

Revenue Generating: No

Founded: 2004

Partnering interest/ investor needs:

The company's shares are listed for trading on the Nasdaq First North Growth Market Stockholm 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 6.6 million are affected by fungal infections and more than 2.5 million people die every year. The number continue to increase 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 BSG005 a polyene macrolide, into a new first line treatment choice for resistant and/or difficult to treat invasive fungal strains, setting a new standard for combatting invasive fungal diseases where current therapies fall short and thereby save thousands of lives every year. BSG005 is designed to kill the fungus and have few side effects. BSG005 is based on two decades of scientific work at NTNU in collaboration with the Biotechnology and Nano-medicine department at SINTEF.


COMPETITION / DIFFERENTIATOR



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



- Only polyenes kill the fungus. Besides BSG005 there is one polyene on the market Amphotericin B that has severe side effects limiting the use of the drug.
- Azoles and echinocandins are 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

KEY ACHIEVEMENTS:

- Genetically engineered to a more targeted polyene macrolide
- Shown better safety and efficacy in vivo
- Phase 1 in healthy subjects showed no severe side effects in particular liver and kidney parameters
- Signed a co-development agreement with Alkem LTD
- Two first cohorts in clinical trial enrolled. Eight patients successfully treated. Two patients withdrawn for reasons independently of treatment.

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

IND ult. 2025.
Material for further clinical testing Q42025.
Topline results for Proof of Concept study Q1 2026
Phase 2/3 studies initiated H1 2026

