



Equity Analysis

ONCOZENGE AB (PUBL)

by Impala Nordic
12th August 2025



IMPALA NORDIC

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1. INTRODUCTION

OncoZenge AB (publ) ("OncoZenge" or the "Company") is a Swedish research company in clinical phase developing BupiZenge™, a lozenge for the treatment of oral mucositis with analgesic properties.

BupiZenge™ has the potential to improve the quality of life for patients suffering from oral mucositis and has demonstrated benefits in Phase 1 and Phase 2 clinical trials. Its rapid onset and pain-relieving effect facilitate, among other things, food intake for patients, which can strengthen the immune system and accelerate recovery during cancer treatment.

A potential future development is that the Company expands the approved product label for BupiZenge™ to additional indications and medical conditions, such as local anaesthesia in dental procedures.

The Company and its commercialisation partner, Molteni Farmaceutici ("Molteni"), are preparing a European Phase 3 clinical trial, followed by a market launch in Europe. The agreement has the potential to generate up to EUR 4.3 million in milestone payments, with royalties on product sales ranging between 15–20%.

To secure funding for the planned European Phase 3 trial, an investment of SEK 30.2 million has been secured from Sichuan Yangtian Bio-Pharmaceutical ("Yangtian Pharma"), to be executed through directed share issues in several tranches. To date, 20% of the investment has been received. OncoZenge has also entered into a SEK 7.5 million convertible loan agreement with major shareholder Linc AB, to ensure sufficient financial flexibility for the Phase 3 trial. Milestone payments from Molteni will also contribute to enabling the execution of the Phase 3 study.

The planned Phase 3 trial can, due to its relatively short administration time and follow-up period, be completed faster than an average Phase 3 study. Oral mucositis is also a common condition, which facilitates patient recruitment for the trial.

The Phase 3 study is expected to commence during the first half of 2026, which could enable European marketing authorisation in 2027. European approval could also facilitate product launches in Latin America, parts of Asia, Canada, and Africa.

Company details

Ticker ONCOZ
List First North Stockholm
Stock price 6,3 SEK
Shares 12 647 174
Market cap 80 MSEK
CEO Stian Kildal
Chairman Daniel Ehrenstråhle

Ownership

| Share | Shareholders |
|----------------|---|
| 10,2 % | Niclas Holmgren |
| 9,3 % | Linc AB |
| 8,6 % | Andreas Özbek |
| 7,4 % (28,5 %) | Yangtian Pharma (completed investment) |
| 4,2 % | Avanza Pension |
| 3,2 % | Kalle Holmgren |
| 3 % | Stian Kildal |
| 2,5 % | Nordnet Pension |
| 2,4 % | Jimmy Mattias Olsson |
| 2,2 % | Paul Murtagh |

Share price



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2. CASE SUMMARY

Summary of the case

- » Potential to receive up to EUR 4.3 million in milestone payments under the agreement with European partner Molteni.
- » Secured total funding of approximately SEK 47 million, earmarked for the planned European Phase 3 trial.
- » The Company's European Phase 3 trial is expected to commence during the first half of 2026.
- » Potential marketing approval in Europe could be obtained in 2027.

The Company's main focus areas over the next 12 months

- » Secure execution of the European Phase 3 trial with the objective of achieving commercial launch in Europe in 2027.
- » Secure additional commercial partnerships: Evaluate further commercial partners in markets where EMA approval can be leveraged, such as Latin America, parts of Asia, Canada, Africa, and other regions.
- » Refine strategy for entry into the Chinese market: Finalise a collaboration agreement with Yangtze Pharma to ensure an efficient pathway to marketing authorisation and product launch in China.
- » Evaluate options for entry into the U.S. market: Determine the optimal pathway to U.S. FDA approval, in collaboration with an industry pharmaceutical partner or financial partner. The project scope will be optimised by leveraging European data and considering the FDA's evolving priorities. OncoZenge will seek direct dialogue with the FDA to discuss the Company's IND and registration requirements.
- » Explore additional indications: Continue to assess new indications, with particular focus on significant opportunities in dental applications.



3. INVESTMENT CASE

Targeting initiation of a European Phase 3 trial

OncoZenge intends to conduct a fully European Phase 3 trial to serve as the basis for obtaining marketing authorisation for BupiZenge™ in Europe. The scope of the trial is currently under planning, and suitable clinical sites across Europe will be utilised for patient recruitment. The planning is carried out in close collaboration with the Company's European licensing partner, Molteni. To identify appropriate clinical sites and gather further information on trial execution, the Company has also engaged LINK Medical, which is currently conducting a feasibility study. The study is planned to be completed in August.

The purpose of the Phase 3 trial is to confirm the analgesic effect previously demonstrated by BupiZenge™. The trial will include patients with oral mucositis, which is the primary target population. The plan is to engage a Contract Research Organisation (CRO) for the trial during Q3 2025.

Potential EU market approval in 2027

The primary objective of the Company's upcoming Phase 3 study is to meet the regulatory requirements for market authorization within the EU. Approval from the European Medicines Agency (EMA) serves as the basis for national approvals in the member states. The study may also generate valuable data for a potential future regulatory process in the United States.

The standard review period at the EMA is approximately 10 months, which in our view means that a potential market authorization could be in place as early as the first half of 2027. The actual timeline will depend partly on when the Phase 3 study can commence, and partly on whether the Company chooses to apply for accelerated assessment. Such a procedure could shorten the regulatory review period to approximately 6 months, but is considered less likely.

European commercialization partner secured

OncoZenge has secured a European partner in Molteni for the commercialization of BupiZenge™ in Europe. A decision has also recently been made to initiate collaboration with Meribel Pharma Solutions ("Meribel Pharma") in Sweden for the manufacturing of clinical trial material ahead of the Phase 3 study. OncoZenge and Meribel Pharma will now work together to complete the necessary activities and documentation for submission of the Clinical Trial Application ("CTA") as well as for the execution of the project.

The binding agreement with Molteni grants exclusive rights to commercialize BupiZenge™ in Europe. The agreement includes royalty payments to OncoZenge as follows:

- » 15% on annual sales up to EUR 30 million,
- » 18% on sales between EUR 30 million and EUR 60 million, and
- » 20% on annual sales exceeding EUR 60 million.

In addition, OncoZenge may receive up to EUR 4.3 million in milestone payments.

Molteni is a leading Italian pharmaceutical company with specialist expertise in pain management and the treatment of drug addiction. Founded in 1892, the company is headquartered in Florence, Italy. Molteni has in-house capabilities in manufacturing, research and development, regulatory affairs, supply chain, marketing, and distribution. The company has broad distribution reach across Europe and globally, and employs over 300 people.

3. INVESTMENT CASE

Financing secured

OncoZenge has entered into an investment agreement of SEK 30.2 million with Yangtian Pharma. The agreement secures funding for the execution of the Company's European Phase 3 study. The investment is planned to be carried out through four directed share issues to the investor, corresponding to 10%, 10%, 30%, and 50% of the total investment amount, respectively. The first two tranches, totaling 20% and approximately SEK 6 million, were received on July 11, 2025.

To further strengthen its financial flexibility, the Company has, in addition to the investment from Yangtian Pharma, secured a convertible loan of SEK 7.5 million from its main shareholder, Linc AB. The loan runs until July 31, 2027, and carries an annual interest rate of 8% from the date of drawdown. Conversion of the loan into shares through a directed share issue may take place at the lender's request no earlier than March 1, 2026. The conversion price for such an issue has been set at SEK 6.47 per share.

In addition, the Company may raise up to SEK 8.54 million through outstanding warrants held by the Board and management. A total of 1,550,000 warrants are outstanding, which may be exercised for subscription of new shares during the period November 11 – December 11, 2025. Each warrant entitles the holder to subscribe for one (1) new share in the Company at a price of SEK 5.51 per share.

Well-defined patient need

Currently, treatment options for oral mucositis are often inadequate or associated with side effects that may be harmful to the patient. The most commonly used substance for pain relief is lidocaine, which is typically administered as a mouth rinse. For patients experiencing severe pain, opioids are instead used, which carry significant risks, particularly with regard to dependency issues.

In the Company's planned Phase 3 study, the pain-relieving effect of BupiZenge™ will be evaluated in comparison with lidocaine in the treatment of oral pain.

USA – a major opportunity

The Company is currently focusing exclusively on the European market, in close collaboration with its commercialization partner Molteni. The next major step for the Company will be to conduct a U.S. Phase 3 study, which will require a financial or industrial partner. The United States represents the geography with the greatest market potential, and the primary risk lies in the uncertainty regarding the structure of a future partnership and the size of the capital requirement for an additional Phase 3 study.



4. RISKS

Study data

Given the general risk that Phase 3 study data may fail to meet the predefined efficacy endpoints, we consider the upcoming European Phase 3 study to be one of the significant overall risk factors for the Company. At the same time, BupiZenge™ is based on the well-established substance bupivacaine, which has been used as a local anesthetic in healthcare for over 50 years. In our assessment, this reduces the clinical risk associated with the project.

Bupivacaine is currently used in injectable form for local anesthesia during surgeries and medical procedures. One of the main risks associated with the substance is its toxicity at high doses, which can lead to cardiac effects. However, based on the Company's previous clinical data, we assess the risk of patients exceeding the established safety limits as low.

Regulatory challenges

To obtain market authorization in Europe, the standard procedure requires that the Committee for Medicinal Products for Human Use (CHMP), the expert panel of the European Medicines Agency (EMA), issues a positive recommendation for the medicine to be approved within the EU. Even if the Company achieves the primary endpoints in the planned Phase 3 study, regulatory questions may remain that must be addressed. This means that general regulatory risk persists, even in the case of seemingly positive study results.

Based on previous experience, we assess the regulatory risk in the United States to be higher than in Europe. The U.S. Food and Drug Administration (FDA) generally applies stricter requirements, including a lower allowable threshold for systemic exposure to bupivacaine (1,000 ng/mL compared to the EMA's 2,000 ng/mL). This constitutes a clear difference between the markets and is an important factor in assessing regulatory risk.

Commercial risk

In our assessment, the market for pain-relieving treatment of oral mucositis is fragmented, with several different treatment options depending on the severity of pain and level of care. This entails a certain degree of commercial risk related to the ability to achieve broad market penetration for BupiZenge™. At the same time, this can be seen as a general risk for research-based companies and is not unique to OncoZenge.

The upcoming Phase 3 study will be decisive in this regard. If the study data demonstrate significant advantages compared to the current standard treatment with lidocaine, we believe this could create the conditions for both higher pricing and broader market uptake.

5. ABOUT THE COMPANY

About The Company

OncoZenge is a Swedish research company developing BupiZenge™, a lozenge intended to relieve pain in patients suffering from oral mucositis. In clinical Phase 1 and Phase 2 studies, BupiZenge™ has demonstrated clear advantages over existing standard treatments for oral pain, particularly through its rapid onset of action. The treatment has the potential to improve the quality of life for cancer patients with oral mucositis, as effective pain relief facilitates food intake, which in turn can help strengthen the immune system and accelerate recovery.

The Company is a spin-off from Moberg Pharma and was listed on the Nasdaq First North Growth Market in early 2021. Following internal disagreements regarding the Company's strategic direction, the Board of Directors and management were replaced at the initiative of the main shareholder, Niclas Holmgren. The current focus is on preparing for a European Phase 3 study and identifying a partner to support the Company in bringing BupiZenge™ to market. OncoZenge is listed on First North with a market capitalization of approximately SEK 80 million.

The logo for OncoZenge is displayed in a bold, orange, sans-serif font. It is centered within a large rectangular area that features a background pattern of overlapping circles in various shades of light gray and beige, creating a textured, honeycomb-like effect.

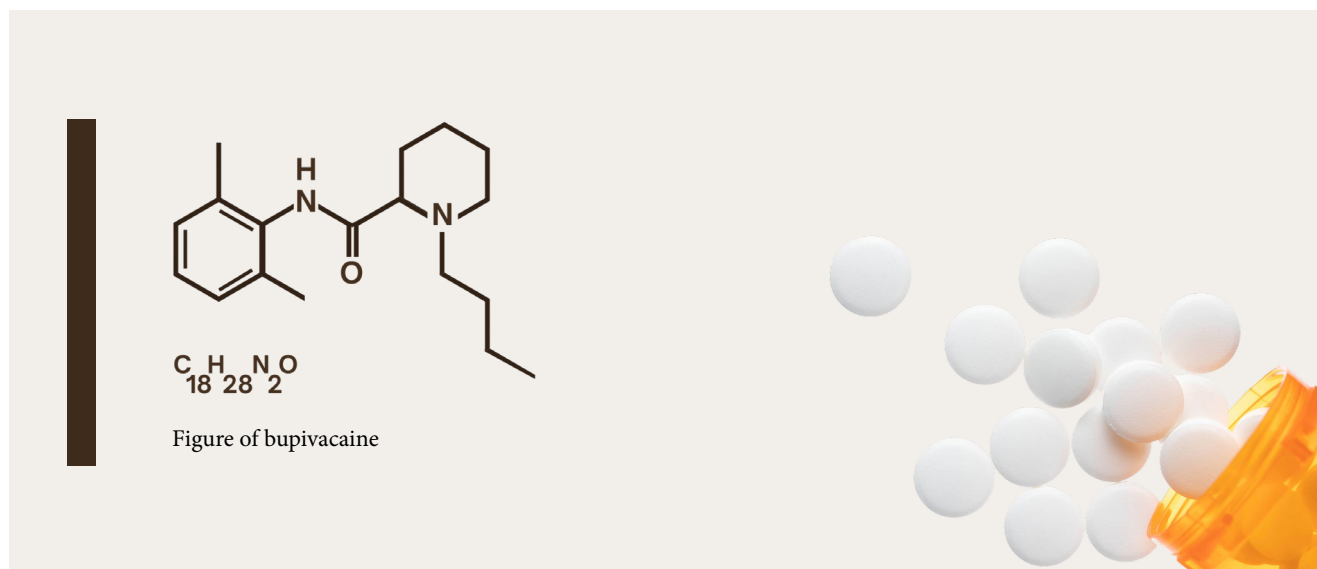
6. PRODUCT – BUPIZENGE™

Product – BupiZenge™

OncoZenge is developing BupiZenge™, an analgesic lozenge primarily intended for the treatment of oral mucositis, an inflammatory condition of the oral mucosa that can cause painful sores and ulcers. The condition is common among cancer patients undergoing chemotherapy or radiotherapy, where the associated pain is often severe. The most affected patient group is individuals with head and neck cancer receiving both radiation and chemotherapy, in which an estimated 90–100% develop severe oral mucositis.

The active substance in BupiZenge™ is bupivacaine, a well-documented local anesthetic that has been used in healthcare since the 1960s. It works by blocking nerve impulses in the treated area and is currently used, among other things, in surgical procedures and as local anesthesia. The fact that bupivacaine is already clinically established facilitates the development of BupiZenge™, as its safety profile and mechanism of action are well known.

A key advantage of bupivacaine is that it is not an opioid and is not classified as a narcotic. This means BupiZenge™ could provide a non-opioid alternative for pain relief in the oral and throat region. The relevance of this is underscored by the opioid crisis in, for example, the United States, where over 54,000 opioid-related deaths were recorded in 2024. The need for effective, non-opioid treatment options is therefore substantial, both from a medical and a socio-economic perspective.



7. ORAL MUCOSITIS

Oral mucositis

A person affected by oral mucositis is typically a cancer patient with a weakened immune system as a result of chemo- and/or radiotherapy. Cancer therapy impacts cell renewal in the oral mucosa, making the tissue more sensitive and prone to inflammation and ulceration. Oral mucositis usually develops 12–17 days after the initiation of radiotherapy to the head and neck region, but in some cases can persist anywhere from 7 to 98 days.

Once the condition manifests, patients often experience sores, burning sensations, and intense pain, making eating, swallowing, and speaking difficult. The reduced oral hygiene that frequently follows can, in turn, lead to further complications, including secondary infections.

Healing from oral mucositis often takes at least 2–3 weeks, but depends on the resumption of white blood cell production in the bone marrow. For some, the pain is so severe that oral intake becomes impossible, requiring feeding via a nasogastric tube. In severe cases, the condition can force healthcare providers to adjust the dosage or even discontinue cancer treatment, which may negatively impact the disease prognosis. In addition to cancer patients, the majority of patients who have undergone stem cell transplantation also develop oral mucositis.

From an economic perspective, oral mucositis is associated with significant additional healthcare costs. Exact costs vary depending on the type of treatment and underlying disease, but studies indicate that the additional expense can range from approximately USD 1,700 to 6,000 per patient undergoing chemotherapy. For radiotherapy, reported costs range between USD 5,000 and 30,000 per patient. As an estimated 40% of all cancer patients are affected by oral mucositis, this represents a substantial economic burden on healthcare systems—regardless of the cost assumptions used.

Grades of oral mucositis according to the WHO



| Grade 1 | Grade 2 | Grade 3 | Grade 4 |
|-------------------------------------|---|--|---|
| Mild pain and redness in the mouth. | Redness and sores in the mouth, still possible to eat solid food. | Sores in the mouth and the patient can only eat liquid food. | The patient is so severely affected that they are unable to eat at all. |

8. OTHER AREAS OF USE FOR BUPIZENGE™

Other areas of use for BupiZenge™

In addition to its primary focus on oral mucositis, OncoZenge has identified future potential to broaden the use of BupiZenge™ to other indications where the need for alternative pain relief is high. The Company has mentioned several possible applications, including pain relief during endoscopic procedures, surgery of the oral cavity and throat, dental care, and for the difficult-to-treat condition known as Burning Mouth Syndrome (BMS).

These applications should, however, currently be regarded as options and do not form part of the Company's core strategy. Some of the alternative uses for BupiZenge™ have already been explored in smaller studies, and in the event of an approval for the treatment of oral mucositis, the pathway for developing other indications would also be facilitated.

Burning Mouth Syndrome

Burning Mouth Syndrome (BMS) is a chronic pain condition characterized by a burning, stinging, or tingling sensation in the mouth—often on the tongue, lips, palate, or across the entire oral mucosa—without visible changes upon examination. BupiZenge™ could potentially be developed for pain relief among BMS patients.

One of the standard treatments is topical clonazepam (administered as a mouth rinse or lozenge). Clonazepam belongs to the benzodiazepine class of drugs, which are addictive and harmful when used for more than short periods.

According to studies, BMS has an estimated prevalence of 1.7% in the global general population, with the highest prevalence found in Europe, affecting 5.6% of the general population. In clinical populations, a prevalence of 7.7% has been reported. BMS is significantly more common among women, particularly in older age groups (50 years and above).

Local anesthesia in dentistry

Dentistry is considered one of the most immediate areas for a potential expansion of BupiZenge™'s use. Impala Nordic notes in particular that dentist Paul Murtagh has emerged as one of the Company's larger shareholders, which we find noteworthy in this context.

Within dentistry, there is a wide range of procedures where local anesthesia and subsequent pain relief are necessary. Examples include wisdom tooth extraction, root canal treatments, and jaw surgery, where postoperative pain is common. In such cases, BupiZenge™ could serve as a complement or alternative to existing pain relief medications, particularly in situations where the use of opioids is to be avoided.

BupiZenge™ therefore offers not only a well-established, non-opioid substance in a new formulation, but also the possibility of simple, localized administration, which may be attractive in the dental field.

8. OTHER AREAS OF USE FOR BUPIZENGE™

Oral and throat surgery

In oral and pharyngeal surgery—such as tonsillectomy, uvulopalatopharyngoplasty (UPPP), tooth extractions, or resection of oral lesions—pain is often intense during the first postoperative days. BupiZenge™ could help reduce the need for systemic analgesics, including opioids, thereby lowering the risk of their side effects (e.g., respiratory depression, nausea, and constipation). Given that oral and throat surgeries encompass a wide range of procedures, the market potential is also substantial.

Currently, pain relief often involves a combination of analgesics to achieve optimal pain control with minimal side effects. This includes common medications such as paracetamol, NSAIDs (ibuprofen), opioids, or various forms of local anesthesia.

Paracetamol is primarily used as a baseline treatment for mild to moderate pain, typically administered regularly during the first few days. NSAIDs (e.g., ibuprofen) are effective against inflammatory pain but are used cautiously in cases with a risk of bleeding, particularly after tonsillectomy. Opioids are reserved for severe pain due to their substantial risk of adverse effects. Local anesthesia is sometimes used during surgery or immediately postoperatively to provide localized relief.

Sjögren's syndrome (dry mouth)

Sjögren's syndrome is a chronic autoimmune disease in which the body's own immune system primarily attacks the salivary and tear glands, leading to dry mouth and dry eyes. The disease can also cause joint and muscle pain, fatigue, nerve damage, and in some cases affect organs such as the lungs and blood vessels.

One of the more debilitating aspects of Sjögren's syndrome is pain in the oral mucosa, often associated with sores, a burning sensation, or secondary infections, combined with constant dry mouth. This can contribute to difficulties in eating, speaking, and sleeping.

There is potential for BupiZenge™ in this area, particularly for localized pain in the oral mucosa. As bupivacaine is long-acting, it could be used for pain relief. However, Sjögren's syndrome is a very rare condition, with a prevalence of 0.07% in Sweden according to Region Östergötland.

Oral inflammations

Similar to oral mucositis, there are a range of other inflammatory conditions that can affect the oral cavity and cause significant pain. One of the most common forms of inflammation is gingivitis, an inflammation of the gums often caused by plaque and bacteria. If left untreated, gingivitis can progress to periodontitis, which also affects the bone and tissues surrounding the teeth. Pain levels vary, but tenderness or mild gum pain—particularly when touched or during chewing—is not uncommon.

Glossitis is an inflammation of the tongue, which can cause swelling, redness, and burning sensations. It may be due to vitamin deficiencies, infections, allergic reactions, or autoimmune conditions such as Sjögren's syndrome, mentioned above.

Another common inflammatory condition is pericoronitis, which affects the tissue around a partially erupted tooth, often a wisdom tooth. It can cause pain, swelling, and difficulty opening the mouth, and often requires cleaning and, in some cases, surgical intervention.

Viral infections can also cause oral inflammation, such as in herpetic stomatitis, where the herpes virus causes painful blisters and sores in the mouth, particularly in children during a primary infection.

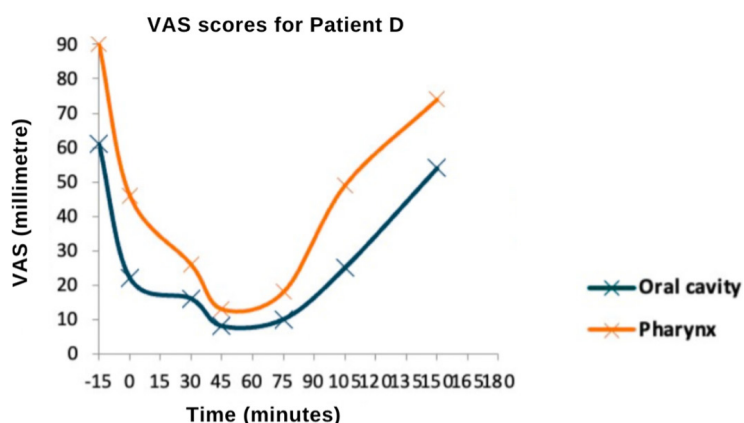
9. CLINICAL EVIDENCE

Phase 2-study

BupiZenge™ has a strong, well-documented analgesic effect, as demonstrated by OncoZenge in both Phase 1 and Phase 2 studies involving patients suffering from oral mucositis. In both studies, BupiZenge™ was shown to be safe to use, with no serious adverse events reported. The Phase 2 study results are particularly promising, showing a 31% reduction in pain in the oral cavity/throat, and a substantial 50% reduction observed in the oral cavity alone. The 7-day clinical Phase 2 study included patients with head and neck cancer who had developed oral mucositis.

The chart on the right illustrates a patient's perceived pain in the oral cavity and pharynx. The diagram shows a clear reduction in pain from 90 and 60, respectively, down to 15 and 10.

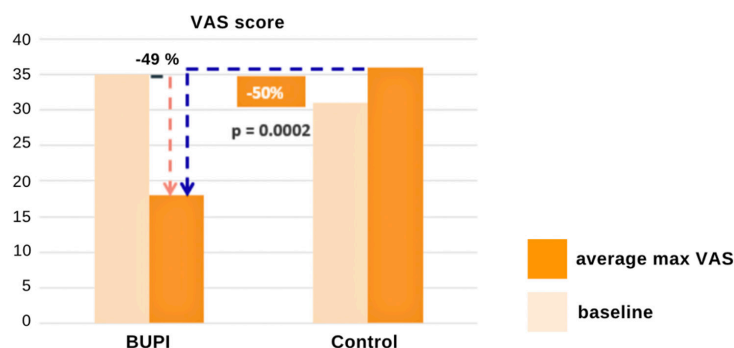
As a reference, a score of 50–60 on the VAS scale is considered moderate pain, while 80 or higher corresponds to severe pain. VAS stands for Visual Analogue Scale and is one of the most widely used pain assessment tools for subjective evaluation. Patients indicate their perceived pain on a scale from no pain at all (0) to the worst imaginable pain (100).



The chart demonstrates that pain relief is noticeable as early as 15 minutes after BupiZenge™ begins to dissolve in the mouth—faster than with other treatment methods. For example, the substance lidocaine, often used in mouth rinse treatments, typically achieves effective pain relief only after about one hour.

It should be noted, however, that the effect may vary between patients, as pain perception is subjective. The use of BupiZenge™ may also differ depending on the stage of cancer treatment the patient is undergoing.

The chart on the right presents results from the Company's Phase 2 study, which included 38 patients with head and neck cancer. The study compared BupiZenge™ with standard treatments containing lidocaine in the form of ointment, oral painkillers, and morphine. In the "BUPI" group, lidocaine was replaced with BupiZenge™, resulting in a 50% reduction in oral cavity pain.



10. MARKET

Market

The global market potential for BupiZenge™ in the indication of oral mucositis within cancer supportive care is estimated at approximately USD 1 billion. Of this potential, roughly half is considered addressable through approval in Europe, which could also pave the way for regulatory approvals in additional geographies outside the United States.

The remaining half of the market potential lies in the U.S., which we consider to be the single largest long-term value driver. This is primarily due to the opportunity for significantly higher pricing compared to other markets, combined with the large patient population and the strong demand for non-opioid pain relief options in cancer supportive care.

Current standard of care for OM-patients

Current treatment options for oral mucositis vary depending on the patient's condition and the severity of pain experienced. Several options for treatment and prevention are available, including:

- » Various mouth rinses ("magic mouthwash") containing different analgesic substances, primarily lidocaine. This is the most common treatment method.
- » Opioid pain tablets, such as morphine, primarily used for patients experiencing severe pain.
- » Cryotherapy, which involves different methods to cool the mouth and prevent severe oral mucositis.
- » Oral gels that form a protective coating in the mouth.
- » Preventive measures through dietary changes.

There is currently no universally accepted standard treatment for oral mucositis, as the effectiveness of these options varies significantly depending on the patient's condition. An option such as BupiZenge™, which is easy to use and safer than opioids, has the potential to be of significant benefit to patients with oral mucositis. It is also worth noting that patients often still experience pain even when they have access to opioids such as morphine.



Image: Bayview Pharmacy

Example of "magic mouthwash" containing lidocaine

11. SALES POTENTIAL – ORAL MUCOSITIS (OM)

In our tables illustrating the market potential in each geography, we have chosen to regard the percentage market penetration as a share of the defined population. In other words, the full population of OM patients is not used.

Sales potential in Europe

The market for BupiZenge™ is significant, and the Company has shared its own estimates of its annual value. According to the Company's calculations, the potential for BupiZenge™ is up to SEK 2.5 billion annually, based on potential peak sales figures for 2034. This would correspond to approximately SEK 500 million in royalties for OncoZenge.

The assumption is based on an estimated 1,300,000 cancer patients developing OM annually, with an annual growth rate of 2–3%. Furthermore, it assumes that maximum uptake among these patients could reach 30% of the population and that the price per lozenge would be SEK 30–35. The average revenue per patient is therefore estimated at SEK 5,500.

In our assessment of the market potential in Europe, we have assumed a treatment period of 6 weeks, with patients taking an average of 4 lozenges per day.

Market potential in Europe

| Adoption rate | 20% | 25% | 30% | 35% | 40% |
|---------------|-------------|-------------|-------------|-------------|-------------|
| EUR | 260 000 pat | 325 000 pat | 390 000 pat | 455 000 pat | 520 000 pat |
| 2,5 EUR | 109 200 000 | 136 500 000 | 163 800 000 | 191 100 000 | 218 400 000 |
| 3 EUR | 131 040 000 | 163 800 000 | 196 560 000 | 229 320 000 | 262 080 000 |
| 3,5 EUR | 152 880 000 | 191 100 000 | 229 320 000 | 267 540 000 | 305 760 000 |

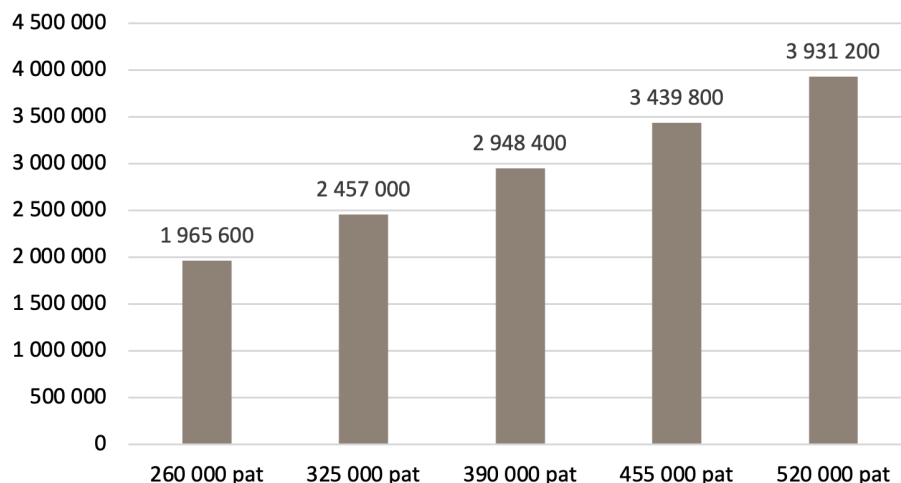
Market penetration and revenue at €3 per tablet

| EUR | 260 000 pat | 325 000 pat | 390 000 pat | 455 000 pat | 520 000 pat |
|-----|-------------|-------------|-------------|-------------|-------------|
| 1% | 1 310 400 | 1 638 000 | 1 965 600 | 2 293 200 | 2 620 800 |
| 2% | 2 620 800 | 3 276 000 | 3 931 200 | 4 586 400 | 5 241 600 |
| 5% | 6 552 000 | 8 190 000 | 9 828 000 | 11 466 000 | 13 104 000 |
| 10% | 13 104 000 | 16 380 000 | 19 656 000 | 22 932 000 | 26 208 000 |
| 20% | 26 208 000 | 32 760 000 | 39 312 000 | 45 864 000 | 52 416 000 |
| 30% | 39 312 000 | 49 140 000 | 58 968 000 | 68 796 000 | 78 624 000 |

Royalties from Molteni based on an average revenue of €3 per tablet

| EUR | 260 000 pat | 325 000 pat | 390 000 pat | 455 000 pat | 520 000 pat |
|-----|-------------|-------------|-------------|-------------|-------------|
| 1% | 196 560 | 245 700 | 294 840 | 343 980 | 393 120 |
| 2% | 393 120 | 491 400 | 589 680 | 687 960 | 786 240 |
| 5% | 982 800 | 1 228 500 | 1 474 200 | 1 719 900 | 1 965 600 |
| 10% | 1 965 600 | 2 457 000 | 2 948 400 | 3 439 800 | 3 931 200 |
| 20% | 3 931 200 | 4 914 000 | 5 896 800 | 6 879 600 | 7 862 400 |
| 30% | 5 896 800 | 7 371 000 | 8 845 200 | 10 319 400 | 11 793 600 |

Royalties based on 10 % market penetration (EUR)



11. SALES POTENTIAL – ORAL MUCOSITIS (OM)

Sales potential in the US

The Company's assessment of the value of the U.S. market is that potential annual peak sales for BupiZenge™ could reach SEK 5 billion by 2034, with potential annual royalty revenues for OncoZenge of SEK 1 billion in 2034. The assumptions are based on an estimated 750,000 patients developing OM annually, with an annual increase of 2–3%. It is further assumed that the maximum uptake for BupiZenge™ will reach 40% of this population and that the price per BupiZenge™ lozenge will be SEK 60–80.

Although potential approval in the U.S. is expected to occur later than in Europe, assumptions have been included in the analysis to illustrate how revenues could develop. These assumptions are based on an average patient taking 4 lozenges per day for a 6-week treatment period.

A licensing deal or partnership yielding 20% royalties is assumed, which is considered reasonable given that such a partnership would likely be entered into after European Phase 3 data is available.

USA market potential

| Adoption rate | 30% | 35% | 40% | 45% | 50% |
|---------------|-------------|-------------|-------------|-------------|-------------|
| USD | 225 000 pat | 262 500 pat | 300 000 pat | 337 500 pat | 375 000 pat |
| 6 USD | 226 800 000 | 264 600 000 | 302 400 000 | 340 200 000 | 378 000 000 |
| 7 USD | 264 600 000 | 308 700 000 | 352 800 000 | 396 900 000 | 441 000 000 |
| 8 USD | 302 400 000 | 352 800 000 | 403 200 000 | 453 600 000 | 504 000 000 |

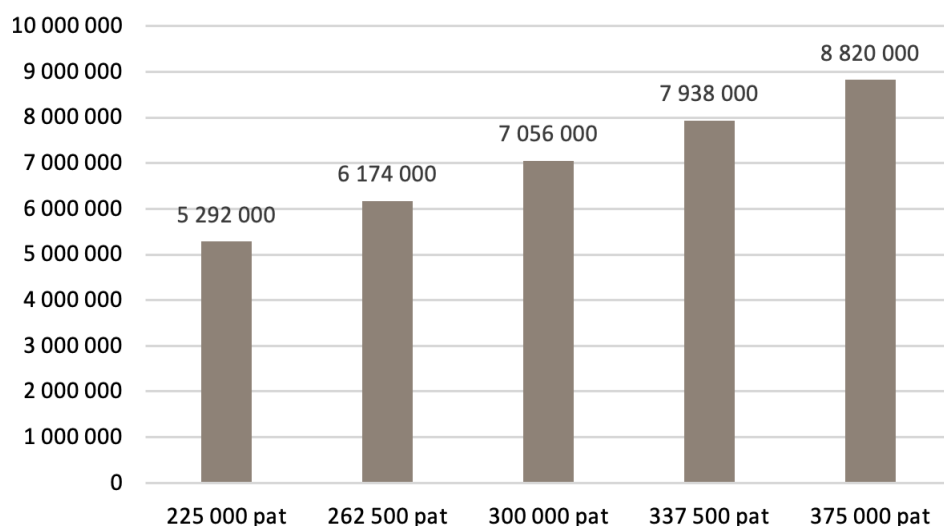
Market penetration and revenue at \$7 per tablet

| USD | 225 000 pat | 262 500 pat | 300 000 pat | 337 500 pat | 375 000 pat |
|-----|-------------|-------------|-------------|-------------|-------------|
| 1% | 2 646 000 | 3 087 000 | 3 528 000 | 3 969 000 | 4 410 000 |
| 2% | 5 292 000 | 6 174 000 | 7 056 000 | 7 938 000 | 8 820 000 |
| 5% | 13 230 000 | 15 435 000 | 17 640 000 | 19 845 000 | 22 050 000 |
| 10% | 26 460 000 | 30 870 000 | 35 280 000 | 39 690 000 | 44 100 000 |
| 20% | 52 920 000 | 61 740 000 | 70 560 000 | 79 380 000 | 88 200 000 |
| 30% | 79 380 000 | 92 610 000 | 105 840 000 | 119 070 000 | 132 300 000 |

20 % royalty

| USD | 225 000 pat | 262 500 pat | 300 000 pat | 337 500 pat | 375 000 pat |
|-----|-------------|-------------|-------------|-------------|-------------|
| 1% | 529 200 | 617 400 | 705 600 | 793 800 | 882 000 |
| 2% | 1 058 400 | 1 234 800 | 1 411 200 | 1 587 600 | 1 764 000 |
| 5% | 2 646 000 | 3 087 000 | 3 528 000 | 3 969 000 | 4 410 000 |
| 10% | 5 292 000 | 6 174 000 | 7 056 000 | 7 938 000 | 8 820 000 |
| 20% | 10 584 000 | 12 348 000 | 14 112 000 | 15 876 000 | 17 640 000 |
| 30% | 15 876 000 | 18 522 000 | 21 168 000 | 23 814 000 | 26 460 000 |

Royalties based on 10 % market penetration (USD)



12. SALES POTENTIAL OTHER GEOGRAPHIES

Geographies where EMA approval can be leveraged

In Latin America, parts of Asia, Canada, Africa, and other regions, local approvals can be obtained based on EMA approval. The Company estimates that the number of patients developing OM annually in these geographies amounts to 2,500,000, with an annual growth rate of 2–3%. OncoZenge estimates that BupiZenge™ could achieve peak uptake of 15% among OM patients in these regions. The average price per lozenge is estimated at SEK 15–17.

Potential annual peak sales for BupiZenge™ in 2034 are estimated at SEK 1.5 billion, which could generate up to SEK 300 million in annual royalty revenues for OncoZenge in 2034.

Market potential in geographies where EMA approval can support local approvals

| Adoption rate | 10% | 12,5% | 15% | 17,5% | 20% |
|---------------|-------------|-------------|-------------|-------------|-------------|
| USD | 250 000 pat | 312 500 pat | 375 000 pat | 437 500 pat | 500 000 pat |
| 1,5 USD | 63 000 000 | 78 750 000 | 94 500 000 | 110 250 000 | 126 000 000 |
| 1,6 USD | 67 200 000 | 84 000 000 | 100 800 000 | 117 600 000 | 134 400 000 |
| 1,7 USD | 71 400 000 | 89 250 000 | 107 100 000 | 124 950 000 | 142 800 000 |

Market penetration and revenue at \$1.6 per tablet

| USD | 250 000 pat | 312 500 pat | 375 000 pat | 437 500 pat | 500 000 pat |
|-----|-------------|-------------|-------------|-------------|-------------|
| 1% | 672 000 | 840 000 | 1 008 000 | 1 176 000 | 1 344 000 |
| 2% | 1 344 000 | 1 680 000 | 2 016 000 | 2 352 000 | 2 688 000 |
| 5% | 3 360 000 | 4 200 000 | 5 040 000 | 5 880 000 | 6 720 000 |
| 10% | 6 720 000 | 8 400 000 | 10 080 000 | 11 760 000 | 13 440 000 |
| 20% | 13 440 000 | 16 800 000 | 20 160 000 | 23 520 000 | 26 880 000 |
| 30% | 20 160 000 | 25 200 000 | 30 240 000 | 35 280 000 | 40 320 000 |

20 % royalty

| USD | 250 000 pat | 312 500 pat | 375 000 pat | 437 500 pat | 500 000 pat |
|-----|-------------|-------------|-------------|-------------|-------------|
| 1% | 134 400 | 168 000 | 201 600 | 235 200 | 268 800 |
| 2% | 268 800 | 336 000 | 403 200 | 470 400 | 537 600 |
| 5% | 672 000 | 840 000 | 1 008 000 | 1 176 000 | 1 344 000 |
| 10% | 1 344 000 | 1 680 000 | 2 016 000 | 2 352 000 | 2 688 000 |
| 20% | 2 688 000 | 3 360 000 | 4 032 000 | 4 704 000 | 5 376 000 |
| 30% | 4 032 000 | 5 040 000 | 6 048 000 | 7 056 000 | 8 064 000 |

12. SALES POTENTIAL OTHER GEOGRAPHIES

Sales potential in China

To launch in China, OncoZenge is dependent on securing financing or a partnership agreement—potentially with Yangtian Pharma—that would cover a local Phase 3 or bridging study for regulatory approval. The market also represents a significant opportunity, and having Yangtian Pharma as a major shareholder could likely facilitate this process. The Company estimates that the number of patients developing OM annually amounts to 1,500,000, with a similar annual growth rate of 2–3% as in the rest of the world.

Furthermore, the Company considers a price per lozenge of SEK 15–20 to be reasonable and believes that peak uptake could reach 30% of the population. Based on these assumptions, OncoZenge estimates potential annual peak sales for BupiZenge™ of SEK 2 billion in 2034, of which up to SEK 400 million could accrue to the Company in the form of royalties.

Market potential in China

| Adoption rate | 20% | 25% | 30% | 35% | 40% |
|---------------|-------------|-------------|-------------|-------------|-------------|
| USD | 300 000 pat | 375 000 pat | 450 000 pat | 525 000 pat | 600 000 pat |
| 1,5 USD | 75 600 000 | 94 500 000 | 113 400 000 | 132 300 000 | 151 200 000 |
| 1,75 USD | 88 200 000 | 110 250 000 | 132 300 000 | 154 350 000 | 176 400 000 |
| 2 USD | 100 800 000 | 126 000 000 | 151 200 000 | 176 400 000 | 201 600 000 |

Market penetration and revenue at \$1.75 per tablet

| USD | 300 000 pat | 375 000 pat | 450 000 pat | 525 000 pat | 600 000 pat |
|-----|-------------|-------------|-------------|-------------|-------------|
| 1% | 882 000 | 1 102 500 | 1 323 000 | 1 543 500 | 1 764 000 |
| 2% | 1 764 000 | 2 205 000 | 2 646 000 | 3 087 000 | 3 528 000 |
| 5% | 4 410 000 | 5 512 500 | 6 615 000 | 7 717 500 | 8 820 000 |
| 10% | 8 820 000 | 11 025 000 | 13 230 000 | 15 435 000 | 17 640 000 |
| 20% | 17 640 000 | 22 050 000 | 26 460 000 | 30 870 000 | 35 280 000 |
| 30% | 26 460 000 | 33 075 000 | 39 690 000 | 46 305 000 | 52 920 000 |

20 % royalty

| USD | 300 000 pat | 375 000 pat | 450 000 pat | 525 000 pat | 600 000 pat |
|-----|-------------|-------------|-------------|-------------|-------------|
| 1% | 176 400 | 220 500 | 264 600 | 308 700 | 352 800 |
| 2% | 352 800 | 441 000 | 529 200 | 617 400 | 705 600 |
| 5% | 882 000 | 1 102 500 | 1 323 000 | 1 543 500 | 1 764 000 |
| 10% | 1 764 000 | 2 205 000 | 2 646 000 | 3 087 000 | 3 528 000 |
| 20% | 3 528 000 | 4 410 000 | 5 292 000 | 6 174 000 | 7 056 000 |
| 30% | 5 292 000 | 6 615 000 | 7 938 000 | 9 261 000 | 10 584 000 |

13. SALES POTENTIAL OTHER INDICATIONS

In addition to the primary indication of oral mucositis, there are several potential areas where BupiZenge™ could be used. We have identified two areas that we believe will be the focus, and where BupiZenge™ could serve as a complement to existing pain treatments.

Burning Mouth Syndrome (BMS) – a chronic pain condition in the oral cavity with no clear underlying cause, where there is a strong need for effective and well-tolerated treatments.

Local anesthesia in dentistry – particularly for postoperative pain following procedures such as wisdom tooth extraction, root canal treatment, or minor jaw surgery, where a non-invasive alternative such as BupiZenge™ may be attractive.

At present, we consider it difficult to quantify the addressable patient share within these areas. For this reason, these indications should currently be regarded as long-term options in the case.

Burning Mouth Syndrome

According to studies, BMS has an estimated prevalence of 1.7% in the global general population, with the highest prevalence found in Europe, where 5.6% of the general population is affected according to studies. The total population of Europe, excluding Russia, amounts to approximately 600 million inhabitants.

We have chosen to make an estimate of the population of BMS patients who would be suitable for BupiZenge™.

- » An assumed prevalence of 5% in Europe, excluding Russia, results in a total population of 30 million patients.
- » We assume that 10% of these patients would be suitable for BupiZenge™, corresponding to a market of 3 million BMS patients.
- » For simplicity, we have chosen to assume a treatment cycle equivalent to that for OM patients, with a corresponding revenue per patient.

Market potential BMS Europe

| EUR | 4 EUR | 5 EUR | 6 EUR |
|-----|-------------|-------------|-------------|
| 1% | 20 160 000 | 25 200 000 | 30 240 000 |
| 2% | 40 320 000 | 50 400 000 | 60 480 000 |
| 3% | 60 480 000 | 75 600 000 | 90 720 000 |
| 4% | 80 640 000 | 100 800 000 | 120 960 000 |
| 5% | 100 800 000 | 126 000 000 | 151 200 000 |

15 % royalty

| USD | 4 EUR | 5 EUR | 6 EUR |
|-----|------------|------------|------------|
| 1% | 3 024 000 | 3 780 000 | 4 536 000 |
| 2% | 6 048 000 | 7 560 000 | 9 072 000 |
| 3% | 9 072 000 | 11 340 000 | 13 608 000 |
| 4% | 12 096 000 | 15 120 000 | 18 144 000 |
| 5% | 15 120 000 | 18 900 000 | 22 680 000 |

13. SALES POTENTIAL OTHER INDICATIONS

Local anesthesia in dentistry

According to Verified Market Reports, the market for analgesics in dentistry amounted to USD 8.5 billion in 2024. Approximately 20% of this market is in Europe, corresponding to USD 1.7 billion. At present, it is difficult to determine what proportion of patients would potentially be suitable for treatment with BupiZenge™, but to provide an indication of the potential, we have outlined an estimated market size below.

Market potential for dental care in Europe

| Market share | EUR |
|--------------|------------|
| 1% | 15 000 000 |
| 2% | 30 000 000 |
| 3% | 45 000 000 |
| 4% | 60 000 000 |
| 5% | 75 000 000 |

15 % royalty

| Market potential 1 EUR | |
|------------------------|------------|
| 1% | 2 250 000 |
| 2% | 4 500 000 |
| 3% | 6 750 000 |
| 4% | 9 000 000 |
| 5% | 11 250 000 |

14. PATENT PROTECTION

Patent protection

OncoZenge currently holds granted patents in the United States, Canada, Australia, and Europe. In 2021, the Company was granted a new European patent valid until 2032/2033. This patent provides broad protection for lozenges containing bupivacaine for the treatment of pain in the oral cavity and builds on the Company's original patent relating to the use of lozenges for the treatment of oral mucositis in cancer patients.

To further strengthen and extend its intellectual property protection, OncoZenge has filed a new patent application. If granted, this would extend patent protection for BupiZenge™ until 2045. The application has already received a positive opinion in the form of an international search report and a written opinion from the Patent Cooperation Treaty (PCT) authority, which is a strong indication of patentability.

The next step in the process is to file applications at the national or regional level in the countries and jurisdictions prioritized under the Company's patent strategy.

The PCT (Patent Cooperation Treaty) is an international system that enables applicants to seek patent protection for innovations in more than 150 countries through a single application. The system provides a preliminary assessment of the invention's patentability before entering the so-called national phase, in which individual countries examine and potentially grant the applications at the national or regional level.



*OncoZenge has granted patents in
USA, Canada, Australia and Europe.*

15. PARTNERSHIPS SECURED

Molteni Farmaceutici

OncoZenge has entered into a binding agreement with Molteni regarding the commercialization of BupiZenge™ in Europe. The binding agreement grants Molteni exclusive rights for commercialization within the region. The agreement includes the following royalty structure for OncoZenge:

- » 15% royalty on annual sales up to EUR 30 million
- » 18% royalty on sales between EUR 30–60 million
- » 20% royalty on annual sales above EUR 60 million

In addition, OncoZenge may receive up to EUR 4.3 million in milestone payments. Should Molteni sublicense the rights in individual European countries, OncoZenge is entitled to 50% of any upfront payments from such agreements. With support from Molteni, OncoZenge will now proceed to finalize the Phase 3 study protocol.

Milestone payments

OncoZenge will be entitled to a total of EUR 4.3 million in potential milestone payments from Molteni. To date, the Company has received a milestone payment of EUR 250,000, which was paid upon the signing of the final partnership agreement on March 28, 2025.

| Milestone | Payment |
|---|---------------|
| Final agreement | 250 000 EUR |
| Approval for phase 3 clinical trial application | 550 000 EUR |
| 10 MEUR accumulated net sales | 500 000 EUR |
| 20 MEUR accumulated net sales | 1 000 000 EUR |
| 30 MEUR accumulated net sales | 1 000 000 EUR |
| 40 MEUR accumulated net sales | 1 000 000 EUR |

About Molteni Farmaceutici

Molteni is a leading Italian pharmaceutical company specializing in therapeutic solutions for pain management and the treatment of drug addiction. Founded in 1892, the company is headquartered in Florence, Italy, with in-house capabilities in manufacturing, R&D, regulatory affairs, supply, marketing, and distribution. Molteni has a broad distribution reach across Europe and globally, and employs over 300 people.

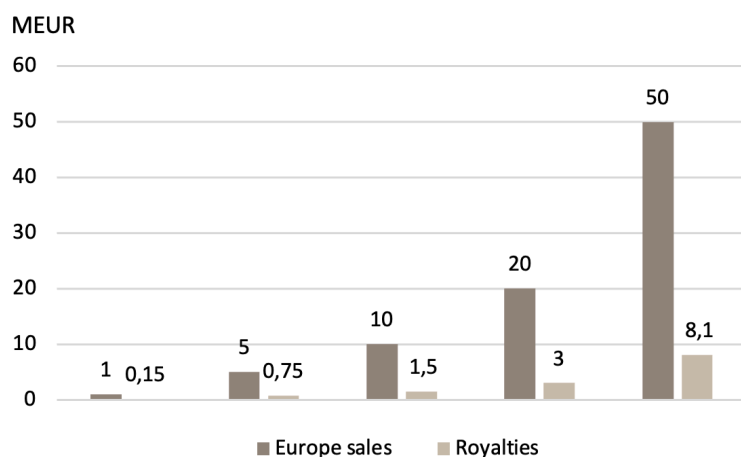
Molteni has a well-matched profile, with a large share of its revenues coming from opioids and analgesics. BupiZenge™ therefore fits well within the existing product portfolio and expands the company's activities into oncology.



15. PARTNERSHIPS SECURED

Royalties

The relatively “low” potential milestone payments mean that assumptions regarding future royalties become critical. For the Company to generate significant royalties from Europe, substantial sales volumes will be required. In our assessment, it will therefore be important for OncoZenge to secure licensing agreements in additional markets.



Sichuan Yangtian Bio-Pharmaceutical

OncoZenge has entered into an investment agreement of SEK 30.2 million with Yangtian Pharma, securing the funding for the Company's planned European Phase 3 study of BupiZenge™.

The agreement entails the issuance of up to approximately 4.7 million new shares to Yangtian Pharma through four directed share issues. The subscription price represents a premium of approximately 40% compared to the volume-weighted average price (VWAP) over the 20 trading days up to January 24, 2025. The total number of shares in OncoZenge will thereby increase from approximately 11.7 million to 16.4 million, representing a manageable dilution for existing shareholders.

Following the full completion of the investment, Yangtian Pharma is expected to become the largest shareholder in OncoZenge, with an ownership stake of approximately 28.5% of the share capital. Impala Nordic views the transaction positively, as it provides the Company with a substantial capital injection, thereby securing the financing for the Phase 3 study.

In addition, Yangtian's interest in evaluating the U.S. market signals a strategically important opportunity. As the U.S. is by far the largest commercial market for BupiZenge™, the ability to access this market is critical to the Company's future revenue potential. Having Yangtian Pharma as a major shareholder may also offer strategic advantages for a future launch in Asia, where OncoZenge, as a smaller company, could benefit from Yangtian's local presence and expertise.

15. PARTNERSHIPS SECURED

Breakdown of the share issue

Tranches 1 and 2 were received on July 11, 2025, from Yangtian Pharma and were conditional upon shareholder approval of the directed share issues and the completion of the Phase 3 study plan. Tranche 3 is conditional upon the Company submitting the complete application for the European Phase 3 clinical trial of BupiZenge™, and Tranche 4 is conditional upon the Company obtaining European approval for the Phase 3 clinical trial application.

Yangtian Pharma investment tranches

| Tranches | Amount of investment | Amount | Time for payment | Terms |
|-----------|----------------------|-----------|-------------------|--|
| Tranche 1 | 10% | 3 MSEK | 11 july 2025 | Approval from AGM |
| Tranche 2 | 10% | 3 MSEK | 11 july 2025 | Finalized phase 3-study plan |
| Tranche 3 | 30% | 9,1 MSEK | Q3 2025 - Q1 2026 | Submission of application for phase 3 clinical trial |
| Tranche 4 | 50% | 15,1 MSEK | Q3 2025 - Q1 2026 | Approval for phase 3 clinical trial application |

About Yangtian Pharma

Yangtian Pharma Co. is a Chinese pharmaceutical company founded in 1993 and headquartered in Chengdu, Sichuan. The company develops, manufactures, and distributes medicines based on both modern medicine and traditional Chinese medicine.



Use of proceeds

Approximately 67 percent of the investment from Yangtian will be used to conduct the clinical Phase 3 study. The remaining proceeds will be used for general corporate purposes and operational activities during 2025–2026, including work related to licensing in markets outside Europe, commercial preparations, and the development of a strategy for the launch of a U.S. market plan.

15. PARTNERSHIPS SECURED

Licensing Agreement in the GCC Region with Avernus Pharma

OncoZenge has signed a licensing agreement with Avernus Pharma for the distribution of BupiZenge™ in the GCC region, which includes Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, and the United Arab Emirates. Under the agreement, Avernus Pharma will become the exclusive distributor of BupiZenge™ in the region, provided that the Phase 3 study is successfully completed and approval is obtained from the Gulf Central Committee for Drug Registration (GCC-DR).

OncoZenge will support Avernus Pharma in regulatory applications as well as in establishing volume supply of the product. Avernus Pharma will be responsible for financing both the regulatory processes and the necessary marketing and distribution infrastructure to enable an effective launch.

The agreement also includes commercial milestones of up to a total of USD 130,000, to be paid by Avernus Pharma in two stages:

- » Upon first market approval in a GCC country
- » Upon achieving sales targets

The GCC region has a total population of over 60 million people, with Saudi Arabia accounting for more than half. The region's increasing investment in specialized healthcare, combined with a growing oncology patient population, makes the market strategically important for OncoZenge in the medium term.

About Avernus Pharma

Avernus Pharma is a Dubai-based pharmaceutical company and part of ZAS Group. The company focuses on marketing and distributing innovative pharmaceuticals and medical devices across the Middle East, particularly within the Gulf Cooperation Council (GCC) countries. With over 130 employees and offices in Dubai, Avernus is an established player in regional pharmaceutical distribution, serving as a bridge between global pharmaceutical and biotechnology companies and the Middle Eastern markets.

We view positively the fact that OncoZenge has secured licensing beyond Europe, while another player confirms the interest and potential for BupiZenge™. The financial impact of the agreement is relatively limited, and in our view, it should be considered a bonus to the investment case, with the main focus remaining on the European pathway.



16. PHASE 3 UPCOMING

The upcoming Phase 3 study represents the single most important milestone in OncoZenge's development, as it will form the basis for a potential market authorization in Europe. A feasibility study is currently being conducted by LINK Medical, aimed at identifying suitable clinics, optimizing patient recruitment, and clarifying the study's overall timeline. The study is expected to commence sometime during the first half of 2026.

The trial is planned to include approximately 150 patients and will be conducted exclusively at European clinics. This marks a change from the previous plans for a multinational design. Although a purely European study entails higher costs, this strategy is made possible through accelerated milestone payments from Molteni and a convertible loan from the main shareholder, Linc.

The relatively limited size of the study—with 150 patients, only six weeks of treatment, and one month of follow-up—helps keep the cost level significantly lower than that of an average Phase 3 trial. Furthermore, it is a logistically uncomplicated study, with few physical visits, as follow-up often takes place remotely or in connection with the patients' regular radiotherapy sessions.

Since oral mucositis is a common condition, patient recruitment is not expected to present a major obstacle. The decision to conduct a fully European study also entails several strategic advantages:

- » Simplified regulatory process, as all patients are enrolled within the region where approval is being sought.
- » Reduced regulatory and operational risk, as the data will be directly relevant for European authorities.
- » Access to a strong network of European Key Opinion Leaders (KOLs), strengthening the Company's position ahead of a future market launch of BupiZenge™ in Europe.

Meribel Pharma Solutions Engaged as CDMO

OncoZenge has engaged Meribel Pharma Solutions (formerly Recipharm) as its contract development and manufacturing organization (CDMO) for the production of clinical trial material for the upcoming Phase 3 study of BupiZenge™. Meribel is responsible for manufacturing the investigational medicinal product, and the companies are working together to complete all necessary activities and documentation ahead of the submission of the Clinical Trial Application (CTA) and subsequent project delivery.

We consider Meribel to be a competent and strategically well-suited CDMO partner for OncoZenge. The fact that Meribel was previously part of Recipharm, one of Europe's leading contract manufacturing companies, is viewed as a clear mark of quality. Recipharm was formerly publicly listed but was acquired in 2021 in a high-profile transaction by founders Thomas Eldered and Lars Backsell, together with EQT. The offer at the time valued Recipharm at nearly SEK 25 billion.

The partnership with Meribel therefore strengthens the conditions for a regulatory and operationally robust execution of the Phase 3 study and demonstrates that the Company has secured a professional and experienced production chain for its clinical development.



16. PHASE 3 UPCOMING

Objectives of the Phase 3 Study

Primary objective: To evaluate the efficacy of BupiZenge™ compared with lidocaine in the treatment of oral cavity pain.

Primary endpoint: Mean patient-reported oral cavity pain intensity and duration during treatment, assessed one hour after dosing during the first two weeks following randomization. For the first 14 days after treatment initiation, starting on Day 2, participants will assess their pain on a Numerical Rating Scale (NRS) 60 minutes after dosing, three times per day, every other day. If fewer than three doses are taken on a given day, pain assessments will only be performed at the actual dosing times, and unused time points will be excluded. Reminder strategies (e.g., push notifications) will be used to promote compliance.

Key secondary objectives and endpoints: Safety and tolerability, use of systemic opioids, patient-reported quality of life, the patient's ability to eat and drink, the progression of oral mucositis, and pharmacokinetics (assessed in a subgroup of patients).

Inclusion criteria

- » Adults aged 18–80 years with histologically confirmed squamous cell carcinoma of the head and neck (HNC) undergoing or about to begin intensity-modulated radiotherapy (IMRT), with an expected survival of at least six months.
- » Must not have pre-existing pain in the mouth or throat, prior radiotherapy to the head or neck, ongoing treatment with high-dose corticosteroids, mouth or throat pain solely attributable to the primary tumor or surgical wound rather than oral mucositis (OM), or be taking opioids for any reason before study start.

Randomization criteria

- » New-onset oral and/or throat pain due to oral mucositis, rated at least 4 on an 11-point Numerical Rating Scale (NRS) on at least one occasion after starting HNC treatment.
- » Oral mucositis of grade 1 or higher.



17. USA

Going forward

OncoZenge has not yet communicated a clear plan for establishing a presence in the U.S., but is working toward eventually reaching the market through partnerships. We assess that the Company is likely to postpone initiating studies or entering into partnerships in the U.S. until results from the planned European Phase 3 study are available, or a potential European marketing authorization has been obtained. This would both provide clear proof of concept and strengthen the commercial value of BupiZenge™ in potential future negotiations with U.S. licensees or partners.

To obtain FDA marketing approval, regulatory practice requires that clinical studies be conducted in U.S. patients. The scope of such a future study is expected to vary depending on the strength of the data generated in the European Phase 3 study. Strong European study results could potentially strengthen the data package for a future U.S. application, although an American registration-enabling study will still be required.

It is also important to note that the scope of such a U.S. study will significantly affect the Company's future capital requirements. However, an approved product in Europe with documented clinical efficacy could, at that stage, increase the likelihood of attracting a strong and well-capitalized partner for the U.S. market.

Background to Previous Suspension of U.S. Plans Previous Flavoring

Due to stricter regulatory requirements from the U.S. Food and Drug Administration (FDA), OncoZenge initially decided to focus on a European launch of BupiZenge™. One key issue in earlier FDA discussions concerned the original flavoring (licorice), which triggered requirements for additional safety studies.

Bupivacaine has a very bitter taste, requiring effective flavor masking for tolerability in oral administration. In the earlier formulation, licorice was used as the flavoring agent. However, the FDA raised concerns that glycyrrhizic acid – the sweet-tasting main component in licorice – may, at high doses and with prolonged intake, cause electrolyte imbalances and elevated blood pressure.

To address this regulatory challenge, the Company reformulated the product, replacing the licorice flavor with orange, thereby eliminating the need for additional safety studies related to the licorice component. This change effectively removed the FDA-related regulatory hurdle.

Protocol Deviation – Safety Threshold Exceeded

In April 2022, OncoZenge announced in a press release that the then-planned patient study with BupiZenge™ was discontinued, after the drug candidate was deemed to pose a potential patient safety risk under U.S. regulatory requirements.

The decision was based on the fact that the U.S. Food and Drug Administration (FDA) applies a stricter threshold for non-toxic plasma concentrations of bupivacaine, with a maximum limit of 1,000 ng/mL. This is lower than in other geographies, where the threshold is typically set at 2,000 ng/mL.

In a previously conducted Phase II patient study with seven days of treatment using BupiZenge™ (25 mg lozenges), one patient recorded slightly higher plasma concentrations than the FDA's threshold. It is important to note the following: no serious adverse events were observed in the study; all other participants had plasma concentrations well below the applicable thresholds; and the single patient who exceeded the FDA limit deviated from the study protocol, which likely explains the observed result.

18. PEERS

For a company approaching Phase 3, OncoZenge is valued at a notably low level compared to the typical company at a similar stage. At the same time, we find it difficult to conduct a fair peer comparison, as no other company on the Swedish stock market operates within the same indication. That said, we note that OncoZenge is among the research companies with the lowest market capitalisation relative to its development stage and market potential.

Sample of peers

| Company | Lead candidate | Indication | MCAP (MSEK) |
|------------------|--------------------|-----------------------|-------------|
| Acucort | Commercial | Allergic reactions | 150 |
| Initiator Pharma | Completed Phase 2b | Erectile dysfunction | 240 |
| SynAct Pharma | Phase 2b | Inflammatory diseases | 1 000 |
| Moberg Pharma | Commercial | Nail fungus | 450 |
| Klaria Pharma | Commercial | Migraine | 125 |
| Dicot Pharma | Phase 2a | Erectile dysfunction | 1 400 |
| OncoZenge | Phase 3 | Oral mucositis | 80 |



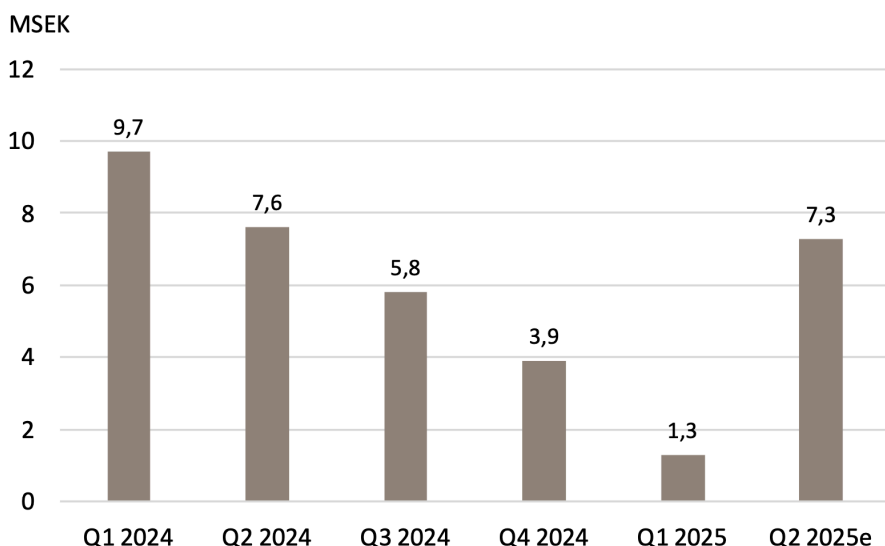
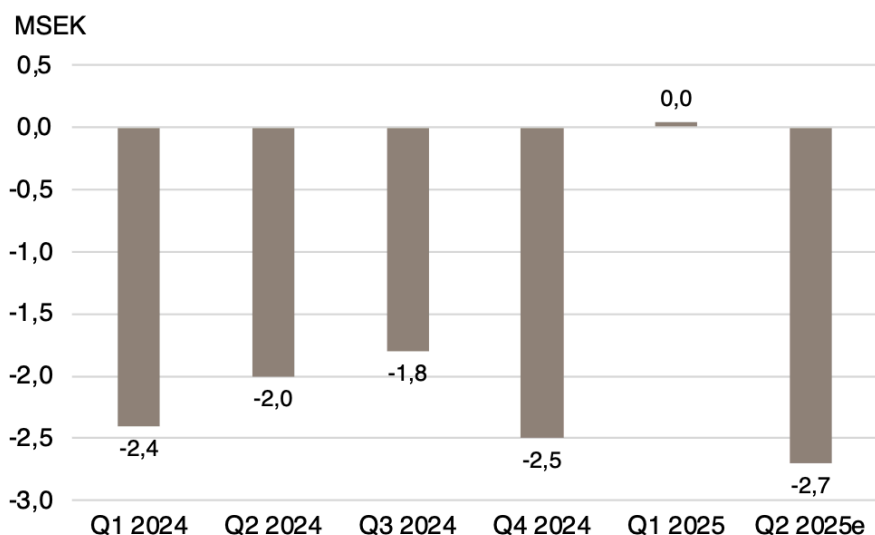
19. FINANCIALS

Financing secured

OncoZenge currently reports no recurring revenues apart from milestone payments from its licensing partner Molteni. In connection with the final agreement in April 2025, the company received a payment of approximately SEK 2.7 million, which was recognised as net sales in Q1. However, the amount was not booked as cash, which means the reported cash position appears lower.

The company's cost base over the past two quarters has been around SEK 2.5 million per quarter, mainly consisting of operating expenses and costs related to the planning of the upcoming Phase 3 trial. We expect costs to increase significantly as the Phase 3 project transitions from planning to execution.

This anticipated cost increase is expected to be balanced by previously secured external funding, including investment capital from Yangtian Pharma (SEK 30.2 million), milestone payments from Molteni (EUR 550,000) and a convertible loan of SEK 7.5 million from main shareholder Linc AB. This combination of funding sources means OncoZenge is currently considered to have sufficient financial capacity to complete its Phase 3 trial without additional capital raising in the short term.



20. VALUE DRIVERS AND RISKS

Value drivers



The main value drivers for OncoZenge going forward include the execution of the Phase 3 trial and subsequent study results. Positive data from the trial will be critical both for obtaining market approval and for enabling more favourable pricing upon a future product launch. A potential European market approval is regarded as the most significant value driver, and we expect such approval could be achieved in 2027.

Furthermore, there is potential for out-licensing in new geographic regions, which could broaden the company's revenue base. Finally, initiating activities targeting the U.S. market will be highly important for OncoZenge's long-term revenue potential, where we expect the company to seek a commercial partner.

Summary of value drivers:

- » Approval to initiate study
- » Commencement of patient enrollment for Phase 3
- » Completion of patient enrollment
- » Positive results from Phase 3
- » Strong study results may support higher pricing
- » Market authorization in Europe
- » Out-licensing in new regions
- » Activation of U.S. market strategy

Risks



One of the key risks for the case going forward is the outcome of the Phase 3 study, which will be decisive for obtaining market approval. In addition, there is a risk of delays in the execution of the study, which would impact the Company's capital requirements. An example would be challenges in patient recruitment, although oral mucositis is considered a relatively straightforward patient population to enroll.

On the commercial side, there may also be challenges in establishing BupiZenge™ as a new standard of care, which should not be underestimated. Furthermore, regulatory risks remain significant, as the Company is dependent on approvals from the relevant authorities to commercialise the product. However, these are general risks to which all research-based companies are exposed.

Finally, the financing of a potential U.S. study represents an additional uncertainty, as it will likely require significant capital.

Summary of risks:

- » Phase 3 study data
- » Study delays
- » Commercial risks
- » Regulatory risks
- » Financing of U.S. study

21. SWOT

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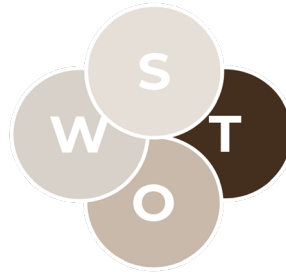
STRENGTHS

- » Financing for Phase 3 study secured
- » Partner-led strategy ensures financial backing
- » EMA approval provides global spillover effect
- » Financially strong major shareholder in Linc
- » Yangtian Pharma can support launch in Asia

WEAKNESSES

W

- » Dependent on external capital
- » Uncertainty regarding pathway to the U.S. market
- » Relatively low upfront and milestone payments from Molteni
- » Uncertain pricing scenario and adoption rate



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OPPORTUNITIES

- » U.S. market and commercialization partner
- » Secure licensees in additional markets
- » Expand future market approval to additional indications

THREATS

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- » New regulatory requirements
- » Delay of the Phase 3 trial
- » Future capital raising on unfavorable terms

22. CORPORATE GOVERNANCE

Management

Stian Kildal, CEO

Stian Kildal has held several leadership positions with responsibility for P&L, product portfolios, and business development in an international setting. Most recently, he served as CEO of the Irish company Ammeon Ltd, which was sold to Intive GmbH following a structured exit process. Previous roles have included leadership in challenging restructuring situations as well as growth ambitions. Stian's leadership is characterized by taking on challenges with a clear vision and strategy, building teams and structures to drive change, and executing towards set goals.

Stian Kildal joined OncoZenge in 2023 and owns 500,000 warrants and 350,000 shares in OncoZenge, directly and through companies.



Michael Owens, CFO

Michael Owens has over 20 years of experience in finance, with a focus on both large and small life science companies. His experience includes auditing at Arthur Andersen and being a Certified Auditor at EY, an active role in listing Karolinska Development, and financial and controller roles for several companies listed on NASDAQ First North. Previous roles have involved business development with divestments, acquisitions, financing, and asset listings.

Michael joined OncoZenge in 2023, and has 10,000 shares in the company.



22. CORPORATE GOVERNANCE

Board of directors

Daniel Ehrenstråhle, Chairman of the board

Born in 1974, Daniel brings extensive experience as an executive, consultant, and advisor across various industries. Central to many of his roles is a broad scope of responsibilities covering strategy, transactions, M&A (buy and sell-side), portfolio management, governance, and go-to-market strategies in an international context. Prior to his 6 years in the executive group for global business units at Ericsson, Daniel worked 7 years at McKinsey and, before that, 3 years at ZS Associates in Paris, focusing on the pharmaceutical sector.

Daniel Ehrenstråhle is independent in relation to both the Company and its management, as well as larger shareholders in the Company. Daniel Ehrenstråhle joined the board in 2023 and holds 350,000 warrants in OncoZenge AB.



Christoph Nowak, MD, PhD, Dipl-Psych, Board member

Born in 1986, Christoph Nowak holds a PhD in molecular epidemiology from Uppsala University, a medical degree from the University of Oxford (UK), and is a licensed psychologist (Diplom-Psychologe) from Braunschweig's Technical University (Germany). Previous experiences include serving as an Assistant Professor at the Karolinska Institute and a physician at Raigmore Hospital in Inverness (Scotland). Chris has authored >60 scientific articles published in peer-reviewed journals, with over 20 as the lead author. Significant roles in other companies include Chief Medical and Business Officer at Diamyd Medical AB and Chief Medical Officer at Melius Pharma AB.

Christoph Nowak is independent in relation to both the Company and its management, as well as larger shareholders in the Company. Christoph Nowak joined the board in 2023 and holds 27,000 Shares and 350,000 warrants in OncoZenge AB.



Mats Lindskog MSc, PhD, MBA, Board member

Born in 1974, Mats Lindskog holds a MSc in Chemical Engineering and a PhD in Biotechnology from the Royal Institute of Technology (KTH) in Stockholm, a postdoctoral fellowship in bioinformatics from Stockholm University, and an MBA from the Blekinge Institute of Technology. He has over 19 years of experience in the pharmaceutical and biotech industries, with leadership roles spanning business development, commercial excellence, sales, marketing, strategy, and operations. Mats currently serves as Chief Business Officer at Oblique Therapeutics and has previously held senior positions at Unimedica Pharma, Allergan, Shire, Novartis, AstraZeneca, and Amgen. He has successfully led multiple licensing agreements and R&D collaborations, including with Eli Lilly, and has built and transformed commercial teams across the Nordic region. In addition to executive roles, Mats has served as a board member for WntResearch and InOrbit Therapeutics.

Mats Lindskog is independent in relation to both the company and its management, as well as major shareholders. He joined the board of OncoZenge AB in 2025.



23. OWNERSHIP

Top 10 owners (based on data from 30th june)

Capital

| | |
|---|-------------|
| Niclas Holmgren | 10,2% |
| Linc AB | 9,3% |
| Andreas Özbek | 8,6% |
| Yangtian Pharma (when completed investment) | 7,4%(28,5%) |
| Avanza Pension | 4,2% |
| Kalle Holmgren | 3,2% |
| Stian Kildal | 3,0% |
| Nordnet Pension | 2,5% |
| Jimmy Mattias Olsson | 2,4% |
| Paul Murtagh | 2,2% |

24. FINAL WORDS

Impala Nordic summarizes

We believe the investment case for OncoZenge has strengthened significantly in 2025, with most obstacles to initiating the Phase 3 study now cleared. The company has secured a commercial partnership for Europe, a distribution partner in the GCC region, and a financial partner in Yangtian Pharma, ensuring funding for the planned European Phase 3 study. The relatively simple study design and short treatment duration point to a swift execution, with potential market approval in Europe in 2027. At the same time, the share is trading at what we consider a low level, given both historical valuation and the progress achieved.

Looking ahead, we see several important triggers, including the start of patient recruitment and study data expected in the second half of 2026. There is also potential to secure partnerships in additional geographies, with the U.S. being the most significant, as well as to develop a strategy for the Chinese market, where majority owner Yangtian Pharma is likely to have a strong interest in commercialization.

With funding for the Phase 3 project secured, OncoZenge now faces the most critical milestones in its history over the next two years. We also view positively that major shareholder Linc AB continues to provide financial support, including through a convertible loan of SEK 7.5 million.



25. DISCLAIMER

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