

Opportunities for the IPO of Psychedelics Companies (or, How to Change Investors' Minds)

If anyone had suggested only a few years ago that it is a realistic proposition to float a psychedelics company on any of the London market, that suggestion would likely have been met with derision. Commentators would have pointed to a lack of understanding and therefore acceptance of psychedelics in the investment community and to potential problems under the Proceeds of Crime Act 2002 (POCA).

However, times are changing. First, the Financial Conduct Authority (FCA) has given guidance about floating medicinal cannabis companies and we believe (for the reasons set out later) that the guidance can be applied to psychedelics companies. Secondly, in the last few years there has been a growing awareness of how widespread mental illness is and also of the potential of psychedelic drugs to treat certain mental illnesses effectively. For evidence of psychedelics' journey towards the mainstream, one need look no further than the success of the Netflix series "How to change your mind" or the fact that in late November 2022 there was a lengthy article about psilocybin in The Sunday Times magazine. Finally, an ecosystem of leading academic research and expertise in clinical trials has developed in the UK and elsewhere, led in the UK by institutions such as Imperial College London and King's College London.

It is reasonable to assume that the investment community will recognise these points and we therefore consider that there may well be an opportunity for psychedelics companies to carry out an IPO on one of the UK markets. Investment into UK-based psychedelics ventures, typically led by newly-established specialist funds and private family offices, is starting to gather pace, although listings of such businesses have so far taken place only in the US (such as Compass Pathways on NASDAQ) or Canada (such as Small Pharma on the TSX-V).

What Are Psychedelics?

Readers of this article are likely to be more qualified than me to answer this question, but (in summary) "psychedelics" are a class of psychoactive substances, that is, a

substance that can produce a psychoactive effect in a person who consumes it. There is a psychoactive effect in a person if, by stimulating or depressing the person's central nervous system, a substance affects the person's mental functioning. In other words, a substance causes a psychoactive effect in a person if it produces temporary changes in perception, mood and cognitive processes which affect all the senses. The psychedelic that is most often referred to is psilocybin, which is the active ingredient in (so-called) "magic mushrooms". However, that is by no means the only psychedelic. Other examples include LSD, mescaline, ayahuasca, MDMA (the "ecstasy" drug), and a derivative of ketamine. Psilocybin can also be synthesised: that is, produced in a laboratory.

How Widespread is Mental Illness?

Mental health issues affect many people. Recent estimates state that in the UK one in six adults experienced a "common mental disorder" such as depression or anxiety in the past week, and one in six children aged between six and 16 experienced a "common mental disorder" in 2021. In 2020, the leading cause of death for people in the UK aged five to 34 was "intentional self-harm". It is estimated that mental health problems cost the UK economy £118 billion per year, mainly in lost productivity and work absence. In 2021, the World Health Organisation estimated that one in four people in the world will be affected by mental or neurological disorders at some point in their lives. Levels of depression and anxiety are reported to be at a global all-time high, which is not surprising following the Covid-19 pandemic and worldwide lockdowns.

It is therefore clear that there is a great need for effective treatments for mental illness. Many instances of depression do not respond to traditional therapies or drug treatments, a phenomenon known as "treatment-resistant depression". If psychedelics can add to the treatments that medical clinicians can use then this would be a very welcome development with a potential to improve people's lives significantly. Psychedelics companies would then have a role to play in researching, developing and eventually supplying such treatments, and that role would benefit both the world at large and psychedelics companies.

Why are Psychedelics Potentially Useful?

Research is being carried out across the world into the potential use of psilocybin in the treatment of depression, PTSD, anorexia, tobacco addiction and alcohol dependency.

In recent years there has been increasing focus on and public acceptance of the use of psilocybin. A small, early-stage (but widely reported, including a programme shown on BBC1) study carried out by Imperial College London's Centre for Psychedelic Research has suggested that psilocybin is as good at reducing symptoms of depression as conventional treatment. Unlike conventional treatments, which may cause the unwelcome side effect of blunting positive emotions (as well as negative emotions), it is thought that psilocybin works on receptors in the brain associated with "re-ordering" the way we think about things. Boris Johnson indicated in 2021 that he would consider calls to legalise psilocybin in response to the potential for treatment of mental health conditions.

Psychedelics are therefore expected to be an area of interest for pharmaceutical investors in the near future. For example, in early November 2022, Compass Pathways announced the results of a peer-reviewed randomised control trial of 233 people led by King's College London and published in The New England Journal of Medicine. The study found that one 25mg dose of the drug, alongside psychotherapeutic support, significantly reduced symptoms of depression in patients who did not respond to other medication.

What Impediments to Investment Does Current Drugs Legislation Present?

The main UK controlled drugs legislation are the Misuse of Drugs Act 1971 (MDA) and the Misuse of Drugs Regulations 2001 (MDR), each as amended. Section 2 of the MDA defines a controlled drug as "any substance or product for the time being specified in Part I, II or III of Schedule 2 [of the MDA] or in a temporary class drug order". Schedule 2 classifies controlled drugs under a three-tier system (classes A, B and C in Parts I, II and III of the Schedule respectively) depending on the assessment of their medical use, their relative abuse potential and their risks of dependence. Class A drugs are considered the



most harmful and have the highest level of control. Psilocin is a psychedelic drug listed as a Class A drug in paragraph 1 of Part I of Schedule 2 to the MDA. Psilocin and its ester (that is, a derivative) psilocybin are therefore controlled drugs.

The MDA describes a number of criminal offences relating to controlled drugs including prohibitions on: the importation and exportation of a controlled drug; the production and supply of a controlled drug; and the possession of a controlled drug. However, the MDA also sets out some exceptions and defences to those offences, in particular, in the case of operations in the UK, where the handling and use of the controlled substance has been licensed by the Home Office pursuant to its powers under the MDR, as discussed further below. The investment community has therefore rightly been wary

of companies that might be considered to be committing a criminal offence, particularly as any investment might generate criminal proceeds in the hands of an investor under POCA.

The Medicinal Cannabis Precedent

On 18 September 2020, the FCA issued guidance (FCA Guidance) relating to the listing of cannabis-related businesses, setting out its approach to cannabis-related companies interested in listing in the UK. The FCA Guidance categorises UK and overseas businesses separately, as discussed below.

In relation to UK cannabis-related operations, the position is straightforward: the FCA Guidance states that “The legal position of purely UK-based medicinal cannabis companies and cannabis oil companies is clear. UK-based medicinal

cannabis companies can be admitted to the Official List, if the company has the appropriate Home Office licences for their activities where they are required.”

As regards overseas companies, the FCA Guidance states that “For medicinal cannabis and cannabis oil companies with overseas activities, the company will need to satisfy us that their activities would be legal if carried out in the UK. We will also need to understand the legal basis of the company’s overseas activities, for example the nature of the local licensing and the licences the company holds.”

In July 2021, the FCA issued Primary Market Bulletin 35 which included a draft technical note (TN 104.1) setting out in further detail the FCA’s approach to the listing of companies carrying on cannabis-



related activities. TN 104.1 remains in draft, but (as the FCA has not withdrawn the draft) we consider that it provides a useful indication as to how the FCA would view the listing of a company carrying on cannabis-related activities. If one assumes that the FCA's view sets a "gold standard" then TN 104.1 can be taken to show how the listing or admission of a company carrying on cannabis-related activities on AIM or AQSE should be approached.

The FCA Guidance and TN 104.1 make it clear that, provided additional due diligence is carried out (that is, over and above that which would normally be expected on a listing), then the FCA will consider listing a company developing, producing or selling cannabis-based medicinal products, licensed cannabis-based medicines or consumer products containing cannabidiol (usually referred to as CBD).

In summary, if a purely UK-based company (that is, where the entirety of its operations, including supply chain, are UK-based) holds the appropriate Home Office licences for their activities (or requires none), and can satisfy the FCA of this, then the FCA will permit that company to list (assuming it otherwise satisfies the criteria for listing).

By contrast, a company with cannabis-related activities legally operated overseas is in a different position. The securities of such a company may be listed, provided the FCA is satisfied its business does not give rise to any money laundering offence under POCA and it otherwise satisfies the criteria for listing. A company with cannabis-related activities legally operated overseas will need to satisfy the FCA that those activities are for a purpose that is also lawful in the UK.

The FCA will also need to understand the legal basis of the company's overseas

activities, for example the nature of the local licensing and the licences the company holds. To satisfy the FCA on these points, after consideration of the company's operations and the relevant jurisdictions, the FCA will request appropriate legal opinion(s) on the overseas company's cannabis activities. Any legal opinion(s) should at least address the following points: the activities of the company; confirmation of the legality of each of the activities covered by the opinion in the jurisdiction in which they occur; confirmation that such an activity or activities are for purposes which are lawful in the UK; where the legality of the activity in question relies on licensing, information about the jurisdiction's licensing system and details of the track record of the company carrying out the activities in question.

How Does The Medicinal Cannabis Precedent Apply to Psilocybin?

There are good grounds to believe that the regulatory framework and approach for the listing of a psilocybin company would be the same as for a medicinal cannabis company. This is because both cannabis and psilocybin are controlled drugs listed in Schedule 1 to the MDR and therefore conceptually should be treated in the same way.

It is worth noting that in 2018 there was a rescheduling of cannabis-based products for medicinal use in humans (or CBPMs) prior to market authorisation as a medicine, to allow those products to become available for prescription, under the supervision of specially qualified medical professionals, without the need for a Home Office licence. This was on the basis that there was conclusive evidence of the therapeutic benefit of cannabis-based medicinal products for certain medicinal conditions, and reasonable evidence of therapeutic benefit in several other medical conditions, and the rescheduling was intended to act

as a spur to further research and testing of such products, recognising that it would be significantly easier for scientists to research CBPMs under Schedule 2 controls. It is surely no coincidence that there have been a number of listings of medicinal cannabis-focused companies on the UK markets since 2018.

A similar rescheduling of psilocybin is not imminent, but certainly there are well-regarded lobby groups which propose moving psilocybin into the less restrictive Schedule 2 category (as for CBPMs) for research purposes. There is a scientific consensus that it exhibits negligible toxicity or addictive properties.

Research into psilocybin is still at a relatively early stage and, at present, only a very limited number of global regulators approve the use of psychedelics to treat mental health conditions. However, as we have discussed above, the "direction of travel" in the thinking about psilocybin is towards a conclusion that it may form the basis of the development of much-needed novel treatments for mental health conditions and it might well therefore be the case that there will be a change in the view of regulators in future. Because of this, investors may consider that we are at an inflection point and this is a good time to invest in psychedelics companies and may look beyond the current volatility in the markets. We therefore consider that there could be an opportunity for psychedelics companies to conduct an IPO in the UK, particularly given the leading role that UK academic institutions are taking in the research into psilocybin.



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