Initiation of coverage

BIOSERGEN AB

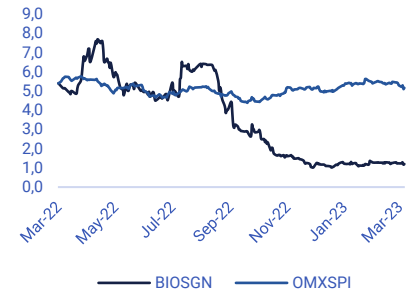
CEO: Peder Andersen
CoB: Torsten Goesch
www.biosergen.net

Bloomberg: BIOSGN:SS
Reuters Eikon: BIOSGN.ST

Stock Exchange List: Nasdaq First North

Last share price: SEK 1.3
Market Cap: SEK 54 million

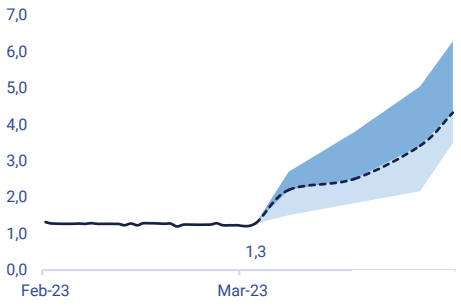
SHARE PRICE DEVELOPMENT



	12M	YTD	3M	1M
Development (%)	-79.4	-69.2	-72.7	-36.7

Source: S&P Capital IQ

VALUATION RANGE



	BEAR	BASE	BULL
Share price (kr)	3.5	4.3	6.1
Potential (%)	169.2	230.8	369.2

Source: S&P Capital IQ and Carlsquare estimates

CARLSQUARE EQUITY RESEARCH

Herman Kuntscher
Equity Analyst

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Make antifungals great again

Carlsquare Equity Research initiates coverage of Biosergen and identifies an infectious disease research company with solid prospects. The company is developing an innovative drug against invasive fungal infections with high mortality rates such as Aspergillosis, Candidiasis and Mucormycosis.
The drug candidate BSG005 is designed to be significantly less toxic to humans than other drugs of the same (polyene) class but still maintain or even improve the fungicidal effect. We estimate sales potential on the US, European and India markets to exceed USD 515 million with a possible early launch in 2025 with NPU-sales. We estimate a risk-adjusted share value of 4.3 SEK.

An enticing combination of innovation and positioning

Biosergen is a Nordic company developing a drug candidate for invasive fungal infections such as Candidiasis and Aspergillosis. BSG005 is a modified polyene, part of an established drug class that includes the market leader AmBisome (2022 sales reported by Gilead: USD 497m). Polyenes are effective fungicides, but their use is hampered by toxicity. Preclinical evidence for BSG005 points to treatment and safety benefits over similar drugs. A well-known mechanism of action and potentially lower toxicity should translate into a higher-than-average probability of success and, possibly, in our view shortened clinical development times. The management team is small but has relevant experience from all phases of clinical development, e.g., Forward Pharma which reached a USD 1.25bn license deal with Biogen. The company has a royalty deal strategy with a possible early launch in the lethal mucormycosis indication.

Strategy plays into current macro trends and pathology

The number of immunocompromised persons at high risk for fungal infections is rising globally (some 3 per cent of the population). For these patients, high mortality rates when infected is a severe concern. The need for more potent and safer antifungals is clear but innovation in the field has been slow. However, several promising drug candidates are now in the pipeline, including Biosergen's BSG005. The plan is to conduct research and to outsource as much as possible in the pursuit of a licensing deal.

Valuation hints at a fruitful opportunity

With the recent rights issue providing over SEK 42 million at a 70 % subscription rate, Biosergen could complete the Phase I trial in healthy volunteers. A positive topline data readout was recently published, with the lead compound BSG005 showing a satisfactory safety profile, no serious adverse events and no impact on kidney and liver parameters. Furthermore, the plasma levels after ascending doses over seven days approached the No Observable Adverse Effect Level (NOAEL) defined in the toxicology studies. The clinical success lays the foundation for continued studies in phase II.

Financial Key Ratios (SEKm)

	2021A	2022E	2023E	2024E	2025E	2026E
Net sales	0.0	0.0	0.0	282.0	580.0	796.9
Gross profit	8.6	3.1	0.0	282.0	580.0	796.9
EBITDA	-34.1	-40.5	-56.2	225.0	521.7	737.3
EBIT	-34.1	-40.5	-56.2	225.0	521.7	737.3
EBT	-34.4	-40.4	-56.5	225.0	521.7	737.9
EPS	-0.97	-1.00	-1.09	2.20	5.12	7.24
Growth. revenue	NaN	NaN	NaN	NaN	106%	37%
Gross margin	NM	NM	NaN	100.0%	100.0%	100.0%
EBITDA margin	NM	NM	NaN	79.8%	90.0%	92.5%
EBIT-margin	NM	NM	NaN	79.8%	90.0%	92.5%
EV/Sales	NaN	NaN	NaN	0.1x	0.1x	0.0x
EV/EBITDA	NM	NM	NM	0.2x	0.1x	0.1x
EV/EBIT	NM	NM	NM	0.2x	0.1x	0.1x

Source: Company information and Carlsquare estimates

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Investment Case

Carlsquare Equity Research initiates coverage of Biosergen and identifies an antifungal research company with potential. The Company is developing an innovative drug candidate against invasive fungal diseases such as aspergillosis and candidiasis, both of which are associated with high mortality. With a limited competitive landscape and a clear niche in its molecular class, we believe BSG005 can strategically position itself in the rapidly growing fungal infections market. We expect peak sales in all relevant markets to reach USD 515 million. The intention to license the candidate allows Biosergen to avoid significant costs and receive valuable milestone payments during development. We estimate that BSG005 has a LOA of 18.3 %, with a launch expected in 2025. The market is characterized by a strong medical need for new treatment options in Europe, India, and the US. We estimate a risk-adjusted fair share value of approximately SEK 4.3.

Macro and research combine

Improved version of a well-documented molecule

Biosergen's drug candidate, BSG005, belongs to the same molecular class as one of the most effective antifungal drugs on the market, amphotericin B. The fungicidal effects of the drug have been confirmed in numerous clinical programs over the last 50 years. The extensive research for this molecular class has generated data that Biosergen has been able to use to modify an improved version of current treatment options. Furthermore, BSG005 has undergone over two decades of internal development and modifications to produce the current version of the candidate. The version established in 2008 is defined as a polyene macrolide antifungal molecule and belongs to the Polyene class of molecules. In total, efficacy for over 200 fungal strains has been confirmed in *in vitro* studies.

BSG005 is expected to have a significantly better safety profile than current treatments in the same molecular class, while preclinical studies also have indicated that better efficacy can potentially be achieved in certain fungal pathogens compared to the candidate's closest competitors.

Prevalence of fungal infections under rapid growth

The prevalence of the pathogens relevant to Biosergen is shown in the table below. The market for the treatment of invasive fungal infections is expected to grow at around 6.5% per annum, driven by, among other things, a growing problem of multi-resistance against current treatment options. There are only three classes of molecules with many drug derivatives based on them, which constitute today's standard treatment. Due to the few new options, drug resistance has become such a major concern that the WHO has declared it a global health threat. BSG005 can potentially drive the use of the least used class of molecules, polyenes, and contribute to the reduction of resistance.

Assumptions about peak sales BSG005

2034E	US	EU, UK, JP	India	Total
Prevalence, Invasive Candidiasis	31 094	60 588	130 426	222 108
Prevalence, Invasive Aspergillosis	15 716	30 729	65 919	112 364
Prevalence, Invasive Cryptoccocis	5 166	10 102	21 669	36 937
Prevalence, Invasive Mucormycosis	3 315	6 838	14 720	24 873
Number of patients	*55 291*	*108 257*	*232 734*	*396 282*
BSG005 marketshare	20%	12%	13%	13%
BSG005-patients	10 850	12 890	29 527	53 267
Sales, MUSD	**222.0**	**93.0**	**200.2**	**515.2**

Source: Carlsquare estimates

Outsourcing and deal making integral

The Company intends to work with CRO's and outsource development, ultimately partnering with a bigger pharmaceutical company for commercialization. This means that the company can receive "biobucks" in the form of vital milestones that in turn can fuel the development of BSG005. Naturally, this also entails risk as dealmaking opportunities can be impacted by many exogenous factors, potentially limiting future licensing income.

Limited competition in the field

In the last ten years, only one new drug has reached the market in invasive fungal infections. Our research indicates that a handful of new candidates could reach market approval in the next 2-8 years. Most of them belong to the two molecule classes echinocandines and azoles - where the development of resistance is most pronounced. At the same time, there is little investment from one of the major pharmaceutical companies in this area and most of the projects in development belong to smaller up-and-coming drug companies. As a result, BSG005, if successfully studied and launched, is well-positioned to gain market share in its chosen field rapidly.

Comparatively Short Way to Market

Developments in infectious diseases, such as invasive fungal infections, where the disease progression is aggressive and relatively short, often generate faster studies. This means that smaller studies, such as a Phase I study, can at best present top-line data only six months after the first patient in the study started treatment. We believe it is critically important that the study design for Phase II and III programs be designed in a way that enables the candidate to achieve superiority in efficacy as well as a good safety profile. This means that these programs will likely require tougher selection at patient enrollment - including the right pathogen, resistance, and the right choice of treatment to compare BSG005 against (Phase III). Overall, BSG005 could reach the market as early as 2025, just two years from today's date, albeit in the form of non-prescription usage, or NPU-sales for short, for the Mucormycosis indication in particular. Given the high sales potential, this creates, in our view, an exciting investment opportunity.

Expected timeline for clinical development with BSG005

	Discovery	Preclinical	GMP/Tox	Phase I	Phase IIa	Phase IIb	Phase III	NDA
BSG005				→	H2 2024	H1 2025	H2 2026	2025-2027
BSG005 *Nano*		→	*2023*					
BSG005 *Oral*		→	*2023*					

Source: Carlsquare Equity Research

Forecasts and Valuation

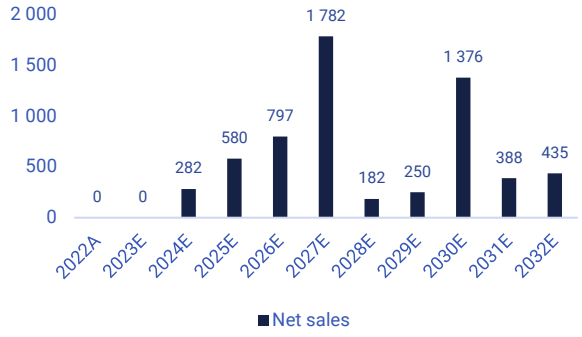
Conservative assumptions indicate sales over USD 515 million

Biosergen's drug candidate, regardless of formulation, may change the standard of care for at least four invasive pathogens. If BSG005 shows a favorable safety profile against competitive polyenes, there is a good chance that it could replace AmBisome. Should it also show superiority in terms of efficacy, there is also a great upside in our projections regarding sales potential. Over time, there is a decent chance to include other fungal pathogens, given the broad spectrum of action BSG005 has on most pathogens of relevant fungal infections. We expect pricing a touch above current premium-priced candidates on the market. With orphan drug designation for invasive Aspergillosis by the FDA, there may be a more significant upside in terms of pricing power.

Competition is currently mostly limited to candidates in other molecular classes as compared to BSG005. That said, invasive fungal infections are challenging from a diagnostic and treatment perspective, making sales more challenging than in many other disease areas.

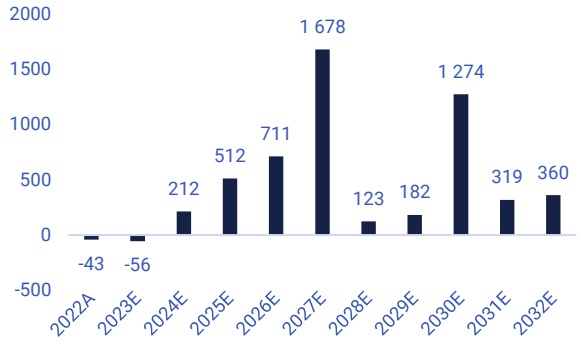
Overall, our assumption includes invasive candidiasis, aspergillosis, mucormycosis and cryptococcosis with peak sales potential at approximately USD 515 million in major markets globally. Furthermore, there is further potential for significantly greater sales potential if BSG005 shows data indicating it for more pathogens, such as pneumocystis.

Net revenues (SEKm) (Nominal values)



Sources: Company Information and Carlsquare estimates.

Cash flow from operations (SEKm) (Nominal values)



Sources: Company Information and Carlsquare estimates.

Shares Trading below base case

We estimate a fair share value of SEK 4.3 in the base case after financing activities. This rises to SEK 6.1 in an optimistic bull case and goes down to SEK 3.5 in a pessimistic bear case.

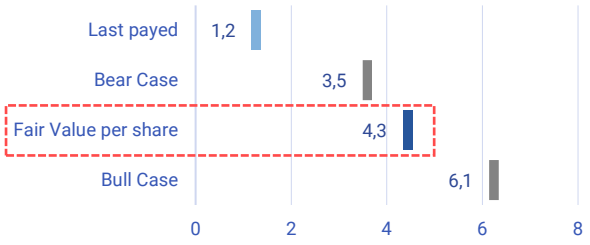
The shares are currently trading at around SEK 1.3. Today's price clearly discounts the lower probability of BSG005 achieving approval, the potential efficacy as well as the financial stability of the company. Given the candidate's proven efficacy and solid data from multiple preclinical activities, we believe a LOA of 18.3 % is reasonable.

Overview, Sum-of-the-parts-valuation, Base case

Project	Indication	LOA, %	Peak Sales, USDm	Launch	rNPV, SEKm
BSG005	4 pathogens fungal infections	18.3%	515	2025	325
Cash (22'Q4E)					15
Fair Value					**340**
Number of shares					42.2
Per share					8.1
Discount attributable to financing					42%
Fair value per share					**4.3**

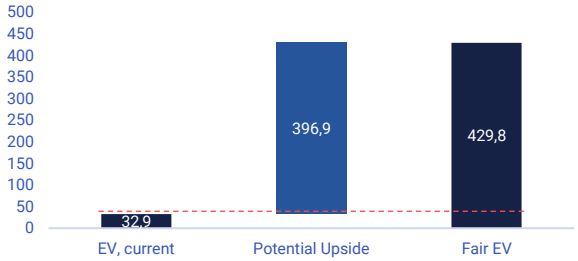
Source: Carlsquare Equity Research

Fair value within a range, SEK



Source: Carlsquare estimates

Visualization of enterprise value



Source: Carlsquare estimates

Risks and Challenges

Early Phase

BSG005 is still in the early stages of development. Clinical development in humans is a big difference compared to preclinical data. Given the mechanism of action of the drug candidate, the safety profile is unlikely to limit further development after the Phase I study. However, when BSG005 enters more extensive Phase II and III clinical programs where efficacy in patients is required, there are always risks.

Rights issues and potential licensing deal

Biosergen had a cash position of SEK 5.7m by June 30. The board decided on a rights issue in early September that would bring in SEK 60.2 million if fully subscribed. The issue was covered by approximately 70 % through both subscription commitments and underwriters. Östersjöstiftelsen represented 33 % of the issue through subscription undertakings. Guarantee commitments further constituted about 37 % or SEK 22 million. The large owner Rosetta Capital did not pledge to commit any money although the management group did.

The subscription period ended on September 29 with the outcome that a total of approximately 2.8 million units had been subscribed. This in turn meant an influx of about SEK 42.2 million before issue costs. Around SEK 7.8 million of this constituted an offset to debt. Furthermore, predicated on a full exercise of the series TO2 warrants, the company will be provided an additional SEK 37.9 million during Q3 in 2023. The issue resulted in an increase in shares by just above 14 million, with the TO2 warrants granting at maximum 8.4 million more, entailing a dilution of approximately 33.3 % for existing shareholders should TO2 be exercised.

We expect that a substantial amount of capital will need to be raised until the launch of BSG005. However, depending on the specifics of a potential licensing deal, the amount of capital and sequential dilution is uncertain.

Company description

Biosergen is an early-stage biopharmaceutical and development company developing a novel candidate for the treatment of systemic fungal infections. The research behind it builds on nearly two decades of development and modification to reach the current version of the drug candidate. In 2021, the Company listed its shares on Nasdaq First North and raised SEK 50 million before transaction costs to initiate the first clinical trials. Extensive preclinical studies combined with well-documented data on similar molecules have generated much evidence for the candidate's use in several fungal pathogens. The Board and operational management have extensive experience in drug development, regulatory processes, and commercial activities. The Company's shareholders are dominated by reputable foundations and investment companies and the Company's CEO.

Introduction to Biosergen

Norwegian innovation behind new antifungal-treatment

Biosergen is a Nordic biopharmaceutical company developing treatments for severe fungal infections, also known as invasive fungal infections. The Company has one drug candidate in development with three different formulations of the same compound. The oldest formulation is administered intravenously and is in clinical development. The current corporate structure was founded in 2019 and has historically attracted over NOK 40 million in various forms of grants that have contributed to extensive preclinical documentation on the BSG005 drug candidate.

The strategy is to pursue full clinical development of the lead candidate BSG005. The company intends to enter a partnership with a bigger company in order to commercialize the product and make it available globally. Given the high severity and lethality of the mucormycosis indication, NPU-sales are possible in India, where the fungus has been an increasing problem.

Biosergens pipeline

Project	Modality	Target	Molecular class	Pathogens	Dev. Phase
BSG005	Fungicidal	Ergosterol	Polyenes	4 pathogens	Phase I
BSG005 Nano	Fungicidal	Ergosterol	Polyenes	4 pathogens	Discovery
BSG005 Oral	Fungicidal	Ergosterol	Polyenes	4 pathogens	Discovery

Source: Company information

BSG005 belongs to the same molecular class as one of the most effective antifungal drugs on the market, amphotericin B. The fungicidal effects of the drug candidate have been confirmed in numerous clinical programs over the last 50 years. The extensive research for this molecular class has generated data that Biosergen has been able to use to modify an improved version of current treatment options. Furthermore, BSG005 has undergone over two decades of internal development and modification to lead to the current version of the drug candidate. A version established in 2008 is defined as a polyene macrolide antifungal molecule and belongs to the Polyenes class of molecules. Efficacy on over 200 fungal strains has been confirmed in *in vitro* studies.

The patent rights are relatively extensive and cover all relevant markets in North America, Europe, Japan, and Asia. The majority of the patents extend to mid-2028. A number of events could strengthen the drug candidate's protection, including the confirmed orphan drug status in a particular fungal pathogen in the US, giving the Company extended market exclusivity. The different formulations of the same compound could extend the life cycle.

Management team

Peder M. Anderson has been CEO since 2017. He is a Doctor of Medicine from Copenhagen-Hagen University. Peder was previously CEO of Forward Pharma, where he was involved in listing the Company on NY. Nasdaq, among other things. Peder is the fifth-largest shareholder (June, 2022), with 1.2 million shares and 56,500 options.

Chief Operation Officer is **Tine Kold Olesen.** Tine holds a PhD in Medicine & Research and a Master's degree in Pharmaceutical Research. She has extensive experience in drug development, both in preclinical and clinical development. During her 19 years at Ferring Pharmaceuticals, she has taken candidates through clinical to market approval - which is relevant given Biosergen's strategy.

Niels Laursen is Chief Financial Officer. He holds an MBA from Copenhagen University. Niels has broad experience from leading roles in smaller pharmaceutical companies. Amongst others as CFO at both Oncology Venture and Medical Prognosis Institute. Niels holds ownership of 34,285 shares, 20,000 options and 8,571 warrants.

Source: Company information

Board members

Chairman **Torsten Goesch** has been chairman of the Board since 2015. He holds an MD and a PhD from the University of Dusseldorf. Dr. Goesch is a partner and director of Biosergen's next largest shareholder (31.5%), Rosetta Capital Limited. Torsten has extensive experience in senior positions at both Biogen and Merck KgaA. In addition to his responsibilities as SO of Biosergen, he holds board positions in, among others, Modus AB, Karolinska Invest AB, and Eyesense GmbH.

Dr. **Lena Degling Wikingsson.** Lena holds both a Ph.D. and a Master of Science from Uppsala University. She is currently CEO of Dilafor AB and a board member of Alzinova. Lena does not own any shares in Biosergen at the time of writing.

Achim Kaufhold has a background, including roles as CMO at Basilea Pharmaceutica in Switzerland. Dr. Kaufhold has also been a board member of VAXIMM GmbH, CEO of Affitech, Pharmexa and CMO of Berna Biotech. He is also the CMO of Hansa Biopharma AB. As of today's date, Achim does not own any shares or options in the Company.

Marianne Kock holds a Master's degree in Pharmacy from the University of Copenhagen and an Executive MBA in Business Administration (MBA) from Copenhagen Business School. Marianne Kock is currently General Manager at Ferring Pharmaceuticals A/S IPC Development Unit in Copenhagen. In addition, she is a board member of Asarina Pharma AB (publ). Today, Marianne does not own any shares or options in the Company.

Henrik Moltke co-founded NeuroSearch and served as the Company's Chief Financial Officer. Since 2006, Henrik Moltke has held senior management and board positions at several small and medium-sized biotechnology companies, including CFO at Oncology Venture A/S (now Allarity Therapeutics A/S), Scandinavian Micro Biodevices Aps (now Zoetis Denmark Aps) and as CFO at Zoetis Denmark ApS. Henrik owns 17, 140 shares.

Hanne Mette Dyrlie Kristensen holds a Master in Technology Management (MTM) from the Norwegian University of Science and Technology. Hanne is also the CEO of the Life Science Cluster and founder of Oslo Life Science Advisors AS. In addition, she is a board member of Regionale Forskningsfond, RFF Viken and Oslo Cancer Cluster Incubator.

Mattias Klintemar previous experience includes Hexaformer Produktion AB and ABG Sundal Collier AB. Mattias Klintemar has also been Chairman of Dilafor AB and SealFX AB and a Board member of Axelar AB, Phoniro AB, Oatly AB, and ASSA ABLOY Global Solutions AB. Mr. Klintemar currently works as Investment Director at the Baltic Sea Foundation (43.3% ownership).

Source: Company information

Management

Peder M. Andersen previously served as the CEO of Forward Pharma between 2012 and 2017. Forward Pharma developed a proprietary formulation FP187 of immune modulator DMF which is the active ingredient in Biogen's Multiple Sclerosis drug Tecfidera. In February 2017, FP187, a Phase III asset, was licensed to Biogen for a non-refundable cash payment of USD 1.25bn in conjunction with a patent dispute between the two companies. The dispute has later been ruled in Biogen's favor.

We believe that, e.g., the Forward Pharma years demonstrate that the CEO has relevant experience of leading value-creating clinical and business development activities. Also, the COO has a strong background in preclinical and clinical development.

We consider it a good signal that the CEO, Peder, is the Company's fifth-largest shareholder with a 4.3 percent stake. However, the other members of the management only have relatively small holdings.

Experienced board

Biosergen has a relatively large board of directors compared to the Company's market value. Torsten Goesch is Chairman of the Board and represents the Company's second-largest shareholder, Rosetta Capital. All of them accepted their roles in 2021.

Overall, we believe that the relevant expertise and network are present in the current board composition. It is positive to see broad experience throughout the drug development lifecycle - from project development, to clinical development, and commercialization. The Board has some connections to other biotech companies in the Nordic region, such as Modus AB, Asarina Pharma, and Hansa Biopharma. There are also clear connections with Karolinska Development (5th largest shareholder).

Given that Mattias Klintemar and Torsten represent the two largest owners, the percentage of insiders on the Board is high. However, among the other members of the board, only Henrik Moltke owns any shares which is disappointing.

Ownership

The two largest shareholders in Biosergen have joint ownership of approximately 65 percent of the capital and votes. This can be seen as both a strength and as a risk. The positive aspect of the structure is that the two owners are well-capitalized and can support the Company in case of issuance needs. On the other hand, concentrated ownership means that decision-making is mainly in their hands. As mentioned earlier, the ownership of shares and options by the Company's management, in particular by the CEO, is a strength. We also note that listed Karolinska Development is among the Company's largest shareholders.

The flipside is the low free float, which limits the daily liquidity of the Company's stock.

Top ten owners

Owner	Share of Capital	Voting rights	Verification date
Östersjöstiftelsen	44.3%	44.3%	2022-12-28
Rosetta Capital	21.1%	21.1%	2022-12-28
Stiftelsen Sintef	6.7%	6.7%	2022-12-28
Tuvedalen Ltd	4.4%	4.4%	2022-12-28
Peder M. Andersen	4.3%	4.3%	2022-06-28
Karolinska Development	2.1%	2.1%	2022-12-28
Avanza Pension	1.4%	1.4%	2022-12-28
Formue Nord A/S	1.4%	1.4%	2022-12-28
Johan Thorell	1.0%	1.0%	2022-12-28
Tellus Equity Partners AB	0.9%	0.9%	2022-12-28

Source: Company information

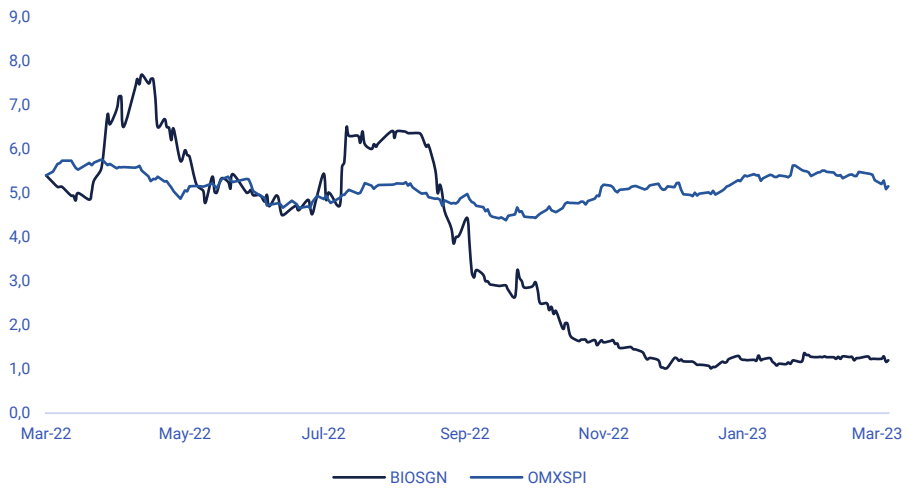
Weak price development in anticipation of Phase I read-outs

Biosergen was listed on First North on June 24, 2021, where five million new shares were issued at SEK 10 per share, corresponding to a valuation of approximately SEK 280 million.

Since then, the stock has been volatile and choppy under a slight downward trend. During the first month, the stock traded relatively unchanged after falling by 20 percent on the first day of trading. The stock then rose sharply for a short time in August 2021 and reached an ATH of SEK 17.5, but it fell back just as quickly to around SEK 8-9. The Company received orphan drug designation for its drug candidate BSG005 from the FDA while also getting its Phase I protocol approved by Australian authorities.

The share price decreased by over 80 % during 2022. The share issue and some delay in the start of the Phase I clinical trial in Australia are possible reasons for the weak share price performance. More recently however, the drastic drop in share price is probably mostly due to the share issue. We view it as a negative sign that the issue was primarily subscribed to by the underwriters, while some of the largest owners do not seem to have participated. At the same time, the biotech sector has also fallen relatively sharply over the past year. Year-to-date the share is up over 20 %, ramping up towards the positive topline data readout.

Share price development



Source: S&P Capital IQ and Carlsquare

Indications

Invasive fungal infections with life-threatening conditions

There are hundreds of thousands of different species of fungi, about a hundred of which can infect humans, but a limited number are lethal. According to a compilation by the Journal of Fungi (JOF), the prevalence exceeds 1 billion globally, where any variant of fungal infection has been identified. These are distributed among different fungal strains that are more or less severe for the infected person. The collective name for the most severe infections is invasive (systemic). Overall, it is estimated that around 1.5 million people die from fungal infections annually (Bongomin et al. Journal of Fungi, October 2017). Particularly affected are developing countries in terms of incidence and overall prevalence. Most all-serious invasive fungal infections belong to five specific fungal pathogens: Candida, Aspergillus, Cryptococcus, Pneumocystis and Mucormycosis. All of which Biosergen's drug candidate BSG005 is considered to be effective against.

Candidiasis

Systemic Candida infections settle in the bloodstream and larger organs, particularly in patients with weaker immune systems, including those with diabetes or HIV. According to the CDC, the incidence (rate of new infections) of invasive candidiasis is approximately 9 per 100,000 people or about 25,000 in the US. In-hospital all-cause mortality is estimated at about 25 per cent.

Aspergillus

Aspergillus causes aspergillosis, which also affects people with weak immune systems. These fungi also cause allergic reactions. Types of aspergilloses include allergic bronchopulmonary aspergillosis and invasive aspergillosis. Nearly 15,000 aspergillosis-associated hospitalizations occurred in the United States in 2014, at an estimated cost of $1.2 billion Among immunocompromised patients who become infected, the mortality rate is unfortunately high. The incidence rate for invasive aspergillus is around 4.5 people per 100,000.

Cryptococcus

Cryptococcus is rare in healthy people but common in HIV infection and AIDS patients. For these people, it can cause meningitis. JOF estimates that approximately 200,000 AIDS patients develop life-threatening Cryptococcosis each year while the overall incidence rate globally is around 1.5 persons per 100,000. The mortality rate associated with this fungal pathogen is estimated at 20-70%.

Pneumocystis pneumonia

Pneumocystis is often the source of opportunistic lung infections (affecting people with compromised immune systems). It is often seen in patients suffering from HIV infection and AIDS and in patients using immunosuppressive (patients with a weak immune system) drugs and people with cancer, autoimmune or inflammatory conditions, or chronic diseases. The incidence rate of Pneumocystis pneumonia is estimated at 3.3 persons per 100,000. The mortality rate is approximately 20-80%.

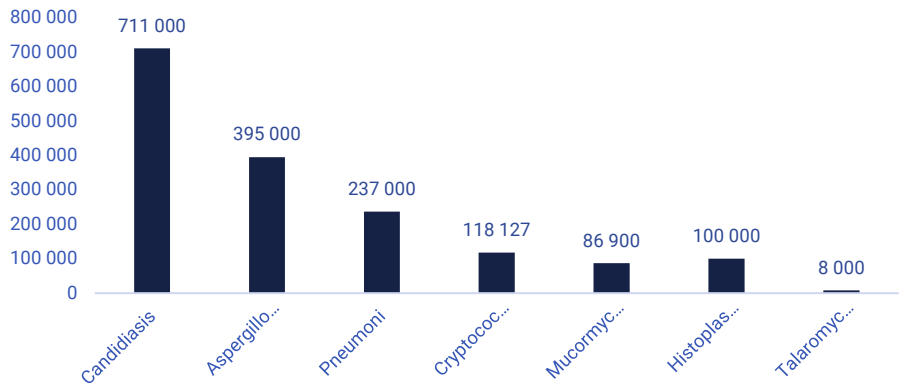
Mucormycosis

Mucormycosis, or as it is also called; “Black Fungus”, is a severe fungal infection that is more likely in immunocompromised people. The infection is chiefly associated with nose, sinuses, and eyes with a plethora of initial symptoms including, but not limited to, a runny nose or a headache varying with the part of the body catching the infection. Although estimated to be quite rare with less than 100 000 cases worldwide per year the true incidence statistic is unknown as diagnosing it correctly is hard. In connection to a Covid-19 outbreak in India there was an outbreak of Mucormycosis, inflating the local incidence rate by an estimate 70 times

the normal number. Mortality is highly dependent on which part of the body catches the infection but is widely estimated around 54 % overall.

The figure below illustrates the annual incidence of the seven most common invasive fungal infections.

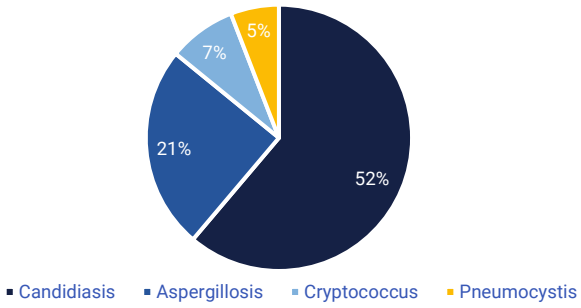
The annual incidence of invasive fungal infection, globally



Source: Market Research, CDC

According to Market Research, it is estimated that about 52% of the sales of antifungals are attributed to the Candidiasis pathogen. The chart below illustrates the distribution between the four different primary fungal pathogens in terms of sales.

Sales by the four most common fungal pathogens



Source: Market Research, JOF

Great medical need for new treatments

The points below explain the common denominators between the five invasive fungal pathogens mentioned.

- In most cases of the above-mentioned fungal pathogens, the patient has a compromised immune system for various reasons. This may be due to chronic conditions and/or local infections or other viral infections.
- Regardless of the fungal pathogen, the population's mortality rate is high. The mortality rate varies between 20-95%.
- In severe infection and undefined pathogen, the patient often dies within 5-14 days. This means treatment must be started early for all of the above referenced infections.

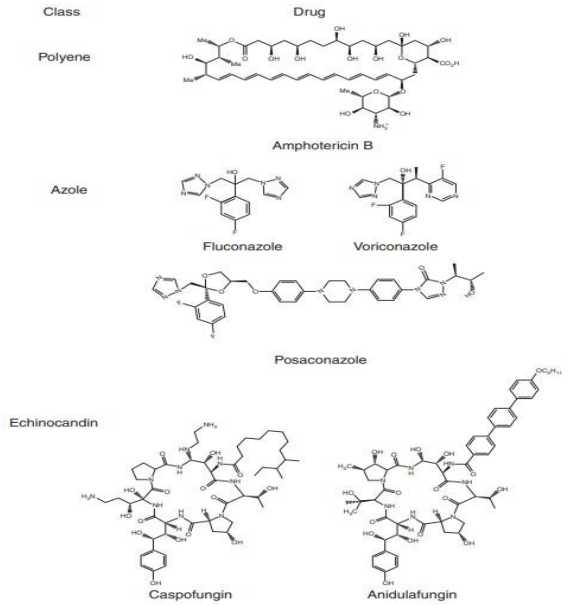
One challenge that makes serious fungal infections challenging to treat is the ineffective and limited diagnosis of the actual fungal pathogen. Given the severity

of the progression of systemic fungal infections, physicians rarely have the time to use advanced diagnostics to identify the fungal pathogen the patient is suffering from. The consequences include that the patient may be treated blindly or without any medication at all, something that in turn can contribute to the problem of mycotic resistance.

Four classes of molecules make up the current treatments

The acute nature of the condition means that patients who are treated often get treated for a short time, between 1-5 days. The diagnostic challenges combined with a short treatment cycle may be two reasons why few new treatment options are available. In total, only four molecular classes are used clinically in antimicrobials. The four classes of molecules currently used to treat invasive fungal infection are Polyenes, Azoles, Echinocandins and Allylamines/Pyrimidines.

The Four most common classes of molecules

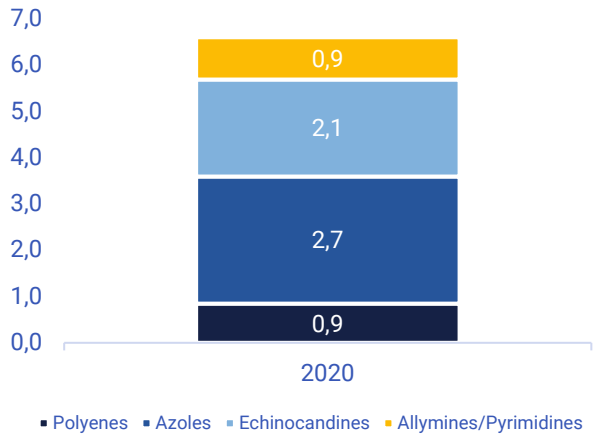


Source: Market Research, JOF

As shown in the picture above, there are more derivatives based on the three most common different molecular classes, which make up a number of medicines - both original and generic alternatives.

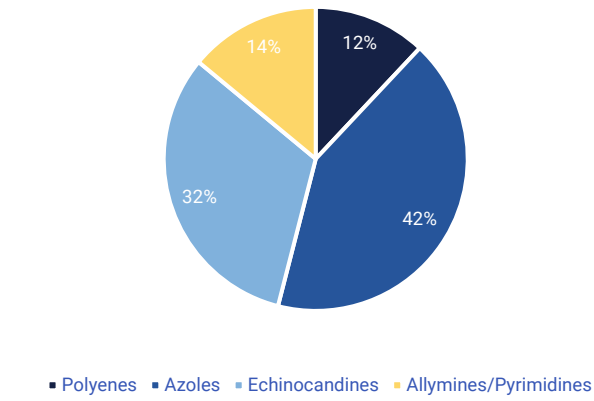
Illustrated below is the total market for treatments of invasive fungal infections, which, according to Market Research, amounted to around USD 6.5 billion in 2021. Fungal infections are more prevalent in developing countries in terms of overall prevalence. At the same time, sales of drugs related to treatment are dominated by Europe and the US, which together account for more than 70% of the total market.

Market: Invasive fungal infections, global (billion USD)



Source: Market Research, JOF, WHO, Carlsquare Equity Research

Market: Invasive fungal infections per molecule class



Source: Market Research, JOF, WHO, Carlsquare Equity Research

As can be seen, drug candidates from the azole and Echinocandin molecular classes account for almost 75% of the current market.

Azoles

The first Azole derivatives were discovered in the late 1960s. They inhibit the synthesis of crucial lipid components in the fungal cell wall. The azoles are fungistatic with low toxicity. Well-known drugs in this class include Fluconazole, Ketoconazole, Miconazole and Voriconazole.

Echinocandins

Echinocandin class drugs inhibit the synthesis of a fungal antigen in the fungal cell wall called ß-glucan. They are the newest class of antifungal drugs, having been discovered in the 1970s. The echinocandins are fungistatic with activity against several fungal pathogens, particularly Candidiasis species. Like the azoles, the side effect profile is favorable. However, they have poor bioavailability and are administered intravenously. Well-known echinocandins include Caspofungin and Micafungin.

Polyenes

Polyenes were already discovered in the early 1950s. By forming channels in the fungal cell wall, they allow leakage into the cell, leading to cell death. Amphotericin B is the best known of the polyenes. Other drugs in this class include candicidin and nystatin. New formulations of amphotericin B, such as the liposomal formulation Ambisome, aim to achieve lower toxicity with at least the same effect as the parent compound.

Allylamines and Pyrimidines

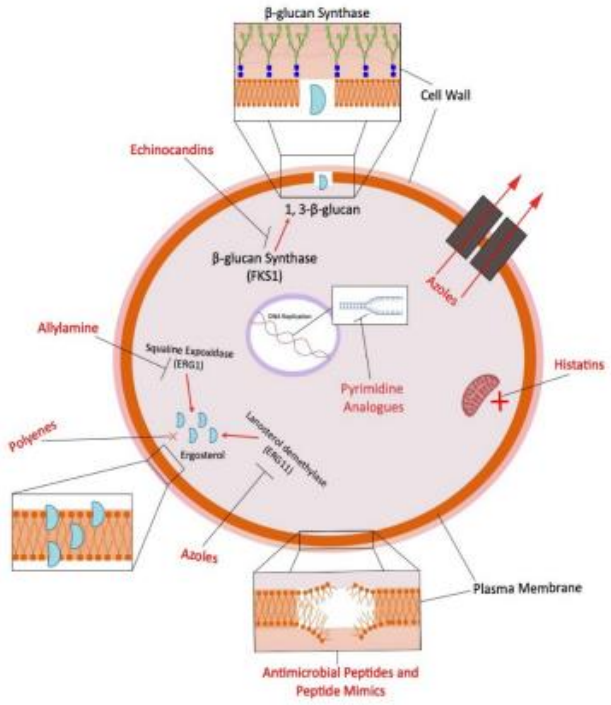
Allylamines act by inhibiting an enzyme required to develop the fungal cell wall. Like the echinocandins, they were discovered in the 1970s. Pyrimidines act by interfering with the protein synthesis of the fungus. They were introduced as antifungal agents in the late 1950s.

Based on the same mechanism of action

Today's antifungal drugs in medical treatment have a mechanism of action targeting the fungal cell wall. In simple terms, the treatments aim to affect the fungal cells and their transplantation directly. By directly targeting the fungal cell and its cell wall, research suggests that few side effects can be achieved - this is thanks to the differences inherent to human cells compared to fungal cells.

Biosergen's drug candidate, BSG005, belongs to the class of polyenes. The molecular class is clearly distinguished as being the most fungicidal against several fungal strains. At the same time, it is considered to have limited resistance development despite its early origin. The serious side effects have limited the use of drugs in the class, despite a better efficacy than other treatment options. Biosergen is believed to have a drug candidate with at least the same good efficacy but with a more favorable safety profile than the polyenes currently in use.

Illustration of modes of action per molecular class

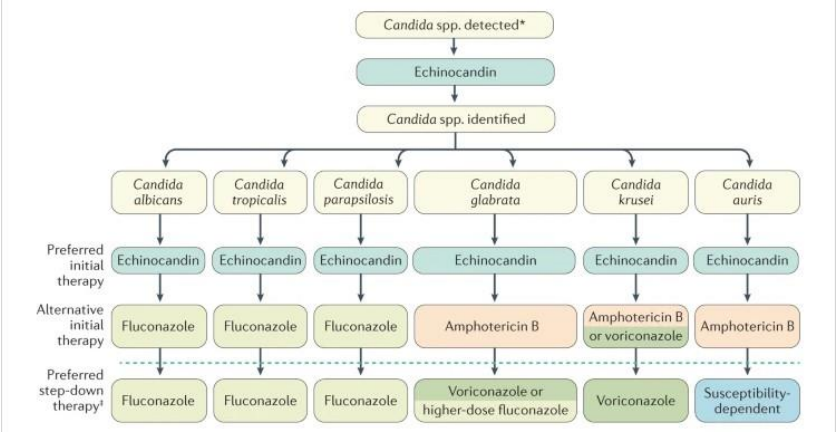


Source: Nature Reviews

Resistance development is a growing problem

The limited diagnosis options and aggressive progression means that doctors often start treating patients before the diagnosis is fully established. Given the favorable safety profile of azoles and echinocandines, they are often used in the first line of treatment. Either in combination with each other or individually. The challenge is that the drugs tend to be fungistatic and not fungicidal, which means that the fungus does not get killed. The candidates tend to suffer from resistance development. The widespread use of the two classes of molecules is a global problem recognized by the WHO and the CDC (United States Centre for Disease Control). The organizations see the rise of multidrug-resistant fungal strains as a health threat.

Illustration of treatment alternatives per molecular classes in Candidiasis



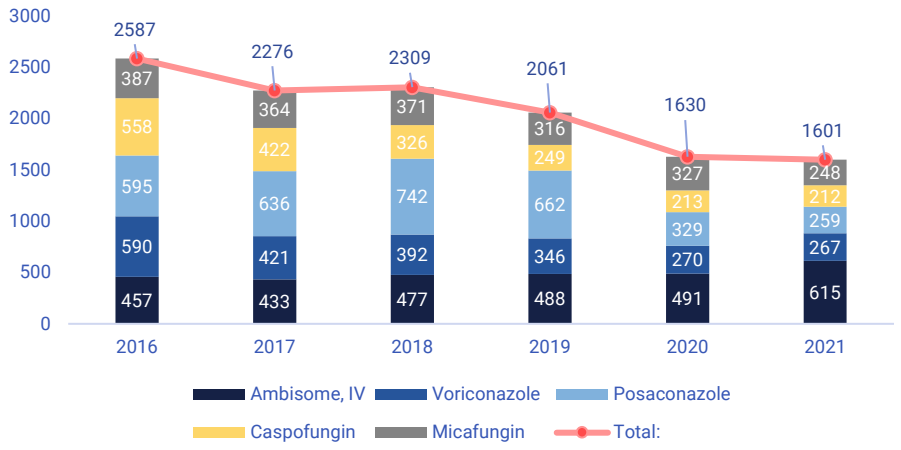
Source: Nature Reviews

Derivatives of the same molecular class dominate the market

There are over 72 launched drugs to use to treat various forms of invasive fungal infections. The majority target many different fungal pathogens and are often used in combination. Given the early discoveries of the above classes of molecules, the original drugs have seen their patents expire. This results in a fragmented market with both generic and improved versions based on the same parent molecule. This means that there is currently no "best-selling" original drug.

The table below illustrates the best-selling drugs between 2016-2021. As can be seen, sales of the five best-selling drugs have declined from around $2.6 billion in 2016 to just over $1.6 billion by 2021, even though the underlying market has grown steadily – as explained by the increasing number of generics being launched.

Market: Invasive fungal infections by drug (USD million)



Source: Refinitiv Eikon, Novel antifungal agents in clinical trials V.2

Ambisome with the largest market share

Among the best-selling drugs is the liposomal version of amphotericin B from Gilead /Astellas Pharma. The drug is traditionally administered over 30-60 minutes but can be administered over 2 hours at higher doses.

Ambisome is amphotericin B encapsulated in small fat particles (liposomes) – a delivery method that has been shown in numerous studies to have lower side

effects than traditional intravenous amphotericin B, particularly for the patient's kidneys (ambisome.com/safety-and-efficacy). The candidate was already approved in 1997, then against the parasitic infection Visceral leishmaniasis (VL). Use has broadened against several indications to date, with a predominance of invasive fungal infections. As the table above indicates, Ambisome IV is the only drug that has grown in recent years, selling USD 540 million in 2021, which is likely explained by a growing incidence, molecular resistance, and good efficacy.

Azoles and Echinocandins face generic alternatives

The two pharmaceutical giants, Pfizer and Merck & Co have drugs in commercial Phase from the azole class of molecules. The most notable are Posaconazole and Voriconazole, which collectively sold for over $1 billion in 2018. Since then, a number of generic alternatives have come out.

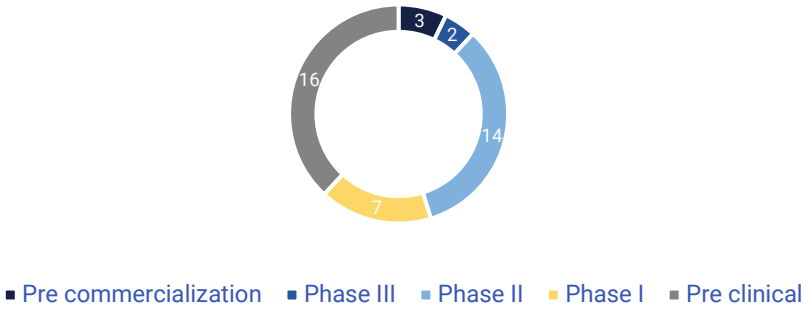
Both drugs are recommended to be taken orally and have, compared to Ambisome, lower nephrotoxicity. They both attack the fungal cell by inhibiting a critical enzyme synthesis in the fungal cell membrane. As mentioned earlier, these candidates tend to have lower fungicidal efficacy than the polyenes. That said, fungal infections are not black and white. It differs significantly between the patient population and the fungal pathogen involved. A study from 2002 (*Voriconazole versus Amphotericin B for Primary Therapy of Invasive Aspergillosis*) shows favorable results for Voriconazole in terms of Survival Rate after 12 weeks in comparison to traditional Amphotericin B. Another study from the same year instead compares Ambisome against Voriconazole (*Voriconazole Compared with Liposomal Amphotericin B for Empirical Anti-fungal Therapy in Patients with Neutropenia and Persistent Fever*). This study shows a favorable overall success rate for AmBisome. 26 percent overall success rate was seen among patients using Voriconazole, while patients receiving Ambisome achieved 30.6 percent overall success rate.

Caspofungin from Merck & Co is the best-selling echinocandin met by generic equivalents. The drug is administered intravenously and inhibits the important 1,3beta-glucan (an enzyme) synthesis in the fungal cell membrane. Like molecules from the azoles, caspofungin and its derivatives are fungistatic and, as previously described, inhibitory.

Projects under development

The diagram below illustrates the number of candidates per developmental Phase working against similar fungal pathogens as BSG005. Most of the projects under development are small molecules and further related to the azoles, echinocandins, and several generic candidates. However, there are also antibody molecules in early preclinical development, which are currently not on the market.

Candidates by stage of development (2022)



Source: Refinitiv Eikon, Novel antifungal agents in clinical trials V.2

Some of the more exciting molecules worth mentioning are described below:

- **Oteseconazole (VT-1161)** is a small molecule defined as the azole family's third-generation molecular class. The candidate has undergone extensive clinical programs. In recurrent vulvovaginal candidiasis (RVVC), the Company behind the molecule, Mycovia Pharmaceuticals, has presented strong data in two large Phase III trials. The Company has received Fast Track from the FDA and is now awaiting approval. At the same time, we believe that this candidate is likely to encounter resistance development problems because the design of the mechanism of action, which aims to inhibit enzyme synthesis in the fungal cell membrane, is similar to other molecules.

- **Encoleated Amphotericin B (MAT2203)** from Matinas BioPharma in the US is, like BSG005, of the molecular class polyene. This molecule is similar to Ambisome. The difference is that the candidate can be administered orally whereas Ambisome requires intravenous administration. Top-line data from phase II trials indicate that it achieves its endpoint of ≥ 50% improvement in symptoms and clinical impact. We believe this candidate will be the biggest future competitor for Biosergen as BSG005 is taken intravenously in its longest-running version.

- **Rezafungin** from Cidara Therapeutics belongs to the echinocandins whose mechanism of action, like caspofungin, inhibits glycosynthesis in the fungus cell wall. Rezafungin has shown robust data from clinical programs in immunocompromised patients. The candidate has received Fast Track designation from the FDA and saw Phase III STRIVE trial outcome in December, which met its endpoints. However, we note that the global cure between rezafungin and caspofungin was 60.6% and 59.5% for rezafungin.

- **Ibrexafungerp citrate** from Scynexis is also an echinocandin. The drug candidate was launched as an oral alternative against VVC (vulvovaginal candidiasis) on the market in 2021. The molecule targets various strains and has shown efficacy against multidrug-resistant pathogens, especially against candidiasis that has undergone prior azoles treatment. The drug can be administered orally and via IV; previous echinocandin drugs have only been administered intravenously. Ibrexafungerp acts by inhibiting the synthesis of β-(1,3)-D-glucan in the fungal cell wall. The drug candidate is expected to reach the market for IV administration against invasive candidiasis in late 2024.

The molecules above are some of the most developed drug candidates on their way to market with clinical evidence behind them or recently launched. We believe that the drug candidates look likely to be rapidly affected by resistance development based on publish-ready data. At the same time, the reported Phase II/III trials seem to have difficulty demonstrating significantly better efficacy than the treatments they are going head-to-head against in the study design.

Could modified polyenes be the next big clinical breakthrough?

Our overall view of the studies reviewed confirms that new versions of already well-used drugs improve treatment options relatively marginally in terms of efficacy. At the same time, toxicity challenges are somewhat more prominent. Azoles and Echinocandins face significant challenges with multidrug resistance. This should not be surprising, given the widespread use of combination therapies with the same molecular classes in the absence of proper diagnosis. As a result, the most effective way forward for research might be to develop drug candidates in the polyene class, as Biosergen is doing. If a drug candidate successfully

reduces the associated toxicities with amphotericin B, higher doses should be administered, and the fungicidal efficacy increased, possibly showing clinical superiority.

We believe that these antifungals' relatively few development projects are partly explained by the challenges of presenting clinical superiority against existing treatment options. At the same time, studies often require large numbers of patients, making them relatively expensive. This can weaken the ROI calculation for pharmaceutical companies in invasive fungal infections.

BSG005 – Modified candidate of Amb

Biosergen's drug candidate BSG005 is expected to be administered intravenously (IV) against several fungal pathogens. These include the Aspergillus pathogen, for which the FDA has granted the Company Orphan Drug Designation. To broaden the potential use of the molecule, two additional formulations have been developed and are expected to reach clinical studies.

BSG005 Nano

Where BSG005 Nano aims to reach fungal infection in the lungs intravenously more effectively, the Company has received SEK 9.3 million in research funding for further development of the nano-formulation into Phase I clinical trials covering approximately 50% of the estimated costs.

BSG005 Oral

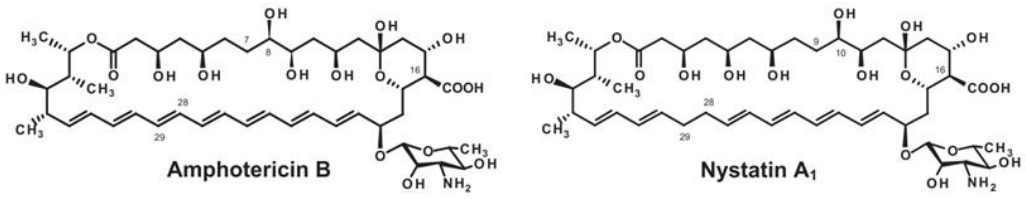
BSG005 Oral is also a nano-formulation that allows the patient to take the treatment orally via pills in their home.

Expected timeline for clinical development with BSG005

	Discovery	Preclinical	GMP/Tox	Phase I	Phase IIa	Phase IIb	Phase III	NDA
BSG005	→			→	H2 2024	H1 2025	H2 2026	2025-2027
BSG005 *Nano*	→		*2023*					
BSG005 *Oral*	→		*2023*					

Source: Carlsquare Equity Research

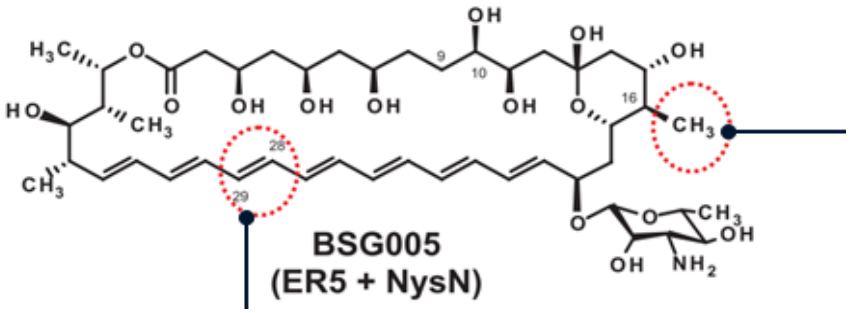
Molecular structure of Amphotericin B and Nystatin



Source: Company information

In the picture above, we want to show that the molecular structures of Amphotericin and Nystatin are similar to BSG005. The modification made by the researchers is essentially in the common property of the carboxyl group (an acid found, among other things, in amino acids used to build proteins), an acid found in the first two. This change appears to have significantly reduced the toxicity of BSG005. A re-formulation of the third position from the left in the lower part of the molecular body (see image below) has significantly boosted the molecule's amphotericin levels. In the segment below the picture, we explain the mechanism of action of the base molecule Amphotericin B in more detail.

Molecular structure of BSG005



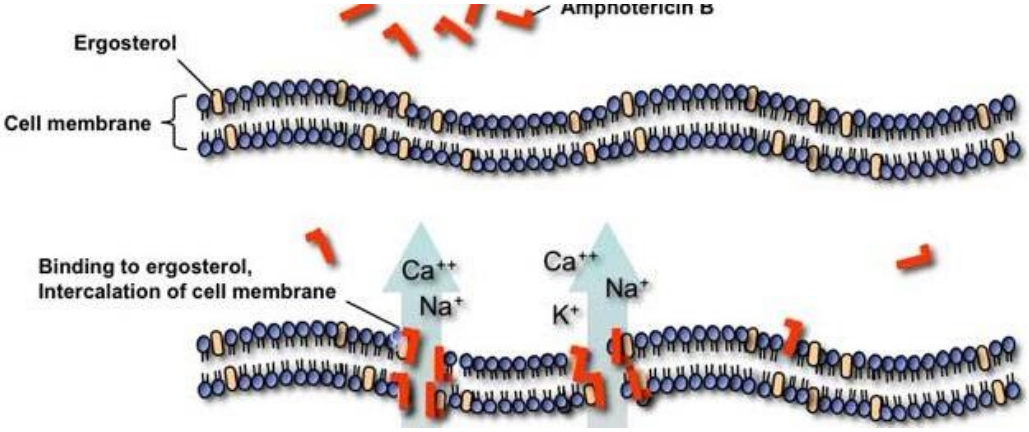
Source: Company information

Mechanism of action with fungicidal effect on the fungal cell membrane

BSG005 can be described as a modified and improved version of amphotericin B. A molecule that is still seen as one of the most important discoveries of the century. Amphotericin B is an isolate from a common bacterial strain called Streptomyces. The same bacterial strain is behind a number of antibacterial, antiparasitic, and antifungal treatments. The molecule was discovered in 1956 by scientists Donovick, Gold, Pagano, and Stout (Donovick R, Gold W, Pagano JF, Stout HA. Amphotericins A, and B, antifungal antibiotics produced by a streptomycete. In In vitro studies Antibiot Annu. 1955; 3:579-586).

The mechanism of action of amphotericin B was briefly discussed in the description of the liposomal version Ambisome. The fungicidal effects of the molecule are based on the disruption of essential processes in the fungal cell membrane. Ergosterol is required in the fungal cell membrane for many of today's fungal cells to live. Ergosterol can be described as a carbon sterol for animal cells (including humans) and is essential for the cell to produce various hormones and vitamins to survive. For Amphotericin B its mechanism of action is to bind to this particular sterol. Binding to ergosterol creates small ion channels in the cell membrane, which in turn generates leakage and causes cell death (Gray KC, Palacios DS, Dailey I, et al. Amphotericin primarily kills yeast by simply binding ergosterol. Proc Natl Acad Sci. 2012;109(7):2234).

Description of the mechanism of action of polyenes such as Amphotericin B and BSG005



Source: https://drfungus.org/knowledge-base/antifungal-pharmacology/

The picture above illustrates how Amphotericin B creates the ion channels in the cell membrane and enables the leakage that eventually causes necrosis.

Manufacturing of BSG005

The aforementioned Streptomyces bacteria produce all polyene drugs. The manufacturing process for the BSG005 was developed at the laboratories in Trondheim, Norway. The final necessary steps for scale-up and GMP-approved process were achieved in 2021.

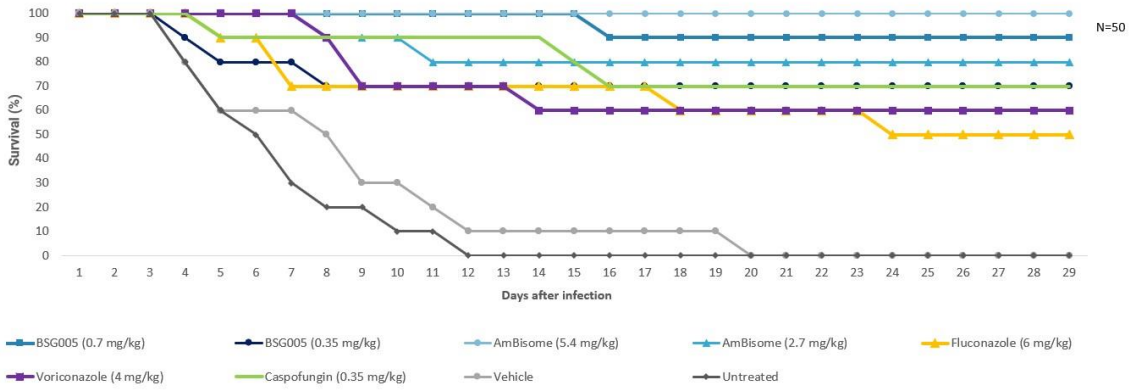
Promising data in preclinical activities

Given the extensive research and early conception of BSG005, there is a lot of shared data from preclinical activities. In cells outside living organisms (*In vitro*), the molecule has shown fungicidal activity on most fungal strains. Furthermore, preclinical In vivo studies (In living organisms) have demonstrated good fungicidal activity for all four pathogens in invasive infection. The candidate shows efficacy against multidrug-resistant strains of Aspergillus and Candidiasis, where the annual incidence is extensive. One should be aware however that preclinical studies are in the early phase of drug development.

An early indication of good efficacy

The documented fungicidal effect of polyenes is, as previously mentioned, significant. The picture below illustrates a comparative study on the Candidiasis pathogen in immunocompromised mice. Survival (%) is shown on the Y-axis. As can be seen, BSG005 exhibits good efficacy at similar dose levels to the other molecular classes. We are not surprised that BSG005 and Ambisome show close to identical data as they belong to the same molecular class.

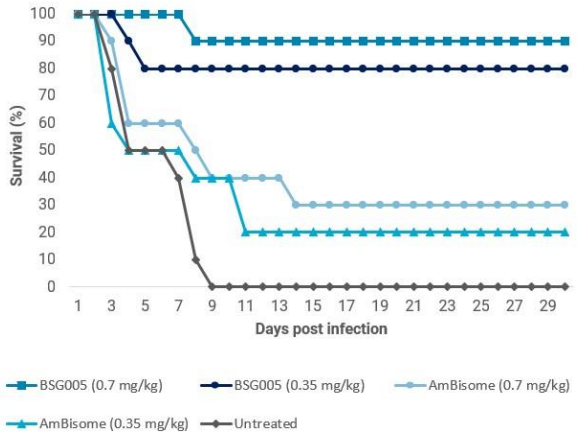
BSG005 compared to other Polyenes, Azoles and Echinocandins (Candidiasis)



Source: Company information

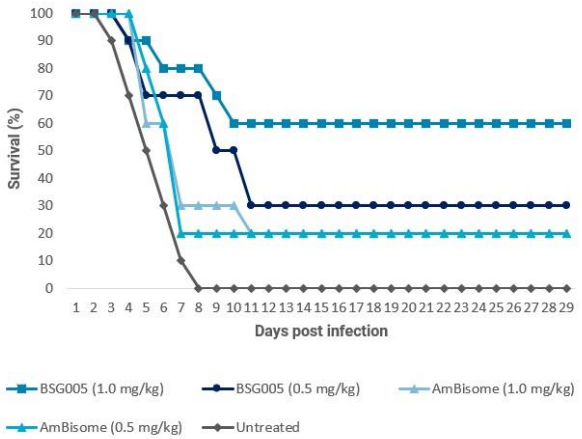
Worth mentioning from the above referenced study is the lower dose of BSG005 used (0.7mg/kg and 0.35mg/kg) compared to AmBisome clinical doses (2.7mg/kg and 5.4mg/kg). BSG005 shows clearly better outcomes at equivalent dose levels, which could result in the candidate being more effective against specific Candidiasis and Aspergillus strains than Ambisome.

BSG005 compared to Ambisome against Candidiasis



Source: Market Research, JOFA, WHO

BSG005 compared to Ambisome against Aspergillosis



Source: Market Research, JOFA, WHO

Toxicity will be crucial

Kidney toxicity and other side effects are the main reasons for the relatively limited use of polyenes. AmBisome's improved safety profile compared to traditional Amb (Abelcet) has contributed to the drug being the best-fungicidal today. In a 2007 study in invasive Candidiasis, Ambisome showed a superior side effect profile in serious adverse events (*A Comparison of AmBisome® to Amphotericin B for Treatment of Systemic Candidiasis*). These included:

- Observation of renal toxicity: 21% (Ambisome) vs 55% (Abelcet)
- Observation liver toxicity: (21% vs 65%) in favor of AmBisome

BSG005 has shown in animal studies significantly lower toxicity compared to traditional Amphotericin B at equivalent doses. In particular, the enzyme marker N-Acetyl-β-(D)-glycosaminidase (NAG) has been used to measure changes in the kidney. The data presented indicate that BSG005 has between 3-5 times lower renal toxicity than traditional Amb. In our view, keeping toxicity low is crucial to the drug candidate's success. Given the similarities with Ambisome, physicians are likely to compare the side-effect profile between BSG005 and Ambisome rather than against traditional Amb. Of course, this is dependent mainly on the efficacy of BSG005 in the clinic.

Clinical development programs

Biosergen aims to submit an NDA (New Drug Application) to the FDA by mid-2026. The Company's clinical development started in the spring of 2022 with a Phase I study in Australia. The planned clinical activities are outlined below:

Phase I clinical trial

The study was designed as a placebo-controlled, double-blind randomized 4:2 study. The test population consisted of 24 test subjects who received a single dose during the Single Ascending Dose (SAD) part of the study, with 12 subjects participating in the Multiple Ascending Dose (MAD) part. The study had one primary endpoint with 6 secondary endpoints. The chief objectives with the study were:

- To test the overall safety of BSG005, especially pertaining to kidney function.
- To test the tolerability of intravenous infusion and the risk of any adverse effects on body functions.

- To investigate pharmacokinetics in order to determine drug concentrations as well as time periods the drug is present in the blood stream per dose levels.

The study was initially scheduled to start in late 2021, but challenges in the manufacturing process of the candidate delayed the start of the study. According to the Company, this was not serious, and the study started in late March 2022. The study presented topline data on March 13, 2023. There were no major safety concerns, with no negative safety signals on kidney and liver parameters. Plasma levels following a week of daily infusions approached the NOAEL-levels from the previous toxicology studies. We expect more data, including dose levels, to be presented in the full set of results.

Infusion reactions in early dosing cohorts

The trial consists of two parts: Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD). The first (SAD) part was concluded in early September after four cohorts of six participants each (Four active and two placebo). Mild to moderate infusion reactions, constituting dose-limiting toxicity, were observed in the third and fourth cohorts. It should however be noted that the investigators have not reported any kidney or liver toxicity during the entirety of the phase I study.

The Safety Review Committee recommended that the trial move into the MAD part with the dose level from the second SAD cohort. At this point, it appears that the infusion reactions are not severe per se, and infusion reactions are not uncommon for polyenes (however less frequent for the AmBisome formulation). However, in a negative scenario, the recommended dose of BSG005 may be lower than planned, which in turn could impact the efficacy of the treatment. Sometimes it is possible to ameliorate such reactions by longer infusion times or through premedication. As a reference, AmBisome is dosed at 3-5 mg/kg per day with 120 minutes intravenous infusion. Preclinical studies suggest about 0,5-1 mg/kg as a therapeutic dose for BSG005.

Phase II programs in selected groups

The Phase II program is planned to include 2-3 trials in the following indications:

- Neutropenic patients (low white blood cell count following chemotherapy) with clinical symptoms of invasive fungal infection, but with or without diagnosis of the specific fungal strain.
- Aspergillosis patients. Biosergen will focus on the rare disease without including chronic pulmonary aspergillosis.
- Mucormycosis patients.

The first trial Phase II trial is planned for mucormycosis patients. Due to the seriousness of this disease, Biosergen sees an opportunity of an adaptive design and subsequently turning this trial into a Phase II/III in a total of 80 patients. The study is to be initially conducted in India but later expand to other countries. As a reference, Isavuconazole (Cresemba) was approved for the treatment of mucormycosis in 2015 based on results in a subgroup (n=37) of invasive fungal disease patients. Mortality (38 per cent through day 42) and response success rates (31 per cent at end of treatment) were compared to the natural history of the disease. We assume that the endpoint will be similar for BSG005 and that there will be no control arm. According to the CDC, the mortality rate of mucormycosis varies by, e.g., site of infection, but is generally estimated at 54 percent. This suggests a level to calculate a possible bar for approval from, but the threshold will likely also depend on what patient groups are eventually included in the trial. Cresemba is an azole, i.e., not a fungicidal substance. Provided a good safety profile is confirmed, we think there is good reason to be relatively optimistic about BSG005 in this population.

In addition, Biosergen will start Phase II trials with 35 patients in one or two of the other indications. The plan is to have enough safety data for two indications. In a positive scenario, Biosergen believe they may already seek accelerated approval for mucormycosis and move BSG005 into Phase III in fungal infections patients following Phase II. We assume a subsequent Phase III trial in invasive or resistant fungal disease will include patients that either do not tolerate or are refractory to Amphotericin B, alternatively febrile, neutropenic patients with presumed fungal infection following anti-bacterial treatment. We believe it will likely be a much larger head-to-head study, possibly against AmBisome, as a non-inferiority trial. Similar trials have amounted to some 500 patients.

In immunocompromised patients with invasive aspergillosis and other life-threatening fungal infections, AmBisome has demonstrated a favorable response in half of the patients and a 72 percent survival rate 12 weeks after the end of treatment (94 percent after 14 days) (Source: Gilead “Data Show Efficacy of Standard Dosing Regimen of AmBisome(R) is Similar to High Loading Dose for Patients with Invasive Fungal Infections”). As such BSG005 is a promising drug candidate but with much to prove.

The extensive but early data on BSG005 gives confidence in the drug candidate's potential. The critical issue will be finding the "optimal" indication and demonstrating clinical superiority with a good safety profile. Much of the research confirms strong efficacy and safety profile variation between the different molecule classes. Given AmBisome’s launch, there is an improved alternative in the polyenes. Against this drug, BSG005 either needs higher safety or better efficacy in one or more fungal pathogens. Another critical part of the research on fungal infections is whether any new drug candidates under development in the azole or echinocandin class will be able to challenge the current resistance problem. In particular, the development against resistance of Ibrexafungerp citrate, which has shown efficacy against resistant pathogens against azoles, will be essential to follow closely. Given the superior safety profile of the two classes of molecules compared to the polyenes, there are good incentives to favor drug candidates from these classes. However, based on the clinical projects in development, we do not see this happening in the short to medium term.

Receiving orphan drug designation from the FDA for invasive aspergillosis is an important step to initially focus on one of the most severe fungal infections where the candidate has strong preclinical data. As mentioned, the azoles and echinocandines generally have inferior efficacy in the two strains, aspergillosis, and candidiasis.

Market and competition

The market for invasive fungal infections is expected to grow to more than USD 9 billion by 2030. An accelerating problem of multidrug resistance means that mortality rates remain high at the same time. Against the background of a few new treatment options, the market is increasingly dominated by generic alternatives derived from compounds from four different molecular classes. A number of clinical projects are under development and are expected to drive the market. Due to the rapid course of progression and increase in disease places, coupled with faster demands on correctly diagnosing infection and fungal pathogenesis for the affected person, advances in this area could increase the use of strategic antifungals with clinical superiority.

Increased use of antifungals

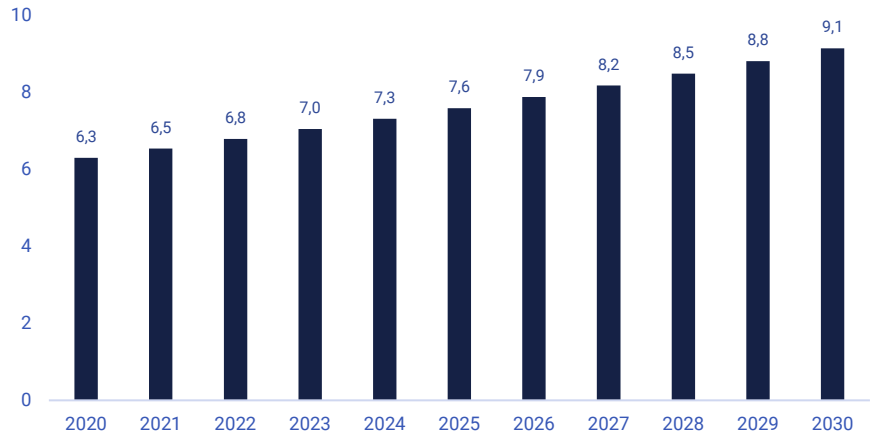
Improved versions expected to drive market

Despite the growing issue of invasive fungi there is a lack of substantial and qualitative data. We assume that the annual incidence of systemic fungal infection is estimated to be around 1.9 million cases globally (JOF). Ambisome is currently

the clear shining star in terms of the polyene molecular class and is expected to remain the first choice. The oral formulation with similar characteristics "MAT2203 (oral amphotericin B)" is expected to submit an NDA application in 2023, according to Matinas Pharma. The candidate could enable broader use of polyenes. Scynexis is a smaller player whose candidate Ibrexafungerp was approved in 2021, where consensus estimates are that the candidate could reach peak sales of around million 500 USD in 2028. Furthermore, the market is expected to be driven by expanded use of antifungals partly due to the developed resistance that exists between candidates in the same molecular class - this opens up increased use of combination therapies.

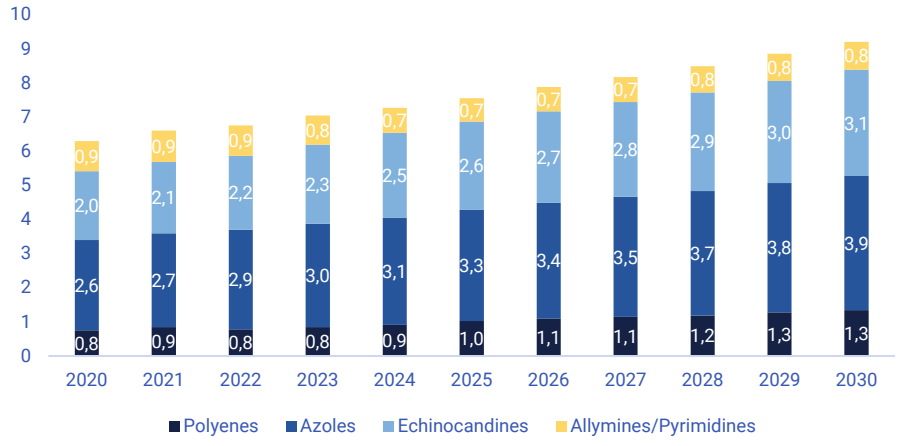
As shown below, the market was valued at USD 6.5 billion in 2021 and is expected to grow to USD 9.1 billion by the end of 2030, according to research and markets. The estimate gives a CAGR of 3.8% with the market 70 percent allocated to North America. Echinocandines and Azoles are still expected to hold the largest market share by molecular class. We assess that the most likely scenario is that polyenes as a class has the potential to grow over time should favorable results be achieved. Given the fungicidal effects of the molecule, lower developed resistance, and limited research progress, there is significant market share to be gained for drug candidates that show favorable safety profiles.

Market: size in billions of USD, global



Source: Research and Markets

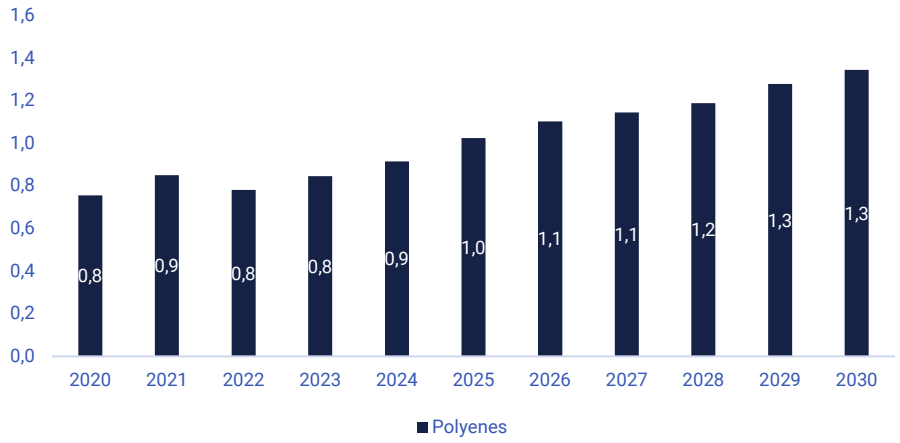
Market: sales by molecule class, billions USD



Source: Market Research, JOF, Research Markets

The polyenes market is of particular interest for Biosergen.

Market: sales expectations, polyenes, billions USD



Source: Market Research, JOF, Research Markets

The treatments on the market are marketed mainly by subsidiaries of major pharmaceutical companies such as Pfizer (Amplyx Pharmaceuticals Inc), Gilead and Merck. The market structure is partly the result of acquisition activity, with Gilead buying Nexstar Pharmaceuticals, the Company behind Ambisome (liposomal amphotericin), in 1999.

Listed comparable companies

Below we present the valuation of two of the most relevant companies listed with a primary focus on fungal infections. The two companies are listed in the US with a significantly higher market capitalization than Biosergen. That said, both companies are further along in their project development.

Listed companies within Fungal infection

Company	EV (SEKm)	Phase	Molecule class	Main targeted indications	Market launch
SCYNEXIS, Inc.	241	3	Echino-candines	VVC, IC, IA	2021 (oral), 2024 (IV)
Matinas BioPharma Holdings, Inc.	1 268	2	Polyenes	IC	2022/2023 (IV)
Median	**755**				
Biosergen AB	**72**	**1**	**Polyenes**	**IC, IA, MM, CC**	**2024-2026**

Source: CapitalQ, Carlsquare Equity Research

Companies focusing on fungal diseases

Scynexis Therapeutics Inc

SCYNEXIS, Inc., a biotechnology company, delivers therapies to treat fungal infections in the United States. It is developing its lead product candidate, Ibrexafungerp, as a novel oral and intravenous drug to treat various fungal infections, including vulvovaginal candidiasis, invasive aspergillosis, and invasive candidiasis, and refractory invasive fungal infections. The Company develops Ibrexafungerp, which has completed Phase II clinical trials to treat vulvovaginal candidiasis. It has research collaborations with Merck Sharp & Dohme Corp., Hansoh (Shanghai) Health Technology Co., Ltd., Jiangsu Hansoh Pharmaceutical Group Company Limited, and R-Pharm, CJSC, to develop and commercialize rights for Ibrexafungerp. The Company was formerly known as SCYNEXIS Chemistry & Automation, Inc. and changed its name to SCYNEXIS, Inc. in June 2002. SCYNEXIS, Inc. was incorporated in 1999 and is headquartered in Jersey City, New Jersey.

Matinas Biopharma Inc

Matinas BioPharma Holdings, Inc., a clinical-stage biopharmaceutical company, is researching and developing various product candidates. It develops products using its lipid nanocrystal (LNC) platform technology. The company's LNC delivery technology platform utilizes lipid nanocrystals for the delivery of small molecules, nucleic acids, gene therapies, vaccines, proteins, and peptides. The company is developing MAT2203, an oral formulation of amphotericin B that is in Phase II clinical trials for the prevention of invasive fungal infections due to immunosuppressive therapy in patients. In addition, it provides MAT2501, an orally administered formulation of the broad-spectrum aminoglycoside antibiotic amikacin that has completed Phase I clinical trials to treat various types of multidrug-resistant bacteria, including non-tuberculous mycobacterium infections, as well as various multidrug-resistant gram negative and intracellular bacterial infections.

Financial history and Carlsquare forecasts

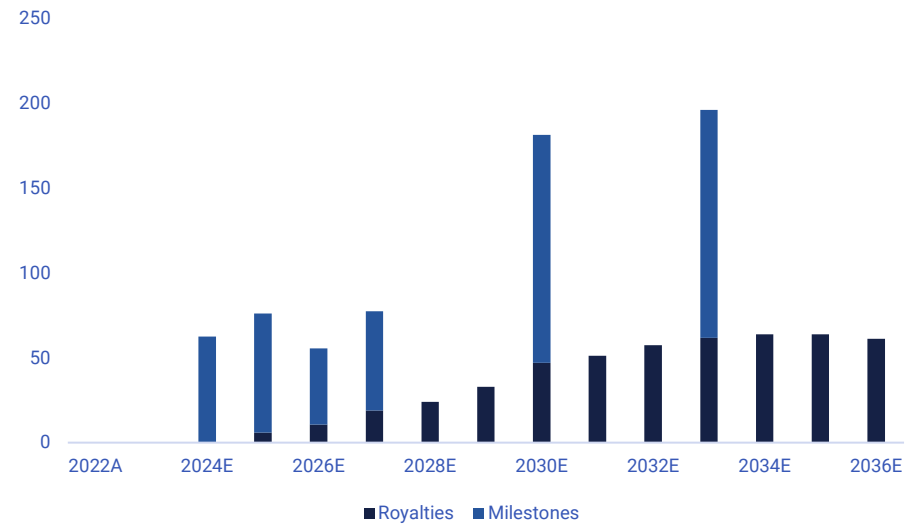
Biosergen is estimated to face relatively high costs in 2023, mainly related to the current phase I clinical trial as well as the expected initiation of a phase IIa study. Given the issue of units we estimate the company can sustain the cash burn until Q4 2023, with the help of a short-term loan near the middle of the year. The market is in a favorable position with limited options but increasing prevalence of underlying diseases. Considering the state of the market and the total number of addressable patients we estimate that BSG005 could reach peak sales figures of roughly USD 515 million. With previous licensing deals in mind, a two-digit royalty of 10 per cent on sales is reasonable, with upfront, regulatory and commercial milestones amounting for over USD 360 million.

Revenue and profitability forecasts

Expected sources of funding need to be completed

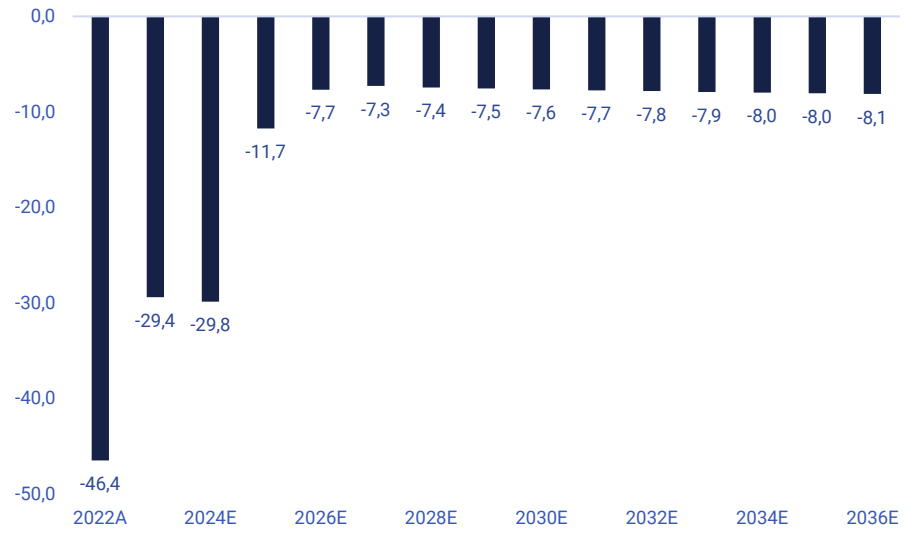
Currently the company is under way with preparing for phase II in India, among other countries, with the phase I study recently completing. Previously funded by numerous grants and research initiatives, we believe costs will grow steadily as R&D progresses. Considering the Company's strategy, the main driver of costs will continue to be costs related to research and development. A possibility exists for Biosergen to be able to sell directly in some regions which sequentially would introduce direct costs.

Net sales, (SEKm) (Risk-adjusted)



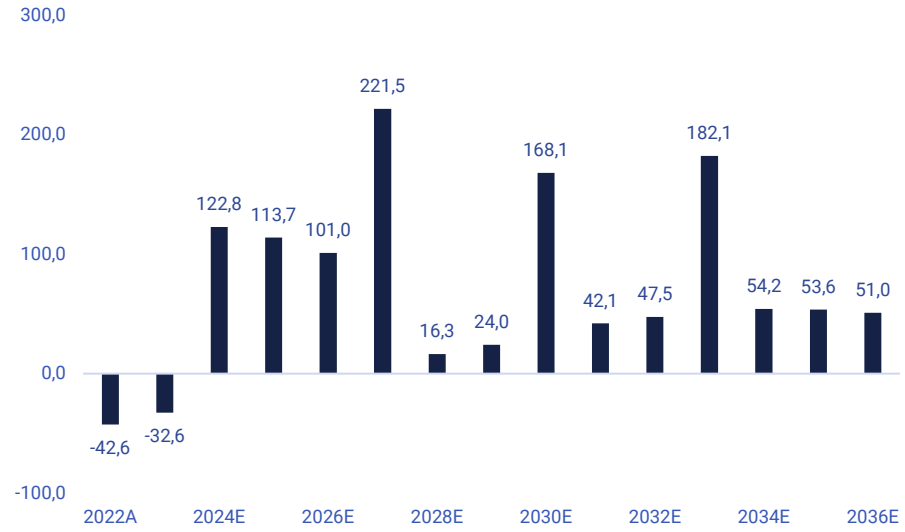
Source: Carlsquare Estimates

Total cost forecasts, (SEKm) (Risk-adjusted)



Source: Carlsquare Estimates

Expected cash flow from operating activities (SEKm) (Risk-adjusted)



Source: Carlsquare Estimates

Project assumptions

BSG005 (IV, Nano, Oral)

The most relevant reference on the market to calculate the cost of BSG005 is currently Ambisome, which varies widely depending on dosing, geography, and area of use. We note that the drug is used against more infectious diseases related to HIV in developing countries. Scynexis has indicated its price point and initial target patient population for its drug candidate. We estimate a list price of approximately $ 330 for 15 mg (in the US). This would translate into an approximate cost for a treatment cycle (14 days with 0.75 mg/kg/qd at average weight of 65 kg) of 15 015 $. We judge that the drug candidate justifies a higher price than both current Ibrexafungerp and Fluconazole and is in line with Ambisome. Pricing of Ambisome varies widely, including in the US, which is why we believe BSG005 will need to be priced strategically and not at too large a premium. This is mainly because other classes of molecules are cheaper and are likely to continue to have a more favorable safety profile than BSG005 in the clinic. However, should the

candidate show strong data indicating better efficacy and equivalent safety to echinocandines and azoles, it justifies a higher premium price. There are no strong drug candidates in development, but one should be aware that the treatment regimen is complex and not adopted overnight.

Based on data regarding prevalence from the CDC and other sources the total amount of potential patients lies just under 365,000 when looking at Aspergillosis, Candidiasis, Mucormycosis and Cryptococcosis. Furthermore, using hospitalization rates regarding the ICU, the combined first line treatment rate for Candidiasis and Aspergillosis is estimated at 63 % with Cryptococcosis at 100 % owing to the particular pathology. Mucormycosis, being the rarest but also very lethal, is estimated at 85 %. Being a fungicidal, without the nephrotoxicity, we judge that BSG005 will be deployed as a first line choice for patients, especially considering the increasing problem of antimycotic resistance. This entails that the total number of treated patients in the peak sales year of 2034 amounts to roughly 53 000 cases. In relative terms, for all pathogens except Mucormycosis, this amounts to roughly 16 % patient market share in the US and 11 % outside the US. For the deadly black fungus, the peak market share occurs earlier in 2033 and amounts to 24 % in the US and 15 % for the other markets. In light of the assumptions and estimates described above we estimate peak sales to occur in 2034 and amount to approximately USD 515 million.

Assumptions about peak sales BSG005

2034E	US	EU, UK, JP	India	Total
Prevalence, Invasive Candidiasis	31 094	60 588	130 426	222 108
Prevalence, Invasive Aspergillosis	15 716	30 729	65 919	112 364
Prevalence, Invasive Cryptoccocis	5 166	10 102	21 669	36 937
Prevalence, Invasive Mucormycosis	3 315	6 838	14 720	24 873
Number of patients	*55 291*	*108 257*	*232 734*	*396 282*
BSG005 marketshare	20%	12%	13%	13%
BSG005-patients	10 850	12 890	29 527	53 267
Sales, MUSD	**222.0**	**93.0**	**200.2**	**515.2**

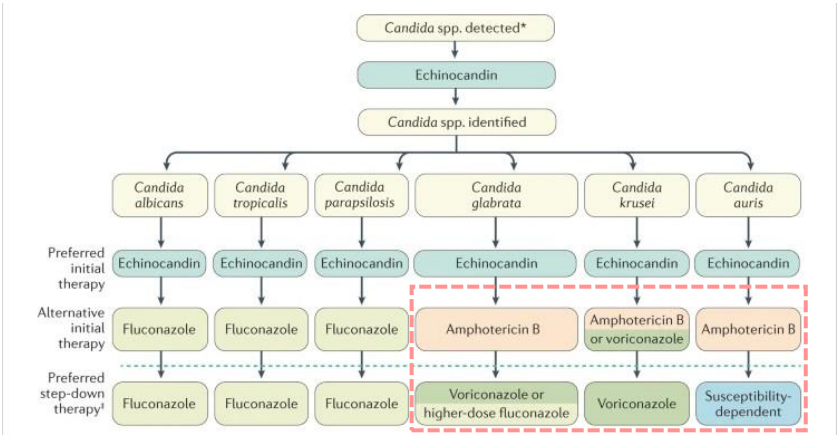
Source: Carlsquare estimates

As can be viewed above we have chosen to align our estimates with the communicated position of the company and to primarily evaluate the drug candidate against the previously mentioned four pathogens. This is in our view a reasonable position when considering the current clinical evidence and the underlying conditions that facilitate these fungal infections such as HIV and diabetes. Worth of note is also the potential for further indications in the future as increasing resistance appears to be a growing concern.

The assumptions and estimates described above would gain additional weight if a number of questions were to be answered. For example, there is the problem of AmBisome currently being a popular antimycotic. Being a fellow polyene and seeing heavy usage in e.g., India there is a risk that resistant strains develop during the time BSG005 is in development. The favorable safety profile with no to little nephrotoxicity might be key to gaining market share as this would allow for better combinatory therapeutic options together with e.g., an azole. Even so the infusion

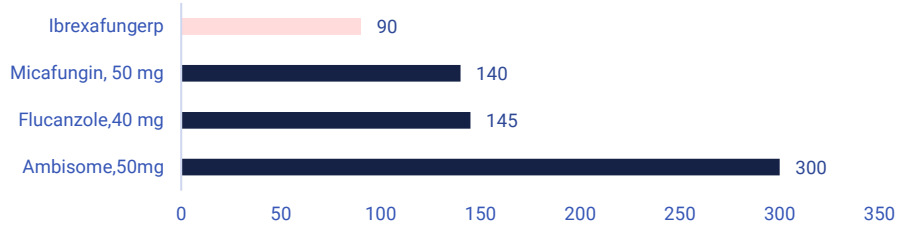
reactions could be a limiting factor when it comes to escalating doses to levels of sufficient efficacy.

Illustration of treatment lines by molecular class in Candidiasis



Source: Nature Reviews

Pricing of relevant antifungals on US market, USD



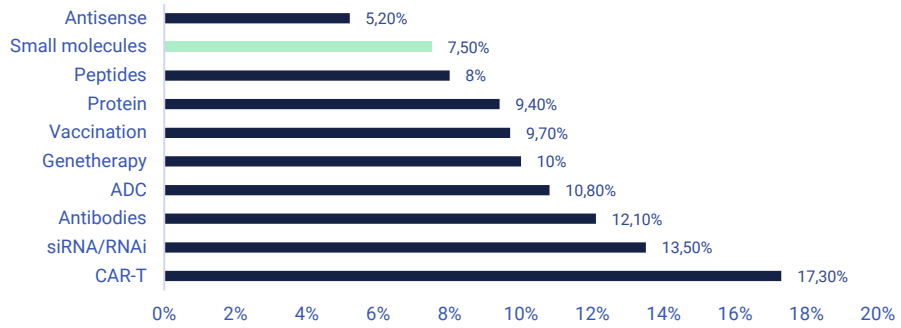
Source: Scynexis pharma, TLV, company information

We assume a net price in line with AmBisome. Treatment duration for affected patients has enormous variability, historically affecting pricing significantly. A large number of generic products is another contributing factor. Once the pricing of Ibrexafungerp IV is seen in the Scynexis books, more data will be available to reinforce a relevant pricing picture for BSG005. But most likely, we believe, is pricing just north of AmBisome.

Probability to market

Using statistics pertaining to drug development possibilities of success (POS) one has to consider the dual nature of a drug for infectious disease and an orphan drug. The former meaning a POS in phase II of 38.4 % with the latter entailing a POS of 44.6 %. Considering the company's current stage and the extensive preclinical data available, the LOA is 18.3 % in the base case. This increases to 19.2 % in the optimistic bull case, taking into account the heightened probability of orphan drugs. Naturally, factors such as modality and indications affect the chances of the drug but given the well-documented mode of action for BSG005 we consider the LOA to be reasonable. Worth of note however is the parallel processes for mucormycosis compared to the other indications, as mentioned previously, that could entail an earlier launch in 2025, which in the bull case is 2024 with NPU-sales.

Likelihood of approval from Phase I, by modality



Source: Bio/Informa Pharma/QLS, NCBI

Breakdown of valuation assumption

Indication	$POS_{1,2}$	$POS_{2,3}$	$POS_{3,NDA}$	POS_{NDA}
Infectious Disease	57.8%	38.4%	64.0%	92.9%
Rare Disease	67.4%	44.6%	60.4%	93.6%

Source: Bio/Informa Pharma/QLS

Our forecasts are based on the launch of BSG005 in 2027

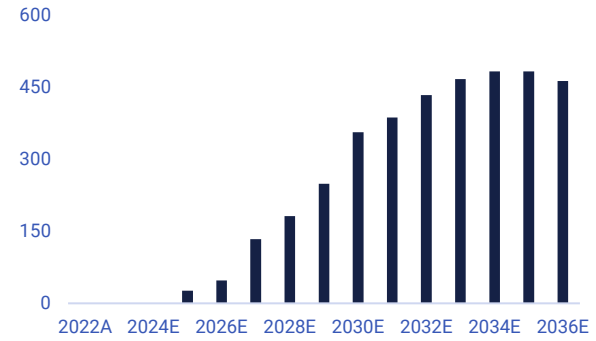
Our revenue projections are based on Biosergen licensing BSG005 on all major markets for mucormycosis in 2025 and for the other indications beginning in 2027. The starting year for NPU-sales of 2025 we expect royalties of over SEK 316 million could be achieved with the number jumping up to SEK 443 million in 2027 after the launch for all pursued indications. We expect a licensing deal following positive phase-IIA results at the end of 2024. The combination of an upfront payment, regulatory milestones and NPU-sales sustains the cash-burn and keeps the company in the black.

Licensing deals, antifungals

Licensor	Licensee	Project	Value (USDm)	Upfront (USDm)	Royalties
Cidara Therapeutics	Melinta	Rezafungin	460	30	Low double digit to mid teen
BioAlliance Pharma	Par Pharmaceutical	Loramyc	92	15	50-50 Joint venture
F2G Ltd.	Shionogi	Olorofim	480	100	Double digit
Basilea	Pfizer	Cresemba	408	87	Double digit
Average			**360**	**58**	
Median			**434**	**59**	

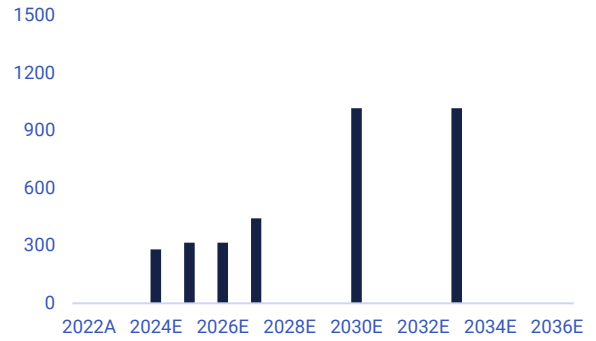
Source: Carlsquare estimates

Estimated royalties, (SEKm) (Nominal values)



Source: Carlsquare estimates

Estimated milestones (SEKm) (Nominal values)



Source: Carlsquare estimates

Valuation

Fair value SEK 4.3 in base case scenario

Explosive growth provides valuation support

In the base case the above-mentioned sales are used in the forecasting and corresponding valuation. We have utilized a risk adjusted DCF valuation, as described below. For our model a discount rate of 15.5 per cent has been used in conjunction with a risk-free rate of 2.4 per cent, a beta value of 1.2, a size premium of 4.2 per cent and a market risk premium of 6.7 per cent. The latter of which is based on the latest PwC Risk Premium Study.

We have assumed a royalty rate of 10 per cent with milestones of USD 361 million. There is upside potential in the royalty rate depending on when the deal is struck, but we have estimated a deal being made after phase IIa data and in conjunction with initiation of phase IIb studies. In total this boils down to a justified value of approximately SEK 4.3 per share.

Overview, Sum-of-the-parts-valuation, Base case

Project	Indication	LOA, %	Peak Sales, USDm	Launch	rNPV, SEKm
BSG005	4 pathogens fungal infections	18.3%	515	2025	325
Cash (22'Q4E)					15
Fair Value					**340**
Number of shares					42.2
Per share					8.1
Discount attributable to financing					42%
Fair value per share					**4.3**

Source: Carlsquare estimates

Valuation range

In an optimistic bull scenario, we expect:

- NPU-sales starting in 2024
- LOA increases to 19.2 per cent
- Royalty rate increases to 15 per cent

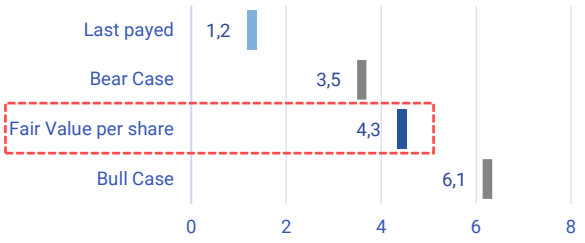
We estimate a justified value of SEK 535 million or around SEK 6.1 per share.

In a **cautious Bear** scenario, we expect:

- failure to achieve high enough dosage to compete effectively, thusly becoming a 2L treatment option

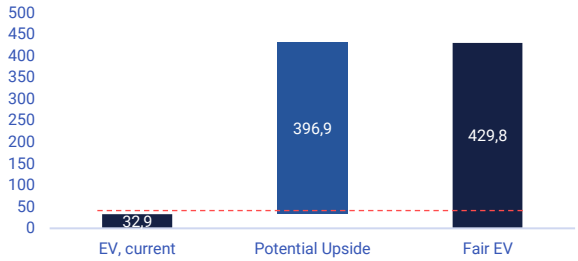
We estimate a justified value of SEK 241 million or around SEK 3.5 per share.

Fair value within a range, SEK



Source: Carlsquare estimates

Visualization of enterprise value



Source: Carlsquare estimates

Key Figures and Accounts

Income statement, quarterly (SEKm)

	2022. Q1	2022. Q2	2022. Q3	2022. Q4	2023. Q1	2023. Q2
Net revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Total revenue	1.3	1.4	0.0	0.0	0.0	0.0
Gross profit	**1.3**	**1.3**	**0.0**	**0.0**	**0.0**	**0.0**
Total operating costs	-6.3	-9.4	-16.0	-15.8	-21.6	-21.6
EBIT	**-5.0**	**-8.0**	**-16.0**	**-15.8**	**-21.6**	**-21.6**
EBITDA	**-5.0**	**-8.0**	**-16.0**	**-15.8**	**-21.6**	**-21.6**
EBT	**-5.0**	**-8.0**	**-16.0**	**-15.8**	**-21.6**	**-21.6**
Earnings per share	**-0.18**	**-0.28**	**-0.46**	**-0.37**	**-0.51**	**-0.28**

Source: Company information and Carlsquare estimates

Income Statement (SEKm)

	2021A	2022E	2023E	2024E	2025E	2026E
Net revenues	**0.0**	**0.0**	**0.0**	**282.0**	**580.0**	**796.9**
Other operating income	8.6	3.2	0.0	0.0	0.0	0.0
Total revenues	8.6	3.2	0.0	282.0	580.0	796.9
Purchase of commodities	-0.2	-0.1	0.0	0.0	0.0	0.0
Gross profit	**8.4**	**3.1**	**0.0**	**282.0**	**580.0**	**796.9**
Adjusted gross profit	8.4	3.1	0.0	282.0	580.0	796.9
Other external costs	-40.6	-34.7	-49.3	-50.2	-51.6	-52.8
Personnel costs	-1.5	-7.2	-5.4	-5.4	-5.5	-5.5
Depreciation and amortisation	0.0	0.0	0.0	0.0	0.0	0.0
Other operating expenses	-0.4	-1.7	-1.5	-1.4	-1.2	-1.3
Total Operating costs	-42.6	-43.7	-56.2	-57.0	-58.3	-59.6
EBIT	**-34.1**	**-40.5**	**-56.2**	**225.0**	**521.7**	**737.3**
EBITDA	**-34.1**	**-40.5**	**-56.2**	**225.0**	**521.7**	**737.3**
Net finance	-0.3	0.0	-0.3	0.1	0.1	0.5
Pretax profit	**-34.4**	**-40.4**	**-56.5**	**225.0**	**521.7**	**737.9**
Taxes	0.0	0.0	0.0	-7.0	-13.6	-19.2
Net profit	-34.4	-40.4	-56.5	218.1	508.2	718.7
Earnings per share	**-0.97**	**-1.00**	**-1.09**	**2.20**	**5.12**	**7.24**

Growth	2021A	2022E	2023E	2024E	2025E	2026E
Net revenues	NaN	NaN	NaN	NaN	106%	37%
Total revenues	NaN	-62%	-100%	NaN	106%	37%
Gross profit	NaN	-63%	-100%	NaN	106%	37%
Adjusted gross profit	NaN	-63%	-100%	NaN	106%	37%
EBIT	NaN	-19%	-39%	501%	132%	41%
EBITDA	NaN	-19%	-39%	501%	132%	41%
EBT	NaN	-18%	-40%	499%	132%	41%
Net profit	NaN	-18%	-40%	486%	133%	41%
Earnings per share	31%	3%	9%	-301%	133%	41%

Margins	2021A	2022E	2023E	2024E	2025E	2026E
Gross margin	98%	96%	NaN	100%	100%	100%
Adjusted gross margin	98%	96%	NaN	100%	100%	100%
EBIT-margin	Neg.	Neg.	NaN	80%	90%	93%
EBITDA-margin	Neg.	Neg.	NaN	80%	90%	93%
Net Profit margin	Neg.	Neg.	NaN	77%	88%	90%

**Adjusted gross profit = net revenues less purchase of commodities.*
***Adjusted gross margin = Net revenues less purchase of commodities. divided by net revenues.*
Source: Company information and Carlsquare estimates.

Balance Sheet (SEKm)

	2021A	2022E	2023E	2024E	2025E	2026E
ASSETS						
Intangible Assets	0.0	0.0	0.0	0.0	0.0	0.0
Tangible Fixed Assets	0.0	0.0	0.0	0.0	0.0	0.0
Financial Fixed Assets	0.0	0.0	0.0	0.0	0.0	0.0
Sum Tangible Assets	0.0	0.0	0.0	0.0	0.0	0.0
Inventory	0.0	0.0	0.0	5.6	1.3	8.7
Trade receivables	0.0	0.0	0.0	5.6	1.3	8.7
Other current receivables	3.2	0.0	0.0	0.0	0.0	0.0
Prepaid expenses and accrued income	4.7	0.0	0.0	0.0	0.0	0.0
Cash and bank	21.7	15.5	48.8	261.2	773.7	1 484.5
Total current assets	29.5	15.5	48.8	272.5	776.4	1 502.0
Sum assets	**29.5**	**15.5**	**48.8**	**272.5**	**776.4**	**1 502.0**
EQUITY						
Sum Equity	20.2	15.5	48.8	266.9	775.0	1 493.3
LIABILITIES						
Liabilities to credit institutions	0.0	0.0	0.0	0.0	0.0	0.0
Total long-term liabilities	0.0	0.0	0.0	0.0	0.0	0.0
Liabilities to credit institutions	0.0	0.0	0.0	0.0	0.0	0.0
Accounts payable	6.8	0.0	0.0	5.6	1.3	8.7
Other liabilities	0.1	0.0	0.0	0.0	0.0	0.0
Accrued expenses and deferred income	2.4	0.0	0.0	0.0	0.0	0.0
Total current liabilities	9.3	0.0	0.0	5.6	1.3	8.7
Sum Equity and Liabilities	**29.5**	**15.5**	**48.8**	**272.5**	**776.4**	**1 502.0**

Liquidity	2021A	2022E	2023E	2024E	2025E	2026E
Current ratio	3.2x	NaN	NaN	48.3x	589.3x	172.0x
Cash ratio	2.3x	NaN	NaN	46.3x	587.3x	170.0x

Indebtedness and Solvency	2021A	2022E	2023E	2024E	2025E	2026E
Net debt (-)/ Net Cash (+)	21.7	11.2	49.6	87.9	8.4	27.3
Net debt/EBITDA	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.
Net debt/Equity	N.M.	N.M.	N.M.	N.M.	N.M.	N.M.
Debt/Equity	61%	0%	0%	0%	49%	0%
Solvency ratio	161%	100%	100%	100%	149%	100%

Return on capital	2021A	2022E	2023E	2024E	2025E	2026E
ROA	Neg.	Neg.	Neg.	111%	79%	51%
ROE	Neg.	Neg.	Neg.	113%	80%	52%
ROIC	Neg.	Neg.	Neg.	Neg.	3165%	5951%

Source: Company information and Carlsquare estimates.

Cash Flow (SEKm)

	2021A	2022E	2023E	2024E	2025E	2026E
CF ongoing operations	-30.8	-42.6	-56.5	212.4	512.5	710.8
CF investment activities	4.0	0.0	0.0	0.0	0.0	0.0
CF financing activities	42.8	36.4	89.8	0.0	0.0	0.0
Cash flow for the period	-5.6	-6.2	33.3	212.4	512.5	710.8
Cash. beginning of period	21.7	21.7	15.5	48.8	261.2	773.7
Cash. end of period	16.1	15.5	48.8	261.2	773.7	1484.5

Source: Company information and Carlsquare estimates.

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