NEXALIS THERAPEUTICS

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ASX: NX1

FAVOURABLE U.S. PSYCHEDELIC POLICY DEVELOPMENTS SUPPORT ADVANCEMENT OF SRX-25 FOR TREATMENT-RESISTANT DEPRESSION

HIGHLIGHTS

- **U.S. Executive Order signed on 18 April 2026 to accelerate access to treatments for serious mental illness**
- **Significant increase in capital markets activity across psychedelic and CNS-focused assets, signalling renewed investor interest**
- **SRX-25 positioned as a differentiated oral esketamine-based therapy targeting treatment-resistant depression ("TRD")**
- **Designed to improve accessibility, tolerability and patient compliance versus existing intranasal therapies**
- **Development via FDA 505(b)(2) regulatory pathway, enabling a faster and more cost-efficient path to market**
- **Exposure to a ~US$4bn TRD market with ~2.8 million patients by 2030 in the U.S. alone**

Melbourne, Australia – Nexalis Therapeutics Ltd ("**NX1**" or "**the Company**") is pleased to provide an update on recent U.S. policy developments and corresponding capital markets activity that are expected to support the advancement of its SRX-25 program for treatment-resistant depression ("**TRD**").

On 18 April 2026, a new Executive Order was signed to accelerate access to innovative treatments for mental health disorders. In parallel, there has been a notable increase in trading activity across psychedelic-focused exchange-traded funds (ETFs), reflecting growing investor attention toward next-generation mental health therapies.

Market Signal – Psychedelic Sector Re-rating

Recent market data indicates a sharp increase in trading activity in a leading Psychedelic ETF, with volumes reaching multi-month highs in April 2026. This spike aligns closely with the timing of the U.S. policy announcement and suggests a sector-wide re-rating of mental health and CNS innovation assets.

Management Commentary

Nexalis CEO Darryl Davies said: "We are seeing a clear convergence of regulatory momentum and capital market interest in next-generation mental health therapies. The recent surge in psychedelic sector activity reinforces investor recognition of the scale of opportunity in this space.

SRX-25 is uniquely positioned to capitalise on these tailwinds, offering a more accessible and patient-friendly approach to esketamine therapy for treatment-resistant depression."

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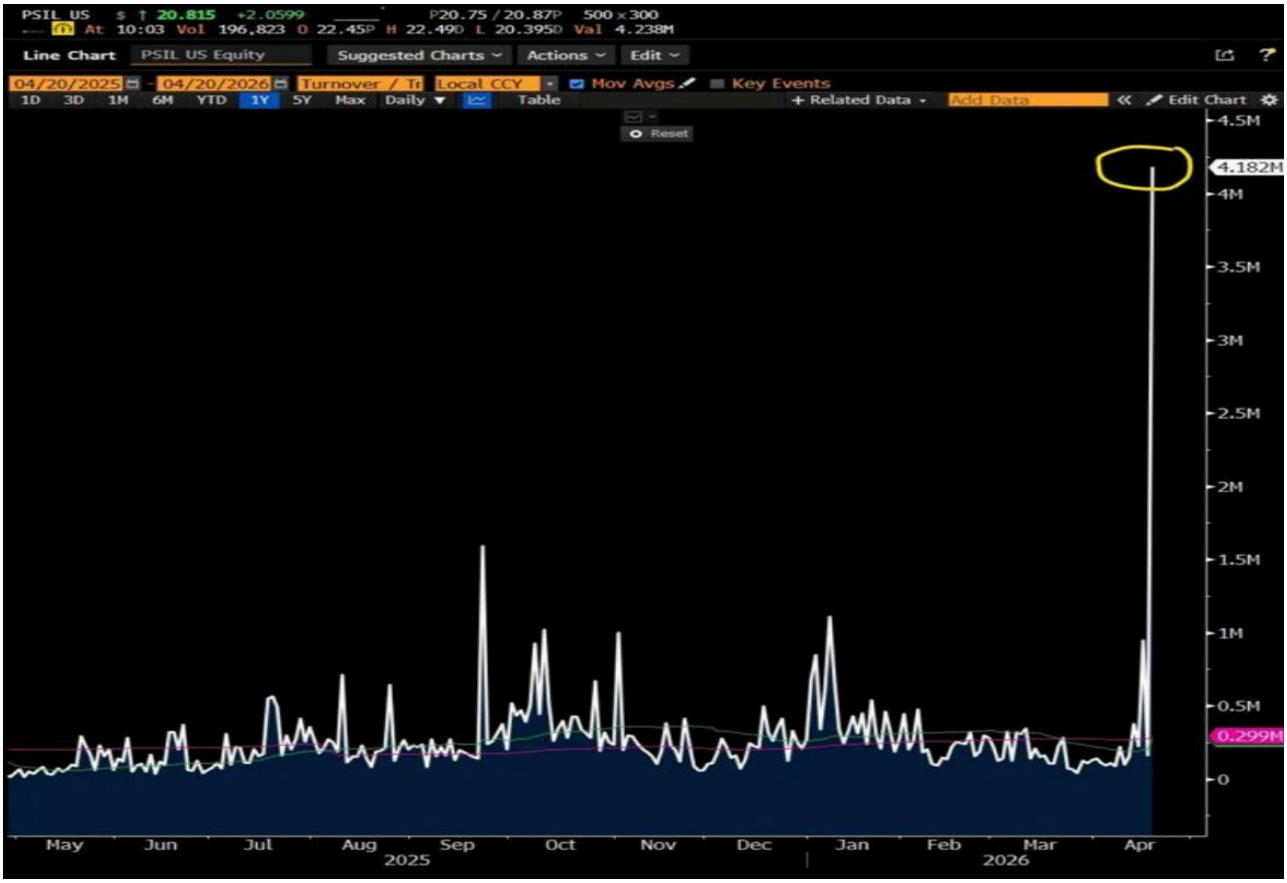

Figure 1: Psychedelics (PSIF.NYSE) ETF

This trend highlights:

- Renewed institutional and retail capital inflows into mental health innovation
- Increased visibility for companies developing novel central nervous system ("**CNS**") therapeutics
- Strengthening sentiment toward regulatory acceleration in this category
- Strategic relevance to SRX-25

SRX-25 is Nexalis' oral esketamine-based therapeutic candidate, designed to address key limitations of current TRD treatments.

- Combines esketamine with a CYP-450 inhibitor to optimise pharmacokinetics
- Designed to replicate the efficacy of Spravato while improving convenience
- Targets improved patient adherence and scalability outside clinic settings

Current therapies require supervised administration and are associated with tolerability challenges, creating a clear gap in accessible treatment options.

Key Policy Developments

The Executive Order introduces several initiatives relevant to SRX-25:

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- Accelerated US Food & Drug Administration ('**FDA**") pathways for high-impact therapies
- Expanded Right to Try access for patients with limited alternatives
- US$50 million ARPA-H funding for mental health innovation
- Increased clinical trial participation, particularly among veterans
- Proactive DEA scheduling reviews, reducing approval-to-market delays

Implications for Nexalis

Nexalis believes the combination of regulatory acceleration, increased funding support and strengthening capital markets sentiment represents a structural inflection point for CNS drug development.

For SRX-25, this may translate into:

- More efficient clinical and regulatory pathways
- Improved patient access frameworks
- Enhanced partnering and commercialisation opportunities

Market Opportunity – TRD

- Estimated ~US$4bn market by 2030.
- ~2.8 million TRD patients in the U.S.
- U.S. represents >50% of global market.

Existing therapies (e.g. Spravato) generate >US$1bn annually, yet remain constrained by access and tolerability limitations.

Development Strategy

SRX-25 is being advanced via the FDA 505(b)(2) pathway, enabling:

- Leveraging of existing safety data
- Reduced development cost and timelines
- Potential Phase 3 readiness within ~3 years

It is also worth reiterating that the clinical development costs associated with this program are fully funded under Nexalis' existing funding facility.

NX1 will continue to provide updates as the SRX-25 program advances.

Authorised for release by the Board of Directors.

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ABOUT NEXALIS THERAPEUTICS LTD (ASX: NX1)

Nexalis Therapeutics Ltd is an Australian Clinical Stage Drug Development Company that is developing rapid onset therapies to address unmet medical needs in pain management and mental health sectors. The Company has secured a funding partner with a facility of up to $52.3m to accelerate the development of IRX-211 to treat Breakthrough Cancer Pain ('**BTcP**'), IRX-616a to treat Panic Disorder ('**PD**') and SRX-25 for the treatment of Treatment-Resistant Depression ('**TRD**').

The overarching goal is to pursue U.S. FDA approval and registration using rapid and cost-effective regulatory pathways, such as 505(b)(2).

There is a significant economic opportunity for NX1 and the Company's shareholders, the clinical indications under investigation have been carefully selected in consultation with regulatory authorities. Bringing new approved medications to market will address critical gaps whereby there's currently mismatched treatment options that can carry dependency concerns.