Psyence Group

Psyence receives MHRA approval for Phase 2 trial

Psyence Group ("Psyence") has announced formal approval from the UK's Medicines and Healthcare Regulatory Agency (MHRA) to commence their highly anticipated Phase 2 trial. The trial will assess the safety and efficacy of psilocybin-assisted psychotherapy versus psychotherapy alone for the treatment of adjustment disorder due to an incurable cancer diagnosis in a palliative care context. The trial approval marks an important milestone for Psyence, one of the few companies exploring the therapeutic potential of psilocybin in larger Phase 2 studies for the treatment of neuropsychiatric diseases with high unmet need. We believe the MHRA's approval underpins our strong conviction in Psyence's Rx portfolio, with the trial expected to commence before year end and the primary endpoint available in Q2 2024. Further upcoming catalysts include UK rollout of GOODMIND products expected in October 2022.

Approval allows Psyence to commence Phase 2 trials before year end

MHRA trial approval allows Psyence to proceed with the Phase 2 trial, with first patients expected to be screened in Q4 2022. Trial approval now gives Psyence the chance to create a paradigm shift in the treatment of patients suffering from terminal illness and drive significant quality-of-life improvements in this patient population. The opportunity appears compelling and urgent - current management of adjustment disorder in palliative care has a low rate of success, as existing pharmacological treatments such as antidepressants are ineffective or have a poor safety profile. Furthermore, the trial will allow Psyence to advance psilocybin research, particularly in the UK, and put further credence into the therapeutic utility of psilocybin to treat mental health illnesses with large disease burden. Interest in psilocybin research has also been supported by the FDA, who granted Breakthrough Therapy designation in 2018 for psilocybin-assisted psychotherapy for treatment-resistant depression. Global palliative care diagnoses are estimated to be ~40 million annually, with 34% of those suffering from cancer-related diseases according to the World Health Organisation (WHO), and 75% of those exhibiting symptoms of depression and/or anxiety post-diagnosis. We conservatively assume 20% of that population will be eligible for treatment, based on life expectancy, tolerability and access to palliative care, providing an estimated target market of 2 million patients for Psyence's treatment.

Psyence continues to advance aggressive Rx commercialisation strategy

A unique aspect of Psyence's aggressive Rx commercialisation strategy is the Company's strong partnerships. Delivery of the Phase 2 trial will be accelerated by Clerkenwell Health, a leading psychedelic Contract Research Organisation (CRO) with extensive experience in both conducting psychedelic research and designing psychedelic clinical trials. Filament Health, who are leaders in botanical psychedelic drug processing, have also licensed their natural psilocybin drug and associated IP for use in Psyence's upcoming Phase 2 trial in order to expedite its clinical use as the Company gears towards using their own natural psilocybin in future trials. Psyence plans to complete the trial by the end of Q3 2024 and generate important data sets ahead of a future Phase 3 pivotal trial expected to start in H2 2024 before expected regulatory submissions in Q3 2026.

Valuation: C$0.55/sh target price offers 450% upside as catalysts approach

MHRA approval of Psyence's psilocybin-based Phase 2 trial, which is set to commence in Q4 2022, gives us further confidence in our valuation which we leave unchanged. We construct a risked C$62.4m NPV12% for Psyence's palliative care asset alone, offering additional upside as the remaining line-up matures. This is based upon H&Pe peak sales of ~US$1.1bn combined with a modelled 23.6% probability of regulatory approvals. Adjusting for net cash and outstanding options, we derive a fully diluted C$0.55/sh target price, offering 450% upside from the current price. Psyence also offers a compelling valuation vs. psychedelic peers, a gap we believe will narrow as the Phase 2 trial begins shortly.

See our recently published initiation here for more details

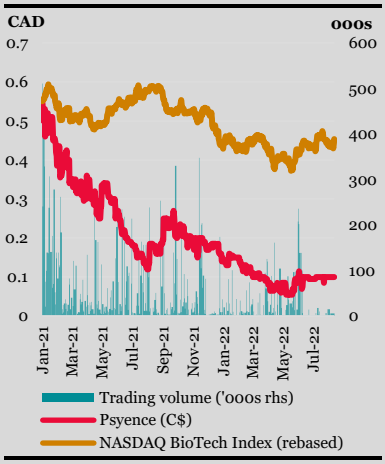
GICS Sector	Health Care
Ticker	CNSX:PSYG
Market cap 20-Sep-22 (C$m)	8.6
Share price 20-Sep-22 (C$)	0.10
Target price 30-Jun-23 (C$)	0.55

Phase 2 trial approved

Trial set to commence Q4 2022

450%

Upside from current share price to H&Pe price target



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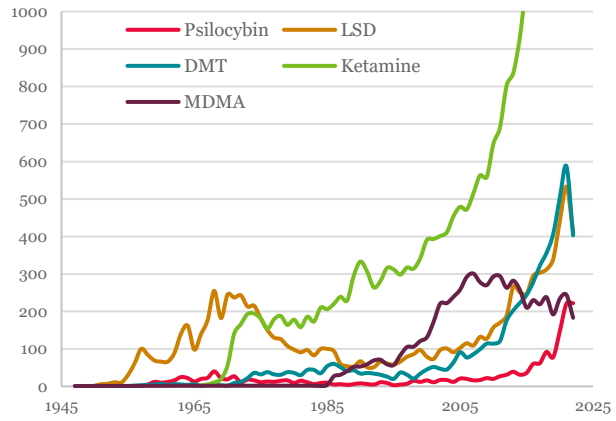
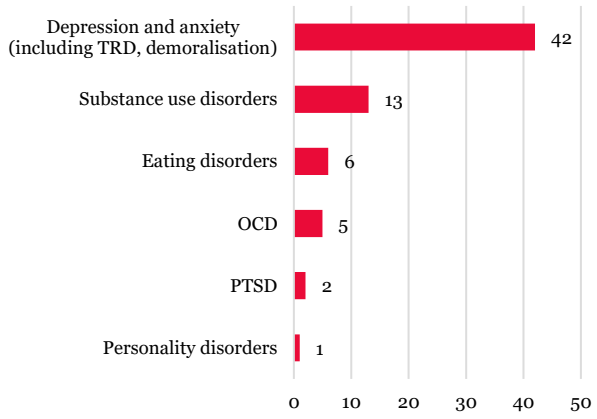
Key Charts

Clinical psychedelic research surging in recent years after Schedule 1 classification induced rut from the 70's (# of manuscripts)



Source: PubMed, H&P estimates

Exploring wide range of indications with a focus on neuropsychiatry; exceptional safety profile to date (# of trials by indication)



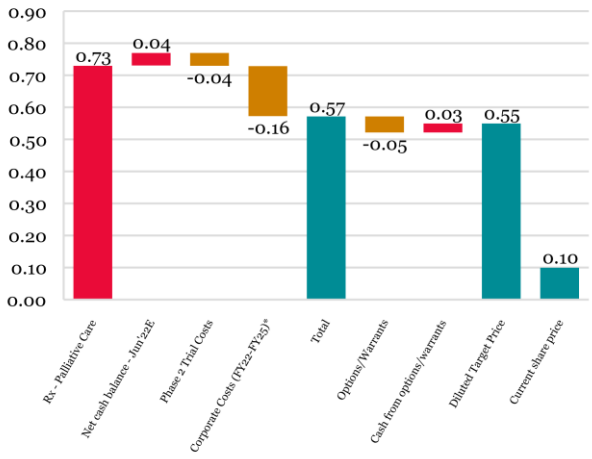
Source: Clinicaltrials.gov

H&Pe valuation for Psyence's Rx assets

	Product
	Psilocybin-assisted psychotherapy
Indication	Adjustment disorder (palliative care)
Launch	2027
Peak Sales (US$m)	1,137
Value (C$m)	264
Probability (%)	23.6%
rNPV* (C$m)	62.4
NPV/share (C$c/sh)	**0.55**

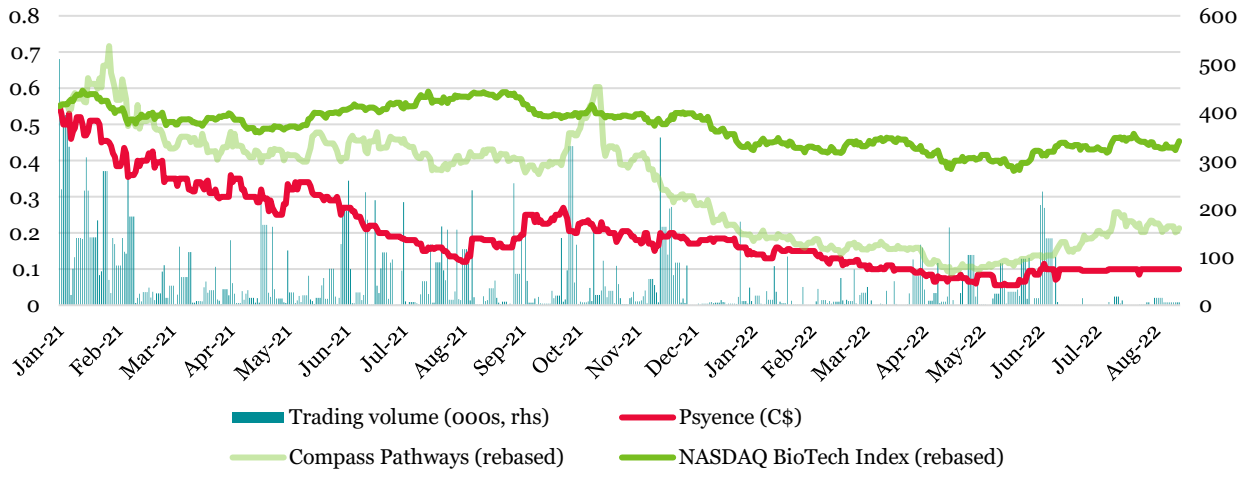
Source: Company reports, H&P estimates. *rNPV = risked net present value

Sum of the parts valuation offers C$0.55/sh target price



Source: Company reports, H&P estimates, *excludes R&D costs

Psyence share price history



Source: BBG, Company reports, H&P estimates

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