PRESS RELEASE

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ZICCUM AB: key targeted technology developments underpin new strategic focus

Select key technology developments will underpin Ziccum's new strategic focus of generating further data in three vaccine platforms, including mRNA/LNP, so strengthening its position as an attractive industrial partner. The key technology developments will run in parallel with Ziccum's streamlined project program. Chairman Fredrik Sjövall: "These projects will enable and drive forward business development and strengthen the company's offering and data to industrial partners."

Ziccum is now focusing on a targeted program of technology development, in parallel with a streamlined project program targeting three key vaccine platforms. The strategy will focus and drive forward business development and significantly strengthen the company's offering to industrial partners. It will also serve as a foundation for generating new patents – not least in the area of mRNA.

Chairman Fredrik Sjövall: "Our early collaborations and discussions with external parties provided strong guidance on where we should put our focus in terms of technological development in order to increase the probability of entering commercial agreements. For example, we needed to have an industrial conceptual design for LaminarPace (LAPA), so we did that with our Fill and Finish blueprint with KeyPlants. These new targeted developments are also built on key learnings from external collaborations."

Driven by QbD

As it progresses towards its ultimate long-term goal of establishing LaminarPace (LAPA) as an integrated part of the industrial production of vaccines, Ziccum works using a highly focused Quality by Design (QbD) approach. QbD is a systematic risk-based methodology, recognized and encouraged in pharmaceutical manufacture by the FDA, that identifies potential risks and variables in all aspects of product manufacture and development.

The current LAPA system is the fourth generation in development, with several key improvements having been implemented – from critical components and material selection and design (for example Teflon tubing replacing silicon and Nitrogen replacing air to further reduce moisture), to advanced sensor arrays inside the system to map and monitor the flow of the drying procedure itself, to software and control optimization and sealed glovebox collection to ensure the safety of the operator and the product.

Key priority areas in LAPA's development towards eventual GMP industrial manufacturing status include continuing to explore ways to optimize production capacity, reproducibility, reliability, cleanability and sterilization. The current focus areas all impact on these metrics.

KEY TECHNOLOGY DEVELOPMENTS UNDERWAY – AND RECENTLY COMPLETED

New powder collector: Ziccum has now installed a new sealed, contained collection unit that enables the inhouse study of a wider range of test substances. The new unit increases safety, reduces humidity and enables quicker, more efficient collection of drier formulations.

New nitrogen usage: Ziccum has now introduced Nitrogen gas (N2) into the drying column to replace air. N2 is a highly efficient remover of moisture. The first nitrogen-based generation of LAPA is installed and has performed well in tests.

New nebulizer: LAPA has been used throughout its history to dry small amounts of test substance in a lab setting. The system's nebulizer feature is a key component in optimizing the system's capacity, reproducibility and reliability. Ziccum has carried out a first phase in optimizing the nebulization step and is now collaborating with a specialist engineering partner in a second evaluation stage. These external collaborations and partnerships are expected to continue in LAPA' s ongoing development. The current stage of nebulizer development is estimated to be completed by H2 2023.

New membrane: The central membrane in LAPA's drying column is a critical component. Intensive work is currently underway in optimizing the membrane for future GMP compatibility – examining its porosity, mounting and materials for industrial setting. This current development stage will be completed by H2 2023.

Fredrik Sjövall: "LAPA is a highly innovative system with unique capabilities. The projects we are now focusing on are crucial steps towards reaching the industrial production environment - increasing the value of our technology, and therefore the opportunities for it to enter into commercial agreements. The projects will be run in parallel with our evaluation programs together with external partners, and our internal mRNA / LNP work, and will form the basis for new patent applications - both for ourselves and our customers."

For more information about Ziccum, please contact:

Fredrik Sjöval,
Chairman of the Board, Ziccum AB
Mail: sjovall@ziccum.com
Mobile: +46 706 45 08 75

Certified Adviser
Erik Penser Bank AB
Mail: certifiedadviser@penser.se
Phone: +46 8 463 83 00

About Ziccum

Ziccum develops new thermostable versions of the world's most urgently needed, life-saving vaccines. The Company's patented technology, LaminarPace, enables the production of new, gently air-dried formulations that can be transported easily and cost-effectively, with no need for a costly and complicated cold chain, all the way from the factory to the last child in the last mile of the supply chain.

Attachments

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