

OncoZenge

Year-end Report

January 1 - December 31, 2025



Year-end report

October 1 - December 31, 2025

Summary of the Fourth Quarter

OncoZenge has during the fourth quarter submitted the Clinical Trial Application (CTA) for its pivotal Phase III trial (BZ003) of BupiZenge™ to the European Medicines Agency (EMA).

The company is currently working towards achieving market approval and commercial launch of BupiZenge™ in Europe and adjacent markets where a European approval can be used for market access. In light of the confirmed financing, the company has signed Meribel Pharma Solutions for manufacturing of lozenges for the Phase III trial and LINK Medical has been retained as CRO preparing site initiation with selected hospitals in Norway, Sweden, Denmark and Germany. Molteni Farmaceutici has acquired the pan-European license for commercialization of BupiZenge™ in Europe. In addition to financial support and committing to secure an efficient market introduction in Europe, Molteni offers valuable R&D support to the Phase III program, and has contractually committed to establish a scalable volume supply chain in time for launch.

In January, an investment agreement worth SEK 30.2 million was signed with the new strategic investor Sichuan Yangtian Bio-Pharmaceutical Co. Ltd, to be executed through directed share issues. The first two share issues were subscribed by the investor during the second quarter. Proceeds were received and the new share issue was reported in the third quarter. The third share issue was subscribed by the investor and is reported as a pending new share issue in the fourth quarter. Proceeds were received in February of 2026. The company's financing depends on the completion of the remaining directed share issue, which is planned to be consummated in the second quarter of 2026 upon the anticipated Clinical Trial Application approval.

Fourth Quarter (Oct-Dec) 2025

Net sales: SEK 0 thousand (0)
 Operating result: SEK -9,748 thousand (-2,501)
 Earnings per share before and after dilution:
 SEK -0.78 (-0.21)

Reporting Period (Jan-Dec) 2025

Net sales: SEK 2,664 thousand (0)
 Operating result: SEK -15,787 thousand (-8,685)
 Earnings per share before and after dilution:
 SEK -1.31 (-0.74)

Selected Financial Data

000's	2025 Oct-Dec	2024 Oct-Dec	2025 Jan-Dec	2024 Jan-Dec
Net sales	-	-	2 664	-
Operating result	-9 748	-2 501	-15 787	-8 685
Result after tax	-9 886	-2 501	-15 940	-8 688
Total assets	24 401	11 434	24 401	11 434
Cash flow for the period	-7 876	-1 967	-149	-8 764
Cash flow per share (SEK)	-0.62	-0.17	-0.01	-0.75
Cash	3 714	3 863	3 714	3 863
Result per share prior to and after dilution (SEK)	-0.78	-0.21	-1.31	-0.74
Shareholders equity per share (SEK)	0.67	0.85	0.67	0.85
Equity ratio, %	34.74	87.02	34.74	87.02

Company in brief

OncoZenge AB is a Swedish pharmaceutical company developing a new treatment for pain relief in patients suffering from oral mucositis, an oral pain caused by radiation therapy and chemotherapy for cancer.

The company's product candidate, BupiZenge™, is a lozenge designed for pain relief in the mouth and throat. The active substance, bupivacaine, has a well-documented pain-relieving effect on patients with oral mucositis, as demonstrated in previous clinical Phase I and II studies. The company was founded in 2020 and is listed on Nasdaq First North Growth Market (OMX: ONCOZ). OncoZenge is headquartered in Stockholm.

OncoZenge estimates that at least 35% of cancer patients develop oral mucositis after beginning treatment. The pain caused by oral mucositis can lead to patients not completing their cancer treatments potentially shortening progression-free survival and/or overall survival. It may also result in significant weight loss due to difficulties in eating. There are currently no satisfactory alternatives to help these patients with pain relief.

BupiZenge™ has the potential to annually help millions of patients with pain relief and could create a new market with more than SEK 10 billion in annual revenue for licensees globally.

CEO comments

2025 closed on a high note for OncoZenge building on the investment funds secured last summer. We achieved a major milestone by submitting our Phase III Clinical Trial Application (CTA) to European authorities in December, right on schedule.

First and foremost, I'd like to extend my sincere thanks to our internal team, as well as partner teams, for their dedication and commitment. Our submission is comprehensive, well-prepared and acknowledged complete and in-review by the European Medicines Agency (EMA). We will now address any questions from EMA as part of their standard process. Barring any major revisions, we anticipate CTA approval in the second half of April or early May at the latest. This timeline aligns with our objective of dosing the first patient in Q2 2026.

Key achievements

- *Successful manufacturing of BupiZenge™ lozenges at Meribel Pharma.*
- *Site selection in Norway, Sweden, Denmark, and Germany, supported by LINK Medical.*
- *Extensive work on CTA documentation, including refining details of the study protocol, endpoints, patient safety, and more.*
- *Molteni Farmaceutici has committed to establish a scalable volume supply chain for the European launch.*
- *Conclusion of the patient study at UCLA, where 40% of head & neck cancer patients reported pain of 9-10, and 74% of patients reported pain of 7-10, on a 10-point scale, despite use of any and all available pain medications, including opioids.*

In addition, we participated in several external events, which strengthened our dialogues with potential partners and investors. These interactions not only reconfirmed BupiZenge's potential but also opened doors to new collaboration opportunities.

Opportunity and risks

As we approach 1st patient in our Phase III trial, our opportunity is both significant and meaningful. BupiZenge™ promises to redefine the standard of care and thereby the quality of life for millions of patients. That prospect is both motivating and a large market opportunity.

While we await CTA approval this is also a good time to remind ourselves about the inherent risks in drug development, particularly regarding regulatory

feedback and manufacturing. Specifically to our project, our selected hospitals have provided their patient recruitment goals, but also reminded us that summer staffing levels create uncertainty in recruitment. The trial has been scoped to mitigate for this and aim for "last patient out" by year-end 2026. We will provide updates on progress and timelines when we see the actual recruitment pace during the summer.

Unlocking future value creation

The confirmation of the European trial will serve as an important enabler for unlocking other opportunities. As we look into 2026 our strategic priorities have not changed; **1)** Ensure successful execution of the European Phase III trial, **2)** Secure additional commercial partnerships where EMA approval can be leveraged, **3)** Refine the China market entry strategy and finalize a collaboration agreement with Yangtian Pharma, **4)** Assess options for USA market entry and the optimal path to a US FDA approval, and **5)** Explore new indications for BupiZenge™ that effectively increases potential for use, and thereby our addressable market, such as in dental.

Looking forward

2026 promises to be a defining year for OncoZenge. We enter it with a mix of anticipation but also confidence, with a strong submission behind us, a great team and supportive partners.

Thank you again for your trust and support on our journey.

Sincerely,

Stian Kildal



Chief Executive Officer

Stockholm
February 26,
2026

Significant events during the fourth quarter

- **October 9, 2025:** It was announced that the University of California, Los Angeles (UCLA) has enrolled its first patient in the patient engagement study. Led by Principal Investigator Dr. Michelle Ann Eala, the patient engagement study leverages UCLA's expertise in oncology and radiation therapy, providing valuable data to inform the clinical development of BupiZenge™. The study will recruit up to 45 patients to provide insights supporting the European Clinical Trial Application (CTA) later this year.
- **November 17, 2025:** It was announced the addition of Dr. Torben Mogensen to its Advisory Board. Dr. Mogensen and his team were the original inventors of bupivacaine-based lozenges, backed by extensive research and clinical trials in Denmark.
- **December 3, 2025:** An amended agreement with OncoZenge's strategic partner Molteni Farmaceutici was announced: Molteni will assume commercial manufacturing of BupiZenge™ for Europe.
- **December 18, 2025:** It was announced that OncoZenge has submitted its Clinical Trial Application (CTA) for its pivotal Phase III trial (BZ003) of BupiZenge™ to the European Medicines Agency (EMA).

The BupiZenge™ Phase III trial (BZ003) is designed as a multi-center, randomized registrational trial to evaluate the efficacy and safety of BupiZenge™ compared to lidocaine in patients experiencing pain due to oral mucositis induced by radiotherapy with or without concomitant chemotherapy, in head and neck cancer patients. The trial will recruit 150 patients and be conducted across multiple sites in Norway, Sweden, Denmark and Germany. Patient recruitment is expected to commence in Q2 2026, following regulatory approval.

- **December 19, 2025:** It was announced that OncoZenge resolved on a directed share issue to Sichuan Yangtian Bio-Pharmaceutical pursuant to existing investment agreement. The Board of Directors has, based on the authorisation granted by the Annual General Meeting on 28 May 2025, resolved on a directed share issue of 1,400,894 shares to the strategic investor Sichuan Yangtian Bio-Pharmaceutical Co, Ltd at a subscription price of SEK 6.47 per share. The Directed Share Issue has been resolved upon after the Company has successfully submitted the complete phase III Clinical Trial Application (CTA) for BupiZenge™ in Europe. All 1,400,894 shares have been formally subscribed for by the Investor and allotted by the Board of Directors, which means that the Company will receive approximately SEK 9.1 million before deduction of transaction costs. The Directed Share Issue constitutes the third of four tranches under the SEK 30.2 million investment undertaking, pursuant to the investment agreement entered into by the Company and the Investor on 27 January 2025 and previously communicated (the "Investment Agreement").

Significant events after the reporting period

- **January 21, 2026:** OncoZenge announced uncertainty regarding payment of subscription proceeds and liquidity impact. OncoZenge has been informed that the strategic investor Sichuan Yangtian Bio-Pharmaceutical Co, Ltd (the "Investor") will not be able to pay the subscription proceeds of approximately SEK 9.1 million by the end of the payment deadline in the directed share issue resolved by the Board of Directors of the Company and communicated on 19 December 2025.
- **January 22, 2026:** It was announced that OncoZenge has entered into an agreement for a bridge financing solution of SEK 5 million, via a convertible note with Linc AB ("Linc") to be repaid upon payment of the third tranche in the directed share issue to Sichuan Yangtian Bio-Pharmaceutical Co, Ltd, resolved by the Board of Directors of the Company and communicated on 19 December 2025. Furthermore, the Company has received a written letter of commitment from the Investor that the Investor irrevocably will pay the subscription proceeds of approximately SEK 9.1 million in the Directed Share Issue on or before 21 February 2026. The Board of Directors has extended the time for payment in the Directed Share Issue until 21 February 2026 and has secured the Company's liquidity for the period until that date, and following receipt of the subscription proceeds, until the middle of Q2 2026, in line with the CTA milestone in the existing financial plan.
- **January 30, 2026:** It was announced that the one-month stability study results for its BupiZenge™ lozenge technology batch are within specifications. The batch was successfully manufactured at Meribel Pharma Solutions in Solna, Sweden, in December 2025 following a technology transfer conducted in collaboration with Molteni Farmaceutici.
- **February 2, 2026:** Announced the appointment of Dr. Marie-Louise Fjällskog, MD, PhD, as Chief Medical Officer (CMO), effective February 1, 2026. Dr. Fjällskog, a board-certified oncologist and Associate Professor of Oncology (Docent) at Uppsala University, brings extensive expertise in clinical development, regulatory strategy, and oncology drug development.
- **February 4, 2026:** Announced Key Insights from UCLA Patient Engagement Study on Oral Mucositis Pain Management conducted in collaboration with UCLA Health. The study, completed in December 2025, gathered perspectives from 43 patients undergoing or having completed radiation therapy for head and neck cancer, and a focus group discussion with four participants. These insights highlight unmet needs in managing oral mucositis pain and have directly informed optimizations to the design of OncoZenge's upcoming Phase III clinical trial for BupiZenge™ in Europe.
- **February 12, 2026:** Announced receipt of the third tranche of investment capital from Sichuan Yangtian Bio-Pharmaceutical Co., Ltd. The third tranche is in the amount of SEK 9.1m. This investment is consummated at the same price per share as in the two previous tranches, SEK 6,47 and will provide the investor with 1,400,894 new shares in the company.

Significant events earlier in the reporting period

- **January 13, 2025:** It was announced that the company has entered into a non-binding agreement with the intent to collaborate with Molteni Farmaceutici ("Molteni") regarding exclusive commercialization rights for BupiZenge™ in Europe, with the goal of signing a final licensing agreement by April 30, 2025.
- **January 16, 2025:** It was announced that the company has filed a patent application under the Patent Cooperation Treaty (PCT) procedure, a significant milestone in the company's intellectual property strategy for the drug candidate BupiZenge™. This application follows the patent application filed with priority at the Swedish Patent and Registration Office (PRV) in February 2024, in accordance with international PCT requirements.
- **January 27, 2025:** It was announced that OncoZenge has entered into an investment agreement worth SEK 30.2 million with the new strategic investor Sichuan Yangtian Bio- Pharmaceutical Co., Ltd ("Yangtian Pharma"), to be executed through directed share issues. The board has called an extraordinary general meeting to be held on March 3, 2025, to authorize the board to decide on the directed share issues and to propose amendments to the limits on the number of shares and share capital in the company's articles of association to enable the investment. The company's financing depends on the completion of the proposed directed share issue, planned for the fourth quarter of 2025 to the first quarter of 2026.
- **March 3, 2025:** An extraordinary general meeting was held in Stockholm. The meeting resolved to authorize the issuance and amend the articles of association in accordance with the board's proposal. The purpose of the authorization is to fulfill the company's obligations under the investment agreement entered into with Yangtian Pharma on January 27, 2025, which was announced via a press release on the same day. The meeting resolved to authorize the board, until the next annual general meeting and in addition to the authorization decided at the 2024 annual general meeting, to decide on new share issues to Sichuan Yangtian Bio-Pharmaceutical Co., Ltd, or to a wholly-owned subsidiary of the investor, with deviation from the shareholders' preferential rights. Payment for subscribed shares issued under the authorization shall only be made in cash. The total number of shares that may be issued under the authorization amounts to a maximum of 4,669,647 new shares.
- **March 4, 2025:** It was announced that a positive opinion has been received regarding the patentability of the new international application submitted for PCT earlier this year. The patent application, which includes claims directed toward the product, meets all patentability criteria. The next step is to file the application in the countries and regions prioritized in the company's patent strategy and to have the application approved at the national or regional level. Upon approval, BupiZenge™ for pain relief in oral mucositis, or potential future variants of BupiZenge™ for other applications, will be patent-protected until 2045.
- **March 28, 2025:** It was announced that OncoZenge has entered into a binding agreement with L. Molteni & C. dei F.lli Alitti Società di Esercizio S.p.A ("Molteni Farmaceutici") regarding exclusive commercialization rights for BupiZenge™ in Europe. The agreement includes royalties and commercial milestone payments.

- **April 2, 2025:** It was announced that OncoZenge's board member, Dr. Christoph Nowak, will present an abstract for the company's European Phase III study for BupiZenge™ at the annual meeting of the Multinational Association of Supportive Care in Cancer (MASCC), taking place in Seattle, USA, on June 26-28, 2025.
- **April 4, 2025:** It was announced that the sponsor team for the Phase III project with BupiZenge™ is being strengthened to handle regulatory matters. OncoZenge is pleased to announce that Christina Junvik is joining the company through an expanded collaboration with PharmaRelations to enhance the company's preparedness for the Phase III project with BupiZenge™.
- **April 10, 2025:** It was announced that Christoph Nowak, MD, PhD, Dipl-Psych, who has been a board member since autumn 2023, is joining the company's management team in the role of Chief Medical Officer (CMO).
- **April 11, 2025:** It was announced that the first milestone payment has been received from the licensee, Molteni Farmaceutici. The first milestone payment, amounting to approximately SEK 2.7 million, was received with a valuation date of April 11, 2025, and was included in OncoZenge's financial results and position as of March 31, 2025.
- **April 11, 2025:** It was announced that OncoZenge and Avernus Pharma General Trading LLC ("Avernus"), a pharmaceutical company focused on marketing and distribution in the Middle East, have signed an exclusive licensing agreement for BupiZenge™ for commercialization and distribution in the Gulf Cooperation Council (GCC) region.
- **April 25, 2025:** It was announced that OncoZenge and Yangtian Pharma have entered into an amendment to the original investment agreement, extending the timeframe for the Outbound Direct Investment (ODI) process to May 31, 2025, without affecting other terms, to account for the processing time required to complete the ODI process.
- **May 12, 2025:** It was announced that OncoZenge received confirmation that the National Development and Reform Commission (NDRC) has issued an approval certificate for the investment agreement entered into between the company and Yangtian Pharma on January 27, 2025.
- **June 5, 2025:** It was announced that OncoZenge has received confirmation that the Department of Commerce has issued a certificate of approval for the investment agreement entered into by the Company and Sichuan-Yangtian Biopharmaceuticals Co, Ltd. on January 27th, 2025.
- **June 6, 2025:** It was announced that LINK Medical has been engaged to conduct a feasibility study in Europe for the company's planned Phase III study for European approval of BupiZenge™. The study aims to confirm the availability of suitable clinics in Europe, with a focus on Germany, Denmark, Norway, and Sweden. The study will also provide important validation of the expected patient recruitment rate and thus the overall timeline.
- **June 27, 2025:** It was announced that the company received confirmation that the State Administration of Foreign Exchange (SAFE) has completed its review of the investment agreement entered into between the company and Yangtian Pharma on January 27, 2025.

- July 2, 2025:** It was announced that the Board of Directors of OncoZenge, with the support of the renewed authorization obtained at the annual general meeting on May 28, 2025, has decided on a directed share issue of 933,930 shares to the new strategic investor Yangtian Pharma at a subscription price of SEK 6.47 per share. The decision on the directed share issue was made after the delegated bank in China completed the foreign exchange registration with a positive outcome and confirmation that the mandatory so-called Overseas Direct Investment process in China has been completed. All 933,930 shares have been formally subscribed by the investor and allocated by the Board, meaning the company will receive approximately SEK 6 million before transaction costs. The directed share issue corresponds to 20 percent of the total investment commitment of SEK 30.2 million in accordance with the investment agreement entered into by the company and the investor on January 27, 2025.
- July 8, 2025:** It was announced that the sponsor team for the Phase III project with BupiZenge™ is being strengthened with the addition of Tuulikki Lindmark, who joins the company as responsible for Chemistry, Manufacturing, and Controls (CMC). Tuulikki will lead the collaboration with the CDMO (Contract Development and Manufacturing Organization) ahead of production start and the regulatory application for the Phase III study of BupiZenge™.
- July 9, 2025:** It was announced that the company has entered into an agreement for a bridge financing solution of SEK 7.5 million through a convertible loan with Linc AB, which runs until July 31, 2027. The convertible loan carries an annual interest rate of 8.0 percent from the date of disbursement. Interest is capitalized until the loan's repayment date or the date of any potential conversion to shares. Conversion of the loan through a directed share issue can occur at the lender's request as early as March 1, 2026. The conversion price in a directed share issue to Linc shall be SEK 6.47. Conversion may also occur in connection with a rights issue of shares at the corresponding subscription price of the rights issue. Through the convertible loan, the company estimates it has secured liquidity beyond the readout of the study results for its clinical Phase III study.
- July 11, 2025:** It was announced that the first investment proceeds have been received from Yangtian Pharma. The first two investment tranches, amounting to 20% and approximately SEK 6 million, were received on July 11, 2025. It should be noted that the regulatory process for foreign direct investments in China (ODI) has approved the entire investment agreement, and therefore does not need to be repeated for tranches 3 and 4, which are expected to be completed during the fourth quarter of 2025 to the first quarter of 2026, depending on regulatory lead times.
- July 17, 2025:** It was announced the signing of an amendment to the license and supply agreement with Molteni Farmaceutici. This amendment accelerates certain milestones, totalling €550,000, to 'Clinical Trial Application Approval' with payment of such amount not earlier than March 1st, 2026. This accelerated milestone payment replaces the milestones due upon 'Successful Trial Completion' and 'First Commercial Sale'. The accelerated milestone payment, together with previously announced convertible note financing from Linc AB, enable a strategic shift to execute on a fully European Phase III project for BupiZenge™.

- **July 30, 2025:** A comprehensive market and strategy update was announced after successfully securing full funding for its BupiZenge™ Phase III clinical trial aimed at achieving EMA approval for the European market.
- **August 13, 2025:** OncoZenge announced the change to English as reporting language in order to meet the needs of the Company's international investors, partners and stakeholders
- **September 10, 2025:** it was announced that OncoZenge AB has selected LINK Medical, a Nordic-based clinical research organization (CRO), to lead the Phase III trial for BupiZenge™, its innovative drug candidate designed to relieve oral pain from mucositis in cancer patients.
- **September 17, 2025:** it was announced that OncoZenge has entered into a new collaboration with the University of California, Los Angeles (UCLA). The partnership focuses on a patient engagement study to gather insights on the unmet needs in managing oral mucositis pain, while exploring potential pathways toward a future Investigational New Drug (IND) application in the United States for BupiZenge™.

Company Description

Product Status

OncoZenge has developed several formulations of BupiZenge™ with different coatings and strengths (15mg and 25mg).

The latest BupiZenge™ tablet intended for commercialization includes improvements ensuring that the product can be manufactured within specified limits and meets packaging and shelf-life requirements. The product formulation has been developed in close collaboration with the company's Swedish development partner, Galenica, which has contributed to continuity in development. The knowledge built over time has also been highly valuable in developing new patent opportunities.

OncoZenge has decided to use the latest 25mg tablet with orange flavor coating in the upcoming Phase III study. The other formulation variants may still be an asset for the company in future business opportunities, for example, for indications beyond oral mucositis that may require a lower tablet strength.

During the company's business development activities in 2024 and 2025, several pharmaceutical companies, service providers in the pharmaceutical industry, and Key Opinion Leaders have confirmed the need for a locally acting non-opioid, offering effective pain relief without the risk of dependency.



Phase III-Program Status

OncoZenge's strategy is to secure strategic partners for a Phase III program, prioritizing approval in the EU to leverage partner expertise and generate financial contributions to the project.

Following an evaluation of various partner opportunities in 2024, the company decided on a commercial collaboration with Molteni Farmaceutici, now serving as the company's strategic partner for European commercialization, and volume manufacturer of BupiZenge™.

The company has adopted a partner strategy also in the development phase through a collaboration with the leading Nordic life sciences company, PharmaRelations. Through this collaboration, OncoZenge gains flexible access to specialist expertise, a critical factor in taking on the responsibility as a sponsor for a clinical Phase III project. After evaluating development partner options the company decided to collaborate with Meribel Pharma Solutions in Sweden as CDMO, and LINK Medical a leading Nordic CRO (Contract Research Organization) for execution of the clinical trial project.

The sponsor team for the Phase III project has been fully staffed covering roles such as project management, medical, regulatory, CMC, quality, and clinical trial leadership. The study protocol has been thoroughly developed internally, recently in collaboration with Molteni Farmaceutici's R&D team, and by external Key Opinion Leaders (KOLs) and other subject matter experts.

Following CTA submission in December 2025 OncoZenge is now engaging with regulatory authorities on questions and any requests for complementing the filing, in line with EMA's defined process. Denmark has been appointed as Reference Member State, and the company expect a CTA approval decision 2nd half of April, or early May the latest. The trial proposal takes into account previous regulatory guidance, scoped with 150 patients, lidocaine as comparator and executed over a 6 week period at 14 hospitals in Norway, Sweden, Denmark and Germany. First patient is planned for Q2 following CTA approval, with the hospitals' estimates for patient recruitment currently indicating last patient out towards the end of 2026. Notably, actual recruitment pace in the trial will determine timing for study closure and readout. The company will communicate further on refined timeline expectations as, and when, actual recruitment data becomes available.

In support of the BupiZenge™ Phase III trial are positive results from Phase I and II studies, toxicology data, and literature demonstrating the safety and efficacy of the active substance bupivacaine, from decades of use in other indications and formulations. OncoZenge has received clear and positive feedback regarding a registration-enabling Phase III study in Europe through scientific advice from the EMA (EU's medicines agency), the Swedish Medical Products Agency, and Germany's BfArM (Federal Institute for Drugs and Medical Devices).

Market Opportunity

Market Overview

Oral Mucositis (OM) is a serious and common side effect of cancer treatment, caused by an inflammation of the mucous membranes in the mouth and throat leading to painful sores and blisters. Nearly all patients undergoing radiation therapy in the head and neck region develop OM, and among patients treated with chemotherapy, 20-90 percent are affected, depending on the type of chemotherapy. Overall, the company estimates that at least 35% of cancer patients beginning treatment will develop OM.

OM typically appears a few days to a couple of weeks after the start of radiation therapy or chemotherapy and can often persist for four to six weeks. OM significantly impacts patients' quality of life, causing pain that makes it difficult or sometimes impossible to eat, drink, speak, or sleep. The difficulty in eating and drinking can lead to malnutrition at a stage when the patient's immune system is already weakened due to cancer treatment. In some cases, the pain can be so severe that the patient requires hospitalization for intravenous nutrition or is forced to interrupt cancer treatment with radiation or chemotherapy.

Pain Management in Oral Mucositis

The current standard treatment for pain relief in OM includes various mouth rinses containing the local anesthetic lidocaine or morphine, as well as systemic pain relief with opioids. Local anesthetic treatments with lidocaine have a short duration of effect, and systemic opioids have well-known side effects, including risks of tolerance development and dependency, as well as inadequate effectiveness for severe localized oral pain.

OncoZenge's assessment, supported by studies, is that existing treatment options are insufficient for addressing the localized pain caused by OM and that some of these treatments also carry significant risks of serious side effects. There is a substantial medical need for a new, effective treatment for OM and other pain conditions in the mouth.

UCLA Patient Study

During 2025/2026, OncoZenge conducted a patient engagement study in collaboration with UCLA Health to deepen the understanding of pain-related needs among patients suffering from oral mucositis during head and neck cancer therapy. The study, which included interviews and focus groups with a total of 47 patients, confirmed that current standard treatments often fail to provide adequate relief. Many patients reported severe pain affecting their ability to eat, drink, and sleep, with 40 percent experiencing pain levels of 9-10 out of 10 despite the use of opioids and lidocaine. The findings also highlight significant concerns regarding opioid dependence and a clear preference for fast-acting, longer-lasting, non-opioid treatment alternatives.

The insights from this study have directly informed the design of the upcoming Phase III trial for BupiZenge™, developed to deliver targeted, rapid, and more sustained pain relief for oral mucositis. This work underscores the substantial unmet medical need in this patient population and reinforces the company's commitment to advancing a safer and more effective therapeutic option.

Opioid Crisis

The United States is experiencing a widespread opioid crisis. In 2024, over 80,000 drug overdoses were recorded, with more than 50,000 deaths attributed to opioids. The opioid epidemic has been a persistent, complex, and decades-long crisis since 1995, when OxyContin was approved and falsely marketed as a safe opioid analgesic with low risk. Opioid misuse costs tens of billions of dollars annually, not only in healthcare costs but also in terms of a weakened workforce. The crisis has reached such a scale that it impacts the economy. In recent years, the U.S. government has taken several measures to address the crisis. In February 2022, the FDA published draft guidance for companies developing non-opioid analgesics for acute pain. The FDA noted that, when appropriately prescribed, opioid analgesics are an important part of acute pain management, but even at prescribed doses, they pose risks of dependency, misuse, or overdose that can lead to death. A non-opioid analgesic for acute pain that eliminates or significantly reduces the need for opioids could have a major positive impact on public health by relieving acute pain while minimizing the risks associated with opioid use. The FDA's guidance aims to encourage the development of non-addictive treatment alternatives and provide patients with access to better pain relief without opioids.

Other countries with increasing opioid use, such as Australia and Canada, are also implementing policies to address the issue. Conversely, in countries with more restrictive opioid use, the impact on patients' quality of life is even greater.

BupiZenge™ contains the effective, non-opioid, long-acting pain-relieving substance bupivacaine. BupiZenge™ is designed to relieve pain locally in the mouth and throat associated with oral mucositis. The company's goal is to develop an effective pain-relieving drug that can be introduced in numerous markets, including the United States.

Addressable Market

OncoZenge estimates that the global annual revenue opportunity for commercial licensees will be more than BSEK 10 by 2034. Europe and adjacent markets where a European approval can be directly leveraged for market access, e.g., Latin America, parts of Asia, Africa, Canada, could represent a BSEK 4 revenue opportunity, the US market could represent a BSEK 5 revenue opportunity, and China could represent a BSEK 2. There could be additional revenue opportunities in Japan and South Korea.

The company's assumptions for future licensee revenues are contingent on an uptake of BupiZenge™ in patients with OM of 15-40% depending on region, an average of 168 BupiZenge™ lozenges per treated patient, and an average price per lozenge of SEK 10-80 depending on region.

The company projects future own revenues from double-digit royalties from partner revenues and commercial milestone payments from partners. By 2034 and at global commercial scale, the company could generate own annual revenues in excess of BSEK 2.

The current company focus on European approval could unlock own annual revenues of MSEK 800 by 2034 with a similar internal cost structure to today.

Beyond the company's current focus to treat the pain caused by oral mucositis, there are significant opportunities for OncoZenge and its partners to expand approvals over time. Examples include pain relief for dental care, endoscopy, tonsillectomy, other surgical procedures in the mouth and throat, Burning Mouth Syndrome (BMS).

Further details on OncoZenge's market potential were communicated in the Market and Strategy Update on July 30, 2025. Ensuring robust execution of the European phase III trial.

Strategy

After a period of strategic transition, OncoZenge's organization, product, partnerships, and intellectual property are now in place to advance BupiZenge™ through its final registrational trial for a European launch. The main strategic pillars and focus areas of the company currently include:

1. Ensuring robust and successful execution of the European Phase III study.
2. Securing additional commercial partnerships in markets where EMA approval can be leveraged, i.e., Latin America, parts of Asia, Canada, Africa, etc.
3. Refining the China market entry strategy and finalizing a collaboration agreement with Yangtian Pharma for an efficient route to China market approval and launch.
4. Assessing options for USA market entry and determining the optimal path to US FDA approval, optimizing the project scope by leveraging European data.
5. Exploring additional indications, with a particular focus on opportunities within dental applications.

Intellectual Property (IP)

On December 8, 2020, OncoZenge and Moberg Pharma entered into a transfer agreement for BupiZenge™, through which OncoZenge acquired the intellectual property assets for a total purchase price of approximately SEK 22.1 million, with the patents valued at SEK 6.85 million.

In January 2021, OncoZenge was granted a new European patent for BupiZenge™, which provides general protection for lozenges containing bupivacaine for the treatment of pain in the mouth. This patent builds on a previously granted patent that specifically protects the use of lozenges for oral mucositis in cancer patients, with its validity extending until 2032/33.

On February 7, 2024, OncoZenge announced the submission of a priority-establishing patent application to the Swedish Patent and Registration Office (PRV). The application aims to secure broader protection for the product and serve as the foundation for global protection for BupiZenge™ licensees. If approved, this new patent application will ensure that BupiZenge™, for pain relief in oral mucositis or potential future variants for other applications, remains patent-protected until 2045.

On January 16, 2025, the company announced the filing of a patent application under the Patent Cooperation Treaty (PCT) procedure, marking a significant milestone in its intellectual property strategy for the drug candidate BupiZenge™. This application follows the priority patent application filed with the PRV in February 2024, adhering to international PCT requirements.

On March 4, 2025, OncoZenge announced that it had received a positive opinion on the patentability of the new international application submitted to the PCT earlier in the year. The patent application, which includes claims directed toward the product, meets all patentability criteria. The next step involves filing the application in the countries and regions prioritized in the company's patent strategy to secure approval at the national or regional level. Upon approval, BupiZenge™ for pain relief in oral mucositis, or potential future variants for other applications, will be patent-protected until 2045.

Country/Region	Patent number
USA	9,956,211 and 10,493,068
Canada	2,860,373 and 2,972,211
EPO	2,701,681 and 3,284,459

Partners

Strategic partnerships are a central part of OncoZenge's business strategy and a key component in the company's continued development and commercialization of BupiZenge™. In 2025, OncoZenge initiated partnerships with Molteni Farmaceutici and Avernus Pharma, two established players in the pharmaceutical industry with a focus on different regions: Europe and the Gulf Cooperation Council (GCC) region, respectively.

Molteni Farmaceutici

On March 28, 2025, OncoZenge entered into a binding agreement with the Italian company Molteni Farmaceutici, granting the company exclusive rights to commercialize BupiZenge™ in Europe, including the EU27, EEA, Switzerland, and the United Kingdom. The agreement includes:

- Initial and performance-based milestone payments: €250,000 upon signing the agreement, €550,000 upon Clinical Trial Application Approval (not earlier than March 1st, 2026), and additional payments upon reaching sales targets up to €40 million in cumulative net sales.
- Royalty structure: OncoZenge will receive a 15% royalty on annual sales up to €30 million, 18% on sales between €30–60 million, and 20% on sales exceeding €60 million.

Molteni is a leading European player in pain management and addiction care, with operations in over 40 countries.



Avernus Pharma

On April 11, 2025, OncoZenge signed an exclusive licensing agreement with Avernus Pharma General Trading LLC for the commercialization and distribution of BupiZenge™ in the Gulf Cooperation Council (GCC) region, which includes Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates. The agreement stipulates that:

- Avernus is responsible for regulatory applications and market preparations in the region.
- OncoZenge provides regulatory support and ensures volume delivery of BupiZenge™.
- Commercial milestone payments of up to \$130,000 will be made upon the first market approval and achievement of sales targets.

Avernus has a strong presence in oncology in the GCC region and is an ideal partner for introducing BupiZenge™ to patients with a significant need for effective, non-opioid pain relief.



LINK Medical

On June 3, 2025, OncoZenge appointed LINK Medical as its Clinical Research Organization (CRO) for the execution of the Phase III clinical study. OncoZenge also appointed LINK Medical to conduct a feasibility study in Europe for the Company's planned Phase III study for European approval of BupiZenge™.

LINK Medical is a well-recognized Nordic CRO with broad European operations and expertise in oncology, regulatory affairs, data management, and clinical trial execution.

- The collaboration ensures a high operational standard for the Phase III program, including regulatory preparations, site selection, clinical monitoring, and patient recruitment across Europe.
- LINK Medical's established infrastructure and regional experience provide essential support for the timely and efficient delivery of this critical study.



Meribel Pharma Solutions

On July 21, 2025, OncoZenge appointed Meribel Pharma Solutions as its Contract Development and Manufacturing Organization (CDMO).

To support the development and manufacturing of clinical trial material for the Phase III program, OncoZenge collaborates with Meribel Pharma Solutions, a leading contract development and manufacturing organization formed through the merger of Recipharm's and Synerlab's operations in Sweden, France and Spain.

- Meribel provides advanced pharmaceutical development capabilities, high-quality GMP manufacturing, and extensive experience working with oral dosage forms.
- Meribel plays a key role in preparing BupiZenge™ for late-stage clinical development by ensuring reliable production, quality control, and readiness for potential future scale-up associated with commercialization.



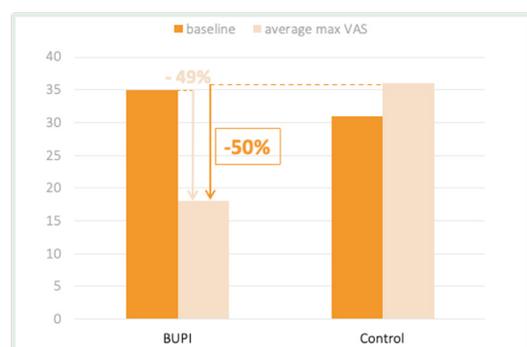
Development

Clinical Studies and Product Development

Clinics in Denmark have conducted a Phase I study on healthy volunteers and patients with head and neck cancer, as well as a 7-day clinical Phase II study involving patients with head and neck cancer who developed oral mucositis. The study demonstrated statistically significant pain relief in both the oral cavity/pharynx (31% lower) and the oral cavity alone (50% lower) compared to standard treatment.

The Phase II study was an open-label, randomized, controlled parallel-group study aimed at investigating the efficacy and tolerability of repeated administration of bupivacaine in lozenge form (25 mg) for pain relief. Both groups had access to standard pain treatment during the study. The control group also had access to a locally acting anesthetic for the oral cavity in the form of lidocaine gel.

In the completed Phase I and II studies, the bupivacaine lozenge showed good safety with no serious adverse effects. The results from the Phase II study demonstrate, with high statistical significance, a strong analgesic effect that is substantially better than the available standard treatment. The company's assessment is that BupiZenge™ has significant potential to be developed into an effective treatment for relieving pain in oral mucositis and other painful conditions in the oral cavity and pharynx following future decisions on label expansion.



OncoZenge currently possesses unique knowledge and data for the development of a painrelieving product for the treatment of oral mucositis. Work has been carried out to develop an optimized product formulation of BupiZenge™ and to produce two tablet strengths, 15 mg and 25 mg, with the latter being the subject of a Phase III study aimed at obtaining approval for use in relieving oral mucositis pain in cancer patients.

The company has successfully completed a six-week toxicology study. The existing toxicology documentation is sufficient for the European Medicines Agency (EMA), while the U.S. Food and Drug Administration (FDA) has requested a supplementary six-week toxicology study in an alternative animal species.

The company is now mobilizing a Phase III study with the goal of meeting the regulatory requirements for approval in the EU, in countries that rely on EU approval for their local approvals, and to provide critical data toward approval in the U.S.

Several studies in other areas, such as gastro-endoscopy and Burning Mouth Syndrome (BMS), serve as useful references for future work to expand the scope of use with additional indications beyond oral mucositis. The company also intends to explore opportunities for use in dentistry. [Example references: Clin Med Insights Gastroenterol. 2014 Oct 28;7:55-9 and Randomized controlled trial > Oral Dis. 2016 Mar;22(2):123-31].

Comparative Studies with Bupivacaine

Bupivacaine has been approved for local anesthesia in humans on European markets since 1958, but no oral formulations are approved within the EU; bupivacaine has also not been approved for the treatment or pain relief of oral mucositis. There are several commercially available bupivacaine products; the most relevant from a regulatory perspective (original product and current approvals with clinical data) are listed in **Table 1** below.

Table 1. Relevant approvals of bupivacaine for human use

Product	Approval	Indication	Route of administration	Approved use and exposure duration
Marcaïne, solution for injection	1958	Intrathecal (subarachnoid) spinal anaesthesia for surgery in adults and children of all ages	Intrathecal injection	Single dose
Exparel liposomal, prolonged-release dispersion for injection	2011 (US) 2020 (EU)	Brachial plexus block or femoral nerve block for treatment of post- op pain in adults, and as a field block for treatment of somatic post-op pain from small- to medium- sized surgical wounds in adults	By infiltration or perineural use	Single dose. Detectable systemic plasma levels through 96h after local infiltration and through 120 hours after nerve block.
Xaracoll, implant	2020 (US)	For placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair in adults	Implant	Single dose. Detectable plasma levels of bupivacaine throughout the 96-hour observation period.
Zynrelef (bupivacaine/meloxicam), prolonged-release wound solution	2020 (EU) 2021 (US)	Treatment of somatic postoperative pain from small- to medium-sized surgical wounds in adults	Intralesional	Single-dose. Local application into surgical site results in detectable plasma levels of bupivacaine through 72h
Posimir, solution	2021 (US)	For administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72h following arthroscopic subacromial decompression in adults.	Infiltration	Single dose. Infiltration into surgical wound results in plasma levels of bupivacaine that can persist for 168h

History

The original innovation is the result of work carried out at Hvidovre Hospital in Copenhagen. In 2014, Moberg Pharma AB acquired the global rights to BupiZenge™ from Oracain ApS, a patent-pending topical formulation for the treatment of pain in the mouth and throat. The acquisition of the rights to BupiZenge™ has been paid in full, and Oracain ApS holds no rights to future licensing fees from OncoZenge.

In 2017, positive study results were published from a Phase II study in which patients with head and neck cancer participated in the efficacy analysis. The study showed that BupiZenge™ provided a statistically significant pain reduction in the oral cavity compared to standard treatment. In summary, the clinical study demonstrated that BupiZenge™ has the potential to become an effective and well-functioning treatment for pain from oral mucositis.

OncoZenge AB (publ) was formed in 2020. In November 2020, Moberg Pharma announced its intention to transfer BupiZenge™ to OncoZenge and to spin off and separately list the business to advance the project to registration-enabling clinical studies. OncoZenge was listed on Nasdaq First North on February 12, 2021.

In September 2023, a new board and management team took office. The company communicated a partner-led strategy with a focus on achieving market approval in the EU, given the positive 'Scientific Advice' received from EMA. In 2024, development and stability studies in collaboration with Galenica confirmed that an improved formulation of BupiZenge™ is ready for a clinical Phase III study aimed at approval in Europe.

A priority-founding patent application was submitted to the Swedish Patent and Registration Office (PRV) in 2024, which, after review, received a positive PCT opinion. The new application strengthens the company's patent portfolio and lays the groundwork for local and regional patent applications to support licensees globally.

Eurosin Capital AB has been engaged as an advisor to explore strategic alternatives for the introduction of BupiZenge™ in China. A strategic collaboration began in 2025 with Yangtian Pharma through an investment agreement that finances the company's Phase III study toward European approval.

A close-up photograph of a healthcare professional, likely a doctor or nurse, wearing blue scrubs. A stethoscope is draped around their neck. They are holding a white clipboard and writing on a document with a pen. The image has a blue tint and a dark teal gradient on the left side.

Financial Development

Financial Development

Operating Revenues

The operating revenues during the reporting period relate to a milestone payment from Molteni Farmaceutici in accordance with the signed licensing agreement.

Results and Financial Position – Fourth Quarter (Oct-Dec)

Net sales amounted to SEK 0 (0) thousand, and other operating income amounted to SEK 1 (0) thousand.

Operating expenses amounted to SEK 9,749 (2,501) thousand, of which personnel costs amounted to SEK 627 (569) thousand.

Other external costs amounted to SEK 9,122 (1,932) thousand, of which research and development costs totaled SEK 8,075 (309) thousand. Research and development costs have increased considerably resulting from development expenses for the company's ongoing projects. The main cost drivers have been related to consulting activities in preparation the Clinical Trial Application, upstart of the Clinical Research Organization and the clinical trial hospitals, technology transfer and establishment of Clinical Trial Material manufacturing.

Other operational expenses relate to personnel costs, legal and consulting costs for business development, communication costs and patent costs.

Operating result amounted to SEK -9,748 (-2,501) thousand, and result after financial items amounted to SEK -9,886 (-2,501) thousand. Result after tax amounted to SEK -9,886 (-2,501) thousand. Result per share before and after dilution amounted to SEK -0.78 (-0.21).

Cash flow for the period amounted to SEK -7,876 (-1,967) thousand.

Cash flow per share amounted to SEK -0.62 (-0.17).

Results and Financial Position - Reporting Period (Jan-Dec)

Operating net sales amounted to SEK 2,664 (0) thousand, and other operating income amounted to SEK 120 (1) thousand.

Operating expenses amounted to SEK 18,571 (8,686) thousand, of which personnel costs amounted to SEK 2,960 (2,147) thousand.

Other external costs amounted to SEK 15,574 (6,536) thousand, of which research and development costs totaled SEK 11,030 (1,719) thousand.

Operating result amounted to SEK -15,787 (-8,685) thousand, and result after financial items amounted to SEK -15,940 (-8,688) thousand. Result after tax amounted to SEK -15,940 (-8,688) thousand. Result per share before and after dilution amounted to SEK -1.31 (-0.74).

Cash flow for the period amounted to SEK -149 (-8,764) thousand. Cash flow for the period prior to the directed new share issue and convertible loan amounted to -13,057 (-8,764) thousand.

Cash flow per share amounted to SEK -0.01 (-0.75). Cash flow per share for the period prior to the directed new share issue and convertible loan amounted to SEK -1.07 (-0.75).

Cash and cash equivalents as of December 31, 2025, amounted to SEK 3,714 thousand, compared to SEK 3,863 thousand as of December 31, 2024.

The company's equity as of December 31, 2025, amounted to SEK 8,477 thousand, compared to SEK 9,950 thousand as of December 31, 2024. Equity per share as of December 31, 2025, amounted to SEK 0.67, compared to SEK 0.85 as of December 31, 2024.

The company's equity ratio as of December 31, 2025, was 34.74%, compared to 87.02% as of December 31, 2024.

The increase in liquidity is attributable to the directed new share issue to Yangtian Biopharmaceuticals, as well as the convertible loan issued to Linc AB.

The decrease in equity ratio is attributable to increase in operational costs and in total liabilities.

The financial performance is in line with expectations according to plan.

Operating revenues consist of license revenues in the form of a milestone payment from Molteni Farmaceutici in accordance with the licensing agreement signed during the reporting period.

The main expenses relate to research and development costs, which have increased considerably relating to consulting activities in preparation the Clinical Trial Application, upstart of the Clinical Research Organization and the clinical trial hospitals, and manufacturing of the Clinical Trial Material. Other operational expenses relate to personnel costs, legal and consulting costs for business development, communication costs and patent costs.

Personnel costs have increased compared to the previous year due to salary revisions.

Risks and Uncertainties in Brief

Significant Risk and Uncertainty Factors

OncoZenge's significant risk and uncertainty factors include operational risks such as those related to market and technological development, patents, competitors, and future financing. The company is in clinical phase carrying typical life science development and regulatory risks, and there is a risk that it may not achieve sufficient profitability. OncoZenge's value is largely dependent on the success of its development projects and its ability to enter into partnerships with larger pharmaceutical companies. The company has not generated sufficient revenues to achieve positive cash flow, meaning it requires access to capital until its cash flow becomes positive. Access to capital may be limited at times when the company needs it.

Russia's invasion of Ukraine and geopolitical turmoil have created significant uncertainty in the financial markets. Prevailing market conditions make it more challenging to raise capital. In parallel with ongoing business development, aimed at securing necessary collaboration agreements, the board continuously evaluates various financing alternatives.

The company has tax loss carryforwards that could be lost if a new owner gains control of more than 50% of the voting rights in the company or if new owners, each controlling at least 5% of the voting rights, collectively control more than 50% of the voting rights. As of December 31, 2024, the tax loss carryforwards amounted to approximately SEK 82.8 million. The loss of these carryforwards would mean that future taxable profits could not be offset against accumulated tax losses.

Going Concern

In January 2025, an investment agreement worth SEK 30.2 million was signed with the new strategic investor Sichuan Yangtian Bio-Pharmaceutical Co. Ltd, to be executed through directed share issues. The first two planned share issues were subscribed by the investor during the second quarter. The company's financing depends on the completion of the remaining directed share issues. The third tranche of the investment amounted to SEK 9.1m and was received by the company on February 12, 2026. The fourth and final tranche of investment is planned for the second quarter of 2026. The company assesses that these share issues, once completed, together with the convertible loan mentioned below, will finance the company's operations until the fourth quarter of 2026.

In March 2025, a commercialization agreement was signed with Molteni Farmaceutici S.P.A. regarding the European territory. The first milestone payment was received during the second quarter.

During the reporting period, the company entered into an agreement for a bridge financing solution of SEK 7.5 million through a convertible loan with Linc AB, which runs until July 31, 2027.

The board's ambition is to finance and initiate a clinical Phase III study in 2026. Partner activities have commenced. The board and the CEO assess that the company will be able to secure the necessary liquidity to continue operations for at least twelve months following the issuance of this financial report. The report has been prepared based on this assessment in accordance with the going concern principle.

Should critical conditions not be met, there is a risk concerning the company's ability to continue as a going concern.

Financial Calendar

April 30, 2026

ANNUAL REPORT

May 20, 2026

INTERIM REPORT JAN-MAR 2026

August 27, 2026

INTERIM REPORT JAN-JUN 2026

November 11, 2026

INTERIM REPORT JAN-SEP 2026

May 27, 2026

ANNUAL GENERAL MEETING 2026

OncoZenge's financial reports are available on the company's website at www.oncozenge.com.

Shares and Shareholder Structure

As of January 1, 2025, the total number of shares amounted to 11,713,244. A directed new share issue increased the number of outstanding shares by 933,930, and, consequently on the balance sheet date of December 31, 2026, the total number of outstanding shares amounted to 12,647,174. The share capital increased by SEK 103,770 to SEK 1,405,242. The new share issue was registered by Bolagsverket on July 24, 2025.

OncoZenge AB is listed on the Nasdaq First North Growth Market with the ticker symbol ONCOZ and ISIN SE0015504097 since February 12, 2021.

The closing price for the company's share on the last trading day of the reporting period, December 30, 2025, was SEK 6.76.

Shareholders as of December 31, 2025

Name	Number shares	Capital & votes
Niclas Holmgren	1 323 027	10,46%
Andreas Adnan Özbek	1 230 500	9,73%
Linc AB	1 170 607	9,26%
Sichuan Yangtian Bio-Pharmaceutical Co, Ltd	933 930	7,38%
Avanza Pension	692 078	5,47%
Stian Kildal	500 000	3,95%
Kalle Holmgren	425 000	3,36%
Nordnet Pensionsförsäkring	323 320	2,56%
Fenix Dental/Paul Murtagh	303 750	2,40%
Jimmy Mattias Olsson	298 300	2,36%
Dan Mikael Joacim Friberg	260 000	2,06%
Emad Masihzadeh	221 000	1,75%
Gunvald Berger	120 000	0,95%
Lisa Knight	99 895	0,79%
Josefin Evertsson	97 312	0,77%
Johan Gunnar Fredrik Sällqvist	97 135	0,77%
Sedcon AB	82 137	0,65%
Nadim Moued	73 931	0,58%
Christer Persson	71 134	0,56%
Stefan Raskovic	65 579	0,52%
Top 20 shareholders	8 388 635	66,33%
Other	4 258 539	33,67%
Total	12 647 174	100,00%

At publication of this report Stian Kildal, CEO, held 500 000 shares and 500 000 options.

Income Statement

SEK 000	2025 Oct-Dec	2024 Oct-Dec	2025 Jan-Dec	2024 Jan-Dec
Operating income				
Net sales	-	-	2 664	-
Other income	1	-	120	1
Revenue	1	0	2 784	1
Operating costs				
Other external costs	-9 122	-1 932	-15 574	-6 536
Personnel costs	-627	-569	-2 960	-2 147
Other operating costs	-	-	-37	-3
Operating loss	-9 748	-2 501	-15 787	-8 685
Result from financial items				
Other interest income and similar profit/loss items	15	-	16	1
Interest expense and similar profit/loss items	-153	-	-169	-4
Result after financial items	-9 886	-2 501	-15 940	-8 688
Tax on current year income	-	-	-	-
Result for the period	-9 886	-2 501	-15 940	-8 688
Result per share				
SEK				
Result per share before and after dilution*	-0.78	-0.21	-1.31	-0.74
Number of shares, weighted average	12 647 174	11 713 244	12 130 691	11 713 244
Number of shares at end of reporting period	12 647 174	11 713 244	12 647 174	11 713 244

As of December 31, 2025, there were 12 647 174 common shares outstanding each carrying one vote.

*No dilution effects exist: The previously issued warrants expired in december without subscription.

Balance Sheet

SEK 000	Note	Dec 31 2025	Dec 31 2024
ASSETS			
Subscribed, unpaid share capital	2	9 064	-
<i>Non-current assets</i>			
Patents		6 850	6 850
Total non-current assets		15 914	6 850
Current assets			
<i>Current receivables</i>			
Other receivables		2 540	519
Prepaid expenses and accrued income		2 233	202
Total current assets		4 773	721
Cash and cash equivalents		3 714	3 863
Total current assets		8 487	4 584
TOTAL ASSETS	2	24 401	11 434
EQUITY AND LIABILITIES			
Equity			
<i>Restricted equity</i>			
Share capital	3	1 405	1 301
Total restricted equity		1 405	1 301
<i>Unrestricted equity</i>			
Share premium reserve		98 773	84 410
Profits or losses carried forward		-75 761	-67 073
Current year income		-15 940	-8 688
Total unrestricted equity		7 072	8 649
Total equity		8 477	9 950
<i>Long term liabilities</i>			
Convertible loan		7 500	-
<i>Current liabilities</i>			
Accounts payable		6 797	657
Other current liabilities		73	46
Accrued expenses and prepaid income		1 554	781
Total current liabilities		8 424	1 484
Total liabilities		15 924	1 484
TOTAL EQUITY AND LIABILITIES		24 401	11 434

Statement of Changes in Shareholders Equity

SEK 000	Restricted equity		Unrestricted equity		
	Share capital	Share premium reserve	Accumulated losses	Net profit/loss for the period	Total equity
Opening equity on Jan 1, 2024	1 301	84 410	-51 168	-15 902	18 641
Appropriation of previous year result			-15 902	15 902	
Current year result				-8 688	-8 688
Closing equity on Dec 31 2024	1 301	84 410	-67 070	-8 688	9 950
Opening equity on Jan 1, 2025	1 301	84 410	-67 070	-8 688	9 950
Appropriation of previous year result			-8 688	8 688	
Current year result				-15 940	-15 940
Transactions with shareholders					
New share issue	104	5 939			6 043
Share issue costs		-635			-635
Pending new share issue		9 064			9 064
Closing equity on Dec 31, 2025	1 405	98 773	-75 761	-15 940	8 477

Cash Flow Analysis

SEK 000	2025 Oct-Dec	2024 Oct-Dec	2025 Jan-Dec	2024 Jan-Dec
Operating activities				
Operating profit/loss	-9 748	-2 501	-15 787	-8 685
Received/paid interest	-138	-	-153	-3
Cash flow from operating activities before changes in working capital	-9 886	-2 501	-15 940	-8 688
Cash flow from changes in working capital				
Increase (-)/Decrease (+) in operating receivables	-3 380	252	-4 057	142
Increase (+)/Decrease (-) in operating liabilities	5 390	282	6 940	-218
Cash flow from operating activities	-7 876	-1 967	-13 057	-8 764
Financing activities				
Convertible loan	-	-	7 500	-
Share issue	-	-	6 043	-
Share issue costs	-	-	-635	-
Cash flow from financing activities	0	0	12 908	0
Cash flow for the period	-7 876	-1 967	-149	-8 764
Cash and cash equivalents at the beginning of the period	11 590	5 830	3 863	12 627
Cash at end of period	3 714	3 863	3 714	3 863

A close-up photograph of a doctor in a light blue coat. The doctor is holding a clipboard with a silver metal clip and a white sheet of paper. A stethoscope is visible around the doctor's neck. The background is a blurred wooden chair. The word "Notes" is written in a bold, orange font on the left side of the image.

Notes

Notes

Note 1 Accounting principles

The interim report, like the annual financial statements, has been prepared in accordance with the principles under the Swedish Accounting Standards Board's general recommendations BFNAR 2012:1 K3. The basis for preparing OncoZenge's financial reports is the going concern principle, which means that the company reports revenues, expenses, assets, and liabilities on the assumption that the company will continue to operate for the foreseeable future. More information about the accounting principles applied can be found in OncoZenge's annual report for the fiscal year 2024.

Amounts are stated in Swedish kronor, rounded to the nearest thousand unless otherwise specified. Rounding to thousands of kronor may mean that the amounts do not add up correctly.

Note 2 Pending new share issue

The third tranche of the investment agreement with investor Sichuan Yangtian Bio-Pharmaceutical Co, Ltd, amounted to subscription proceeds of approximately SEK 9.1m, which were received by OncoZenge in February 2026.

Note 3 New share issue

On January 27, 2025, it was announced that OncoZenge had entered into an investment agreement for SEK 30.2 million with the new strategic investor Sichuan Yangtian Bio-Pharmaceutical Co, Ltd, to be implemented through directed new share issues. The total number of shares that can be issued amounts to a maximum of 4,669,647 new shares.

During the second quarter of 2025, the investor subscribed for shares related to tranches one and two, amounting to 20% of the total investment, which corresponds to SEK 6,042,527. The board, with the support of the renewed authorization received at the annual general meeting on May 28, 2025, has decided on a directed new share issue of 933,930 shares to the new investor at a subscription price of SEK 6.47 per share. The funds were received during the reporting period. The shares were registered with the Swedish Companies Registration Office on July 24, 2025.

Note 4 Pledged assets and contingent liabilities

SEK 000	2025-12-31	2024-12-31
Molteni Farmaceutici	2,664	-
Total	2,664	-

The amount corresponds to the first milestone payment in accordance with the license agreement entered into during the reporting period with Molteni Farmaceutici in Italy. The amount must be repaid to Molteni if the company's clinical Phase III study is not completed within thirty months of signing of the license agreement, i.e. by September 28, 2027.

Note 5 Significant events after the reporting period

- January 21, 2026:** OncoZenge announced uncertainty regarding payment of subscription proceeds and liquidity impact. OncoZenge has been informed that the strategic investor Sichuan Yangtian Bio-Pharmaceutical Co, Ltd (the "Investor") will not be able to pay the subscription proceeds of approximately SEK 9.1 million by the end of the payment deadline in the directed share issue resolved by the Board of Directors of the Company and communicated on 19 December 2025. According to the preliminary information received by the Company, payment is expected to be made within approximately 30 days. As a result, the Company will not receive the expected proceeds within the anticipated timeframe. This means that the Company currently lacks sufficient liquidity to cover its obligations for the coming month.
- January 22, 2026:** it was announced that OncoZenge has entered into an agreement for a bridge financing solution of SEK 5 million, via a convertible note with Linc AB ("Linc") to be repaid upon payment of the third tranche in the directed share issue to Sichuan Yangtian Bio-Pharmaceutical Co, Ltd, resolved by the Board of Directors of the Company and communicated on 19 December 2025. Furthermore, the Company has received a written subscription proceeds of approximately SEK 9.1 million in the Directed Share Issue on or before 21 February 2026. The Board of Directors has extended the time for payment in the Directed Share Issue until 21 February 2026 and has secured the Company's liquidity for the period until that date, and following receipt of the subscription proceeds, until the middle of Q2 2026, in line with the CTA milestone in the existing financial plan.
- January 30, 2026:** it was announced that the one-month stability study results for its BupiZenge™ lozenge technology batch are within specifications. The batch was successfully manufactured at Meribel Pharma Solutions in Solna, Sweden, in December 2025 following a technology transfer conducted in collaboration with Molteni Farmaceutici.
- February 2, 2026:** announced the appointment of Dr. Marie-Louise Fjällskog, MD, PhD, as Chief Medical Officer (CMO), effective February 1, 2026. Dr. Fjällskog, a board-certified oncologist and Associate Professor of Oncology (Docent) at Uppsala University, brings extensive expertise in clinical development, regulatory strategy, and oncology drug development.
- February 4, 2026:** announced Key Insights from UCLA Patient Engagement Study on Oral Mucositis Pain Management conducted in collaboration with UCLA Health. The study, completed in December 2025, gathered perspectives from 43 patients undergoing or having completed radiation therapy for head and neck cancer, and a focus group discussion with four participants. These insights highlight unmet needs in managing oral mucositis pain and have directly informed optimizations to the design of OncoZenge's upcoming Phase III clinical trial for BupiZenge™ in Europe.
- February 12, 2026:** announced receipt of the third tranche of investment capital from Sichuan Yangtian Bio-Pharmaceutical Co., Ltd. The third tranche is in the amount of SEK 9.1m. This investment is consummated at the same price per share as in the two previous tranches, SEK 6,47 and will provide the investor with 1 400 894 new shares in the company.

Related party transactions

During the reporting period, costs related to the company's CFO, Michael Owens, through the related companies M Owens Management Consulting AB and FirstBase AB, amounted to approximately SEK 561 (496) thousand. Costs related to the company's board member Christoph Nowak as Chief Medical Officer through the related company Osher AB amounted to approximately SEK 97 (40) thousand. The above mentioned costs are deemed to be at fair market prices.

These fees cover financial and regulatory administration as well as IT services.

Board fees have been paid in accordance with the annual general meeting's decision.

There were no other significant related-party transactions during the reporting period.

Financial definitions

Key figure definitions

Alternative key figures are indicated as they complement the measures defined in applicable rules for financial reporting. The starting point for submitted alternative key figures is that they are used by the company's management to assess the financial development and thus considered to provide analysts and other stakeholders with valuable information. Below are definitions of all used alternative key figures.

Key figure	Definition	Motivation
Number of shares	Number of shares at end of period	Relevant when computing equity per share
Total assets	Total assets at end of period	Relevant when computing equity
Equity per share	Total equity divided by number of shares at end of period	Measure to describe equity per share
Average number of shares	Average number of shares outstanding during the reporting period	Relevant when computing result per share
Net sales	Sales during the period	Value of sales of goods and services
Reporting period	January 1 - December 31, 2025	Explanation of period comprised by the financial report
Result per share	Result for the period divided by average number of shares	Measure to describe result per share
Equity ratio	Total equity as percentage of total assets	Measure to describe company's capacity to fulfill its financial commitments

Deduction of certain key figures

	2025 Oct-Dec	2024 Oct-Dec	2025 Jan-Dec	2024 Jan-Dec
Cash flow per share				
Cash flow for the period, 000's	-7 876	-1 967	-149	-8 764
Average number of shares	12 647 174	11 713 244	12 130 691	11 713 244
Cash flow per share (SEK)	-0.62	-0.17	-0.01	-0.75
Equity per share				
Equity, 000's	8 477	9 950	8 477	9 950
Number of shares at end of period	12 647 174	11 713 244	12 647 174	11 713 244
Equity per share (SEK)	0.67	0.85	0.67	0.85
Equity ratio				
Equity, 000's	8 477	9 950	8 477	9 950
Total equity and liabilities, 000's	24 401	11 434	24 401	11 434
Equity, %	34.74%	87.02%	34.74%	87.02%

This financial report has not been subject to a limited audit review.

The Board of Directors propose that no dividend be paid for the fiscal year 2025.

Certification

The Board of Directors and the CEO certify that this report provides a fair presentation of the company's operations, income, and statement of financial position and describes significant risks and uncertainties faced by the company

Stockholm, February 26, 2026

Daniel Ehrenstråhle
Chairman

Mats Lindskog
Board Member

Christoph Nowak
Board Member

Stian Kildal
Chief Executive Officer

Publication

The information was submitted by the CEO on February 26, 2026, at 8:00 AM (CEST).

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For further information about OncoZenge's operations, please refer to the company's website, www.oncozenge.se.

The company's corporate name is OncoZenge AB (publ) ("OncoZenge").

The company's corporate registration number is 559261-9968.

Certified Adviser

Redeye Sweden AB is the company's Certified Adviser.

OncoZenge

BupiZenge™

Potential to be the leading treatment for oral pain