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Psychedelics could see increased European investor confidence with UK's Real World Evidence pathway – analysis - Analysis

 Proprietary Intelligence

Story

- UK's RWE rigorous regime provides fast route to market, credibility
- US IPOs set valuation precedent
- Investor education and telemedicine drive growth

The UK Medicines and Healthcare products Regulatory Agency's (MHRA) guidance on the use of Real World Evidence (RWE) trials looks set to boost European investor appetite to market psychedelic medicines.

Considered rigorous, yet expeditious, the RWE pathway offered by the UK regulator provides increased confidence in the use of psychedelics as medicines, experts say.

Psychedelics lend themselves well to the UK's RWE pathway as the safety profile of the molecule is known and compounds can therefore bypass Phase I and go into Phase III, according to Malcolm Barratt-Johnson, Chief Medical Officer at Canadian group **Albert Labs** [CSE:ABRT].

This accelerates market access and provides a low-cost way to commercialisation, while adhering to rigorous and safe methodology, he added.

Psychedelics are also backed by extensive [research](#) showing that drugs in this category produce rapid and sustained therapeutic effects across multiple neuropsychiatric disorders, including depression and post-traumatic stress disorder (PTSD), among others.

From 2018 to 2021, around 80% of investment in the psychedelic sector has been in companies focused on psychedelic R&D, with investment exceeded USD 2bn globally up from USD 60m in 2019, according to L.E.K. [data](#).

Majors such as Johnson & Johnson Services, part of **J&J** [NYSE:JNJ], **Jazz Pharmaceuticals** [NASDAQ:JAZZ], **Celon Pharma** [WSE:CLN], **COMPASS Pathways** [NASDAQ:CMPS], **NeuroRX** [NASDAQ:NRXP], **Hikma Pharmaceuticals** [LON: HIK] and **Amneal Pharmaceuticals** [NYSE: AMRX] are expected to be among the main players in the space, according to published [research](#).

Over the past five years there has been an evolution in the understanding of psychedelics and their clinical benefit – and this has extended to the investor community, according to Robert Darwin, Partner at law firm **Dechert**. Regulators are becoming more open-minded in assessing what were previously heavily controlled-use substances for potential benefits in tackling mental health conditions, he said.

If a company with a psychoactive compound as one of its main assets can list on a stock exchange – as was the [case](#) with the UK's **COMPASS Pathways** [NASDAQ:CMPS] in the US last year – it shows that the company meets disclosure requirements within a credible market, Darwin said. It also evidences the value of the substance as a potential clinical tool, he added.

The UK is well-placed from an academic standpoint to investigate further the benefit of these psychedelic compounds, according to Adrienne Rivlin, Partner at **L.E.K Consulting** in London.

The RWE pathway could be a useful tool to expedite access to these therapies to patients given their safety profile and the burgeoning mental healthcare crisis.

With an increased understanding of mental health and its multifaceted nature, patients' environmental factors will need to be considered, Rivlin said. Investors and drug developers will need to address the service delivery aspect with healthcare systems which will require reshaping, Rivlin said. Deep Brain Stimulation (DBS) could be viewed as an analogue service to draw from, she added.

Europe will also need to assess how to implement mitigation strategies - such as the US FDA's Risk Evaluation and Mitigation Strategies (REMS) system – including assessing factors such as the most appropriate cadence of therapeutic intervention, Rivlin said.

Other	Johnson & Johnson
Other	Hikma Pharmaceut
Other	Celon Pharma S.A.
Other	Amneal Pharmaceu L.L.C.
Other	[company record pe
Other	NeuroRx
Target	COMPASS Pathway
TS	DS
Joint book- runner	Berenberg Bank
Lead Manager	BTIG, LLC
Lead Manager	Cantor Fitzgerald, I
Joint book- runner	Cowen Group, Inc.
Joint book- runner	Evercore Inc.
Target	ATAI Life Sciences /
TS	DS
Joint book- runner	Berenberg Bank
Joint book- runner	Canaccord Genuity
Joint book- runner	Cantor Fitzgerald, I
Joint book- runner	Citi
Joint book- runner	Cowen and Compai
Joint book- runner	Credit Suisse
Joint book- runner	RBC Capital Marke
Target	IntelGenx Corp
Bidder	ATAI Life Sciences /
TS	DS
Target	GH Research Irelan
TS	DS
Joint book- runner	Canaccord Genuity Inc.
Joint book- runner	Cowen Group, Inc.
Joint book- runner	JMP Securities
Joint book- runner	Stifel/KBW
Target	neuroCare Group C
Vendor	bm-t Beteiligungsmanag Thueringen GmbH
Vendor	Apeiron Investmen Ltd
Bidder	neuroCare Group C

There could also be an opportunity to capture the preventative healthcare market, which will alleviate the burden of mental health while also enabling investors to capture wider patient populations. Preventing disease onset is worth exploring, but will be dependent on what the evidence says, Rivlin said.

The RWE system

Though cost-effective and potentially time-saving, the RWE system is specific to the UK and product-dependent, meaning it cannot be used for all compounds, Barratt-Johnson conceded.

Yet for those that get a pass into the system, the RWE pathway provides a route to combatting complex conditions such as treatment-resistant depression or PTSD, Darwin echoed.

Albert Labs is one of the first psychedelic drug development companies to be able to [license](#) its natural psilocybin medicine (KRN-101) using the UK's RWE approach, as a treatment for cancer-related anxiety, Barratt-Johnson said.

This will accelerate access to treatment and benefit patients not only in the UK but also the rest of Europe, Canada, and the US, he added. Other psychedelic companies have broader indications while Albert Labs has a focused indication that can be extended to adjacent therapeutic ones, Barratt-Johnson said.

The company's valuation will substantially increase when investors see a quick route to market with early use of the drug, the company's CEO Michael Raymont argued. This proves the legitimacy of the whole psychedelic segment, he added.

Albert Labs anticipates its psilocybin drug will receive approval in late 2022 and obtain reimbursement in 2023, generating revenue in 2023 and profit by 2024, Raymont added.

US sets valuation precedents

Several European biopharmaceutical companies developing psychedelics for psychiatric treatments have provided evidence of investor appetite in the space by garnering hefty valuations on US Nasdaq listings in the last 12-18 months.

UK-based COMPASS Pathways, which is developing psilocybin therapy for use in mental health, raised USD 144m at its US IPO last year, for which it was advised by investment banks **Cowen**, **Evercore ISI**, **Berenberg**, **Cantor Fitzgerald** and **BTIG**. The company [reported](#) statistical significance for its Phase IIb results for its COMP360 psilocybin therapy for treatment-resistant depression.

Similarly, German **atai Life Sciences** [NASDAQ:ATAI] [launched](#) a USD 214m US IPO in June based on a USD 2.3bn valuation with a portfolio of psychedelic compounds and digital therapeutics. The transaction follows its [acquisition](#) of Canadian delivery specialist **IntelGenx Technologies** for USD 12.3m (EUR 10.9m).

Meanwhile, Ireland-headquartered **GH Research** [NASDAQ:GHR] [raised](#) USD 116m in June in its US IPO based on its Phase II proprietary inhalable 5-MeO-DMT candidate for treatment-resistant depression (TRD).

This sets a favourable precedent for other European companies that are looking to IPO such as Germany-incorporated [neurocare Group](#), a mental health digital therapy company, which is looking to list on NASDAQ by the end of 2022, with a view to raise north of EUR 50m (USD 56m). German **HMNC Brain Health**, which is developing personalised therapies for depression and anxiety, is also [looking](#) to raise at least EUR 50m in Series B funds ahead of a US IPO expected for this year or next.

Companies have turned to the US regime as a way of garnering credibility and outcome data. The US Food and Drug Administration (FDA) granted psilocybins "breakthrough" therapy designation, and as this accelerates the time a drug can get to market, the UK's RWE pathway echoes this system.

Fundraising and M&A

Ahead of a listing, European companies are raising substantial VC funding, harnessing valuations set by North American companies. For example Oxford-based **Beckley**

Target	HMNC Brain Health
Other	ICON plc
Other	Scope International
Other	ATAI Life Sciences /
Other	COMPASS Pathway
Other	GH Research Ireland
Target	Beckley Psytech
PR	FTI Consulting
Financial advisor	LifeSci Advisors, LLC
Bidder	Adage Capital Management, L.P.
Bidder	Prime Movers Lab LLC
Bidder	Palo Santo Investor
Bidder	Integrated
Bidder	Delphi VC, LLC
Bidder	Leafy Tunnel
Bidder	Negev Capital
Bidder	Universal Ibogaine
TS DS	
Financial Advisor/Sponsor	Canadian Imperia Commerce
Accountant	Deloitte Canada
Bidder	Braxia Scientific
TS DS	
Other	ATAI Life Sciences /
Other	COMPASS Pathway
Target	Lucid Psycheutic
Bidder	FSD Pharma Inc.
TS DS	
Bidder	PharmAla Biotech Holdings, Inc
Other	Numinus Wellness
Other	Awakn Life Science
Target	PharmAla Biotech Holdings, Inc
Bidder	Psygen Labs
Commercial Banker	Bank of Montreal
Lawyer	Borden Ladner Ger LLP
Accountant	MNP LLP
Commercial Banker	Royal Bank of Canada
Other	Noetic
Other	Iter Investments
Other	Vine Ventures
Target	Filament Ventures (UK)

Psytech, a start-up developing psychedelic drugs to treat psychiatric and neurological conditions, [raised](#) about EUR 68m in August last year.

Companies are combining operations through M&A.

According to recent *Mergermarket* intelligence, Canadian **Universal Ibogaine** [TSX.V:IBO] which is developing medicalised ibogaine-centered addiction treatments, is looking to acquire new clinics following its September reverse [merger](#) with **P Squared Renewables**, while psychedelic research company **Braxia Scientific** [CSE:BRAX], which has four ketamine therapy clinics in Canada is looking to [expand](#) its footprint in the US by acquiring psychedelic therapy clinics in the next two years.

M&A can also help biopharma companies with a heavy retail investor base obtain institutional investors by acquiring another asset in the space and then unlock value by educating the investor community, according to Dr Lakshmi Kotra at Canada-based **FSD Pharma** [CNSX: HUGE].

FSD Pharma which [acquired](#) **Lucid Psycheceuticals** in 2021 is using psychedelic-based treatments for mental health and neurodegenerative conditions such as multiple sclerosis.

Preclinical studies have shown that its neuroprotective compound Lucid-MS has disease modifying potential to reverse myelin degradation in progressive multiple sclerosis. Its Lucid-PSYCH is a psychedelic molecule that is undergoing IND enabling studies with a targeted treatment for neuropsychiatric disorders, such as Major Depressive Disorder (MDD).

The enterprise value of a company becomes associated not only with its IP but also by clinical trial outcomes and positive pipeline milestones, Kotra said.

The psychedelics business model is predicated on successful clinical trials that radically improve outcomes within a few months thereby calling in biotech-style investor, according to Simon Tankel CEO at US-based mental health services provider **Heading Health**. There are higher outcomes in psychedelics and as these are FDA approved drugs, it calls for institutional grade investors, he said.

A fast-acting effect on patients coupled with positive clinical data in the majority of patients, differentiate these treatments from cannabis, Tankels said, noting that with psychedelics there is a higher burden of proof. These treatments also fall in line with the adoption of digital health in terms of remote monitoring and telehealth.

Investors see opportunity in telemedicine

Psychedelics also lend themselves well to the combined business model of telemedicine and drug administration.

One such example is **TripSitter Clinic** [CSE: KETA], which is focused on delivering at-home ketamine telemedicine therapy, for treatment-resistant depression, PTSD and alcoholism among other indications. Its founder Dr. John Huber explained that psychedelics offer an 80% success rate which supports clinical data. Most patients experience results after consistent treatment via infusion and other methods of ketamine therapy, he said, which improves outcomes with limited side effects and saves time and money.

The benefits of these compounds herald wider pharmaceutical development in the space. Ketamine creates neural plasticity by changing states of consciousness in a controlled environment and kickstarts neurogenesis, which is the ability to create neuropathways to reboot the brain giving it therapeutic effect. Ketamine also has a cleaner safety profile, Huber said, coupled with ease of administration which can be oral or nasal for use at home.

Canadian companies have focused on showing the efficacy of ketamine and other psychedelic compounds in treating opioid-addictions and are looking to ramp up operations through acquisitions of psychedelics drug developers or treatment clinics.

PharmAla, a manufacturer of generic MDMA and developer of MDMA-like drugs is looking to make [acquisition](#) in the space ahead of a Canadian stock exchange listing, according to *Mergermarket* intelligence, while **Psygen Labs**, a manufacturer of pharmaceutical-grade psychedelic drugs for clinical research and therapeutic

Target	MagicMed Industri
Bidder	Enveric Biosciences
TS DS	
Target	CaaMTech, Inc.
Bidder	Noetic
Sectors	Agriculture Biotechnology Chemicals and mate Computer software Consumer: Other Financial Services Medical Medical: Pharmace Other Services (other)
SubSectors	Biotechnology relat research Business support se Conglomerates Crop cultivation Drug development Drug manufacture Drug supply Fine chemicals- pharmaceuticals Fund management Health institutions Manufacture and su other consumer prc Medical equipment services Personal care Principal finance Other services Application softwar products Venture Capital/Pri Equity
Topics	Analysis Macro Drivers
Intel Type	Bolt on/Oppportunis Cross Border IPO Large/Transformati Acquisitions Private equity relat
Geography	Canada Cayman Islands Germany Ireland (Republic) Jordan Malta Poland United Kingdom USA
Intel. Grade	Confirmed
Intelligence ID	3365577

applications, is also looking to [expand](#) its manufacturing capability through acquisitions.

Other considerable fundraising or acquisitions in psychedelic companies in 2021 include Canadian **Filament Ventures** reverse [takeover](#) for EUR 40m; US-based **Enveric Biosciences**' [NASDAQ:ENVB] [acquisition](#) of Canadian **MagicMed Industries** for EUR 22m; and US based **CaaMTech**'s USD 22m Series A [financing](#) round led by **Noetic Fund**.

by Mintoi Chessa-Florea in London with analytics by Jonathan Klonowski

Source	Proprietary Intelligence
Value	
Stake Value	N/A