



PRESS RELEASE

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ZICCUM to publish White Paper on world's first industrial air-drying of vaccines using its LaminarPace technology

The White Paper will describe in detail the integration of Ziccum AB's LaminarPace technology into a Fill and Finish (F/F) manufacturing facility of the world's first plant for formulating and packaging thermostable air-dried vaccines at volume. The new vaccines could be produced at an estimated -65% lower OPEX and -50% lower CAPEX cost than today's freeze drying (lyophilization) F/F plants. The vaccines produced could be stored and transported at ambient temperatures, requiring no Cold Chain.

The vast majority of today's F/F plants – the final stage in vaccine manufacture and distribution - formulate and package vaccines as liquid or lyophilized (freeze-dried) solutions. Both are complex, costly processes requiring energy-intensive freezing or refrigeration. Ziccum AB has now produced a White Paper ~~pilot study~~ that includes costings and a detailed blueprint of a modular F/F plant that would be the first in the world to formulate and package thermostable dry powder vaccines, at volume, that met WHO CTC (Controlled Temperature Chain) requirements. CTC is a specification for vaccines to withstand one trip outside the cold chain for 3 days at 40°C.

The plant has been co-designed by Ziccum collaboration partner KeyPlants AB, a global leader in modular solutions who have designed and produced more than 50 modular projects globally, including F/F vaccine facilities.

The plant is a 36 m x 27 m two-floor modular facility that could be assembled within 24 months on any greenfield site. The waste and cost reductions in particular have attracted interest from key NGOs. The pilot study analyzes the costs of the proposed new air-drying facility in comparison to the standard costs of a current freeze drying, or lyophilization, facility. It found that the proposed plant offers:

80% less energy use. The facility's core air-drying technology, LaminarPace, does not require refrigeration or freezing, including energy-intensive steam, chilled water or Water for Injection, all key elements in lyophilization. 80% energy reduction aligns with UN Strategic Development Goals.

65% less OPEX costs. Half the number of staffs would be required to run an air-dried facility compared to a freeze-drying one, calculated at 200 days of operation/year and 65% usage of utilities.

50% less CAPEX costs. Lyophilization is capital- as well as energy-intensive. Typically, it can take three days at minus 80 degrees C to minus 40 degrees C using large-scale capital equipment that

needs to be washed between each batch using cubic meters of the solvent Water-for-Injection, which is itself expensive to generate.

A typical process yield of 80%. This is in sharp contrast to lyophilization, where a 0.5 – 0.7 log titer reduction is not uncommon, resulting in the end production of only 20% effective vaccine. In much lyophilization stabilizing additives need to be added to manage these losses, with five times more vaccine bulk needing to be produced to compensate for losses specifically due to lyophilization. Overall, waste is an urgent challenge in vaccine manufacture. The WHO estimates that more than 50% of vaccines may be wasted globally every year because of temperature control, logistics and shipment-related issues.

The Fill and Finish machine itself, installed within an aseptic isolator room, could process between 20-30 million vials of vaccine per year, formulating 20–300 million individual dried vaccines doses (depending on number of doses per vial).

The active dry vaccine powder produced will be blended with bulking agent then compacted into a 10 cubic mm (0.01 cubic cm) dry-powder plug. Ziccum is exploring offering a range of administration route packages—including a dual blister pack for injection (one chamber containing the plug, the other sterilized water for rehydration) to non-injectables such as Microarray patches. The *active dry powder* plug of vaccine itself, able to be transported and stored for extended periods without refrigeration, remains at the core of the operation. The White Paper is attracting interest from some leading vaccine NGOs.

Ziccum CEO Göran Conradson: ““This is an idea whose time has come. When we scale up LaminarPace, our dry-formulation technology, we also scale up its signature benefits, producing a low-waste competitive solution that can produce cost-effective, affordable vaccines – at volume - that meet WHO CTC requirements.

“And let’s remember, at its core, air-drying is not a new technology. We all consume many of life’s essentials in dry form every day, without even thinking about it, because that way they can reach more people, quickly and cost-effectively. So why can’t we do the same with vaccines? The fact is, we can. With 1.5 million children a year dying from vaccine-preventable diseases, and the need for vaccines growing urgently worldwide, we all know *why* we need to improve vaccine coverage. I believe this pilot study now shows us *how*.”

The complete White Paper will be released on www.ziccum.com within the next two weeks.

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About Ziccum

Ziccum AB (publ) develops new patented formulations of vaccines where sensitivity to temperature differences, especially during transportation, currently limits medical and so commercial potential. The company's patented technology, LaminarPace, develops dry powder formulations of vaccines that currently only exist in liquid, or in lyophilized form. By doing so Ziccum can increase the availability of drugs and vaccines in existing markets—and open up new ones.

This press release has been submitted for publication by the company's CEO at 08.00 (CET) on Monday 19 October 2020.