



Biosergen publishes interim report for the third quarter 2025

November 19, 2024: Biosergen AB ("Biosergen" or the "Company") hereby publishes the interim report for the third quarter 2025. The interim report is available as an attached document and on the company website (www.biosergen.net)

ADVANCING BSG005 TOWARD COHORT 3 AND KEY APPOINTMENTS

Progress in GMP Manufacturing of BSG005 and U.S. IND Submission Preparations

"During the third quarter of 2025, we focused on preparing for the next phase of BSG005's development. The manufacturing of a new GMP-compliant batch is progressing according to plan and will support both Cohort 3 and our upcoming Phase 2 program. This upgraded production process is designed to meet the stringent regulatory standards in all key regions—India, the U.S., and Europe—ensuring global readiness not only for the upcoming clinical phases but also for commercial supply in the years to come. At the same time, we advanced our regulatory strategy, with preparations underway for an IND submission to the U.S. FDA, which we aim to file early next year. We also welcomed Mark Beveridge as Chief Financial Officer, whose expertise will be a valuable asset as we move forward. With these developments, we are building a strong foundation to meet all future production needs while actively expanding our clinical opportunities, ensuring multiple pathways for the continued advancement of BSG005 as a novel antifungal therapy." —Tine Olesen, CEO Biosergen

CONSOLIDATED FINANCIAL HIGHLIGHTS AND RATIOS

TSEK	2025 Jul-Sep	2024 Jul-Sep	2025 Jan-Sep	2024 Jan-Sep	2024 Jan-Dec
Profit/loss					
Other income	131	1,081	2,087	1,560	1.940
Profit/loss before depreciation (EBITDA)	-12,190	-11,149	-28,366	-16,877	-19.203
Operating profit/loss before net financials	-12,190	-11,149	-28,366	-16,877	-19.203
Net financials	22	-78	12	-78	8
Net profit/loss for the period	-12,168	-11,227	-28,354	-16,955	-19.195
Earnings per share (SEK)	-0,05	-0,05	-0,12	-0,18	-0,08
Diluted earnings per share	-0,05	-0,05	-0,12	-0,18	-0,08

Highlights during Q3 2025

- On July 24. Appointment of Mark Beveridge as Chief Financial Officer

CEO STATEMENT

As we have now closed the third quarter of 2025, I am pleased to report that Biosergen continues to advance steadily across all key areas of development.

As you may recall, we completed the second cohort of our BSG005 proof-of-concept trial earlier this year, delivering very encouraging results. Across both cohorts, all patients who completed treatment experienced either full recovery or marked clinical improvement without any severe side effects. These patients were treated for a range of life-threatening fungal infections, including drug-resistant *Aspergillus*, pulmonary *Mucormycosis*, and even co-infections involving both pathogens, cases that typically carry extremely high mortality risks. These results provide compelling proof of concept for BSG005 as a potentially life-saving antifungal therapy.

Due in part to the investigators' willingness to treat patients longer than originally planned, we nearly exhausted our existing stock of BSG005 and have therefore paused the initiation of the third cohort until new drug supply becomes available. This also provided an opportunity to upgrade the BSG005 production process. The new GMP-compliant drug substance is being manufactured not only to support the third cohort but also to meet the higher standards required for our upcoming Phase 2 trials and future global regulatory submissions. This new batch of BSG005 is on track for release in early 2026.

I am especially pleased with this development, as manufacturing BSG005 is far more complex than many realize. As a genetically engineered polyene macrolide, the production process is inherently challenging and further complicated by the need to comply with stringent regulatory requirements across all regions where we expect to operate in the future, including India, the United States, and Europe.

We are engaging with the U.S. Food and Drug Administration. This work is supported by our preclinical data, completed Phase 1 results, and the positive clinical outcomes observed in both patient cohorts to date. These efforts are directed toward the submission of an Investigational New Drug (IND) application early next year, which would represent an important milestone in establishing BSG005's development path in the U.S.

During the quarter, we also strengthened our leadership team. In July, Mark Beveridge joined Biosergen as our new Chief Financial Officer. We warmly welcome Mark to the team and thank his predecessor, Niels Laursen, for his valuable contributions and steady guidance since 2021.

Looking ahead, our priorities are clear: to finalize and release the new BSG005 drug batch, and to continue expanding our regulatory engagements in both Europe and the United States.

I want to thank our investigators, partners, and shareholders for their continued commitment. With each step forward, we move closer to potentially establishing BSG005 as a globally relevant treatment for patients suffering from life-threatening fungal infections.

Sincerely,

Tine Olesen
CEO Biosergen

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The Company's Certified Adviser is Carnegie Investment Bank AB (publ).

ABOUT BIOSERGEN

Biosergen is a biotechnology company in the clinical stage within the therapeutic field of life-threatening fungal diseases. Biosergen' s mission is to develop the drug candidate BSG005, into a new first line treatment choice for resistant and/or difficult to treat invasive fungal infections, to save thousands of lives of immune-compromised cancer- transplant- and AIDS patients every year.