that COMPASS will continue benefitting from their vision, with George as Chairman of the Board and Ekaterina as Chief Innovation Officer and Director.

2022: evolution

2022 was a transformative year for COMPASS. As the potential of psychedelics to treat multiple mental health challenges became a hot topic in clinical and public discussions, we matched this growing interest with first-of-its-kind clinical evidence. The New England Journal of Medicine's publication of our phase 2b trial data for investigational COMP360 psilocybin therapy in treatment-resistant depression (TRD) was a watershed moment on this new therapeutic frontier. And it came on the heels of COMPASS being awarded the innovative medicine designation, the Innovation Passport, for COMP360 for TRD. The Innovation Passport is the entry point to the MHRA's Innovative Licensing and Access Pathway (ILAP), which aims to accelerate patient access to safe, financially sustainable and innovative medicines.

Now COMPASS is sustaining momentum with the initiation of our pivotal phase 3 programme, which will offer a deeper understanding of the safety, efficacy, and dosing methodologies for COMP360 psilocybin therapy in TRD. You can read more about the innovation behind these trials in this report. We also made meaningful progress in our research of COMP360 in other potential indications, beginning a phase 2 trial in anorexia nervosa and continuing our phase 2 trial in post-traumatic stress disorder.

“ The New England Journal of Medicine's publication of our phase 2b trial data for investigational COMP360 psilocybin therapy in treatment-resistant depression (TRD) was a watershed moment on this new therapeutic frontier. ”

2022 also saw encouraging signals of early efficacy from exploratory investigator-initiated studies (IIS), including in bipolar disorder, anorexia nervosa, severe TRD, and major depressive disorder. COMPASS began supporting new IISs in bipolar and autism spectrum disorders as well, with the latter the first-ever mechanistic study of psilocybin in autistic adults.

Meanwhile, we're creating the systems, expertise and processes necessary to support this new approach to mental health care. We began training therapists for our phase 3 TRD trials, developed innovative digital support tools for patients and therapists in our clinical trials, and continued our work in developing machine learning, which has the potential to support the prediction of treatment outcomes based on patient experiences with COMP360 so far.

Partnerships and collaborations are key to achieving our mission. With a view to transforming future delivery of mental health care, in March 2022 we announced our partnership with King's College London and the South London and Maudsley NHS Foundation Trust to establish the Centre for Mental Health Research and Innovation. You can learn more about this exciting collaboration in this report. We're also proud to have partnered with One Mind, a leading mental health non-profit, to sponsor three "COMPASS-One Mind Rising Star Awards" which fund three early career scientists pursuing research with the potential to dramatically advance the understanding and treatment of mental health conditions, and to improve patient outcomes.

Finally, of course, we continued to develop our own potential. Companies are only as dynamic and successful as their people, and it's a priority of mine to sustain the team's energy and enthusiasm that has inspired me from day one. By remaining true to our culture and values, in 2022 we were certified as a Most Loved Workplace® in the UK, based upon authentic employee feedback.

2023: acceleration

Looking to the year ahead, I expect COMPASS's work to be just as pioneering and exciting as last year's. In 2023, we'll be squarely focused on our global phase 3 TRD programme, while continuing to pursue other indications with equal urgency.

This year we will also increase focus on preparing for commercialisation. We'll build on our training of research therapists and start training content development for commercial launch, and in the US, we're starting to engage with potential commercial delivery partners in earnest. In short, we're taking steps to prepare for potential regulatory approval of COMP360 psilocybin therapy and its introduction into health systems, should our phase 3 programme validate the results of our phase 2b study.

Why we're here

The urgent need for better mental health care drives us in everything we do. In 2022, our accomplishments kept us on track to deliver on the vision of our co-founders. Our motivation and passion continue to grow as COMPASS transforms from a start-up with a great idea, to a mental health company with an evidence-affirmed pipeline and a clear plan to deliver.

There is nowhere else I would rather be and there's no company I would rather have joined.

Sincerely,

Kabir Nath



March

COMPASS announced the launch of The Centre for Mental Health Research and Innovation, in the UK



May

COMPASS awarded Innovation Passport as part of the UK MHRA Innovative Licensing and Access Pathway



May

Data from investigator-initiated studies in anorexia nervosa and severe treatment-resistant depression presented at the Society of Biological Psychiatry Annual Meeting



May

COMPASS announced that it will fund an investigator-initiated study of investigational COMP360 psilocybin in autistic adults



July

COMPASS launched phase 2 clinical trial of COMP360 psilocybin therapy in anorexia nervosa



August

Kabir Nath appointed as CEO of COMPASS Pathways



September

One Mind announced the winners of the COMPASS-One Mind Rising Star Awards



October

COMPASS announced the design of our pivotal phase 3 programme



November

COMPASS was certified as a Most Loved Workplace



November

COMPASS's phase 2b data published in the *New England Journal of Medicine*

COMPASS

Spotlight series

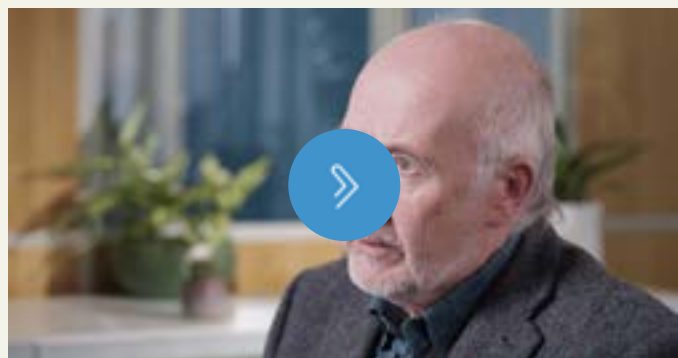


In 2022 we made great progress in many areas of our work. Importantly, we saw the publication of our phase 2b data in the New England Journal of Medicine and initiated our phase 3 programme of COMP360 psilocybin therapy in treatment-resistant depression.

We also began a phase 2 trial of COMP360 in anorexia nervosa and received encouraging signals of early efficacy from a variety of investigator-initiated studies. And we were proud to partner with King's College London and South London and Maudsley NHS Foundation Trust to establish the Centre for Mental Health Research and Innovation. Click below to hear more about these exciting highlights in our spotlight series.

New England Journal of Medicine publication

Dr Guy Goodwin talks about our publication in the New England Journal of Medicine



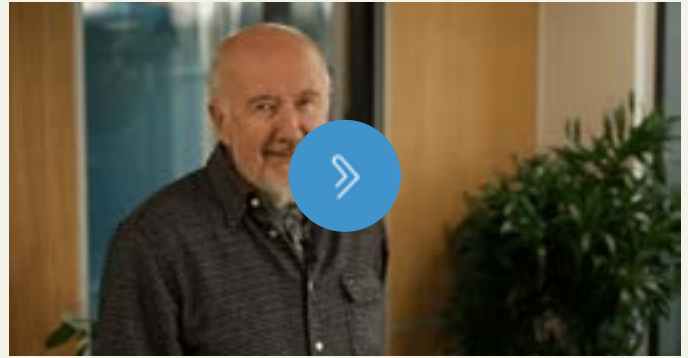
After reporting positive top-line results from our phase 2b study of investigational COMP360 psilocybin therapy for treatment-resistant depression (TRD) in 2021, the prestigious New England Journal of Medicine accepted the data and additional analysis for publication last November. Seeing our data published in this highly respected journal was a proud moment for the entire team.

TRD is not just major depression. It is defined as depression that does not respond to two or more antidepressant medications in a single depressive episode for a patient. It is a condition that is particularly difficult to treat, and many patients suffer for extended periods of time with huge negative impact on their quality of life. Our phase 2b study showed that a substantial number of people who received the highest dose of COMP360 psilocybin (25mg), with psychological support, experienced rapid improvement in their symptoms of depression, with effects lasting until the end of the study (three months).

We want to thank everyone involved—our research partners, the principal and sub-investigators, study coordinators, nurses, therapists, pharmacists, raters, and the COMPASS team—for the rigorous work that went into designing a trial that gave a clear and robust signal of the safety and efficacy of COMP360 in treatment-resistant depression.

Phase 3 programme in treatment-resistant depression (TRD)

Dr Guy Goodwin, Chief Medical Officer at COMPASS Pathways, talks about our phase 3 programme in TRD



Having pioneered a first-of-its-kind phase 2b trial for investigational COMP360 psilocybin therapy in TRD, in 2022 COMPASS scaled up our ambitions by preparing and initiating our phase 3 programme, which represents the largest and most comprehensive study to date of the potential of psilocybin-based therapy.

COMPASS has worked carefully to structure two trials—one against placebo, one with a fixed repeat dose—that between them can offer a comprehensive understanding of COMP360 psilocybin therapy's effectiveness as a treatment for TRD. This is the first time anyone has aligned the specific demands of a psilocybin trial to the scale of a phase 3 clinical study, continuing COMPASS's history of pioneering new processes in the pursuit of novel, urgently needed therapies.

This critical research is a major step towards regulatory approval, and access through healthcare systems. Each step forward takes us closer to our vision of a world of mental wellbeing.

Phase 2 trial in anorexia nervosa

Dr Himmerich, Clinical Senior Lecturer in Eating Disorders at King's College London and Consultant Psychiatrist at South London and Maudsley NHS Foundation Trust, talks about our phase 2 trial in anorexia nervosa



In 2022, our clinical research programme for investigational COMP360 included anorexia nervosa, an eating disorder characterised by low weight, calorie restriction, and preoccupation with weight and body image. 3.9 million people suffer with anorexia nervosa around the world. It affects up to 4% of women at some point in their lives, with one in five cases becoming persistent. It is extremely difficult to treat and has the highest mortality rate of all psychiatric disorders. Currently there are no approved pharmacological options for those living with the condition.

The hypothesis is that, similarly to treatment-resistant depression, COMP360 psilocybin therapy may help disrupt the mental processes that lock patients into negative cycles of behaviour and thought.

After encouraging results from an investigator-initiated study of 10 patients in May, COMPASS launched a multi-centre, double-blind randomised controlled phase 2 trial of 60 US and UK patients in July 2022. The study will examine whether COMP360 is effective in treating anorexia nervosa, and if a therapeutic response is elicited, by comparing the effects of 25mg vs 1mg doses, administered with psychological support.

UK Centre of Excellence

David Bradley, Chief Executive Officer at South London and Maudsley NHS Foundation Trust, talks about launching a Centre of Excellence, in the UK



Last year, we announced a long-term strategic partnership with South London and Maudsley NHS Foundation Trust, the largest mental health trust in the UK National Health Service (NHS) and the Institute of Psychiatry, Psychology and Neuroscience at King's College London to accelerate psychedelic research and develop new models of care for mental health in the UK.

As of the beginning of 2023, renovations on The Centre for Mental Health Research and Innovation unit are officially underway at Maudsley Hospital in London. It is expected that the unit will be open for research in the first half of this year.

This pioneering collaboration will provide patient access to cutting edge research studies in multiple areas of high unmet need in mental health, beginning with our phase 3 programme in TRD. The Centre will also enable therapist training, evaluate real-world evidence, and prototype digital technologies that may be able to help deliver personalised, predictive and preventative care models.

We're grateful to King's College London and the South London and Maudsley NHS Foundation Trust, for joining us in this important partnership to build the future of mental health care.

Data from investigator-initiated studies

In addition to the publication of our phase 2b data in the *New England Journal of Medicine*, 2022 saw several exploratory investigator-initiated studies (IIS) of COMP360 reporting positive signals of early efficacy.



Anorexia nervosa

COMP360 psilocybin therapy showed signs of effectiveness in **anorexia nervosa**, in a study of 10 people conducted at the University of California San Diego. After a single 25mg dose,

40%*

of participants (n=4) experienced clinically significant reductions in eating disorder psychopathology at the 3-month follow-up.

Type 2 bipolar disorder

In a study of 14 people with **type 2 bipolar disorder** at Sheppard Pratt Baltimore,

86%*

of participants met response and remission criteria for the Montgomery-Åsberg Depression Rating Scale (MADRS) at 12 weeks after a single 25mg dose of COMP360 psilocybin therapy.

Severe treatment-resistant depression

An IIS into COMP360 psilocybin therapy for **severe treatment-resistant depression**, also conducted at Sheppard Pratt, found that

53.3%*

(n=7) of 12 participants maintained MADRS response criteria at 12 weeks after treatment with a single 25mg dose, and a quarter had maintained remission (n=3).

Major depressive disorder

In Zurich, a double-blind, randomised clinical trial of 52 participants with **major depressive disorder** compared a single moderate dose of COMP360 with placebo, with equal amounts of psychological support. At 14 days follow-up,

58%*

of participants in the psilocybin group met MADRS response criteria, compared to 16% of participants in the placebo group.

At each of these encouraging milestones, COMPASS's conviction in the potential of COMP360 to transform the future of mental health care has continued to grow.

* Data reported from trial investigator

Impact strategy

In 2022, COMPASS developed a wide-reaching new impact strategy that applies across our organisation.

Our strategy is designed to further our efforts to act responsibly and make a positive impact on everyone we work with, including patients participating in our clinical trials, therapists, our partners, and COMPASS team members.

[Learn about our impact strategy](#)

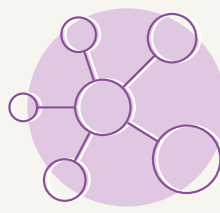
Our strategy is designed to further our efforts to act responsibly and make a positive impact on everyone we work with, including patients participating in our clinical trials, therapists, our partners, and COMPASS team members.

The strategy includes our commitments to patients and therapists taking part in our trials (formerly known as [our charters](#)). You can read more about these pillars, our focus areas and our actions [here](#).

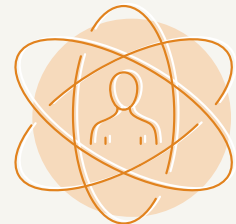
COMPASS' impact strategy contains three pillars:



Our work to develop **transformative therapies** for people not helped by existing treatments



Our contribution to building the **mental health ecosystem** of the future that promotes access and health equity over the long term



The actions that make us a **responsible organisation**

Our impact strategy is already leading us towards new programmes to help make a positive difference; for example, we have recently incorporated a diversity, equity and inclusion (DEI) advisory group into our therapist training programme. The group is already engaged with our therapist teams to address the biases of their own experience and engage with every patient participating in our clinical trials in a manner mindful of their cultures and identities.

We're excited to launch more initiatives in the coming years, as our impact strategy informs COMPASS's behaviour at every level, from the front line to the boardroom.

We think differently about mental health so you can too

For more information, please see our Annual Report on Form 10-K for the year ended December 31, 2022, which has been filed with the U.S. Securities and Exchange Commission and is available on our investor website.

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