

QUARTERLY ACTIVITIES, CASHFLOW REPORT AND OPERATIONS UPDATE

31 July 2026

Quarter ended 30 June 2026

Melbourne, Australia – Nexalis Therapeutics Ltd (ASX: NX1), ('Nexalis', 'NX1' or 'the Company'), is pleased to provide its quarterly activities report for the period ended 30 June 2026.

Highlights and significant developments for the quarter include:

1. **IRX-616a Phase 1 dosing completed:** Dosing was completed across all three cohorts in the first-in-human study, with no serious adverse events reported.
2. **IRX-211 Phase 2:** Site evaluation visits were undertaken at two additional potential clinical sites to broaden the prospective recruitment pool.
3. **SRX-25 development planning advanced:** Work continued on the proposed Phase 1 clinical development plan, intellectual property strategy and potential US 505(b)(2) regulatory pathway.
4. **Cancellation of funding facility:** On 20th May 2026 Linlithgow Family Office ('LFO') permanently cancelled the remaining available commitment under the LFO Facility.
5. **The Company is currently assessing clinical development priorities** with a view to determining a revised clinical development plan and timeline for its portfolio of drug candidates.
6. **Company received \$490k in Research & Development Tax Incentive ('RDTI') proceeds** following the lodgement of its 2025 income tax return.

Cancellation of Funding Facility

On 31 October 2025 Nexalis entered into a debt funding facility agreement with LFO which provided for funding of up to \$52.3m ('**LFO Facility**') 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**').

On 20th May 2026 LFO issued notice under the LFO Facility that it had permanently cancelled the remaining available commitment under the LFO Facility and would not be accepting any further drawdown requests. The Company is presently considering its options in response to LFO's actions.

Since inception of the LFO Facility, a total of \$2.4 million of drawdown requests were submitted, of which \$0.8 million of funding was received by the Company.

The Company's board continues to seek potential alternate funding partners to ensure continuity of funding of its clinical trial programs. However, there are presently no meaningful discussions underway in that regard. Further updates will be provided as opportunities develop.

Clinical Development Strategy and Outlook

The Company's objective is to obtain US Food & Drug Administration ('**FDA**') of a New Drug

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Approval ('**NDA**') for each indication. The Company's clinical trial programs aim to demonstrate the safety, tolerability and efficacy for treating a targeted range of pain and mental health related conditions.

NXI currently has three drug candidates under development:

1. **IRX-616a** - an inhaled treatment for **PD** which successfully dosed all three cohorts within its Phase 1 clinical trial, with no Serious Adverse Events ('**SAE**') reported.
2. **IRX-211** - an inhaled treatment for BTcP, which completed Site Evaluation Visits ('**SEV**') for two additional sites in its Phase 2 clinical trial, following challenges the lead site (Vitalis) has experienced with recruiting within the patient population.
3. **SRX-25** - an oral treatment for TRD, which is advancing through planning stages in consultation with patent attorneys.

Clinical Development Plan Update

Following the cancellation of the LFO Facility's remaining funding commitment, the Company was forced to temporarily suspend the current study orders with iNGENū CRO Pty Ltd ('**iNGENū**') for both IRX-211, Ph2 and IRX-616a, Ph1. While the suspension remains in place, management is reviewing the clinical development strategy for each asset to ensure that programs can progress in a focused, capital-efficient and commercially appropriate manner. This involves direct communication with sites and vendors to evaluate positioning.

The Company is pleased to confirm that the IRX-616a Phase 1 clinical trial has been completed, with results exceeding expectations and no SAE's reported. The Phase 1 data confirmed the safety and tolerability of IRX-616a in healthy volunteers and provided valuable dose-ranging insights to inform the design of future patient studies.

While the temporary suspension of the remaining study-order activities will delay completion of Database Lock and the formal Clinical Study Report ('**CSR**'), the Company has access to sufficient data and clinical insights to allow Phase 2 planning to continue.

The Company's current clinical development priorities include:

1) IRX-616a – Phase 2 development planning

Building on the successful completion of the Phase 1 trial, the Company is progressing the design of the IRX-616a Phase 2 program. Management is evaluating a flexible and appropriately scaled development pathway, which may include an initial cost-effective proof-of-concept study to demonstrate therapeutic activity and efficacy in the target patient population before progressing to a larger confirmatory study.

2) IRX-211 – Phase 2 trial optimisation

The Company is currently engaging directly with participating and potential clinical trial sites regarding study budgets, recruitment processes and operational requirements. In parallel, a detailed review of the current status of the IRX-211 Phase 2 trial is being undertaken to identify the factors contributing to the recent level of patient recruitment and screening.

This review will assess recruitment pathways, site-specific limitations, patient identification processes and the overall operational structure of the trial, with the objective of identifying opportunities to progress the study in a more streamlined, timely and cost-effective manner. The Company will also consider whether amendments to the IRX-211 Phase 2 protocol may be

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appropriate, including potential refinements to the patient inclusion and exclusion criteria or adjustments to the broader trial design.

3) SRX-25 – Phase 1 planning

The SRX-25 oral clinical program remains in the planning phase. The Company intends to progress formulation and manufacturing planning activities alongside the development of an appropriate Phase 1 trial design for implementation in Australia. The timing and scope of this work will be managed carefully to ensure that it does not divert time, attention or available financial resources from the Company's Phase 2-ready drug candidates.

The Company will provide a further update as these clinical development reviews and planning activities progress.

Summary of Clinical Activities

IRX-616a – Panic Disorder (Phase 1)

During the quarter, the Company completed dosing in its randomised, double-blind, placebo-controlled, single ascending dose Phase 1 study of IRX-616a. The study successfully evaluated the pharmacokinetics, safety and tolerability of IRX-616a, informing subsequent development and dosing for use in treating PD.

The study was conducted at CMAX Clinical Research in Adelaide and was designed to evaluate IRX-616a in ascending doses in 24 healthy volunteers across three cohorts. Progression between cohorts occurred following review of available safety, tolerability and pharmacokinetic data by the independent Safety Review Committee.

The last participant last dose milestone was achieved on 14 May 2026. No SAE's were reported during the study.

Following completion of dosing, activities have progressed toward database lock, final data analysis and preparation of the clinical study report.

The Company has also commenced Phase 2 planning and associated regulatory preparation for the potential development of IRX-616a in panic disorder.

IRX-211 – Breakthrough Cancer Pain (Phase 2)

The study is a multicentre, randomised, double-blind, placebo-controlled crossover study incorporating individual dose titration. It is designed to evaluate the efficacy, safety and patient-reported outcomes associated with IRX-211 in opioid-tolerant cancer patients experiencing breakthrough cancer pain.

The current study design has a target enrolment of 156 participants, with the crossover design intended to allow participants to act as their own control during the comparative treatment periods.

Recruitment at the lead clinical site (Vitalis) has progressed more slowly than expected. In response, the Company and its clinical partners have undertaken site evaluation visits at two additional Genesis Care sites located in New South Wales and Western Australia.

Genesis Care operates a national oncology research network comprising more than 45 clinical sites, over 55 dedicated research staff and more than 150 Principal Investigators, with established capabilities across medical oncology, radiation oncology, haematology and theragnostic. Through these sites, the Company gets direct access to a substantial population of patients receiving cancer treatment, established clinical-trial infrastructure and current experience conducting Phase 2 oncology studies could position Genesis Care well to support the efficient identification, screening

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and recruitment of patients experiencing Breakthrough Cancer Pain.

This expansion was intended to broaden the potential recruitment footprint across Victoria, New South Wales and Western Australia. Site budget and contracting discussions also continued during the quarter.

Following the change in the Company's funding position, the IRX-211 study order was temporarily suspended. Since that time, management has engaged independently with Genesis Care and additional sites with a view to activating more clinical sites to assist with recruitment activities.

During the quarter, the Company continued to advance the IRX-211 Phase 2 clinical program, focusing on site readiness and patient recruitment preparation.

Key activities included:

1. Continued pre-screening and patient identification activities at the lead clinical site (until the study order suspension came into effect).
2. SEV's at two Gensis Care sites, one in NSW and one in WA in preparation for activation.
3. Ongoing engagement with potential new NSW clinical sites, including budgeting negotiations.

IRX-211 remains a key value driver within the Company's pipeline, targeting a significant unmet need in breakthrough cancer pain with a non-opioid, rapid onset therapeutic approach.

SRX-25 – Treatment-Resistant Depression (Planning Phase)

SRX-25 is an oral esketamine-based development program targeting treatment-resistant depression.

During the quarter, the Company continued development planning for a proposed Phase 1 clinical study, including protocol development, preliminary operational planning and engagement with patent counsel regarding the intellectual property strategy for the asset.

The Company is evaluating a potential FDA 505(b)(2) regulatory pathway, which may permit reliance on certain existing findings relating to an already approved active pharmaceutical ingredient, subject to agreement with the FDA and generation of the required product-specific data.

The Company also reviewed US policy developments relating to serious mental illness and access to innovative treatments. These developments provide relevant sector context but do not constitute clinical or regulatory validation of SRX-25.

Progression into clinical development will be subject to completion of the development plan, availability of funding and the necessary regulatory and governance approvals.

The SRX-25 program continued to advance during the quarter, transitioning into a more defined development phase.

Key progress included:

1. Finalisation of the Phase 1 clinical trial protocol.
2. Advancement of the Company's intellectual property strategy, including engagement with patent counsel to support defensible positioning of the asset.
3. Continued planning activities to support the initiation of the Phase 1 clinical program.

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SRX-25 is being developed as an oral therapy targeting treatment-resistant depression, with the potential to improve accessibility and patient adherence compared to existing treatment modalities.

Immediate objectives

Nexalis remains focused on the following immediate objectives:

1. Identifying available options for funding its clinical development programs, including securing funding with a replacement funding partner.
2. Establishing clinical development priorities to best focus its time and resources in the absence of a funding partner arrangement. This includes direct contact with sites in relation to budgeting and patient recruitment,
3. Planning for the efficient execution of the clinical trial programs for each indication once the Study Orders are reinstated with a view to advancing assets toward regulatory approval pathways, including the FDA.

Corporate Update

During the June quarter Dr Ron Wise and Anthony Fitzgerald resigned as directors of the Company in order to focus on other commitments. Company Secretary, James Barrie and Chief Executive Officer Darryl Davies were appointed as interim directors.

The Board is reviewing its composition and governance requirements having regard to the Company's clinical development priorities, funding position and future strategic requirements and will commence a process to identify appropriate candidates once it has addressed the above mentioned immediate objectives.

GICS Reclassification

During the quarter, the Company received confirmation from ASX, following a request by the Company, that a reclassification of its Global Industry Classification Standard ('GICS') code had been made to more accurately reflect the current operations of the Company.

GICS is a standardised classification system for equities developed jointly by Morgan Stanley Capital International and Standard & Poor's. It is used as a basis for certain financial market indexes in which each listed entity is assigned to a sub-industry, and a corresponding industry group and sector, depending on the entity's principal business activity.

Since 2021, the Company has strategically pivoted from marketing health monitoring devices and associated technology to developing pharmaceutical solutions for the treatment of unmet medical needs.

Following reclassification, the Company's GICS is now as follows:

- Industry Group: 3520 Pharmaceuticals, Biotechnology & Life Sciences.
- Industry: 352020 Pharmaceuticals.
- Sub-Industry: 35202010 Pharmaceuticals.

Payments to Directors & Related Parties

There were no cash payments to Directors during the June 2026 quarter. \$20k in salaries was paid to Key Management Personnel.

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Use of funds

The net cash surplus from operating activities during the quarter was \$648k, with \$900k received in relation to the Company's 2025 RDTI claim. \$410k of these proceeds were applied to the repayment of the Radium RDTI facility (inclusive of \$41k of interest costs).

The Company incurred \$170k in clinical development costs for the June 2026 quarter. There was no funding provided under the Funding Agreement with LFO for the quarter (refer comments above).

During the quarter, funds spent on operating activities comprised:

- \$170k in clinical development costs;
- \$58k in general corporate costs, including: insurance (\$31k); legal costs (\$11k); company secretary (\$8k); CFO (\$4k); share registry & ASX (\$3k); and other costs (\$1k);
- \$41k in interest charges related to the Radium RDTI facility;
- \$10k in salaries paid to employees; and
- \$6k in investor relations costs.

The Company received ATO net refunds totaling \$44k related to GST during the quarter.

GST is included in the amounts noted above as applicable.

The Company will provide further updates in due course.

Authorised for release by the Board of Directors.

For further information:

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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 is currently focused on 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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