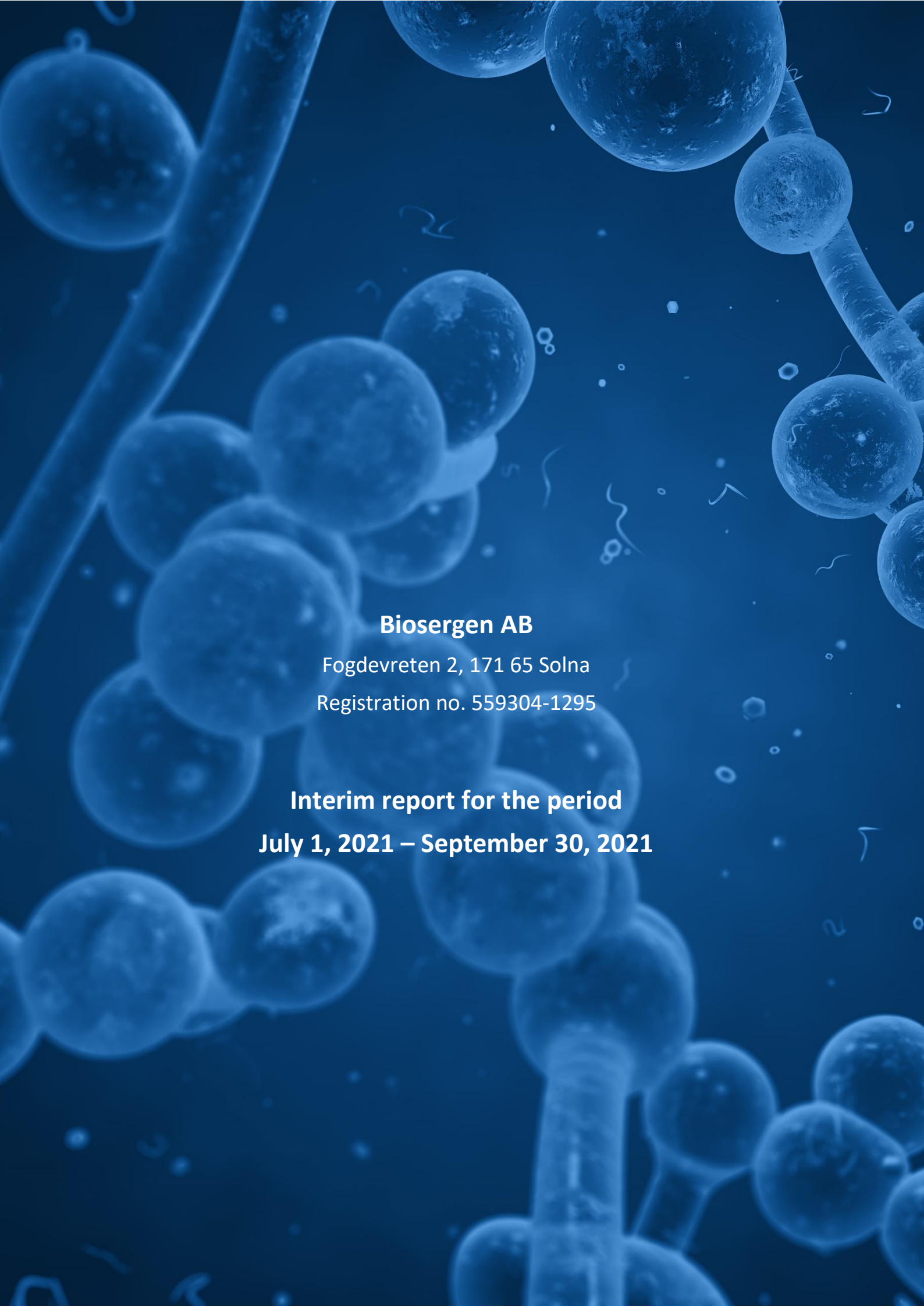

Biosergen AB

Fogdevreten 2, 171 65 Solna

Registration no. 559304-1295

Interim report for the period

July 1, 2021 – September 30, 2021

Contents

Statement by the Board of Directors and the Executive Board

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

Stockholm, Sweden, November 30, 2021

Executive Board

Peder M. Andersen

Board of Directors

Torsten Goesch Chairman	Achim Kaufhold	Hanne Mette Dyrlie Kristensen
Henrik Moltke	Lena Degling Wikingsson	Marianne Kock
Mattias Klintemar		

CONSOLIDATED FINANCIAL HIGHLIGHTS AND RATIOS

Amounts in SEK '000	July- Sep. 2021	Feb.- Sep. 2021 *)
Profit/loss		
Other Income	2 709	2 709
Profit/loss before depreciation (EBITDA)	-6 583	-19 127
Operating profit/loss before net financials	- 6 583	-19 127
Net financials	-146	-157
Net profit/loss for the period	-6 729	-19 284
Balance sheet		
Cash	36 838	36 838
Balance sheet total	40 244	40 244
Equity	29 915	29 915
Cash flows		
Cash flows from:		
Operating activities	-4 225	-16 926
Investing activities	0	3 978
Financing activities	-363	49 637
Ratios		
Solvency		74 %
Earnings per share (SEK)		-0,87
Diluted earnings per share (SEK)		-0,87

*) Biosergen AB was registered February 26, 2021, so there are no comparative figures for previous year.

HIGHLIGHTS DURING Q3 2021

- On August 31, 2021, Biosergen AB announced publication of the interim report for the second quarter 2021
- On August 24, 2021, Biosergen AB announced that it has received positive feedback from the Australian regulatory authorities on the application to initiate a phase I study in Australia of the Company's proprietary antifungal drug candidate BSG005. With the approval, Biosergen is ready to conduct its First in Man clinical trial with BSG005.
- On August 19, 2021, Biosergen AB Announced that it has appointed Tine Kold Olesen as COO of Biosergen. Tine Kold Olesen (MSc, MBA, PhD) has an impressive resume in international drug development.

HIGHLIGHTS AFTER THE PERIOD

There have been no highlights after the period.

CEO LETTER

CEO letter

For us at Biosergen, these last few months have been dedicated entirely to two things: Getting ready for the phase I trial in Australia, which as you may recall was approved by the Australian authorities on August 24, 2021. Our Australian trial partner has started recruiting efforts for healthy volunteers for the first cohort of the trial, and we expect to be able to ship clinical trial product (i.e. clinical grade BSG005) to Australia in the next few weeks.

The second thing which has kept us busy are the preparations for the first phase II trial we expect will follow after the completion of the phase I study. We have almost, as previously announced, finalised the trial design with our advisors, and are currently, among other preparations, planning a large phase II clinical trial drug production with our manufacturing partners that will provide clinical material for full phase II program. We are all eagerly looking forward to starting the testing of BSG005 in human patients, and we will of course keep you posted.

Thank you for your continued support.

Peder M. Andersen, MD, CEO of Biosergen

ABOUT BIOSERGEN

Vision and mission of the Company

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

The Company intends to achieve its mission through a combination of academic and commercial excellence, strategic partnerships, and highly experienced leadership. Biosergen's vision is to emerge over the next five years 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.

Business model

Biosergen is a No-Research-Development-Only biopharmaceutical company, meaning that the Company intends to employ the vast majority of its financial and organizational resources on clinical development. The Company's continuing research activities will be conducted in collaboration with its academic partners and will be sought funded whenever possible through public grants from Norwegian, European, or other international sources, whereas most of its general and administrative functions are outsourced. In time, the Company will establish the 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.

FUNGAL INFECTIONS

Of the hundreds of thousands of fungal species, only a few hundred are able to infect humans and even fewer have the capacity to cause serious health problems. However, when they do infect humans, fungi can cause a variety of illnesses with symptoms ranging from a mild rash to life threatening pneumonia and death.

It is estimated that fungal infections kill more than 1.5 million people every year[1] and the number of cases continues to increase[2]. 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]

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.

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

[2] Kainz et al. Microbial Cell, June 2020

[3] Is 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

INVASIVE FUNGAL INFECTIONS

Most invasive fungal infection-related serious illnesses and deaths are caused by four 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, particularly in immunocompromised patients, affect over 90,000 people a year in the United States alone. 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 750,000 people worldwide develop invasive Candidiasis every year[4] and that more than half of all sales of antifungal drugs (52%) are directed against the *Candida* pathogen[5]

Aspergillus

Aspergillus cause Aspergillosis which primarily develops in people with weakened immune systems or lung diseases. These fungi also cause allergic reactions. Types of 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 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.

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 2020[6]. 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. Polyenes work by forming ion-channel like pores in the fungal cell wall, which causes certain ions to leak out of the cell, leading to cell death. The polyenes are fungicidal and very effective with almost no resistance build over more than 50 years, but their use is restricted by their toxicity, particularly to the kidney. Amphotericin B is the most well-known of the polyenes. Other drugs in this class include Candicidin and Nystatin. New formulations of Amphotericin B such as the liposomal formulation Ambisome aims to achieve lower toxicity with at least similar efficacy compared to the parent compound. However, so far it has not been possible to eliminate nephrotoxicity as the main dose limiting side effect. This is the primary reason that the polyenes despite their effectiveness comprise only approximately 10% of the total antifungal drug market.

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

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

[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.

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

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

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

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

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 by definition the cells that already were resistant to the drug or acquired the ability to resist through mutation during the treatment course. Another reason for the rise in resistant fungal strains is the broad and often indiscriminate use of antifungals in agricultural and livestock production. Certain of the azoles are even used in industrial coatings and for timber preservation. All international public health organizations, including the WHO and the CDC (The United States Centre for Disease Control) as well as the European

Commission recognizes the rise in fungal infections and not least the rise in Multi Drug Resistant (MDR) fungal strains as a global health threat[7].

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.

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.

Biosergen's management is aware of other new antifungal products currently in development including five that are in early clinical trials: Ibrexafungerp, Rezafungin, Olorofim, Fosmanogepix and ATI-2307. Ibrexafungerp and Rezafungin target the same protein as the Echinocandins and may therefore face similar issues with early resistance development. Furthermore, Ibrexafungerp, Rezafungin and ATI-2307 seem to interfere with enzymes with central roles in human metabolism and/or epithelial integrity, potentially limiting their therapeutic windows. Based on the results published so far, Ibrexafungerp, Olorofim and Fosmanogepix all appear to have gaps in their fungal species coverage that makes them less suited for first line empiric therapy in invasive fungus disease.

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.

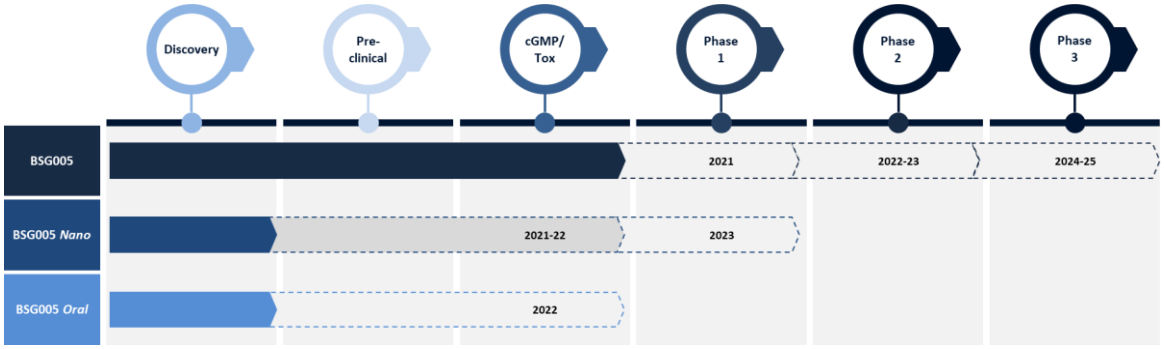
Environmental changes
There is increasing evidence that climate changes could result in an expansion of fungal diseases simply by increasing the geographical reach of certain species[8].

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

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

RESEARCH AND DEVELOPMENT ACTIVITIES

Biosergen's pipeline



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 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).

The extensive research behind BSG005

Biosergen's antifungal drug candidate BSG005 is based on two decades of scientific work at Norges Teknisk-Naturvitenskapelige Universitet (NTNU) in Trondheim in collaboration with the Department of Biotechnology and Nanomedicine at SINTEF[9], originally funded by the Research Council of Norway. Using state-of-art gene editing techniques the researchers set out to develop an improved version of Nystatin, a naturally occurring fungicidal chemical in the bacterial strain *Streptomyces noursei*. They were looking for minute genetic modifications that would retain or even improve the efficacy of Amphotericin B while removing the well-known dose limiting toxicity that has always been this drug's Achilles heel. They eventually expressed and evaluated in various *in vitro* and *in vivo* models more than 20 drug candidates. Over the years, this groundbreaking work to finally get to BSG005 in 2008 has been published in 23 peer reviewed scientific publications.

Peer reviewed scientific publications from SINTEF, NTNU and the Company describing various aspects of the work to get to BSG005

1. Sekurova O, Sletta H, Ellingsen TE, Valla S, Zotchev S: **Molecular cloning and analysis of a pleiotropic regulatory gene locus from the nystatin producer Streptomyces noursei ATCC11455**. *Fems Microbiology Letters* 1999, **177**(2):297-304.
2. Brautaset T, Sekurova ON, Sletta H, Ellingsen TE, Strom AR, Valla S, Zotchev SB: **Biosynthesis of the polyene antifungal antibiotic nystatin in Streptomyces noursei ATCC 11455: analysis of the gene cluster and deduction of the biosynthetic pathway**. *Chemistry & Biology* 2000, **7**(6):395-403.
3. Zotchev S, Haugan K, Sekurova O, Sletta H, Ellingsen TE, Valla S: **Identification of a gene cluster for antibacterial polyketide-derived antibiotic biosynthesis in the nystatin producer Streptomyces noursei ATCC 11455**. *Microbiology-Uk* 2000, **146**:611-619.
4. Brautaset T, Bruheim P, Sletta H, Hagen L, Ellingsen TE, Strom AR, Valla S, Zotchev SB: **Hexaene derivatives of nystatin produced as a result of an induced rearrangement within the nysC polyketide synthase gene in S. noursei ATCC 11455**. *Chemistry & Biology* 2002, **9**(3):367-373.
5. Aparicio JF, Caffrey P, Gil JA, Zotchev SB: **Polyene antibiotic biosynthesis gene clusters**. *Applied Microbiology and Biotechnology* 2003, **61**(3):179-188.
6. Brautaset T, Borgos SEF, Sletta H, Ellingsen TE, Zotchev SB: **Site-specific mutagenesis and domain substitutions in the loading module of the nystatin polyketide synthase, and their effects on nystatin biosynthesis in Streptomyces noursei**. *Journal of Biological Chemistry* 2003, **278**(17):14913-14919.

[9] Having its main offices in Trondheim, Norway, SINTEF is one of Europe's largest private research institutions with more than 2,000 employees.

7. Bruheim P, Borgos SEF, Tsan P, Sletta H, Ellingsen TE, Lancelin JM, Zotchev SB: **Chemical diversity of polyene macrolides produced by Streptomyces noursei ATCC 11455 and recombinant strain ERD44 with genetically altered polyketide synthase NysC**. *Antimicrobial Agents and Chemotherapy* 2004, **48**(11):4120-4129.

8. Sekurova ON, Brautaset T, Sletta H, Borgos SEF, Jakobsen OM, Ellingsen TE, Strom AR, Valla S, Zotchev SB: **In vivo analysis of the regulatory genes in the nystatin biosynthetic gene cluster of Streptomyces noursei ATCC 11455 reveals their differential control over antibiotic biosynthesis**. *Journal of Bacteriology* 2004, **186**(5):1345-1354.

9. Fjaervik E, Zotchev SB: **Biosynthesis of the polyene macrolide antibiotic nystatin in Streptomyces noursei**. *Applied Microbiology and Biotechnology* 2005, **67**(4):436-443.

10. Sletta H, Borgos SEF, Bruheim P, Sekurova ON, Grasdalen H, Aune R, Ellingsen TE, Zotchev SB: **Nystatin biosynthesis and transport: nysH and nysG genes encoding a putative ABC transporter system in Streptomyces noursei ATCC 11455 are required for efficient conversion of 10-deoxynystatin to nystatin**. *Antimicrobial Agents and Chemotherapy* 2005, **49**(11):4576-4583.

11. Volokhan O, Sletta H, Sekurova ON, Ellingsen TE, Zotchev SB: **An unexpected role for the putative 4 '-phosphopantetheinyl transferase-encoding gene nysF in the regulation of nystatin blosynthesis in Streptomyces noursei ATCC 11455**. *Fems Microbiology Letters* 2005, **249**(1):57-64.

12. Borgos SEF, Sletta H, Fjaervik E, Brautaset T, Ellingsen TE, Gulliksen OM, Zotchev SB: **Effect of glucose limitation and specific mutations in the module 5 enoyl reductase domains in the nystatin and amphotericin polyketide synthases on polyene macrolide biosynthesis**. *Archives of Microbiology* 2006, **185**(3):165-171.

13. Borgos SEF, Tsan P, Sletta H, Ellingsen TE, Lancelin JM, Zotchev SB: **Probing the structure-function relationship of polyene macrolides: Engineered biosynthesis of soluble nystatin analogues**. *Journal of Medicinal Chemistry* 2006, **49**(8):2431-2439.

14. Volokhan O, Sletta H, Ellingsen TE, Zotchev SB: **Characterization of the P450 monooxygenase NysL, responsible for C-10 hydroxylation during biosynthesis of the polyene macrolide antibiotic nystatin in Streptomyces noursei**. *Applied and Environmental Microbiology* 2006, **72**(4):2514-2519.

15. Nedal A, Sletta H, Brautaset T, Borgos SEF, Sekurova ON, Ellingsen TE, Zotchev SB: **Analysis of the mycosamine biosynthesis and attachment genes in the nystatin Biosynthetic gene cluster of Streptomyces noursei ATCC 11455**. *Applied and Environmental Microbiology* 2007, **73**(22):7400-7407.

16. Brautaset T, Sletta H, Nedal A, Borgos SEF, Degnes KF, Bakke I, Volokhan O, Sekurova ON, Treshalin ID, Mirchink EP *et al*: **Improved Antifungal Polyene Macrolides via Engineering of the Nystatin Biosynthetic Genes in Streptomyces noursei**. *Chemistry & Biology* 2008, **15**(11):1198-1206.

17. Caffrey P, Aparicio JF, Malpartida F, Zotchev SB: **Biosynthetic engineering of polyene macrolides towards generation of improved antifungal and antiparasitic agents**. *Current Topics in Medicinal Chemistry* 2008, **8**(8):639-653.

18. Preobrazhenskaya MN, Olsufyeva EN, Solovieva SE, Tevyashova AN, Reznikova MI, Luzikov YN, Terekhova LP, Trenin AS, Galatenko OA, Treshalin ID *et al*: **Chemical Modification and Biological Evaluation of New Semisynthetic Derivatives of 28,29-Didehydronystatin A(1) (S44HP), a Genetically Engineered Antifungal Polyene Macrolide Antibiotic**. *Journal of Medicinal Chemistry* 2009, **52**(1):189-196.

19. Zotchev S, Caffrey P: **GENETIC ANALYSIS OF NYSTATIN AND AMPHOTERICIN BIOSYNTHESIS**. In: *Complex Enzymes in Microbial Natural Product Biosynthesis, Part B: Polyketides, Aminocoumarins and Carbohydrates.* Edited by Hopwood DA, vol. 459; 2009: 243-258.

20. Preobrazhenskaya MN, Olsufyeva EN, Tevyashova AN, Printsevskaya SS, Solovieva SE, Reznikova MI, Trenin AS, Galatenko OA, Treshalin ID, Pereverzeva ER *et al*: **Synthesis and study of the antifungal activity of new mono- and disubstituted derivatives of a genetically engineered polyene antibiotic 28,29-didehydronystatin A(1) (S44HP)**. *Journal of Antibiotics* 2010, **63**(2):55-64.

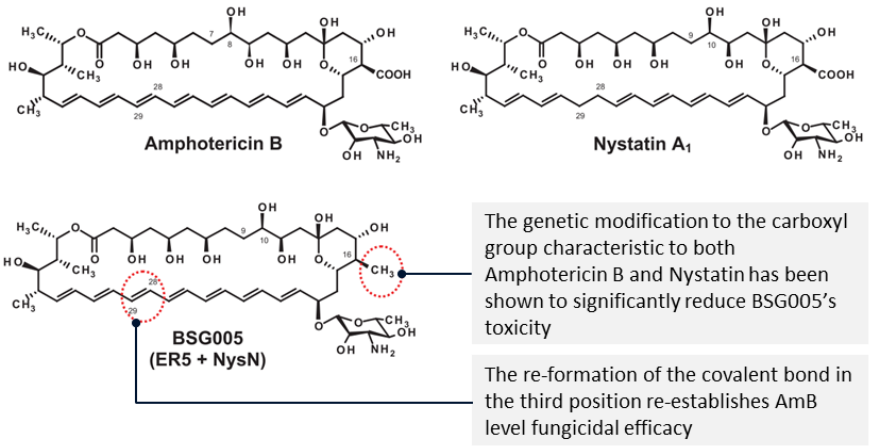
21. Brautaset T, Sletta H, Degnes KF, Sekurova ON, Bakke I, Volokhan O, Andreassen T, Ellingsen TE, Zotchev SB: **New Nystatin-Related Antifungal Polyene Macrolides with Altered Polyol Region Generated via Biosynthetic Engineering of Streptomyces noursei**. *Applied and Environmental Microbiology* 2011, **77**(18):6636-6643.

22. Heia S, Borgos SEF, Sletta H, Escudero L, Seco EM, Malpartida F, Ellingsen TE, Zotchev SB: **Initiation of Polyene Macrolide Biosynthesis: Interplay between Polyketide Synthase Domains and Modules as Revealed via Domain Swapping, Mutagenesis, and Heterologous Complementation**. *Applied and Environmental Microbiology* 2011, **77**(19):6982-6990.

23. Tevyashova AN, Olsufyeva EN, Solovieva SE, Printsevskaya SS, Reznikova MI, Trenin AS, Galatenko OA, Treshalin ID, Pereverzeva ER, Mirchink EP *et al*: **Structure-Antifungal Activity Relationships of Polyene Antibiotics of the Amphotericin B Group**. *Antimicrobial Agents and Chemotherapy* 2013, **57**(8):3815-3822.

BSG005 is a Polyene macrolide antifungal molecule belonging to the same antifungal class as Nystatin and Amphotericin B. As with the other Polyenes, BSG005's mode of action is inference with the microbial cell wall.

BSG005 belongs to the same class of molecules as Amphotericin B



In preclinical trials, BSG005 has shown up to three to four times higher potency than Amphotericin B at same dose levels. More importantly, in toxicity studies the molecule is completely safe with a wide therapeutic window. Specifically, it shows no signs of the potentially fatal kidney toxicity seen with Amphotericin B.

Preclinical development

As a result of the extensive research that has gone into the BSG005 program, the molecule has been through a comprehensive *in vitro* and *in vivo* pharmacology program and have generated a large body of pre-clinical data. 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. *In vivo* testing has revealed excellent and broad antifungal protection, including against multi-resistant *Aspergillus* and *Candida* strains. Importantly, BSG005 repeatedly shows better protection against Azole resistant *Aspergillus* than liposomal Amphotericin B.

Broad antifungal activity

An example of one of the many *in vitro* tests of BSG005 is shown below. In this study, BSG005 demonstrated potent broad-spectrum fungicidal activity against both yeast and filamentous fungal isolates, and particularly against *Aspergillus* species, as highlighted in the table. Furthermore, the fungicidal activity of BSG005 is equivalent to that of Amphotericin B and superior to the activity of the other comparators, whose activity in this experiment as expected was largely fungistatic.

The antifungal activity of BSG005 is equivalent or superior to Amphotericin B and other antifungals *in vitro*

Antifungals (MIC_{90}) (µG/ML)	Candida			
	C. Albicans (fluconazole-susceptible)	C. Albicans (fluconazole-resistant)	C. Glabrata (sensitive)	C. Glabrata (increased MIC capsofungin)
	n=13	n=7	n=14	n=6
Amphotericin B	0.5	0.5	0.5	0.5
Caspofungin	0.25	1	0.5	2
Fluconazole	0.25	>32	64	64
Voriconazole	0.06	0.5	4	4
BSG005	0.5	1	2	1

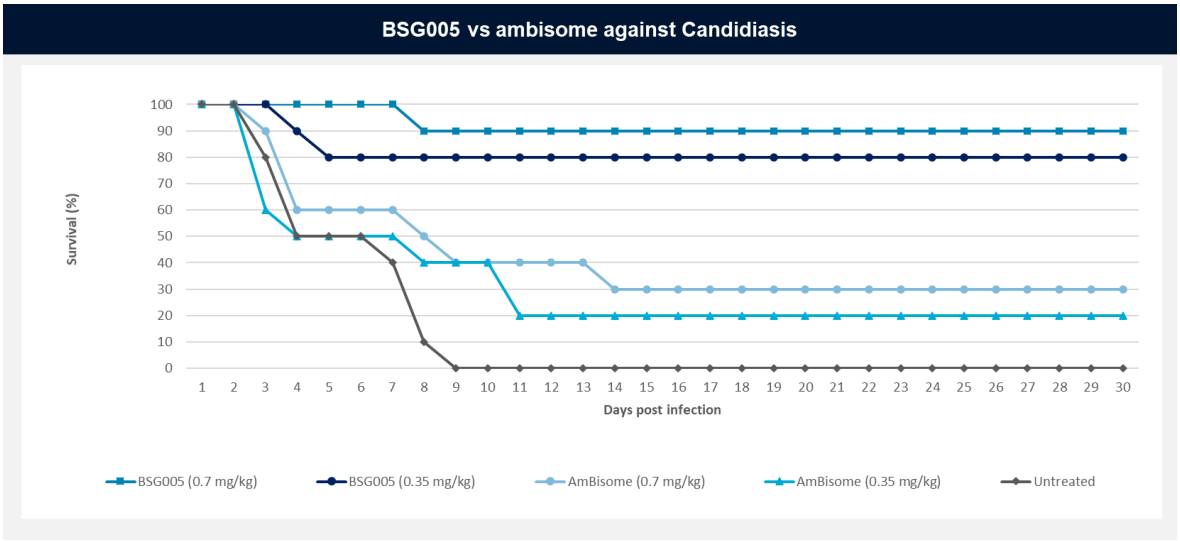
Antifungals (MFC_{90}) (µG/ML)	Aspergillus			
	A. flavus	A. fumigatus	A. niger	A. terreus
	n=20	n=20	n=20	n=10
Amphotericin B	>32	>8	>8	>32
Caspofungin	>32	>32	>32	>32
Fluconazole	>64	64	>64	>64
Voriconazole	>16	>8	>8	>4
BSG005	>4	>4	4	>4

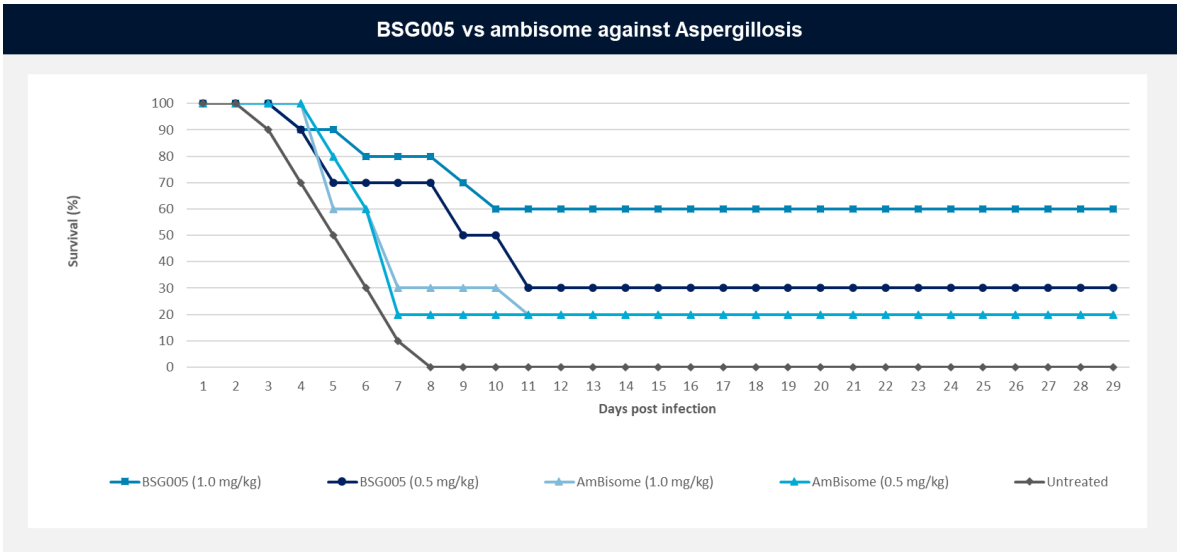
In this experiment, BSG005 and four competing antifungal drugs were tested against 8 common fungal strains from the *Candida* and *Aspergillus* families. BSG005 was at least as good as, or superior to, the comparator drugs. Antifungal activity was measured as MIC (minimum Inhibitory Concentration) and MFC (Minimum Fungicidal Concentration). Fungicidal activity requires >/= 99.9% reduction in colony forming units/milliliter (CFU/mL) while fungistatic activity has < 99.9% reduction in CFU/mL. A drug is considered fungicidal if MFC/MIC is </= 4 and fungistatic if MFC/MIC > 4. BSG005 was the only drug with true fungicidal activity against the Aspergillus strains tested.

Superior protection compared to Amphotericin B

Most of the *in vivo* tests were performed in a well-established immunocompromised mouse model, with comparator drugs including various Azoles and Amphotericin B and/or Ambisome. In the test depicted below, the researchers followed the survival of the immunocompromised mice after they had been challenged with various *Aspergillus* and *Candida* strains. The table below show two tests comparing the abilities of BSG005 and a liposomal formulation of Amphotericin B to protect immunocompromised mice against lethal challenges with *Candida and Aspergillus*, respectively, at equivalent doses.

BSG005 vs. Ambisome in Candidiasis and Aspergillosis

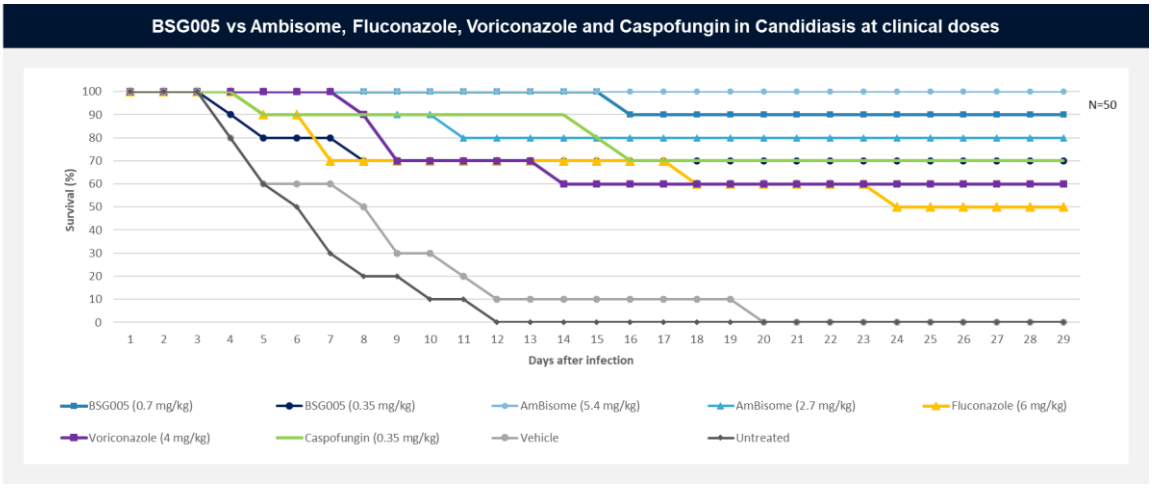




On the top panel 50 immunocompromised mice were divided into five groups. All untreated mice had died from the *Candida* infection by day 9. On the last day in the experiment, day 29, 90% of the mice treated with the highest dose of BSG005 were still alive, versus 30% of the mice treated with the highest dose of liposomal Amphotericin B. On the lower panel 50 immunocompromised mice were divided into five groups. All untreated mice had died from the *Aspergillus* infection by day 8. On the last day in the experiment, day 29, 60% of the mice treated with the highest dose of BSG005 were still alive, versus 20% of the mice treated with liposomal Amphotericin B.

In a similar experiment of candidiasis in immunocompromised mice using clinical doses shown below, BSG005 provided superior protection compared to Fluconazole, Voriconazole and Caspofungin and equal protection to Ambisome but at a much lower dose of 0,7 mg/kg compared to the 5,4 mg/kg dose of Ambisome required to obtain a similar level of protection.

BSG005 vs. Ambisome, Fluconazole, Voriconazole and Caspofungin in Candidiasis at clinical doses

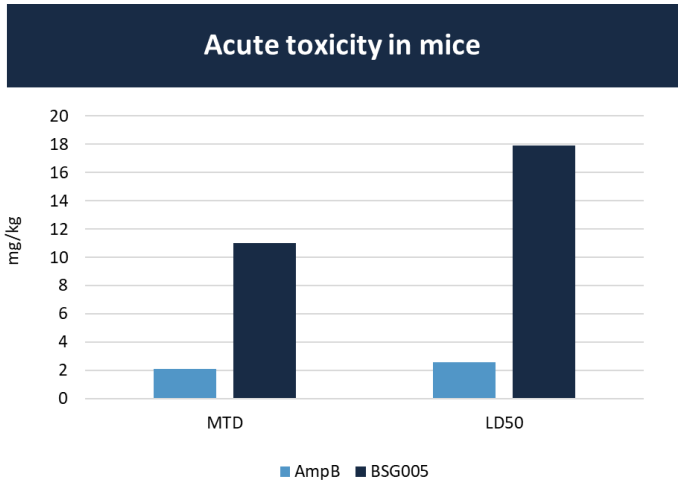


In summary, BSG005 has been shown to have a very broad spectrum of action, not least against Azole and Echinocandin resistant *Aspergillus* and *Candida* strains. At similar dose levels, the drug demonstrates a potency advantage over new liposomal formulations of Amphotericin B, the current standard 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.

BSG005 is safe

The central ambition of the entire program behind BSG005 was to develop a drug with a superior safety profile over Amphotericin B. As a direct result of this ambition, the Company and its academic collaborators in Trondheim over the years have carried out an extensive battery of toxicology tests. Early on, the 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. Dose limits have been established in recognised animal models, including a safe starting dose for human trials.

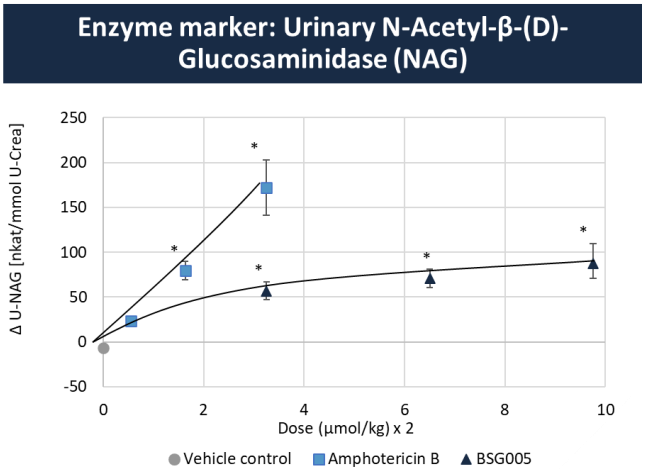
BSG005 is five times less toxic than Amphotericin B



In this standard animal model of acute toxicity, the MTD (maximum tolerated dose, the dose at which side effects become unacceptable) was more than 5 times higher for BSG005 than Amphotericin B. BSG005 also outperformed Amphotericin on LD (lethal dose, the dose at which 50% of the test population die) by a factor of 5.

Perhaps most importantly, none of the tests have indicated a significant kidney toxicity potential, suggesting a favourable and crucial differentiation from Amphotericin B, the drug with which BSG005 will most directly compete. The results from one of the tests are illustrated below.

BSG005 shows significantly less toxicity in the kidneys



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.

Clinical development program

The clinical program for BSG005 is designed to secure the fullest possible indication profile of BSG005.

Phase I clinical trial

The study is designed as a placebo-controlled, double-blinded study. Up to sixty (60) healthy adult male subjects will participate. The primary objective is to evaluate the safety and tolerability of BSG005 in healthy adult male subjects. The secondary objective is to assess the pharmacokinetics of BSG005 after single and multiple dosing in healthy male subjects, to assess any plasma accumulation and the excretion of BSG005 in urine. The safety results from Phase I are key to the clinical development as the fungicidal effect of polyenes and BSG005 are well known. The data will be presented to the FDA at a pre-IND meeting, where also the Phase II program will be discussed.

Phase II clinical trial program
The phase II program is expected to include 3 to 4 clinical trials within the following indication areas:

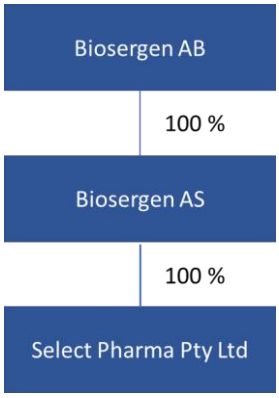
- Neutropenic patients (low white blood cell count after chemotherapy) with clinical symptoms of invasive fungal infection, but with or without a diagnosis of the specific fungal strain
- Patients with a secured diagnosis of invasive aspergillosis with single or multi-resistant fungal strains
- Patients with chronic pulmonary aspergillosis with a secured diagnosis of resistant fungal strains
- Patient with invasive fungal infection, diagnosed and not diagnosed microbiologically and under ECMO (extra corporal membrane oxygenation) therapy

Each of these Proof of Concept (PoC) trials are expected to have 30 – 35 patients. The program objective is to document the clinical efficacy of BSG005 and to secure the full indication profile of BSG005 across a range of invasive fungal infections. The Company expects the first trial patient to be recruited in Q3 2022 and to be able to report top line date from the first trial in Q3 2023. The Company further expects that the data from the phase II trials will allow it to discuss a phase III program to achieve first line treatment status for the treatment of invasive fungal infections with the FDA by the end of 2023 at the "End of Phase II meeting".

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. A similar application has been filed with EMA. With an orphan drug status, one of the benefits is guaranteed market exclusivity for a limited period after the drug is approved (currently 7 years in the United States and 10 years in the EU). 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 5 years).

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 a number of new routes. For instance, for prophylactic use or as follow-on treatments in the patient's own home after transplants or chemotherapy. If successful, the new nano formulations of BSG005 would enter clinical trials during 2024.

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 September 30, 2019.

Name	Number of shares	Percentage of voting right and capital (%)
ÖSTERSJÖSTIFTELSEN	12,132,747	43.2%
ROSETTA CAPITAL IV SARL	8,864,619	31.5%
Sparebank 1 Markets AS	1,872,829	6.7%
Others	5,231,580	18.6 %
	28,101,75	**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, 2021, the number of shares was 28,101,775. The average number of shares in The Company in Q3 2021 was 28,101,775. 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.

Investor warrants
5,000,000 investor warrants have been granted to investors in connection with subscription of Offer Units in the rights issued carried out May/June 2021. All Warrants were vested as per the grant date. The warrants may be utilized for subscription of shares from 30 May 2022 up to, and including, 10 June 2022. Each warrant entitles the holder to subscribe for one (1) new share in the Company at SEK 20.

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

For further information, please contact

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Certified Advisor

Erik Penser Bank AB
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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. As the group is new there are no comparative figures.

Income statement 2021
Revenue amounted to KSEK 2 709 in the third quarter and for the year to date. During the quarter the operating loss amounted to KSEK -6 583 and KSEK -19 127 year to date.

The financial net amounted to KSEK -146 in the third quarter and KSEK -157 for the year to date, which lead up to group's net profit thus totaling of KSEK -6 729 in the third quarter and KSEK -19 284 for year to date. Net profit per share was SEK -0,89 year to date.

Balance sheet
Total assets amounted to KSEK 40 244, whereof cash and cash equivalents amounted to SEK 36 838. Current liabilities amounted to KSEK 10 329. At the end of the period, the Group's equity amounted to KSEK 29 915.

Cash flows
The Group's cash flow from operating activities amounted to KSEK -4 076 in the quarter and KSEK -16 777 for the year to date. The outflow from operating activities is attributable to primarily to increased development activities and preparation of clinical development activities in Australia and Norway. During the quarter the cash flow from investing activities was KSEK 0 and 3 978 for the year to date, relating to the acquisition of Biosergen AS and its subsidiary. The Group's cash flow from financing activities amounted to KSEK -363 in the quarter. Year to date the financing activities was KSEK 49 637, and the major part was related to a new share issue of KSEK 50 000.

Comments to the Parent company´s financial reports

Income statement 2021
During the quarter EBITDA amounted to KSEK -2 542 and KSEK -7 242 for the period. The negative EBITDA in both the quarter and year to date is mainly due to IPO cost.

Balance sheet
Total assets amounted to KSEK 51 833, whereof cash and cash equivalents amounted to SEK 19 443. Current liabilities amounted to KSEK 1 186. At the end of the period, the Company's equity amounted to KSEK 50 647.

Cash flows
The Company's cash flow from operating activities amounted to KSEK -3 252 in the quarter and KSEK -6 628 for the year. During the quarter the cash flow from investing activities was KSEK -14 480 and 23 929 year to date, relating to transactions with Group companies. The Company's cash flow from financing activities amounted to KSEK 0 in the quarter. Financing activities for the year to date was KSEK 50 000 and the major part was related to a new share issue of KSEK 50 000.

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 Sep 30, 2021, the Company and in the Group as well had one employee, CEO Peder M. Andersen.

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
Q3 2021 interim report planned to be published on November 30, 2021
Q4 report is planned on March 31, 2022.
Annual Report for 2021 is planned to be published on March 31, 2022.
Annual General Meeting 2022 is planned to be held on the April 28, 2022.

Consolidated income statement and statement of comprehensive income

Amounts in SEK '000		Jul.-Sep. 2021	Feb.-Sep. 2021*)
Operating income			
Other operating income		2 709	2 709
Total operating income		**2 709**	**2 709**
Operating expenses			
Consumables		-178	-178
Other external costs		-8 146	-20 524
Other operating expenses		-152	-318
Personnel costs	2	-816	-816
Operating profit/loss		**-6 583**	**-19 127**
Profit/loss from financial items			
Other interest income and similar income statement items		0	0
Interest expenses and similar income statement items		-146	-157
Total financial items		**-146**	**-157**
Profit/loss a**fter financial items**			
Profit/loss for the period		**-6 729**	**-19 284**

*) Biosergen AB was registered February 26, 2021, so there are no comparative figures from previous year.

Consolidated balance sheet

Amounts in SEK '000	Jul.-Sep. 2021*)
Current assets	
Current receivables	
Accounts receivable-trade	25
Other receivables	532
Prepaid expenses and accrued income	2 849
Total current receivables	**3 406**
Cash and bank balances	36 838
Total cash and bank balances	**36 838**
TOTAL ASSETS	**40 244**
Equity and liabilities	
Equity	
Share capital	702
Total restricted equity	**702**
Unrestricted equity	
Share premium reserve	48 497
Profit/loss for the period	-19 284
Total non-restricted equity	**29 213**
Total equity	**29 915**
Current liabilities	
Suppliers liabilities	4 326
Other debts	3 018
Accrued expenses and prepaid income	2 985
Total current liabilities	**10 329**
TOTAL EQUITY AND LIABILITIES	**40 244**

*) Biosergen AB was registered February 26, 2021, so there are no comparative figures from previous year.

Change in equity	Share Capital	Share premium resere	Profit/loss for the period	Total
Opening balance, 26 Feb 2021	**0**	**0**	**0**	**0**
Deposit of share capital Feb 2021	25			**25**
Acquisition of subsidiaries		-8 857		**-8 857**
New share issue	558	558		**1 116**
New share issue	125	49 875		**50 000**
Change, decrease in shares	-25			**-25**
Emission	19	6 754		**6 773**
Exchange rate		-195		**-195**
Profit/loss for the period			-12 555	**-12 555**
Opening balance, 1 July 2021	**702**	**48 135**	**-12 555**	**36 282**
Exchange rate		362		**362**
Profit/loss for the period			-6 729	**-6 729**
Closing balance, 30 Sep 2021	**702**	**48 497**	**-19 284**	**29 915**

ONGOING OPERATIONS	Jul.-Sep. 2021	Feb.-Sep 2021 *)
Operating profits before financial items	-6 583	-19 127
Interest paid	-146	-157
	-6 729	**-19 284**
Increase/decrease in other current receivables	-1 470	-2 280
Increase/decrease in suppliers liabilities	-1 880	-5 372
Increase/decrease in other operating liabilities	6 003	5 599
Cash flow from ongoing operations	**-4 076**	**-16 777**
INESTMENT OPERATIONS		
Acquired subsidiaries	-	3 978
Cash flow from investment activities	**-**	**3 978**
FINANCING ACTIVITIES		
New share issue	-	50 000
Amortization	-363	-363
Cash flow from financing activities	**-363**	**49 637**
Cash flow for the year/period	**-4 439**	**36 838**
Liquid funds at the beginning of the year/period	**41 277**	**0**
Exchange rate and other changes in liquid funds	**0**	**0**
Liquid funds at end of period	**36 838**	**36 838**

*) Biosergen AB was registered February 26, 2021, so there are no comparative figures from previous year.

Parent company income statement

Amounts in SEK '000		Jul.- Sep. 2021	Feb.- Sep. 2021*)
Operating income			
Net sales		-	
Other operating income		-	
Total operating income		**-**	
Consumables		-178	-178
Other external expenses		-1 538	-6 211
Other operating expenses		-11	-38
Staf expences	2	-816	-816
Operating profit/loss		**-2 542**	**-7 242**
Profit/loss after financial items		-2 542	-7 242
Profit/loss for the period		**-2 542**	**-7 242**

*) Biosergen AB was registered February 2021, so there are no comparative figures from previous year.

Parent company balance sheet

Amounts in SEK '000		Jul.-Sep. 2021	*)
Assets			
Fixed assets			
Financial assets			
Participations in Group companies	3,4	1 115	
Receivables from Group companies	5	30 703	
Total fixed assets		**31 818**	
Current assets			
Current receivables			
Other receivables		520	
Prepaid cost and accrued income		52	
Total current receivables		**572**	
Total cash and bank balances			
Cash and bank balances		19 443	
Total cash and bank balances		**19 443**	
TOTAL ASSETS		**51 833**	
Equity and liabilities			
Equity			
Share capital		703	
Total restricted equity		**703**	
Non-restricted equity			
Share premium reserve		56 629	
Profit/loss brought forward		558	
Profit/loss for the period		-7 242	
Total non-restricted equity		**49 945**	
Total equity		**50 647**	
Current liabilities			
Suppliers liabilities		340	
Other liabilities		-	
Accrued expenses and deferred income		846	
Total current liabilities		**1 186**	
TOTAL LIABILITIES AND EQUITY		**51 833**	

*) Biosergen AB was registered February 26, 2021, so there are no comparative figures from previous year.

Parent company statement of changes in equity

Amounts in SEK '000

Change in equity	Share Capital	Share Premium Reserve	Profit/loss brought forward	Profit/loss for the period	Total
Opening balance 26 Feb 2021	**0**	**0**			**0**
Deposit of share capital Feb 2021	25				**25**
Non-cash issue	558		558		**1 116**
Change, decrease in shares	-25				**-25**
New share issue	19	6 754			**6 773**
IPO	125	49 875			**50 000**
Profit/loss for the period				-4700	**-4 700**
Opening balance, 1 July. 2021	**702**	**56 629**	**558**	**-4 700**	**53 189**
Profit/loss for the period				-2 542	**-2 542**
Closing balance, 30 Sep 2021	**702**	**56 629**	**558**	**-7 242**	**50 647**

Parent company cashflow

ONGOING OPERATIONS	Jul.-Sep. 2021	Feb.-Sep. 2021 *)
Operating profits before financial items	-2 542	-7 242
	-2 542	**-7 242**
Increase/decrease in other current receivables	- 529	-572
Increase/decrease in suppliers liabilities	340	340
Increase/decrease in other operating liabilities	-521	846
Cash flow from ongoing operations	**-3 252**	**-6 628**
INESTMENT OPERATIONS		
Investments in other financial fixed assets	-14 480	-23 929
Cash flow from investment activities	**-14 840**	**-23 929**
FINANCING ACTIVITIES		
New share issue	-	50 000
Cash flow from financing activities	**-**	**50 000**
Cash flow for the year/period	**-18 092**	**19 443**
Liquid funds at the beginning of the year/period	**37 535**	**0**
Exchange rate and other changes in liquid funds	**0**	**0**
Liquid funds at end of period	**19 443**	**19 443**

*) Biosergen AB was registered February 26, 2021, so there are no comparative figures from previous year