

## ASX ANNOUNCEMENT

25 March 2026

# Clarity signs a large-scale Manufacturing Supply Agreement for copper-64 with Theragenics

**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 large-scale Manufacturing Supply Agreement for copper-64 with Theragenics.

The agreement relates to Theragenics' 134,000 square foot production facility with a fleet of 14 cyclotrons close to Atlanta, Georgia, a major US transport hub, for centralised, large-scale copper-64 (Cu-64 or  $^{64}\text{Cu}$ ) production ahead of anticipated  $^{64}\text{Cu}$ -SAR-bisPSMA commercial launch upon successful completion of Clarity's Phase III registrational trials with this product, AMPLIFY<sup>1</sup> and CLARIFY<sup>2</sup>, and subsequent US Food and Drug Administration (FDA) New Drug Application (NDA) approval.

Theragenics have substantial cyclotron expertise with 40 years of routine radiometal production and considerable experience in production of radioisotopes for medical use. Combined with a sizeable fleet of high-current cyclotrons, this constitutes an opportunity for large-scale copper-64 manufacturing at the site. Theragenics have capacity to produce around 100Ci (3.7 TBq) of copper-64 per day on a single cyclotron, which translates into around 2,000 patient doses per day on each cyclotron at 200 MBq per dose with a 48-hour shelf life. Together with Clarity's existing copper-64 supply agreements with SpectronRx and Nusano, this agreement with Theragenics further enhances Clarity's broad network of high-volume copper-64 manufacturers in distinct US geographies. The network is designed to support commercial-scale demand across multiple large oncology indications with secure, seamless and abundant supply of this diagnostic isotope, made possible with the 12.7-hour half-life of copper-64, which is unique in the radiopharmaceutical commercial space.

**Mark Pugh, CEO of Theragenics, commented,** "We are excited to enter into this Manufacturing Supply Agreement for copper-64 with Clarity. Having a current commercial sales force in prostate cancer, we have a deep insight into this field and have seen the excitement from key opinion leaders around  $^{64}\text{Cu}$ -SAR-bisPSMA. This agreement continues our expansion into the contract manufacturing organisation (CMO) isotope market, and we see Clarity as an ideal partner to advance this vision. Clarity is in a unique position with two diagnostic Phase III trials nearing completion, three Fast Track Designations (FTDs) from the US FDA and impressive data generated to date. With our core expertise and experience in producing radiometals for commercial medical purposes at Theragenics, together we can expand access to radiopharmaceuticals and bring a next-generation platform to patients in need of better diagnostics in the US."

**Dr Alan Taylor, Executive Chairperson of Clarity Pharmaceuticals, commented,** "Clarity is closer than ever to commercialisation of  $^{64}\text{Cu}$ -SAR-bisPSMA, with outstanding data recently released from the head-to-head Co-PSMA investigator-initiated trial<sup>3</sup> and our announcement on achieving our target number of participants in the Phase III AMPLIFY trial just months since imaging the first patient<sup>4</sup>.

"The growing body of scientific evidence, along with the FTDs from the FDA are providing great momentum for  $^{64}\text{Cu}$ -SAR-bisPSMA. Building out a secure, reliable and abundant supply and manufacturing strategy is now coming into play, ensuring a solid base for our commercial launch and accelerated market expansion, subject to FDA approval. Our team is committed to continue working closely with our vendors, clinicians, participating clinical trial sites, regulatory agencies and supply and manufacturing facilities to get  $^{64}\text{Cu}$ -SAR-bisPSMA to patients in need as soon as possible, at scale to meet the future demand.

"The longer half-life of copper-64 (12.7 hours vs. less than 2 hours for the radionuclides currently used in prostate-specific membrane antigen [PSMA] positron emission tomography [PET], i.e. gallium-68 and fluorine-18) translates into a shelf-life of up to 48 hours for  $^{64}\text{Cu}$ -SAR-bisPSMA. As such, copper-64 offers greater flexibility for supply and scheduling of patients, overcoming various limitations of the short half-life isotopes currently used in

radiodiagnostics. This represents a unique opportunity to implement a multi-tiered service approach comprising of large, local, centralised manufacturing with broad geographic distribution. Importantly, we have the opportunity to avoid the excessive costs, waste and inefficiencies associated with the supply and manufacture of short half-life isotopes. Our goal is to take the industry in a new direction of scalability and profitability while delivering universal access to radiodiagnostics for physicians and the patients they serve.

"Theragenics has decades of experience in the commercial production of radiometals for medical purposes and valuable insight into the prostate cancer field based on their existing brachytherapy business. We look forward to working with them as we prepare to take the next steps in our development."

The Manufacturing Supply Agreement is effective as of 25 March 2026. Cancellation and extension provisions are aligned with industry standard rates.

#### Disclaimer

<sup>64</sup>Cu-SAR-bisPSMA is an unregistered product. Its 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 this product will become commercially available.

#### About Theragenics

Theragenics ([www.theragenics.com](http://www.theragenics.com)) is a leader in cutting-edge medical solutions, offering minimally invasive medical devices and radiation-based treatments that improve patient outcomes.

#### 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](http://www.claritypharmaceuticals.com)

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#### References

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2. ClinicalTrials.gov Identifier: NCT06056830. <https://clinicaltrials.gov/study/NCT06056830>
3. Clarity Pharmaceuticals. Co-PSMA data presented at EAU Annual Congress 2026 with manuscript accepted for publication in the European Urology Journal. <https://www.claritypharmaceuticals.com/news/co-psma-eau/>
4. Clarity Pharmaceuticals. Registrational Phase III AMPLIFY trial: Target number of participants achieved. [https://www.claritypharmaceuticals.com/news/amplify\\_target\\_achieved/](https://www.claritypharmaceuticals.com/news/amplify_target_achieved/)

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