Biosergen

Mangold Insight – Commissioned research - 05 april 2023

Reduced risk after positive phase 1-studies

Biosergen, that develops a drug for the treatment of invasive fungal diseases, has successfully completed phase 1 studies in March. Its drug candidate BSG005 has proved to have a satisfactory safety profile, which means that the company now can proceed to phase 2 studies. BSG005 is a strong contender for Amphotericin B that is associated with serious side effects leading to early treatment withdrawal. BSG005 is to become the first drug of choice and to be used before a diagnosis is established.

Clear challenge to its main competitor

Biosergen intends to conduct a phase 2a study to demonstrate the potential that BSG005 possesses. The study includes testing cases with different fungi strains in invasive fungal disease in patients. The study will take around six months, starting in the second quarter of 2023. The aim is to show that BSG005 can be used for treatment in patients who have to be taken off Amphotericin B treatment due to the side effects. Biosergen will after the Phase 2a study proceed to a larger registration based Phase 2b study in indications previously announced.

Interesting time for the stock

Mangold initiated coverage of Biosergen i January 2023. Since then, Biosergen has completed phase 1 studies with a positive outcome and intends to launch a Phase 2a study for which it has funding. Success with this should raise the value of the company considerably and attract pharmaceutical companies that looks for replacements. The fair value for the stock has theirfore increased. Mangold set the price target to SEK 3.50.

Key Data	
Price target (SEK)	3,50
Risk	High
Price (SEK)	1,24
Market value (MSEK)	53
No. of shares (million)	42,4
Free float	28,1 %
Ticker	BIOSGN
Next earnings report	31 May 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%
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%
Tellus Equity Partners	0,4	0,9%

Price performance %	1m	3m	12m
BIOSGN	-0,8	8,0	-73,6
OMXSPI	-2,4	5,1	-19,4

Key ratios	2021	2022	2023E	2024E	2025E
Sales (TSEK)	-	-	-	-	-
EBIT (TSEK)	-34 078	-39 987	-35 080	-35 080	-35 080
Profit before tax (TSEK)	-34 318	-39 878	-34 980	-34 980	-34 980
VPA, dilution (SEK)	-0,81	-0,94	-0,82	-0,82	-0,82
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 Insight update Biosergen and reiterate buy with a price target of SEK 3.50 per share over a 12-month period (2.70). Upside potential exceeds 180 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 side effects found with competing drugs on the market.

Buy Biosergen, price target SEK 3.50 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 Phase 2-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 effective profile.

Kills the fungus and reduces resistance

Safety first

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.

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 great. Mangold use the Base-case which gives a fair value of SEK 224 million. The risk in pharmaceutical-developing companies is very high and the value of the company is entirely dependent on a product.

Large upside in Base-case

Biosergen - Update

Reduced risk after positive phase 1-studies

Biosergen has completed its phase 1 study with BSG005 for the treatment of invasive fungal diseases. Topline data showed that BSG005 can be safely used as a human drug. The Phase 1 study, conducted in Melbourne, Australia, had an important well-defined goal that the company achieved. This was to show no undesirable effects on the kidney or liver. Side effects on the kidney are a big problem for the drug Ambisome (Amphotericin B) used as an infusion to treat invasive fungal diseases. No serious adverse reaction observations were reported in the phase 1 study at all, which is a confirmation of the toxicological studies conducted where no kidney toxicity was observed.

BSG005 has been shown to be safe in Phase 1 studies

No adverse reactions occurred in Phase 1 studies

Time for the next step

Biosergen intends to match Amphotericin B in a phase 2a study. Amphotericin B is used as a last resort in the treatment of severe invasive diseases. This multi-indication study (treatment of several different types of fungal invasive diseases) is expected to start in the second quarter of 2023. Topline data are expected at the beginning of the first quarter of 2024. .

A Phase 2a study starts Q223

The study will include 15 patients. Examples of fungi to be studied include mucormycosis, and aspergillosis. Studies in patients with febrile condition, neutropenia and immunodeficiency diseases who have invasive fungal diseases may later also be included. The purpose of the study is to include mainly patients who have been treated with Amphotericin B but had to stop treatment due to side effects mainly on the kidney.

BSG005 vs Amphotericin B

Can replace Amphotericin B

Since BSG005 has been shown not to affect the liver and kidney, this substance may be the drug used in the treatment of invasive disease with difficult to treat fungal strains. Approximately 20-40 percent of patients who use Amphotericin B must stop their treatment due to side effects mainly affecting the kidney. In patients with mucormycosis there is a high risk of substantial damage to the internal organs, which can lead to life-threatening injuries and disabilities.

A large proportion of patients are unable to take Amphotericin B

Phase 2a study paves the way

If Biosergen succeeds in showing that BSG005 can be used as a drug for pa- tients with invasive fungal diseases who have no treatment options, there are good opportunities to attract capital and proceed in a registration-based phase 2b study with a single-oriented indication. Biosergen has the capital to carry out this phase 2a study but needs funding to carry out the next studies. In august TO 2 can add approximately SEK 38 million in an additional capital injection.

Needs funding for Phase 2b

TO2 in august 2023

Biosergen – Update

Market update

The market for antifungals is expected to increase significantly in the coming years. The global antifungal market is valued at $13.1 billion in 2021 with growth of over 3 percent on average per year over the period 2022 to 2028. Increased research and development are estimated to lead to new drugs on the market. This will lead to increased activity within M&A (mergers and acquisitions).

Activity increased in the field

FDA approval for rezafungin

Cidara Therapeutics developing rezafungin (Rezzayo) have shown positive Phase 3 results in comparison to Caspofungin. Rezafunging has been approved by the FDA for the treatment of candidemia and invasive candida in adults with no treatment options. Rezafungin is expected to become the next generation of echinocandin, a new drug in this field, invasive candida, has not been released since 2006 when anidulafungin (Eraxis) was approved. Rezafungin has been tested against caspofungin which has been on the market since 2001. Rezzayo is expected to be available on the market in the summer 2023. Cidara Theapeutics develops rezafungin together with Melinta Therapeutics. Cidara is an American biotechnology company listed on the Nasdaq stock exchange. 2023 has been a positive year so far. The Cidara stock has risen by more than 70 percent.

Rezafungin has received FDA approval

Cidara stock has risen sharply

Olorofim launched

The UK based company F2G, which develops drugs in the field of rare fungal diseases, has received FDA approval for its olorofim drug to treat an invasive fungal disease. Launch date (PDUFA) is set for June 17, 2023. This launch (NDA, New Drug Application) has been based on the company's Phase 2b study which showed strong data. Launch has been made possible through the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD pathway).

F2G launches olorofim in June

MANGOLD - PIPELINE ANTIFUNGIS NEW MOA

Substance	Class	MoA	Company	Phase
ATI-2307	Arylamidine	Mitochondrial membrane	Appili Therapeutics	Phase 2
Fosmanogepix	Gwt1 Inhibitor	Inhibit Gwt1 protein	Pfizer/Amplyx	Phase 2
MAT2203	Polyene	Polyen/CAmB	Matinas Biopharma	Phase 2
Olorofim	Orotomide	Pyrimidine-inhibitor	F2G	Phase 2b/NDA
Rezafungin	Echinocandin	Echinocandin	Cidara Therapeutics	Phase 3/NDA

Source: Mangold Insight

Biosergen – Update valuation

Increased LoA in DCF

Increased likelihood of approval

To derive a fair value for the stock, Mangold has chosen to assume the potential of BSG005 discounted in a risk-adjusted DCF model. The risks associated with drug development are managed by adjusting the project based on its likelihood of approval (LoA). For infectious diseases, which include invasive fungal diseases, LoA for phase 2 studies is 22.8 percent according to BIO (Biotechnology Innovation Organization). Mangold chose LoA to 20 percent hence a Phase 2a study will be conducted.

LoA raised to 20%

MANGOLD - ASSUMPTIONS DCF	
Market launch (year)	2026
Peak Sales Base case (MUSD)	600
Ramp up (years)	7
Peak Sales (year)	2 033
LoA (%)	20,0
PACME	16%

Source: Mangold Insight

Higher Fair Value

Consideration of full dilution

Mangold value Biosergen based on a Sum of the Parts model. To generate an EV (enterprise value) for the BSG005 project, we have chosen to use the recommended discount rates for early projects (Alacrita). We have also applied a small company supplement since the market capitalization amounts to approximately SEK 50 million, which together results in a discount rate of 20 percent. We use full dilution for shares and the value has been converted into SEK at the exchange rate of USD 10.30/SEK. In a sensitivity analysis, we have developed justifications for different cases (see initial analysis) and compared these with different yield requirements. Fair value in a Base case amounts to SEK 4.12.

Fair value increased

BIOSERGEN - SUM OF THE PARTS	
EV (MSEK)	320
rNPV (MSEK)	224
Expenses	30%
Fair Value (MSEK)	224
No. of shares (Million)	54,5
Fair value (SEK/share)	4,12

Source: Mangold Insight

BIOSERGEN - SENSITIVITY ANALYSIS

	Bear	Base	Bull
18%	3,5	4,9	8,1
20%	3,0	4,1	6,9
22%	2,5	3,5	5,9

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

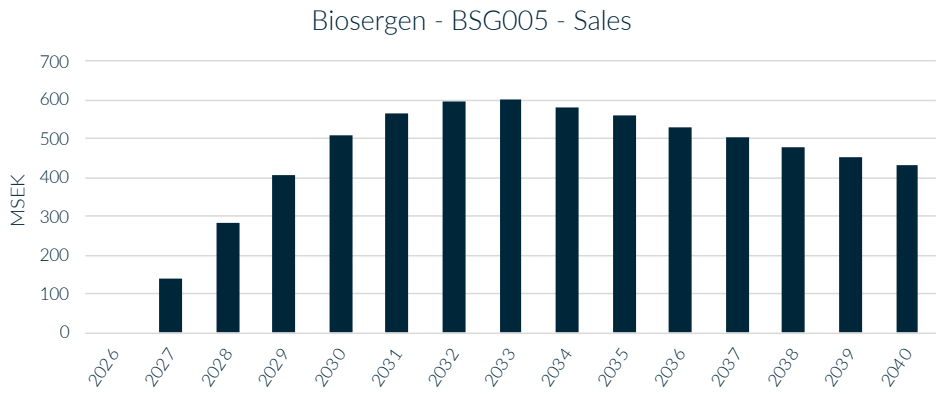
Opportunities

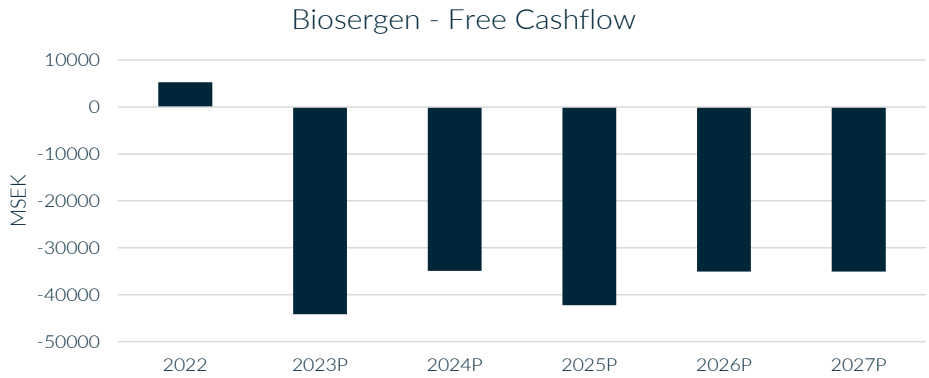
- BSG005 can reach blockbuster status
- Become a first-line treatment option
- Broaden to oral administration form
- Premium positioning

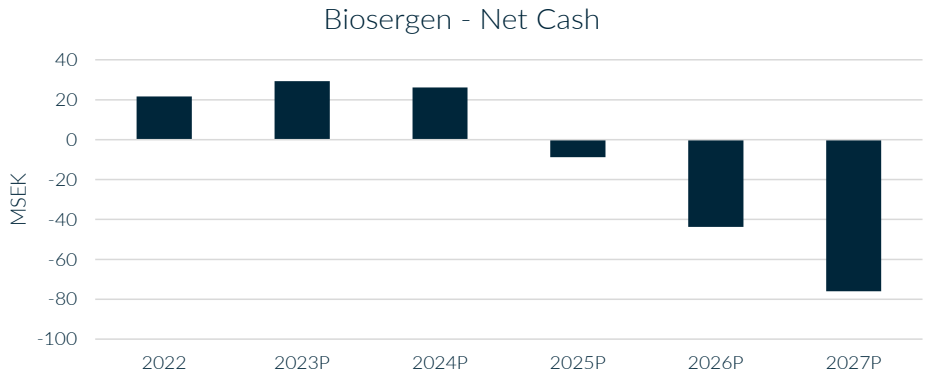
Threats

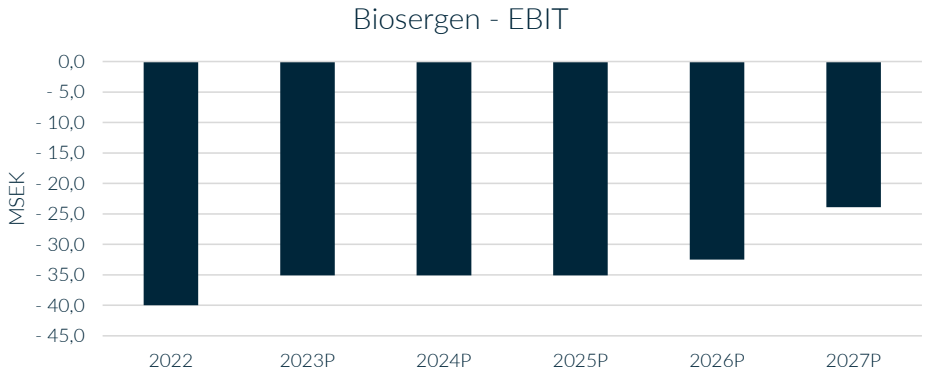
- Competing drugs
- Studies are delayed
- Lack of capital

Biosergen – Appendix









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

Disclaimer

Mangold Fondkommission AB ('Mangold' or 'Mangold Insight') offers financial solutions to companies and private individuals with potential, delivered in a personalised manner with a high level of service and availability. The company currently operates in two segments: i) Investment Banking and ii) Private Banking. Mangold comes under the supervision of Finansinspektionen (FI), Sweden's financial supervisory authority, and conducts business with transferable securities, in accordance with the Securities Market Act (2007:528). Mangold is a member of NASDAQ Stockholm, Spotlight Stock Market and Nordic Growth Market, and a derivative member on NASDAQ Stockholm.

This publication has been compiled by Mangold Insight for information purposes and should not be viewed as advice. Mangold Insight only publishes commissioned research based on and/or containing publicly disclosed information. If undisclosed, price sensitive information is shared with Mangold, publishing of the commissioned research will be halted until the information has been publicly disclosed. The content is based on information from publicly accessible sources that have been deemed reliable. The accuracy and totality of the subject content, as well as any estimates and recommendations provided, can thereby not be guaranteed. Mangold Insight does not provide any advance conclusions and/or judgements in the publication.

Any opinions provided in the publication are those of the analyst at the time of its preparation, and these may change. No assurance is given that future events will be in accordance with opinions conveyed in the publication. Mangold disclaims all liability for direct or indirect damage that may be attributed to this publication. Investments in financial instruments are associated with financial risk. The historical performance of an investment is no guarantee for the future. Mangold thereby disclaims all liability for any loss or damage of any kind attributable to the use of this publication.

This publication may not be reproduced for any purpose other than personal use. The document may not be distributed to physical or legal entities who are citizens of or resident in a country where such distribution is prohibited under applicable laws or other provisions. Mangold's written consent is required in order to distribute all or any part of this publication. Mangold may carry out publications on behalf of, and against payment from, the company highlighted in the analysis, or an issuing institute in conjunction with M&A, new issues or IPOs.

In relation to the execution of this publication, the reader may assume that Mangold receives remuneration from the company. A client/assignment relationship or consulting situation may also exist between the company and another department at Mangold. Mangold has guidelines for managing conflicts of interest, and restrictions on when trading may take place in financial instruments. Analysts at Mangold Insight are not allowed to own or trade any securities issued by a company they are responsible for analysing. The analysts are also not allowed to be members of the client's board of directors, or in any other capacity, be operational within the company.

Mangolds last analysis of Biosergen was on the 24 of January 2023
Mangold's analyst does not own shares in Biosergen.
Mangold does own shares in Biosergen, such as for own stock.
Mangold own shares in Biosergen through assignments, such as a liquidity guarantor.
Mangold has performed services for the company and has received remuneration from the company for these.
Mangold comes under the supervision of Finansinspektionen (FI), Sweden's financial supervisory authority.

Recommendation structure:
Mangold Insight grades its share recommendations over a 12-month period, according to the following structure:
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%