20 April 2026

ASX: NX1

SIGNIFICANT MILESTONE ACHIEVED FIRST PATIENT SCREENED IN PHASE 2 IRX-211 STUDY FOR BREAKTHROUGH CANCER PAIN

HIGHLIGHTS

- **Major clinical milestone achieved with first patient screened in Phase 2 trial of IRX-211for Breakthrough Cancer Pain ('BTcP').**
- **Large and growing market opportunity, with the global cancer pain market estimated at ~US$11bn by 2028**
- **The Phase 2 trial is a multicentre, randomised, double-blind, placebo-controlled cross-over study with dose titration.**
- **Study designed to evaluate efficacy,, safety and patient-reported outcomes in opioid-tolerant cancer patients.**
- **The trial is targeting recruitment of 156 patients, with individualised dosing followed by controlled cross-over evaluation.**

  Positions the program for value-driving clinical data and future partnering discussions

Melbourne, Australia – Nexalis Therapeutics Ltd ('**NX1**' or the '**Company**') is pleased to announce a key clinical milestone with the first patient screened in the Company's Phase 2 clinical trial evaluating IRX-211 for the treatment of Breakthrough Cancer Pain ('BTcP').

This milestone represents the transition of IRX-211 into controlled clinical evaluation in its intended patient population, marking a significant advancement in the development program.

The Phase 2 study is a multicentre, randomised, double-blind, placebo-controlled, cross-over trial with an initial open-label titration phase in adult cancer patients experiencing BTcP despite stable background opioid therapy.

The study consists of two parts:

- Part A (Open-label titration): Patients self-titrate IRX-211 over a defined period to identify an individualised effective dose.
- Part B (Double-blind cross-over): Patients treat multiple BTcP episodes with either IRX-211 or placebo in a randomised sequence, enabling within-patient comparison of efficacy and safety.

The study plans to enrol approximately 156 patients, from multiple sites with at least 78 of those achieving an effective dose in Part A proceeding to complete the randomised cross-over phase in Part B.

The completed Phase 1 program in healthy volunteers demonstrated an excellentsafety profile, rapid systemic exposure and consistent pharmacokinetics, supporting further clinical development.

CONTACT US
NEXALIS THERAPEUTICS
T: +61 3 9070 1221 | **E:** investors@nexalistherapeutics.com | **W:** https://www.nexalistherapeutics.com

Breakthrough Cancer Pain represents a high-burden and inadequately addressed condition within oncology supportive care.

- BTcP episodes are rapid in onset, often escalating within minutes, while many currently available opioid treatments have delayed onset, creating a meaningful treatment gap.
- A significant proportion of cancer patients continue to experience poorly controlled breakthrough pain despite access to opioids.
- The global cancer pain market is projected to grow at a CAGR of 6.4% from USD 8.87b in 2026 to USD 12.91b in 2032[1].

IRX-211 is designed as a proprietary inhaled therapy to deliver rapid, predictable and patient-controlled relief, aligning with the clinical needs of BTcP patients.

Nexalis Therapeutics CEO, Darryl Davies, said "Screening the first patient in our Phase 2 study represents a significant milestone for Nexalis and the IRX-211 program, and importantly marks the beginning of generating efficacy data in patients with Breakthrough Cancer Pain.

BTcP remains poorly served by existing therapies, particularly given the rapid onset of pain episodes and limitations of current opioid options. IRX-211 has been specifically designed to address this gap through fast-acting, patient-controlled delivery.

We believe this study provides a strong foundation for demonstrating clinical benefit, while positioning the program for future development and potential partnering opportunities".

NX1 will provide further updates as the study progresses and additional milestones are achieved.

Authorised for release by the Board of Directors.

For further information:
www.nexalistherapeutics.com

James Barrie, Company Secretary
T: +61 3 9070 1221
E: investors@nexalistherapeutics.com

Investor relations
Matthew Wright
NWR Communications
M: 0451 896 420
E: matt@nwrcommunications.com.au

[1] Cancer Pain Management Market Size, Share & Forecast to 2032

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.

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