



Subscribe

PHARMA

## CDMO Nucleus RadioPharma links up with ARTBIO to help produce prostate cancer candidate for clinical trials

By **Fraiser Kansteiner**

May 7, 2024 8:47am

Nucleus RadioPharma

ARTBIO

radiopharmaceuticals

radiotherapy



Nucleus RadioPharma has previously said the success of radiopharmaceuticals has been "broadly hampered" by manufacturing and supply chain woes. (Love Employee/iStock/Getty Images Plus)

Following Nucleus RadioPharma's 2022 debut, the GE HealthCare- and Mayo Clinic-backed radiopharmaceuticals CDMO is ready to put its production thesis to the test.

Nucleus on Tuesday revealed that it has signed

<https://www.businesswire.com/news/home/20240507825344/en/ARTBIO-and-Nucleus-RadioPharma-Announce-Collaboration-to-Manufacture-GMP-Grade-Therapeutic-Products-Containing-Radioisotope-Pb-212-to-Support-Emerging-Clinical-Trials>) its first commercial partnership with clinical-stage radiopharma player ARTBIO. Under the deal, Nucleus is on deck to help manufacture ARTBIO's Pb212-radiolabeled therapies from its facility in Rochester, Minnesota.

The production deal will support ARTBIO's planned phase 1 and 2 clinical trials of its lead program in prostate cancer, AB001, the companies noted. The financial terms of the deal were not disclosed.

Nucleus, which was founded (<https://www.fiercepharma.com/manufacturing/mayo-clinic-backed-cdmo-nucleus-radiopharma-emerges-mission-overhaul-radiotherapy>) by venture capital firm Eclipse and the Mayo Clinic in October 2022, touts itself as the world's first fully integrated development, manufacturing and supply chain organization for radiopharmaceuticals.

The company is developing multiple sites around the U.S. to help make delivery of "scarce, hard-to-manufacture" nuclear medicines more efficient by cutting production timelines and easing supply chain constraints, Nucleus' CEO Charles Conroy said via email.



Radiopharmaceuticals, also known as radiotherapies, are essentially guided radioactive drugs that can be used to help diagnose diseases in smaller amounts and treat certain cancers and other conditions in higher quantities.

The field has attracted significant interest in recent years, but the unique makeup and characteristics of the drugs often raise manufacturing and logistical concerns. Novartis, which makes the radiopharmaceuticals Lutathera and Pluvicto, had to temporarily [stop producing](https://www.fiercepharma.com/manufacturing/novartis-halts-us-production-radioligand-cancer-therapies-citing-manufacturing) (https://www.fiercepharma.com/manufacturing/novartis-halts-us-production-radioligand-cancer-therapies-citing-manufacturing) the drugs in May 2022 thanks to potential quality issues at sites in Ivrea, Italy, and Millburn, New Jersey.

Novartis has since [resolved](https://www.fiercepharma.com/manufacturing/novartis-brings-radiotherapy-production-back-online-expansion-plan) (https://www.fiercepharma.com/manufacturing/novartis-brings-radiotherapy-production-back-online-expansion-plan) the issues and subsequently [charted](https://www.fiercepharma.com/manufacturing/novartis-expands-pluvicto-manufacturing-footprint-fda-blessing-indianapolis) (https://www.fiercepharma.com/manufacturing/novartis-expands-pluvicto-manufacturing-footprint-fda-blessing-indianapolis) a number of major radiotherapy production expansions.

For its part, Nucleus has previously suggested the success of radiopharmaceuticals has been “broadly hampered” by manufacturing and supply chain woes. It has already wooed major investors to help address these concerns.

Last October, the CDMO [ginned up](https://www.fiercepharma.com/manufacturing/nucleus-radiopharma-draws-56m-series-round-boost-manufacture-radiopharmaceuticals) (https://www.fiercepharma.com/manufacturing/nucleus-radiopharma-draws-56m-series-round-boost-manufacture-radiopharmaceuticals) an oversubscribed, \$56 million, series A investment round led by Eclipse and GE HealthCare, which Nucleus said it would use to fund new facilities in the U.S.

ARTBIO, for its part, [launched](https://artbio.com/artbio-launches-alpha-radioligand-therapies-therapeutic-potential) (https://artbio.com/artbio-launches-alpha-radioligand-therapies-therapeutic-potential) last summer. Less than six months after its debut, the biotech [secured](https://www.fiercebitech.com/biotech/artbio-pours-90m-its-coffers-less-six-months-after-launching) (https://www.fiercebitech.com/biotech/artbio-pours-90m-its-coffers-less-six-months-after-launching) a \$90 million series A round to build out its radiotherapy platform, solidify its manufacturing network and enter the clinic with a lead asset.

Partnerships and production advances in the radiotherapy field have been coming at a steady clip in 2024.

In January, Novartis snared FDA approval to begin cranking out commercial doses of Pluvicto at its “largest and most advanced” radiotherapy plant in Indianapolis.

The following month, Bayer [enlisted](https://www.fiercepharma.com/manufacturing/bayer-cowboys-pantera-which-supplies-starting-material-next-generation) (https://www.fiercepharma.com/manufacturing/bayer-cowboys-pantera-which-supplies-starting-material-next-generation) production specialist PanTera to crank out the alpha-emitting isotope actinium-225 (Ac-225) for clinical trial needs starting in the second half of 2024.

Meanwhile, Australia’s Telix Pharmaceuticals recently inked back-to-back buyouts of Texas-based CDMO [IsoTherapeutics](https://www.fiercepharma.com/manufacturing/telix-moves-acquire-isotherapeutics-cash-and-stock-deal-valued-136m) (https://www.fiercepharma.com/manufacturing/telix-moves-acquire-isotherapeutics-cash-and-stock-deal-valued-136m) and Canada’s [ARTMS Inc](https://www.fiercepharma.com/manufacturing/australias-telix-pharma-shells-out-82m-boost-isotope-production-artms-buyout) (https://www.fiercepharma.com/manufacturing/australias-telix-pharma-shells-out-82m-boost-isotope-production-artms-buyout).



**Let Google know we are your trusted source.**

Add our editorial as a preferred source in your search results.

Trust this Source





By **Fraiser Kansteiner**  
ASSOCIATE EDITOR  
FIERCE PHARMA

## ATTEND EVENTS

**27-13**  
JAN-MAY

### Fierce Outsourcing Awards

Winners Celebrated Live at Fierce Biotech Week

**24-26**  
MAR

### Patients as Partners in Clinical Research

Boston, MA

**31**  
MAR

### Drug Development & Delivery Day

Free Virtual Event

## PHARMA

# As questions swirl around ATTR competition, Alnylam plots path to market leadership for Amvuttra

By **Angus Liu**

Mar 26, 2026 02:08pm

[Pfizer](#)
[AstraZeneca](#)
[ATTR](#)
[cardiovascular disease](#)

Alnylam has big ambitions for Amvuttra. But despite an explosive transthyretin amyloid cardiomyopathy (ATTR-CM) launch in 2025, three [questions remain](https://www.fiercepharma.com/pharma/alnylam-turns-profitable-even-amvuttra-attr-revenue-disappoints-q4) (<https://www.fiercepharma.com/pharma/alnylam-turns-profitable-even-amvuttra-attr-revenue-disappoints-q4>): potential upcoming competition from AstraZeneca and Ionis' rival silencer Wainua, the genericization of Pfizer's market-leading tafamidis, and the overall opportunity of the ATTR-CM market.

Addressing those questions, Alnylam management on Tuesday [outlined](https://www.businesswire.com/news/home/20260324507498/en/Alnylam-Advances-Future-of-ATTR-CM-Care-Through-Strategic-Collaboration-with-Viz.ai-and-Support-for-the-American-Heart-Association) (<https://www.businesswire.com/news/home/20260324507498/en/Alnylam-Advances-Future-of-ATTR-CM-Care-Through-Strategic-Collaboration-with-Viz.ai-and-Support-for-the-American-Heart-Association>) a path for Amvuttra to become the revenue leader in an expansive ATTR-CM space of more than 75,000 U.S. patients on treatment by 2030, with data, diagnosis and marketing campaigns and physician experience tipped to drive the siRNA therapy's future growth.

Alnylam's confidence is rooted in its Amvuttra [achievements](https://www.fiercepharma.com/pharma/alnylam-turns-profitable-even-amvuttra-attr-revenue-disappoints-q4) (<https://www.fiercepharma.com/pharma/alnylam-turns-profitable-even-amvuttra-attr-revenue-disappoints-q4>) so far at the one-year anniversary of the med's ATTR-CM approval.

As the third market entrant in the indication, Amvuttra had gained 35% new-to-brand market share as of the end of 2025, just three quarters into its launch.

“That’s a clear signal of unmet need and willingness from both physicians and patients to adapt a new treatment approach,” Alnylam chief commercial officer Tolga Tanguler said on Tuesday’s investor call.

## Upcoming competition from Wainua

While Amvuttra is currently the sole ATTR silencer in the ATTR-CM field, AZ and Ionis are [preparing to challenge \(https://www.fiercepharma.com/pharma/astrazeneca-80-billion-revenue-target-very-much-within-reach-cfo-says\)](https://www.fiercepharma.com/pharma/astrazeneca-80-billion-revenue-target-very-much-within-reach-cfo-says) Alnylam’s position with their own offering, Wainua. With phase 3 data from the Cardio-TTRansform trial expected this year, Wainua could differentiate itself by potentially rolling tafamidis combination into its indication.

However, John Kennedy, Alnylam’s TTR franchise global commercialization lead, argued that another silencer is a “net positive” for the category.

That’s because “the large majority of cardiologists believe favorable combination treatment data will support a broader class effect,” he explained on the call.

Although Amvuttra doesn’t have combination with tafamidis specifically spelled out in its present FDA indication, the phase 3 Helios-B study that supported its ATTR-CM use has demonstrated treatment effect whether Alnylam’s drug was used with or without background tafamidis. Therefore, a positive combo readout from Cardio-TTRansform would corroborate findings from Helios-B and bolster the case for Amvuttra combination as well, Kennedy said.

The two meds are already butting heads in another form of ATTR, hereditary ATTR polyneuropathy (ATTR-PN), and Amvuttra has maintained about 70% of new starts and more than 80% of total market share in that category.

“We believe these dynamics are all transferable to cardiomyopathy,” Kennedy said.

As to potential changes in pricing and access dynamics, Kennedy again pointed to the current ATTR-PN competition, where Amvuttra is leading. Besides, Amvuttra has strong access with 90% coverage in first-line ATTR-CM treatment while competing with cheaper oral stabilizers, proving that “having another pharmacy benefit medicine in the mix does not change the calculus,” he added.

## Addressing potential threats from generic tafamidis

The anticipated loss of exclusivity (LOE) for Pfizer’s Vyndamax franchise in late 2028 is often [viewed as a threat \(https://www.fiercepharma.com/pharma/bridgebio-shares-slide-amid-pfizer-reported-decision-withdraw-vyndamax-eu-patent\)](https://www.fiercepharma.com/pharma/bridgebio-shares-slide-amid-pfizer-reported-decision-withdraw-vyndamax-eu-patent) to branded therapies, but Alnylam leadership categorizes it as a potential catalyst for growth.

For one thing, Amvuttra is already establishing itself as a first-line option among physicians. According to Tanguler, physicians who have tried Amvuttra are increasingly reaching for the injection as their first-line therapy for new patients. This is critical because, as doctors build experience, they expand its use to more patients.

To Mark Soued, Alnylam’s head of U.S. and TTR lead, that preference build ahead of tafamidis’ LOE “positions us well for sustained growth over the long term.”

Soued argued that genericization will not lead to unfavorable universal step edit requirements for Amvuttra reimbursement.

“It’s also important to remember that in Medicare fee-for-service, which is our single largest payer segment and represents approximately half of our business today, Amvuttra is covered to label with no step edits, and we would expect that dynamic to continue following tafamidis’ LOE,” he said.

But the executive did not rule out step edit policies especially in the commercial market. Nevertheless, he noted that even with a step edit today, patients can access Amvuttra either through appeals or progression from a stabilizer.

Rather than a threat, Alnylam sees the tafamidis cliff as a potential growth opportunity—the availability of generic stabilizers could significantly reduce the cost of combinations with silencers, according to the company.

“Cardiologists are already accustomed to adding on and combining therapies in cardiovascular disease. This is how they practice,” Soued said.

Again, AZ and Ionis’ rival data could increase confidence in combination approaches. And Alnylam is collecting real-world evidence through the DemonsTTRate observational study, which the company expects to analyze data across competitions and combinations.

## **Crunching the numbers on ATTR-CM market potential**

While Amvuttra and BridgeBio’s stabilizer Attruby delivered explosive growth numbers in 2025, a revenue dip for Pfizer’s Vyndamax in the U.S. has [sparked debate \(https://www.fiercepharma.com/pharma/pfizer-reported-attr-sales-decline-us-should-alnylam-bridgebio-worry\)](https://www.fiercepharma.com/pharma/pfizer-reported-attr-sales-decline-us-should-alnylam-bridgebio-worry) over the eventual size of the ATTR-CM market.

Based on market patterns in other diseases such as pulmonary arterial hypertension and atrial fibrillation, Soued suggested that the entire ATTR-CM category is still in its infancy. Diagnosis rates for these new diseases could eventually reach around 70% “as awareness, screening practices, clinical guidelines and the treatment landscape all evolve,” he said

Today, roughly 80% of the estimated 200,000 ATTR-CM patients in the U.S. remain untreated, Soued said. This patient pool is already bigger than the 125,000 that Alnylam had provided in October 2024.

Pfizer alone managed to increase the ATTR-CM treatment population by 56% annually in 2023 and 2024, Tanguler noted. That growth rate accelerated to 77% in 2025, suggesting a contribution to overall market expansion from new treatment options.

In addition, Alnylam estimates that about 15,000 patients are getting treatment for the first time per year, an increase from about 10,000 in the company’s previous calculation. Besides, about half of patients appear to progress after receiving a stabilizer, representing another target population for Amvuttra.

To maintain that momentum, Alnylam is investing in awareness campaigns, new technologies to enable earlier diagnosis and better coordinated care for patients.

The first pillar of Alnylam’s strategy is direct-to-consumer ads, where the company is taking a very tailored approach.

“Our target audience is seeing it, and it’s working,” Kennedy said. “Already today, we’re the most requested ATTR-CM therapy by patients.”

To identify patients earlier in their disease course, Alnylam just [unveiled](https://www.viz.ai/news/viz-ai-partners-with-alnylam-pharmaceuticals-to-advance-earlier-identification-and-care-coordination-in-cardiac-amyloidosis#new-ai-care-pathway-combines-ai-echocardiography-analysis-with-coordinated-guideline-based-next-steps-for-cardiology-and-heart-failure-teams) (<https://www.viz.ai/news/viz-ai-partners-with-alnylam-pharmaceuticals-to-advance-earlier-identification-and-care-coordination-in-cardiac-amyloidosis#new-ai-care-pathway-combines-ai-echocardiography-analysis-with-coordinated-guideline-based-next-steps-for-cardiology-and-heart-failure-teams>) a partnership with Viz.ai. Together, through a prospective implementation study, the two companies are integrating an AI algorithm with electronic health records across five large U.S. health systems to help clinicians identify patients early and guide diagnosis confirmation and referral.

Additionally, a three-year initiative between the Massachusetts biotech and the American Heart Association will convene 10 sites to identify “ideal models of care” for ATTR-CM patients, according to Kennedy.

With all those efforts in place, Alnylam sees potential for more than 75,000 patients being treated for ATTR-CM in the U.S. by 2030, Tangler said. “It will be a competitive market, but one in which Amvuttra is poised to stand out and be the revenue leader in TTR by 2030.”



**Let Google know we are your trusted source.**

Add our editorial as a preferred source in your search results.

Trust this Source



By **Angus Liu**  
DEPUTY EDITOR  
FIERCE PHARMA

Questex

© 2025 Questex Inc. All rights reserved.

