

COMPASS Pathways news | July 2019 issue

2019-07-23

Here are highlights of our activities in the first half of 2019 that we hope will move us closer to our goal of improving mental health care for as many as possible.

The resurgence in psychedelic research began two decades ago, with a handful of dedicated individuals and institutions studying the potential impact of substances such as psilocybin, MDMA and ketamine, in mental health care. Now, in 2019, psychedelic therapy is taking centre stage, with discussions on the subject taking place at high-profile global events such as TED and the World Economic Forum in Davos, as well as at mainstream healthcare and life sciences conferences.

We welcome this growing interest and are fortunate to collaborate and work with so many people who share our ambition of better care for those suffering with mental illness. Our commitment to our mission is as strong as it was when we began; we want to accelerate patient access to evidence-based innovation in mental health. Psychedelic research is a good place to start.

Treatment-resistant depression study in progress

Thirteen of our clinical trial sites are now active: we have three sites in the UK, three in the Netherlands, three in the USA, two in Spain, and one in each of Ireland and Canada. Further sites will be opening over the next few months. In total, our sites will be recruiting 216 patients with treatment-resistant depression, from across Europe and North America, to take part in this Psilocybin Therapy phase IIb trial.

As part of the trial recruitment process, potential participants are very carefully screened, by our trial sites and independent eligibility reviewers, to ensure their eligibility for the treatment. Our training of therapists is equally rigorous. We have now trained 65 therapists and assisting therapists in Europe, US and Canada. For a map of our current sites, click [here](#).

Healthy volunteers study completed

We have completed our study of healthy volunteers, looking at the short- and long-term effects of medium and high dose psilocybin on social, emotional and cognitive functioning, compared with placebo. With 89 participants, this is the largest psilocybin study ever done. We are now processing the data and will be reporting full results later in the year.

Dr James Rucker, study clinician at King's College London where the trial took place, said "To hear participants speaking afterwards about their deeply positive and heartfelt experiences was an emotional experience for me. 'Blown away', 'profound and amazing' and 'years of the deepest psychotherapy' were some of the phrases that come to mind. There was immense gratitude for the experience and for the attention to detail of the set-up and the study team."

Investigator-instigated studies

In addition to progressing our own studies with psilocybin, we collaborate with select academic institutions and researchers, supporting research that could help patients and lead to a change in mental health outcomes. We provide our GMP (good manufacturing practice) psilocybin for these studies, free of charge, in exchange for the right to use the safety data generated. We are currently working or in discussion with 20 research teams on studies covering a broad spectrum of topics.

It is critically important that scientific research in this area continues, given the large unmet need in so many mental illnesses. At the same time, any innovation or breakthrough has to move out of the lab and into the reach of patients. We are committed to developing any promising results from early studies into the robust, large-scale research programmes required to generate the evidence needed by regulators, payers and health systems.

Funding our next phase of growth

We have raised \$35 million to date, from a number of investors, all of whom are committed to our mission to improve patient access to innovation, and to see a shift in the way in which mental illness is treated and managed. We begin a further funding round later this month, and will use the money raised to drive our next phase of growth, operationally and in R&D. Our R&D work will include our own research, as well as any development programmes that emerge from our academic collaborations. Large-scale clinical trials require significant investment but are the only route by which we can move from innovation to patients.

Our team is expanding; we now have over 20 talented and committed people in our UK and US offices, as well as a thriving internship programme. This summer we welcomed interns from MIT, UPenn, UCL and Cambridge, working across different functions, including R&D, Clinical Operations, Patient Access, Business Development, and Technology.

We are already seeing the benefits of the **Breakthrough Therapy designation** that the FDA has given to our protocol of Psilocybin Therapy for treatment-resistant depression. FDA experts are helping us with our Clinical Development Plan for Psilocybin Therapy, as well as our plans for additional studies. And we are continuing to talk to payers, insurers, and patient advocacy organisations about patient access, and to explore ideas for how we make Psilocybin Therapy available to as many patients as possible.

While Psilocybin Therapy for treatment-resistant depression remains our priority and focus, our R&D team are also looking at other new compounds, innovative technologies and treatment modalities that might help patients for whom existing treatments don't work. We are committed to bringing innovation to these patients as quickly as we can, and to understanding how we get people well and keep them well.

Your feedback

If you'd like to know more about what we are doing or have any comments about COMPASS Pathways News, please get in touch with us at info@compasspathways.com.