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Lilly Looks To Take POINT On Emerging Cancer Radiopharmaceutical Space

by Joseph Haas

Lilly has agreed to pay $1.4bn to acquire Point even though the company's two lead candidates are out-licensed to Lantheus. The deal looks like an early-stage play to build a strong position in an emerging field.

Eli Lilly and Company continued a year of strategic bolt-on acquisitions on 3 October with the planned buyout of the radiopharmaceutical company *POINT Biopharma Global Inc.*, with a tender offer that it expects to total approximately $1.4bn. The deal marks Lilly's move into radioligand therapies for cancer, and Point's early-stage pipeline and its isotope supply chain seems to have driven it, as it has already out-licensed a pair of late-stage radiopharmaceutical candidates that it is positioning to compete with *Novartis AG*'s Lutathera and Pluvicto.

In its statement on the deal, Lilly compared the transaction to previous moves to further its pipeline and capabilities in small molecule and biologic therapies for cancer, noting that in recent years, "well-designed" radiopharmaceuticals have been integrated into the standard of care and brought meaningful benefits to cancer patients. Lilly added that it thinks it is getting into the space in its early days and that radiopharmaceuticals will provide another modality for addressing hard-to-treat cancers.

Based in Indianapolis, like Lilly, Point's

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By Ayisha Sharma

11 Aug 2022
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pipeline includes the Phase III candidates PNT2002, a prostate-specific membrane antigen (PSMA) for patients with metastatic castration-resistant prostate cancer (mCRPC), and PNT2003, a somatostatin receptor (SSTR) radioligand therapy for gastroenteropancreatic neuroendocrine tumors (GEP-NETs). (Also see "*Finance Watch: Third Harmonic Launches The Largest IPO In Months*" - Scrip, 15 Sep, 2022.) Data from the Phase III SPLASH trial of PNT2002 in second-line mCRPC are expected in Q4 2023.

Analysts expect those two products, each of which includes a lutetium-177 payload, like Lutathera (lutetium Lu 177 dotatate) and Pluvicto (lutetium Lu 177 vipivotide tetraxetan), to compete directly with the Novartis products, which are indicated for second-line GEP-NET and later-line mCRPC, respectively. In September, Novartis unveiled Phase III data that may enable an expansion of Lutathera's indication into the first-line treatment setting, which would be a first for a radiopharmaceutical. (Also see "*Novartis's Lutathera To Be First Radiopharmaceutical In Frontline Use After Trial Success*" - Scrip, 25 Sep, 2023.) Novartis reported sales revenue of $471m for Lutathera in 2022 and Biomedtracker projects that the product will bring in $615m in 2023; the pharma does not disclose sales revenues for Pluvicto.

Key Takeaways

- Lilly moves into another frontier in oncology by acquiring radiopharmaceutical specialist Point Biopharma for a proposed $1.4bn.
- Point has two radioligand therapies in Phase III, with commercial rights already licensed off to Lantheus, but Lilly may be motivated by the firm's earlier-stage pipeline and supply chain assets.
- Supply chain, particularly access to a dependable supply of radioisotopes, is key for success in the radiopharmaceutical space.

PNT2002 and PNT2003 offer a revenue opportunity for Lilly, but that probably is not the principal driver behind the deal, since Point licensed global commercial rights to both products to *Lantheus Holdings, Inc.* last November. (Also see "*Deal Watch: BMS Backs Out Of UniQure Gene Therapy Collaboration*" - Scrip, 29 Nov, 2022.) Lantheus paid $260m up front for the two candidates with potential for Point to earn more than $1.56bn in regulatory and commercial milestones, as well as 20% sales royalties on '2002 and 15% royalties on '2003.

Lilly's Motivation Likely In Early Pipeline, Supply Chain

In a 3 October note, Evercore ISI analyst Umer Raffat said those royalties offer a good revenue opportunity for Lilly, but the deal's greater value likely is in earlier-stage candidates that will use

the , and therefore easier for clinicians to handle, actinium-225 as a payload. That includes Point's PNT2004, which targets fibroblast activation protein-alpha (FAP-α) and is in Phase I as a potential pan-cancer therapeutic.

Raffat said the radiopharmaceutical space has begun to place more emphasis on therapies using "alpha emitters" like actinium-225, because they are safer to store and handle than radioisotope-based products using lutetium-177. Actinium therapeutics are "potentially more lethal to cancer cells, inducing double-strand DNA breaks," he said, and can avoid safety liabilities such as disposing of radioactive waste and social isolation after dosing for patients.

In addition, Lilly probably wants Point's supply chain, which includes three suppliers of GMP-grade lutetium-177 in the US, EU and Israel along with multiple partnerships with potential suppliers of actinium. Under the deal, Lilly would also acquire a 180,000-square-foot manufacturing facility in Indianapolis and a research and development site in Toronto. "Isotope supply is critical to commercial success," Raffat pointed out. "Any radiopharma company is only as good as how much radioisotope supply they can get."

Acquiring this critical mass likely is crucial to Lilly's potential success in the radiopharmaceutical space, because manufacturing and supply chain needs are very different from other pharmaceutical modalities. A manufacturer must create a radioisotope in a special nuclear reactor using rare earth elements before shipping it to a production facility for bonding with the relevant target compounds. The drug is then packaged in special lead-shielded containers as single-patient doses due to the rapidly diminishing activity of the radioisotope.

Deal De-Risks Point's Phase III Readout Versus Expected Novartis Data

Leerink Partners' analyst Faisal Khurshid said the deal looks like good value for Point and its shareholders as it comes before the Phase III SPLASH readout for PNT2002. Novartis also anticipates Phase III data for Pluvicto in metastatic prostate cancer, which the analyst said could be a risk as the readouts could position either the Point drug or the Novartis drug well ahead of the other. "Overall, we see the deal as a positive for Point and the radiopharmaceutical space as a whole," Khurshid said in a 3 October note.

Both Lilly and Point's boards have agreed to the proposed transaction; the big pharma will pay $12.50 per share, an 87% premium to Point's share price at the close of business on 2 October and a 68% premium over the stock's 30-day average price. Point's board unanimously recommended that shareholders approve the tender offer, with Lilly saying it expects the transaction to close before the end of 2023. Closing also will require sign-off by the US Nuclear Regulatory Commission for a transfer of Point's license for radioisotope access to Lilly.

If the deal closes, it will be Lilly's fifth M&A transaction of 2023 and its third with an upfront value of at least $1bn. Evercore's Raffat praised Lilly's business development strategy, saying

some cash-rich biopharmaceutical firms "find a way to spend [their] cash recklessly – wrong companies and horrible valuations."

Lilly's acquisitions this year include:

- *DICE Therapeutics, Inc.*, which is developing IL-17 antagonists for autoimmune and inflammatory indications, for $2.4bn on 20 June (Also see "*Lilly Wants To Gamble On Dice's Oral IL-17 Drugs For Psoriasis*" - Scrip, 20 Jun, 2023.);

- The $344.2m purchase of *Sigilon Therapeutics, Inc.*, developing gene therapies for acute and chronic conditions, on 29 June;

- The cancer antibody-drug conjugate-focused *Emergence Therapeutics AG* for $12m, also on 29 June; and

- The $1.925bn takeout of cardiometabolic disease-focused *Versanis Bio*, including the Phase IIb antibody candidate bimagrumab, which is being studied in combination with incretin therapies for obesity, on 14 July. (Also see "*Lilly Looks To Complement Mounjaro, Obesity Pipeline With Versanis Buyout*" - Scrip, 14 Jul, 2023.)

Point was a privately held biotech until it entered the public markets in March 2021 via a combination with special purpose acquisition company (SPAC) Research Alliance Corp. 1, backed by RA Capital Management, a deal that gave Point a cash position of roughly $300m at closing. (Also see "*Finance Watch: Biopharma IPOs Regain Momentum With Slate Of New Offerings*" - Scrip, 24 Mar, 2021.) The biotech then added to its coffers last September with a $125m raise by selling 13.9 million shares for $9 apiece.