

Awakn

Welcoming a new era of psychedelic-assisted therapy

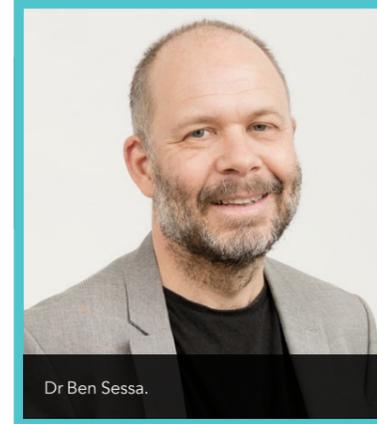
Dr Ben Sessa is a psychiatrist, researcher, writer, and Co-founder and Head of Psychedelic Medicine at Awakn Life Sciences. His academic research coupled with his therapeutic practice have yielded vital insights into the safety and efficacy of psychedelic-assisted therapy. Now, practicing with the biotechnology company Awakn Life Sciences, he is working to increase the availability of these revolutionary treatments. As we move ever closer to the medicalisation of psychedelic drugs, Sessa is uniquely equipped to extol the virtues of ketamine, MDMA, and psilocybin as adjuncts to psychotherapy. Research Outreach caught up with him two years after our last interview, to talk about the exciting developments in the field.

Could you give our readers a brief introduction to psychedelic-assisted therapy?

I think the most interesting thing about this is psychotherapy and psychopharmacology are very disparate subjects, at opposite ends of the spectrum. For the last 50 years of medicine in psychiatry, we've been giving drugs that don't typically have a directly felt psychoactive effect, but change people's mental states in a much more subtle way. Then you have your psychotherapy appointment in which you talk about your psychological issues. Psychedelic-assisted therapy is fascinating because it's bringing these two things together. We're carrying out psychotherapy in an altered state of consciousness.

So, although there's a lot of focus on drugs, it's much more about psychotherapy than it is the drug. Whether it's ketamine, MDMA, or psilocybin, it's about the altered state of consciousness and how this can provide a deeper, more effective form of psychotherapy. It is an adjunct to psychotherapy using psychedelic drugs of all different types to make it more effective for patients, in that it can be faster and more effective, and this is important because it is showing that patients who are so far treatment-resistant to the traditional model of either drugs or therapy, do respond to this. This is a revolutionary breakthrough in the way we do psychiatry.

Since we last interviewed you two years ago, do you feel there has been a notable



Dr Ben Sessa.

shift in public and scientific attitudes towards this type of therapy?

Yes. I've been working in psychedelics for 15 to 20 years, primarily in an academic context, within universities carrying out research studies and publishing the results. What has happened in the last two years is phenomenal. There's been a shift away from academia towards developing meaningful healthcare systems with psychedelics, and we have seen a plethora of psychedelic start-up companies carrying out research, and also creating treatment protocols for patients. Now, in terms of how the community has accepted this, it's wholly positive. There has been far more research and studies than ever before, but also a lot more media and public attention, and the medical profession is also accepting it. I think the validation of scientific research, particularly neuroimaging, adds a scientific edge to the work. So, while there was a tremendous amount of work in the sixties, it comes across as less scientific and more experiential, whereas when you can put someone into a scanner and see pretty pictures of their brain and the different compounds, and then talk about how that links into psychotherapy, it gives us a neurobiological mechanism for how these drugs work in psychotherapy. It adds this extra 'scientific' edge. That can only be a good thing in terms



Awakn has clinics in Bristol, London, and Oslo.



The Awakn clinic in London, UK.



The Awakn clinics offers a tranquil space for expert psychedelic-assisted therapy.



The psychedelic medical clinic offers ketamine-assisted therapy.

This is a revolutionary breakthrough in the way we do psychiatry.

of stigma and having these drugs accepted both by the public and by healthcare systems.

Could you introduce us to the important work being undertaken by Awakn?

I'd been working in the field as an academic for over 15 years, and then I was approached by the co-founders of Awakn and we set up the company about two years ago. There are lots of different start-ups doing some parts of psychedelic medicine. Some are developing new molecules, some are moving drugs towards approval status, some are opening clinics, some are doing psychedelic training. We're doing all of those in Awakn.

For me, the clinics are the most exciting part. While there are numerous companies making molecules and developing drugs, there are very few places to go and get these drugs once they become approved. MAPS, which is spearheading the work with MDMA, is not building clinics. COMPASS Pathways, which is spearheading the working with psilocybin, they're not building clinics. We're building physical bricks and mortar clinics. We have three clinics open now, London, Bristol, and Oslo, with a view to opening 10 to 15 in the next four or so years. We

want to be the high street, physical presence, where you go to get your psychedelic therapy.

At the moment, ketamine remains the only licensed psychedelic drug. MDMA, psilocybin, LSD, DMT, these are wonderful compounds with great potential, but they are not officially medicines. They are research chemicals. You can't use them to treat patients. You can only use those drugs in research protocols and carrying out research is very different from carrying out treatments. So, ketamine is all we've got.

At Awakn, I'm trained as an MDMA therapist, a psilocybin therapist, and a ketamine therapist, and so we use ketamine-assisted psychedelic therapy as part of the treatment with psychotherapy. In the last ten years there have been a huge number of so-called ketamine infusion clinics opening, about 600 of them in North America. They just give ketamine with little or no psychotherapy, and it works as an effective, rapid-acting antidepressant, but we think they're missing a trick. So, we're not just giving ketamine as an antidepressant, we're giving it in the same way we would use MDMA or psilocybin, as an adjunct to psychotherapy.

We don't want to be considered a ketamine clinic. We want to be considered a psychedelic medical clinic. One way of thinking of it is: 'Awakn Life Sciences' Psychedelic Clinic; ketamine now, MDMA and psilocybin coming soon'. We will soon be a more generalised psychedelic medical clinic with a broader range of compounds, as soon as they get approved.

Does it look likely that MDMA and psilocybin will have the same treatment status as ketamine in the coming months and years?

The development of a molecule into medicine is pretty standardised and it's no different for psychedelics than it is for paracetamol or penicillin. You go through these research stages: you do toxicity studies, animal studies, in vitro studies and then you do phase one, two, and three which includes large, multisite, international studies, before you get approval. The whole process takes 15 or 20 years and costs a hundred million dollars, say. The fact that psychedelics are banned substances creates extra complications with scheduling, and Home Office approval, and that kind of thing, but in terms of the hoops you must jump through, it's just like any other drug.

MDMA is at the front of the pack at the moment. The goalposts shift all the time, but we are very close now. MDMA is likely to be over the line first in late 2024. Psilocybin is being spearheaded primarily by COMPASS Pathways and they're in late phase two, going into phase three. They're a couple of years behind MDMA. So, in answer to your question, we should have MDMA approved by 2024 and psilocybin a couple of years behind that.

You appeared in the Netflix documentary, 'How to Change Your Mind'. How important are these forms of popular scientific communication in terms of changing public attitudes?



The Awakn Bristol clinic team with Professor David Nutt, Chief Research Officer of Awakn..



Dr Ben Sessa and Dr Laurie Higbed with a client undergoing ketamine-assisted therapy.



Dr Laurie Higbed with a client at Awakn's Bristol clinic.

What's great about Michael Pollen's book and now the Netflix documentary is that Pollen is a very big name in America, as a mainstream broadcaster and journalist. His covering of the subject has really pushed things forward because he isn't part of the established psychedelic community, preaching to the converted.

I think the documentary was done well. There are four parts: LSD, psilocybin, MDMA, and mescaline. It is interesting that they chose mescaline for the fourth part and I think that highlights an American approach, because mescaline is not a widely used drug anywhere, not even in the States, and certainly not outside of the States. The reason they put that in from what I can see is to highlight the Indigenous Native American population, showing how there is a respect for that culture and indigenous uses of these drugs. Personally, I would've done LSD, psilocybin, MDMA, and ketamine because ketamine is used globally.

I think the documentary has a good balance of personal experiences in terms of patients describing their experiences in very moving terms. There is lots of science pitched at a level for the public. Most of the main figures in the movement are featured, with some exceptions. I think it was really well produced and it's been tremendous for us at Awakn. We've

had a huge increase in traffic in terms of interest and people contacting us on the back of it. There must be 200 psychedelic start-ups in the world, and Awakn Life Sciences was the only one featured in the documentary. So that's great, a great scoop for us. We've had loads of people ringing, emailing, contacting us, a lot of them saying, 'That was fantastic, can I get MDMA?' Of course, then we have to say, 'No. We showcased MDMA, but you can't. You can only get ketamine.' My phone's just been ringing off the hook with media interest since then.

You recently shared an image on Twitter showing a humorous mock-up of commercialised MDMA packaging. What was the reaction to this image?

Going back to one of your earlier questions about attitudes changing, there is something interesting occurring within the psychedelic community. Some of the old guard don't support the concept of medicalisation, which they see as corporatisation. Personally, I don't, I see medicalisation as accessibility. Psychedelic drugs have been around for thousands of years, yet the number of people who have used them and certainly used them therapeutically is very, very small. This is because they're not accessible, unless you're prepared to break the law and go to an underground therapist. So, I'm supportive of what we call medicalisation. For me, it's about getting these

compounds out there for those patients who could benefit from them, those who are not prepared to break the law (or sit in a shaman's hut in Peru or Totnes). They want to go to their GP and have this. So, medicalisation is a good thing. It's about bringing these medicines to more people. So, I fully support it. Now, on the other side of the coin: I can understand concerns from the psychedelic community that we don't want this to become a profit-driven pharma industry. There's a lot we can learn from mistakes in the past, but we also have to accept that if this is going to be made medicine, it has to be a pharma industry because that's how medicine works. We can make an ethical pharma industry, but it has to be a pharma industry. So, it's moving so fast. There are companies opening and others closing all the time. It's really going to be fascinating in the next five years to see where this goes.

Are you still undertaking research, or is your role currently more active and hands-on with regards to the therapy side of things?

So, I've got multiple roles in Awakn as Founder. I started out as the Chief Medical Officer because we needed a CMO when we formed the company. Any medical company has to have a CMO who holds ultimate medical responsibility. I've recently relinquished that role and we've got another CMO starting now.

We will soon be a more generalised psychedelic medical clinic with a broader range of compounds, as soon as they get approved.

My official title is Co-Founder and Head of Psychedelic Medicine. So, that means I am still having a clinical role – I have a small caseload in Bristol – but not as much as the full-time therapists, I see approximately three patients a week in ketamine therapy.

I also have a communications role, I do all media interviews, I travel around the world. I talk at conferences as the public face of Awakn and you're quite right, we're also carrying out research. We're carrying out research most specifically towards addictions and particularly alcohol-use disorder. We're developing ketamine as a treatment for alcohol-use disorder, with a view to having it approved for that condition. The MDMA study that I'm sure we talked about last time which we did in Bristol, we're expanding that to a phase 2b study, a placebo-controlled study, and we're doing behavioural addictions as well, using ketamine-assisted therapy for various disorders including pornography and sex addiction. So, really exciting

research and development going on at Awakn, as well as the clinics.

I think I know the answer to this from the tone of your answers, but do you feel optimistic about the future success and widespread adoption of psychedelic-assisted therapy?

I do feel incredibly optimistic, and I think it's a great question. Mind you, I'm biased because I'm incredibly optimistic about everyone and everything anyway. It goes back to the issue about this concept of medicalisation. I think this can only be a good thing. Psychedelics have languished in the background for a very long time as these bad, unhelpful, dangerous, addictive, unsafe and illegal substances, and they're none of those things. They're very safe, very effective medicines.

It's really interesting and exciting to see that shift away from this underground community into an overground, legal, regulated community. It can only be a good thing for accessibility. Now, I'm going back to this issue of the old guard

saying things like, 'Doctors, get your hands off our sacred molecule,' as if medicalising them will somehow lose the magic. I do not see any evidence of that. On the contrary, I would say in the last 15 years of the psychedelic renaissance we're seeing the success of psychedelic culture. There's no evidence to suggest that just because we are moving towards medicalisation we're somehow not having festivals and raves. They are thriving. The psychedelics, the clubs, the groups, the gatherings, the meetings, the conferences are huge. They're everywhere. There are far more than 15 years ago when I started. So, I don't see any evidence that medicalisation is somehow strangulating psychedelic culture. I think psychedelic culture has thrived while at the same time we're legitimising it for medicine as well. So, it's a win-win.

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