

The background of the entire page is a deep blue color. It is populated with various microscopic-looking elements. There are numerous spherical particles of different sizes, some of which have a textured, crater-like surface. Interspersed among these spheres are long, thin, cylindrical structures that resemble tubes or filaments. Some of these tubes have small, circular openings or pores along their length. The overall composition gives the impression of a complex biological or chemical environment, possibly a microfluidic device or a cellular structure, viewed under a microscope.

Biosergen AB

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**Interim report for the period
1 January 2025 – 30 September 2025**

ADVANCING BSG005 TOWARD COHORT 3 AND KEY APPOINTMENTS

Progress in GMP Manufacturing of BSG005 and U.S. IND Submission Preparations

“During the third quarter of 2025, we focused on preparing for the next phase of BSG005’s development. The manufacturing of a new GMP-compliant batch is progressing according to plan and will support both Cohort 3 and our upcoming Phase 2 program. This upgraded production process is designed to meet the stringent regulatory standards in all key regions—India, the U.S., and Europe—ensuring global readiness not only for the upcoming clinical phases but also for commercial supply in the years to come. At the same time, we advanced our regulatory strategy, with preparations underway for an IND submission to the U.S. FDA, which we aim to file early next year. We also welcomed Mark Beveridge as Chief Financial Officer, whose expertise will be a valuable asset as we move forward. With these developments, we are building a strong foundation to meet all future production needs while actively expanding our clinical opportunities, ensuring multiple pathways for the continued advancement of BSG005 as a novel antifungal therapy.” —Tine Olesen, CEO Biosergen

CONSOLIDATED FINANCIAL HIGHLIGHTS AND RATIOS

TSEK	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Profit/loss					
Other income	131	1,081	2,087	1,560	1,940
Profit/loss before depreciation (EBITDA)	-12,190	-11,149	-28,366	-16,877	-19,203
Operating profit/loss before net financials	-12,190	-11,149	-28,366	-16,877	-19,203
Net financials	22	-78	12	-78	8
Net profit for the period	-12,168	-11,227	-28,354	-16,955	-19,195
Balance sheet					
Cash	22,713	10,242	22,713	10,242	50,612
Balance sheet total	25,523	14,560	25,523	14,560	53,022
Equity	20,260	11,705	20,260	11,705	48,207
Cash flows					
Cash flows from:					
Operating activities	-10,440	-28,314	-27,786	-17,816	-10,178
Financing activities	-	26,175	-	26,175	58,907
Ratios					
Solvency (%)	79	80	79	80	91
Earnings per share (SEK)	-0,05	-0,05	-0,12	-0,18	-0,08
Diluted earnings per share	-0,05	-0,05	-0,12	-0,18	-0,08

HIGHLIGHTS DURING Q3 2025

- On July 24. Appointment of Mark Beveridge as Chief Financial Officer

CEO STATEMENT

As we have now closed the third quarter of 2025, I am pleased to report that Biosergen continues to advance steadily across all key areas of development.

As you may recall, we completed the second cohort of our BSG005 proof-of-concept trial earlier this year, delivering very encouraging results. Across both cohorts, all patients who completed treatment experienced either full recovery or marked clinical improvement without any severe side effects. These patients were treated for a range of life-threatening fungal infections, including drug-resistant *Aspergillus*, pulmonary *Mucormycosis*, and even co-infections involving both pathogens, cases that typically carry extremely high mortality risks. These results provide compelling proof of concept for BSG005 as a potentially life-saving antifungal therapy.

Due in part to the investigators' willingness to treat patients longer than originally planned, we nearly exhausted our existing stock of BSG005 and have therefore paused the initiation of the third cohort until new drug supply becomes available. This also provided an opportunity to upgrade the BSG005 production process. The new GMP-compliant drug substance is being manufactured not only to support the third cohort but also to meet the higher standards required for our upcoming Phase 2 trials and future global regulatory submissions. This new batch of BSG005 is on track for release in early 2026.

I am especially pleased with this development, as manufacturing BSG005 is far more complex than many realize. As a genetically engineered polyene macrolide, the production process is inherently challenging and further complicated by the need to comply with stringent regulatory requirements across all regions where we expect to operate in the future, including India, the United States, and Europe.

We are engaging with the U.S. Food and Drug Administration. This work is supported by our preclinical data, completed Phase 1 results, and the positive clinical outcomes observed in both patient cohorts to date. These efforts are directed toward the submission of an Investigational New Drug (IND) application early next year, which would represent an important milestone in establishing BSG005's development path in the U.S.

During the quarter, we also strengthened our leadership team. In July, Mark Beveridge joined Biosergen as our new Chief Financial Officer. We warmly welcome Mark to the team and thank his predecessor, Niels Laursen, for his valuable contributions and steady guidance since 2021.

Looking ahead, our priorities are clear: to finalize and release the new BSG005 drug batch, and to continue expanding our regulatory engagements in both Europe and the United States.

I want to thank our investigators, partners, and shareholders for their continued commitment. With each step forward, we move closer to potentially establishing BSG005 as a globally relevant treatment for patients suffering from life-threatening fungal infections.

Sincerely,

Tine K. Olesen
CEO, Biosergen AB

ABOUT BIOSERGEN

Vision and mission of the Company

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

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

BSG005 in brief

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

Business model

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

Strategic partnerships

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

Alkem is among the five largest pharmaceutical companies in India, and has more than 17.000 employees, with affiliates in the USA, Australia, UK, Germany, and many other emerging countries. Alkem is a leader in the anti-infective market, with clinical development expertise and an established commercial infrastructure. Moreover, Alkem has 144 ANDAs, two manufacturing sites and two R&D sites in the US market. Alkem, with its established clinical development engine, access to a broad clinical network and strong commercialization capabilities, is an ideal corporate partner for Biosergen.

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

Patents

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

Orphan drug status - Aspergillosis

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

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

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

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

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

FUNGAL INFECTIONS ARE INCREASING

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

Fungal infection is an increasing problem

In January 2024, new numbers on the incidence of severe life-threatening fungal disease were published. It is estimated that 6.5 million people have life threatening fungal disease. The mortality rate attributable to fungal disease alone is 2.5 million people. In other words, these are patients whose cause of death is fungal disease, regardless of any other condition they may have¹. It is an increase of 66 percent compared to numbers published in 2017. One notable patient group included in the current numbers are patients with chronic obstructive pulmonary disease (COPD). These have not previously been included. The risk for a COPD patient of being infected with a life-threatening disease is much higher than previously anticipated.

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

Opportunistic fungal infection

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

¹ David Denning, The Lancet Infectious Diseases, January 2024

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

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 year³, and that more than half of all sales of antifungal drugs (52%) are directed against the *Candida* pathogen⁴

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 year¹ and that approximately 21 percent of all sales of antifungal drugs are directed against the *Aspergillus* pathogen.

Cryptococcus

Cryptococcus is rare in healthy people but in patients suffering from HIV infections and AIDS it can cause life threatening forms of meningitis and meningo-encephalitis. It is estimated that approximately 150.000 AIDS patients develop life threatening Cryptococcosis every year and that approximately 7 percent of all sales of antifungal drugs are directed against the *Cryptococcus* pathogen.

Pneumocystis

Pneumocystis is a frequent source of opportunistic lung infections in people with a weak immune system or other predisposing health conditions. It is often seen in patients suffering from HIV infections and AIDS but is also found in patients using immunosuppressing medications and people with cancer, autoimmune or inflammatory conditions, and chronic lung disease. It is estimated that approximately 400.000 people develop pneumocystis pneumonia every year and that less than 5 percent of all sales of antifungal drugs are directed against the *Pneumocystis* pathogen.

³ Bongomin et al. Journal of Fungi, October 2017

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

Incidence and crude mortality for severe fungal infections compared²

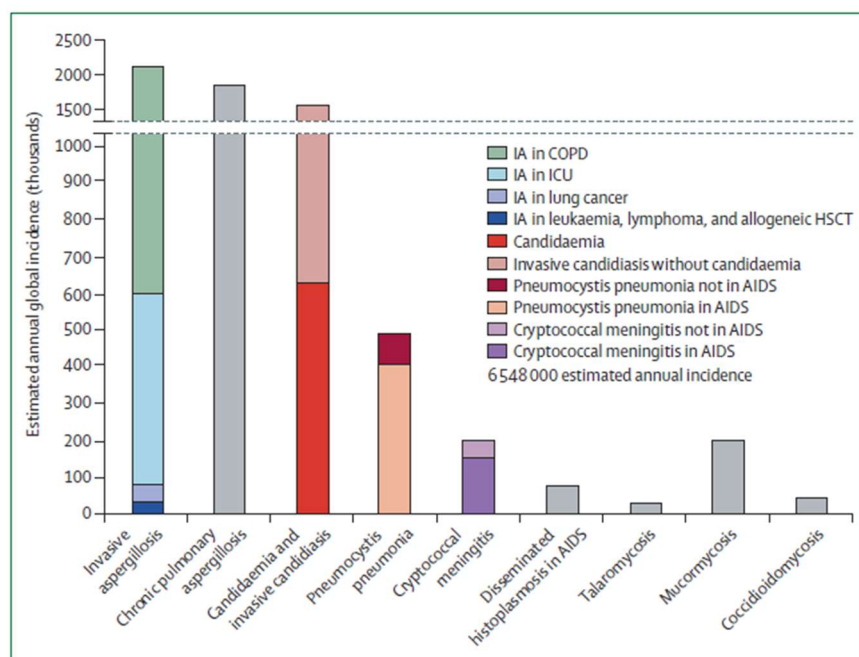


Figure 1: Estimated annual incidence of life-threatening invasive mycoses, together with chronic pulmonary aspergillosis

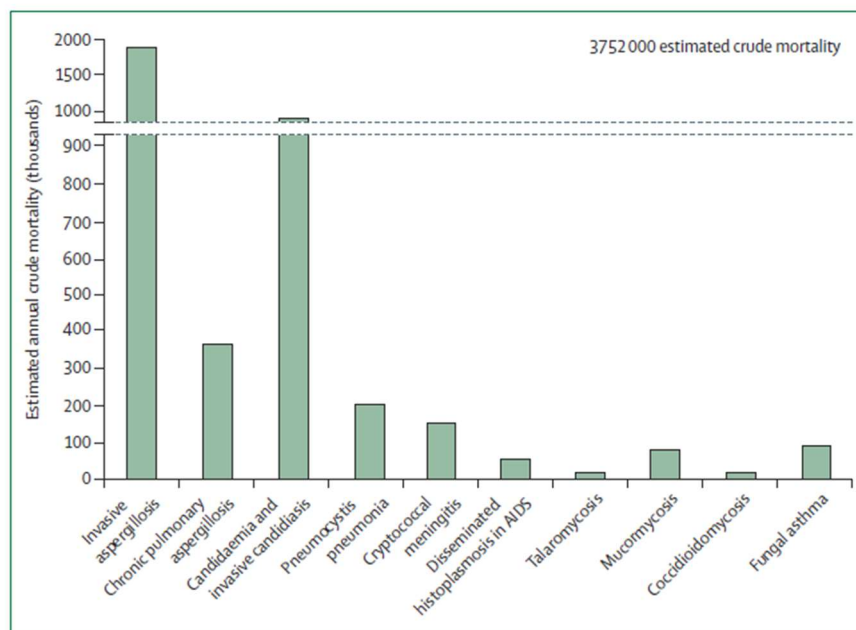


Figure 2: Estimated crude mortality of severe fungal disease, worldwide

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

Diagnosing and treating invasive fungal infection is difficult

The diagnosis of fungal infection poses a particular problem because of 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 are often presented 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 2020⁵. Sales are growing by six to seven percent per year. Although most serious infections occur in the developing world,, the United States and Europe make up approximately 70 percent of the market.

The 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 built over more than 50 years, but their use is restricted by their toxicity, particularly to the kidney. Amphotericin B is the most well-known of the polyenes. Other drugs in this class include Candicidin and Nystatin. New formulations of Amphotericin B, such as the liposomal formulation Ambisome, aims to achieve lower toxicity while maintaining at least similar efficacy compared to the parent compound. However, nephrotoxicity remains a significant dose-limiting side effect that has not been eliminated. This is the primary reason that the polyenes, despite their effectiveness, make up only approximately 10 percent of the total antifungal drug market.

The Azoles

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

The Echinocandins

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

The Allylamines and Pyrimidines

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

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.

In development

Currently, three publicly disclosed compounds targeting invasive fungal infections are in active clinical development, spanning different phases from Phase 1 to Phase 3. These programs represent important advancements within the antifungal treatment landscape. We continue to monitor the respective companies and the clinical progress of these compounds closely, as they may hold strategic relevance for Biosergen's long-term positioning in this therapeutic area.

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 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 threat⁶.

BSG005's position in the market

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

Competition

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

Market trends

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

Demographic and economic development

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

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 species⁷.

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

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

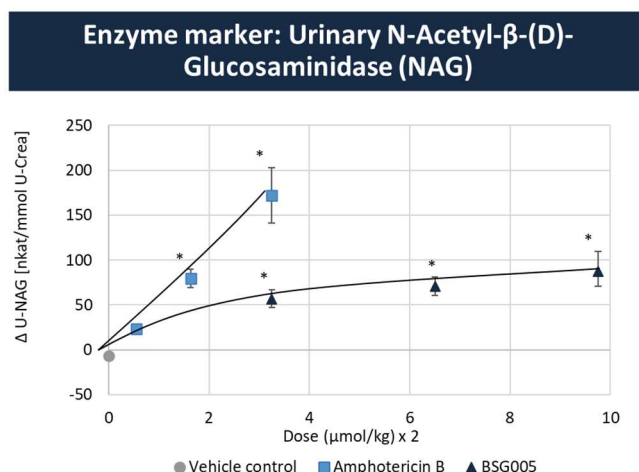
BSG005

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

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



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

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

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

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

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

Phase 1 clinical trial data for BSG005

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

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

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

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

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

CLINICAL DEVELOPMENT PROGRAM

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

Clinical Development Program in Patients

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

To take 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 like *Candida Auris* and resistant aspergillus. It should also include treating patients with mild to moderate renal impairment.

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

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

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

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

Phase 2/3 clinical trial program

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

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

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

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

Invasive candidiasis has a high incidence and is one of the highest mortalities within invasive fungal diseases. There are clear benefits of a basket study within the mycotic environment where the response to several fungal strains can be tested within one protocol. It is difficult to diagnose a particular fungal strain early and published data indicate that

the mortality increases exponentially with late onset of adequate treatment. The ideal candidate in this setting is a broad-spectrum antifungal as BSG005.

BSG005 Nano and BSG005 Nano Oral

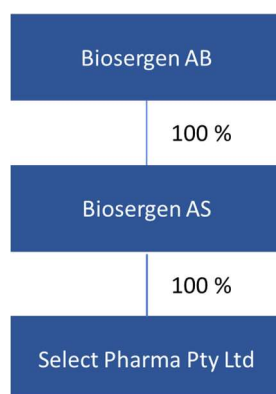
Several of the most serious fungal infections either start or become located in the lungs of the patient. Biosergen and the Nano Group at SINTEF have therefore started a project to develop a special Nano formulation of BSG005. The main purpose of which is to achieve a higher concentration of the drug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

Future challenges

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

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 five percent of the votes and capital in Biosergen AB on 30 September 2025.

Name	Number of shares	Percentage of voting right and capital (%)
ÖSTERSJÖSTIFTELSEN	98,733,144	42.05
Ribbskottet Aktiebolag	40,000,000	17.03
Rosetta Capital IV SARL	14,517,009	6.18
Others	81,572,906	34.74
	234,823,212	100.00

The share

The shares of Biosergen AB were listed on Nasdaq Stockholm First North on June 24, 2021. The short name/ticker is BIOSGN and the ISIN code is SE0016013460. Per September 30, 2025, the number of shares was 234,823,212. The average number of shares in The Company during the quarter was 234,823,212. The Company has one class of shares. Every stock share equals the same rights to The Company's assets and results.

Warrants

As an incentive for employees, Board Members, and key persons Biosergen has implemented four warrant programs. Key persons incentive program 2021 consisting of 1,219,423 warrants whereof all have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 1.06. Key persons incentive program 2022 consisting of 669,144 warrants whereof 350,000 have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 10. Warrants 2024/2031:1 consisting of 4.263.366 warrants where all have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 0.45. Warrants 2024/2031:2 consisting of 1,421,122 warrants where 1,200,000 have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 0.45. Warrants 2025/2031:1 consisting of 1,390,665 warrants whereof all have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 0.45. Warrants 2025/2031:2 consisting of 350,000 warrants whereof all have been subscribed. Each assigned warrant gives the beneficiary the right to subscribe for one new share in the Company against payment of SEK 0.45.

No warrants have yet been exercised.

Subscription of shares with the support of warrants from programs 2021-2024 may take place no later than December 31, 2031.

Subscription of shares with the support of warrants from programs 2025 may take place no later than December 31, 2032.

Auditor's review

The financial report has not been reviewed by The Company's auditor.

For further information, please contact

Tine Olesen, CEO

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Cell Phone: +45 3135 5707

Website: www.biosergen.net

Certified Advisor

DNB 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 SEK 0.1 million (0.4) in the quarter. During the quarter the operating loss amounted to SEK -12.2 million (-4.4) as the company invests in preparations for the next proof of concept study and further clinical studies. This includes work for regulatory approvals.

The group's net profit amounted to SEK -12.2 million (-4.3). Net profit per share was SEK -0.05 (-0.05).

Balance sheet

Total assets amounted to SEK 25.5 (14.6) million whereof cash and cash equivalents amounted to SEK 22.7 (10.2) million. Current liabilities amounted to SEK 5.3 million (2.9) and consists of supplier invoices. At the end of the period. The Group's equity amounted to SEK 20.2 million (11.7).

Cash flows

The Group's cash flow from operating activities amounted to SEK -10.4 million (-1.9) for the quarter. The outflow from operating activities is attributable to clinical trial preparation, regulatory work and R&D Manufacturing. The Group's cash flow from financing activities amounted to SEK 0 million.

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 30 September 2025, the Company and the Group has one full time employee of whom is a woman. Biosergen actively works with consultants and partners for various tasks who are responsible for specific functions of the business.

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. A description of these risks can be found in the [latest annual report](#). During the quarter no significant changes with respect to these risks or uncertainty factors have arisen.

Principles for preparation of the financial 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 January- December 2025	February 10, 2026
Interim report for January – March 2026	May 6, 2026
Interim report for January – June 2026	August 18, 2026

The Annual General Meeting of Biosergen will be held on May 19, 2026. The last date for shareholders to request to have a matter considered at the Annual General Meeting is April 1, 2026.

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, 19 November 2025

Executive Board

Tine Kold Olesen

Board of Directors

Anna Ljung
Chairperson

Marianne Kock
Deputy Chair

Marco Taglietti

Mattias Klintemar

Robert Molander

Consolidated income statement

TSEK	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Operating income					
Other operating income	131	388	2,087	1,560	1,940
	131	388	2,087	1,560	1,940
Operating expenses					
Consumables	-	-	-	-	-
Other external expenses	-11,581	-3,072	-25,523	-13,058	-15,404
Personnel expenses	-1,146	-924	-4,409	-4,617	-5,288
Other operating expenses	406	-743	-521	-762	-451
Operating profit/loss	-12,190	-4,351	-28,366	-16,877	-19,203
Net financial items	22	17	12	-78	8
Profit after financial items	-12,168	-4,334	-28,354	-16,955	-19,195
Profit/loss for the period	-12,168	-4,334	-28,354	-16,955	-19,195

Consolidated balance sheet in summary

TSEK	2025-09-30	2024-09-30	2024-12-31
Assets			
Receivables	2,810	4,318	2,410
Cash & Bank	22,713	10,242	50,612
Total assets	25,523	14,560	53,022
Equity and liabilities			
Equity	20,260	11,705	48,208
Current liabilities	5,263	2,855	4,814
Total equity and liabilities	25,523	14,560	53,022

Consolidated statement of changes in equity

TSEK	2025-09-30	2024-09-30	2024-12-31
Opening balance	48,208	2,116	2,116
Profit for the period	-28,354	-16,955	-19,195
Exchange rate differences	407	369	-73
Transactions with shareholders			
New share issue	-	27,510	72,804
Emission cost	-	-1,335	-7,444
Closing balance	20,260	11,705	48,208

Consolidated cash flow statement

TSEK	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Operating activities					
Operating profit before financial items	-12,190	-4,351	-28,366	-16,877	-12,382
Net financial items	12	17	2	-78	12
Cash flow from operating activities before changes in working capital	-12,178	-4,334	-28,364	-16,955	-12,370
Cash flow from changes in working capital					
Change in receivables	1,715	2,699	-535	1,000	1,715
Changes in current liabilities	24	-290	1,114	-1,861	24
Cash flow from operating activities	-10,440	-1,925	-27,786	-17,816	-10,631
Financing activities					
New share issue	-	-	-	26,175	-
Cash flow from financing activities	-	-	-	26,175	-
Cash flow for the period	-10,440	-1,925	-27,786	8,359	-10,631
Cash at the beginning of the period	33,266	12,167	50,635	1,883	33,266
Exchange Rate Effect	-113		-269	-	-
Cash at the end of the period	22,713	10,242	22,580	10,242	50,612

Parent income statement

TSEK	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Operating income					
Net sales	-	1,150	983	1,762	2,268
	-	1,150	983	1,762	2,268
Operating expenses					
Other external expenses	-681	-1,144	-3,041	-6,186	-5,725
Personnel expenses	-1,176	-903	-4,409	-4,554	-5,208
Other operating expenses	-	-	-	-	-
Operating profit/loss	-1,857	-897	-6,467	-8,978	-8,665
Net financial items	-5	-680	-778	-771	-8,043
Profit after financial items	-1,862	-1,577	-7,245	-9,749	-16,708

Parent balance sheet in summary

TSEK	2025-09-30	2024-09-30	2024-12-31
Assets			
Financial assets	159,194	146,230	139,426
Other receivables	523	673	585
Cash & Bank	19,935	7,707	47,315
Total assets	179,652	154,610	187,326
Equity and liabilities			
Equity	179,045	154,064	186,290
Current liabilities	607	546	1,036
Total equity and liabilities	179,652	154,610	187,326

Parent cash flow statement

TSEK	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Operating activities					
Operating profit/loss	-2,638	-897	-7,246	-8,978	-8,665
Financial items	774	-680	1	-771	87
Cash flow from operating activities before changes in working capital	-1,864	-1,577	-7,245	-9,749	-8,578
Changes in working capital					
Change in receivables	284	431	62	-152	-64
Changes in operating liabilities	-659	-875	-429	-655	6,288
Cash flow from operating activities	-2,239	-2,021	-7,612	-10,556	-2,354
Investing activities					
Investments in intercompany loans	-9,542	-477	-19,768	-9,163	-10,489
Cash flow from investing activities	-9,542	-477	-19,768	-9,163	-10,489
Financing activities					
New share issue	-	-	-	26,175	58,907
Cash flow from financing activities	-	-	-	26,175	58,907
Cash flow for the period	-11,781	-2,498	-27,380	6,456	46,064
Cash at the beginning of the period	31,716	10,205	47,315	1,251	1,251
Cash at the end of the period	19,935	7,707	19,935	7,707	47,315