Biosergen

Mangold Insight – Commissioned research - 24 January 2023

Fungicide with potential

Mangold Insight initiate coverage of the biotechnology company Biosergen with a buy recommendation and a price target of SEK 2.70 per share. This gives an upside of over 110 percent. The company develops a potent drug against invasive fungal diseases. There is a need for better treatment options against invasive fungal diseases, which have recently received increasing attention in the media and from health organisations, as well as drug companies requiring new candidates. The treatment options that are available have far too many side effects and are developing resistance.

Safe and effective candidate

Biosergen's drug candidate, BSG005, is undergoing phase 1 studies, and has so far proven to be safe, without toxic effects on the kidneys or liver, something that is common with competing fungicides. Creating an effective and safe treatment option will make BSG005 an attractive drug candidate to licence for the major drug companies. The ongoing phase 1 study is expected to be completed in the first quarter of 2023. Top line results are then also expected. The clinical programme is scheduled to end in 2026.

Potential in three different cases

Mangold has carried out a thorough analysis of competitors, and values the company based on a SOTP model. A risk-adjusted DCF model has been used to obtain a fair value. Based on three different scenarios, the potential for BSG005 appears to be significant. Mangold has chosen the Base case, which gives a fair value of 148 MSEK. The risk in drug development companies is very high, and the company's value is completely dependent on one product.

Key Data	
Price target (SEK)	2,70
Risk	High
Price (SEK)	1,25
Market value (MSEK)	53
No. of shares (million)	42,4
Free float	27,4 %
Ticker	BIOSGN
Next earnings report	31 March 2023
Website	biosergen.net
Analyst	Jan Glevén

Ownership structure	Shares	Capital
Östersjöstiftelsen	18,8	44,3%
Rosetta Capital	8,9	21,1%
Stiftelsen Sintef	1,9	4,4%
Tuvedalen Ltd	1,9	4,4%
Mangold FK	1,7	4,0%
Peder M. Andersen	1,2	2,8%
Karolinska Development	0,9	2,1%
Avanza Pension	0,6	1,4%
Formue Nord A/S	0,6	1,4%
Johan Thorell	0,4	1,0%
Totalt	**42,4**	**100%**

Price performance %	1m	3m	12m
BIOSGN	14,1	-46,1	-76,9
OMXSPI	9,5	18,6	-19,4

Key ratios	2021	2022E	2023E	2024E	2025E
Sales (TSEK)	-	-	-	-	-
EBIT (TSEK)	-34 078	-41 928	-40 626	-40 626	-40 626
Profit before tax (TSEK)	-34 078	-41 928	-40 626	-40 626	-40 626
VPA, dilution (SEK)	-1.21	-1.49	-1.45	-1.45	-1.45
EV/Sales	nm	nm	nm	nm	nm
EV/EBITDA	nm	nm	nm	nm	nm
EV/EBIT	nm	nm	nm	nm	nm
P/E	nm	nm	nm	nm	nm

Biosergen - Investment Case

Fungicide with potential

Buy Biosergen, price target SEK 2.70 per share

Mangold Insight initiate coverage of the biotechnology company Biosergen with a buy recommendation and a price target of SEK 2.70 per share over a 12-month period. Biosergen develops a potential fungicide against invasive fungal diseases (see appendix p.18). The number of individuals dying from invasive fungal infections is increasing, yet treatment options remain inadequate, as resistance and serious side effects are a major problem. Biosergen intends to develop a drug that kills the fungus and without side effects found with competing drugs on the market.

Treatment area underdeveloped

Significant need for new drugs

Few studies to develop new treatment methods have been carried out before. One reason is that the expected return for the drug companies on such an investment is limited. Efforts have been made to develop new treatment methods, in line with invasive fungal diseases becoming an ever greater problem. In recent years, several studies have been carried out to develop new drugs. The major drug companies have shown great interest in introducing new drugs into their portfolio. Several acquisitions and lucrative licence agreements have been made within this segment.

BSG005 - a potent drug

Kills the fungus and reduces resistance

Biosergen is developing a drug candidate that is a genetically engineered, improved version of a previously known molecule, Nystatin. BSG005 has in animal studies proven to be safe, without the toxic effects on the kidneys and liver found with competing drugs, especially those with Amphotericin B. BSG005 is a polyene that is fungicidal and kills the fungus. Most antifungals are fungistatic and only slow down fungal growth. BSG005 can also contribute to reduced resistance.

Safety first

BSG005 has no toxic effect on the kidneys or liver

During phase 1 studies, BSG005 has so far shown no impact on either the kidneys or liver, which is a huge step forward for the company. Its efficacy has been demonstrated in preclinical studies, where it has proven superior to competing drugs, such as AmBisome (Amphotericin B). Successful phase 1 studies and upcoming phase 2 studies are expected to add significant value to the company. BSG005 has a good chance of becoming a first-line option for invasive fungal diseases due to its safe and effective profile.

Increased attention

WHO issues concern for global health

The increased mortality from invasive fungal diseases has prompted the WHO to act and warn about particular fungi that risk threatening global health. In several articles during the Autumn of 2022, the Wall Street Journal drew attention to fungal diseases and the need for treatment options that are more effective and have a less toxic impact.

Biosergen - About the company

The company in brief

Biosergen is a drug development company that was listed on the Nasdaq First North Growth Market in Stockholm in June 2021. The company has its headquarters at Karolinska Institutet Science Park in Solna and comprises a virtual organisation with the intention of using external consultants and partners. The company develops fungicides (antimycotics) and has a drug candidate, BSG005, against invasive fungal diseases in clinical phase 1. This candidate has been researched by the Norwegian University of Science and Technology (NTNU) in Trondheim, Norway, and SINTEF (Foundation for Scientific and Industrial Research at the Norwegian Institute of Technology). The intention is to position BSG005 as a first-line treatment for invasive fungal diseases. It is intended for intravenous administration in intensive care units.

Biosergen develops drugs against invasive fungal diseases

Carrying out phase 1 studies

The company is carrying out phase 1 studies in Australia, where results are expected at the end of the first quarter 2023. Fungal infections are a growing problem, not least due to multi-resistance and an increased incidence of invasive fungal diseases (see appendix) that are particularly serious. Orphan drug designation was granted in the US by the FDA (Medicine Agency in the United States) in June 2021 for the treatment of aspergillosis. Orphan drug designation gives the company access to special advice during clinical studies and extended market exclusivity. The company intends to collaborate with a strategic partner to bring BSG005 to market. The ambition is to be able to complete studies in 2025 and then apply for approval and launch.

Granted orphan drug designation in the US

Treatment of invasive fungal diseases

Invasive fungal infections have gone from previously being rare to becoming a global health problem. This mainly applies to individuals with a compromised immune system as a result of chemotherapy treatments, transplants, and HIV infections, or immunosuppressed patients. The symptoms of fungal infections are often non-specific, making it difficult to diagnose. For many fungal diseases, the first four to five days are decisive, as many of the diseases have a fatal outcome. Treatment is therefore often initiated before an exact diagnosis is established. It takes time to diagnose, and it is difficult to know exactly which species of fungus is causing the infection. The use of fungistatic antimycotics has contributed to increasing resistance to a certain extent, which is problematic in the case of invasive fungal diseases. Because of Increased resistance to treatment, WHO has classified four species as particularly risky; candida (albicans and auris), aspergillus fumigatus and cryptococcus neoformans.

New fungicides are needed

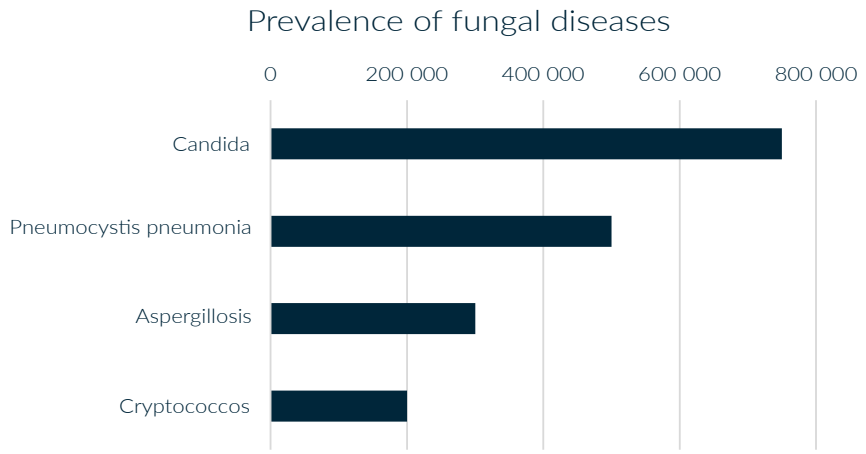
WHO-warning

Biosergen - Products

Resistance - a problem

BSG005 is fungicidal and does not develop resistance

The reason behind increased resistance is, the increased use of azole and echinocandin drugs (see appendix). These drugs are more fungistatic, that is, inhibiting the growth of fungi without killing the fungus. Fungicides are effective and kill the fungus but are associated with side effects. Biosergen is developing a drug candidate which belongs to the group of polyenes that are fungicidal but with fewer side effects than drugs on the market. The fungal species that Biosergen targets, and the annual prevalence worldwide, are shown in the diagram.



Source: Market Research Future

About BSG005

Effects well known

The drug candidate BSG005 has demonstrated a fungicidal effect in animals in preclinical studies. The antifungal effect of polyenes, to which BSG005 belongs, is already well known. Developing a safe drug without side effects is therefore considered the greatest challenge for Biosergen.

Safe study

Few side effects with BSG005

During the ongoing phase 1 study, the safety review committee gave the green light for further studies. After four cohorts, no effect on the kidneys, or any other renal parameters, was seen. This is of great importance, as standard treatment with Amphotericin B induces renal toxicity. BSG005 has shown rapid onset and broad fungicidal efficacy in preclinical studies. Infusion reactions have occurred, which is considered normal.

Biosergen - Products cont.

Origin of the candidate

Molecule developed by Nystatin

BSG005 is a polyene macrolide antifungal molecule. It is a further development of Nystatin (see appendix) which has been shown to have a broad spectrum of response to invasive fungal diseases, such as aspergillus and candida. The company has used gene editing technology to research a new formulation of Nystatin. The aim has been to remove the toxic effects but retain those that are fungicidal. Consequently, a drug that has the same or better effect as Amphotericin B, but with fewer side effects and no toxic effect on the kidneys. The mechanism of action for BSG005 is the same as for Amphotericin B and Nystatin, that is, interference with the fungal cell wall. BSG005 has shown in vivo to have potential advantages over new formulations, such as lipovariants of Amphotericin B (AmBisome), for patients unresponsive to azole and echinocandin therapy.

Broad spectrum potential

Unique profile with a broad spectrum

Wide antifungal activity (broad spectrum), primarily against multi-resistant strains of aspergillus and candida, has also been shown. BSG005 can be used on a broad spectrum without toxic effects on the kidneys. Overall, its strong safety and efficacy profile is expected to be a strong challenger to the drugs on the market. Its unique profile is also deemed to be able to command a premium price.

MANGOLD - SPECTRUM ANTI FUNGALS

Class	Substances	Fungal species				
		Candida	Aspergillus	Fusarium	Mucor	Cryptococcus
Polyene	**BSG005**	x	x	x	x	x
	Amphotericin B	x	x	x	x	x
Azole	Fluconazole	(x)	-	-	-	x
	Posaconazole	(x)	x	-	-	x
	Voriconazole	x	x	(x)	-	x
	Isavuconazole	x	x	(x)	(x)	x
Echinocandin	Caspofungin	x	x	-	-	-

x - activity, (x) - variable activity

Source: Biosergen

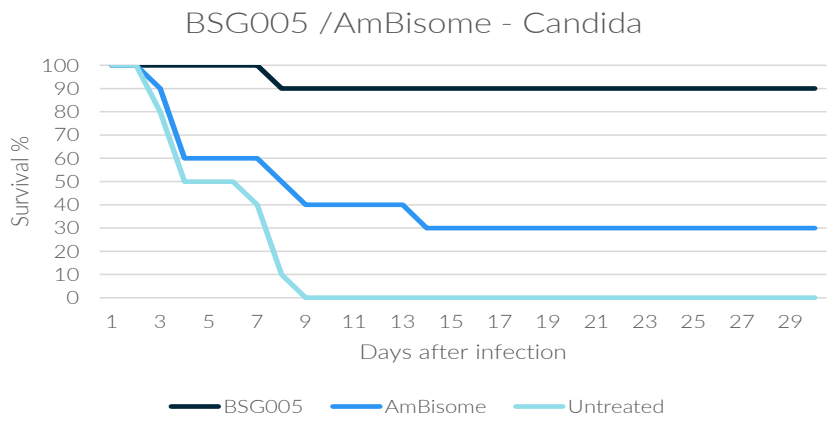
Superior to AmBisome by comparison

Strong preclinical data for BSG005

A comparison has been made in in vivo tests with BSG005 and AmBisome (lipo formulation of Amphotercin B). In this test, BSG005 appears superior to AmBisome against candida and aspergillosis at the same doses. The test shows that immunosuppressed mice died, untreated, nine days after infection. 30 percent of mice treated with AmBisome survived after 30 days, while 90 percent of mice treated with BSG005 survived. Even in tests against aspergillosis, BSG005 has proven to be a better treatment option compared to AmBisome.

Biosergen - Products cont.

Tests have also been carried out with BSG005 in comparison to Fluconazole, Voriconazole and Caspofungin, with good results and superior protection.



Source: Biosergen

Phase 1 studies with BSG005

Biosergen received approval from Australian authorities to begin clinical studies in August 2021. However, it was discovered that BSG005 also killed microorganisms in its vicinity, which was undesirable and which the company remedied. The phase 1 study with BSG005 then began in April 2022. The study is expected to be completed in the first quarter of 2023.

Phase 1 expected to be completed the first quarter of 2023

BSG005, its safety and its tolerability, will be ensured in the phase 1 study. It is a placebo-controlled double-blind test involving 72 healthy volunteers. They will receive either BSG005 or a placebo. The study's design consists of up to two parts. The first part was carried out with 42 individuals, divided up to seven groups of six individuals who either received BSG005 as a single dose (SAD, single ascending dose) or a placebo. No effects on the kidneys or changes in the liver could be observed in this first part.

Safe profile targeting for phase 1

Part two of the phase 1 study began in September. In this part, the dosage (MAD, multiple ascending dose) is increased over seven days at each dose level to see if there are accumulation in the blood och and to investigate the plasma levels of BSG005 to obtain the correct treatment dose, and maximum dose. Up to 30 individuals are included, divided into five groups with six people in each group (cohort). The aim of the study is to test the safety in general, and specifically its effect on the kidneys. Tolerability during infusion, as well as pharmacokinetics, i.e. how the drug is absorbed in the body at different doses, are also studied in this part.

Part 2 of the phase 1-study began in September 2022

Biosergen - Products cont.

The phase 2 study plan

Several fungal species in phase 2

The company is planning for phase 2 studies with several different fungi, which are expected to include 30-35 patients. The effect and indication profile are the objectives in phase 2. The goal is to be able to recruit the first patient during the second quarter of 2023. Results from the first patient study is expected in the first quarter of 2024. Data from the full phase 2 (program of 2-3 studies) is expected to be sufficient to be able to start a complete phase 3 study.

BIOSERGEN - IMPORTANT EVENTS	
BSG005, results of phase 1 studies	Q1-2023
BSG005, start of phase 2 studies	Q3-2023
Results of phase 2 studies	Q3/Q4-2024

Source: Biosergen

Amphotericin B causes kidney damage

Biosergen also intends to conduct a phase 2 study against mucormycosis (see appendix). During the Covid-19 pandemic, an epidemic outbreak of mucormyrcosis occurred in India, where the company plans to conduct a study. Mucormyrcosis is treated with Amphotericin B but causes kidney damage. A big problem in India is that many suffer from diabetes and so limits the use of Amphotericin B, which can damage the kidneys. The company expects to be able to present data from the first part of the phase 2 study against mucormycosis in the fourth quarter of 2024. The company's clinical programme is designed for an application for a new drug, NDA (New Drug Application) during Q2 2026. The goal is to attain first-line treatment status with BSG005.

Source: Biosergen

Development project with BSG005

Oral formulation is being developed

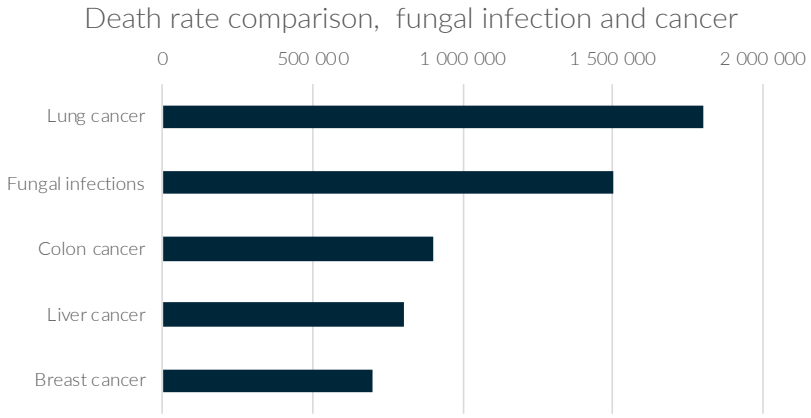
The company is also implementing a project in collaboration with SINTEF to develop nano formulations with BSG005. If the projects are successful, they could be taken to clinical trials in 2025. BSG005 Nano IV targets the lungs, where invasive fungal infections first establish. BSG005 Nano Oral is designed as a pill intended to expand the drug's area of use, in the form that follow-up treatments can be simplified, for continued treatment at home after surgery.

Biosergen - Market

Market

Fungal diseases pose an increased threat

Over 1.6 million people die each year from fungal infections, according to Global Action for Fungal Infections. This exceeds diseases such as both tuberculosis and malaria. In the US, over 75 000 patients with fungal infections are hospitalised each year. According to the Centers for Disease Control and Prevention, around 7 000 people in the US died due to fungal infections in 2021.

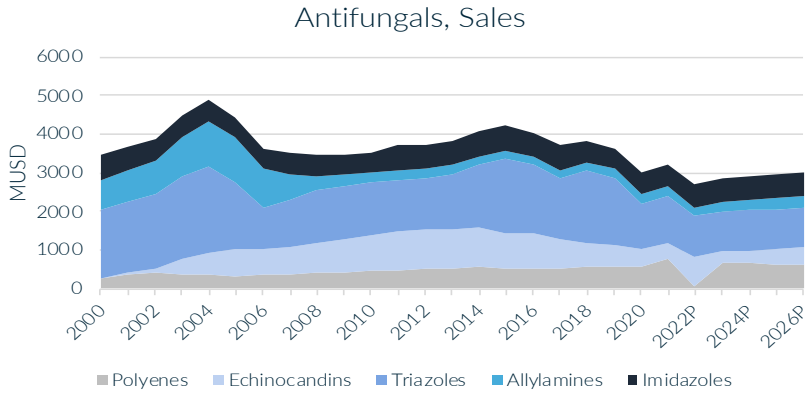


Source: Biosergen

The market for invasive fungal diseases is expected to reach USD 8.1 billion by 2027

The market for fungal infections totaled USD 14.8 billion in 2021. It is expected to grow by 3.7 percent from 2022 to 2030. An increased prevalence of fungal infections with aspergillosis and candida is driving the market growth. Growth for the invasive fungal disease market is expected to be 4 percent on average during the period 2021 to 2027. In 2021, the value of this market amounted to USD 6.5 billion, and is expected to grow to USD 8.1 billion in 2027. Geographically, the market consists largely of North America, which makes up 40 percent, followed by Europe at 29 percent, and Asia at 21 percent. The Middle East makes up 10 percent of this market. The drug market for antifungals (fungicides) can be divided into different classes. In 2021, Azoles (Triazoles and Imidazoles) accounted for the largest share of just over 47 percent of the total market. Generics make up a significant share of around 60 percent.

Azoles make up the largest proportion of antifungals



Source: Market Research Future

Biosergen - Market cont.

Competing drugs to BSG005

Few news within antifungals

The drugs approved for fungal diseases have been new versions of the same class and already existing substances. New mechanisms of action are needed (MoA) when resistance development increases. There has therefore been an increase in fungicidal development projects and launched drugs in recent years. For more on fungicides see the appendix (fungicides on the market).

Similar mechanism of action

Treatment of invasive fungal diseases can be divided into three main classes, consisting of polyenes, azoles, and echinocandins. Common to these are that they work by inhibiting an enzyme that is required for the development of the fungal cell wall. Pyrimidines and allylamines are used to a lesser extent. Polyenes make pores in the cell wall letting flux out of cell material. Azoles and Echinocandins are inhibiting enzymes important for cell wall synthesis. The pyrimidines act by interfering with the protein synthesis of the fungus.

MANGOLD - FUNGAL DRUG CLASSES

Polyenes	Azoles	Triazoles	Echinocandins
Fungizone	Posaconazole	Voricanazole	Caspofungin
AmBisome	Itraconazole	Flukonazole	Micafungin
Mycostatin		Isavuconazole	Anidulafungin

Drugs with a new mechanism of action

Rezafungin on track for launch in March 2023

Cidara Therapeutics has developed **Rezafungin**, which showed positive phase 3 results in a comparison with Caspofungin. It has been developed to be used in resistant candida auris, and with a longer effect, which can be given once a week. It is an improvement compared to Caspofungin. An approval is expected in March 2023. Further phase 3 studies are ongoing, which could broaden its area of use against candida, aspergillus and pneumocystis, for patients receiving blood transfusions and bone marrow transplants. Peak sales for Cidara are expected to amount to MUSD 400 in 2033. If Cidara succeeds in broadening the area of use, Rezafungin's sales are estimated to increase by MUSD 350.

MANGOLD - MILESTONES CIDARA (MUSD)

Licence agreement	Upfront	Regulatory	Commercial	Total
Melinta Therapeutics	30	60	370	460
Mundipharma	30	42	487	559

Source: Cidara Therapeutics

Lucrative agreements for biotech companies researching fungi

Cidara entered into a licence agreement with Melinta Therapeutics for sales in the US. Cidara has received MUSD 30 in upfront milestones and could receive an additional MUSD 60 upon approval. In total, the agreement amounts to milestones of MUSD 460, as well as royalties on sales. As for the EU, there is an agreement with Mundipharma worth MUSD 559 in possible milestone payments, plus an investment of MUSD 9 in the company.

Biosergen - Market cont.

Olorofim has a profound effect on fungi

F2G, a privately held British company focused on invasive fungal diseases, has received a MSUD 100 upfront milestone from Japanese drug company Shinogi to commercialise **olorofim** in Europe and Asia, as well as MUSD 380 for additional milestones and royalties on sales. A private group of investors has also invested MUSD 70 to bring olorofim to market. Olorifim constitutes a new class, orotomides, which has a profound effect on fungi, primarily aspergillus.

Pfizer need a replacement for Vfend

Amplyx was acquired by Pfizer in 2021 in order to introduce a project in fungicides into its portfolio. Pfizer needs to broaden its portfolio in infectious diseases, where its best-selling drug, Vfend, has lost sales. No purchase price for the deal has been disclosed. The company had plans to go public in 2021, but then received a MUSD 93 investment from Pfizer to advance **fosmanogepix** to phase 2. Fosmanogepix is available in oral and intravenous forms of administration. It has shown efficacy in multi-resistant and difficult-to-treat infections.

Fungi represent a threat within biochemical warfare

Applili Therapeutix is a Canadian biotechnology company, focused on fungal diseases and biochemical defenses. The company has received funding from the US Department of Defense and US Air Force of MUSD 14 for the development of **ATI-1701**. The company's ATI-1701 is being developed as a vaccine to combat Francisella tularensis, classified as an organism of high risk to national security and public health by the US NIH.

MANGOLD - PIPELINE ANTIFUNGALS NEW MECHANISM OF ACTION

Substance	Class	MoA	Company	Phase
ATI-2307	Arylamidine	Mitochondrial membrane	Appili Therapeutics	Phase 2
Fosmanogepix	Gwt1 Inhibitor	Inhibits Gwt1 protein	Pfizer/Amplyx	Phase 2
MAT2203	Polyene	Polyen/CAmB	Matinas Biopharma	Phase 2
Olorofim	Orotomide	Pyrimidine inhibitor	F2G	Phase 2b
Rezafungin	Echinocandin	Echinocandin	Cidara Therapeutics	Phase 3
Ibrexafungerp	Triterpinoid	Glucan synthase inhibitor	Scynexis	Launched
Oteseconazole	Tetrazole	14 alpha demethylase inhibitor	Mycovia/Gedeon	Launched

Source: Mangold Insight

Brexafemme may reach MUSD 600 in sales in the US

Scynexis is an American biotechnology company that develops drug candidates for invasive fungal diseases. The company received a grant from the NIH to be able to develop the drug candidate **Ibexafungerp**. This candidate is aimed at the treatment of infections with candida and aspergillus, in particular the resistant C auris. Ibexafungerp belongs to a new class, triterpenoids. It targets the same component of the fungal cell wall as echinocandins. The substance is sold as Brexafemme and costs about USD 475 per treatment. Brexafemme will take on Pfizer's Diflucan, and the company estimates that it may reach MUSD 400 to MUSD 600 in sales in the US. Brexafemme is mainly used for vaginal infections and is administered orally.

Biosergen - Finances

Finances

Well capitalised to move on to phase 2

Biosergen took in 50 million in a new share issue (NI) in conjunction with the company being listed in June 2021. In October 2022, another new share issue was carried out, where Mangold was financial advisor. The company received MSEK 42 before share issue costs, of which MSEK 7.8 was used to pay off an earlier loan. The share issue was subscribed to 70 percent. Additional capital can be raised via subscription warrants (TO2) of MSEK 39. Subscription can take place during the period 14 to 25 August 2023. The subscription price is set at 70 percent of a weighted average price during the period 28 July to 10 August.

BIOSERGE - SCHEDULE BSG005

	Phase 1	Phase 2	Phase 3	Launch
Period	2022	2023	2025	2026H2
Financing	NI (implemented)	NI	Licence agreement	

Source: Mangold Insight

The company is looking for a strategic partner for phase 3

The company intends to complete phase 1 studies with BSG005 during the first quarter 2023. Also, top line data is expected in the first quarter of 2023. The company is expected to apply for phase 2 studies during the first quarter, which are planned to include two or three trials. The proceeds from upcoming subscription warrants are intended to be used for product development and manufacturing in phase 2. Mangold estimates that additional capital will be required to complete phase 2 studies. For any phase 3 studies, the company intends to conclude an agreement with a strategic partner who can launch and market BSG005 on the market.

BIOSERGEN - BSG005 OUTLINE NI 2022

Complete Phase 1	40%
Product development and manufacture for phase 2	25%
Begin Phase 2	25%
Develop BSG005	10%
Total	100%

Source: Mangold Insight

Biosergen – Forecasts

Assumptions, forecasts

Addressed market is based on the number of patients treated in hospital

In the US, 75 000 patients were hospitalised for fungal diseases in 2014. Diagnosed fungal diseases amounted to 670 000 patients in 2018, of which 20 percent needed hospital care, according to NCBI, which represents approximately 140 000 patients. North America accounted for 41.5 percent of the total drug market for antifungals in 2021. A reasonable estimate is that the number of patients globally is 262 500.

MANGOLD - ASSUMPTIONS	
Prevalence globally, candida	750 000
Prevalence globally, aspergillos	300 000
Addressable market (25%)	262 500
Penetration	30%
Patient base	78 750
Price dollar/treatment	7 700
Income (MUSD)	606

Source: Mangold Insight

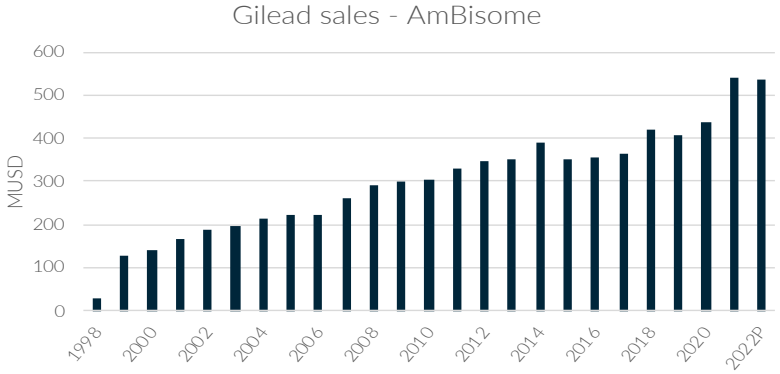
Benchmark other drugs

Premium pricing for BSG005

Mangold has chosen to assume a Base case, where the starting point was the potential market for fungal infections related to candida and aspergillosis. Based on prevalence, we have estimated the number of patients who need hospital care (addressable market). We have then chosen to assume that BSG005 takes a market share of 30 percent. The price for Cresemba (see Appendix) in the US is USD 7 400 per treatment. In our model, we have chosen a higher price of USD 7 700 per treatment. Biosergen intends to price BSG005 at a premium, based on its safe and effective profile.

AmBisome, a direct competitor

We have also compared sales forecasts with AmBisome, a direct competitor with a similar broad spectrum, but with unwanted side effects. Peak sales for AmBisome expect to be MUSD 550. As for Cresemba, a competing drug, peak sales are expected to reach MUSD 600 after a ramp up of 7-8 years.



Source: Gilead

Biosergen – Valuation

Risk-adjusted DCF model

LOA at 13.2 percent

Mangold has chosen to value Biosergen based on a Sum of the Parts model. We have used the potential of BSG005 as the basis, which is discounted in a risk-adjusted DCF model. The risks of drug development are managed by risk-adjusting the project, based on the latest Biotechnology Innovation Organization 2021 (BIO) report. For infectious diseases, which include invasive fungal diseases, the likelihood of an approval (LOA) from phase 1 studies is 13.2 percent. Mangold has therefore chosen to use 13.2 percent as the LOA in this analysis. In the event of successful phase 1 studies, the LOA may be adjusted to a higher probability. When the company enters phase 2, the risk thereby decreases. We have chosen not to include milestones in our valuation model. Market launch is estimated to take place in 2026.

MANGOLD - ASSUMPTIONS DCF

Market launch (year)	2026
Peak Sales Base case (MUSD)	600
Ramp up (years)	7
Peak Sales (year)	2033
LoA (%)	13.2%
PACME	16%

Source: Mangold Insight

Calculation of EV

Small company risk premium for Biosergen

Full dilution has been taken into account

To obtain an EV (enterprise value) for the BLG005 project, we have chosen to assume recommended discount rates for early projects (Alacrita). We have also applied a small company supplement, as the market value amounts to less than MSEK 50, which in total gives a discount rate of 20 percent. We have also taken account of costs. Projected cash has not been added. In calculating the number of shares, we have used full dilution for TO2. EV is calculated in dollars and has then been converted to kronor at the exchange rate of 10.30 USD/SEK.

BIOSERGEN - SUM OF THE PARTS

EV (MSEK)	211
rNPV (MSEK)	148
Expenses	30%
Fair Value (MSEK)	148
No. of shares (Million)	54,5
Fair value (SEK/share)	2,72

Source: Mangold Insight

Biosergen – Case

Case analysis

Mangold has chosen to assume three different cases. In our **Base case**, we assume the previously used market approach and peak sales of MSEK 600 for BSG005. It is on par with sales for AmBisome. The Fair value in the Base Case amounts to SEK 2.72 per share.

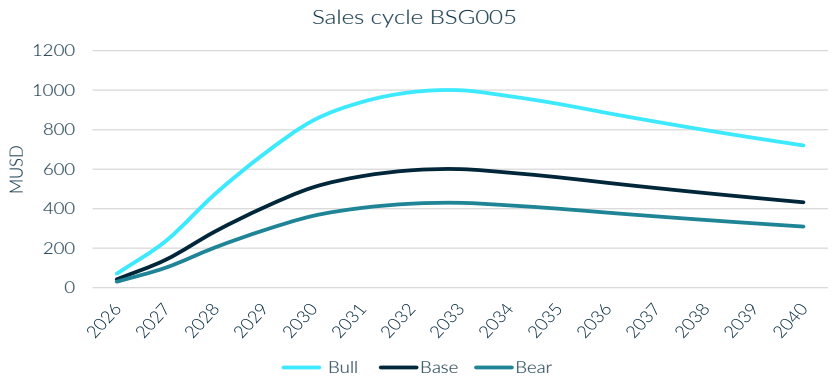
Base case gives SEK 2.72 per share

In a **Bull case**, we assume that BSG005 will take a larger share of the market and reach Blockbuster sales of USD 1 billion in sales. This is something that Biosergen has indicated its drug candidate can achieve as it covers a broad spectrum and can become an option for first-line treatment. This justifies a Blockbuster candidate. Our blue sky scenario would result in a Fair value of SEK 4.50 per share.

Bull case gives SEK 4.50 per share

In a **Bear case**, we have assumed a lower market share and sales that fall below Cresemba and AmBisome's levels. Peak sales then land at MUSD 430. The Fair value based on this scenario is SEK 2.00 per share.

Bear case gives SEK 2.00 per shares



Scenario analysis

In order to see how the value changes at higher and lower peak sales, as well as a changed required rates of return, we have chosen to carry out a sensitivity analysis. Peak sales in the Bull case increase by 67 percent and decrease by 28 percent in the Bear case. In this analysis, it is found that the company's Fair value amounts to a maximum of SEK 5.40 in the Bull case and a minimum of SEK 1.70 per share in the Bear case. Mangold chooses to use the price target which corresponds to the Base case at SEK 2.70 per share,

Price target set at SEK 2.70 per share

BIOSERGEN - SENSITIVITY ANALYSIS

	Bear	Base	Bull
18%	2,3	3,2	5,4
20%	2,0	2,7	4,5
22%	1,7	2,3	3,9

Source: Mangold Insight

Biosergen – SWOT

Strengths

- Robust preclinical data for BSG005
- BSG005 has proven safe and has fewer side effects than competitors
- BSG005 has a fast effect and a broad spectrum

Weaknesses

- Early clinical phase, no efficacy studies on patients
- Capital requirements for future studies
- One product company, high risk

Opportunities

- BSG005 can reach blockbuster status
- Become a first-line treatment option
- Broaden to oral administration form
- Premium positioning

Threats

- Competing drugs
- Studies are delayed
- Lack of capital

Biosergen – Appendix - Management

Management

Peder Møller Andersen is the CEO and a board member. He has a medical degree from Copenhagen University. Peder was previously the CEO of Forward Pharma A/S and was involved in the company's IPO on the Nasdaq Stock Exchange in New York. He is currently a clinical advisor to PharmNovo. Peder is also a board member of Select Pharma Pty Ltd.

Niels Laursen is the CFO. Niels has a master's degree in business administration and a bachelor's degree from Copenhagen Business School. Niels previously worked as the CFO at Oncology Ventures A/S (now Allarity Therapeutics) and was a co-owner of DWork, a consulting firm in strategy and business development.

Tine Kold Olesen is the COO at Biosergen. She has a PhD in Medicine and Health Sciences from Ghent University, an MSc in Pharmaceutical Sciences from Copenhagen University and a MSc in Business Administration from Imperial College.

Tine has previously worked with clinical research in international pharmaceutical companies such as Novo Nordisk, GSK and Orion Pharma. She has had a leading role in the Ferring Pharmaceuticals Oncology/Urology portfolio in the US. She is currently a board member of the American company Pharma15 Corp.

Board of Directors

Torsten Goesch is the Chair of the Board. He has a medical degree and PhD from Heinrich Heine University Düsseldorf and a master's degree in business administration from Northwestern University's J.L. Kellogg Graduate School of Management. He previously worked as head of the German-speaking countries within Biogen. He was commercial manager for global generic pharmaceutical operations and head of strategy and acquisitions within pharmaceuticals at Merck KGaAs. Torsten has been Chair of the Board of Clanotech and is Chair of the Board of Dilafor and Obvia Pharmaceuticals Ltd. He is a co-owner and board member of Rosetta Capital Limited, as well as a board member of Modus, Eyesense GmbH, Forward Pharma A/S, Karolinska Development Invest, Promore Pharma and Vistagen Pte Ltd.

Lena Degling Wikingsson is a board member. She is a pharmacist and has a master's degree in pharmacy from Uppsala University. She has extensive experience in the pharmaceutical industry, in regulatory issues and the development of biological drugs and vaccines from companies such as Avaris, Independent Pharmaceutica, SBL Vaccines, and Accuro Immunology. In addition, she has worked as a biotechnology evaluator at the Swedish Medicines Agency. Lena has previously been Chair of the Board of NextCell Pharma. She is currently Chair of the Board of XNK Therapeutics, Simplexa, and Dilafor Incentive, as well as a board member of Alzinova. She is also the CEO of Dilafor.

Biosergen – Appendix - Board of Directors cont.

Achim Kaufhold is a board member. He has a medical degree from the University of Cologne and a professorship in Medical Microbiology and Infectious Diseases from the University of Aachen. He most recently served as the CMO at Basilea Pharmaceutica in Switzerland and has been a board member of Vaximm GmbH, CEO at Affitech, Pharmexa and the CMO at Berna Biotech. He is currently the CMO at Hansa Biopharma.

Marianne Kock is a board member. She has a master's degree in pharmacy from the Danish University of Pharmacy and in business administration from the Scandinavian International Management Institute. Marianne has held several senior positions at Ferring Pharmaceuticals A/S and served as a board member at Fertin Pharma A/S and Bionor Pharma AS. She is currently the General Manager at Ferring Pharmaceuticals A/S IPC Development Unit in Copenhagen and is a board member of Asarina Pharma.

Henrik Moltke is a board member. He has a master's degree in economics and a bachelor's degree in strategy and international economics from Copenhagen Business School. Henrik was a co-founder of NeuroSearch and served as the company's CFO. He has held senior positions and board positions at several small and medium-sized biotechnology companies, at Oncology Venture A/S (now Allarity Therapeutics), Scandinavian Micro Biodevices Aps (now Zoetis Denmark Aps). He is currently the CFO at FluoGuide A/S and a board member of Initiator Pharma A/S and Hartmanns A/S.

Hanne Mette Dyrlie Kristensen is a board member. She has a master's degree in technology management from the Norwegian University of Science and Technology and MIT, Sloan School of Management. She also has a bachelor's degree in chemistry, specialising in biochemistry, from the University of Oslo. Hanne has previously held leading positions at Innovation Norway, Oslo Cancer Cluster, Oslo Cancer Cluster Incubator, and Norway Health Tech. She is currently the CEO of Life Science Cluster and founder of Oslo Life Science Advisors AS. In addition, she is a board member of Regionale Forskningfond, RFF Viken, and Oslo Cancer Cluster Incubator.

Mattias Klintemar is a board member. He has a bachelor's degree in business administration from Karlstad University. Mattias' previous experience includes companies such as Hexaformer Produktion and ABG Sundal Collier. He has also been Chair of the Board of Dilafor and SealFX, as well as a board member of Axelar, Phoniro, Oatly and Assa Abloy Global Solutions. He currently works as the Investment Director at the Baltic Sea Foundation, and as Chair of the Board of Luci Intressenter. He is also a board member of Palette Life Sciences (formerly Pharmanest), Moberg Pharma, Cereal Base CEBA, Oatly Group, Klintemar Konsult, Castello di Vaglio Serra, OncoZenga and DBT Capital. Mattias is a deputy board member of Oatly, MEA, MLJK Konsult and Havrekärnan.

Biosergen– Appendix - Fungal infections

Fungi and infections

The number of fungi that can infect humans is estimated to be around one hundred. They usually cause mild infections and rashes, but a yeast infection can also lead to serious health problems. Fungi are divided into groups, where yeasts and filamentous fungi are among the most common.

Yeast fungi are normally found in the skin without causing any problems. If the body's immune system deteriorates, or if the normal bacterial flora is disturbed, this can lead to serious infections. Examples of yeast fungi are candida and malassezia, which can cause infections in the abdomen and eczema. Candida infection usually causes a superficial infection in the skin, nails or on the mucous membrane.

Filamentous fungi are not normally found in the skin. These can be caught via floors in gyms and bathhouses and give rise to, among other things, athlete's foot. Moulds and dermatophytes are also included in the group of filamentous fungi. If the immune system is impaired, an opportunistic infection occurs. Opportunistic fungi are usually candida and aspergillus (moulds).

Yeast fungi	Filamentous fungi
Candida	Aspergillus
Cryptococcus	Fusarium
	Mucorales

Opportunistic fungi only attack the body if the patient's defenses are compromised. If the body's immune system deteriorates, fungi can infect various organs in the body, such as the lungs, intestines and brain, which is called invasive fungal infections. Examples of diseases that can cause this are cancer and HIV, but others at risk include patients who have undergone a transplant or are being treated with cytostatic. Invasive fungal infections have increased in frequency. These mainly affect patients who are immunosuppressed (often after organ transplantation), and those undergoing advanced medical treatment or major surgery. It is common for infections to be acquired in hospitals (nosocomial infections). This is an effect of more hospital patients with weakened immune systems, an increased number of elderly patients, more invasive medical procedures, lack of sanitary controls, and routine use of antifungal drugs (antimycotics). Most invasive fungal diseases are caused by four fungal pathogens: Candida, Aspergillus, Cryptococcus and Pneumocystis.

Biosergen– Appendix - Fungal diseases

Fungal diseases

Candidiasis – a fungal infection caused by yeast fungi belonging to the genus Candida. It is found worldwide and normally occurs in the normal flora of humans.

Aspergillus – a fungal infection that can give rise to more diseases, such as mycotoxicosis, allergy, invasive disease affecting the lungs and other organs, and systemic disease in the central nervous system, heart, kidneys, and intestines. Aspergillus is most often transmitted via the respiratory tract, and sometimes via wounds.

Pneumocystis jirovecii – can cause pneumonia in people with compromised immune systems such as patients with HIV, hematological disease and transplant patients.

Cryptococcus – a fungal infection caused by the yeast Cryptococcus neoforman. It mainly affects people with a compromised immune system. The infection arises in the lungs but can also occur as meningitis (cryptococcal meningitis).

Mucormycosis – a rare fungal infection caused by mucorales (absidia, mucor, rhizopus etc.) It appears as an opportunistic infection. The fungus mucorales, called black fungus, often establishes itself in the nose, sinuses or eyes. If the eyes become infected, they may need to be surgically removed to prevent spreading to the brain, which is associated with high mortality.

Trichosporiasis – causes opportunistic infections such as endocarditis (infection of the heart valves).

Some fungi live in specific areas. Blastomycosis is a fungal infection caused by Blastomyces. It is common in the US in the areas around the state of Ohio and in the valleys of the Mississippi River and the Great Lakes on the border between the US and Canada. Blastomyces can be inhaled and cause fever and cough. If left untreated, it can spread from the lung to other organs.

Other types of fungal infections are Coccidioidomycosis (Valley Fever), which usually occurs in South America and Mexico.

Diagnosis in cases of invasive fungal infections

Invasive fungal infections are usually difficult to diagnose, and treatment is often initiated when there is only a slight suspicion of infection. If treatment is delayed or incorrect, it can lead to high mortality. A combination of different examinations is usually done in cases of yeast or mould fungal infections. This comprises cultures, microscopy, and biopsy, as well as antigen tests carried out in a laboratory. Computed tomography (CT) and magnetic resonance imaging (MRI) are also used for diagnosis. Other types of examinations consist of ultrasound and ophthalmoscopy. Tests for yeast fungi are taken as a normal bacterial culture. Certain types of fungi, such as malassezia, can be detected via microscopy.

Biosergen– Appendix - Treatment

Fungal infections - Treatment

Fungal infections are usually treated with antifungals, which are fungicides. Most antifungals target ergosterol, a steroid found in fungi. Ergosterol is the fungal equivalent of human cholesterol. It is a cholesterol that forms the basis and origin of the formation of other steroids in the body.

Polyenes

Polyenes have been used since the 1950s to prevent invasive fungal diseases. Polyenes are effective but associated with toxicity on the kidneys (nephrotoxicity). The most common treatment method is Amphotericin B, which has a broad spectrum. This class also includes Nystatin and new formulations of Amphotericin B.

Azoles

Azoles represent a large part of the treatment used for fungal infections. This is because of their effectiveness with a wide range of fungal pathogens, and that Azoles do not exhibit the renal toxicity significant for polyenes. Azoles are available in oral form and as an injection. These are more widely used in clinics due to the strong safety profile. One problem, however, is that Azoles are one of the reasons why resistance is increasing. This is because it is used beyond the treatment of fungus. Azoles are also used in agriculture, on golf courses, and for wood treatment. The fungus Aspergillus, for example, has developed high levels of resistance to treatments with Azoles. The drug Fluconazole (Diflucan) belongs to azoles, and was developed by researcher Ken Richardson. It has been in use since 1988 and is on the WHO's List of Essential Medicines.

Echinocandins

Amphotericin B and azoles have been standard treatments for fungal diseases, but side effects and resistance have led drug companies to seek new treatment methods. Echinocandins are a new class that mitigate toxicity on the kidneys. Echinocandins act by inhibiting a fungal cell wall component essential for homeostasis. Echinocandins are available as generics, and have similar effects to azoles and polyenes, but must be administered intravenously due to poor bioavailability. The first drug to be approved was Caspofungin (Cancidas), developed by Merck & Co and approved by the FDA in 2001. Other variants are anidulafungin, which is not metabolised in the liver or excreted via the kidneys. Another option is micafungin.

Pyrimidines and allylamines

Pyrimidines, such as flucytosine, are often used in combination with Amphotericin B. It is a common treatment option against Cryptococcus infections and other less invasive fungal diseases.

Biosergen– Appendix - Treatment cont.

Nystatin

Nystatin was discovered by the two female researchers Elizabeth Lee Hazen and Rachel Fuller Brown, at the Division of Laboratories and Research in the New York State Department of Health during the 1950s. These scientists were inspired by Nobel laureate Alexander Fleming, who discovered penicillin. Nystatin, named after the New York State, was discovered after a series of different tests were carried out, most of which proved to be highly toxic in animal experiments. Finally, a fungicidal species from the bacterium streptomycetes was found, which was later named Streptomycetes noursei after Walter B. Noourse, whose farm the sample was taken from. Since its discovery, Nystatin has been widely used for the treatment of fungal infections against Candida and Cryptococcus. Nystatin binds to ergosterol, a major component (a steroid) in the fungal cell membrane, in the same way as Amphotericin B, and belongs to the Polyenes group. Nystatin is sold as Mycostatin but is available in several different generic forms.

Amphotericin B

Amphotericin B is an antifungal antibiotic used in the treatment of invasive fungal infections. It has been used as a standard treatment against candida for a long time, since being licensed in 1959 and then introduced to the market in 1960 as Fungizone by the American pharmaceutical company Bristol-Myers Squibb. The discovery was made in 1955, in a laboratory at the Squibb Institute for Medical Research.

Amphotericin B has a broad spectrum but is primarily used against candida and aspergillus species. The medicine has a fungicidal effect which entails a low risk of developing resistance. However, Amphotericin B is associated with side effects, and new formulations (lipid complexes) with fewer side effects have been introduced to the market. These are AmBisome, Abelcet, and Amphpocil/Amphotec. All of these formulations have shown lower renal toxicity than Amphotericin B in studies, and have proven to be at least as effective as Amphotericin B. For some institutions, costs have been a limiting factor and Amphotericin B has therefore continued to maintain its status as a standard treatment.

Fungicides on the market

Cresemba (Isavuconazonium sulfate), within the drug group triazoles (azoles), was launched on the market in 2017. The drug was developed by Basilea Pharmaceutica, a spin-out from Roche listed on the stock exchange in Switzerland. Pfizer has rights for the European market and Astella for North America. The drug was developed by Basilea Pharmaceutica, a spin-out from Roche listed on the stock exchange in Switzerland. The drug has been granted orphan drug designation in major markets for the treatment of aspergillosis, mucormycosis and invasive candida. By June 2022, Cresemba had launched in 57 countries and had total sales of MUSD 324 in 2021. In the twelve-month rolling period up to March 2022, sales globally had increased to MUSD 344. The price for treatment with Cresemba is estimated to be USD 7 400 per patient in the US. Peak sales for Cresemba are estimated at USD 600.

Biosergen– Appendix - Treatment cont.

Pfizerz's **Vfend** (voriconazole), which is the standard treatment for invasive fungal diseases, reached peak sales of MUSD 825 in 2010, but has been facing competition from generics. Sales have subsequently declined. It is also a triazole (fungicide within azoles). The price for treatment has averaged USD 4 500 per patient.

Cancidas (Caspofungin) is an echinocandin marketed by a number of different drug companies, but was originally developed by Merck &Co. It is now available as a generic and is sold for a total of around MUSD 700 per year.

AmBisome, a polyene and an improvement of Amphotericin B, is still a nephrotoxic (drugs that affect and can damage the kidney). It is developed by Nexstar Pharmaceuticals which was acquired by Gilead Sciences. AmBisome is marketed in Europe by Gilead and Astella in the US.

Mycamine (Micafungin) is an echinocandin launched in 2005 by Astellas. It was primarily developed for use in stem cell transplants and the treatment of candida infections.

Noxafil (Posaconazole) is a broad-spectrum triazole approved for the treatment of invasive aspergillus and candida infections, primarily targeting high-risk patients, in 2006. Schering-Plough has marketed Noxafil, which is now available as a generic.

MANGOLD - ANTIFUNGALS

Drug	Substance	Company	Sales 2021 (MUSD)
AmBisome	Amphotericin B	Gilead	540
Vfend	Voriconazole	Pfizer	267
Noxafil	Posaconazole	Merck	259
Cancidas	Caspogungin	Merck	212

Source: Mangold Insight

Biosergen– Appendix - Other

Orphan drug designation

Orphan drugs are developed for the treatment of rare diseases. They are given this name as they are intended for a small number of patients suffering from rare conditions. According to the EMA, around 30 million people in the EU area suffer from rare diseases. Rare diseases (also called orphan diseases or unusual diseases) are an area of increased focus for drug companies. It originates from the Orphan Drug Act of 1983, which was established in the US to stimulate the development of drugs for patients with rare diseases. A regulation has also been adopted for orphan drugs in Europe, which took place in 1999, as well as in Japan in 1993. In order to be called an orphan disease in the US, the number of people affected may not exceed 200 000 people. In Europe, an orphan disease is defined as a condition that affects no more than five out of 10 000 European citizens without satisfactory diagnosis or treatment. Examples of orphan diseases are cystic fibrosis, glioma, pancreatic cancer, myeloma, leukemia, renal cell carcinoma, ovarian cancer, and Duchenne muscular dystrophy.

The background to the Orphan Drug Act is that the cost of developing a drug is high, regardless of whether it is intended for a small or large patient group. This has meant that drug companies have historically chosen to develop drugs for large patient groups. Following the introduction of policy initiatives in the US, Japan and Europe, companies are encouraged to develop new drugs for the treatment of rare diseases. In order to produce more orphan drugs, the regulatory framework has been eased, which contributes to lower development costs and the possibility of longer exclusivity on the market. An orphan drug receives seven (7) years of market exclusivity from marketing approval in the US. In Europe, ten (10) years of market exclusivity applies from sales approval. There is also support for the design of clinical studies, tax breaks, and fewer fees, as well as the right to various grants.

May attain GAIN status

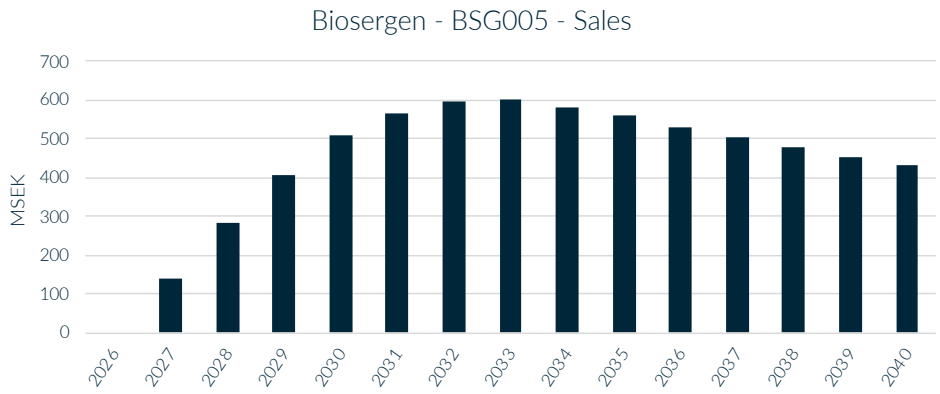
GAIN (Generating Antibiotic Incentives Now), approved by the US congress, was created to increase the incentives for the development of antibacterial and antifungal drugs intended for patients with serious and life-threatening infections. The background is increased resistance to antibiotics. A medicine can be designated as a qualified infectious disease product (QIDP) if it meets certain criteria. If a drug candidate is designated QIDP, it receives increased priority and review, as well as extended market exclusivity for five (5) years. Biosergen deems that their drug candidate is qualified and intends to apply for QIDP after completed phase 2 studies.

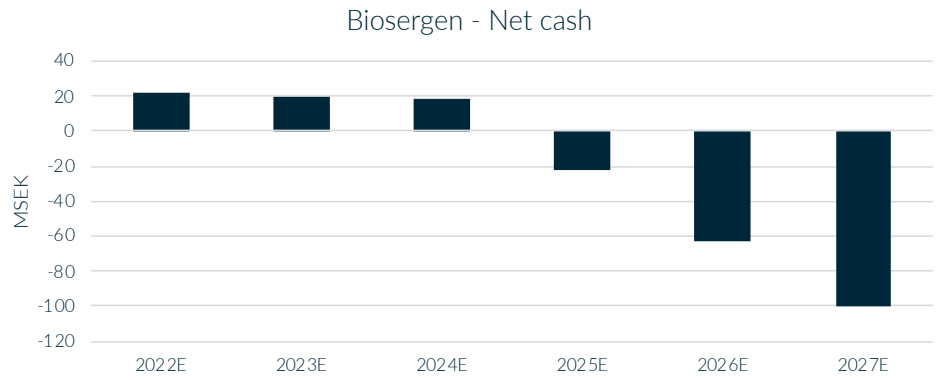
Strong patent protection

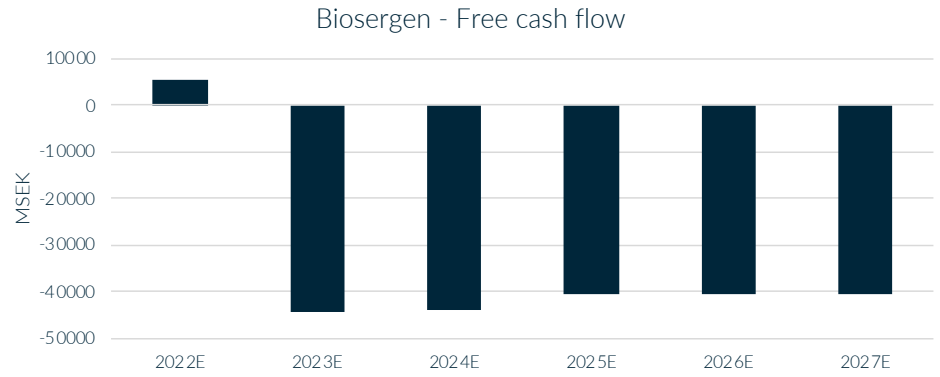
Region	IP	Exclusivity (years)
USA	2033	7 (Orphan Drug)
EU	2028	2
Japan	2033	6-10
China	2028	6

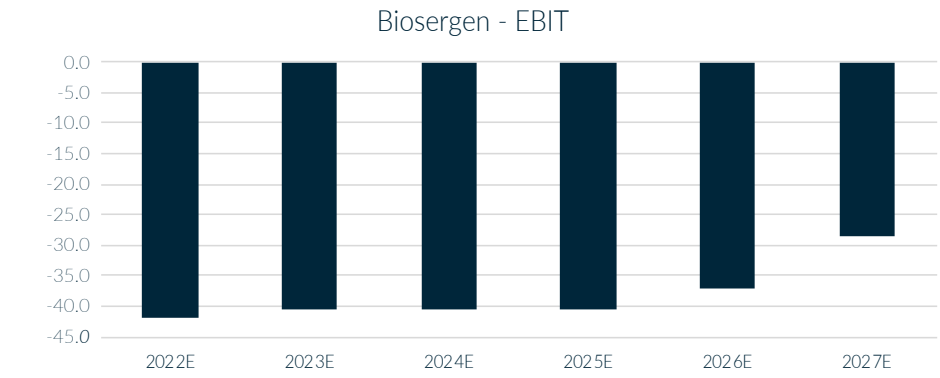
Source: Biosergen

Biosergen – Appendix









Biosergen – Income statement & balance sheet

Income statement (TSEK)	2021	2022E	2023E	2024E	2025E	2026E	2027E
Income/Milestones	0	0	0	0	0	6 880	22 753
Other operating income	8 573	3 800	3 800	3 800	3 800	2 500	0
Cost of goods sold	-178	-114	-114	-114	-114	-2 064	-6 826
Gross profit	8 395	3 686	3 686	3 686	3 686	7 316	15 927
Operating result	**-34 078**	**-41 928**	**-40 626**	**-40 626**	**-40 626**	**-36 996**	**-28 385**
Net interest income	0	0	0	0	0	0	0
Result after net financial items	-34 078	-41 928	-40 626	-40 626	-40 626	-36 996	-28 385
Taxes	0	0	0	0	0	0	6 245
Net profit	**-34 078**	**-41 928**	**-40 626**	**-40 626**	**-40 626**	**-36 996**	**-22 140**

Balance sheet (TSEK)	2021	2022E	2023E	2024E	2025E	2026E	2027E
Assets							
Cash and bank balances	21 665	20 037	18 411	-22 215	-62 841	-99 677	-121 509
Accounts receivable	7 821	468	468	468	468	308	0
Inventory	0	19	19	19	19	339	1 122
Fixed assets	0	0	0	0	0	0	0
Total assets	29 486	20 524	18 898	-21 728	-62 354	-99 030	-120 387
Liabilities							
Total liabilities	**9 253**	**19**	**19**	**19**	**19**	**339**	**1 122**
Equity							
Restricted equity	65 235	107 435	146 435	146 435	146 435	146 435	146 435
Unrestricted equity	-45 002	-86 930	-127 556	-168 182	-208 808	-245 804	-267 944
Total equity	20 233	20 505	18 879	-21 747	-62 373	-99 369	-121 509
Liabilities and equity	**29 486**	**20 524**	**18 898**	**-21 728**	**-62 354**	**-99 030**	**-120 387**

Source: Mangold Insight

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Mangold does own shares in Biosergen, such as for own stock.

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Buy – An upside in the share of at least 20%
Increase – An upside in the share of 10–20%
Neutral – An upside and downside in the share of 0–10%
Decrease – A downside in the share of 10–20%
Sell – A downside in the share of at least 20%