

OncoZenge – Report Comment

Green Light to Initiate Phase III

Impala Nordic comments on OncoZenge AB (publ) ("OncoZenge" or the "Company") Q1 2026 report, published shortly before the Company announced the receiving of full European regulatory approval to initiate the pivotal Phase III BEAM-Pain trial of BupiZenge™. The CTA approval is one of the most important milestones in the Company's history, removes the primary near-term uncertainty, and triggers committed financing from both Yangtian Pharma and Molteni Farmaceutici amounting to approximately 21 MSEK. The spotlight now shifts decisively to first patient enrollment, recruitment pace, and ultimately trial readout.

CTA Approval Clears the Path to Phase III Initiation

The full regulatory approval to initiate the Phase III trial was granted, with Denmark serving as the Reference Member State and Sweden, Norway, and Germany as Concerned Member States. The Clinical Trial Application (CTA) was submitted to the European Medicines Agency (EMA) in December 2025. Even though the CTA approval was largely expected, it remains significant as it demonstrates the Company's transformation from a near-liquidation situation in 2023 to now having approval to initiate a Phase III study with a commercial partner in place.

The upcoming Phase III study will be conducted as a randomized, multi-center registrational trial comparing BupiZenge™ to lidocaine in head and neck cancer patients with radiotherapy-induced oral mucositis, enrolling 150 patients across up to 12 sites in four countries with LINK Medical serving as CRO. First patient enrollment is targeted for Q2 2026, meaning the transition from preparation to active clinical execution is now imminent.

The Q1 report confirms that the operational groundwork is firmly in place. The sponsor team is fully staffed across medical, regulatory, CMC, quality and clinical trial leadership functions. Meribel Pharma Solutions has successfully manufactured clinical trial material, with both one-month and three-month stability data confirmed within specification. LINK Medical has prepared site initiation with 14 sites selected across the four countries. Molteni Farmaceutici, which holds the European commercialization license, has been actively involved in the study protocol development and has contractually committed to establishing a scalable volume supply chain ahead of launch. In our view, the breadth and quality of the partner-led execution model provides a meaningful operational buffer for OncoZenge.

Financials and Funding

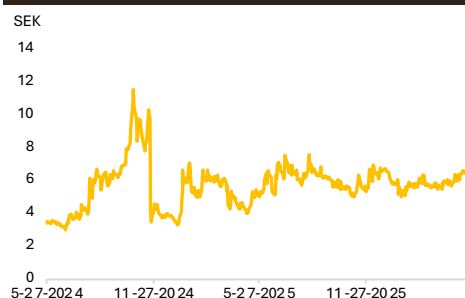
The Q1 financials reflect a company in full trial preparation mode. Net sales were zero, while operating costs rose to 6.8 MSEK from 2.7 MSEK in the prior-year period. The increase is driven almost entirely by R&D, which jumped from 0.2 MSEK to 5.3 MSEK, reflecting CTA preparation, CRO onboarding, site initiation activities and CTM manufacturing. The operating loss for the period was 6.8 MSEK, and the result after financial items was -7.1 MSEK including interest on the Linc AB bridge facility. Cash at period end amounted to 0.9 MSEK, a lean position that underscores the importance of the imminent CTA Approval milestone payments of approximately 21 MSEK.

As stated, the CTA approval materially changes the near-term funding picture. It triggers two committed payments: the fourth and final Yangtian tranche of 15.1 MSEK, which will lift Yangtian's ownership in OncoZenge to approximately 28.5%, and a 550,000 EUR milestone from Molteni Farmaceutici. Together these inflows, combined with the 2 MSEK bridge facility from Linc AB announced on May 22, provide the Company with a strengthened financial position ahead of trial execution. The episode with the delayed third tranche earlier in the year, where Yangtian cited an unexpected tax liability, is a reminder that payment execution should be monitored. That said, completion of the full investment agreement now appears straightforward given the CTA trigger has been met.

COMPANY OVERVIEW

Ticker	ONCOZ
List	First North Stockholm
Share Price	7,3 SEK
Number of Shares	14 048 068
Market Cap	103 MSEK
CEO	Stian Kildal
Chairman	Daniel Ehrenstråle

SHARE PRICE DEVELOPMENT



OWNERSHIP STRUCTURE (2026-04-28)

Yangtian Pharma	16.6 %
Niclas Holmgren	10.5 %
Andreas Özbek	9.1 %
Linc AB	8.3 %
Avanza Pension	4.9 %
Stian Kildal	3.6 %
Kalle Holmgren	3.0 %
Nordnet Pensionsförsäkring	2.3 %
Paul Murtagh	2.3 %
Jimmy Mattias Olsson	2.1 %

**What Matters Next**

With CTA approval in hand and first patient enrollment targeted for Q2, the program enters the most consequential phase in the Company's history. The near-term focus shifts to site activation cadence and early recruitment momentum, which will be the primary indicator of whether the end-of-2026 last-patient-out target is achievable. Hospital-level estimates cited in the Q1 report support that timeline, though actual recruitment pace will determine study closure and readout timing, with the Company committing to communicate refined expectations as data becomes available. Beyond the core Phase III execution, management continues to advance the China path with Yangtian, assess additional commercial partnerships in markets that can leverage EMA approval directly, and evaluate the optimal US entry route. Additional indications including dental applications remain a longer-term optionality. In our view, the immediate priority is a clean and rapid trial start, and the conditions for that are now in place.



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Conflict of interest

Analyst owns shares in the Company: **No**

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

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