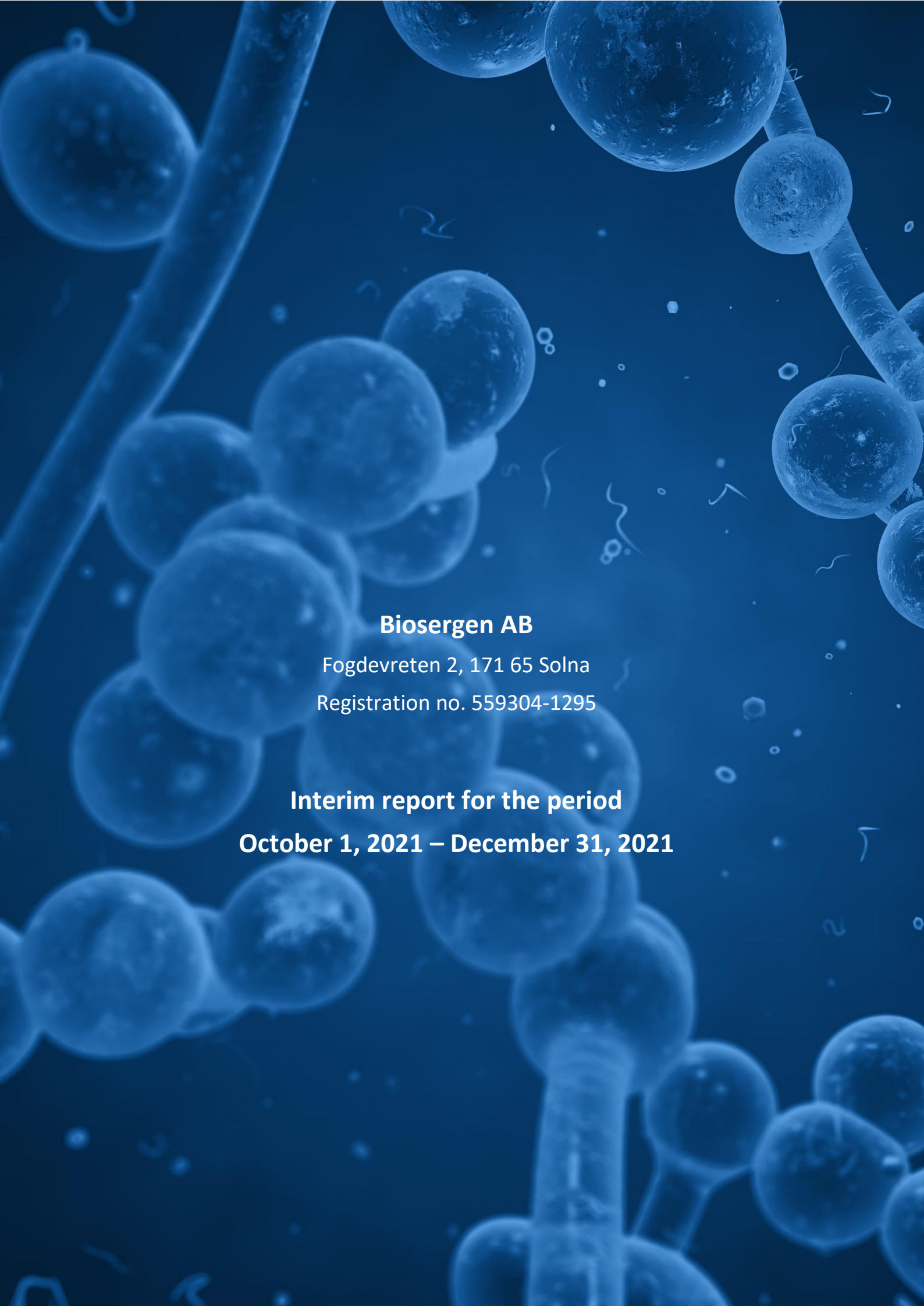

Biosergen AB

Fogdevreten 2, 171 65 Solna

Registration no. 559304-1295

Interim report for the period

October 1, 2021 – December 31, 2021

Contents

Statement by the Board of Directors and the Executive Board	3
Management's review	4
Consolidated income statement and statement of comprehensive income	19
Consolidated balance sheet	20
Consolidated statement of changes in equity	21
Consolidated cash flow statement	22
Parent company income statement	23
Parent company balance sheet	24
Parent company statement of changes in equity	25
Parent company cash flow statement	26

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, March 31, 2022

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	Oct- Dec. 2021	Jan.-Dec. 2021 *)	Jan.-Dec. 2020
Profit/loss			
Other Income	8 861	11 570	4 432
Profit/loss before depreciation (EBITDA)	-14 950	-34 077	-6 226
Operating profit/loss before net financials	- 14 950	-34 077	-6 226
Net financials	-83	-240	-498
Net profit/loss for the period	-15 034	-34 318	-6 724
Balance sheet			
Cash	21 665	21 665	589
Balance sheet total	32 648	32 648	4 797
Equity	20 233	20 233	-10 924
Cash flows			
Cash flows from:			
Operating activities	-15 173	-37 749	-4 584
Investing activities	0	0	0
Financing activities	0	58 825	0
Ratios			
Solvency	62 %	62 %	neg
Earnings per share (SEK)	-0,62	-1,42	-
Diluted earnings per share (SEK)	-0,62	-1,42	-

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

HIGHLIGHTS DURING Q4 2021

- On November 30, 2021, Biosergen AB announced publication of the interim report for the third quarter 2021

HIGHLIGHTS AFTER THE PERIOD

There have been no highlights after the period

CEO LETTER

Biosergen's lead product is BSG005 It is a polyene macrolide anti-fungal molecule genetically modulated of NYSTATIN, which is an old well established anti-fungal compound. BSG005 has shown broad and fungicidal effect towards many fungal strains including strains resistant to other anti-fungal drugs and strains that are difficult to treat. In vivo animal data suggest higher potency and better safety that the other main fungicidal product called Ambisome.

Since last quarterly report we have advanced further with regards to our phase 1 trial in Australia and on the manufacture of BSG005 biomass. The BSG005 product is in Australia, it has been labelled, packed, and stored in a competent facility and will soon be on its way to the clinical site in Melbourne. After the initial approval of the protocol, minor corrections have been done in the submission documents, and all have been approved by the responsible authority for this trial. The testing of BSG005 in humans first time is a major milestone.

Biosergen and its manufacture partner has manufactured large scale fermentation material which will be the basis for most of the phase II clinical program once it has been purified and formulated to the final drug product. The phase II clinical program strategy has been finalized with the clinical advisors and the protocol development will continue over the coming months.

We are excited finally to be in the clinical phase starting with the single ascending dose part of the trial. We will keep all investors and the public updated on the progress of the study.

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 Research and Development biopharmaceutical company, meaning that the Company intends to employ most of its financial and organizational resources on research of all aspects of BSG005 to supply the best possible product and catalyze this into the 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. In time, the Company will establish limited sales and marketing infrastructure necessary to cover specific regions, first and foremost Europe and the United States, and otherwise form strategic partnerships with pharmaceutical and biotechnology companies when relevant to commercialize its products in the different regions of the world.

Patents

Biosergen has strong patent protection in four regions, USA, EU, Japan, and China. The patents are composition of matter patents. In addition, Biosergen has received orphan drug protection in the USA.

FUNGAL INFECTIONS

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

It is estimated that fungal infections kill more than 1.5 million people every 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.

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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

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

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

Candida
Candida is a yeast that causes infections in individuals with deficient immune systems. Systemic *Candida* infections of the bloodstream and major organs, particularly in immunocompromised patients, affect over 90,000 people a year in the United States alone. 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.

BSG005 is an important new drug in the field of anti-fungals due to its fungicidal effect (It kills the fungus) and its very broad cover of fungal strains. BSG005 has also shown effect against resistant fungal strains and strains that have been difficult to treat with the drugs available on the 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 Polyenes
The Polyenes were discovered already in the early 1950s based on the observation that certain types of *streptomyces* bacteria were able to kill fungal cells in their vicinity. Polyenes work by forming ion-channel like pores in the fungal cell wall, which causes certain ions to leak out of the cell, leading to cell death. The polyenes are fungicidal and very effective with almost no resistance build over more than 50 years, but their use is restricted by their toxicity, particularly to the kidney. Amphotericin B is the most well-known of the polyenes. Other drugs in this class include Candicidin and Nystatin. New formulations of Amphotericin B such as the liposomal formulation Ambisome aims to achieve lower toxicity with at least similar efficacy compared to the parent compound. However, so far it has not been possible to eliminate nephrotoxicity as the main dose limiting side effect. This is the primary reason that the polyenes despite their effectiveness comprise only approximately 10% of the total antifungal drug market.

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

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

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

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

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. The market potential is large. The market share covered by Amphotericin B and lipid versions is about 450 M USD and the other products used in invasive fungal infections is in the B USD. None of the products has the profile of BSG005 and the market potential in this field is large because of the unmet medical need in these severe fungal infections.

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

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.

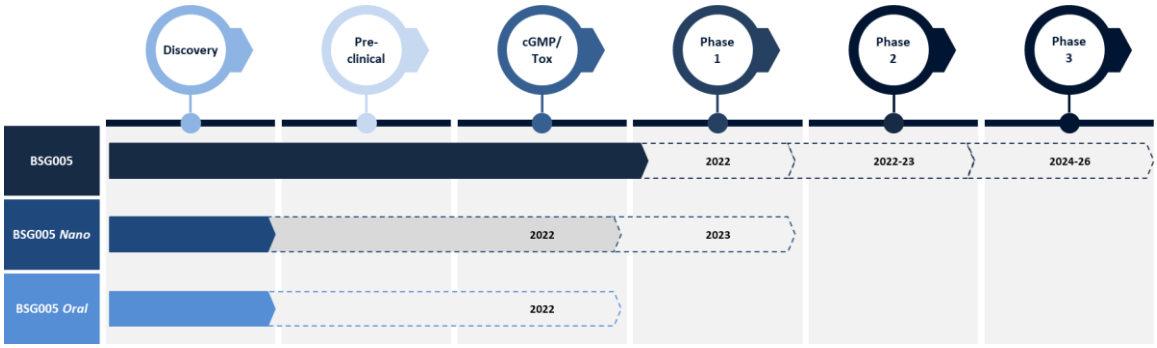
Increased demand for food production
Human population growth fuels a demand for increasing food production. Antifungals are widely used in agriculture and the resulting resistance problems spill over into the human population. The problem is further exacerbated when the plant's natural antifungal defenses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

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

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].

DEVELOPMENT ACTIVITIES
Biosergen's research and development pipeline is built around formulations of BSG005. The most advanced formulation is intravenous, comparable to other treatment regimens for severe systemic fungal infections. BSG005 Nano is a novel nano formulation developed at SINTEF which specifically target the lungs where many systemic fungal infections 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.

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

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

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.

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.

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.

Pre-clinical development

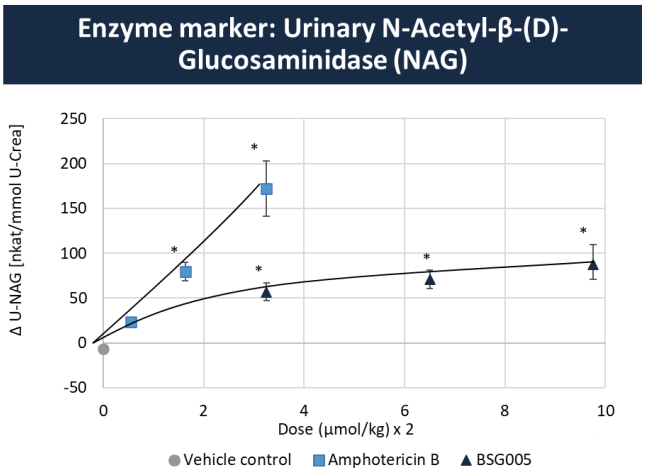
The *in vitro* testing of BSG005 against more than 200 different fungal strains has shown a fungicidal effect against most strains, including strains resistant to Azoles and Echinocandins. *In vivo* testing has revealed excellent and broad antifungal protection, including against multi-resistant *Aspergillus* and *Candida* strains. Importantly, BSG005 repeatedly shows better protection against Azole resistant *Aspergillus* than liposomal Amphotericin B.

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.

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.

Perhaps most importantly, none of the tests have indicated a significant kidney toxicity potential, suggesting a favorable 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.

<u>BSG005 shows significantly less toxicity in the kidneys</u>



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 (72) 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.

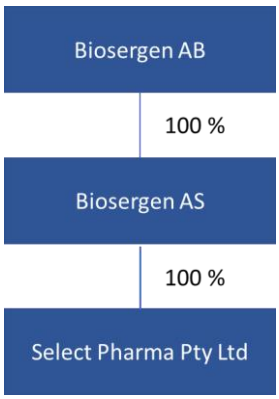
Phase II clinical trial program
The phase II program is expected to include as a minimum 2 and maybe 3 to 4 clinical trials in resistant or difficult to treat fungal species.

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 in the primary focus indications and with the secondary focus to secure the full indication profile of BSG005 across a range of invasive fungal infections. The primary goal is to reach phase III readiness as soon as possible. The Company expects the first trial patient to be recruited in Q1/2 2023 and to be able to report top line date from the first trial in Q1 2024. 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 specific invasive fungal infections with the FDA by the end of Q3 2024 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.. 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 lung target Nano IV and a Nano Oral formulation of BSG005. Other than the ability to target the lungs specifically, an oral formulation opens several 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 2024/25.

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%
	28,101,775	**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 December 31, 2021, the number of shares was 28,101,775. The average number of shares in The Company in Q4 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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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 8 861 in the fourth quarter and for the year to date. During the quarter the operating loss amounted to KSEK -14 950 and KSEK -34 077 year to date.

The financial net amounted to KSEK -83 in the fourth quarter and KSEK -240 for the year to date, which lead up to group's net profit thus totaling of KSEK -15 034 in the fourth quarter and KSEK -34 318 for year to date. Net profit per share was SEK -1,42 year to date.

Balance sheet
Total assets amounted to KSEK 32 648, whereof cash and cash equivalents amounted to SEK 21 665. Current liabilities amounted to KSEK 12 415. At the end of the period, the Group's equity amounted to KSEK 20 233.

Cash flows
The Group's cash flow from operating activities amounted to KSEK -15 173 in the quarter and KSEK -37 749 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 0 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 0 in the quarter. Year to date the financing activities was KSEK 58 825, 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 -4 136 and KSEK -11 378 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 269 724, whereof cash and cash equivalents amounted to SEK 16 761. Current liabilities amounted to KSEK 960. At the end of the period, the Company's total equity amounted to KSEK 268 765.

Cash flows
The Company's cash flow from operating activities amounted to KSEK -4 588 in the quarter and KSEK -11 216 for the year. During the quarter the cash flow from investing activities was KSEK 1 906 and -22 023 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 December 31, 2021, the Company and the Group had two employees.

Risk and uncertainty factors
A pharmaceutical development company such as Biosergen is exposed to operational and financial risk. Biosergen's operational risk mainly consist of risks related to research and development, clinical trials and dependance on key employees. The risk to which the company is exposed in its current phase and the risk that the necessary financing cannot be secured. 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
Q1 2022 interim report planned to be published on May 31, 2022
Annual Report for 2021 is planned to be published on June 7, 2022.
Annual General Meeting 2022 is planned to be held on the June 30, 2022.
Q2 2022 interim report planned to be published on August 31, 2022
Q3 2022 interim report planned to be published on November 30, 2022

Consolidated income statement and statement of comprehensive income

Amounts in SEK '000	Okt.-Dec. 2021	Jan.-Dec. 2021*)	Jan.-Dec 2020
Operating income			
Other operating income	8 861	11 570	4 432
Total operating income	**8 861**	**11 570**	**4 432**
Operating expenses			
Consumables	-178	-178	0
Other external costs	-23 117	-43 641	-10 528
Other operating expenses	-54	-372	-130
Personnel costs	-641	-1 457	0
Operating profit/loss	**-14 950**	**-34 077**	**-6 226**
Profit/loss from financial items			
Other interest income and similar income statement items	0	0	0
Interest expenses and similar income statement items	-83	-240	-498
Total financial items	**-83**	**-240**	**-498**
Profit/loss a**fter financial items**			
Profit/loss for the period	**-15 034**	**-34 318**	**-6 724**

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

Consolidated balance sheet

Amounts in SEK '000	Jan.-Dec 2021*)	Jan.-Dec 2020
Current receivables		
Accounts receivable-trade	3 187	24
Other receivables	3 150	1 194
Prepaid expenses and accrued income	4 647	2 990
Total current receivables	**10 983**	**4 208**
Cash and bank balances	21 665	589
Total cash and bank balances	**21 665**	**589**
TOTAL ASSETS	**32 648**	**4 797**
Equity and liabilities		
Equity		
Share capital	702	2 649
Total restricted equity	**702**	**2 649**
Unrestricted equity		
Share premium reserve	53 849	-6 849
Profit/loss for the period	-34 318	-6 724
Total non-restricted equity	**19 531**	**-13 573**
Total equity	**20 233**	**-10 924**
Current liabilities		
Suppliers liabilities	9 909	5 118
Other debts	96	0
Accrued expenses and prepaid income	2 410	10 603
Total current liabilities	**12 415**	**15 721**
TOTAL EQUITY AND LIABILITIES	**32 648**	**4 797**

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

Consolidated statement of changes in equity

Change in equity	Share Capital	Share premium reserve	Profit/loss for the period	Total
Opening balance, January 1, 2021	**2 649**	**-13 573**		**-10 924**
Emission	60	8 765		**8 825**
Apportemission	-2 151	2 151		**0**
Emission	19	6 754		**6 773**
Emission	125	49 875		**50 000**
Exchange rate		-123		**-123**
Profit/loss for the period			-34 318	**-34 318**
Closing balance, December 31, 2021	**702**	**53 849**	**-34 318**	**20 233**

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

ONGOING OPERATIONS	Oct.-Dec. 2021	Jan.-Dec 2021	Jan.-Dec 2020 *)
Operating profits before financial items	-14 951	-36 152	-6 226
Interest paid	-83	-240	-498
	-14 952	**-34 078**	**-6 724**
Increase/decrease in accounts receivable	-3 162	-3 162	-24
Increase/decrease in other current receivables	-4 531	-3 729	-2 725
Increase/decrease in suppliers liabilities	-5 226	-4 791	-383
Increase/decrease in other operating liabilities	2 329	1 331	4 506
Cash flow from ongoing operations	**-15 173**	**-37 749**	**-4 584**
INVESTMENT OPERATIONS			
Acquired subsidiaries	-	-	-
Cash flow from investment activities	**-**	**-**	**-**
FINANCING ACTIVITIES			
New share issues (Biosergen AS and Biosergen AB)	-	58 825	-
Amortization	-	-	-
Cash flow from financing activities	**-**	**58 825**	**-**
Cash flow for the year/period	**-15 173**	**21 076**	**-4 584**
Liquid funds at the beginning of the year/period	**36 838**	**589**	**5 173**
Exchange rate and other changes in liquid funds		**0**	**0**
Liquid funds at end of period	**21 665**	**21 665**	**589**

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

Parent company income statement

Amounts in SEK '000	Oct.- Dec. 2021	Feb.- Dec. 2021*)
Operating income		
Net sales	589	-
Other operating income	-	-
Total operating income	**589**	**-**
Consumables	-	-178
Other external costs	-4 082	-10 293
Other operating expenses	-2	-40
Personnel costs	-641	-1 457
Operating profit/loss	**-4 136**	**-11 378**
Profit/loss from financial items		
Interest income	403	403
Interest expenses	-82	-82
Total financial items	**321**	**321**
Profit/loss after financial items	-3 815	-11 057
Profit/loss for the period	**-3 815**	**-11 057**

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

Parent company balance sheet

Amounts in SEK '000	Oct.-Dec. 2021*)
Financial assets	
Participations in Group companies	247 963
Receivables from Group companies	3 882
Total fixed assets	**251 845**
Current receivables	
Other receivables	843
Prepaid cost and accrued income	275
Total current receivables	**1 118**
Total cash and bank balances	
Cash and bank balances	16 761
Total cash and bank balances	**16 761**
TOTAL ASSETS	**269 724**
Equity	
Share capital	703
Total restricted equity	**703**
Non-restricted equity	
Share premium reserve	278 562
Profit/loss brought forward	558
Profit/loss for the period	-11 057
Total non-restricted equity	**268 062**
Total equity	**268 765**
Current liabilities	
Suppliers liabilities	413
Other liabilities	86
Accrued expenses and deferred income	460
Total current liabilities	**960**
TOTAL LIABILITIES AND EQUITY	**269 724**

*) 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 February 2021	**0**	**0**			**0**
Deposit of share capital February 2021	25				**25**
Apportemission	1 116	221 993			**223 049**
Non-cash issue	-558		558		**0**
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				-11 057	**-11 057**
Closing balanser, 31 December 2021	**702**	**278 622**	**558**	**-11 057**	**268 765**

Parent company cashflow

ONGOING OPERATIONS	Oct.-Dec. 2021	Feb.-Dec. 2021 *)
Operating profits before financial items	-4 136	-11 378
Interest received	403	403
Interest paid	-83	-83
	-3 816	**-11 058**
Increase/decrease in other current receivables	-547	-1 119
Increase/decrease in suppliers liabilities	73	413
Increase/decrease in other operating liabilities	-298	548
Cash flow from ongoing operations	**-4 588**	**-11 216**
INESTMENT OPERATIONS		
Investments in other financial fixed assets	1 906	-22 023
Cash flow from investment activities	**1 906**	**-22 023**
FINANCING ACTIVITIES		
New share issue	-	50 000
Cash flow from financing activities	**-**	**50 000**
Cash flow for the year/period	**-2 682**	**16 761**
Liquid funds at the beginning of the year/period	**19 443**	**0**
Exchange rate and other changes in liquid funds	**0**	**0**
Liquid funds at end of period	**16 761**	**16 761**

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