

OncoZenge – Coverage comment

OncoZenge enters the next phase with CTA submitted and additional funding triggered

Impala Nordic comments on the news that OncoZenge AB (publ) (“OncoZenge” or the “Company”) has submitted the Clinical Trial Application (CTA) for its pivotal European Phase III study of BupiZenge™. The submission also triggered a 9.1 MSEK funding tranche under the existing investment agreement with Sichuan Yangtian Bio-Pharmaceutical Ltd. We view this as a critical step that sets the Phase III program in motion.

The Phase III draws closer

With the CTA now filed, the program moves from preparation into formal European regulatory review ahead of site activation. The pivotal Phase III study, named 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 the second quarter of 2026, following regulatory clearance. We view the European design and site selection as supportive of data quality and regulatory relevance for an EU filing. LINK Medical is contracted as Contract Research Organization (CRO), which aligns with the European focus and provides continuity from feasibility into delivery.

Funding tranche executed

Under the existing investment agreement with strategic investor Sichuan Yangtian Bio-Pharmaceutical, the submitted CTA triggered a directed share issue of 1 400 894 shares at 6,47 SEK per share, providing OncoZenge approximately 9,1 MSEK before costs. Notably, the subscription price represents a premium of about 4,7 % compared with the volume-weighted average price (VWAP) on 18 December 2025. This is the third tranche under the 30,2 MSEK investment agreement. Proceeds are allocated to preparations ahead of the planned trial start, including continuation of CDMO activities, sourcing of the lidocaine comparator and other activities.

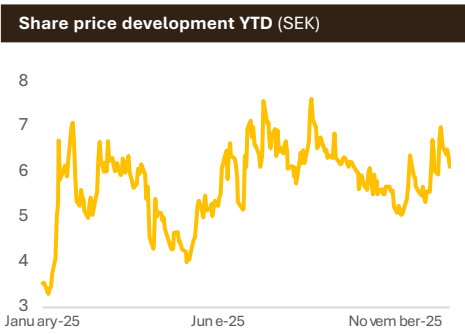
Following this tranche, the investor holds about 16,6 % of the Company’s shares, which would increase to approximately 28,5 % upon CTA approval and the release of the fourth tranche.

Built for execution in 2026

The CTA submission follows a series of steps during the year that anchor execution and future commercialization of BupiZenge™ in Europe. Earlier in 2025, the Company signed an exclusive commercialization agreement with Molteni and expanded the partnership in December so that Molteni assumes responsibility for commercial-scale manufacturing in Europe. Meribel Pharma was appointed as CDMO for clinical material, and LINK Medical was appointed as CRO for the Phase III. Taken together, this commercial set-up supports a coherent path from trial delivery to a potential European launch.

With the CTA now submitted and a milestone-based funding tranche released, the program enters a more defined Phase III pathway with improved visibility on both regulatory process and near-term financing. In our view, the EU-anchored registrational design, along with the parallel build-out of clinical and commercial infrastructure further reduces uncertainty around European approval relevance and launch readiness. By 2026, the focus shifts increasingly to operational execution: CTA review outcome and timing, site activation, clinical supply readiness, recruitment pace and progress toward first patient.

Company overview	
Ticker.....	ONCOZ
List.....	First North
Stock Price.....	6,17 SEK
Number of shares	12,588,896
Market Value.....	86 MSEK
CEO.....	Stian Kildal
Chairman.....	Daniel Ehrenstråhle
HQ	Stockholm
Q4 Report	18th February



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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Conflict of interest

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

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

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