

The background of the entire page is a blue-tinted microscopic image showing various bacterial structures. There are several long, thin, rod-shaped bacteria (bacilli) and many spherical bacteria (cocci), some of which are arranged in chains or clusters. The image is out of focus, creating a sense of depth and scientific context.

Biosergen AB

Fogdevreten 2, 171 65 Solna
Registration no. 559304-1295

**Interim report for the period
July 1, 2023 – September 30, 2023**

Statement by the Board of Directors and the Executive Board	3
Management's review	4 – 16
Financial review	17
Consolidated income statement and statement of comprehensive income	18
Consolidated balance sheet	19
Consolidated statement of changes in equity	20
Consolidated cash flow statement	21
Parent company income statement	22
Parent company balance sheet	23
Parent company statement of changes in equity	24
Parent company cash flow statement	25

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, November 30, 2023

Executive Board

Peder M. Andersen

Board of Directors

Torsten Goesch
Chairman

Achim Kaufhold

Henrik Moltke

Marianne Kock

Mattias Klintemar

CONSOLIDATED FINANCIAL HIGHLIGHTS AND RATIOS

TSEK	2023 July-Sep	2022 July-Sep	2023 Jan-Sept	2022 Jan-Sep	2022 Jan-Dec
Profit/loss					
Other income	292	493	8.063	3.219	5.183
Profit/loss before depreciation (EBITDA)	-7.537	-14.515	-20.604	-27.496	-34.129
Operating profit/loss before net financials	-7.537	-14.515	-20.604	-27.496	-34.129
Net financials	27	16	36	22	81
Netprofit/loss for the period	-7.510	-14.499	-20.568	-27.474	-34.048
Balance sheet					
Cash	6.407	9.456	6.407	9.456	29.342
Balance sheet total	11.483	12.934	11.483	12.934	33.790
Equity	7.485	-7.769	7.485	-7.769	22.794
Cash flows					
Cash flows from:					
Operating activities	-8.838	3.736	-28.079	-12.209	-29.441
Financing activities	5.144	0	5.144	0	37.118
Ratios					
Solvency (%)	65	neg	65	neg	67
Earnings per share (SEK)	-0,15	-0,51	-0,48	-0,97	-1,09
Diluted earnings per share	-0,15	-0,51	-0,48	-0,97	-1,09

HIGHLIGHTS DURING Q3 2023

- September 25, Biosergen and Alkem Laboratories Ltd collaborates to develop anti-infective for severe fungal infections.
- August 28, Warrants series TO2 were exercised to approximately 96.1 percent and Biosergen AB receives approximately SEK 5.5 million.
- August 16, Biosergen Receives Full Subscription Guarantees for Warrant Exercise from Largest Shareholders and Executive Management.
- August 7, Biosergen Announces Abstract Accepted for Presentation at the 11th Congress on Trends in Medical Mycology (TIMM-11).

HIGHLIGHTS AFTER THE PERIOD

- Abstract presented at the 11th Trends in Medical Mycology publicly available

CEO LETTER

Dear Shareholders,

I am pleased to provide an update on Biosergen's progress during the third quarter of 2023 and the following months. The period has been marked by significant steps forward on our journey to advance our innovative drug candidate, BSG005, as a tool to fight invasive fungal infections.

Our most significant achievement has been reaching an agreement with Alkem Laboratories Ltd. to co-develop BSG005. Alkem, a leading pharmaceutical company in India with extensive clinical development expertise, is an ideal partner as we navigate the rigorous journey of clinical trials. By partnering with Alkem, we will be able to get a high number of patients into our trials, as Alkem has the experience of managing such trials in India, where the frequency of diagnosed severe fungal infections is amongst the highest in the world.

Pending regulatory approvals, Alkem will conduct the Phase 2 and Phase 3 trials required for BSG005 approval in India. The clinical trial, currently in preparation for submission to the Indian health authority, CDSCO, will focus on the advantages of BSG005 and include patients who are intolerant or resistant to treatment with Amphotericin B, patients who have failed on first line therapy and patients who have mild to moderate kidney parameters. This population has a high unmet medical need. Together, we aim to bring BSG005 to the Indian market, addressing the unmet medical need for a new effective antifungal treatment. Biosergen maintains the rights for commercializing BSG005 in the rest of the world, allowing us to advance the drug in other markets in parallel to the planned trial activities in India. Alkem will fund all phase 2 and 3 patient trials in India except the first patient trial with 15 patients. This is expected to cover up to 70% of all patients required for a global regulatory approach.

With this deal with Alkem Biosergen has achieved to save investment of estimated more than 300 M SEK for phase 2 and 3 clinical trials. All these trials in India will be funded by Alkem. And management is on the look for further partnering of both commercial and manufacturing deals that may have major impact on and reduce the need for further financing.

Another noteworthy event happened in August when we conducted a successful financing round. More than 96% of warrant holders chose to exercise their rights to purchase new shares in our company, including Östersjöstiftelsen, our largest shareholder. With full exercise guarantees provided by these investors, alongside our management team, we raised 5.5 million kronor before issuance costs. I would like to thank all investors who participated in supporting Biosergen.

When it comes to making BSG005 more known in the international mycology community, we recently attended the 11th Trends in Medical Mycology Congress in Athens, Greece. At the conference, we presented an abstract based on data from our Phase 1 clinical trial, emphasizing the safety and tolerability of BSG005. The conference provided a unique platform for engaging in discussions with experts in medical mycology. In the years to come, we look forward to advancing BSG005 in collaboration with partners outside India, so meeting with the mycology community is an important activity.

As we move into the next phase of our journey, with testing BSG005 in patients with our target diseases on the horizon, I eagerly anticipate sharing more information as we work towards and beyond this important milestone, and we can share data with the public as we go through this first important trial because the trial is an open trial where we see the results after each treated patient.

Thank you for your ongoing trust and support. Together, we can hopefully one day change the lives of patients suffering from invasive fungal infections.

Best regards,

Dr. Peder M. Andersen

CEO, 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 does. 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 and only 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 sought 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.

Patents

Biosergen has strong patent protection in four regions, USA, EU, Japan, and China and other countries. The patent is a composition of matter patent.

Orphan drug status

Biosergen was in June 2021 granted orphan drug status for BSG005 with the FDA on the basis that less than 200,000 patients per year, with invasive aspergillosis in the United States, will be treated with the drug. With an orphan drug status, one of the benefits is guaranteed market exclusivity for 7 years after the drug is approved.

Similarly, the United States Congress created GAIN in 2012 (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 may be designated as a qualified infectious disease product (QIDP) if it meets the criteria outlined in the statute, which the Company expect BSG005 would do. A drug that receives QIDP designation is eligible under the statute for fast-track designation and priority review, as well as additional market exclusivity (currently 7 years).

Biosergen intends to apply for GAIN/QIDP status in the USA however expect that clinical phase 2 data will be expected to submit a QIDP application. Application can be done at any time in the development process.

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.

It is estimated that fungal infections kill more than 1.5 million people every year¹ and the number of cases continues to increase². The factors behind the increased incidence 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 cancer patients, transplant recipients, people taking medications that weaken the immune system and not least, people living with HIV/AIDS.³ There has also been a widespread use of antifungal drugs as an anti-mold in industry including agriculture and livestock productions.

Hospital acquired infection

Hospital-acquired infections (also known as nosocomial 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, more invasive medical procedures, ever busier medical staff, inadequate sanitation protocols and finally, the routine use of antifungal drugs in hospital settings that creates a selection pressure for the emergence of resistant strains.

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.

INVASIVE FUNGAL INFECTIONS

Most invasive fungal infection-related serious illnesses and deaths are caused by four fungal pathogens: *Candida*, *Aspergillus*, *Cryptococcus* and *Pneumocystis*. But there are also other serious fungal infections such as Mucormycosis as recently seen in an epidemic in India in the middle of the Covid pandemic and *Cryptococcus* infections, where BSG005 has proven efficacy in vitro.

Candida

Candida is a yeast that causes infections in individuals with deficient immune systems. Systemic *Candida* infections of the bloodstream and major organs, particularly in immunocompromised patients, affect over 90,000 people a year in the United States alone. People with diabetes and HIV are particularly susceptible to Candidiasis. It is estimated that approximately 750,000 people worldwide develop invasive Candidiasis every year⁴ and that more than half of all sales of antifungal drugs (52%) are directed against the *Candida* pathogen⁵.

Aspergillus

Aspergillus cause aspergillosis which primarily develops in people with weakened immune systems or lung diseases. These fungi also cause allergic reactions. Aspergillosis include allergic bronchopulmonary aspergillosis and invasive aspergillosis, both of which conditions are potentially lethal. It is estimated that more than 300,000 people worldwide develop aspergillosis every year 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 200,000 AIDS

¹ Bongomin et al. Journal of Fungi, October 2017

² Kainz et al. Microbial Cell, June 2020

³ 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

⁴ Bongomin et al. Journal of Fungi, October 2017

⁵ Market Research Future. *Global Antifungal Treatment Market forecast to 2027*.

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 500,000 people develop pneumocystis pneumonia every year and that less than 5% of all sales of antifungal drugs are directed against the *Pneumocystis* pathogen.

Mucormycetes

Mucormycetes, a group of molds that can be found in various environments including soil, decaying organic matter like compost piles or rotten wood that can cause is a serious fungal infection called Mucormycosis, currently also known as Black Fungus. The transmission of mucormycosis occurs when individuals come in contact with fungal spores present in the environment. Inhaling spores can result in lung or sinus infections, which primarily affect people with preexisting health conditions (such as diabetes) or those taking medications that suppress the immune system (such as steroids during covid 19 therapy). During the COVID-19 pandemic in India notable opportunistic mucormycosis infection outbreaks emerged leading to sharp increase in deaths.

Often, surgery is required to remove dead or infected tissue (black tissue), examples are removal of an eye or part of the upper jaw.

ANTIFUNGALS USED TODAY

The 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 2020⁶. Sales are growing by 6-7% per year. Although the majority of 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. 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 marketed as 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. 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 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

⁶ 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.

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 were discovered in the 1970s. The Pyrimidines 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.

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.

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 fungistatics, some fungal cells survive, and these are 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 industry including agricultural and livestock production. Certain of the 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 threat⁷.

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.

⁷ www.who.int/health-topics/antimicrobial-resistance

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.

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 species⁸.

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 interference 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.

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

⁸ Garcia-Solache and A. Casadevall: Hypothesis: global warming will bring new fungal diseases for mammals. mBio, May 2010.

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.

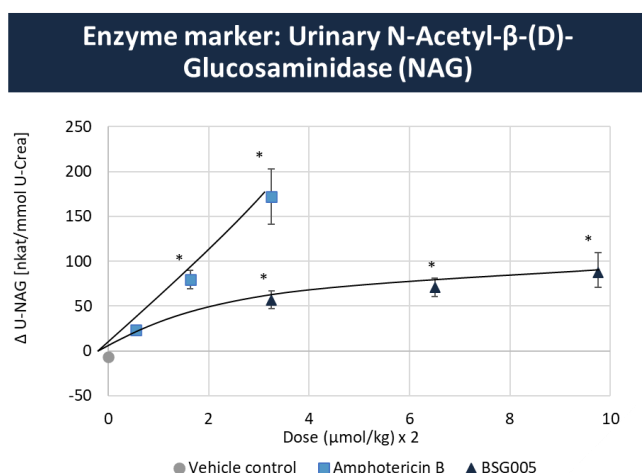
None of the preclinical tests have indicated a significant kidney toxicity potential.

Phase I clinical trial data for BSG005

These promising preclinical safety data were confirmed in the first-in-human Phase I clinical trial in 36 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 36 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.

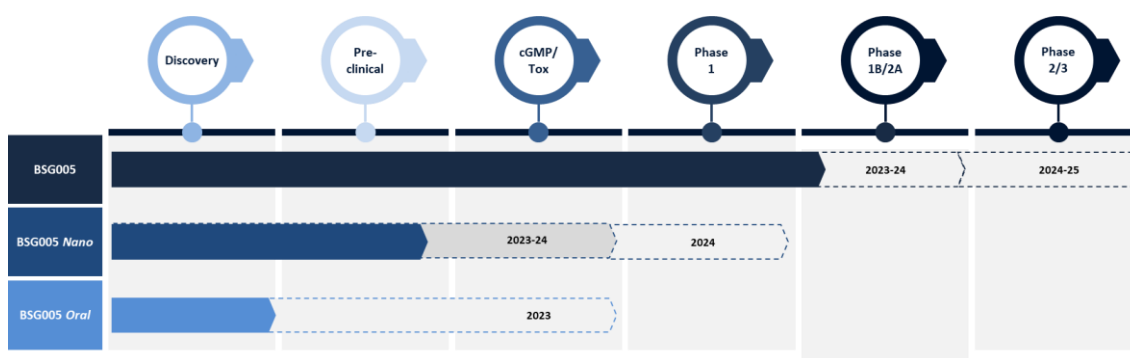
BSG005 shows significantly less toxicity in the kidneys in a preclinical test



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.

DEVELOPMENT ACTIVITIES

Biosergen's research and development pipeline is built around formulations of BSG005. The most advanced formulation is intravenous, comparable to other treatment regimens for severe systemic fungal infections. BSG005 Nano is a novel nano formulation developed at SINTEF which specifically target the lungs where many systemic fungal infections often are first established. BSG005 Oral is also a nano formulation. With BSG005 formulated as a pill, the versatility of the drug would greatly expand (for instance for follow up treatments in the patient's own home after surgery).



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) in multiple indications.

With our co-development deal with Alkem there may be a potential faster due to higher access to our target patients.

Phase 1 clinical trial

As previously mentioned, Biosergen has conducted a placebo-controlled, double-blinded study, enrolling 36 healthy adult volunteers. The primary objective was to evaluate the safety and tolerability of BSG005 in a healthy adult volunteer population at increasing doses. The secondary objective was to assess the pharmacokinetics of BSG005 after single and multiple dosing in healthy subjects, to assess any plasma accumulation and the excretion of BSG005 in urine. An escalating 7-day dosing was included as a part 2 of this trial with the same objectives as the first single dose part. The review of the complete trial data set revealed that there were no serious safety issues reported and all laboratory data were OK with no impact on kidney and liver function at all, and that the BSG005 was measurable in plasma even at low dosing levels. These safety results from Phase 1 are key to the clinical development as the fungicidal effect of polyenes and BSG005 is well known.

Clinical trial program

Biosergen's clinical trial program will be kick started by an initial, open-label, two-center trial in patients with invasive fungal infection. The purpose is to prove BSG005 potency, as well as its superior safety profile. In addition, this initial trial will serve to significantly de-risk the further clinical development of BSG005 in a phase 2/3 setting and increase the probability of attracting future non-dilutive funding.

The first clinical trial will be conducted at two sites in India and is planned to start Q4 2023 with enrolment of the first patient in February 2024. The plan is to enroll a total of 15 patients suffering from invasive fungal infections. The key enrolment criteria is based on the fact that some patients have limited treatment option due to: a) intolerability or toxicity of Amphotericin B (main competitor) b) failure of first line therapy due to drug resistance formation on previous medication c) chronic mild to moderate kidney impairment and thereby not being able to tolerate many of the already marketed drugs but especially Amphotericin B. In the three mentioned key enrolment criteria the common denominator is that patients have been taken off existing treatment and are left without any effective treatment options. The trial design serves several purposes, including demonstrating that BSG005 could become a rescue treatment for a large group of patients with no treatment options as a result of well-known severe side effects, lack of efficacy due to resistance formation or a chronic disease that limits treatment options, a global patient population with a high unmet medical need. The invasive fungal diseases expected to be included are the infectious diseases the Company has previously highlighted as the candidates for registration-oriented Phase 2/3 trials:

aspergillosis, mucormycosis and candidiasis The trial will serve to significantly de-risk the further Phase 2/3 development of BSG005 giving valuable information on effective dose level, treatment periods and safety at higher doses, and off course to increase the probability of attracting future non-dilutive funding. Such data will be valuable in qualifying the decision on what disease to initiate the Company's subsequent registration-oriented single-indication Phase 2/3 trials and ensure an optimized trial design.

Additionally, having data from a human clinical trial verifying that BSG005 shows potency as a valuable treatment for specific patient populations, which globally currently does not have real treatment options, could be a starting point for the initiation of regulatory discussions on a real "Expanded Access/Compassionate Use treatment approval" and make the way for early revenues from such a program.

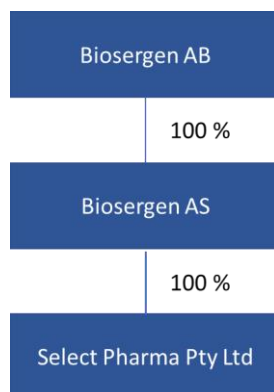
Following data readout from the initial trial, Biosergen expects to initiate single-indication registration-oriented Phase 2 clinical trials in collaboration with our co-development partner Alkem Ltd. The two main targets for registration-oriented Phase 2 trials remain to be Aspergillosis indication for which Biosergen has Orphan Drug Designation in the US and Mucormycosis.

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 lung 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.

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	100.0%

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 September 30, 2023, the number of shares was 50,685,863. The average number of shares in The Company in Q2 2023 was 44,851,263. 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

Peder M Andersen, CEO
E-mail: peder.andersen@biosergen.net
Cell Phone: +45 2080 2470
Website: www.biosergen.net

Niels Laursen, CFO
E-mail: niels.laursen@biosergen.net
Cell Phone: +45 4014 5059

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 292 in the quarter. During the quarter the operating loss amounted to KSEK -7,537.

The financial net amounted to KSEK 27 in the quarter, which lead up to group's net profit thus totaling of KSEK -7,510. Net profit per share was SEK -0,15 for the year to date.

Balance sheet

Total assets amounted to KSEK 11,483 whereof cash and cash equivalents amounted to KSEK 6,407. Current liabilities amounted to KSEK 3,998. At the end of the period, the Group's equity amounted to KSEK 7,485.

Cash flows

The Group's cash flow from operating activities amounted to KSEK -8,838 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 5,144. The Group's cash flow from financing activities amounted to KSEK 5,144.

Comments to the Parent company's financial reports

Income statement

During the quarter EBITDA amounted to KSEK -4,749.

Balance sheet

Total assets amounted to KSEK 160,182, whereof cash and cash equivalents amounted to KSEK 3,909. Current liabilities amounted to KSEK 1,175. At the end of the period, the Company's equity amounted to KSEK 159,007.

Cash flows

The Company's cash flow from operating activities amounted to KSEK -5,944 in the quarter. During the quarter the cash flow from investing activities was KSEK -1,727, relating to transactions with Group companies. The Company's cash flow from financing activities amounted to KSEK 5,297 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 September 30, 2023, the Company and the Group as well had four 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	March 29, 2024
Annual Report	March 29, 2024
Annual General Meeting	May 31, 2024
Interim report, January – March (Q1)	May 31, 2024
Interim Report April – June (Q2)	August 30, 2024

Consolidated income statement and statement of comprehensive income

TSEK	2023 July-Sep	2022 July-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Operating income					
Other operating income	292	493	8.063	3.219	5.183
	292	493	8.063	3.219	5.183
Operating expenses					
Consumables	-2	0	-232	-122	-280
Other external expenses	-3.840	-10.928	-20.398	-23.502	-30.481
Personnel costs	-4.102	-3.359	-7.522	-6.012	-7.808
Other operating expenses	115	-721	-515	-1.079	-743
Operating profit/loss	-7.537	-14.515	-20.604	-27.496	-34.129
Net financial items	27	16	36	22	81
Profit after financial items	-7.510	-14.499	-20.568	-27.474	-34.048
Profit/loss for the period	-7.510	-14.499	-20.568	-27.474	-34.048

	2023	2022	2022
TSEK	Jan-Sept	Jan-Sept	Jan-Dec
Assets			
Receivables	5.076	3.478	4.448
Cash & Bank	6.407	9.456	29.342
Total assets	11.483	12.934	33.790
Equity and liabilities			
Equity	7.485	-7.769	22.794
Current liabilities	3.998	20.703	10.996
Total equity and liabilities	11.483	12.934	33.790

Consolidated statement of changes in equity

Group	2023	2022	2022
TSEK	Jan-Sep	Jan-Sep	Jan-Dec
Opening balance beginning of period	22.794	20.233	20.233
Jan-Mar			
Profit/loss for the period	-5.027	-5.015	-34.048
Exchange rate	-91	-320	-510
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	-
Comprehensiv income for the period	2.188	-7.769	-14.325
Transactions with shareholders			
New share issue	5.450	-	42.153
New share issue	-	-	825
Emission cost	-153	-	-5.859
Jan-Mar			
New share issue for the period incl. IPO	-	-	-
April-June			
New share issue for the period incl. IPO	-	-	-
July-Sep			
New share issue for the period incl. IPO	-	-	-
Closing balance end of period	7.485	-7.769	22.794

Consolidated cash flow statement

TSEK	2023 Jul-Sep	2022 Jul-Sep	2023 Jan-Sep	2022 Jan-Sep	2022 Jan-Dec
Operating activities					
Operating profit/loss	-7.537	-14.515	-20.604	-27.496	-34.129
Net financial items	27	16	36	22	81
Cash flow from operating activities before changes in working capital	-7.510	-14.499	-20.568	-27.474	-34.048
Cash flow from changes in working capital					
Change in receivables	2.183	4.421	-628	4.343	3.373
Changes in current liabilities	-3.511	13.814	-6.883	10.922	1.234
Cash flow from operating activities	-8.838	3.736	-28.079	-12.209	-29.441
Financing activities					
New share issue	5.144	0	5.144	0	37.118
Cash flow from financing activities	5.144	0	5.144	0	37.118
Cash flow for the period	-3.694	3.736	-22.935	-12.209	7.677
Liquid fund at the beginning of the period	10.101	5.720	29.342	21.665	21.665
Liquid funds at the end of the period	6.407	9.456	6.407	9.456	29.342

Parent company income statement

	2023	2022	2023	2022	2022
TSEK	July-Sep	July-Sep	Jan-Sep	Jan-Sept	Jan-Dec
Operating income					
Net sales	1.069	803	2.715	2.107	3.508
	1.069	803	2.715	2.107	3.508
Operating expenses					
Consumables	0	0	0	-61	-203
Other external expenses	-1.748	-5.282	-4.634	-7.204	-5.139
Personnel costs	-4.102	-3.358	-7.522	-5.964	-7.760
Other operating expenses	0	0	0	0	0
Operating profit/loss	-4.781	-7.837	-9.441	-11.122	-9.594
Net financial items	32	-100	-254	-143	-132.884
Profit after financial items	-4.749	-7.937	-9.695	-11.265	-142.478
Profit/loss for the period	-4.749	-7.937	-9.695	-11.265	-142.478

	2023	2022	2022
TSEK	Jan-Sep	Jan-Sep	Jan-Dec
Assets			
Financial assets	155.188	266.318	135.201
Receivables	1.085	995	1.041
Cash & Bank	3.909	1.969	28.956
Total assets	160.182	269.282	165.198
Equity and liabilities			
Equity	159.007	257.500	163.405
Current liabilities	1.175	11.782	1.793
Total equity and liabilities	160.182	269.282	165.198

Parent company statement of changes in equity

Parent company	2023	2022	2022
TSEK	Jan-Sept	Jan-Sept	Jan-Dec
Opening balance beginning of period	163.405	268.764	268.764
Profit/loss for the period			-142.478
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	-
Comprehensiv income for the period	153.711	257.500	126.286
Transactions with shareholders			
New share issue	5.450	-	42.153
New share issue	-	-	825
Emission cost	-153	-	-5.859
April-June			
Deposit of share capital	-	-	-
Apportemission	-	-	-
Reduction of share capital	-	-	-
New share issue for the period incl. IPO	-	-	-
Closing balance end of period	159.008	257.500	163.405

Parent company cashflow statement

	2023	2022	2023	2022	2022
TSEK	July-Sep	July-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Operating activities					
Operating profit/loss	-4.782	-7.837	-9.441	-11.122	-9.594
Net financial items	33	0	-254	0	542
Cash flow from operating activities before changes in working capital	-4.749	-7.837	-9.695	-11.122	-9.052
Cash flow from changes in working capital					
Change in receivables	193	354	-44	124	78
Changes in current liabilities	-1.388	11.128	-618	10.680	834
Cash flow from operating activities	-5.944	3.645	-10.357	-318	-8.140
Investing activities					
Investments in other financial fixed assets	-1.727	-4.839	-19.987	-14.474	-16.783
Cash flow from investing activities	-1.727	-4.839	-19.987	-14.474	-16.783
Financing activities					
New share issue	5.297	0	5.297	0	37.118
Cash flow from financing activities	5.297	0	5.297	0	37.118
Cash flow for the period	-2.374	-1.194	-25.047	-14.792	12.195
Liquid fund at the beginning of the period	6.283	3.163	28.956	16.761	16.761
Liquid funds at the end of the period	3.909	1.969	3.909	1.969	28.956