Lytix Biopharma Q4 2024: Solid clinical results strengthen the path to Phase III and further advancements in 2025

Lytix Biopharma today published the results for the fourth quarter of 2024. The year ended with strong clinical results, a validated technology addressing the major shortcomings in today's cancer treatment alternatives, and a robust capital base setting the stage into a pivotal 2025 for the company.

During the quarter, licensing partner Verrica Pharmaceuticals reported an impressive 97 percent calculated objective response rate in treating patients with basal cell carcinoma, the most common cancer type globally. This demonstrates the strength and efficacy of LTX-315 as a potential first-line therapy. Verrica is preparing for FDA discussions in H1 2025 to outline the path toward a Phase III trial.

"The exceptional clinical results reinforce our confidence in LTX-315's potential. With growing validation from our clinical studies, Lytix Biopharma is closer than ever to achieving a milestone few Norwegian oncology companies have reached – advancing into Phase III trials," says Dr. Øystein Rekdal, CEO of Lytix Biopharma.

Lytix's lead drug candidate, LTX-315, is currently being evaluated in three Phase II studies. Alongside the Verrica-led study in BCC patients, the ATLAS-IT-05 trial, which focuses on late-stage, heavily pre-treated patients, is expected to conclude in H2 2025. Additionally, a new study (NeoLIPA) has commenced at Oslo University Hospital, Radiumhospitalet, targeting early-stage melanoma patients.

In the promising NeoLIPA study, the first melanoma patient was treated with LTX-315 at Radiumhospitalet, Oslo in November 2024. The study evaluates LTX-315 in combination with the standard of care immune checkpoint inhibitor (pembrolizumab) prior to surgery, in early-stage patients with a responsive immune system.

“Melanoma patients often experience relapse following surgery when treated with the standard of care today. Our technology arms the immune system and complements today's treatment options to prevent the cancer from spreading and recurring at a later stage, in addition to kill cancer cells in the locally treated lesions”, says Rekdal.

He continues, “Dr. Jespersen and his team at Oslo University Hospital are well underway recruiting new patients to the study. The potential for LTX-315 in this patient population is significant as they have a strong immune system. Being one of the most severe cancer types, this skin cancer disease also represents a significant commercial opportunity for Lytix. We look forward to the interim results after the summer.”

Lytix strengthened its financial position in December, securing NOK 111 million through a private placement and a PrimaryBid offering. This funding, backed by strong investor support, provides a solid cash runway to advance key clinical milestones. Cash amounts to NOK 131 million at the end of Q4.

Highlights from Q4 2024 and post-period events:
Operational

- Phase II BCC study: 97% objective response rate; Next step is Verrica's end-of-phase-II meeting with FDA to discuss Phase III (H1 2025)
- NeoLIPA study: Patient recruitment ongoing; targets early-stage melanoma patients with strong immune system
- ATLAS-IT-05: 40% disease control in late-stage melanoma, with response lasting up to 22 months; study concludes H2 2025
- LTX-401: New superior formulation with enhanced anticancer effects and extended patent life; clinical trials planned for 2026

Business & financial

- US patent secured for LTX-315 with PD-1 inhibitors
- Successful capital raise of NOK 111m to fund key milestones
- Strengthened management team with Mette Husbyn appointed as new CTO
- Increased focus on late-stage development & partnerships

The results will be presented in a webcast with CEO Øystein Rekdal and CFO Gjest Breistein today at 10.30 CEST.

The presentation and subsequent Q&A session will be held in English and may be viewed live by registering here:
https://channel.royalcast.com/landingpage/hegnarmedia/20250213_13/

A recording of the presentation will be made available on
https://www.lytixbiopharma.com/financial-reports (after the presentation).

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About Lytix
Based in Oslo, Norway, Lytix Biopharma is a clinical-stage biotech company with a highly novel technology based on world leading research in host-defense peptide-derived molecules. Lytix Biopharma's lead product, LTX-315, is a first-in-class oncolytic molecule representing a new principle to boost anti-cancer immunity. Lytix Biopharma has a pipeline of molecules that can work in many different cancer indications and treatment settings, both as mono- and combination therapy.