Biosergen AB

Fogdevreten 2, 171 65 Solna

Registration no. 559304-1295

Interim report for the period
October 1, 2023 – December 31, 2023

Contents

Statement by the Board of Directors and the Executive Board

The Board of Directors and the Executive Board provide their assurance that the interim report provides a fair and true overview of the Parent Company's and the Group's operations, financial position, and results, and describes material risks and uncertainties faced by the parent Company and the companies in the Group.

Stockholm, Sweden, February 29, 2024

Executive Board

Tine Kold Olesen

Board of Directors

Torsten Goesch Chairman	Achim Kaufhold	Henrik Moltke
Marianne Kock	Mattias Klintemar	

CONSOLIDATED FINANCIAL HIGHLIGHTS AND RATIOS

TSEK	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Profit/loss				
Other income	1.315	1.964	9.378	5.183
Profit/loss before depreciation (EBITDA)	-6.662	-12.491	-27.266	-39.987
Operating profit/loss before net financials	-6.662	-12.491	-27.266	-39.987
Net financials	193	87	229	109
Netprofit/loss for the period	-6.469	-12.432	-27.037	-39.906
Balance sheet				
Cash	1.883	29.342	1.883	29.342
Balance sheet totalt	7.201	33.979	7.201	33.979
Equity	2.116	22.793	2.116	22.793
Cash flows				
Cash flows from:				
Operating activities	-4.524	-23.092	-32.603	-35.301
Financing activities	0	42.978	5.144	42.978
Ratios				
Solvency (%)	29%	67%	29%	67%
Earnings per share (SEK)	-0,13	-0,40	-0,53	-1,28
Diluted earings per share	-0,13	-0,40	-0,53	-1,28

HIGHLIGHTS DURING Q4 2023

- December 12, Biosergen's Partner Alkem Laboratories Submits Clinical Trial Application for First Patient Study with BSG005 in Invasive Fungal Infections in India as a Rescue Therapy

HIGHLIGHTS AFTER THE PERIOD

- February 12, Biosergen receives regulatory approval to test lead candidate BSG005 in patients with invasive fungal infection.
- January 30, Biosergen carries out a rights issue of units of approximately SEK 40.5 million, and secures bridge loan
- January 12, Biosergen Announces Leadership Transition: Peder M. Andersen to Step Down as CEO, Tine Olesen Appointed as Successor

CEO LETTER

Dear Shareholders,

As we have closed the financial year 2023, I am pleased to present an overview of the notable progress at Biosergen achieved during the fourth quarter and up until today. This being my very first CEO letter, I wish to extend my gratitude to my predecessor, Peder M. Andersen, for orchestrating a seamless transition and to our esteemed board of directors for their trust and confidence in me.

The fourth quarter was chiefly focused on startup activities for the first clinical trial in patients. This included vendor selection to help executing the trial and completing our clinical trial application in collaboration with Alkem Laboratories, leading to filing with the Central Drugs Standard Control Organization (CDSCO) in India in early December 2023.

The preparatory work is the foundation of our strategy to advance BSG005 through its first-in-patient safety and efficacy study, aiming to meet the urgent needs of patients battling severe fungal infections. These infections pose substantial threats to human health. Based on the promising results in our pre-clinical testing and the results from testing in healthy volunteers we are eager to see the full potential of the clinical benefit.

Despite the recent transition in leadership, our focus remains steadfast. In partnership with Alkem Laboratories, our objective is to demonstrate the clinical benefits through the upcoming first-in-patient, Phase 2, and Phase 3 trials. Building on these findings, Biosergen's long-term aim is to conduct targeted clinical trials outside of India, creating the necessary data for later regulatory filings in non-Indian key markets such as the US and EU.

Under our agreement with Alkem, Biosergen will finance the initial first-in-patient study, after which Alkem will take on the funding for Phase 2 and 3 trials in India. Biosergen will also continue to finance the manufacturing and supply of BSG005 for these studies.

Getting the authorization to raise new capital at the EGM will ensure that we can carry out the announced rights issue and raise up to 40.5 million SEK to finance the mission-critical activities. I extend my heartfelt thanks to the investors who have already provided subscription and/or underwriting commitments, in particularly Östersjöstiftelsen, our largest investor, who has committed subscription of 13.5 million SEK. We hope that many of our other existing investors will also participate in this financing round, as your collective support is crucial in driving our mission forward.

As a final remark, a landmark paper was published in the prestigious medical journal The Lancet in January 2024. It shows that 6.5 mill patients have severe fungal infection and 2.5 mill die of their fungal disease regardless of any other underlying disease. It is a remarkedly increase compared to earlier numbers. It is truly alarming numbers, there is a major unmet medical need and there is a need for new antifungal therapies.

I am convinced that we will be a part of transforming antifungal therapy in the future. I look forward to sharing the milestones of this journey with you as we continue to forge ahead.

Sincerely,

Tine Olesen
CEO of Biosergen

ABOUT BIOSERGEN

Vision and mission of the Company

Biosergen's mission is to develop BSG005, including any derivatives and novel formulations of this compound, into the new first line treatment choice for invasive fungal disease, to save thousands of lives every year while generating significant returns to the Company's shareholders.

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 its own commercial infrastructure and strong partnerships with pharmaceutical companies, key opinion leaders, NGOs, and government agencies all over the world.

BSG005 in brief

In brief, BSG005 can be described as 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). 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 conducted by Biosergen. 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. Finally, in preclinical trials, BSG005 has shown up to three to four times higher potency than Amphotericin B at the same dose levels.

Business model

Biosergen is a clinical stage research and development biopharmaceutical company, who intends to employ its financial and organizational resources on developing and commercializing its unique clinical asset BSG005 into becoming the gold standard for antifungal therapy. The Company is developing BSG005 in collaboration with its academic partners and will be funded whenever possible through public grants from Norwegian, European, or other international sources. In time, the Company will establish limited sales and marketing infrastructure necessary to cover specific regions, first and foremost Europe and the United States, and otherwise form strategic partnerships with pharmaceutical and biotechnology companies when relevant to commercialize its products in the different regions of the world.

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 and access to a broad clinical network, will prove to be a strong corporate partner for Biosergen. Alkem will manage the first clinical patient trial, which is expected to start immediately after the regulatory approval. The trial will enrol 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 the preclinical studies and the phase I trials, BSG005 may provide a suitable treatment option for these patients. Once the clinical trials are successfully initiated 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 clinical development 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, or ii) a 50% premium of the share price at the dates of the conversions. The share conversions shall take place as a staged investment with conversion at completion of the specific clinical studies. The share conversions 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, and China and other countries. The patents consist of both granted patents and patents under evaluation. It will cover the product until 2043.

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 5 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 5 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 II/III adaptive design. The patients to be included should have proven/probable invasive aspergillosis. The endpoint is all cause mortality after 6 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 are able to 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 like 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 mill people have life threatening fungal disease. The mortality rate attributable to fungal disease alone is 2.5 mill people in other words these are patients where the cause of death is fungal disease regardless of any other condition they may have[1]. It is an increase of 66% compared to earlier numbers published in 2017. One remarkable patient group that are 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 (also known as 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 chronic obstructive lung disease, cancer patients, transplant

[1] David Denning, The Lancet Infectious Diseases, January 2024

recipients, people taking medications that weaken the immune system and not least, people living with HIV/AIDS.[2]

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 number of elderly patients and more invasive medical procedures.

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[3] and that more than half of all sales of antifungal drugs (52%) are directed against the *Candida* pathogen[4]

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[1] and that approximately 21% 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% 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% of all sales of antifungal drugs are directed against the *Pneumocystis* pathogen.

Incidence and crude mortality for severe fungal infections compared[2]

[2] 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

[3] Bongomin et al.Journal of Fungi, October 2017

[4] Market Research Future. *Global Antifungal Treatment Market forecast to 2027*.

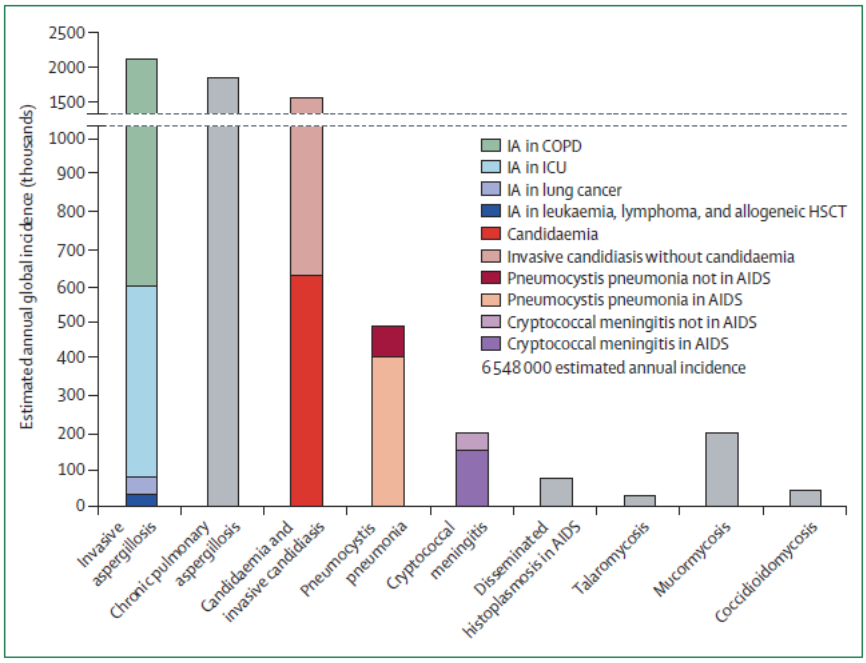


Figure 1: **Estimated annual incidence of life-threatening invasive mycoses, together with chronic pulmonary aspergillosis**

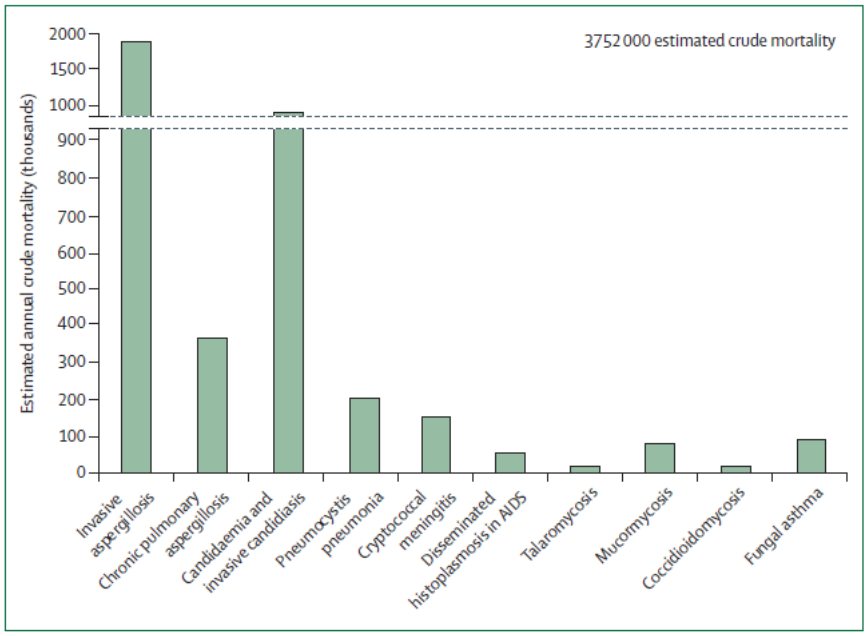


Figure 2: **Estimated crude mortality of severe fungal disease, worldwide**

The crude mortality is 3,75 mill 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[5]. Sales are growing by 6-7% per year. Although most serious infections occur in the developing world, the United States and Europe make up approximately 70% of the market.

The Polyenes
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 with at least similar efficacy compared to the parent compound. However, so far it has not been possible to eliminate nephrotoxicity as the main dose limiting side effect. This is the primary reason that the polyenes despite their effectiveness comprise only approximately 10% 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% 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% 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% of the market.

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.

[5] 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.

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 of the azoles are even used in industrial coatings and for timber preservation. All international public health organisations, including the WHO and the CDC (The United States Centre for Disease Control) as well as the European Commission recognises the rise in fungal infections and not least the rise in Multi Drug Resistant (MDR) fungal strains as a global health threat[6].

BSG005's position in the market
Invasive fungal infection is an aggressive disease with up to 90% 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 antifungal 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 marketed at a price premium. The market potential is large. The market share covered by Amphotericin B and lipid versions is about 450 M USD and the other products used in fungal infections is approximately 20 B USD. 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 are treatments 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 a large number of 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 needs healthcare, a general increase in global wealth also creates an increase in demand for proper healthcare, for instance in newly developed countries.

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.

[6] www.who.int/health-topics/antimicrobial-resistance

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[7].

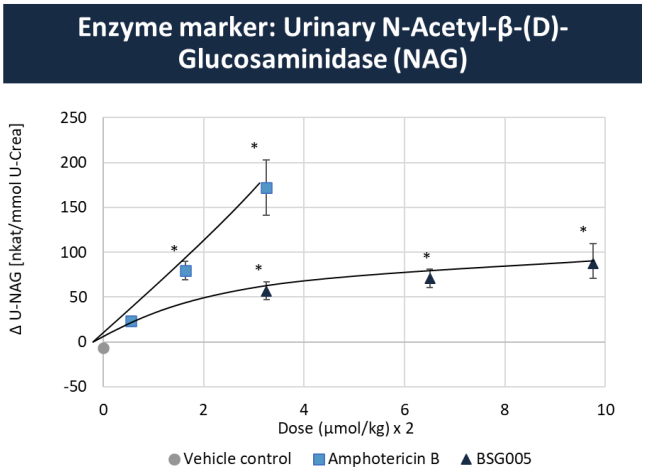
BSG005

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 preclinical trials, BSG005 has shown up to three to four times higher potency than Amphotericin B at same dose levels. More importantly, 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



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.

[7] Garcia-Solache and A. Casadevall: Hypothesis: global warming will bring new fungal diseases for mammals. mBio, May 2010.

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 against Azole and Echinocandin resistant *Aspergillus* and *Candida* strains as well as multi resistant *Candida* auris. At similar 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, of three to four times. The Company is not aware of any other antifungal on the market or in development with a similar profile.

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 I clinical trial data for BSG005
These promising preclinical safety data were confirmed in the first-in-human Phase I clinical trial in 38 volunteers at the Nucleus Network phase I Unit in Melbourne, Australia. Topline data showed a satisfactory safety profile with no serious adverse events reported and no impact on kidney and liver function after BSG005 administration both as single infusions as well as after 7-days repeated IV infusions at multiple dose levels. The clinical phase 1 trial was a double-blinded, placebo-controlled study (randomised 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. The review of the data by the Safety Review Committee revealed that there were no major safety concerns.

All in all, data from both preclinical studies and the Phase I study show that BSG005 has a favorable and crucial differentiation from Amphotericin B, the drug with which BSG005 will most directly compete. The results from one of the preclinical tests are illustrated below.

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.

Phase 1A in healthy subjects- Clinical safety
The first Phase 1 study was a double-blinded, placebo-controlled study to assess the safety, tolerability, and pharmacokinetics of BSG005 following single ("SAD") and multiple ascending doses ("MAD") in healthy subjects.

In total, 38 healthy subjects (randomized to 4 on active treatment and 2 on placebo per cohort) were included.

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.

No subject died or experienced any serious adverse event.

BSG005 was safe and well tolerated in healthy males and females. In particular, no impact at all on kidney function was observed.

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

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, phase 1B
The first study in patients is designed to test the clinical profile of BSG005 as rescue therapy in patients where no effective alternative treatment options are available. Biosergen and the Company's partner, Alkem Laboratories Limited ("Alkem"), have submitted a Clinical Trial Application to the Central Drugs Standard Control Organization (CDSCO) in India. 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.

In total 15 patients will be included in the study. The first patient in the study is expected to be recruited in March 2024. The last patient last visit is planned for Q4 2024

This study is expected to form the basis for an Expanded Access program/Compassionate use program which could include patients represented in the first patient study.

Phase II/III 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 long time before the patients can benefit from new treatments. Therefore, the FDA has modernized their approach to clinical trial over the last 4 years. The

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.

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

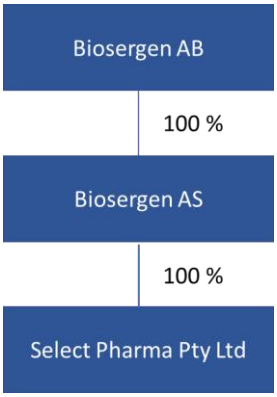
One of these designs is an adaptive design where phases II and III are integrated into one study. Using an adaptive design gives options for changes in design, such as an increase in number of patients based on ongoing evaluation of the data at predetermined timepoints. The second design is a basket 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, 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 exponential 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 aforementioned 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 a clinical studies 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 financing the studies beyond what is funded by the Rights Issue or Alkem.

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, 2022.

Name	Number of shares	Percentage of voting right and capital (%)
ÖSTERSJÖSTIFTELSEN	22,799,419	44,98%
ROSETTA CAPITAL IV SARL	8,931,305	17,62%
Others	18,966,139	37,40%
	50,685,863	**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.ST and the ISIN code is SE0016013460. Per December 31, 2023, the number of shares was 50,685,863. The average number of shares in The Company in Q4 2023 was 50,685,863. 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 Board Members, employees, and key persons Biosergen has implemented two Warrant programs. Program 1 consisting of 1,219,423 warrants where each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of 1.06 SEK. Program 2 consisting of 669,144 warrants where each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of 10 SEK.

Subscription of shares with the support of warrants may take place no later than December 31, 2031.

Auditor´s review
The interim report has not been reviewed by The Company's auditor.

For further information, please contact

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Certified Advisor

Carnegie Investment Bank AB (publ).

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.

Income statement
Other operating income amounted to KSEK 1,315 in the quarter. During the quarter the operating loss amounted to KSEK -6,469.

The financial net amounted to KSEK 193 in the quarter, which lead up to group's net profit thus totaling of KSEK -6,469. Net profit per share was SEK -0,13 for the year to date.

Balance sheet
Total assets amounted to KSEK 7,201 whereof cash and cash equivalents amounted to KSEK 1,883. Current liabilities amounted to KSEK 5,085. At the end of the period, the Group's equity amounted to KSEK 2,116.

Cash flows
The Group's cash flow from operating activities amounted to KSEK 94,524 for the quarter. The outflow from operating activities is attributable to the phase 1 study preparation of the coming patient trial. The cash flow from investing activities was KSEK 0. The Group's cash flow from financing activities amounted to KSEK 0.

Comments to the Parent company´s financial reports
Income statement
During the quarter EBITDA amounted to KSEK -1,941.

Balance sheet
Total assets amounted to KSEK 158,267, whereof cash and cash equivalents amounted to KSEK 1,251. Current liabilities amounted to KSEK 1,200. At the end of the period, the Company's equity amounted to KSEK 157,067.

Cash flows
The Company's cash flow from operating activities amounted to KSEK -1,941 in the quarter. During the quarter the cash flow from investing activities was KSEK -1,308, relating to transactions with Group companies. The Company's cash flow from financing activities amounted to KSEK 0 in the quarter.

Capital resources and Liquidity
The Board and Management are assessing alternatives to secure the company’s long-term capital requirement on an ongoing basis.

Employees
On December 31, 2023, the Company and the Group as well had three employees.

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. During the quarter no significant changes with respect to these risks or uncertainty factors have arisen.

Principles for preparation of the interim report
Biosergen prepares its financial reports in accordance with the Swedish Annual Accounts Act and BFNAR 2021:1 (K3) Annual Reporting and consolidated reports (K3).

FINANCIAL CALENDAR

Year-end Report 2023	February 29, 2024
Annual Report	May 10, 2024
Interim report, January – March (Q1)	May 31, 2024
Annual General Meeting	June 14, 2024
Interim Report April – June (Q2)	August 30, 2024
Interim Report July – September (Q3)	November 29, 2024
Year-end Report 2024	March 31, 2025

Consolidated income statement and statement of comprehensive income

TSEK	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Operating in come				
Other operating income	1,315	1,964	9,378	5,183
	1,315	1,964	**9,378**	5,183
Operating expenses				
Consumables	-224	-158	-456	-280
Other external expenses	-5,328	-12,838	-25,726	-36,340
Personnel costs	-1,070	-1,796	-8,592	-7,808
Other operating expenses	-1,355	337	-1,870	-742
Operating profit/loss	**-6,662**	-12,491	**-27,266**	-39,987
Net financial items	193	87	229	109
Profit after financial items	**-6,469**	-12,404	**-27,037**	-39,878
Tax	0	-28	0	-28
Profit/loss for the period	**-6,469**	-12,432	**-27,037**	-39,906

Consolidated balance sheet

TSEK	2023 Jan-Dec	2022 Jan-Dec
Assets		
Receivables	5,318	4,637
Cash & Bank	1,883	29,342
Total assets	**7,201**	**33,979**
Equity and liabilities		
Equity	2,116	22,793
Current liabilities	5,085	11,186
Total equity and liabilities	**7,201**	**33,979**

Group	2023	2022
TSEK	Jan-Dec	Jan-Dec
Opening balance beginning of period	**22,794**	**20,233**
Jan-Mar		
Profit/loss for the period	-5,027	-5,015
Exchange rate	-91	-320
April-June		
Profit/loss for the period	-8,031	-7,960
Exchange rate	-513	-380
July-Sep		
Profit/loss for the period	-7,510	-14,499
Exchange rate	566	172
Oct- Dec		
Profit/loss for the period	-6,470	-12,433
Exchange rate	1,101	18
Comprehensive income for the period	**-3,181**	**-20,184**
Transactions with shareholders		
Jan-Mar		
New share issue for the period incl. IPO	0	0
April-June		
New share issue for the period incl. IPO	0	0
July-Sep		
New share issue for the period incl. IPO	5,297	0
Oct- Dec		
New share issue for the period incl. IPO	0	42978
Closing balance end of period	**2,116**	**22,794**

Consolidated cash flow statement

TSEK	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Operating activities				
Operating profit/loss	-6,662	-12,,492	-27266	-39,988
Net financial items	193	59	229	81
Cash flow from operating activities before changes in working capital	**-6,469**	**-12,433**	**-27,037**	**-39,907**
Cash flow from changes in working capital				
Change in receivables	-53	-1,159	-681	3184
Changes in current liabilities	1,998	-9,500	-4,885	1,422
Cash flow from operating activities	**-4,524**	**-23,092**	**-32,603**	**-35,301**
Financing activities				
New share issue	0	42,978	5,144	42,978
Cash flow from financing activites	**0**	**42,978**	**5,144**	**42,978**
Cash flow for the period	**-4,524**	**19,886**	**-27,459**	**7,677**
Liquid fund at the beginning of the period	**6,407**	**9,456**	**29,342**	**21,665**
Liquid funds at the end of the period	**1,883**	**29,342**	**1,883**	**29,342**

TSEK	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Operating income				
Net sales	2,011	1,401	4,725	3,508
	2,011	**1,401**	**4,725**	**3,508**
Operating expenses				
Consumables	-75	-142	64	-203
Other external expenses	-2,265	-3,794	-7,030	-5,138
Personnel costs	-1,070	-1,797	-8,592	-7,761
Other operating expenses	0	0	0	0
Operating profit/loss	**-1,399**	**-4,332**	**-10,833**	**-9,594**
Net financial items	-462	714	-716	-132,884
Profit after financial items	**-1,861**	**-3,618**	**-11,549**	**-142,478**
Tax	-80	-28	-86	0
Profit/loss for the period	**-1,941**	**-3,646**	**-11,635**	**-142,478**

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TSEK	2023 Jan-Dec	2022 Jan-Dec
Assets		
Financial assets	156,496	135,201
Receivables	520	1,041
Cash & Bank	1,251	28,956
Total assets	**158,267**	**165,198**
Equity and liabilities		
Equity	157,067	163,405
Current liabilities	1,200	1,793
Total equity and liabilities	**158,267**	**165,198**

Parent company statement of changes in equity

TSEK	2023 Jan-Dec	2022 Jan-Dec
Opening balance beginning of period	**163,405**	**268,764**
Jan-Mar		
Profit/loss for the period	-2,149	-1,482
April-June		
Profit/loss for the period	-2,797	-1,845
July-Sep		
Profit/loss for the period	-4,748	-7,937
Oct-Dec		
Profit/loss for the period	-1,941	-131,213
Comprehensive income for the period	**151,770**	**126,287**
Transactions with shareholders		
April-June		
Deposit of share capital	0	0
Apport emission	0	0
Reduction of share capital	0	0
New share issue for the period incl. IPO	5,297	37,118
Closing balance end of period	**157,067**	**163,405**

Parent company cashflow statement

TSEK	2023 Oct-Dec	2022 Oct-Dec	2023 Jan-Dec	2022 Jan-Dec
Operating activities				
Operating profit/loss	-1,399	1,528	-10,833	-9,594
Net financial items	-542	542	-802	542
Cash flow from operating activities before changes in working capital	**-1,941**	**2,070**	**-11,635**	**-9,052**
Cash flow from changes in working capital				
Change in receivables	565	-46	521	78
Changes in current liabilities	26	-9,846	-593	834
Cash flow from operating activities	**-1,350**	**-7,822**	**-11,707**	**-8,140**
Investing activities				
Investments in other financial fixed assets	-1,308	-2,309	-21,295	-16,783
Cash flow from investing activities	**-1,308**	**-2,309**	**-21,295**	**-16,783**
Financing activities				
New share issue	0	37,118	5,297	37,118
Cash flow from financing activities	**0**	**37,118**	**5,297**	**37,118**
Cash flow for the period	**-2,658**	**26,987**	**-27,705**	**12,195**
Liquid fund at the beginning of the period	**3,909**	**1,969**	**28,956**	**16,761**
Liquid funds at the end of the period	**1,251**	**28,956**	**1,251**	**28,956**