Biosergen

Mangold Insight – Commissioned research - Update - 12 January 2024

Indian collaboration gives boost

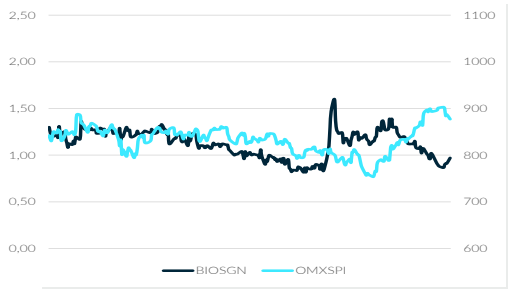
Biosergen will conduct a new phase 1b study in patients with invasive fungal infections with its drug candidate BSG005. This will be done together with the Indian pharmaceutical company Alkem. The benefits of doing clinical studies with Alkem are that Biosergen is guaranteed that future studies will be done and that the development costs for Biosergen will be significantly lower. This is a step done to get BSG005 faster to the market. However, Biosergen must finance the phase 1b study and needs to raise capital for that. Future studies are funded by Alkem.

Launching new Phase 1b study

Biosergen is expected to launch the phase 1b patient study in March. The duration of the study is expected to be short. Topline results are expected to be obtained in October 2024. This phase 1b study will confirm the safety of BSG005 and establish the dose for future studies. The need for new drugs for invasive fungal diseases is huge and there has been increased interest among pharmaceutical companies to include these projects in their portfolios. Mangold believes that Biosergen has a strong candidate which, following positive results from the phase 1b study in patients, should be able to attract a partner for a future global launch.

Multiple triggers in the stock

Mangold value Biosergen using a risk adjusted DCF model. The company's substance is known, which reduces the risk and has so far proved safe in previous clinical studies. The risk in biotechnology equities remains high and should be considered. In our Base Case, a fair value of 3.30 SEK per share is given. Mangold has chosen to set price target to 3.00 SEK. Triggers constitute approval and initiation of the phase 1b-study as well as its topline results this autumn.



Price performance %	1m	3m	12m
BIOSGN	-13,9	-19,8	-25,0
OMXSPI	2,3	9,6	53,1

Key Data	
Price target (SEK)	3,00
Risk	High
Price (SEK)	0,93
Market value (MSEK)	47
No. of shares (million)	50,7
Free float	27,1 %
Ticker	BIOSGN
Next earnings report	31 March 2024
Website	biosergen.net
Analyst	Jan Glevén

Ownership structure	Shares	Capital
Östersjöstiftelsen	22.8	45.0%
Rosetta Capital	8.9	17.6%
Avanza Pension	2.0	4.0%
Stiftelsen Sintef	1.9	3.7%
Peder M. Andersen	1.2	2.4%
Tuvedalen	1.2	2.5%
Karolinska Development	0.9	1.8%
Tim Laibl	0.8	1.6%
Anders Bladh	0.8	1.6%
Johan Thorell	0.7	1.3%
Totalt	**50.7**	**100%**

Key ratios	2021	2022	2023E	2024E	2025E
Sales (TSEK)	-	-	-	-	-
EBIT (TSEK)	-34 078	-34 129	-24 780	-16 980	-16 980
Profit before tax (TSEK)	-34 318	-34 048	-24 780	-16 980	-16 980
VPA, dilution (SEK)	-0,68	-0,67	-0,49	-0,34	-0,34
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

Mangold update Biosergen and reiterate buy with a price target of 3.00 SEK (3.50) per share over a 12-month period. Upside potential exceeds 200 percent. Biosergen develops a fungicidal drug against invasive fungal diseases. The number of individuals dying from invasive fungal infections is increasing, yet treatment options remain inadequate, as resistance and serious side effects are major problems. Biosergen intends to develop a drug that kills the fungus and without the serious side effects found with competing drugs on the market.

Buy Biosergen, price target 3.00 MSEK per share

Underdeveloped treatment area

Few studies have been carried out before to develop new treatment methods in this area. A reason for this is that the expected return for the drug companies on such an investment is limited. Efforts have therefore 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 increasing interest in introducing new drugs into their portfolio. Several acquisitions and lucrative licence agreements have been made within this segment.

Significant need for new drugs

BSG005 - a potent drug

Efficacy for BSG005 has been demonstrated in preclinical studies where it was shown to be superior to competing medicinal products like AmBisome (Amphotericin B). Coming clinical studies are expected to add value for the company. BSG005 aim to become the first-line option in invasive fungal diseases with its safe and broadly effective profile.

Kills the fungus and reduces resistance

Safety first

During phase 1b 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 1b 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.

BSG005 has no toxic effect on the kidneys or liver

High risk/reward

Mangold has carried out a thorough competition analysis and assesses the company based on a SOTP-model. To derive a fair value, a risk-adjusted DCF model has been used. From three different scenarios, the potential for BSG005 appears attractive. Mangold uses the Base Case which gives a fair value of 168 MSEK. The risk in pharmaceutical developing companies is very high and the value of the company is entirely dependent on one product.

Large upside in Base Case

Biosergen - Update

New Study starts in India with Alkem

In the autumn of 2023, Biosergen started a collaboration with the Indian pharmaceutical company Alkem Laboratories (Alkem) for the future development of BSG005. The collaboration is expected to accelerate the route to the market and reduce costs of Biosergen by lowering development costs. Biosergen states that savings of 300 MSEK can be achieved. The deal is without milestones, but it may be added.

Several advantages with Alkem cooperation

Biosergen intends to initiate a phase 1b study with BSG005 together with Alkem. An application for approval of the trial has been submitted to the Indian regulatory organization CDSCO in mid December 2023. A response is expected to take 8-12 weeks. The study is then expected to start in March 2024. It is projected to take 6 months and topline data are expected in October 2024. When completed, further phase 2 and 3 studies are in planning.

Studies with BSG005 will begin in March

BIOSERGEN - TIMEPLAN

BSG005 start phase 1b study	March 2024
Result phase 1b study	October 2024

Source: Biosergen

The way forward

Future phase 2 studies will be designed as a phase 2/3 study. Biosergen believes that cooperation with Alkem will help ensure that the studies will be carried out quickly when access to patients is assured. This phase 2/3 study will focus on aspergillosis and mucormycosis (for more about mucormycosis see appendix). All studies are done according to FDA and EMA standards.

Planning for a phase 2/3 study design

Benefits of working with Alkem are that Biosergen can be sure to get access to patients with severe invasive fungal diseases. India has a high prevalence of serious fungal diseases which poses a threat to public health (se appendix).

High prevalence of fungal diseases in India

Biosergen is guaranteed that phase 2 and phase 3 studies are carried out. 70 percent of patients required for these studies are guaranteed. These studies will be financed by Alkem. Biosergen is also looking for additional partners for these studies. Alkem will finance the project from phase 2, which means that Biosergen provides funding for phase 1b (also see page 4). In return Alkem gets commercial rights for India. Biosergen will receive royalties. For the rest of the world, especially the US and European market, Biosergen needs to sign a contract for commercialization.

Alkem will fund phase 2 and 3

Need funding for phase 1b

Biosergen – Update Phase 1b study

The Phase 1b study

The phase 1b study is a Proof of Concept Study that will be conducted in 15 patients. The study will be carried out by Alkem. The purpose of the study is to confirm safety and tolerability and to find the correct dose to be used in the phase 2 study. The phase 1b study will be conducted with 3 patient cohorts with 5 patients each. Technically, it is a phase 1b study as there will be some pharmacokinetic examination. The company intends to receive information on dose levels for several fungal diseases, mainly from candida and aspergillosis and possibly mucormycosis.

Need Proof of Concept for BSG005

Technically a phase 1b study (see more about phase 1b in appendix)

BIOSERGEN - STUDY DESIGN

Type	Open label, singlearm, multicenter, dose escalation
Nr of patients	15
Population	AmpB intolerent/Azole resistant/Renal impairment

Source: Biosergen

An alternative to Amphotericin B

The study will include patients who have been treated with Amphotericin B but who had to stop treatment because of side effects mainly on their kidneys. Amphotericin B is used as a last resort in the treatment of severe fungal invasive diseases. Approximately 20-40 percent of patients who use Amphotericin B must discontinue their treatment due to adverse effects primarily affecting the kidneys. In patients with mucormycosis, there is a high risk of significant damage to specific organs such as sinuses, eyes, brain, jaw, and lungs, which can lead to life-threatening injuries and disabilities.

The study includes patients who have been previously treated

Financing of the study

Biosergen received 5.5 MSEK via warrants in August 2023. The subscription rate was 96.1 percent. Together with previous assets, the total cash totaled 11.5 MSEK in connection with the latest interim report for the third quarter of 2023.

High subscription rate for its warrant program

For the full year, we expect the loss to amount to 26 MSEK. Now that Biosergen has entered into agreements with Indian Alkem, it is estimated that the company's costs will decrease. According to our estimates, we assume that costs are reduced by 30 percent. The cost level for 2024 is thus estimated to be around 18 MSEK, which is significantly lower than the average of 33 MSEK for the last three years (2021-2023).

Expected reduction in study costs

In view of current cash flow and expected costs for the phase 1b study, we consider that the company needs to raise capital.

Need capital for phase 1b studies

Biosergen – Update Market

Antifungals market update

In late 2022, WHO published a list of priority fungal pathogens, which contributed to increased attention for new antifungal drugs. In 15 years, there has not been any new drugs for fungal diseases. Things are changing, because there are now some new drugs on the market and several candidates in clinical phase.

Fungal drugs are recognized by WHO

Success for Basilea Pharma

Swiss Basilea Pharma (spin-off from Roche) previously focused on cancer drugs but is now in a transformation to antifungals. The company's drug Cresemba has been a success with sales of 445 MUSD worldwide in the period October 2022 to September 2023.

Cresemba is selling well

Cresemba is sold globally in all major regions. Cresemba was approved by the FDA in 2015 for fungal infections such as invasive aspergillosis and mucormycosis. Basilea has a license agreement with Pfizer for Europe and Asia.

Basilea also purchased the rights for fosmanogepix from Amplyx Pharma (a Pfizer company) in November 2023. Basilea plans for phase 3 studies in mid-2024 for the treatment of candidemia, an invasive fungal disease. Basilea has also entered an affair with Gravitas Therapeutics to develop new drugs for fungal diseases.

37 MUSD in upfront for fosmanogepix

Cidara Therapeutics, listed on Nasdaq, has developed Rezzayo (rezafungin) against invasive fungal diseases. It received FDA approval in March 2023 and in the EU (Committee for Medicinal Products for Human Use, CHMP) in December 2023. Cidara has been awarded milestones by Mundipharma, who owns the rights outside of the United States and Japan.

Rezzayo new fungal drug

Scynexis, listed on the Nasdaq, received a marketing authorization for Brexafemme (ibrex-afungerp) in 2021 against vulvovaginal candidiasis. Scynexis has a license agreement with GSK (Glaxo) worth up to $245.5 million. Also, the drug candidate SCY-246 is in a preclinical phase and so far there has been promising results.

Scynexis has a promising candidate in preclinical phase

F2G (private company in UK, Manchester) develops olorofim as a new antifungal drug for invasive aspergillosis. The FDA evaluates olorofim undergoing phase 3 studies. Additional data are required for an FDA approval.

FDA requires more olorofim data

MANGOLD - PIPELINE NOVEL ANTIFUNGIS

Substance	Class	Antifungal spectrum	Company	Phase
Fosmanogepix	Gwt1 Inhibitor	Candida	Basilea Pharma	Phase 3
MAT2203	Polyene	Broad spectrum	Matinas Biopharma	Phase 3
Olorofim	Orotomide	Aspergillus	F2G/Shinogi	Phase 2
SCY-247	Triterpinoid	Mucormycosis	Scynexis	Preklin

Source: Mangold Insight

Biosergen – Update Assumptions

Assumptions for future sales of BSG005

In the United States, 75 000 patients were hospitalized for fungal diseases in 2014. In 2018, 670 000 patients were diagnosed with fungal diseases, of which 20 percent needed hospital treatment according to NCBI, representing approximately 140 000 patients. North America accounted for 41.5 percent of the total pharmaceutical market for antifungals in 2021. It is reasonable to estimate that the number of patients worldwide is 262 500. The exact burden of mucormycosis is not known, as it is not a reportable disease and is rare in developed countries. Mangold has chosen not to make any assumption about the prevalence of mucormycosis. The great potential for BSG005 lies in the treatment of candida and aspergillosis, which we estimate the company will add in future studies.

Potential is found in aspergillosis and candida

Mangold has chosen to base pricing of Cresemba. The price of Cresemba in the United States is 7 400 USD per treatment. Biosergen intends to price BSG005 with a premium based on its safe and effective profile. In our model, we have chosen a price of 7 700 USD per treatment.

Price for Cresemba used

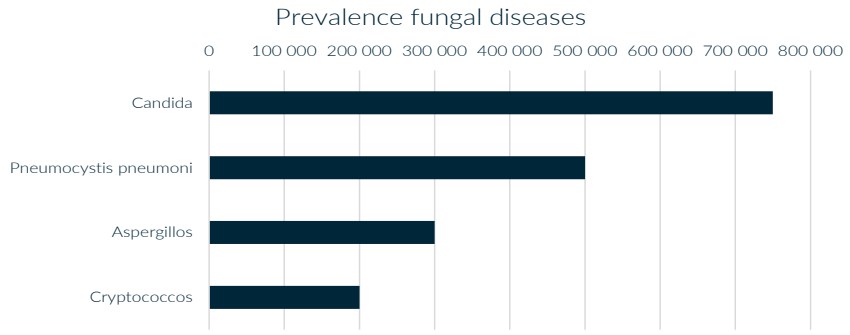
MANGOLD - ASSUMPTIONS	
Prevalence of global candida	750 000
Prevalence of global aspergillos	300 000
Addressable market (25%)	262 500
Penetration	30%
Patients	78 750
Price dollar/treatment	7 700
Revenue (MUSD)	606

Source: Mangold Insight

Base Case

Mangold uses a Base Case where potential market for fungal infections related to candida and aspergillosis is used. Based on prevalence, we estimated number of patients requiring hospital care (addressable market). We have then chosen to assume that BSG005 will take a market share of 30 percent.

Takes a market share of 30%



Source: Market Research Future

Biosergen – Update Valuation

Risk adjusted DCF model

Mangold value Biosergen based on a Sum of the Parts-model. We have assumed the potential of BSG005 discounted in a risk-adjusted DCF model. The risks associated with drug development are managed by risk adjusting the project based on the latest report from the Biotechnology Innovation Organization 2022 (BIO). For infectious diseases, which include invasive fungal diseases, the probability of an approval (LoA) from phase 1b studies is 13.2% and for phase 2 is 22.8%. Mangold has chosen to use 20 percent as LoA. Following positive phase 1b studies in India, the LoA may be adjusted to a higher probability. When the company reaches phase 2, the risk is expected to decrease further. Mangold has chosen not to include milestones in the valuation model. Market launch is expected in 2027.

Previous safe studies indicate a higher LoA

MANGOLD - ANTAGANDEN DCF	
Market launch (year)	2027
Peak Sales Base Case (MUSD)	600
Ramp up (years)	8
Peak Sales (years)	2034
LoA (%)	20.0%
PACME	16%

Source: Mangold Insight

Calculation of EV

To generate an EV (enterprise value) for the BSG005 project, we have chosen recommended discount rates for early projects (Alacrita). We have also applied a small company supplement as the market capitalization is less than 100 MSEK. EV is calculated in dollars and has since been converted into SEK at the exchange rate of 10.20 USD/SEK.

Conservative assumptions

BIOSERGEN - SUM OF THE PARTS	
EV (MSEK)	239
rNPV (MSEK)	167
Fair Value (MSEK)	168
Nr of Shares (M)	50.7
Fair Value (SEK/share)	3.31

Source: Mangold Insight

Biosergen – Update Case

Three Different Cases

Mangold has opted for a case approach based on a rate of return of 20 percent. In our Base Case we assume previously used market approach and peak sales of 600 MUSD for BSG005. It is in line with sales of AmBisome (Amphotericin B). The fair value in the Base Case amounts to 3.30 SEK per share.

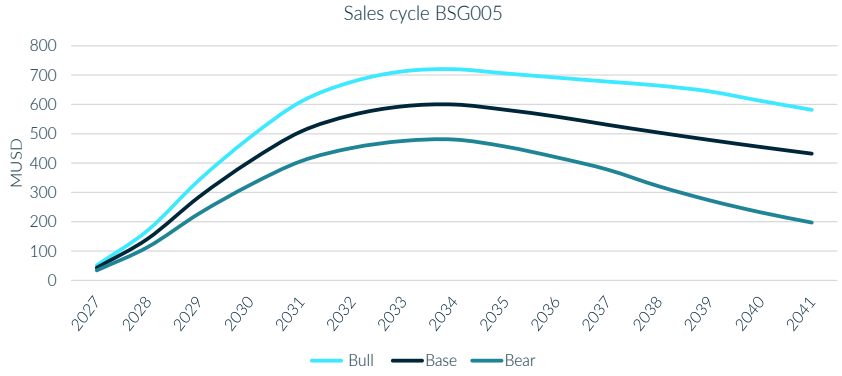
Peaks sales is the highest level a drug can reach in its lifecycle in a year

In a Bull Case, we assume that BSG005 will take a larger share of the market and reach a peak sale of 720 MUSD. Biosergen has indicated that its drug candidate can achieve blockbuster status as it covers a wide range and can become first-line treatment. Our Bull Case scenario leads to a fair value of 4.0 SEK per share.

Presumably able to reach block buster status with sales up to 1 BUSD

In a Bear Case we have assumed a lower market share and sales below AmBisomes (Amphotericin B) levels. Peak sales of 480 MUSD will then be reached. The fair value based on this scenario is 2.8 SEK per share.

Amphotericin B is standard, but does not work for all patients



Source: Mangold Insight

Scenario analysis

To see how the value changes at higher and lower peak sales as well as changing the required rate of return (RRR), we have chosen to conduct a sensitivity analysis. Peak sales in Bull Case increase by 20 percent and decrease by 20 prercent in Bear Case. Biosergen's highest fair value in a Bull Case is 4.7 SEK per share and 2.2 SEK per share in the Bear Case with the highest required rate of return. Target price is 3.0 SEK (3.5) per share. The change from earlier price target is mainly a dollar effect.

Price Target 3.0 SEK per share

BIOSERGEN - SENSITIVITY ANALYSIS

RRR	Bear	Base	Bull
18%	3.0	3.9	4.7
20%	2.6	3.3	4.0
22%	2.2	2.8	3.4

Source: Mangold Insight

Biosergen – Appendix

Previous studies with BSG005

Biosergen conducted phase 1b studies with BSG005 for the treatment of invasive fungal diseases in April 2023. Topline data showed that BSG005 can be used safely in humans. The phase 1b study was carried out in Melbourne, Australia. The aim of the study was to show no undesirable effects on the kidney or liver that Biosergen was able to do. Side effects on the kidney are a major problem for the drug Ambisome (Amphotericin B) used as an infusion to treat invasive fungal diseases. No serious adverse events were reported in the phase 1b study, confirming the toxicological studies conducted with no renal toxicity observed.

BSG005 has been shown to be safe in human tests

Mucormycosis

Mucormycosis is an infection caused by fungi from the group Mucormy-cetes. It is also known as black fungus. This is because it stains the patient's skin black. It is a rare type of fungal infection and not as widespread as candidiasis and aspergillosis. Mucormycosis occurs mainly in soil, leaves, decayed wood and manure. Mucormycosis primarily affects the sinuses, brain and lungs. Symptoms may include facial swelling, headache, nasal congestion, fever and damage to the nose or upper inside of the mouth. Failure to treat Mucormycosis can have serious consequences and may require surgical intervention.

Known as "black fungus"

High Mucormycosis mortality

A review of published mucormycosis cases showed an overall mortality of 54 percent (study conducted in 2018 by the Centers for Disease Control and Prevention). Mortality varied according to underlying patient condition, fungal type, and body part affected (e.g. mortality was 46 percent in sinus infections, 76 percent in lung infections, and 96 percent in disseminated mucormycosis).

More than half died in study with mucormycosis

Problems with fungal diseases in India

In 2021, in connection with covid, attention was drawn to an outbreak of mucormycosis. Covid patients whose immune system has been impaired and who have additional diabetes are particularly vulnerable. Affected Indians were treated with Amphotericin B for up to six weeks. The number of cases is unknown, but data suggest that the prevalence of mucormycosis in India is 70 times higher than global data (NCBI). An Indian minister reported in May 2021 that over 11 700 patients received treatment for mucormycosis.

Mucormycosis became a major problem in India during the pandemic

The Difference between phase 1a and 1b

Phase 1 clinical trials are the first stage of drug development and can be divided into a phase 1a and 1b. The purpose for a phase 1 study is to gather information on a novel therapy's pharmacokinetics (PK), pharmacodynamics, and maximum tolerated dose (MTD). Both are designed to evaluate safety. The phase Ib study designs offer more opportunities to include more complex approaches than the traditional design, as well as dose escalation or dose expansion cohorts to enhance the study's validity and reliability.

A phase 1b study offer more opportunities and enhance the study's validity and reliability

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

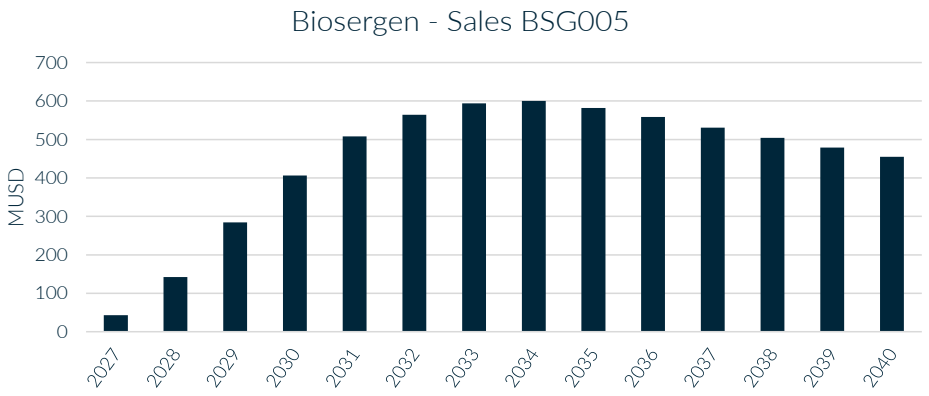
Opportunities

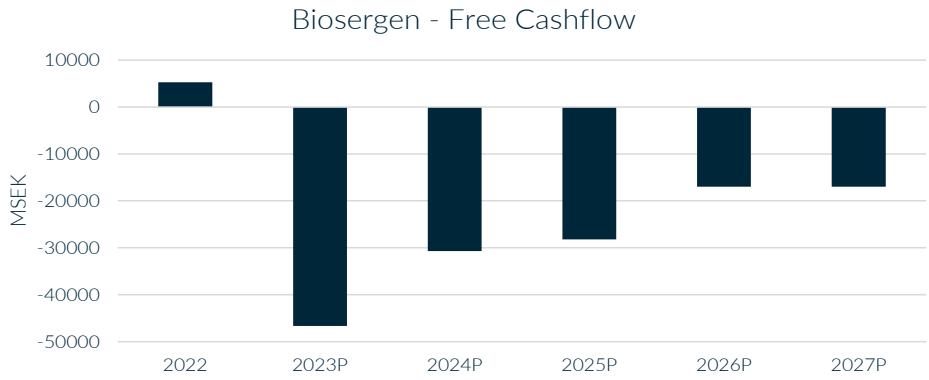
- BSG005 can reach blockbuster status
- Become a first-line treatment option
- Broaden to oral administration form
- Premium positioning

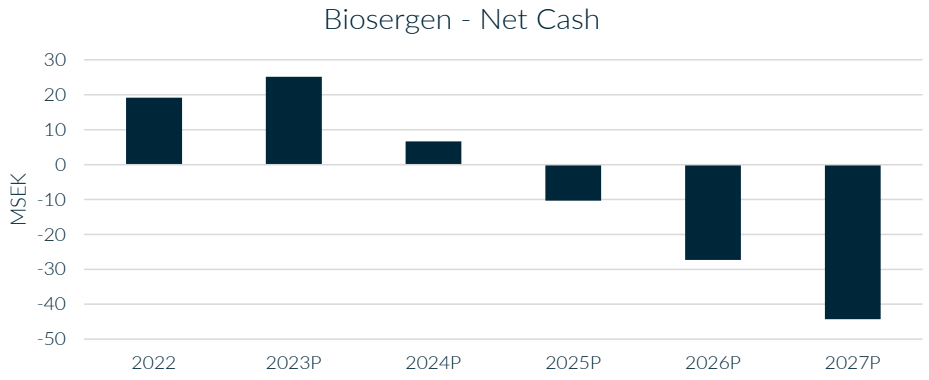
Threats

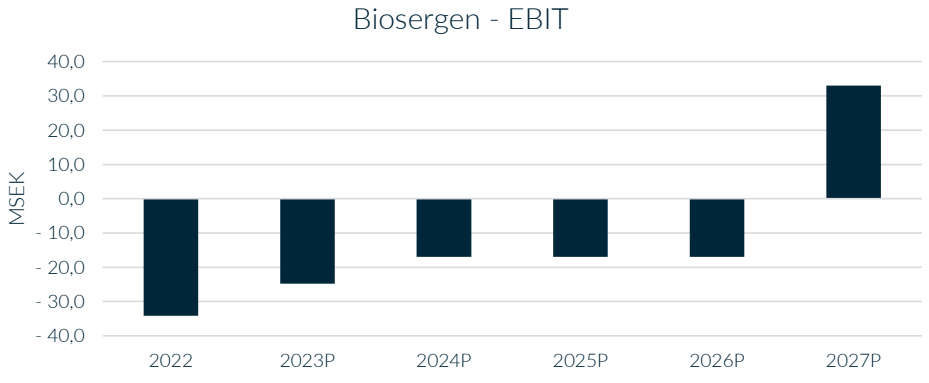
- Competing drugs
- Studies are delayed
- Lack of capital

Biosergen – Appendix









Biosergen – Income statement & balance sheet

Income statement (TSEK)	2021	2022	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	2022	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**
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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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%