Radioligand Therapy Manufacturing Capacity: The CDMO Crunch

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Executive Summary

Radioligand therapy (RLT) manufacturing capacity has become the binding constraint on how many cancer patients can be treated with this class of medicine, not clinical efficacy or regulatory approval. Novartis, the commercial leader with **Pluvicto** (lutetium Lu 177 vipivotide tetraxetan) and **Lutathera** (lutetium Lu 177 dotatate), reported combined 2025 net sales of roughly $2.8 billion (Source: www.biospace.com), with Pluvicto alone reaching $1,994 million in full-year 2025 sales, up 43% year over year (Source: www.novartis.com). Yet from March to October 2023 the FDA classified Pluvicto as being in shortage after Novartis told new patients it could not supply the drug (Source: www.cnn.com), a shortage the FDA declared resolved on October 26, 2023 only after Novartis "more than doubled weekly production capacity" (Source: www.novartis.com).

The report finds that manufacturing capacity has since expanded rapidly but remains structurally fragile. Novartis alone operates or is building at least seven radioligand therapy sites: Millburn (New Jersey), Ivrea (Italy), Zaragoza (Spain), Indianapolis (Indiana, a 70,000 square foot facility approved by the FDA on January 5, 2024) (Source: www.novartis.com), Carlsbad (California, opened November 10, 2025) (Source: www.novartis.com), Winter Park (Florida, announced January 2026), and Denton (Texas, groundbreaking May 7, 2026) (Source: www.novartis.com), all part of a $23 billion, five-year US manufacturing and R&D commitment announced in April 2025 (Source: www.novartis.com). Combined network capacity is targeted at a minimum of 250,000 doses annually (Source: www.novartis.com).

Rivals have entered largely through acquisition rather than organic build-out: Bristol Myers Squibb paid approximately $4.1 billion for RayzeBio in December 2023 (Source: www.cooley.com); Eli Lilly paid roughly $1.4 billion for POINT Biopharma and its 180,000 square foot Indianapolis campus (Source: investor.lilly.com); and AstraZeneca acquired Fusion Pharmaceuticals in a deal valued at approximately $2.4 billion, gaining the actinium-225 based prostate cancer candidate FPI-2265 (Source: www.astrazeneca.com). Contract manufacturers have raised comparable sums: ITM Isotope

Technologies Munich collected €255 million in 2023 and €188 million in 2024 to expand lutetium-177 and actinium-225 production (Source: www.itm-radiopharma.com), and on August 3, 2026, Curium announced a merger with Lantheus valued at up to $8.0 billion, combining Curium's more than 80 global manufacturing sites with Lantheus's US radiodiagnostics business (Source: www.globenewswire.com).

The deeper constraint, this report finds, sits upstream of any single company's factory footprint: the isotopes themselves. Global actinium-225 production from legacy thorium-229 generators is limited to approximately 63 GBq (1.7 curies) per year across just four sites worldwide, enough to treat only 100 to 200 patients annually (Source: www.ncbi.nlm.nih.gov). Lutetium-177 supply, while more mature, is reported by industry sources as currently unable to keep pace with demand, with the University of Missouri Research Reactor standing as the only end-to-end US producer of no-carrier-added Lu-177 (Source: www.murr.missouri.edu). Because both isotopes decay on a timescale of days (Lu-177's half-life is approximately 6.64 to 6.65 days (Source: medical.ezag.com), Ac-225's approximately 10 days (Source: www.isotopes.gov), doses cannot be stockpiled and must be manufactured, shipped, and infused on a fixed clock, a constraint Novartis has built its entire US site-selection strategy around (Source: www.novartis.com).

Market-size estimates for the sector diverge by roughly $15 billion depending on methodology: Precedence Research values the 2025 global radioligand therapy market at $3.20 billion, rising to $36.47 billion by 2035 at a 27.55% compound annual growth rate (Source: www.precedenceresearch.com), while DataM Intelligence puts 2025 value at $2.94 billion, reaching $21.30 billion by 2035 at a 21.9% CAGR (Source: www.datamintelligence.com). Both agree the United States dominates demand, with North America holding an 82% market share in 2025 per Precedence Research (Source: www.precedenceresearch.com). Against that demand curve, the US Department of Energy's Tri-Lab Effort, Oak Ridge National Laboratory's Isotek program, NorthStar Medical Radioisotopes, SHINE Technologies, Orano Med, and ITM's Actineer joint venture with Canadian Nuclear Laboratories are racing to multiply supply of both isotopes, with NorthStar confirming in January 2026 that it had achieved routine, weekly, commercial-scale non-carrier-added actinium-225 production, a milestone the company calls "first to market"(Source: www.northstarnm.com). This report examines the manufacturing landscape, the contract development and manufacturing organization (CDMO) ecosystem, the isotope supply chain, and the half-life-driven logistics that together determine how many radioligand therapy patients the industry can actually treat, as of August 2026.

Introduction and Background

Radioligand therapy (RLT), also called targeted radionuclide therapy, attaches a radioactive isotope to a molecule engineered to bind selectively to receptors expressed on cancer cells, delivering ionizing radiation directly to a tumor while limiting exposure to healthy tissue. The approach moved from a niche nuclear-medicine procedure to a mainstream oncology modality on March 23, 2022, when the US Food and Drug Administration (FDA) approved Novartis's **Pluvicto** (lutetium Lu 177 vipivotide tetraxetan) as the first FDA-approved targeted radioligand therapy for eligible patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC), alongside its companion diagnostic imaging agent Locametz (Source: www.novartis.com). Novartis's earlier approval, **Lutathera** (lutetium Lu 177 dotatate) for neuroendocrine tumors, had already established the commercial template, and the company's 2018 acquisitions of Advanced Accelerator Applications for $3.9 billion (Source: www.globenewswire.com) and Endocyte for approximately $2.1 billion (Source: www.globenewswire.com) built the manufacturing and pipeline assets that made Pluvicto possible.

What followed Pluvicto's approval was not a smooth commercial ramp but a demand shock the manufacturing base was not built to absorb. By March 2023, less than a year after approval, Novartis told physicians it could not supply the drug to new patients because production could not keep pace with demand (Source: www.cnn.com). The FDA formally listed the drug in shortage from March 7 to October 25, 2023 (Source: www.cancernetwork.com), and an academic oncologist told CNN at the time that "many patients are missing months of therapy" (Source: www.cnn.com). The 2023 demand-driven shortage and the separate May 2022 quality-related production suspension at two Novartis sites (Source: www.novartis.com) show that manufacturing, isotope supply, and time-critical distribution can constrain access alongside clinical science and regulatory approval. Which constraint is most important varies by product and isotope.

This report examines that manufacturing capacity constraint from four angles: the build-out underway at Novartis and the pharmaceutical companies that have acquired their way into the field; the contract development and manufacturing organization (CDMO) and isotope-producer ecosystem racing to add capacity; the isotope supply chain itself, particularly for lutetium-177 (Lu-177) and actinium-225 (Ac-225); and the logistics constraints imposed by short radioactive half-lives, which force a fundamentally different manufacturing and distribution model than conventional pharmaceuticals. The analysis draws on company filings and press releases, peer-reviewed nuclear medicine literature, US Department of Energy (DOE) and national laboratory disclosures, and named case studies through August 2026, the publish date of this report. Because radioligand therapy sits at the intersection of nuclear physics, specialty manufacturing, and oncology, understanding its capacity constraints requires assessing isotope production, drug-product manufacturing, and time-critical distribution together; their relative importance varies by product and isotope.

Methodology and Market Context

This report synthesizes primary-source disclosures, official regulatory and government statements, and peer-reviewed nuclear medicine research to characterize radioligand therapy manufacturing capacity as of mid-2026. Quantitative claims are traced to their originating source wherever possible: named market research firms for market-size estimates, company investor relations pages and press releases for facility and financial data, and government or peer-reviewed literature for isotope-production figures. Where sources disagree, such as the market-size divergence between research firms or the varying reported half-life figures for actinium-225, this report presents both figures rather than silently selecting one.

Two named market research firms provide the clearest quantitative baseline for the sector's size. **Precedence Research** valued the global radioligand therapy market at $3.20 billion in 2025, forecasting growth to $36.47 billion by 2035 at a 27.55% compound annual growth rate (CAGR) (Source: www.precedenceresearch.com), with North America holding 82% of that market in 2025 (Source: www.precedenceresearch.com). **DataM Intelligence** produced a lower, though directionally similar, estimate: $2.94 billion in 2025 rising to $21.30 billion by 2035 at a 21.9% CAGR (Source: www.datamintelligence.com). The roughly $15 billion gap between the two firms' 2035 forecasts illustrates how immature and fast-moving this market still is; neither figure should be treated as definitive, but both point to sustained CAGR above 20% for the coming decade. A separate, US-specific estimate cited by Jubilant Radiopharma places the domestic radiopharmaceutical industry (a broader category including diagnostic isotopes) at $5 billion in 2023, growing to a projected $20 billion in 2030 (Source: biopharmaapac.com).

Clinical pipeline breadth corroborates the demand-side growth story. A peer-reviewed 2025 review in Frontiers in Medicine identified 34 active phase 3 radiopharmaceutical therapy trials registered on ClinicalTrials.gov as of September 30, 2024, several expanding existing indications and others testing new isotope-ligand combinations (Source: pmc.ncbi.nlm.nih.gov). The same review found more than 200 radiopharmaceutical therapy trials of all phases currently underway using Lu-177 specifically, 17 of the 34 active phase 3 trials among them (Source: pmc.ncbi.nlm.nih.gov). Individual trial enrollment figures underscore the coming scale problem: the PSMAddition phase 3 trial of 177Lu-PSMA-617 in metastatic hormone-sensitive prostate cancer had already enrolled 1,148 patients, while the planned STAMPEDE2 trial expects to enroll 8,000 patients (Source: pmc.ncbi.nlm.nih.gov). Each of those patients, if the trials succeed and the indications reach commercial approval, will require an individually manufactured, precisely timed radioactive dose, a demand trajectory that manufacturing capacity has struggled to match even for the far smaller number of already-approved indications.

The Manufacturing Capacity Landscape: Novartis and the Pharma Build-Out

Novartis remains the dominant manufacturer of commercial radioligand therapies and the clearest case study in how capacity has had to scale reactively. As of January 2024, the company operated RLT manufacturing across four sites in three countries and two continents: Millburn (New Jersey), Zaragoza (Spain), Ivrea (Italy), and its then-new Indianapolis (Indiana) facility (Source: www.novartis.com). The Millburn site received FDA approval for US commercial production of Pluvicto in April 2023, with Novartis targeting a capacity of at least 250,000 doses annually across the network from 2024 onward (Source: www.novartis.com). The Indianapolis facility, a 70,000 square foot site and Novartis's second US location, received FDA approval for commercial manufacturing on January 5, 2024, and the company described it as its "largest and most advanced" RLT facility worldwide (Source: www.novartis.com), a facility that also brought network capacity to the 250,000-dose target.

The expansion has continued at a rapid pace since. In April 2025, Novartis committed $23 billion over five years to grow its US research and manufacturing footprint, explicitly including two new RLT manufacturing facilities in Florida and Texas plus expansions of the existing Indianapolis, Millburn, and Carlsbad sites (Source: www.novartis.com), part of what the company says will total nearly $50 billion in total US investment. A third US RLT site opened in Carlsbad, California on November 10, 2025, a 10,000 square foot facility (Source: www.novartis.com) designed to serve the western US, Alaska, and Hawaii. In January 2026, Novartis announced a fourth US facility in Winter Park, Florida, a 35,000 square foot site and the company's first in the southeastern US, expected to come online by 2029 (Source: www.novartis.com). Most recently, Novartis broke ground on May 7, 2026 on a 46,000 square foot fifth US RLT site in Denton, Texas, expected to become operational in 2028, with seven new and three expanded facilities already under construction across the US as part of the $23 billion commitment (Source: www.novartis.com). Novartis has also disclosed plans to build manufacturing capability in Sasayama, Japan and Haiyan, Zhejiang, China, extending the network beyond the US and Europe (Source: www.novartis.com).

Table 1 below summarizes the Novartis RLT manufacturing network as disclosed in company press releases through mid-2026; each facility's underlying source citation appears in the surrounding prose above and below.

FACILITY	LOCATION	SIZE	STATUS (AS OF AUG 2026)	KEY DETAIL
Millburn	New Jersey, US	Not disclosed	Operating since April 2023 FDA approval	First US commercial production site for Pluvicto
Ivrea	Italy	Not disclosed	Operating; temporarily suspended May 2022	Part of original 4-site network
Zaragoza	Spain	Not disclosed	Operating	Supplied EU/Asia doses during 2022 US/Italy suspension
Indianapolis	Indiana, US	70,000 sq ft	FDA approved January 5, 2024	"Largest and most advanced" RLT site to date
Carlsbad	California, US	10,000 sq ft	Opened November 10, 2025	Serves western US, AK, HI
Winter Park	Florida, US	35,000 sq ft	Announced January 2026, online by 2029	First southeastern US site, fourth of five
Denton	Texas, US	46,000 sq ft	Groundbreaking May 7, 2026, operational 2028	Fifth US RLT site

The network's growth reflects a company still catching up to demand rather than getting ahead of it. Full-year 2025 Pluvicto net sales reached $1,994 million, up 43% (42% at constant currencies), with fourth-quarter 2025 sales of $605 million alone, up 72% year over year (Source: www.novartis.com). Lutathera added $816 million for the full year 2025, up 13% (12% cc) (Source: www.novartis.com). Combined, the two products generated an estimated $2.8 billion for Novartis in 2025 (Source: www.biospace.com). Novartis, for its part, states that its facility siting strategy is explicitly designed around the isotope's decay clock: with radioactive half-life measured in hours, the company says, "proximity to treatment centers and transit hubs helps ensure patients receive their treatment" (Source: www.novartis.com).

Rival pharmaceutical companies have entered the field primarily through acquisition, gaining manufacturing assets rather than building them organically. Bristol Myers Squibb (BMS) acquired RayzeBio for a total equity value of approximately $4.1 billion, or $3.6 billion net of estimated cash acquired, in a deal signed in December 2023 (Source: www.cooley.com). RayzeBio's Indianapolis manufacturing facility, a $160 million investment, is designed to eventually ship tens of thousands of radiopharmaceutical doses annually if its treatments gain regulatory approval for general use (Source: www.wrtv.com). Eli Lilly agreed in October 2023 to acquire POINT Biopharma for $12.50 per share, an aggregate of approximately $1.4 billion, gaining POINT's 180,000 square foot Indianapolis manufacturing campus and a Toronto research and development center (Source: investor.lilly.com), with the tender offer completing in December 2023 after 72,788,215 shares, roughly 67.97% of outstanding stock, were validly tendered (Source: investor.lilly.com). AstraZeneca's acquisition of Fusion Pharmaceuticals, structured at $21.00 per share in cash plus a contingent value right of $3.00 per share, represented a transaction value of approximately $2.4 billion and was completed in 2024, giving AstraZeneca manufacturing and supply-chain capabilities specifically in actinium-based radioconjugates, including the lead candidate FPI-2265, an actinium-225 PSMA-targeting agent now in Phase II testing for mCRPC (Source: www.astrazeneca.com). Novartis has continued to add pipeline assets as well, agreeing in May 2024 to acquire Mariana Oncology for a $1 billion upfront payment plus up to $750 million in milestone payments (Source: www.novartis.com).

The CDMO and Isotope-Producer Ecosystem

Beyond the branded-drug sponsors, a distinct layer of contract development and manufacturing organizations (CDMOs) and dedicated isotope producers has emerged to supply radioligand therapy manufacturing capacity, either as outsourced production partners or as upstream isotope suppliers. This ecosystem has consolidated and capitalized rapidly since 2023.

Curium, historically the largest global radiopharmaceutical manufacturer, has expanded aggressively through acquisition. In March 2025 it completed the acquisition of Turkish nuclear medicine company Monrol specifically to expand Lu-177 manufacturing capacity, growing its PET (positron emission tomography) footprint from 34 sites across Western Europe and Asia to 46 sites with the addition of 12 Eastern Europe and Middle East/North Africa locations (Source: www.globenewswire.com). The following month, Curium completed the acquisition of PET manufacturer Nucleis, adding to a 32-site Western Europe distribution network (Source: www.curiumpharma.com). Curium had earlier signaled this expansion push when it grew its St. Louis, Missouri headquarters in March 2023, adding more than 100 new jobs over three years and describing a broader "renaissance" underway in

nuclear medicine investment, innovation, and growth (Source: www.curiumpharma.com); its Maryland Heights, Missouri facility alone produces and ships thousands of nuclear medicine doses every week (Source: www.curiumpharma.com). By November 2025, Curium was also expanding manufacturing capacity at that Maryland Heights site and at Noblesville, Indiana, while establishing a new global headquarters in Boston (Source: www.globenewswire.com). The consolidation trend culminated on August 3, 2026, when Curium announced a definitive agreement to merge with Lantheus in a deal with an aggregate transaction value of up to $8.0 billion, a combination the companies said would pair Curium's more than 80 global manufacturing sites and over 3,800 employees across more than 70 countries with Lantheus's US radiodiagnostics commercial infrastructure (Source: www.globenewswire.com). That announcement came roughly a year after private equity firm CapVest Partners recapitalized Curium in a transaction valuing the group at approximately $7 billion (Source: www.globenewswire.com).

ITM Isotope Technologies Munich (ITM) describes itself as the world's largest manufacturer of no-carrier-added Lu-177 (Source: www.globenewswire.com) and has raised significant capital to defend that position: €255 million in June 2023, led by Temasek with participation from BlackRock, funding a second full-scale manufacturing facility in Germany capable of producing multiple radioisotopes and radiotherapies at scale (Source: www.itm-radiopharma.com); and €188 million in June 2024, again led by Temasek with BlackRock and QIA, following the opening of ITM's new NOVA production facility and the launch of its Actineer joint venture (Source: www.itm-radiopharma.com). ITM also relies on a supply agreement with **NTP Radioisotopes** of South Africa, which produces no-carrier-added Lu-177 by irradiating ytterbium-176 (Yb-176) using the SAFARI-1 nuclear reactor under a technology license from ITM (Source: www.globenewswire.com). On the actinium side, ITM's **Actineer** joint venture with Canadian Nuclear Laboratories (CNL), founded in October 2023, began producing Ac-225 by irradiating radium-226 in a cyclotron in October 2024, with GMP-grade (good manufacturing practice) supply expected by mid-2025 (Source: www.itm-radiopharma.com); Actineer's longer-term plan includes construction of a dedicated Actinium Production Facility in Canada (Source: www.itm-radiopharma.com).

NorthStar Medical Radioisotopes, based in Beloit, Wisconsin, has pursued electron-accelerator technology as an alternative to reactor-based isotope production. In January 2023 the company achieved a "two beams on target" milestone validating its proof of concept for large-scale, non-uranium molybdenum-99 (Mo-99) production (Source: www.biospace.com), with its president projecting the facility would eventually meet nearly 40% of US Mo-99 demand once licensed (Source: www.biospace.com). The company broke ground on a dedicated therapeutic radioisotope facility in October 2021, positioning itself to become the first commercial-scale producer of both Ac-225 and copper-67 (Source: radiologybusiness.com), backed cumulatively by more than $100 million in DOE/National Nuclear Security Administration (NNSA) cooperative agreements, including a $37 million award in August 2021 (Source: www.healthimaging.com). That work reached a milestone on January 6, 2026, when NorthStar confirmed it had achieved successful, routine, commercial-scale production of non-carrier-added Ac-225 using its electron-accelerator technology at its Beloit campus, at millicurie-level quantities on a weekly cycle (Source: www.northstarnm.com), a milestone the company's CEO framed as "first to market," aimed at "unlocking the constrained potential in radiopharmaceutical therapeutic development with this isotope" (Source: www.northstarnm.com).

Several smaller and newer entrants round out the ecosystem. **SHINE Technologies** produces Ilumira, its no-carrier-added Lu-177 product, at its Cassiopeia facility in Janesville, Wisconsin, with disclosed capacity for 100,000 doses per year and potential expansion to 200,000 (Source: www.shinefusion.com); in 2024 the company secured $32 million from the DOE's NNSA plus €10.5 million alongside the University Medical Center Groningen (Source: www.shinefusion.com), and in April 2026 the DOE's Office of Energy Dominance Financing issued a conditional loan commitment of up to $263 million to complete SHINE's separate Chrysalis Mo-99 production facility, designed to produce up to 8,200 six-day curies of Mo-99 per week (Source: www.ans.org). **Orano Med** inaugurated ATLab Indianapolis in June 2024, which it describes as the world's first industrial-scale facility dedicated to production of lead-212 (Pb-212) based radioligand therapies, a $20 million investment spanning more than 30,000 square feet (Source: www.oranomed.com); combined with its existing Plano, Texas unit, the company projected the ability to manufacture 10,000 doses a year worldwide as of 2025, with a goal of a tenfold increase by the end of the decade (Source: www.oranomed.com). **ARTBIO** closed a $132 million Series B financing round in July 2025 co-led by Sofinnova Investments and B Capital, earmarked partly for its AlphaDirect isotope isolation technology, which the company says enables flexible, daily production of clinical-grade Pb-212 through a distributed manufacturing network rather than a single facility (Source: www.prnewswire.com). **Jubilant Radiopharma** committed $50 million in June 2024 to add six new PET manufacturing sites, expanding its PET network to nine sites and its overall PET/SPECT (single-photon emission computed tomography) radiopharmacy network to 52 sites (Source: biopharmaapac.com). Finally, **BWXT Medical** operates an 80,000 square foot cGMP manufacturing facility in Ottawa alongside a commercial cyclotron facility within TRIUMF, Canada's particle-acceleration research center (Source: www.prnewswire.com), and in November 2023 expanded its collaboration with Fusion Pharmaceuticals to supply radium-225/actinium-225 generator technology enabling onsite Ac-225 production at Fusion's own GMP facility (Source: www.prnewswire.com).

The scale and pace of this fundraising and dealmaking is itself evidence of the capacity constraint this report describes: no single CDMO or isotope producer has yet demonstrated it can meet even current demand, let alone the pipeline demand implied by more than 200 ongoing Lu-177 trials.

The Isotope Supply Chain: Lutetium-177 and Actinium-225 Constraints

Radioligand therapy manufacturing capacity is ultimately gated by isotope availability, not by drug-product fill-finish capability. The two isotopes at the center of today's commercial and clinical pipeline, lutetium-177 and actinium-225, face very different, but equally binding, supply constraints.

Lutetium-177 can be produced by two distinct nuclear routes. The "direct route" irradiates lutetium-176 (Lu-176) directly in a reactor, yielding "carrier-added" Lu-177 whose specific activity depends on available neutron flux. The "indirect route" instead irradiates enriched ytterbium-176 (Yb-176), which decays to Lu-177, yielding "no-carrier-added" (n.c.a.) product with specific activity close to its theoretical maximum, the form generally preferred for radioligand therapy because it minimizes competing non-radioactive lutetium in the final drug product. The University of Missouri Research Reactor (MURR) is the only end-to-end producer of no-carrier-added Lu-177 in the United States, operating year-round GMP production (Source: www.murr.missouri.edu). Internationally, NTP Radioisotopes in South Africa produces n.c.a. Lu-177 via the Yb-176 indirect route using its SAFARI-1 reactor under license from ITM (Source: www.globenewswire.com), and ITM itself claims to be the world's largest n.c.a. Lu-177 manufacturer (Source: www.globenewswire.com). The Society of Nuclear Medicine and Molecular Imaging (SNMMI) has separately noted that MURR is the only US facility producing molybdenum-99, and that solely for research rather than commercial use, even though roughly 80% of diagnostic nuclear medicine procedures depend on technetium-99m derived from imported Mo-99 (Source: snmmi.org, an illustration of how thin the US isotope-production base remains even for isotopes adjacent to the RLT supply chain.

Concerns about Lu-177 sufficiency predate the current demand surge. A 2021 editorial in the European Journal of Nuclear Medicine and Molecular Imaging warned that worldwide Lu-177 availability "may not be sufficient in the long term" given surging demand from PSMA- and somatostatin-analog-directed therapies (Source: link.springer.com), estimating that Lutathera-related demand alone was already running at roughly 10,000 to 15,000 doses of 7.4 gigabecquerel (GBq) each annually and predicting that PSMA-directed therapy could multiply world Lu-177 demand several times over (Source: link.springer.com). That prediction has materialized: as of late 2025, industry sources describe Lu-177 demand as currently outstripping supply. MURR describes itself more narrowly as the only end-to-end US producer of Lu-177, while SHINE also reports commercial Lu-177 production in Janesville, Wisconsin (Source: www.biospace.com). SNMMI has separately noted that the broader radiopharmaceutical supply chain "is especially fragile due to the short shelf life of isotopes and limited suppliers," and that "geopolitical instability, unplanned reactor outages, and adverse weather can further disrupt supply" (Source: snmmi.org).

That fragility is not hypothetical. Nuclear reactor aging and unplanned outages have already disrupted global isotope supply repeatedly. Canada's National Research Universal (NRU) reactor at Chalk River, online since 1957, was at one point responsible for roughly 40% of the world's supply of medical isotopes used for diagnosis and cancer therapy (Source: www.cbc.ca). A month-long unplanned shutdown in 2007 and a leak-triggered, year-long shutdown beginning in 2009 both caused worldwide shortages of medical isotopes (Source: www.cbc.ca), and the near-simultaneous 2008 to 2010 unplanned outages of NRU and the Netherlands' High Flux Reactor produced a worldwide shortage that a peer-reviewed retrospective specifically cites as a formative supply-chain event for the field (Source: link.springer.com). NRU was permanently shut down on March 31, 2018 (Source: www.cbc.ca), removing capacity that, in its final operating years, had reportedly helped supply medical isotopes to more than 76,000 people daily in more than 80 countries (Source: www.cbc.ca). The episode illustrates a structural vulnerability that persists today: a global medical isotope supply concentrated in a small number of aging research reactors, any one of which can trigger a worldwide shortage if taken offline unexpectedly.

Actinium-225 faces a far more acute constraint. Legacy production relies on thorium-229 (Th-229) "cow" generators, essentially a stockpile of Th-229 that continuously decays into Ac-225 and can be periodically "milked." Only four sites worldwide hold meaningful Th-229 stockpiles: Oak Ridge National Laboratory (ORNL) in the US, the Joint Research Centre in Karlsruhe, Germany, the Institute for Physics and Power Engineering in Russia, and formerly SCK CEN in Belgium. Together they produce approximately 63 GBq (1.7 curies) of Ac-225 annually (Source: www.ncbi.nlm.nih.gov), an amount a 2025 peer-reviewed article states can sustain treatment of only 100 to 200 patients per year globally (Source: www.ncbi.nlm.nih.gov). A 2021 multi-institution review in the Journal of Nuclear Medicine, involving TRIUMF, the International Atomic Energy Agency, and multiple national laboratories, corroborated that figure, finding that only about 12.9 GBq (350 millicuries) of Th-229 had been converted into functioning Ac-225 generators worldwide, limiting global annual Ac-225 production to that same approximately 63 GBq (1.7 curies) (Source: jnm.snmjournals.org). ORNL itself, the primary US supplier for nearly 30 years, has described its own Th-229 cow as yielding "about 1 curie annually," a level the laboratory says is "not enough even for large-scale clinical trials" (Source: www.ornl.gov); trade press coverage similarly notes that ORNL "has increased shipments, but the growth in demand has outpaced its ability to boost output" (Source: www.biospace.com).

Two federally backed initiatives are working to break this bottleneck. The **DOE Tri-Lab Effort**, a collaboration among Brookhaven National Laboratory, Los Alamos National Laboratory, and ORNL active since 2015, produces Ac-225 by irradiating thorium-232 targets with proton accelerators, an approach that sidesteps the fixed Th-229 stockpile entirely. In a June 2021 demonstration, the accelerator route generated approximately 60% of the then-current annual global Ac-225 supply in just 12 days (Source: www.ornl.gov). The effort has since aimed to scale batch sizes from an initial 50 to 100 millicuries to 100 to 1,000 millicuries per batch, and has cumulatively distributed more than 1,102 millicuries of accelerator-produced Ac-225 to evaluators (Source: www.isotopes.gov). Separately, Oak Ridge's Isotek contractor, under the DOE's Thorium Express Project, announced in May 2025 that it had extracted more than 15 grams of rare Th-229 (Source: www.ans.org); the project's underlying uranium-233 downblending work at

ORNL is expected to eventually yield roughly 45,000 milligrams of Th-229 in total, vastly more than the combined 700 to 1,300 milligrams held at all existing legacy sites (Source: jnm.snmjournals.org), a scale-up that, if realized, would represent a step change in global thorium-based Ac-225 capacity rather than an incremental one.

The isotope's half-life is itself reported with some inconsistency across sources: the DOE's National Isotope Development Center states Ac-225 decays with a half-life of 10 days (Source: www.isotopes.gov), while trade press citing academic sources gives a figure of 9.92 days (Source: www.biospace.com); the discrepancy is immaterial to manufacturing planning but illustrates the granularity gap between government reference data and secondary reporting. What is not in dispute is that Ac-225 demand has already outpaced supply enough to disrupt clinical development directly: Bristol Myers Squibb's RayzeBio paused enrollment in a Phase 3 trial of its lead candidate RYZ101 in 2024 specifically because of an actinium-225 shortage (Source: www.biospace.com). Bayer has responded by stacking supply agreements with multiple producers, including BWXT, Ionetix, NorthStar, and PanTera between 2022 and 2024, rather than relying on a single source (Source: www.biospace.com), and AstraZeneca secured its own actinium-225 supply for the Fusion Pharmaceuticals pipeline through a 10-year agreement with Niowave signed in December 2025 (Source: www.biospace.com).

Table 2 below summarizes the half-life, production route, and supply status for the isotopes central to current radioligand therapy manufacturing.

ISOTOPE	HALF-LIFE	PRIMARY PRODUCTION ROUTE	KEY PRODUCERS	SUPPLY STATUS (MID-2026)
Lutetium-177 (Lu-177)	~6.64 to 6.65 days (Source: medical.ezag.com)	Reactor irradiation of Yb-176 (indirect/n.c.a.) or Lu-176 (direct/carrier-added)	MURR (US), NTP Radioisotopes (South Africa), ITM (Germany)	Demand reported to exceed supply (Source: www.biospace.com)
Actinium-225 (Ac-225)	~10 days (Source: www.isotopes.gov) (cited elsewhere as 9.92 days)	Th-229 decay generators (legacy) or accelerator/cyclotron irradiation of Th-232 or Ra-226 (emerging)	ORNL, NorthStar, ITM/Actineer (CNL), Tri-Lab Effort	Severe scarcity; the estimated ~63 GBq/yr and 100–200-patient capacity apply to legacy Th-229-generator production, not total current global supply (Source: www.ncbi.nlm.nih.gov)
Yttrium-90 (Y-90)	~64.1 to 64.2 hours (2.67 days) (Source: jgo.amegroups.org)	Commonly obtained from a Sr-90/Y-90 generator; the Sr-90 parent is recovered from fission products	Established radioembolization suppliers	Mature, established supply chain

The table illustrates why actinium-225 dominates current supply-chain discussion despite lutetium-177 supporting far more approved and late-stage clinical volume: Ac-225's scarcity is roughly two orders of magnitude more severe relative to demand, and its scale-up depends on entirely new production technology (accelerators and cyclotrons) rather than incremental reactor-capacity additions.

Half-Life Logistics: Why Radiopharmaceuticals Cannot Be Stockpiled

Radioligand therapy manufacturing differs from conventional pharmaceutical production in one decisive respect: the active ingredient is continuously decaying from the moment it is produced. Novartis states plainly that "RLT manufacturing operates on a timeline of just hours and days" (Source: www.novartis.com), and that "each RLT dose is manufactured for a patient at a specific day and time" rather than produced to inventory (Source: www.novartis.com). This just-in-time model forces manufacturing site selection, regulatory transport compliance, and distribution logistics to be built around the decay clock rather than around conventional cost or scale considerations.

Facility siting is the clearest example. Novartis has explained that it located its Indianapolis facility to be within roughly 12 hours' driving distance of nearly half the US population (Source: www.novartis.com), and under 10 minutes from Indianapolis International Airport, so that decaying doses can move by air when driving is not fast enough (Source: www.novartis.com). The company's September 2024 announcement of its Indianapolis expansion and new Carlsbad site framed both explicitly around supply-chain resiliency, noting the Indianapolis expansion would establish in-house isotope production specifically to feed decentralized RLT manufacturing (Source: www.prnewswire.com). Novartis has publicly reported that this multi-site, geographically distributed model sustains a network-wide on-time delivery rate above 99% of doses administered on the planned day of

treatment (Source: www.novartis.com). Curium's own facility-expansion history reflects the same logic from the CDMO side: the company frames its Maryland Heights and Noblesville capacity additions as part of a broader industry "renaissance" in nuclear medicine investment rather than isolated site decisions (Source: www.curiumpharma.com).

Transport of radioligand therapies is also subject to a distinct regulatory regime layered on top of standard pharmaceutical shipping rules. Radiopharmaceuticals are classified as Class 7 radioactive materials, jointly regulated by the Nuclear Regulatory Commission (NRC), the Department of Transportation (DOT), and the International Air Transport Association's Dangerous Goods Regulations (Source: www.shipmercury.com). The NRC reports that approximately 3 million packages of radioactive materials are shipped annually across the United States, with package design and in-transit shipment jointly overseen by the NRC and DOT (Source: www.nrc.gov). Most doses ship in Type A packages, which must pass drop, penetration, and water-spray performance testing, and federal rules require Class 7 shipments to be handed directly to an NRC-licensed nuclear pharmacist or authorized radiation safety officer rather than delivered to a general receiving dock (Source: www.shipmercury.com). Because the isotope decays continuously in transit, any delay directly reduces the amount of administrable radioactivity that reaches the patient; one industry compliance guide notes that a connection adding four hours to a Lu-177 shipment, with its roughly 6.7-day half-life, measurably reduces administered activity (Source: www.shipmercury.com). Many Lu-177 and Ac-225 based products additionally require simultaneous cold-chain refrigeration between 2 and 8 degrees Celsius alongside radiation shielding, a packaging-engineering challenge that combines lead or tungsten shielding with validated thermal insulation in a single container (Source: www.shipmercury.com). Upon arrival, recipients perform a "decay verification" step, comparing the activity remaining on receipt against the activity documented at the time of manufacture, to confirm the dose arrived within its therapeutic window (Source: www.shipmercury.com).

The consequence of this decay-driven model is that even a temporary single-site disruption can cascade into a shortage, unless the manufacturing network has geographic redundancy. When Novartis voluntarily suspended production at its Ivrea, Italy and Millburn, New Jersey sites in May 2022 over potential manufacturing quality issues, both commercial and clinical trial supply of Lutathera and Pluvicto were disrupted, with the company initially expecting resolution within about six weeks (Source: www.novartis.com). During that suspension, Novartis noted, some Lutathera doses remained available in Europe and Asia from its Zaragoza, Spain site, though possibly with delays, an early real-world demonstration of how multi-site production provides resilience that a single-site model cannot (Source: www.novartis.com). Industry sources describe the operational consequence of continuous decay bluntly: because "the material is decaying by the hour," enterprise inventory and logistics systems for radioligand therapy must be updated on an hourly cycle rather than the daily or weekly cadence typical of conventional pharmaceutical supply chains (Source: www.biospace.com).

Data Analysis and Evidence

Aggregating the manufacturing and financial data collected across this report clarifies both the scale of capital committed to radioligand therapy manufacturing and the persistent gap between announced capacity and clinical demand. *Table 3* below summarizes major disclosed capacity-related investments and transactions across the sector since 2023.

COMPANY	TRANSACTION/INVESTMENT	AMOUNT	FACILITY/FOCUS	DATE
Novartis	US manufacturing/R&D commitment	$23B (nearly $50B total US investment)	2 new + 3 expanded US RLT sites	April 2025
Bristol Myers Squibb	Acquisition of RayzeBio	~$4.1B equity value (Source: www.cooley.com)	Indianapolis manufacturing ($160M facility) (Source: www.wrtv.com)	December 2023
Eli Lilly	Acquisition of POINT Biopharma	~$1.4B (Source: investor.lilly.com)	180,000 sq ft Indianapolis campus	October 2023
AstraZeneca	Acquisition of Fusion Pharmaceuticals	~$2.4B (Source: www.astrazeneca.com)	Actinium-based radioconjugate manufacturing	2024
Curium / Lantheus	Merger agreement	Up to $8.0B (Source: www.globenewswire.com)	80+ global manufacturing sites	August 2026
ITM	Equity raise	€255M (Source: www.itm-radiopharma.com)	Second German manufacturing facility	June 2023
ITM	Equity raise	€188M (Source: www.itm-radiopharma.com)	NOVA facility, Actineer JV	June 2024
SHINE Technologies	Conditional DOE loan	Up to $263M (Source: www.ans.org)	Chrysalis Mo-99 facility, Janesville WI	April 2026
ARTBIO	Series B financing	$132M (Source: www.prnewswire.com)	Distributed Pb-212 manufacturing	July 2025
Orano Med	Facility investment	$20M (Source: www.oranomed.com)	ATLab Indianapolis, Pb-212	June 2024
Jubilant Radiopharma	Facility investment	$50M (Source: biopharmaapac.com)	6 new PET sites (9 total)	June 2024
NorthStar	DOE/NNSA cooperative agreements	$37M (2021), >$100M cumulative (Source: www.healthimaging.com)	Mo-99 and Ac-225 production, Beloit WI	August 2021

The pattern across Table 3 is consistent: capital is flowing overwhelmingly toward manufacturing and isotope-production infrastructure rather than toward clinical development alone, a signal that the industry itself has concluded manufacturing, not molecule discovery, is the current rate-limiting step. Novartis's disclosed sales growth further quantifies the demand side of this equation. DataM Intelligence reports that Pluvicto generated $1.39 billion globally in 2024, with $1.16 billion from the United States, while Lutathera generated $724.00 million globally, with $513.00 million from the United States (Source: www.datamintelligence.com) (Source: www.datamintelligence.com), figures that both grew again in the company's full-year 2025 results discussed earlier in this report. On the isotope-supply side, the DOE reports the Department of Energy announced $6 million in funding in May 2024 across 12 awards spanning eight research efforts on isotope enrichment, targetry, and separations, explicitly framed by the agency's Isotope Program director as promoting "U.S. independence from foreign supply chains of enabling isotopes" (Source: www.energy.gov). That relatively modest research investment sits alongside SNMMI's own estimate that building genuinely commercial-scale domestic facilities for molybdenum-99 and other medical isotopes in the United States would require approximately 10 to 15 years and significant capital (Source: snmmi.org), and SNMMI's finding that the US imports more than 30 medical isotopes from other nations, consuming more than half of the global technetium-99m supply,

sourced entirely from abroad (Source: snmmi.org). Taken together, the data show a manufacturing base expanding at a pace measured in single-digit years while the underlying isotope-production infrastructure it depends on is measured in decades, a mismatch this report's Implications section addresses directly.

Case Studies and Real-World Examples

The 2023 Pluvicto Shortage and Its Resolution

The most consequential documented capacity failure in radioligand therapy to date is the 2023 Pluvicto shortage. In March 2023, Novartis informed the field that it could not supply Pluvicto to new patients until production increased (Source: www.cnn.com), an announcement that coincided with the temporary suspension, "out of an abundance of caution," of production at its Ivrea, Italy site over potential quality issues, alongside a pause at a New Jersey plant that had been serving Canada (Source: www.cnn.com). The FDA formally listed the shortage from March 7 to October 25, 2023 (Source: www.cancernetwork.com). As of March 2023, Novartis acknowledged that its under-construction Indianapolis plant would not be operational until the end of that year (Source: www.cnn.com), leaving existing capacity as the only lever available in the near term. Novartis responded by "more than doubling" weekly production capacity between May and October 2023 (Source: www.cancernetwork.com), and the FDA classified the shortage as resolved on October 26, 2023, citing that scaled-up production (Source: www.novartis.com), with more than 200 US treatment centers actively ordering doses by that date and roughly 130 more scheduled to come online. During the shortage itself, a Cleveland-based academic oncologist described the human cost directly: "many patients are missing months of therapy" (Source: www.cnn.com).

NorthStar's January 2026 Actinium-225 Production Milestone

On January 6, 2026, NorthStar Medical Radioisotopes announced that it had confirmed successful, routine, commercial-scale production of non-carrier-added Ac-225 using its proprietary electron-accelerator technology at its Beloit, Wisconsin campus, achieving millicurie-level output on a weekly cycle (Source: www.northstarnm.com). The company positioned the achievement as directly addressing "long-term critical constraints in the Ac-225 supply chain" (Source: www.northstarnm.com), and its CEO Frank Scholz described NorthStar as first to market with routine, commercial-scale Ac-225 production (Source: www.northstarnm.com). This milestone, arriving roughly four and a half years after the DOE's Tri-Lab Effort first demonstrated accelerator-based Ac-225 production could generate 60% of then-global annual supply in 12 days (Source: www.ornl.gov), represents the first time an accelerator-based Ac-225 producer has moved from demonstration to routine commercial output, a development this report's Implications section treats as a potential inflection point for the sector's most acute isotope shortage.

SHINE Technologies' $263 Million DOE Loan for Domestic Isotope Capacity

In April 2026, the DOE's Office of Energy Dominance Financing issued a conditional loan commitment of up to $263 million to SHINE Technologies to complete its Chrysalis molybdenum-99 production facility in Janesville, Wisconsin (Source: www.ans.org), a facility designed to use deuterium-tritium fusion neutron generators to produce up to 8,200 six-day curies of Mo-99 per week once fully online (Source: www.ans.org). The case is instructive alongside SHINE's separate Lu-177 production line at its Cassiopeia facility, which already carries disclosed capacity for 100,000 doses per year of its Ilumira product with potential expansion to 200,000 (Source: www.shinefusion.com): it illustrates a single company simultaneously pursuing domestic capacity for both a legacy diagnostic isotope (Mo-99, reliant on federal financing) and a newer therapeutic isotope (Lu-177, reliant on private and DOE co-funding), underscoring how thoroughly government capital has become intertwined with private radioisotope manufacturing capacity in the United States.

Orano Med's ATLab Indianapolis: The First Industrial-Scale Lead-212 Facility

In June 2024, Orano Med inaugurated ATLab Indianapolis, which the company describes as the world's first industrial-scale pharmaceutical facility dedicated to production of lead-212 (Pb-212) based radioligand therapies, representing a $20 million investment across more than 30,000 square feet (Source: www.oranomed.com). Combined with the company's existing Plano, Texas manufacturing unit, Orano Med projected the two sites would together enable production of 10,000 Pb-212 doses per year worldwide as of 2025, with an explicit goal of a tenfold capacity increase, to 100,000 doses annually, by the end of the decade (Source: www.oranomed.com). The case is notable because it represents dedicated industrial capacity built for an isotope, lead-212, that has essentially no legacy commercial manufacturing base to build on, unlike lutetium-177's decades of reactor infrastructure.

The Curium-Lantheus Merger: Consolidation as a Capacity Strategy

On August 3, 2026, Curium and Lantheus announced a definitive merger agreement with an aggregate transaction value of up to $8.0 billion (Source: www.globenewswire.com), pairing Curium's global manufacturing footprint of more than 80 sites, over 3,800 employees, and operations across more than 70 countries (Source: www.globenewswire.com) with Lantheus's US radiodiagnostics commercial infrastructure. The deal, announced just two days before this report's publish date, illustrates a distinct capacity strategy from Novartis's organic build-out: rather than constructing new radioligand therapy sites from scratch, the combined entity gains immediate scale by merging an already-global manufacturing network with commercial distribution reach, a consolidation logic that follows Curium's own 2025 acquisitions of Monrol and Nucleis, both explicitly justified as capacity expansions for lutetium-177 and PET radiopharmaceuticals respectively (Source: www.globenewswire.com).

Implications and Future Directions

The evidence assembled in this report points to three durable conclusions about where radioligand therapy manufacturing capacity is headed. First, capacity expansion is now happening at a scale and pace that would have been difficult to predict even three years ago: Novartis has grown from four RLT sites in January 2024 to seven disclosed RLT sites by mid-2026—five operating, one announced in Winter Park, Florida, and one under construction in Denton, Texas. Its $23 billion US commitment also includes seven new and three expanded facilities across multiple manufacturing and research programs, not ten RLT sites, and sits alongside billions more in CDMO fundraising and pharma M&A activity documented throughout this report. If Novartis, Curium, ITM, NorthStar, SHINE, and Orano Med execute on currently disclosed plans, aggregate manufacturing capacity for finished radioligand therapy doses could plausibly double or triple over the next three to five years relative to 2024 levels.

Second, constraints are layered rather than universal: isotope supply is a major upstream constraint, particularly for Ac-225, while finished-dose manufacturing and distribution have also constrained patient access, as the Pluvicto shortage demonstrated. The 63 GBq global annual ceiling on legacy actinium-225 production (Source: www.ncbi.nlm.nih.gov) cannot be raised by building more drug-product fill-finish facilities; it requires fundamentally new isotope-production technology, which is exactly why NorthStar's January 2026 routine accelerator-based Ac-225 production milestone (Source: www.northstarnm.com), ITM's Actineer cyclotron-based production (Source: www.itm-radiopharma.com), and Oak Ridge's Thorium Express Project (Source: www.ans.org) matter more to the field's long-run trajectory than any single new fill-finish facility. AstraZeneca's decision to secure its own Ac-225 supply through a 10-year Niowave agreement, rather than depend solely on legacy Th-229 stockpiles, is itself a signal that sponsors expect the isotope constraint, not the drug-product constraint, to bind first (Source: www.astrazeneca.com). If accelerator- and cyclotron-based Ac-225 production scales successfully across multiple producers over the next several years, it could materially expand supply beyond the estimated 100-to-200-patient annual capacity of legacy Th-229 generators. No current, comprehensive production dataset supports treating that legacy estimate as a total-market ceiling; if newer routes do not scale, isotope availability may continue to constrain actinium-based radioligand therapy development regardless of drug-product capacity.

Third, the decay-driven logistics constraint means capacity cannot be centralized the way conventional pharmaceutical manufacturing has trended over the past two decades. Every major sponsor examined in this report, Novartis, Curium, ITM, and the emerging CDMO layer, has converged independently on the same geographically distributed, regional manufacturing model, because a single mega-facility, however large, cannot deliver a six-day half-life isotope to patients on the opposite side of a continent within its therapeutic window. This has direct implications for how life-sciences organizations plan commercial launches, supply agreements, and site-selection strategy in this category: proximity to treatment centers, air transport access, and site-specific receipt procedures under applicable licenses are first-order strategic variables, not secondary logistics details. Consultancies and technology partners advising life-sciences organizations navigating this shift, including firms such as **IntuitionLabs**, a life-sciences and AI consultancy, note that the underlying data, regulatory-compliance, and operational-integration challenges this creates are increasingly addressed through analytics and workflow tooling built specifically for regulated pharmaceutical environments rather than generic supply-chain software (Source: intuitionlabs.ai). IntuitionLabs, for its part, describes its own remit as providing "strategic guidance on digital transformation, AI adoption, and technology roadmapping" for pharmaceutical and life-science organizations (Source: intuitionlabs.ai), an adjacent advisory role rather than a manufacturing or isotope-supply one; the company does not manufacture radiopharmaceuticals or isotopes and is not positioned as a participant in the capacity build-out this report describes.

Looking forward, the clearest signal to watch is whether the DOE's Thorium Express Project delivers on its projected roughly 45,000 milligram Th-229 yield (Source: jnm.snmjournals.org), which would represent a step change in the global Ac-225 stockpile rather than incremental growth, and whether NorthStar's, Actineer's, and other accelerator- or cyclotron-based Ac-225 production routes can be replicated at multiple additional sites to reduce single-point-of-failure risk, given the historical precedent set by NRU and HFR reactor outages disrupting global isotope supply twice within a decade (Source: link.springer.com). With more than 200 Lu-177 trials and 34 active phase 3 radiopharmaceutical therapy trials already underway (Source: pmc.ncbi.nlm.nih.gov), the manufacturing and isotope-supply decisions made by sponsors and producers over the next two to three years will largely determine how many of those trials, if successful, can actually reach patients at commercial scale.

Frequently Asked Questions (FAQs)

What is a radioligand therapy CDMO? A radioligand therapy contract development and manufacturing organization (CDMO) is a company that manufactures radiopharmaceutical drug product, isotopes, or both, on behalf of pharmaceutical sponsors rather than developing its own branded therapies for commercial sale. Curium, ITM Isotope Technologies Munich, NorthStar Medical Radioisotopes, SHINE Technologies, Orano Med, and BWXT Medical all operate in this space, supplying isotopes, finished doses, or both to branded sponsors such as Novartis, Bristol Myers Squibb, and AstraZeneca (Source: www.prnewswire.com).

What is causing the lutetium-177 supply shortage? Reported Lu-177 constraints stem from a small number of global producers, principally MURR in the United States, NTP Radioisotopes in South Africa, and ITM in Germany, unable to scale output as quickly as clinical and commercial demand has grown following Pluvicto's and Lutathera's approvals (Source: www.murr.missouri.edu) (Source: www.biospace.com).

Why is actinium-225 so much scarcer than lutetium-177? Ac-225's legacy production route depends on a fixed global stockpile of thorium-229 accumulated decades ago at just four sites. That legacy generator route has been estimated to yield about 63 GBq (1.7 curies) annually, enough for roughly 100 to 200 patients per year; it is not a measure of total current Ac-225 supply, which also includes newer production routes (Source: www.ncbi.nlm.nih.gov). Lu-177 can be produced continuously via ongoing reactor irradiation of ytterbium-176 without depending on a decaying finite stockpile (Source: www.globenewswire.com).

Can radioligand therapy doses be stockpiled like conventional drugs? No. Because the active isotope decays continuously, each dose is manufactured for a specific patient at a specific day and time and shipped under strict transit-time constraints; Novartis states RLT manufacturing operates on a timeline of hours and days, not the weeks or months typical of conventional pharmaceutical inventory management (Source: www.novartis.com).

How much radioligand therapy manufacturing capacity does Novartis have? Novartis has targeted at least 250,000 RLT doses annually across its network since 2024 (Source: www.novartis.com), a figure the company is expanding further through its $23 billion US infrastructure commitment and new sites in Carlsbad, Winter Park, and Denton.

What role do reactor outages play in radiopharmaceutical supply risk? Historical precedent shows aging research reactors can trigger global shortages when taken offline unexpectedly; Canada's NRU reactor, once responsible for roughly 40% of the world's medical isotope supply, caused worldwide shortages during unplanned 2007 and 2009 outages before its permanent 2018 shutdown (Source: www.cbc.ca).

Conclusion

Radioligand therapy manufacturing capacity has moved from an afterthought to the central strategic variable determining how many patients can access an entire class of cancer treatment. The 2023 Pluvicto shortage demonstrated that a leading manufacturer with a multi-site global network could still be caught short by demand it had not anticipated, and the industry's response, billions of dollars in new facilities, acquisitions, and CDMO capitalization documented throughout this report, shows a sector that has internalized the lesson. Novartis's expansion from four to seven disclosed US and international RLT sites within roughly two and a half years, backed by a $23 billion commitment, represents one of the fastest specialty-manufacturing build-outs in recent pharmaceutical history. Bristol Myers Squibb, Eli Lilly, and AstraZeneca have each bought their way into manufacturing capability rather than building from scratch, while Curium's pending $8.0 billion merger with Lantheus signals that consolidation, not just organic construction, will define the next phase of capacity growth.

Yet isotope supply, finished-dose manufacturing capacity, and time-critical distribution are interdependent constraints. Isotope supply is particularly acute for Ac-225, while the Pluvicto shortage showed that finished-dose production can also constrain access. The roughly 63 GBq annual estimate, sufficient for perhaps 100 to 200 patients, describes legacy thorium-229-generator production rather than total current global Ac-225 supply. Expanding supply beyond that legacy route requires accelerator- and cyclotron-based production such as the routes NorthStar, ITM's Actineer, and the DOE's Tri-Lab Effort are developing. Lutetium-177 faces a milder but still real version of the same problem, with demand reported to outstrip supply even as MURR, NTP Radioisotopes, and ITM run their existing reactor capacity at full utilization. And because both isotopes decay on a timescale of days, no amount of manufacturing capacity can substitute for geographic proximity to patients, a constraint that has forced every major sponsor toward the same distributed, regional facility model regardless of company size or strategy. As of August 2026, the radioligand therapy sector has proven it can raise the capital and build the facilities the moment demands; whether it can multiply the underlying isotope supply fast enough to keep pace with a pipeline of more than 200 active Lu-177 trials and a rapidly scaling actinium-225 opportunity will determine whether the "CDMO crunch" of the early 2020s becomes a permanent feature of the field or a transitional growing pain the industry ultimately outgrows.

Tags: radioligand therapy manufacturing capacity, radioligand therapy cdmo, isotope supply chain radiopharmaceuticals, lutetium-177 supply shortage, actinium-225 supply constraints, radiopharmaceutical manufacturing, targeted radionuclide therapy, radiopharma contract manufacturing

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Contact founder Adrien Laurent and team at intuitionlabs.ai/contact for a consultation.

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