

Area/Industry: Life science

#Invasive fungal infection, #Lifesaving treatment #Silent crisis #Nordic initiative

### **Revenue Generating:** No

**Founded:** 2004

# **Partnering interest/** investor needs:

The company's shares are listed for trading on the Nasdag First North Growth Market under the ticker symbol **BIOSGN.ST** 

#### **Development stage:**

Clinical trial in patients

# **Regulatory requirement:**

In dialog with regulators in USA and India around IND application IPR protection: Solid Patent family with protection until 2043 in most regions

Team Experience: The company's management consists of Tine Kold Olesen (CEO), Niels Laursen (CFO), Peder Andersen (CMO). All three have 30+ years in pharmaceutical industry. Some of these years have been as successful entrepreneurs in biotech

#### THE PROBLEM

It is estimated that fungal infections kill more than 2.5 million people every year and the number continues to increase. The incidence of fungal infections is increasing because the number of people with weakened immune systems continues to increase. This group includes patients with chronic obstructive lung disease, cancer, HIV/AIDS, and transplant recipients. The WHO is alarmed. The current treatments are insufficient

## THE SOLUTION

Biosergen's mission is to develop the drug candidate BSG005 (polyene macrolide), into the new first line treatment choice for resistant and/or difficult to treat invasive fungal infections, to save thousands of lives every year while generating significant returns to the Company's shareholders. BSG005 is based on two decades of scientific work at NTNU in collaboration with the Biotechnology and Nanomedicine dept. at SINTEF. BSG005 is designed to kill the fungus and have few side effects

#### **COMPETITION / DIFFERENTIATOR**



The three main classes of antifungal drugs today are polyenes, azoles and echinocandins



there is one polyene on the market Amphotericin B that has severe side effects limiting the use of the drug.



• Azoles and echinocandins is inhibiting the fungus and are thereby less effective with a risk of resistance formation to the drug

Class	Agent	Fungus Genus				
		Candida	Aspergillus	Fusarium	Mucor	Cryptococcus
Polyene macrolide (fungicidal - kills)	BSG005	Yes	Yes	Yes	Yes	Yes
	Amphotericin B (Side effect limits the use)	Yes	Yes	Yes	Yes	Yes
Azole (fungistatic – inhibits growth)	Fluconazole	Variable	No	No	No	Yes
	Posaconazole	Variable	Yes	No	No	Yes
	Voriconazole	Yes	Yes	Variable	No	Yes
	Isavuconazole	Yes	Yes	Variable	Variable	Yes
Echinocandin (fungistatic – inhibits growth)	Caspofungin	Yes	Yes	No	No	No



- Only polyenes kill the fungus. Besides BSG005

# **KEY ACHIEVEMENTS:**

- Genetically engineered to a more targeted polyene macrolide
- Shown better safety and efficacy in vivo
- Performed phase 1 in healthy subjects and shown no severe side effects in particular liver and kidney parameters
- Signed a co-development agreement with Alkem LTD

## **TARGET MARKET & POTENTIAL**

The total sales of antifungals for human medicinal use were estimated to be approximately USD 16.7 billion in 2020. Sales are growing by 6-7% per year. Although most serious infections occur in the developing world, the United States and Europe make up approximately 70% of the market.

## VALUE INFLECTIONS POINTS/STEPS

Read out of first 15 patients treated with BSG005, estimated results October 2024.

Production of additional material for further clinical testing October 25

