

Dear Shareholders,

For Biosergen, 2024 was a year marked by several key achievements.

We initiated our first clinical study. The study targets individuals suffering from invasive fungal infections who have exhausted existing treatment options. For these patients, infections have become lifethreatening. The trial, conducted in India, aims to establish proof-of-concept for our antifungal candidate, BSG005, as a safe and effective treatment in this population.

By early 2025, we achieved two important clinical milestones: the completion of both the first and second patient cohorts. In total, ten patients with severe fungal infections were enrolled. Sadly, one patient passed away from causes unrelated to BSG005, and another chose to leave the trial prematurely. Of the remaining eight who completed the full treatment course, several recovered significantly. All patients who received the planned dosing regimen experienced a clear clinical benefit. There have not been any severe adverse events. Also, unlike our main competitor, whose treatment often requires temporary dosing breaks due to frequent side effects, none of our patients needed such a drug dosing pause. In these early studies BSG005 seems to be safe at very high doses.

These results are particularly promising given that the patient population included individuals with drug-resistant Aspergillus and severe Mucormycosis infections. Encouragingly, for the second cohort, investigators requested—and were granted—permission by the independent safety board to raise the maximum dose from 1.5 to 2.0 mg/kg/day. Such an investigator-request is uncommon and underscores the strong safety profile BSG005 has demonstrated thus far. The investigators' desire to treat patients longer and at higher doses speaks to their confidence in BSG005's tolerability and potential. Importantly, a favorable safety profile may potentially boost a drug's competitiveness, and a long treatment cycle may also prove advantageous in regions where treatment pricing is tied to total consumption of the drug.

We aim to initiate the third cohort once our drug supply is replenished, most likely in the fourth quarter of 2025. Due to the higher-than-anticipated dosing in cohort two following investigators request, we must ensure that we have sufficient drug stock for the third cohort.

Looking ahead, we are preparing for important regulatory interactions: one with India's CDSCO to determine the optimal pathway toward a Phase 2 trial, and with the U.S.A's FDA aimed at having a Pre-IND meeting and at submitting an Investigational New Drug (IND) application, which will allow us to initiate a clinical trial in the U.S. Finally, we prepare for a potential start of a EU phase 2 trial.

A central focus throughout the year was ensuring stable funding for our continued development efforts. It was therefore very gratifying that we successfully raised SEK 26 million through a rights issue in March. This was followed by the full subscription of the TO3 warrants in November, which secured an additional SEK 45 million. The successful capital raising throughout the year enabled us to initiate patient enrollment in our first clinical trial.

There are encouraging signs of increasing international awareness, particularly concerning antimicrobial resistance (AMR). At Biosergen, we closely monitor and remain vigilant for opportunities for non-dilutive funding, such as grants, along with strategic corporate partnerships that supports further development. BSG005 has demonstrated preclinical efficacy against a wide range of the most dangerous fungal pathogens. As awareness of fungal AMR grows, the recognition of BSG005 as part of the solution may increase.

I took over as the CEO in the beginning of the year. Peder Andersen stepped into a role as Chief Medical Officer. I would like to thank Peder Andersen for the work he has done for Biosergen in the previous years, it has been a tremendous effort. In this first year as the CEO, I am very proud of our achievements, we managed to get the first clinical study off the ground and the study creates hope for patients that have a severe life-threatening infection that requires immediate treatment

Finally, I would like to express my sincere gratitude to all our investors, clinical partners, and collaborators for their ongoing support throughout 2024. In 2025, we remain fully dedicated to advancing the development of BSG005 at full speed.

Sincerely,

Tine Olesen
CEO of Biosergen

## OTHER INFORMATION

### BSG005 in brief

In brief, BSG005 is an important new drug in the field of antifungals because of its fungicidal effect (it kills the fungus), which is preferable to drugs with a fungistatic effect (inhibiting the fungus, not killing it). Due to the fungicidal effect BSG005 does not create resistance to treatment as fungistatic antifungals do. Moreover, it is a broad-spectrum antifungal agent, the only approved comparable antifungal drug with a similarly broad cover of fungal strains is Amphotericin B. However, BSG005 does not possess the same toxic properties as Amphotericin B and other drugs from the same drug group (Polyenes), as shown in a Phase 1 trial in healthy subjects. In addition, BSG005 has also shown effect against resistant fungal strains and other strains that have been difficult to treat with the drugs available on the market in vitro. Finally, the first 10 patients have been treated with BSG005 as a rescue therapy generating data in patients that had failed standard of care due to safety or efficacy. Two patients achieved complete recovery, six patients showed significant improvements, one patient voluntarily withdrew and one severely ill patient, unfortunately, passed away due to causes unrelated to BSG005. The positive outcomes underscore BSG005's potential as a secure, life-saving rescue therapy.

#### **Business model**

Biosergen is a clinical stage research and development biopharmaceutical company dedicated to developing and commercializing its unique clinical asset BSG005 into becoming the gold standard in antifungal therapy. The company collaborates with its academic partners and will be funded whenever possible through public grants.

## Strategic partnerships

In September 2023 Biosergen entered into a strategic partnership with the Indian multinational pharmaceutical company Alkem Laboratories Ltd ("Alkem").

Alkem is among the five largest pharmaceutical companies in India, and has more than 17,000 employees, with affiliates in the USA, Australia, UK, Germany, and many other emerging countries. Alkem is a leader in the anti-infective market, with clinical development expertise and an established commercial infrastructure. Moreover, Alkem has 144 ANDAs, two manufacturing sites and two R&D sites in the US market. Alkem, with its established clinical development engine, access to a broad clinical network and strong commercialization capabilities, is an ideal corporate partner for Biosergen.

Alkem is managing the ongoing clinical patient trial, where the first ten patients have completed the study. The trial enrolls patients suffering from severe fungal infections such as Mucormycosis (Black Fungus), aspergillosis, and candidiasis, who are intolerant or resistant to Amphotericin B, failing standard of care or have mild to moderate kidney impairment. Based on the safety and efficacy profile demonstrated in preclinical studies and the phase I trials, BSG005 may provide a suitable treatment option for these patients. Following the ongoing clinical trial in India, Biosergen and Alkem aim to expand its use for similar patient groups in the US and EU via pivotal trials. Alkem will invest in the coming clinical phase 2 and 3 developments of BSG005 by funding all clinical trials in India for local regulatory approvals and will be granted an exclusive license to market it in India. Alkem's investment in clinical development will be converted into Biosergen shares at the higher of i) 10x the share price at closing of the agreement between Alkem and Biosergen, or ii) a 50 percent premium of the share price at the dates of the conversions. The share conversions are dependent on approval by a shear holders meeting and shall take place as a staged investment with conversion at completion of the specific clinical studies.

## **Patents**

Biosergen has strong patent protection family in four regions, USA, EU, Japan, China Australia, major parts of the EU as well as other countries. The patents consist of both granted patents and patents under evaluation, providing patent protection until 2043 if granted.

## Orphan drug status - Aspergillosis

Biosergen was granted orphan drug status for BSG005 by the FDA in June 2021, based on the expectation that fewer than 200,000 patients per year in the USA with invasive aspergillosis will be treated with the medication. One of the advantages of orphan drug status is guaranteed market exclusivity for a limited period after the drug's approval (currently five years in the USA).

In 2012, the United States Congress established GAIN (Generating Antibiotic Incentives Now) to provide incentives for the development of antibacterial and antifungal drugs for human use, intended to treat serious and life-threatening infections. Under GAIN, a drug can be designated as a Qualified Infectious Disease Product ("QIDP"), if it meets the criteria outlined in the statute, which the Company expects BSG005 to fulfill. A drug receiving QIDP designation is eligible for priority designation and review under the statute, along with additional market exclusivity (currently five years).

Biosergen intends to apply for GAIN/QIDP status in the USA after the Phase 2 data has been published, as this information will be required for the application process.

The study planned in aspergillosis is planned to incorporate a phase 2/3 adaptive design. The patients to be included should have proven/probable invasive aspergillosis. The goal is to evaluate all-cause mortality after 12 weeks of treatment. Approximately 150 patients are planned for the adaptive design.

This study is a global study planned to be performed in collaboration with Biosergen's Indian partner, Alkem. Alkem will be responsible for the patients recruited in India and Biosergen will be responsible for the patients coming from the rest of the world. Biosergen can use the data generated in India world-wide.

## **FUNGAL INFECTIONS ARE INCREASING**

Of the hundreds of thousands of fungal species, only a few hundred can infect humans and even fewer have the capacity to cause serious health problems. However, when they do infect humans, fungi can cause a variety of illnesses with symptoms ranging from a mild rash to life threatening pneumonia and death. Well known diseases frequently associated with fungal infection include various allergies, lung infections and meningitis, but also much less dangerous ailments such as athlete's foot and thrush (a mouth infection typical in newborns).

## Fungal infection is an increasing problem

In January 2024, new numbers on the incidence of severe life-threatening fungal disease were published. It is estimated that 6.5 million people have life threatening fungal disease. The mortality rate attributable to fungal disease alone is 2.5 million people. In other words, these are patients whose cause of death is fungal disease, regardless of any other condition they may have<sup>1</sup>. It is an increase of 66 percent compared to numbers published in 2017. One notable patient group included in the current numbers are patients with chronic obstructive pulmonary disease (COPD), these have not previously been included. The risk for a COPD patient of being infected with a life-threatening disease is much higher than previously anticipated.

The factors behind the increased incidence, particularly of serious invasive (systemic) fungal infections, can be grouped into three broad categories:

## Opportunistic fungal infection

The incidence of opportunistic fungal infections, such as cryptococcosis and aspergillosis, is increasing because the number of people with weakened immune systems continues to increase, both in developed and developing countries. This group includes individuals with chronic obstructive lung disease, cancer patients, transplant recipients, people taking medications that weaken the immune system, and those living with HIV/AIDS.<sup>2</sup>

## Hospital-acquired infection

Hospital-acquired infections, including bloodstream infections, pneumonia, and urinary tract infections are on the rise, also in the developed world. The increase has multiple causes, including more hospitalized patients with weakened immune systems, an increasing elderly population, and more invasive medical procedures.

<sup>&</sup>lt;sup>1</sup> David Denning, The Lancet Infectious Diseases, January 2024

<sup>&</sup>lt;sup>2</sup> It is estimated that close to 50% of all AIDS related deaths are attributable to an invasive fungal infection. GAFFI (Global Action Fund for Fungal Infection), August 2017

## Community acquired infection

Certain fungal species live in particular geographies and/or environments and are known to be sensitive to changes in temperature and moisture. There has been an increase in fungal infection outbreaks in recent years in certain regions. These outbreaks are almost certainly linked to demographic changes and climate changes.

## Four species are responsible for the majority of life threatening invasive fungal infections

Most invasive fungal infection-related serious illnesses and deaths are caused by four particular fungal pathogens: *Candida*, *Aspergillus*, *Cryptococcus* and *Pneumocystis*.

#### Candida

Candida is a yeast that causes infections in individuals with deficient immune systems. Systemic Candida infections of the bloodstream and major organs, occur particularly in immunocompromised patients. The infection can occur in the mouth and throat, vagina, or bloodstream. People with diabetes and HIV are particularly susceptible to Candidiasis. It is estimated that approximately 1,500,000 people worldwide develop invasive Candidiasis (including candidemia) every year<sup>3</sup>, and that more than half of all sales of antifungal drugs (52%) are directed against the Candida pathogen<sup>4</sup>

#### Aspergillus

Aspergillus cause Aspergillosis which primarily develops in people with weakened immune systems or lung diseases. These fungi also cause allergic reactions. Types of aspergilloses include chronic obstructive lung disease (COPD), allergic bronchopulmonary aspergillosis and invasive aspergillosis, both of which conditions are potentially lethal. It is estimated that more than 2,000,000 people worldwide develop Aspergillosis every year<sup>1</sup> and that approximately 21 percent of all sales of antifungal drugs are directed against the Aspergillus pathogen.

## **Cryptococcus**

*Cryptococcus* is rare in healthy people but in patients suffering from HIV infections and AIDS it can cause life threatening forms of meningitis and meningo-encephalitis. It is estimated that approximately 150,000 AIDS patients develop life threatening Cryptococcosis every year and that approximately 7 percent of all sales of antifungal drugs are directed against the *Cryptococcus* pathogen.

## **Pneumocystis**

Pneumocystis is a frequent source of opportunistic lung infections in people with a weak immune system or other predisposing health conditions. It is often seen in patients suffering from HIV infections and AIDS but is also found in patients using immunosuppressing medications and people with cancer, autoimmune or inflammatory conditions, and chronic lung disease. It is estimated that approximately 400,000 people develop pneumocystis pneumonia every year and that less than 5 percent of all sales of antifungal drugs are directed against the *Pneumocystis* pathogen.

<sup>&</sup>lt;sup>3</sup> Bongomin et al. Journal of Fungi, October 2017

<sup>&</sup>lt;sup>4</sup> Market Research Future. *Global Antifungal Treatment Market forecast to 2027*.

## Incidence and crude mortality for severe fungal infections compared<sup>2</sup>

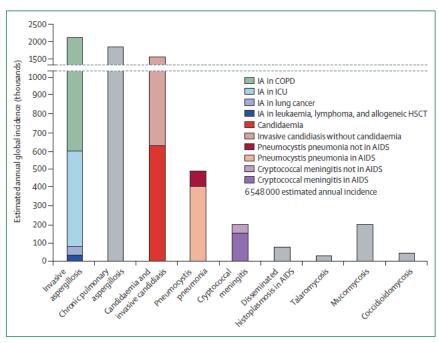


Figure 1: Estimated annual incidence of life-threatening invasive mycoses, together with chronic pulmonary aspergillosis

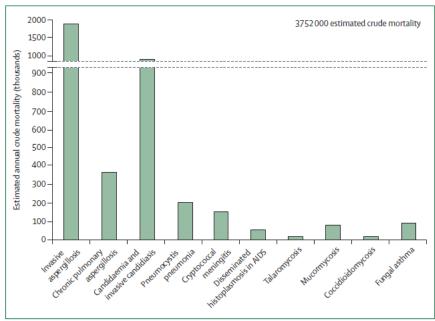


Figure 2: Estimated crude mortality of severe fungal disease, worldwide

The crude mortality is 3.75 million patients of which 2.55 million are directly attributable to fungal disease only.

## Diagnosing and treating invasive fungal infection is difficult

The diagnosis of fungal infection poses a particular problem because diagnostic methods, even in the developed world, often are too slow to be clinically relevant or fail to detect exactly what fungal species is causing the infection. Adding to the problem is that symptoms often present as non-specific, meaning that without access to sophisticated diagnostic tests, a physician would barely be able to establish that the patient is suffering from a fungal infection as opposed to any other invasive microbe, let alone what particular species of fungi the patient is infected with. As a result, fungal infections are often treated in the blind or not treated at all.

## The three classes of antifungals used today

The three main classes of antifungal drugs today are the Polyenes, the Azoles and the Echinocandins. A smaller group of products are the Allylamines and the Pyrimidines. The total sales of antifungals for human medicinal use were estimated to be approximately USD 16.7 billion in 2020<sup>5</sup>. Sales are growing by six to seven percent per year. Although most serious infections occur in the developing world, the United States and Europe make up approximately 70 percent of the market.

#### The Polvenes

The Polyenes were discovered already in the early 1950s based on the observation that certain types of *streptomyces* bacteria were able to kill fungal cells in their vicinity. Polyenes work by forming ion-channel like pores in the fungal cell wall, which causes certain ions to leak out of the cell, leading to cell death. The polyenes are fungicidal and very effective with almost no resistance build over more than 50 years, but their use is restricted by their toxicity, particularly to the kidney. Amphotericin B is the most well-known of the polyenes. Other drugs in this class include Candicidin and Nystatin. New formulations of Amphotericin B, such as the liposomal formulation Ambisome, aims to achieve lower toxicity while maintaining at least similar efficacy compared to the parent compound. However, nephrotoxicity remains a significant dose-limiting side effect that has not been eliminated. This is the primary reason that the polyenes, despite their effectiveness, make up only approximately 10 percent of the total antifungal drug market.

## **The Azoles**

The first Azole derivatives were discovered in the late 1960s. They work by inhibiting the synthesis of certain fat components of the fungal cell wall. In contrast to the Polyenes, they are primarily fungistatic rather than fungicidal, but they are effective against a broad range of fungal pathogens and display none of the kidney toxicity seen with the polyenes. Well-known drugs in this class include Fluconazole, Ketoconazole, Miconazole and Voriconazole. It is estimated that the Azoles comprise approximately 42 percent of the total antifungal drug market.

## **The Echinocandins**

Drugs from the Echinocandin class inhibit the synthesis of yet another component of the fungal cell wall known as ß-glucan. They are the newest class of antifungals, although they were in fact discovered in the 1970s. The Echinocandins are fungistatic, have a fairly broad range particularly against candida species, and have low toxicity. They do however have poor bioavailability and must be administered intravenously. Well known Echinocandins include Caspofungin and Micafungin. It is estimated that the Echinocandins comprise approximately 32 percent of the total antifungal drug market.

## The Allylamines and Pyrimidines

Allylamines work by inhibiting an enzyme required for the development of the fungal cell wall. Like the Echinocandins, they were discovered in the 1970s. The Pyrimidines work by interfering with the fungi's protein synthesis. They were introduced as antifungals in the late 1950s. The Allylamines and Pyrimidines (as well as a few other drugs) make up the remaining 16 percent of the market.

<sup>&</sup>lt;sup>5</sup> Market Research Future. *Global Antifungal Treatment Market forecast to 2027*. The market for fungicides in agriculture and industry is at least as large as the human drug market but is not considered in this discussion.

All three of the main classes of antifungals, the Polyenes, the Azoles and the Echinocandins, target the fungal cell wall because this is the part of the fungal cell that is most different from the human cell. Antifungals whose mechanism of action specifically target the fungal cell wall therefore tend to be less toxic to humans. Because the treatment of invasive fungal infection is often initiated before a precise diagnosis can be reached, the initial treatment usually consists of a combination of drugs. However, common first line treatment combinations consisting of drugs from the Azole and Echinocandin classes are generally only fungistatic, not fungicidal, which makes them vulnerable to resistance development. The Polyenes, the most prominent of which is Amphotericin B, are fungicidal but are used only sparingly as first line treatment because of their toxicity.

## Multidrug resistance is an increasing problem

Fungi, like bacteria, can develop resistance when the particular species develop the ability to defeat the drugs designed to kill them. Since only a few types of antifungal drugs currently exist, antifungal resistance severely limits treatment options. Some species, like *Candida auris*, can become resistant to all three main drug types. Resistance is particularly problematic for patients suffering from invasive fungal infections.

One reason resistance is on the rise is the increasing use of Azole and Echinocandin drugs, both of which are fungistatic rather than fungicidal. With fungistatic, some fungal cells survive, and these are, by definition, the cells that already were resistant to the drug or acquired the ability to resist through mutation during the treatment course. Another reason for the rise in resistant fungal strains is the broad and often indiscriminate use of antifungals in agricultural and livestock production. Certain azoles are even used in industrial coatings and for timber preservation. All international public health organizations, including the WHO and the CDC (The United States Centre for Disease Control) as well as the European Commission recognizes the rise in fungal infections and not least the rise in Multi Drug Resistant (MDR) fungal strains as a global health threat<sup>6</sup>.

## BSG005's position in the market

Invasive fungal infection is an aggressive disease with up to 90 percent of patients dying in the first two weeks, often before the fungal species is even identified. BSG005 will be positioned as first line treatment for invasive fungal infections based on the drug's fungicidal activity, broad coverage of different fungal species, including single drug and multidrug resistant strains, low risk of resistance development and not least, safety. In the Company's opinion, no other anti-fungal currently offers this profile. The typical setting would be for BSG005 to be administered intravenously in Intensive Care Units. Because it offers a unique profile, BSG005 will be positioned at a price premium to reflect its exceptional therapeutic value potential. The market potential is large. The market share covered by Amphotericin B and lipid versions is about USD 450 million and the other products used in fungal infections is approximately USD 20 billion. None of the products has the profile of BSG005 and the market potential in this field is large because of the unmet medical need in these severe fungal infections.

## Competition

The current standard of care for severely ill patients is treatment with an Azole or Echinocandin antifungal and/or Amphotericin B (possibly in combinations). Drug combinations are chosen because individual products have significant gaps in their fungal coverage. As opposed to the Azoles and Echinocandins, drugs based on Amphotericin B and other Polyenes have fungicidal activity, but they can only be given for a short time and at limited concentrations due to their toxicity, which includes irreversible kidney damage.

## **Market trends**

The antifungal market is impacted by several factors, several of which have already been discussed. Other factors impacting the use of antifungals include:

## Demographic and economic development

The aging population in developed countries increases the demand for medicine and health services. Apart from the overall increased number of people that need healthcare, a general increase in global wealth also creates an increase in demand for proper healthcare, for instance in newly developed countries.

<sup>&</sup>lt;sup>6</sup> www.who.int/health-topics/antimicrobial-resistance

## Increased demand for food production

Human population growth fuels a demand for increasing food production. Antifungals are widely used in agriculture and the resulting resistance problems spill over into the human population. The problem is further exacerbated when the plant's natural antifungal defenses are gradually bred out, and yet further exacerbated again by the rising popularity of the Azoles as a fungicide used for crop protection.

## Medical advances increase the susceptible population

Medical advances leading to greater initial survival of cancer or organ transplants inadvertently leave more patients susceptible to secondary attack from opportunistic fungi, further fueling a vicious cycle where more antifungals are used, leading to yet more resistance development.

## **Environmental changes**

There is increasing evidence that climate changes could result in an expansion of fungal diseases simply by increasing the geographical reach of certain species<sup>7</sup>.

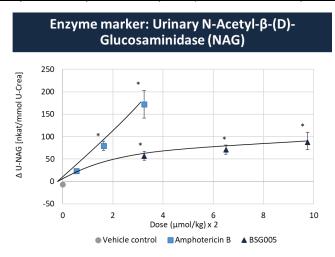
### **BSG005**

BSG005 is a polyene macrolide antifungal molecule belonging to the same antifungal class as Nystatin and Amphotericin B. As with the other Polyenes, BSG005's mode of action is inference with the fungal cell wall by creating pores from which ions and other matter can leak out of the cell and causes cell death.

## **Preclinical data for BSG005**

In toxicology studies the molecule is completely safe for the kidneys with a wide therapeutic window.

BSG005 shows significantly less toxicity in the kidneys in a preclinical test compared to the main competitor.



In this standard model of kidney toxicity, a kidney enzyme called NAG is measured. NAG is known to be strongly correlated with the destruction of certain tubular microstructures in the kidney. Even at a dose three times as high, BSG005 showed less than half the kidney damage when compared to Amphotericin B.

The *in vitro* testing of BSG005 against more than 200 different fungal strains has shown a fungicidal effect against most strains, including strains resistant to Azoles and Echinocandins. Preliminary data also shows strong effect on multi resistant Candida auris. *In vivo* testing has revealed excellent antifungal protection against *Aspergillus* and *Candida* strains also resistant strains.

In summary, BSG005 has in preclinical studies shown to have a very broad spectrum of action, not least resistant *Aspergillus* and *Candida* strains as well as multi resistant *Candida* auris. At slightly lower than expected clinical dose levels, the drug demonstrates a potency advantage over new liposomal formulations of Amphotericin B, the current standard of care for patients not responding to Azole and Echinocandin treatment. The Company is not aware of any other anti-fungal on the market or in development with a similar profile.

<sup>&</sup>lt;sup>7</sup> Garcia-Solache and A. Casadevall: Hypothesis: global warming will bring new fungal diseases for mammals. mBio, May 2010.

The central ambition of the entire program behind BSG005 was to develop a drug with a superior safety profile over Amphotericin B. Early on, the toxicology tests included comparisons of different solid forms of the drug, drug formulations, formulation preparation procedures, intravenous (IV) dosing methods and infusion durations, just to name a few. No genotoxicity has ever been seen. Later safety pharmacology studies found BSG005 to be free of cardiovascular, central nervous and respiratory adverse effects.

None of the preclinical tests have indicated a significant kidney toxicity potential.

## Phase 1 clinical trial data for BSG005

The promising preclinical safety data were confirmed in the first-in-human Phase 1 clinical trial in 38 volunteers at the Nucleus Network Phase 1 Unit in Melbourne, Australia.

The clinical Phase 1 trial was a double-blinded, placebo-controlled study (randomized 4:2), meaning that out of the total of the 38 volunteers, 24 subjects received a single dose in the SAD part and another 12 volunteers received a dose every day for 7 days in the MAD part in a dose escalation fashion.

In summary, BSG005 was found to be safe in healthy subjects during the SAD and MAD parts of the study. There were no notable changes in postbaseline clinical laboratory parameters (including kidney and liver) and vital signs, and no clinically meaningful abnormalities were noted in ECG assessment. All adverse events reported were mild to moderate in severity and no subject experienced any serious adverse event.

All in all, data from both preclinical studies and the Phase 1 study show that BSG005 has a favorable and crucial differentiation from Amphotericin B, the drug with which BSG005 will most directly compete.

The very encouraging data from the study forms the basis for the next study in patients.

#### CLINICAL DEVELOPMENT PROGRAM

The clinical program for BSG005 is designed to lead to the filing of an NDA (New Drug Application) for sales and marketing approval with the United States FDA (Food and Drug Administration) and EMA (European Medicines Agency) by Q2 2029.

## **Clinical Development Program in Patients**

BSG005 has been shown to be safe with no indication of the key severe safety issues reported with the main competitor Amphotericin B. In addition, data on BSG005 has demonstrated that BSG005 is a broad-spectrum antifungal with fungicidal effect and thereby effective with very little risk of resistance formation to treatment.

To take the full advantage of the qualities of BSG005 the aim is to develop BSG005 for the treatment of systemic mycotic infections due to organisms susceptible to BSG005, such as cryptococcosis, disseminated candidiasis, coccidioidomycosis, aspergillosis, histoplasmosis, mucormycosis. This includes resistant and difficult to treat fungi as *Candida Auris* and resistant aspergillus. It should also include treating patients with mild to moderate renal impairment.

The clinical development plan is designed around the broad indication and the safety advantages. The below mentions the primary clinical studies.

## First study in patients with invasive fungal infection, Proof of concept study

The first study in patients which is currently ongoing is designed to test the clinical profile of BSG005 as rescue therapy in patients where no effective alternative treatment options are available. The clinical trial is designed to address unmet medical needs in invasive fungal infections. The study focuses on patient populations intolerant or resistant to Amphotericin B, the current last-resort treatment for severe invasive fungal diseases, as well as those who have experienced treatment failure with first-line therapy. Additionally, patients with mild to moderate kidney impairment, for whom Amphotericin B treatment is not feasible, will be included. These populations urgently require an alternative treatment option. The first two cohorts, including 10 patients, have completed the study. In total up to 15 patients will be included in the study. The third cohort will be initiated when new supplies of BSG005 is ready by Q4 2025

This study is expected to form the basis for an Expanded Access program (enabling doctors to legally prescribe approved and yet-to-be-approved drugs before they are commercially available) or Compassionate use program (enabling patients, among others who cannot be adequately treated with an approved medication, to access drugs that are not approved) which could include patients represented in the first patient study.

## Phase 2/3 clinical trial program

In general, Biosergen will take advantage of clinical study designs that recently have been tested and approved by FDA as a part of a development program. It is generally known in the industry that clinical development programs are expensive and take a long time before the patients can benefit from new treatments. Therefore, the FDA has modernized their approach to clinical trial over the last four years. Modernization includes more agile trial designs, the use of modern technology and integrating the patients view more thoroughly. The latest guideline within this initiative was published June 2023 and it was later adopted by ICH. (The International Council for Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use).

Biosergen can benefit from two new trial designs that have precedence within the regulatory pathway and thereby save resources and time.

One of these designs is an adaptive design where phases 2 and 3 are integrated into one study. Using an adaptive design gives options for changes in design, such as an increase in number of patients based on ongoing evaluation of the data at predetermined timepoints. The second design is a basket study, this is common within oncology, and it has also been seen with new antifungal therapy in development. The advantage with a basket study is a bigger patient pool to recruit from, the possibility to adjust the study during conduct and thereby optimize the resource use and in the end to offer even rare diseases a potential treatment.

# Disseminated Candidiasis together with rare diseases - several invasive fungal infections tested under one protocol

Invasive candidiasis has a high incidence and one of the highest mortalities within invasive fungal diseases. There are clear benefits of a basket study within the mycotic environment where the response to several fungal strains can be tested within one protocol. It is difficult to diagnose a particular fungal strain early and published data indicate that the mortality increases exponentially with late onset of adequate treatment. The ideal candidate in this setting is a broad-spectrum antifungal as BSG005.

## BSG005 Nano and BSG005 Nano Oral

Several of the most serious fungal infections either start or become located in the lungs of the patient. Biosergen and the Nano Group at SINTEF have therefore started a project to develop a special Nano formulation of BSG005, the main purpose of which is to achieve a higher concentration of the drug in the lungs of the patients. The group aims to develop both a Nano IV and a Nano Oral formulation of BSG005. Other than the ability to target the lungs specifically, an oral formulation opens up a number of new options. For instance, for prophylactic use or as follow-on treatments in the patient's own home after transplants or chemotherapy with an oral administration of BSG005 is very interesting due to the very broad activity against most of the fungal strains in question.

## **Future challenges**

The company's main challenges primarily involve obtaining approval and all the unknown factors in execution of clinical studies such as recruitment speed, inclusion/exclusion criteria, dose finding, site non-performance etc. that is required to further develop BSG005 to eventually bring it to market, as well as additional partnering and financing the studies beyond what is funded by future grants or Alkem.

The Board of Directors and the CEO of Biosergen AB hereby present the annual financial and Consolidated statement for the financial year 2024-01-01 – 2024-12-31.

All amounts in the annual report are presented in Swedish krona, SEK. Unless otherwise stated, all amounts are posted in thousands Swedish kronor '000 (TSEK). Data in parentheses refers to the previous year.

## **DIRECTORS REPORT**

## **About Biosergen**

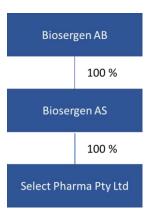
## Vision and mission of the Company

Biosergen's mission is to develop BSG005, including novel formulations of this compound, into a new first line treatment choice against resistant and difficult fungal strains, setting a new standard for combating invasive fungal diseases where current therapies fall short and thereby saving thousands of lives of immune-compromised cancer- transplant- and AIDS patients every year.

The company intends to achieve its mission through a combination of academic and commercial excellence, strategic partnerships, and highly experienced leadership. Biosergen's vision is to emerge as a leading international biotechnology company in the global fight against fungal infections, building strong partnerships with pharmaceutical companies, key opinion leaders, NGOs, and government agencies all over the world.

## **Biosergen Group**

Biosergen AB is the parent company in the group which in addition to the parent company consists of the wholly owned Biosergen AS which in turn owns 100 percent of the Australian subsidiary Select Pharma Pty Ltd.



## **Shareholders**

The table below presents shareholders with over 5% of the votes and capital in Biosergen AB on December 31, 2024.

Name	Number of shares	Percentage of voting right and capital (%)
ÖSTERSJÖSTIFTELSEN	98,733,144	42.05
Ribbskottet Aktiebolag	36,500,000	15.54
Rosetta Capital IV SARL	14,517,009	6.18
Others	85,073,059	36.23
	234,823,212	100.00

## The share

The shares of Biosergen AB were listed on Nasdaq Stockholm First North on June 24, 2021. The short name/ticker is BIOSGN and the ISIN code is SE0016013460. Per December 31, 2024, the number of shares was 234,823,212 distributed among 1668 shareholders. The average number of shares in The Company in Q4 2024 was 163,718,580. The Company has one class of shares. Every stock share equals the same rights to The Company's assets and results.

## Warrants

As an incentive for employees, Board Members, and key persons Biosergen has implemented four warrant programs. Key persons incentive program 2021 consisting of 1,219,423 warrants whereof all have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 1.06. Key persons incentive program 2022 consisting of 669,144 warrants whereof 350,000 have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 10. Warrants 2024/2031:1 consisting of 4,263,366 warrants where all have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 0.45. Warrants 2024/2031:2 consisting of 1,421,122 warrants where 1,200,000 have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 0.45.

No warrants have yet been exercised.

Subscription of shares with the support of warrants from program 1-4 may take place no later than December 31, 2031.

#### **FINANCIAL REVIEW**

Biosergen AB was registered in February 2021. On April 16, 2021, the company acquired Biosergen AS with the subsidiary Select Pharma PTY LTD and formed the group with Biosergen AB as parent company. Biosergen AB has its registered office in Solna, Sweden

## **Capital resources and Liquidity**

In March 2024 the Company completed a Rights Issue. The proceeds SEK 27,5 million were paid into the Company's accounts in April. In December, Biosergen AB received approximately SEK 45,3 million through warrants of series TO3 and at the end of 2024 the company had a cash position of 50,6 million SEK.

In order to continue to run the operations of the Company and to follow the planned development projects the Board and Management are working on various future models to secure the company's long-term capital requirement. If the company does not succeed in obtaining new financing this can significantly affect its continued operations. Considering the company's future prospects, current cash position and ownership structure, the board and management are optimistic about future financing opportunities.

### **Employees**

On December 31, 2024, the Company and the Group as well had two full time employees of whom 50 percent were women. All were employees of the parent company. Besides the full-time employees, the company is associated with consultants and partners for various tasks. The average number of employees during the year was 2.

## Risk and uncertainty factors

A pharmaceutical development company such as Biosergen is exposed to operational and financial risk. Many factors can have a negative impact on the probability of commercial success. Except from beginning testing BSG005 in patients no other changes with respect to these risks or uncertainty factors have arisen.

## **HIGHLIGHTS DURING 2024**

- In January Biosergen Announced Leadership Transition: Peder M. Andersen Stepped Down as CEO and Tine Olesen was Appointed as Successor.
- In February Biosergen received regulatory approval from CDSCO in India to test BSG005 in patients with invasive fungal infection.
- In March Biosergen published a prospectus due to rights issue of units.
- In March members of the board of directors and management subscribed in the ongoing rights is-
- March 26, Biosergen announces the outcome in the rights issue.
- In June, Biosergen to welcome two new board members Anna Ljung as new Chair and Robert Molander based on election at the Annual General Meeting.
- In June Biosergen received the final permission required to test lead candidate BSG005 in patients with invasive fungal infection.
- Conversion of paid subscribed units and first day of trading with warrants of series TO3 took place in April.
- In April Biosergen resolved on a directed issue to underwriters in connection with the completed rights issue.
- In July, the first patient began treatment in the Clinical Trial Treating with BSG005 for Life Threatening Fungal Infection.
- In August the first patient completed treatment with BSG005
- In October, Biosergen completes first cohort of BSG005 clinical trial, showing promising potential in drug-resistant fungal infections. The cohort consisted of five patients: two completely recovered, two saw significant improvements, and one very sick patient passed away because of unrelated causes to BSG005. Seeing two patients who had suffered from some of the most severe fungal infections existing in the world today fully recover is truly remarkable.
- In November, Biosergen announced safety committee approval to proceed with dose escalation and dose first patients in second cohort of BSG005 clinical trial for life-threatening fungal infections

- In December, Biosergen AB received approximately SEK 44,9 million through warrants of series TO3. In total, 91,701,328 warrants of series TO3 were exercised, corresponding to 100.0 percent of the total number of outstanding warrants. The exercise rate amounted to approximately 93.1 percent, and a top underwriting commitment was utilized for the remaining volume.
- In December, Biosergen agreed to accelerated dosing escalation in the second cohort of the ongoing clinical trial. This decision was made following a request from the Principal Investigator, supported by compelling preliminary data, reflecting the investigator team's expectation that BSG005 will deliver even greater clinical benefits at higher doses with no severe side effects. The independent Data Safety Review Committee reviewed and approved this request.

## HIGHLIGHTS AFTER THE PERIOD

On February 4, Biosergen successfully completed the second cohort of BSG005 clinical trial, gaining conclusive proof-of-concept data, and confirming 2025 objectives. With the completion of the second cohort, we now have compelling proof-of-concept data on BSG005, further reinforcing its potential as a life-saving treatment for patients with invasive fungal infections who have no remaining medical treatment options. In short, across cohort 1 and 2, every patient who completed BSG005 treatment experienced clinical benefits, with multiple complete recoveries and significant improvements - all without severe side effects.

## **CONSOLIDATED FINANCIAL HIGHLIGHTS AND RATIOS**

Multi-year review (TSEK)				
Group	2024	2023	2022	2021*)
Income statement				
Other operating income	1,940	9,378	5,183	8,573
Profit/loss before depreciation	-19,203	-27,266	-34,129	-34,078
Profit/loss before net financial items	-19,203	-27,266	-34,129	-34,078
Net financial items	8	229	81	-240
Profit/Loss for the year	-19,195	-27,037	-34,048	-34,318
Balance sheet				
Cash	50,612	1,883	29,342	21,665
Balance sheet total	53,022	7,201	33,790	29,486
Equity	48,208	2,116	22,793	20,233
Cash flow				
Cash flow				
Operating activities	-10,178	-32,603	-29,441	-37,749
Financing activities	58,907	5,144	37,118	58,825
Key ratios				
Solvency (%)	91	29	67	68
Earnings per share (SEK)	-0.08	-0.53	-1.09	-1.22
Diluted earnings per share (SEK)	-0.08	-0.53	-1.09	-1.22
Barrat assurance	2024	2022	2022	2024
Parent company	2024	2023	2022	2021
Solvency (%)	99	99	99	100

For definitions and key ratios, see Accounting and valuation principles.

<sup>\*)</sup> Biosergen AB was registered on February 26, 2021. For accounting purposes, the change of the ownership of Biosergen AS during the year is seen as an internal reorganization/restructuring and the rules of reverse acquisitions are applied. Consequently, Biosergen AS is to be seen as the parent company in the group in 2020. The 2020 comparative figures relate to Biosergen AS with its subsidiary Select Pharma Pty Ltd.

Group	Share capital	Other equity incl. profit for the year			Total
Opening balance, Jan, 2024	1 266	850			2 116
New share issue Emission costs Exchange rate differences Profit/Loss för the year	4 603	68 201 -7 444 -74 -19 195			72 804 -7 444 -74 -19 195
Closing balance, Dec, 2024	5 869	42 338			48 207
Parent company	Share capital	Share premium reserve	Accumulated profit or loss	Profit or loss for the year	Total
Opening balance, Jan, 2024	1 267	320 413	-152 978	-31 064	137 638
Disposition according to decision of this year's AGM:					
Balanced in new account			-31 064	31 064	0
New share issue Emission costs Profit/loss for the year	4 603	68 201 -7 444		-16 708	72 804 -7 444 -16 708
Closing balance, Dec, 2024	5 870	381 170	-184 042	-16 708	186 290

## **Proposed appropriation of earnings**

The Board of Directors proposes that the available funds:

 Share premium reserve
 381 169 815

 Losses brought forward
 -184 042 684

 Loss for the year
 -16 708 323

 180 418 808

Be appropriated as follows:

To be carried forward 180 418 808 180 418 808

The Group's and the Parent Company's earnings and financial positions in general are shown in the following income statements and balance sheets as well as in cash flow analyzes with accompanying Notes.

Income statement TSEK	Note	01/01/2024 31/12/2024	01/01/2023 31/12/2023
Operating income			
Other operating income	3	1.940	9.378
		1.940	9.378
Operating expenses			
Consumables		0	-456
Other external expenses	4	-15.404	-25.725
Personnel costs	5	-5.288	-8.592
Other operating expenses		-451	-1.870
		-21.143	-36.643
Operating profit/loss		-19.203	-27.265
Profit from financial items			
Other interest income and similar items	6	86	237
Interest expenses and similar items	7	-78	-9
		8	228
Profit after financial items		-19.195	-27.037
Profit before tax		-19.195	-27.037
Profit or loss for the year		-19.195	-27.037
Earnings per share (SEK)		-0,08	-0,53
Diluted earnings per share (SEK)		-0,08	-0,53

The result for the year is attributable to the parent company's owners.

## **Consolidated balance sheet**

Balance sheet	Note	31/12/2024	31/12/2023
TSEK			
ASSETS			
Current assets			
Current receivables			
Other receivables		492	342
Prepaid expenses and accrued income	8	1,918	4,976
		2,410	5,318
Cash and bank balance		50,612	1,883
Total current assets		53,022	7,201
Total current assets		55,022	7,201
TOTAL ASSETS		53,022	7,201
EQUITY AND LIABILITIES			
Equity	9		
_4,			
Share capital		5,870	1,266
Other equity including profit for the		42,338	850
year  Equity attributable to the parent com-			
pany's shareholders		48,208	2,116
Total equity		48,208	2,116
Current liabilities			
Accounts payable		2,383	1,698
Other liabilities		32	128
Accrued expenses and deferred income	10	2,399	3,259
Total current liabilities		4,814	5,085
		7,017	3,303
TOTAL EQUITY AND LIABILITIES		53,022	7,201
IOTAL LQUITT AND LIABILITIES		55,022	7,201

## Consolidated cash flow analysis

Cash flow analysis TSEK	Note	01/01/2024 31/12/2024	01/01/2023 31/12/2023
Operating activities			
Operating profit/loss		-19,203	-27,265
Net financial		8	228
Cash flow from operating activities		40.405	27.027
before changes in working capital		-19,195	-27,037
Cash flow from changes in working capital			
Changes in accounts receivable		0	0
Changes in current receivables		2,908	-870
Changes in accounts payable		7,065	-5,113
Changes in current liabilities		-956	417
Cash flow from operating activities		-10,178	-32,603
Financing activities			
New share issue (Biosergen AS and Biosergen AB		58,907	5,144
Oseigen Ab			
Cash flow from financing activities		58,907	5,144
Cash flow for the year		48,729	-27,459
Liquid funds at the beginning of the		4.003	20.242
year		1,883	29,342
Liquid funds at the end of the year		50,612	1,883

## Parent Company income statement

Income statement		01/01/2024	01/01/2023
TSEK	Note	31/12/2024	31/12/2023
Operating income			
		2 260	4.725
Net sales		2,268	4,725
		2,268	4,725
Operating expenses			
Consumables		0	64
Other external expenses	4	-5,725	-7,030
Personnel costs	5	-5,208	-8,592
Other operating expenses		0	0
		-10,933	-15,558
Operating profit/loss		-8,665	-10,833
Profit from financial items			
Profit/loss from shares in group companies	11	-8,130	-19,429
Other interest income and similar items	6	577	959
Interest expenses and similar items	7	-490	-1,761
		-8,043	-20,231
Profit after financial items		-16,708	-31,064
Profit before tax		-16,708	-31,064
Profit or loss for the year		-16,708	-31,064

## **Parent Company balance sheet**

Balance sheet TSEK	Note	31/12/2024	31/12/2023
ASSETS			
Fixed assets			
Financial fixed assets			
Shares in group companies	12, 13	127,283	127 283
Receivables from group companies	14	12,143	9,784
		139,426	137,067
Total fixed assets		139,426	137,067
Current assets			
Receivables			
Other receivables		226	226
Prepaid expenses and accrued income	8	359	295
		585	521
Cash and bank balance		47,315	1,251
Total current assets		47,315	1,251
TOTAL ASSETS		187,326	138,839

## **Parent Company balance sheet**

Balance sheet Note 31/12/2024 31/12/2023

TSEK

## **EQUITY AND LIABILITIES**

**EQUITY** 9,15

Restricted equity

 Share capital
 5,871
 1,267

 5,871
 1,267

Non-restricted equity

 Share premium reserve
 381,170
 320,414

 Accumulated profit or loss
 -184,043
 -152,979

 Profit or loss for the year
 -16,708
 -31,064

 180,419
 136,371

Total equity 186,290 137,638

**Current liabilities** 

Accounts payable 717 365
Other liabilities 32 190
Accrued expenses and deferred income 10 287 645
Total current liabilities 1,036 1,201

TOTAL EQUITY AND LIA-BILITES 187,326 138,839

## Parent Company cash flow analysis

Cash flow analysis	Note	01/01/2024	01/01/2023
TSEK		31/12/2024	31/12/2023
Operating activities		0.665	40.000
Operating profit/loss		-8,665	-10,833
Interest received		577	958
Interest paid		-490	-1,761
Cash flow from operating activities be-		0.570	11.626
fore changes in working capital		-8,578	-11,636
Cash flow from changes in working capital			
Changes in current receivables		-64	522
Changes in accounts payable		6 804	208
Changes in other operating liabilities		-516	-801
		2 254	44 707
Cash flow from operating activities		-2,354	-11,707
Investing activities			
Investments in other financial fixed assets		-10,489	-21,295
Cash flow from investing activities		-10,489	-21,295
Financial activities			
New share issue		58 907	5,297
Cash flow from financing activities		58,907	5,297
Cash flow for the year		46,064	-27,705
cash now for the year		70,004	-21,103
Liquid funds at the beginning of the year		1,251	28,956
Liquid funds at the end of the year		47,315	1,251

## **Notes**

## Note 1 Accounting and valuation principles

### **General Information**

The annual report and consolidated accounts have been prepared in accordance with the Swedish Annual Accounts Act and BFNAR 2012:1 Annual Reporting and consolidated reports (K3).

## **Revenue Recognition**

Revenue has been reported to the fair value of the consideration received or which is receivable and is recognized to the extent that it is probable that the economic benefits will incur to by the Company and when the revenue in question can be measured reliably.

## **Group financial statement**

The legal formation of Biosergen Group during the second quarter of 2021 comprised transactions between entities that were under common control via the ultimate owners of Biosergen AS, (Registration No 987 622 075), incorporated in Trondheim, Norway. As these transactions are not covered by K3, a suitable accounting principle for the historical information has been applied in accordance with IAS 8. An established method, assessed as suitable for Biosergen Group, is to apply the previous carrying amount (predecessor basis of accounting), which is the principle applied in the preparation of these statements. In short, this entails that the assets and liabilities of the units forming part of the Biosergen Group have been aggregated and recognized based on the carrying amounts they represent in Biosergen AS consolidated financial statements as from the date they became part of the Biosergen Group. The legal formation of Biosergen took place on April 16, 2021, when Biosergen AB (publ) acquired all outstanding share in Biosergen AS for a total consideration of SEK 223 048 thousand, in the form of a promissory note, and an extraordinary general meeting of shareholders for the parent company Biosergen AB resolved to carry out an issue of new shares directed to the former shareholders of Biosergen AS. The combined financial statements are intended to present the historical financial information of Biosergen, and have been prepared under the historical cost convention, except as regards financial instruments at fair value. Financial information for the Parent Company, that had no operations until the preparations for Nasdaq First North listing commenced during the second quarter 2021, and the consolidated statements of Biosergen AS prepared in accordance with K3 for the years 2021 and 2020 have been combined, in order to provide meaningful and relevant information for all periods covered by the report.

## **Consolidation method**

The Parent Company has acquired the subsidiary through a reverse acquisition. The consolidated financial statements have otherwise been prepared in accordance with the acquisition method. This implies that the identifiable assets and liabilities of acquired operations are reported at market value in accordance with the prepared acquisition analysis. If the acquisition value of the business exceeds the market value of the expected net assets according to the acquisition analysis, the difference is reported as goodwill.

## Transactions between Group companies

Intra-Group receivables and liabilities as well as transactions between Group companies and unrealized gains are eliminated in their entirety. Unrealized losses are also eliminated unless the transaction corresponds to an impairment loss.

Changes in internal profit during the financial year have been eliminated in the consolidated income statement.

## Translation of foreign subsidiaries

The financial statements of foreign subsidiaries has been recalculated according to the current exchange rate method. All items in the balance sheet have been translated at the closing day rate. All items in the income statement have been translated at the average exchange rate during the financial year. Differences that arise are reported directly in equity.

#### **Financial instruments**

Financial instruments are valued on the basis of the acquisition value. The instrument is reported in the balance sheet when the Company becomes a party to the contractual conditions. Financial assets are derecognized when the rights to receive cash flows from the instrument has expired or been transferred and the Company has transferred substantially all of the risks and rewards associated with ownership. Financial liabilities are derecognized when the obligations have been settled or otherwise terminated.

#### Shares in subsidiaries

Investments in subsidiaries are carried at cost less any impairment losses. The cost includes the purchase price paid for the shares and acquisition costs. Any capital contributions are added to the cost when they arise and an assessment is made as to whether an increase in value has occurred or whether the contribution should be expensed.

## Intangible assets

## **Development costs**

The Company reports internally generated intangible assets according to the capitalization model. The means that all expenses relating to the development of an internally generated intangible asset are expensed during the research phase and capitalized as an asset in the development phase. Expenses previously expensed are not included in the acquisition value of the capitalized asset. Capitalization takes place when the conditions stipulated in BFNAR 2012:1 are met. The asset is depreciated over its estimated useful life. The useful life of such an asset is reconsidered if it is deemed that there is a change in the useful life compared with the previous balance sheet date. Depreciation begins when the asset can be used.

## Accounts receivables/current receivables

Accounts receivables and current receivables are reported as current assets in the amount expected to be paid after deduction of individually assessed impaired loans.

## Loan-liabilities and account payables

Loan liabilities and accounts payables are recognized initially at cost after deduction of transaction costs. If the carrying amount differs from the amount that will be repaid at maturity date, the interest expense is accrued, the difference that over the term of the loan using the effective interest rate of the instrument. This is consistent with the due date of the carrying amount and the amount to be reimbursed.

## Impairment of financial fixed assets

At each balance sheet consideration is given as to whether there are indications of impairment of financial fixed assets. An impairment loss seen to exist if the decline in value is considered to be permanent and the financial fixed assets are examined individually.

## **Income Taxes**

Total tax consists of current tax and deferred tax. Taxes are reported in the income statement, except when the underlying transaction is reported directly in equity, whereby the associated tax effects are reported in equity.

## Current tax

Current tax refers to income tax för the current financial year and that portion of the previous financial year's income tax that has not yet been reported. Current tax is calculated on basis of the tax rate applying on balance sheet date.

## **Deferred tax**

Deferred tax is the income tax relating to future financial years as a result of past events. The accounting is based on the balance sheet method. According to this method deferred tax liabilities and deferred tax assets on temporary differences arising between the tax base of recognized assets and liabilities and for the other tax credits or deficits are reported.

Deferred tax assets are offset against deferred tax liabilities if, and only if, they can be paid with a net amount. Deferred tax is calculated based on the applicable rate as at balance sheet date. Effects of changes in applicable tax rates are reported in the period in which the change comes into effect. Deferred tax assets are reported as financial fixed assets and deferred tax liabilities as a provision.

Deferred tax asset referring to tax losses or utilized tax credits are reported to the extent that it is probable that deductions can be offset against future taxable profits.

Due to the relationships between accounting and taxation, deferred tax liabilities attributable to untaxed reserves are not identified separately.

## **Employee Remuneration**

Employee benefits refer to all types of benefits the Company provides to employees. Short-term employee benefits include wages, paid holidays, paid leave, bonuses and reimbursement upon completion of employment (pension) etc. Short-term employee benefits are reported as an expense and a liability when there is a legal or constructive obligation to pay compensation as a result of a past event, and a reliable estimate of the amount can be made.

### **Public Contributions**

Government grants are reported at their fair value where applicable and when it is certain that the grant will be received, and when the Company will meet the conditions of the grant. Grants intended to cover investments in tangible or intangible fixed assets reduce the acquisition value of the assets and, therefore also their depreciable amount.

## Cash and bank balance

The amount in Cash and bank balance is including a guarantee to Euroclear amounted to 50,000 SEK.

#### Cash Flow Analysis

The cash flow statement is prepared using the indirect method. The reported cash flow includes only transactions involving receipts or disbursements.

The Company classifies cash, in addition to cash on hand, as demand deposits at banks and other credit and short-term liquid investments that are listed on a marketplace and have a maturity of less than three months from acquisition date. Changes in restricted cash are reported in investing activities.

## **Definition of Key Business Ratios**

Equity/assets ratio (%)

Adjusted equity (equity and untaxed reserves with deductions for deferred tax) as a percent of the balance sheet total.

## **Note 2 Estimates and Judgments**

Preparation of financial statements and application of accounting policies, are often based on assessments, estimates and assumptions that are considered to be reasonable at the time at which the assessment is made. Estimates are based on historical experience and various other factors that are considered to be reasonable under the circumstances. The results of these are used to assess the carrying values of assets and liabilities, which are not otherwise apparent from other sources. The actual outcome may differ from these estimates. Estimates and assumptions are reviewed regularly.

Investments in subsidiaries are carried at cost less any impairment losses. The cost includes the purchase price paid for the shares and acquisition costs. Any capital contributions are added to the cost when they arise. The valuation is based on a future value. The board and the management assess the value of the subsidiaries' shares on an ongoing basis during the financial year. This assessment includes that significant judgments are applied by management to conclude on the valuation.

No other significant sources of uncertainty in estimates and assumptions that at balance sheet date are considered to comprise a significant risk of a material adjustment to the carrying amounts of assets and liabilities during the next financial year.

## Note 3 Other operating income

## Group

	2024-01-01 -2024-12-31	2023-01-01 -2023-12-31
Other government grants	1 856	9 008
Exchange rate gains	84	370
	1 940	9 378

## **Note 4 Remuneration to Auditors**

## Group

Audit assignment refers to the audit of the annual financial statements as well as of the reports of the Board of Directors and the CEO, other tasks fulfilled by the Company's auditor as well as advisory service or other assistance deriving from observations made in the course of the performance of the audit or fulfilment of such other tasks.

	2024-01-01	2023-01-01
	-2024-12-31	-2023-12-31
PwC		
Audit engagement	879	954
Other audit engagements separate from audit assignment	481	81
Tax advisory	0	67
Other services	0	0
	1,360	1,102
Parent company		
	2024-01-01	2023-01-01
	-2024-12-31	-2023-12-31
PwC		
Audit engagement	355	729
Other audit engagements separate from audit assignment	274	34
Tax advisory	0	0
Other services	0	0
	629	763

# Note 5 Employees and Personnel Costs Group

Group		
	2024-01-01	2023-01-01
	-2024-12-31	-2023-12-31
Average numbers of employees		
Women	1	2
Men	1	2
	2	4
Salaries and other remuneration		
Board of Directors and CEO	3,367	3,838
Other senior management	1,792	3,134
Other employees	0	1,427
	5,159	8,399
Social security contributions	139	187
Pension costs	0	0
Total salaries, remunerations, social security expenses and		
pension costs	5,298	8,586

# REMUNERATION TO THE BOARD OF DIRECTORS AND SENIOR MANAGEMENT

2023 (Amounts in kSEK)	Base pay	Board fee	Variable- remuneration	Other benefits	Pension	Total
Members of the board						0
Marianne Kock		281				281
Achim Kaufhold		281				281
Henrik Moltke		281				281
Tortsen Rüdiger		450				450
Mattias Klintemar		281				281
CEO Tine Olesen *	1 657					1 657
VD Peder Andersen **	135					135
Other senior management	1 792					1 792
Total	3 584	1 574	0	0	0	5 159

<sup>\*</sup> CEO from 2024-02-01

<sup>\*\*</sup> CEO until. 2024-02-01

2022 (Amounto in IrSEK)	Base	Board	Variable-	Other	Danaian	Total
2023 (Amounts in kSEK)	pay	fee	remuneration	benefits	Pension	ıotai
Members of the board						0
Marianne Kock		290				290
Achim Kaufhold		290				290
Henrik Moltke		290				290
Lena Degling Wikingsson		298				298
Tortsen Goesh		463				463
Mattias Klintemar		297				297
Hanne Kristensen		289				289
CEO Peder Andersen	1 620					1 620
Other Senior Management	3 134					3 134
Total	4 754	2 218	0	0	0	6 972

## **Parent Company**

	2024-01-01	2023-01-01
	-2024-12-31	-2023-12-31
Average numbers of employees		
Women	1	2
Men	1	2
	2	4
Salaries and other remuneration		
Board of Directors and CEO	3,367	3,838
Other senior management	1,792	3,134
Other employees	0	1,427
	5,159	8,399
Social security contributions	139	187
Pension costs	0	0
Total salaries, remunerations, social security expenses and		
pension costs	5,298	8,586

Note 6 Other interest income and similar profit/loss items Group		
	2024-01-01 -2024-12-31	2023-01-01 -2023-12-31
Other interest income	86 <b>86</b>	237 <b>237</b>
Parent Company		
	2024-01-01 -2024-12-31	2023-01-01 -2023-12-31
Interest income from Group companies Other interest income and similar items	490 87 <b>577</b>	749 210 <b>959</b>
Note 7 Interest expenses and similar profit/loss items	5//	959
Group	2024-01-01 -2024-12-31	2023-01-01 -2023-12-31
Other interest expenses	-78 <b>-78</b>	-9 <b>-9</b>
Parent Company		
	2024-01-01 -2024-12-31	2023-01-01 -2023-12-31
Other interest expenses	-142	-9
Exchange rate losses	-348 <b>-490</b>	-1,672 <b>-1,761</b>
Note 8 Prepaid expenses and accrued income		
Group	2024-12-31	2023-12-31
Accrued development grants	1,460	4,587
Prepaid insurance expenses Other prepaid expenses	96 362	36 353
Daward Carrage	1,918	4,976
Parent Company	2024-12-31	2023-12-31
Other prepaid expenses	359 <b>359</b>	294 <b>294</b>

## Note 9 Numbers of shares and quota value

Parent Company		
	Numbers of	Quota
Biosergen AB	Shares	Value
Numbers of shares	234,823,212	0.025
	234,823,212	
Note 10 Accrued expenses and deferred income		
Group		
	2024-12-31	2023-12-31
Accrued vacation pay and salary	59	103
Accrued development expenses	1 558	2,471
Other accrued expenses	782	685
	2 399	3,259
Parent company		
	2024-12-31	2023-12-31
Accrued vacation pay and salary	59	103
Accrued expenses	228	543
	287	646
Note 11 Profit from shares in group companies Parent Company		
	2024-12-31	2023-12-31
Impairment loss	-8,130	-19,429
·	-8,130	-19,429
Note 12 Participations in Group companies Parent Company		
Tarent Company	2024-12-31	2023-12-31
Initial acquisition value	280,139	260,710
Reverse acquisition through non-cash issue	0	0
Capital increase through new share issue	8,130	19,429
Accumulated acquisition value, closing balance	288,269	280,139
· · · · · · · · · · · · · · · · · · ·		
Initial impairment losses	-152,856	-133,427
Impairment loss of the year	-8,130	-19,429
Accumulated impairment losses	-160,986	-152,856
Book value, closing balance	127,283	127,283

# Note 13 Specification of Participation in Group Companies Parent company

	Capital	Shares	Book
Name	share	votes	value
Biosergen AS	100	100	127,283
			127,283

Corp. ID No. Head Office

Biosergen AS 987 622 075 Trondheim,
Norge

Indirectly owned subsidiaries:

Select Pharma Pty Ltd

629 643 205

Southbank, Victoria, Australia

# Note 14 Receivables from Group companies Parent Company

raicht company	2024-12-31	2023-12-31
Initial acquisition value	9,784	7,918
Additional Claims	2,359	4,866
Outgoing receivables	0	0
Reclassification	0	-3,000
	12,143	9,784
	12,143	9,784

## Note 15 Proposed appropriation of earnings Parent Company

2024-12-31

Proposed appropriation of earnings

The Board of Directors proposes that the available funds:

 Share premium reserve
 381,169,815

 Loss brought forward
 -184,042,683

 Loss for the year
 -16,708,323

 180,418,808

be appropriated as follows:

to be carried forward 180,418,808 180,418,808

## Note 16 Significant events after the end of the financial year Group

In order to continue to run operations of the company, and to follow the planned development projects, the management and the board are working on various future capital raising alternatives. If the company does not succeed in obtaining new financing, this can significantly affect its continued operations. The Board and management are optimistic about future financing opportunities.

On February 4, Biosergen successfully completed the second cohort of BSG005 clinical trial, gaining conclusive proof-of-concept data, and confirming 2025 objectives. With the completion of the second cohort, we now have compelling proof-of-concept data on BSG005, further reinforcing its potential as a life-saving treatment for patients with invasive fungal infections who have no remaining medical treatment options. In short, across cohort 1 and 2, every patient who completed BSG005 treatment experienced clinical benefits, with multiple complete recoveries and significant improvements—all without severe side effects.

## STATEMENT BY THE BOARD OF DIRECTORS AND EXECUTIVE BOARD

The Board of Directors and the Executive Board provide their assurance that the annual report provides a true and fair overview of the Parent Company's and the Group's operations, financial position, and results, and describes material the risks and uncertainties to which Parent Company and the companies in the Group are exposed.

Stockholm, Sweden, on the day show	n by our electronic signatures	
Executive Board		
Tine Olesen CEO		
Board of Directors		
Anna Ljung Chairman	Robert Molander	Marianne Kock
Mattias Klintemar		
Our audit has been submitted on the Öhrlings PriceWaterhouseCoopers Al		ures
Johan Engstam Authorized Public Accountant		