

The background of the entire page is a blue-tinted microscopic image showing various types of bacteria. There are several long, thin, rod-shaped bacteria (bacilli) and many spherical bacteria (cocci), some of which are arranged in chains or clusters. The image is out of focus, creating a bokeh effect with soft, glowing spots of light.

Biosergen AB

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

**Interim report for the period
April 1, 2021 – June 30, 2021**

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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, August 31, 2021

Executive Board

Peder M. Andersen

Board of Directors

Torsten Goesch
Chairman

Achim Kaufhold

Hanne Mette Dyrle Kristensen

Henrik Moltke

Lena Degling Wikingsson

Marianne Kock

Mattias Klintemar

CONSOLIDATED FINANCIAL HIGHLIGHTS AND RATIOS

Amounts in SEK '000	Q2 2021	*)
<i>Profit/loss</i>		
Revenue	0	
Profit/loss before depreciation (EBITDA)	-12,544	
Operation profit/loss before net financials	-12,544	
Net financials	-11	
Net Profit/loss for the period	-12,555	
<i>Balance sheet</i>		
Cash	41,277	
Balance sheet total	43,213	
Equity	36,382	
<i>Cash flows</i>		
Cash flows from:		
Operating activities	-12,701	
Investing activities	3,978	
Financing activities	50,000	
Ratios		
Solvency	84 %	
Earnings per share (SEK)	-0.78	
Diluted earnings per share (SEK)	-0.78	

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

HIGHLIGHTS DURING Q2 2021

- On June 27, 2021, Biosergen announced that the United States Food and Drug Administration (the "FDA") has granted BSG005, the Company's groundbreaking antifungal drug of the polyene macrolide class, Orphan Drug status in the United States.
- On June 23, 2021, Biosergen announced that the Company has been approved for listing on Nasdaq First North Growth Market. The first day of trading will be June 24, 2021.,
- On June 8, Biosergen confirmed that its IPO had been successfully executed, raising a gross amount of approximately SEK 50 million. In the event that the investor warrants allocated to the new shares issued are exercised in full during the period from May 30, 2022 through June 10, 2022, the company may receive additional net proceeds from the offering of up to SEK 100 million.
- On May 18, 2021, the Board of Directors of Biosergen decided to conduct a rights issue of shares supported by an authorization granted at the General Meeting. The rights issue comprised of up to 5,000,000 offer units, each consisting of one new share at a subscription price of SEK 10 and a warrant with the exercise price of SEK 20 to be exercised during the period from May 30, 2022 through June 10, 2022.
- On May 4, 2021, the board of directors resolved on an issue by way of set-off to Östersjöstiftelsen in order to improve the Company's financial position. The Company's share capital was increased with SEK 19,923,575 through an issue of 796,943 shares.
- In April 2021, the Company acquired all the shares in Biosergen AS through an issue in kind where the Company's share capital was increased with SEK 1,115,241.6 through an issue of 22,304,832 shares.

HIGHLIGHTS AFTER THE PERIOD

- 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.

CEO LETTER

With our Initial Public Offering successfully behind us, our focus this fall will be on getting the phase I trial of our proprietary polyene macrolide antifungal BSG005 under way. We recently reported that we have received orphan drug status for BSG005 in the United States. This is a very important milestone for us. Partly because it makes the whole clinical development phase which we are now entering a bit easier, partly because it increases the already significant commercial opportunity presented by BSG005. Other than the phase I trial of BSG005 in Australia, we will also be working on finalising the design of the phase II program together with our advisors. And we expect news on our European orphan drug application from EMA. All in all, we expect an eventful fall, and we will of course keep you posted.

Unfortunately, these last few months have witnessed an unprecedented increase in the incidence of systemic fungal infections, and not just in the developing world. India is in the throes of an epidemic outbreak of mucormycosis, also known as the “black fungus”, an outbreak which is strongly suspected to be directly linked to the way COVID-19 is treated in this country. The tragic hypothesis is that the high doses of relatively cheap immune suppressing corticosteroids used in India predispose these COVID-19 patients to mucormycosis. And lately, the United States’ Centers for Disease Control and Prevention (CDC) has been reporting a worrying increase in the incidence of systemic *Candida Auris* infections. These outbreaks, which happen in acute care/intensive care facilities, are very difficult to clean up. In these infections, the *Candida Auris* fungus is everywhere – on all surfaces and in the equipment, including lines and ventilators. When such conditions are combined with weakened immunocompromised patients after chemotherapy or transplantations, who may even suffer from comorbidities such as diabetes, it is life threatening.

These developments are not unexpected, nor have we seen the last of them. We are entering an era where outbreaks of serious fungal infections will become more common. The lingering COVID-19 pandemic may become endemic, that is to say, come back every year like the flu, and this will continue to create opportunities for pathogens like *Candida Auris* and *Aspergillus* to invade the organs of susceptible patients.

It is high time that the world starts to pay closer attention to this problem. We desperately need more treatment options. We need big pharma to come on board and we need governments to step up. Fungal infection is not just a problem in the developing world, or for people living with HIV. It is a threat to all of us.

Thank you for your continued support.

Peder M. Andersen, MD, CEO of Biosergen

ABOUT BIOSERGEN AB

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.

MARKET DESCRIPTION

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

It is estimated that fungal infections kill more than 1.5 million people every year¹ and the number of cases continues to increase². The factors behind the increased incidence particularly of serious invasive (also known as systemic) fungal infections can be grouped into three broad categories:

Opportunistic fungal infection

The incidence of opportunistic fungal infections such as cryptococcosis and aspergillosis is increasing because the number of people with weakened immune systems continues to increase, both in developed and developing countries. This group includes 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 last but not least, 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.

¹ Bongomin et al. Journal of Fungi, October 2017

² Kainz et al. Microbial Cell, June 2020

³ It is estimated that close to 50% of all AIDS related deaths are attributable to an invasive fungal infection. GAFFI (Global Action Fund for Fungal Infection), August 2017

Four species are responsible for the majority of life threatening invasive fungal infections

The majority of invasive fungal infection-related serious illnesses and deaths are caused by four particular fungal pathogens: *Candida*, *Aspergillus*, *Cryptococcus* and *Pneumocystis*.

Candida

Candida is a yeast that causes infections in individuals with deficient immune systems. Systemic *Candida* infections of the bloodstream and major organs, 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 year⁴ and that more than half of all sales of antifungal drugs (52%) are directed against the *Candida* pathogen⁵

Aspergillus

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

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.

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.

The three classes of antifungals used today

The three main classes of antifungal drugs today are the Polyenes, the Azoles and the Echinocandins. A smaller group of products are the Allylamines and the Pyrimidines. The total sales of antifungals for human

⁴ Bongomin et al. Journal of Fungi, October 2017

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

medicinal use were estimated to be approximately USD 16.7 billion in 2020⁶. Sales are growing by 6-7% per year. Although the majority of serious infections occur in the developing world, the United States and Europe make up approximately 70% of the market.

The Polyenes

The Polyenes were discovered already in the early 1950s based on the observation that certain types of *streptomyces* bacteria were able to kill fungal cells in their vicinity. 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 β -glucan. They are the newest class of antifungals, although they were in fact discovered in the 1970s. The Echinocandins are fungistatic, have a fairly broad range particularly against candida species, and have low toxicity. They do however have poor bio-availability 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.

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 threat⁷.

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.

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

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.

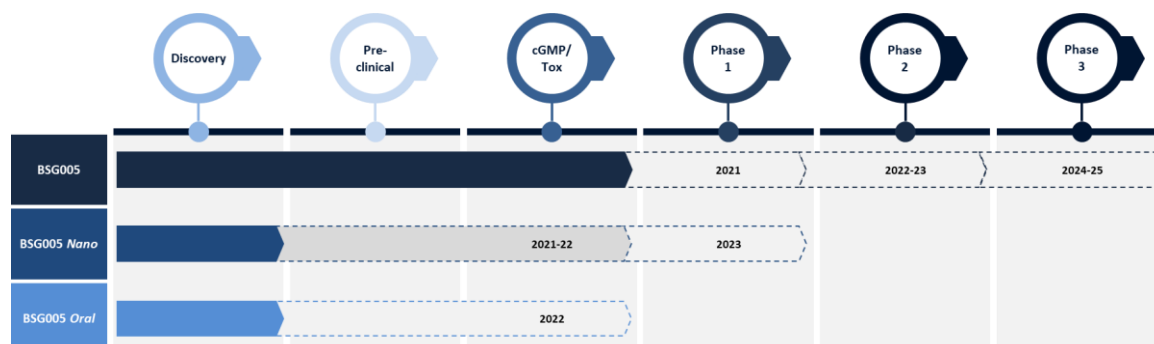
Environmental changes

There is increasing evidence that climate changes could result in an expansion of fungal diseases simply by increasing the geographical reach of certain species⁸.

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 SINTEF⁹, 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

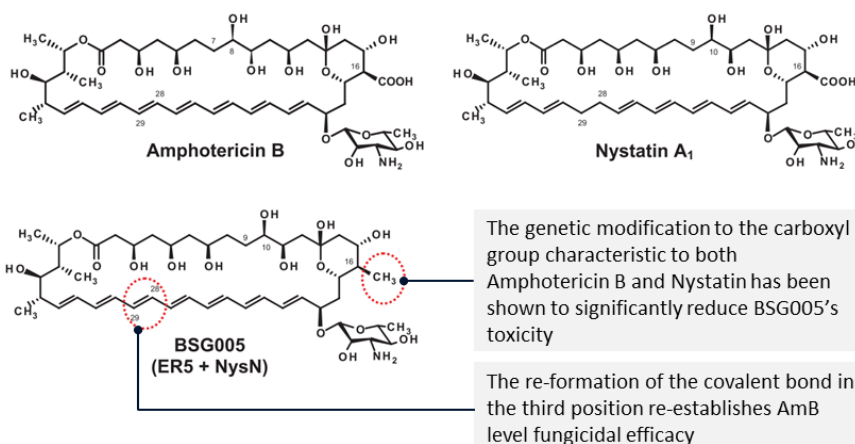
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⁹ Having its main offices in Trondheim, Norway, SINTEF is one of Europe's largest private research institutions with more than 2,000 employees.

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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 an unusually 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.

In vitro testing shows 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*

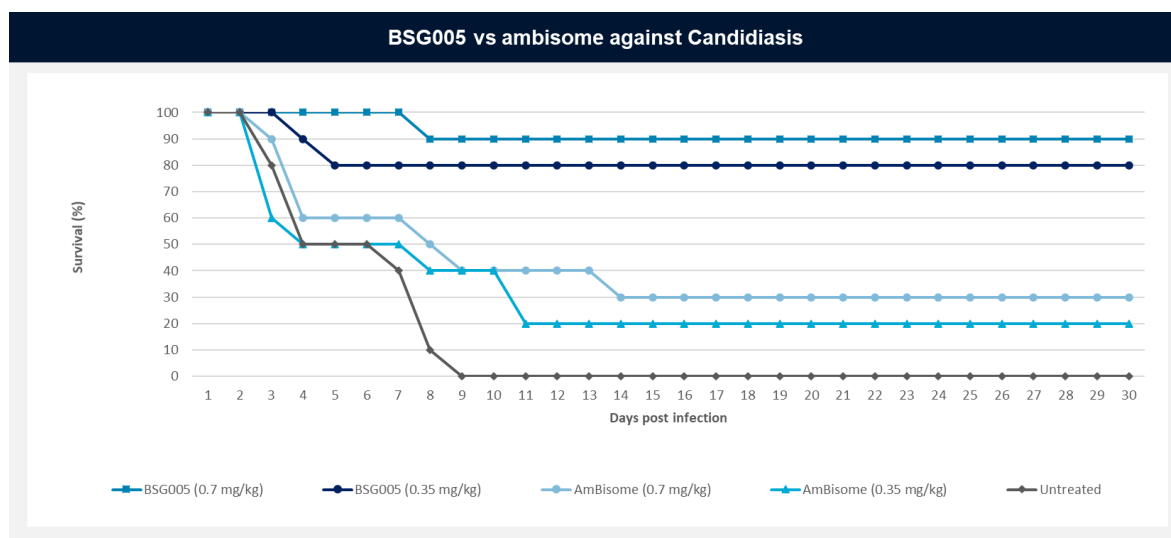
Antifungals (MIC ₉₀) (μG/ML)	Candida				Antifungals (MFC ₉₀) (μG/ML)	Aspergillus			
	C. Albicans (fluconazole- susceptible)	C. Albicans (fluconazole- resistant)	C. Glabrata (sensitive)	C. Glabrata (increased MIC caspofungin)		A. flavus	A. fumigatus	A. niger	A. terreus
	n=13	n=7	n=14	n=6		n=20	n=20	n=20	n=10
Amphotericin B	0.5	0.5	0.5	0.5	Amphotericin B	>32	>8	>8	>32
Caspofungin	0.25	1	0.5	2	Caspofungin	>32	>32	>32	>32
Fluconazole	0.25	>32	64	64	Fluconazole	>64	64	>64	>64
Voriconazole	0.06	0.5	4	4	Voriconazole	>16	>8	>8	>4
BSG005	0.5	1	2	1	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 $\geq 99.9\%$ reduction in colony forming units/millilitre (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.

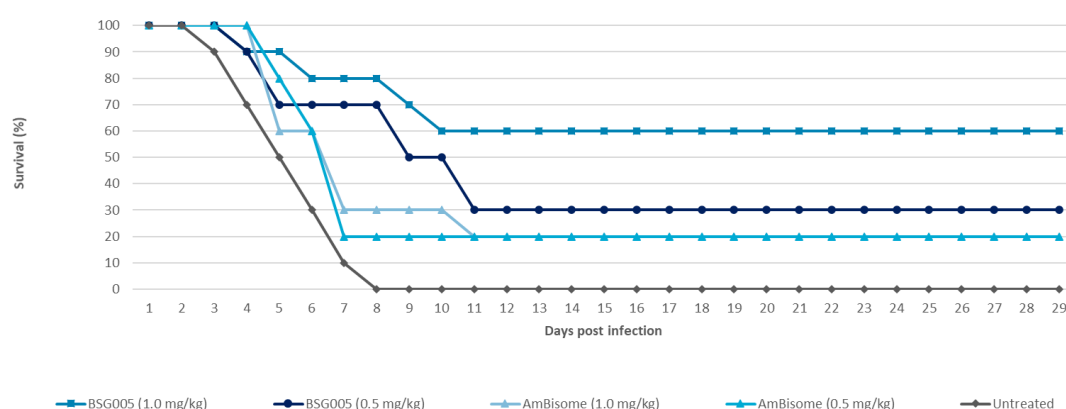
In vivo testing shows superior protection compared to Amphotericin B

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



BSG005 vs ambisome against Aspergillosis

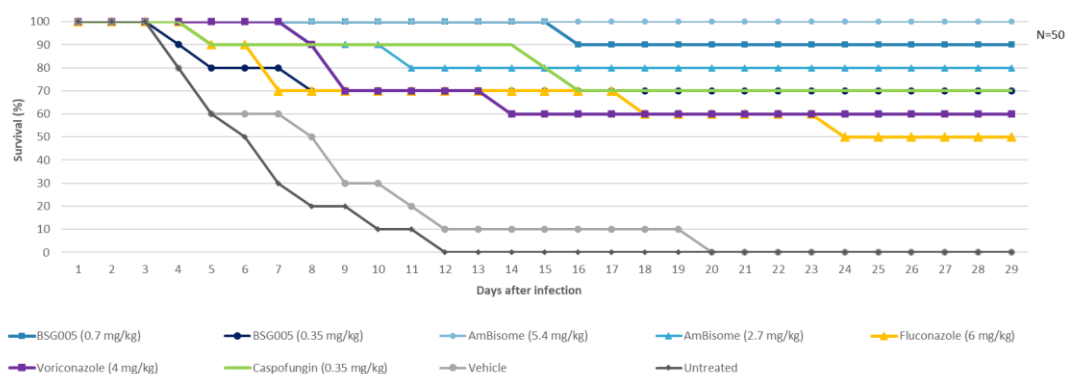


On the top panel 50 immunocompromised mice were divided into five groups. All untreated mice had died from the *Candida* infection by day 9. On the last day in the experiment, day 29, 90% of the mice treated with the highest dose of BSG005 were still alive, versus 30% of the mice treated with the highest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

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



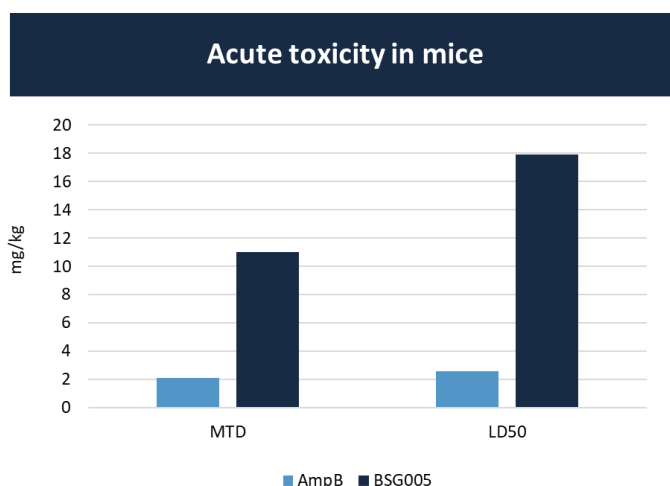
In summary, BSG005 has been shown to have a very broad spectrum of action, not least against Azole and Echinocandin resistant *Aspergillus* and *Candida* strains. At similar dose levels, the drug demonstrates a potency advantage over new liposomal formulations of Amphotericin B, the current standard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

Animal toxicology shows 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.

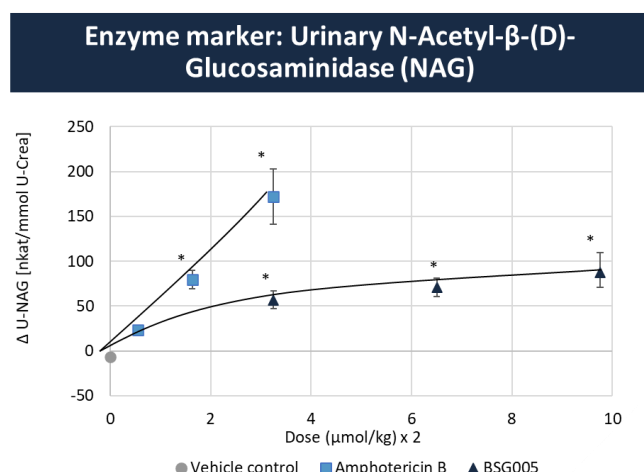
BSG005 is five times less toxic than Amphotericin B



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.

Manufacturing upscaling completed

All the Polyenes are produced by *Streptomyces* bacteria. In BSG005's case, the *Streptomyces noursei* bacteria has been genetically engineered to produce BSG005 instead of the native antifungal Nystatin. One

of the many issues the researchers from NTNU and SINTEF had to solve was to come up with a method by which these genetically engineered *Streptomyces* bacteria would continue to grow and thrive in the larger volumes that are necessary to eventually manufacture BSG005 in quantity. Once this was done, the researchers had to develop the extraction and purification steps. The GMP upscaling was completed in early 2021 and forms an integral part of the Company's phase I filing to start human clinical trials.

A row of 5-liter fermenters producing BSG005 at SINTEF's laboratories in Trondheim

All of the manufacturing upscaling and GMP processing steps have been completed, to the point where Biosergen achieves high fermentation yields exceeding 6 grams/liter of BSG005. The process is clinical trial ready.



Clinical development program

The clinical program for BSG005 is designed to lead to the filing of an NDA (New Drug Application) for sales and marketing approval with the United States FDA (Food and Drug Administration) by the end of 2025 and 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 Company expects the first trial subjects to be recruited in Q3 2021 and to be able to report top line results from the trial by Q1 2022. 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 with the FDA in Q2 2022, 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 Q2 2022 and to be able to report top line data from the first trial in Q2 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 has in June 2021 been 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. Furthermore, in August 2015 Biosergen AS entered into a joint venture agreement with two other parties where Biosergen own 60 percent of the joint venture. However, the joint venture has no activities and is currently under liquidation.

Shareholders

The table below presents shareholders with over 5% of the votes and capital in Biosergen AB on June 30, 2021.

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 June 30, 2021, the number of shares was 28,101,775. The average number of shares in The Company in Q2 2021 was 16,086,526. 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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Cell Phone: (+45) 2080 2470

Website: www.biosergen.net

Certified Advisor

Erik Penser Bank AB.

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 Q2 2021

Net sales amounted to 0. EBITDA amounted to KSEK -12,544.

The company realized a net profit of KSEK -12,544. Net profit per share: SEK -0,78. Total number of shares as of June 30, 2021, was 28,101,775.

Balance sheet

Total assets amounted to KSEK 43,213. Cash and cash equivalents amounted to SEK 41,277. Current liabilities amounted to KSEK 6,563. The Group's equity amounted to KSEK 36,282.

Cash flows

The Group's cash flow from operating activities amounted to KSEK -12,701. The outflow from operating activities is attributable to primarily to increased development activities and preparation of clinical development activities in Australia. The Group's cash flow from financing activities amounted to KSEK 50,000. The increased cash flow is due mainly to the cash capital increase.

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 June 30, 2021, the Company's only employee is its CEO Peder M. Andersen.

Risk and uncertainty factors

The risks and uncertainties that the Company is exposed to are related to factors such as drug development, competition, technology development, patents, regulatory requirements, capital requirements, currencies, and interest rates. During the current period, no significant changes in risk factors or uncertainties have occurred. For more detailed description of risks and uncertainties, refer to the prospectus published in May 2021. The documents are available on the Company's website (<http://www.biosergen.net/>).

Principles for preparation of the interim report

Biosergen prepares its financial reports in accordance with the Swedish Annual Accounts Act and BFNAR 2012:1 Annual Reporting and consolidated reports (K3).

Financial Calendar

Q3 2021 interim report planned to be published on November 30, 2021

Financial Calendar year ends on December 31, 2021.

Q4 2021 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	Q2 2021	*)
Operating income		
Net sales	0	
Other operating income	0	
Total operating income	0	
Operating expenses		
Other external costs	-12,378	
Other operating expenses	-166	
Operating profit/loss	-12,544	
Profit/loss from financial items		
Other interest income and similar income statement items	0	
Interest expenses and similar income statement items	-11	
Total financial items	-11	
Profit/loss after financial items		
Profit/loss for the period	-12,555	

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

Amounts in SEK '000	Q2 2021	*)
Current assets		
Current receivables		
Accounts receivable-trade	25	
Other receivables	1,645	
Prepaid expenses and accrued income	266	
Total current receivables	1,936	
Cash and bank balances	41,277	
Total cash and bank balances	41,277	
TOTAL ASSETS	43,213	
Equity and liabilities		
Equity		
Share capital	702	
Total restricted equity	702	
Unrestricted equity		
Share premium reserve	48,135	
Profit/loss for the year	-	
	12,555	
Total non-restricted equity	35,58	
Total equity	36,282	
Long-term liabilities		
Liabilities to Group companies	368	
Total long-term liabilities	368	
Current liabilities		
Suppliers liabilities	6,563	
Total current liabilities	6,563	
TOTAL EQUITY AND LIABILITIES	43,213	

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

Consolidated statement of changes in equity

Change in equity	Share Capital	Share Premium reserve	Profit/loss for the period	Total
Opening balance, April 1, 2021	25			25
Acquisition of subsidiaries		-8,857		-8,857
New share issue	558	558		1,116
New share issue	125	49,875		50
Change, decrease in shares	25			-25
Emission	19	6754		6,773
Exchange rate		-195		-195
Profit/loss for the period			-12,555	-12,555
Closing balance, June 30, 2021	702	48,135	-12,555	36,282

ONGOING OPERATIONS

Profit/loss before financial items	-12,544
Interest paid	-11
	-12,555

Increase/decrease in other current receivables	3,750
Increase/decrease in suppliers liabilities	-3,492
Increase/decrease in other operating liabilities	-404
Cash flow from ongoing operations	-12,701

INVESTMENT OPERATIONS

Acquired subsidiaries	3,978
Cash flow from investment activities	3,978

FINANCING ACTIVITIES

New share issue	50,000
Cash flow from financing activities	50,000

Cash flow for the year	41,277
Liquid funds at the beginning of the year	0
Exchange rate and other changes in liquid funds	0

Liquid funds at end of period	41,277
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Parent company income statement

Amounts in SEK '000	Q2 2021	*)
Operating income		
Net sales	-	
Other operating income	-	
Total operating income	-	
Other external costs	-4,673	
Other operating expenses	-27	
Operating profit/loss	-4,700	
Profit/loss after financial items	-4,700	
Profit/loss for the period	-4,700	

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

Amounts in SEK '000	Q2 2021	*)
Assets		
Fixed assets		
Financial assets		
Participations in Group companies	1,115	
Receivables with Group companies	15,863	
Total fixed assets	16,978	
Current assets		
Current receivables		
Other receivables	43	
Total current receivables	43	
Total cash and bank balances		
Cash and bank balances	37,535	
Total cash and bank balances	37,535	
TOTAL ASSETS	54,556	
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 year	- 4,700	
Total non-restricted equity	52,487	
Total equity	53,189	
Current liabilities		
Suppliers liabilities	1,367	
Other liabilities	-	
Accrued expenses and deferred income	-	
Total current liabilities	1,367	

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

Parant 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, April 1, 2021	25				25
Non-cash issue	558		558		1,116
Change, decrease in shares	-25				
New share issue	19	6,754			6,773
IPO	125	49,875			50,000
Profit/loss for the period				-4,700	-4,700
Closing balance, June 30, 2021	702	56,629	558	-4,700	53,189