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Catalent, Nanoscope expand partnership for optogenetic gene therapy supply

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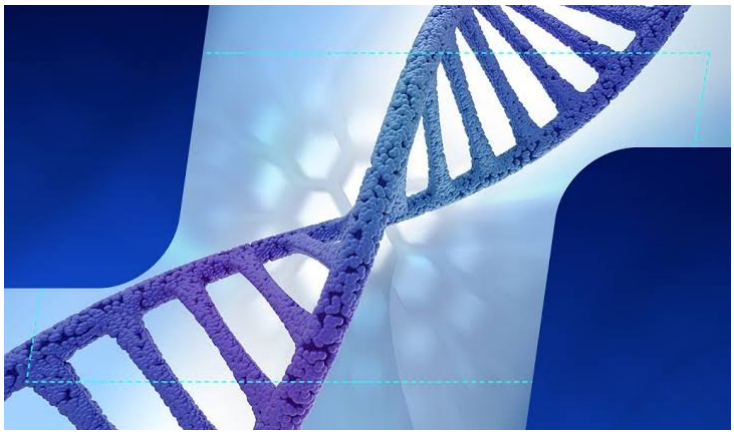
The expanded agreement supports late-phase development, commercial packaging validation and distribution readiness for MCO-010.



Catalent and Nanoscope Therapeutics have expanded their partnership to support late-phase clinical development and commercial supply of MCO-010, Nanoscope's lead optogenetic gene therapy.

Under the expanded agreement, Catalent will provide commercial-compliant packaging and distribution for MCO-010. Catalent has also secured the commercial packaging validation programme intended to support Nanoscope's Biologics License Application.

This is relevant because advanced therapy commercialisation depends on more than clinical efficacy. Gene therapies require specialised manufacturing, packaging, distribution and quality systems before they can be delivered reliably at scale. For therapies approaching regulatory submission, commercial supply readiness becomes a major part of development strategy.

MCO-010 is being developed as a disease-agnostic, vision-restoring optogenetic therapy for patients with photoreceptor loss caused by retinal degenerative diseases. The therapy is intended to reprogramme remaining retinal cells to become light-sensitive.

The lead indication is retinitis pigmentosa. Nanoscope has initiated a rolling BLA submission to the U.S. FDA following positive results from the RESTORE Phase 2b/3 multicentre, randomised, double-masked, sham-controlled trial in retinitis pigmentosa.

If approved, MCO-010 could offer a one-time, in-office injection for patients with retinitis pigmentosa without requiring genetic testing. This is an important differentiator because many inherited retinal disease therapies depend on specific genetic mutations, which can limit eligible patient populations and require complex diagnostic pathways.

The candidate has also shown promising results in the STARLIGHT Phase 2 trial in Stargardt disease, and Nanoscope plans to initiate a Phase 3 registrational trial in 2026. Additional programmes include geographic atrophy and IND-ready work in Leber congenital amaurosis.

MCO-010 has received multiple regulatory designations. These include FDA Fast Track and Orphan Drug designations for retinitis pigmentosa and Stargardt disease, RMAT designation for Stargardt disease, PMDA Sakigake and Orphan designations for inherited retinal dystrophies, and orphan designations from EMA and SFDA for inherited retinal dystrophies.