OncoZenge – Report comment

OncoZenge Q4 2025: Phase III preparations in place

Impala Nordic comments on OncoZenge AB (publ) ("OncoZenge" or the "Company") year-end report. The report positions the case firmly around the upcoming pivotal Phase III study. With the Clinical Trial Application (CTA) submitted in December 2025, the Company expects an approval decision in the second half of April or early May and reiterates its ambition to dose the first patient in Q2 2026. We see very solid groundwork ahead of the start-up phase, with key partners in place, strengthened clinical leadership and financing secured to take the Company through the CTA decision window, which puts the spotlight on a clean CTA outcome, recruitment traction and ultimately the Phase III results.

Pieces in place with milestone submission in Q4

With the CTA submitted in December 2025 to the European Medicines Agency (EMA) and the Company expecting an approval decision in the second half of April or early May, the program moves from preparation into formal review ahead of site activation. The pivotal Phase III study BZ003 is described as a multi-center, randomized registrational study comparing BupiZenge™ to lidocaine in head and neck cancer patients with oral mucositis. About 150 patients will be enrolled across sites in Sweden, Norway, Denmark and Germany, with recruitment guided for Q2 2026, following regulatory clearance. We view the European design and site selection positively given the data quality and regulatory relevance for an EU filing.

The CTA submission follows a series of important steps during 2025 that support the Phase III and potential future commercialization of BupiZenge™ in Europe. LINK Medical is appointed as Contract Research Organization (CRO) to run the operational delivery of the trial following their feasibility study, aligning with the European focus and continuity from feasibility to delivery. Meribel Pharma Solutions is appointed as Contract Development and Manufacturing Organization (CDMO) progressing clinical supply, with successful manufacturing of BupiZenge™ as part of the preparations. On the commercial side, Molteni Farmaceutici holds the European commercialization license for BupiZenge™ and has taken on commercial manufacturing responsibility, alongside a commitment to establish a scalable volume supply chain.

In combination with the Company communicating that the sponsor team is now fully staffed across core roles, and clinical leadership further strengthened by the appointment of Dr. Marie-Louise Fjällskog as Chief Medical Officer (CMO) and the addition of one of the original inventors of bupivacaine-based lozenges Dr. Torben Mogensen to the Advisory Board, the overall picture is a partner-led model where we now look to delivery. In parallel, the UCLA patient engagement study adds useful context to the medical-need narrative of BupiZenge™, with 40 % of patients reporting pain levels of 9-10 out of 10 despite opioids and lidocaine. The Company also states that the findings have been used to adjust the design of the upcoming Phase III, which we view as supportive for the trial positioning.

Financials and funding

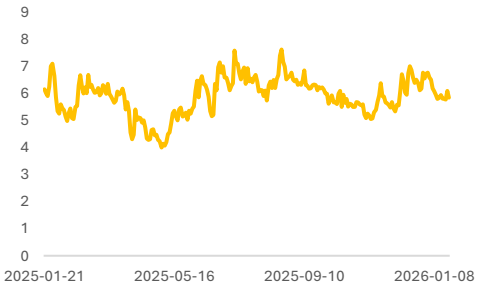
The Company's 2025 income statement is obviously driven by preparations for the upcoming Phase III. For the full year 2025, EBIT amounted to -15,8 MSEK, compared to -8,7 MSEK the year prior. The increased cost base is mainly linked to CTA preparation, CRO activities and other preparations. The current funding plan is largely built around a 30.2 MSEK investment agreement with Sichuan Yangtian Bio-Pharmaceutical ("Yangtian"), structured in four tranches.

Tranches 1-3 have been received, with the third tranche of 9.1 MSEK received in February 2026 following a delay attributed to an unexpected tax liability incurred by Yangtian. During the delay, short-term liquidity was supported through a bridge loan provided by major shareholder Linc AB, underscoring continued backing from key stakeholders. The final tranche of approximately 15.1 MSEK is tied to the anticipated CTA approval and would increase Yangtian's ownership in OncoZenge to around 28.5 %. While we do not interpret the tranche 3 delay as a sign that Yangtian will not complete the investment, it does raise a flag that payment timing should not be taken for granted, which is relevant given that the final tranche is both the largest and CTA-linked. In addition, CTA approval would trigger a 0.55 MEUR milestone payment from Molteni Farmaceutici.

Overview

Ticker	ONCOZ
List	First North
Share Price	6,34 SEK
Number of Shares	14 048 068
Market Cap	89 MSEK
CEO	Stian Kildal
Chairman	Daniel Ehrenstråhle
HQ	Stockholm

Share price development (SEK)



Main shareholders

16,6%	Sichuan Yangtian Bio-Pharmaceutical Co, Ltd
10,5%	Niclas Holmgren
9,5%	Andreas Ozbek
9,3%	Linc AB
5,0%	Avanza Pension
4,0%	Stian Kildal
3,4%	Kalle Holmgren
2,6%	Nordnet Pensionförsäkringar
2,4%	Jimmy Olsson
2,3%	Paul Murtagh

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What matters next

OncoZenge enters the next chapter with a partner-led execution model spanning clinical and commercial infrastructure, and a carefully constructed European-based study design, which in our view increases the probability of a smooth and timely transition from regulatory clearance to first patient. The coming months will be defined by the CTA review outcome and timing, site activation and recruitment momentum, alongside continued progress on clinical supply readiness. Beyond the full Phase III focus, management outlines priorities to broaden the commercial footprint outside Europe, clarify the China path with Yangtian, and assess the most efficient route toward the US, while also exploring additional indications such as dental, which we view as a credible longer-term expansion option, provided the core oral mucositis program delivers as intended.

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Analyst owns shares in the Company: **No**
Impala Nordic or people behind Impala Nordic owns shares in the Company: **No**

Analyst

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