

ASX ANNOUNCEMENT

14 April 2026

Clarity signs a Commercial Manufacturing Agreement for Cu-64 SAR-bisPSMA with Nucleus RadioPharma

Clarity Pharmaceuticals (ASX: CU6) (“Clarity” or “Company”), a clinical-stage radiopharmaceutical company with a mission to develop next-generation products that improve treatment outcomes for patients with cancer, is pleased to announce the signing of a Commercial Manufacturing Agreement for ⁶⁴Cu-SAR-bisPSMA with Nucleus RadioPharma, an innovative contract development and manufacturing organisation (CDMO) in the radiopharmaceutical industry, dedicated to the development and manufacturing of targeted radiotherapies.

The Agreement relates to Nucleus RadioPharma’s state-of-the-art facility in Rochester, Minnesota, which is capable of manufacturing around 50,000 patient doses per year, and future production in Spring House, Pennsylvania. The Spring House facility is a 47,000 square foot site that is planned to open in 2028, enabling broad coverage across the northeast of the US with up to 600,000 doses of ⁶⁴Cu-SAR-bisPSMA per year. Together, these two facilities in Minnesota and Pennsylvania will provide access to key commercial markets with manufacturing and distribution to all 50 states in the US and select international sites, including Europe.

The Commercial Manufacturing Agreement further builds on Clarity’s existing partnership with Nucleus RadioPharma with a Master Services Agreement and ⁶⁷Cu-SAR-bisPSMA Clinical Supply Agreement in place from November 2024¹, covering the existing site in Rochester with additional facilities in Pennsylvania² and future strategic sites to expand patient access.

This Agreement represents an important step in Clarity’s continued build out of its manufacturing capabilities ahead of ⁶⁴Cu-SAR-bisPSMA’s anticipated commercial launch upon successful completion of Phase III registrational trials with this product, AMPLIFY³ and CLARIFY⁴, and subsequent US Food and Drug Administration (FDA) New Drug Application (NDA) approval.

Geoffrey Johnson, MD, PhD, Chief Scientific Officer of Nucleus RadioPharma, commented, “Nucleus RadioPharma is excited to produce a next-generation diagnostic imaging agent, ⁶⁴Cu-SAR-bisPSMA, that data shows is capable of visualising tiny prostate cancer lesions that the current standard of care prostate specific membrane antigen (PSMA) positron emission tomography (PET) fails to detect. Earlier cancer detection and better cancer staging directly affects patient management and treatment outcomes and I firmly believe that seeing is saving. At Nucleus RadioPharma, we are proud to be driving demonstrable advances at the cutting edge of theranostics.”

Stephen Hahn, MD, Chief Executive Officer of Nucleus RadioPharma, commented, “We are pleased to continue growing our partnership with Clarity through this new Commercial Manufacturing Agreement. At Nucleus RadioPharma, we share Clarity’s goal of improving treatment outcomes for patients with cancer and look forward to delivering novel products to people in need of better diagnostic and therapeutic options. ⁶⁴Cu-SAR-bisPSMA is now quickly approaching its market launch, and with recently released data highlighting its detection benefits in comparison to standard of care PSMA PET, we could not be more excited about being part of the change in shaping the future of prostate cancer diagnostics.”

Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented, “Clarity is building a strong foundation with its supply and manufacturing strategy to support a large-scale commercial rollout of ⁶⁴Cu-SAR-bisPSMA from day one, with capability to supply not only the entire existing PSMA PET market, but a larger pool of patients that could benefit from our optimised product, given the promising data we have seen in the clinic to date. With large-scale drug product manufacturing, reinforced by large-scale copper-64 production, we will be able to provide ⁶⁴Cu-SAR-bisPSMA on demand through centralised manufacturing and distribution, broadly with sites servicing the entirety of the US and beyond, including sites close to areas of high demand. The half-life of copper-64 gives us the freedom to deliver a number of models in order to meet the future demand for our products.

“Together with Clarity’s existing copper-64 supply agreements with Nusano and Theragenics, the new Agreement with Nucleus RadioPharma further enhances Clarity’s broad network of high-volume production in distinct US geographies,

building a tiered approach with regional distribution. The network is designed to support commercial-scale demand with secure, seamless and abundant supply and manufacturing.

“Nucleus RadioPharma is a trusted partner with extensive expertise in radiopharmaceuticals across not only the supply and manufacturing side, but also with a unique insight into the impact that radiopharmaceuticals can have on the healthcare system, treating clinicians and their patients. We look forward to continuing to work with their team as we continue to deliver on our promise of improving treatment outcomes for patients with cancer.”

The Commercial Manufacturing Supply Agreement is effective as of 14 April 2026. Cancellation and extension provisions are aligned with industry standard rates.

Disclaimer

⁶⁴Cu-SAR-bisPSMA and ⁶⁷Cu-SAR-bisPSMA are unregistered products. Their safety and efficacy have not been assessed by health authorities such as the US FDA or the Therapeutic Goods Administration (TGA). There is no guarantee that these products will become commercially available.

About Nucleus RadioPharma

Nucleus RadioPharma is an innovative CDMO in the radiopharmaceutical industry, dedicated to the development and manufacturing of targeted radiotherapies. With an emphasis on innovation and quality, the company provides an array of services, from formulation and analytical development to regulatory documentation and drug product manufacturing. Nucleus RadioPharma’s technology platforms are at the forefront of radiopharmaceutical research, designed to advance new therapies through clinical trials to commercialization. Recognized for its flexible approach, the company offers multiple onboarding points to accommodate innovators at various stages of their product lifecycle. Backed by Eclipse, Mayo Clinic, AstraZeneca, GE HealthCare, Echo Global, Fox Chase Cancer Center, Granger Management, Mercy Health, and University of Missouri, Nucleus RadioPharma stands well-supported by leading institutions and organizations committed to advancing healthcare through innovative solutions.

Please visit nucleusrad.com and follow on LinkedIn for more information.

About Clarity Pharmaceuticals

Clarity is a clinical stage radiopharmaceutical company focused on the treatment of serious diseases. The Company is a leader in innovative radiopharmaceuticals, developing Targeted Copper Theranostics based on its SAR Technology Platform for the treatment of cancers.

www.claritypharmaceuticals.com

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References

1. Clarity Pharmaceuticals. Clarity and Nucleus RadioPharma sign Master Services Agreement and Cu-67 SAR-bisPSMA Clinical Supply Agreement. <https://www.claritypharmaceuticals.com/news/nucleus/>
2. Nucleus RadioPharma Expands Radiopharmaceutical Research, Development and Manufacturing Capacity, Addressing Nationwide Supply Chain Constraints, BusinessWire, 21 October 2024, <https://www.businesswire.com/news/home/20241021820034/en/Nucleus-RadioPharma-Expands-Radiopharmaceutical-Research-Development-and-Manufacturing-Capacity-Addressing-Nationwide-Supply-Chain-Constraints>

3. ClinicalTrials.gov Identifier: NCT06970847. <https://clinicaltrials.gov/study/NCT06970847>
4. ClinicalTrials.gov Identifier: NCT06056830. <https://clinicaltrials.gov/study/NCT06056830>

This announcement has been authorised for release by the Executive Chairperson.