

Set vaccines free

Vaccines formulated as dry powders can be transported
anywhere in the world, to every child in the world

With no cold chain required

Introduction

Who we are?



Ziccum

- Technology
- Where is Ziccum going?



Background

- LaminarPace technology developed at Inhalation Sciences AB
 - Micronized powder for inhalation
 - Early test with animal vaccines showed great temperature stability
- Technology spun-out into a newly created company: Ziccum AB
 - 2017



LaminarPace Process (LAPA): Countercurrent spray dryer with separate flows



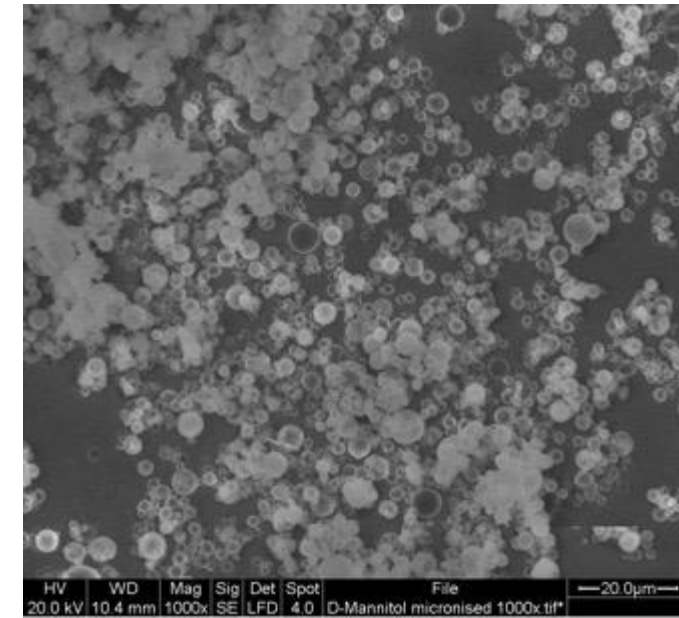
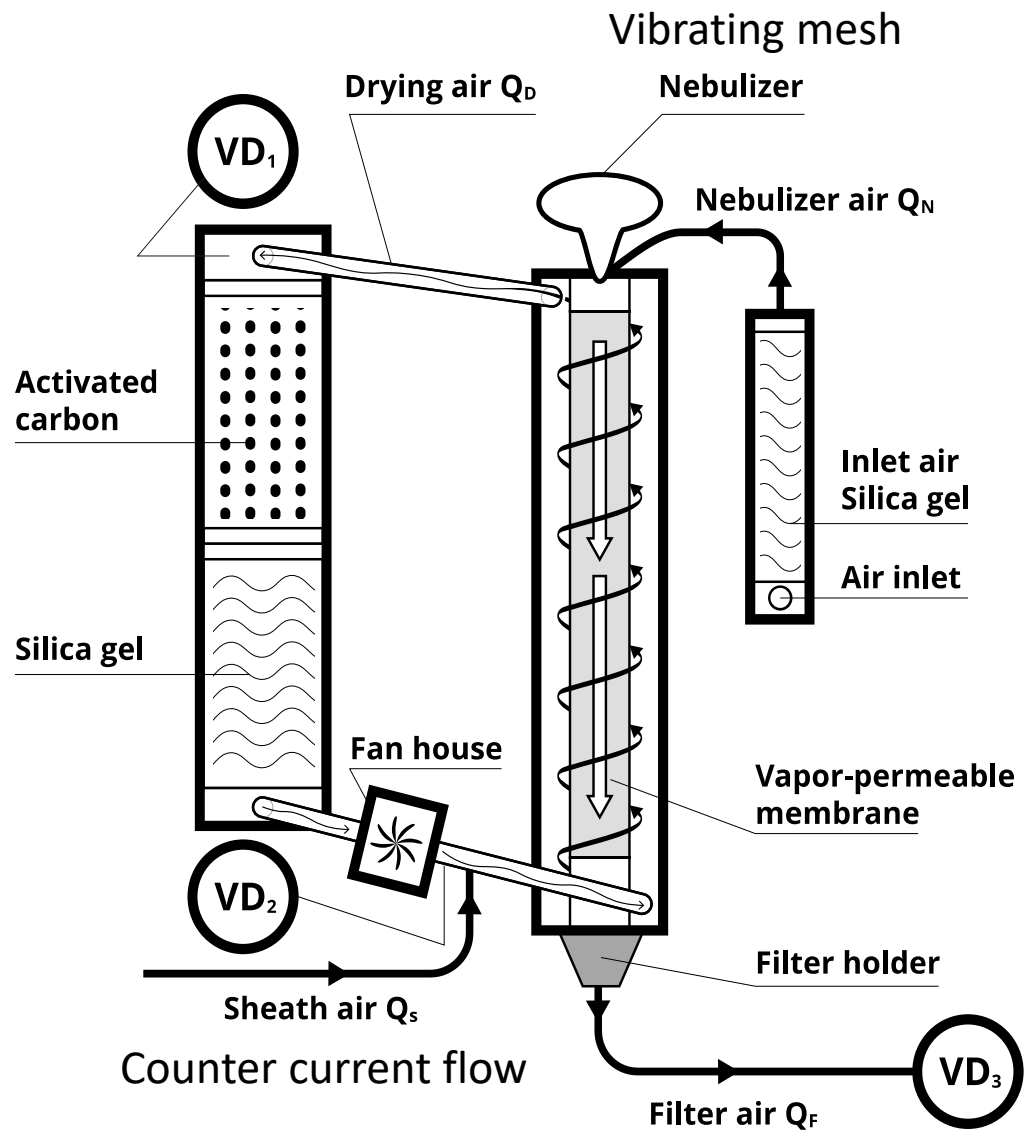
- Room temperature
- Gentle aerosolization

Reduction of the stress of the process

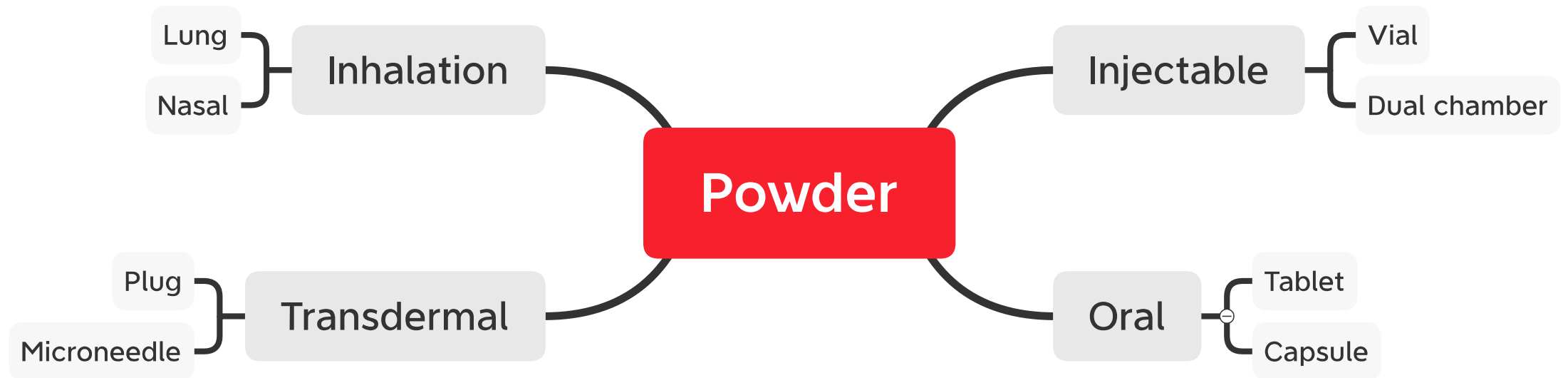
- High yield process (>80%)
- Well defined micronized powder size
- Aseptic process
- Reduction of energy cost

Productivity

LaminarPace Process:



Particle engineering



Dry powder

Theory on stabilization of biologics by sugar in solid state:

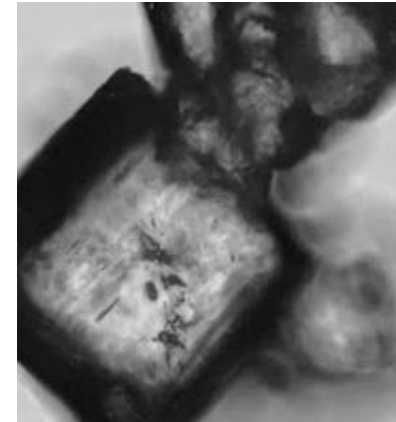
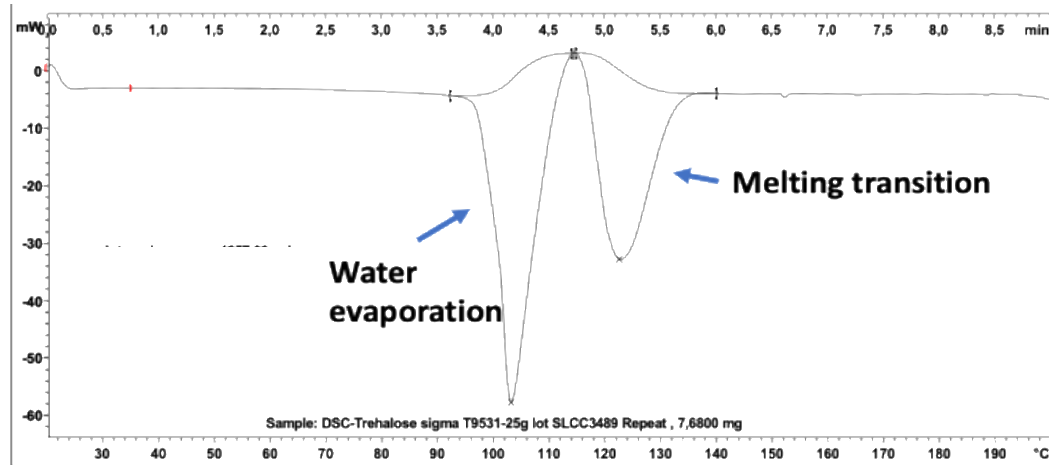
Two theories of the mechanism of stabilization of biologics with sugar matrix in amorphous state:

- The vitrification theory
- Water replacement theory.

The glass transition temperature (T_g) is one characteristic of the glassy state, and is determined by differential scanning calorimetry (DSC).

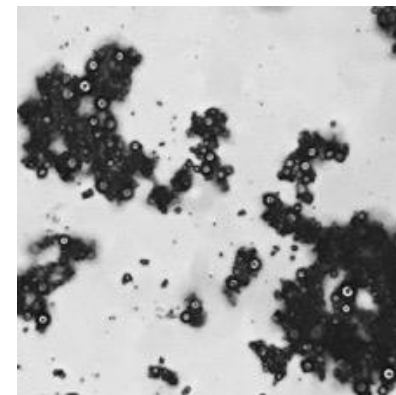
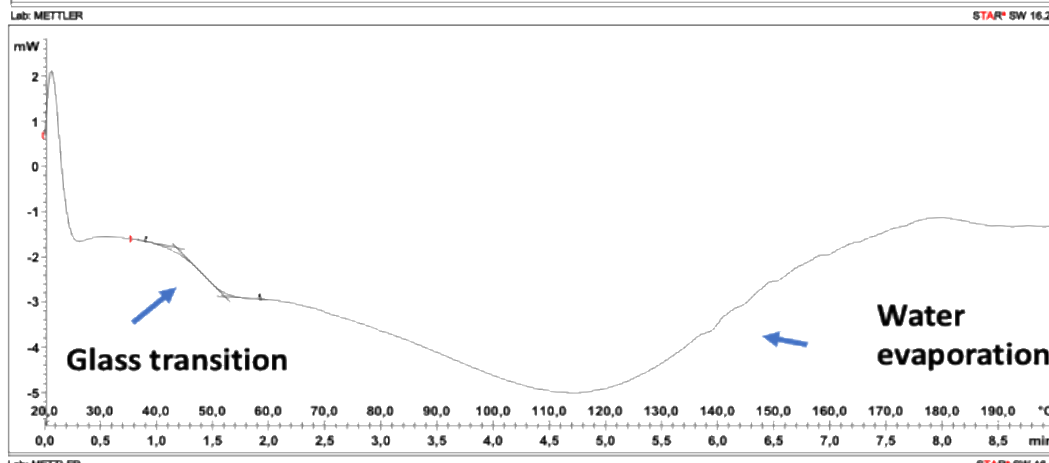
Trehalose shows a typical glass transition after LaminarPace drying

Before
Spray
drying



Light
microscopy
of Dihydrate
trehalose

After
Spray
drying



Light
microscopy
of spray
dried
trehalose

Quality by design approach:

FDA guidance describes the quality by design:

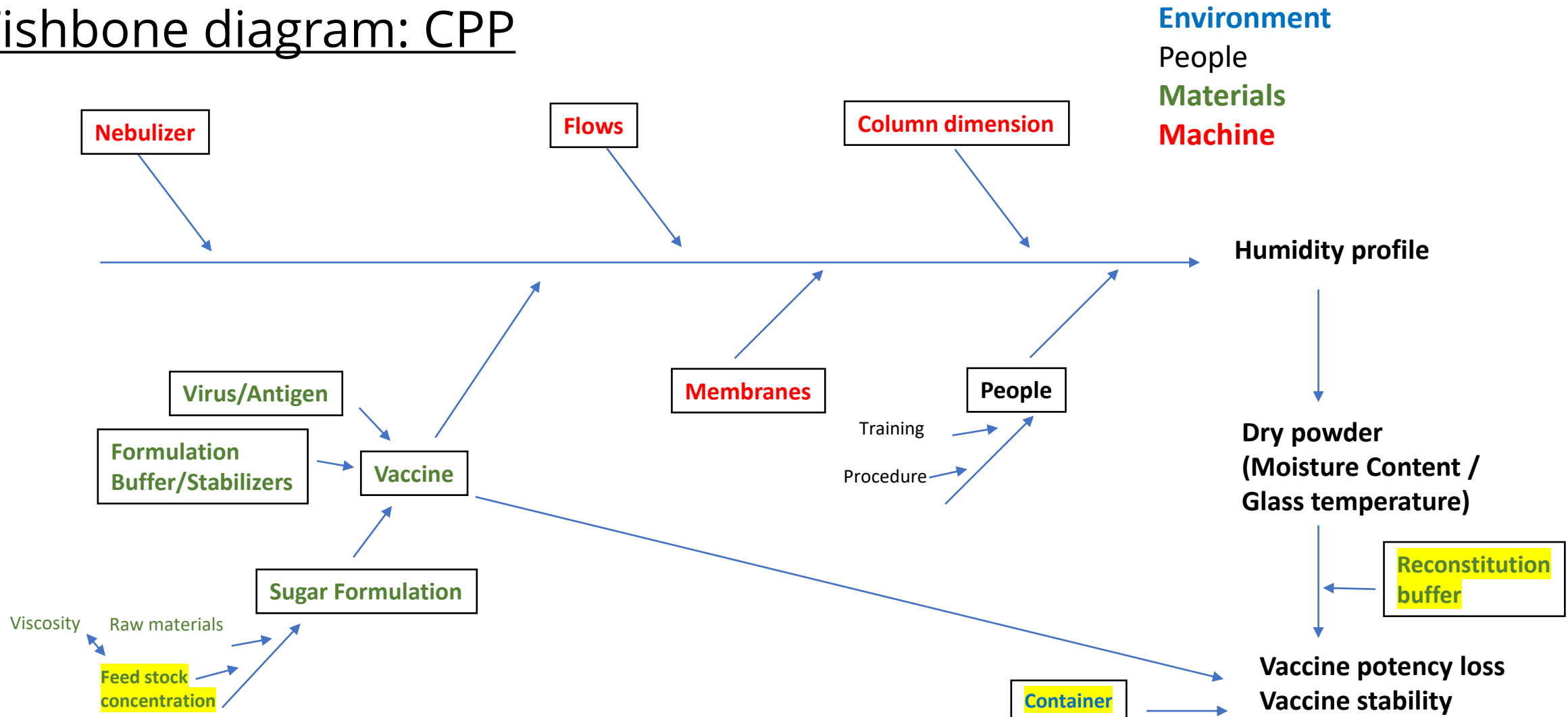
Quality by design means designing and developing manufacturing processes during the product development stage to consistently ensure a predefined quality at the end of the manufacturing process.

Process → Risk analysis → Design of experiment → Design space definition



Quality by Design

Fishbone diagram: CPP



QTPP : Quality target product profile

Powder

- Glass transition temperature
- Moisture content
- Size

Vaccine

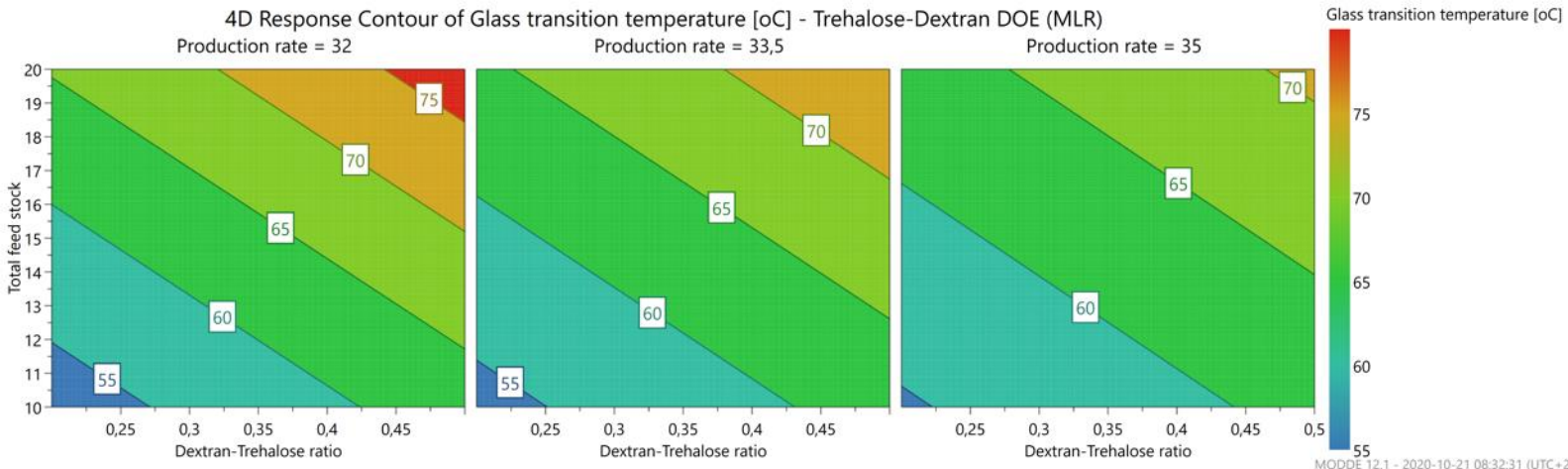
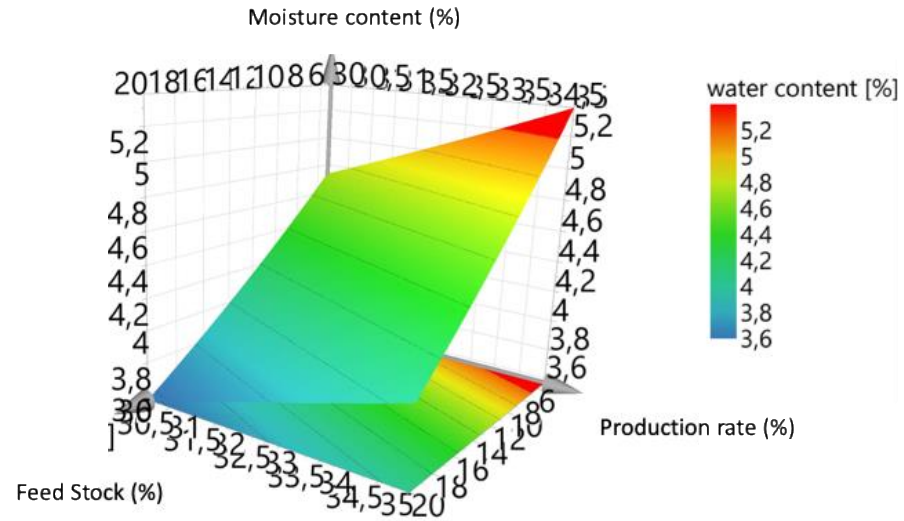
- Potency
- Immunogenicity
- Titer/Count
- Integrity
- In vivo study
- Stability (CTC)

Quality by Design

Design of experiments:

Process optimization:

Formulation optimization:

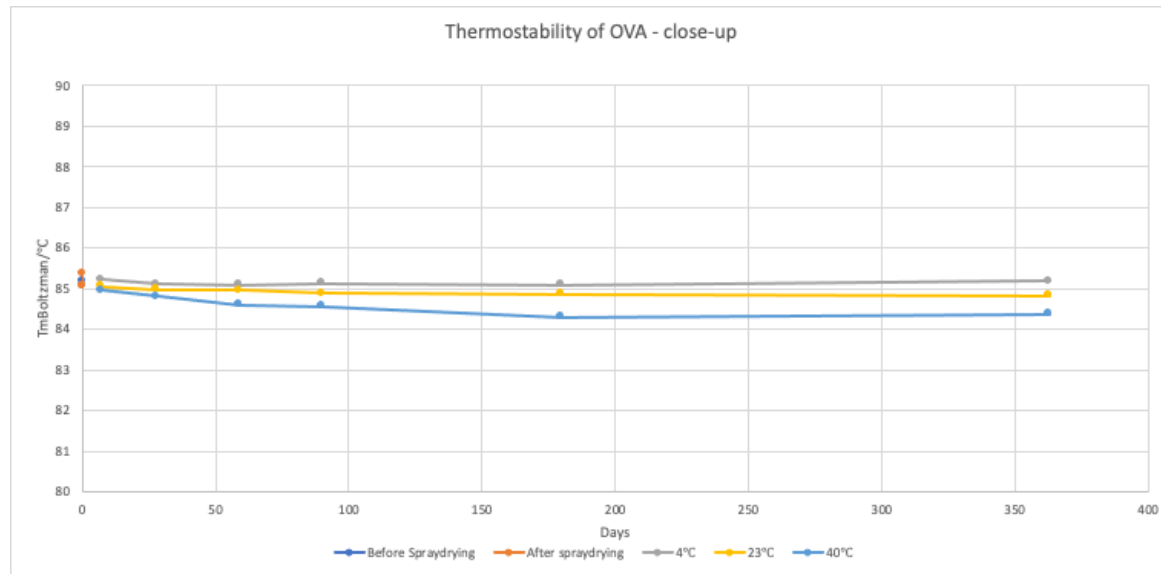


Different vaccine technologies are in development through different collaborations using the LaminarPace technology:

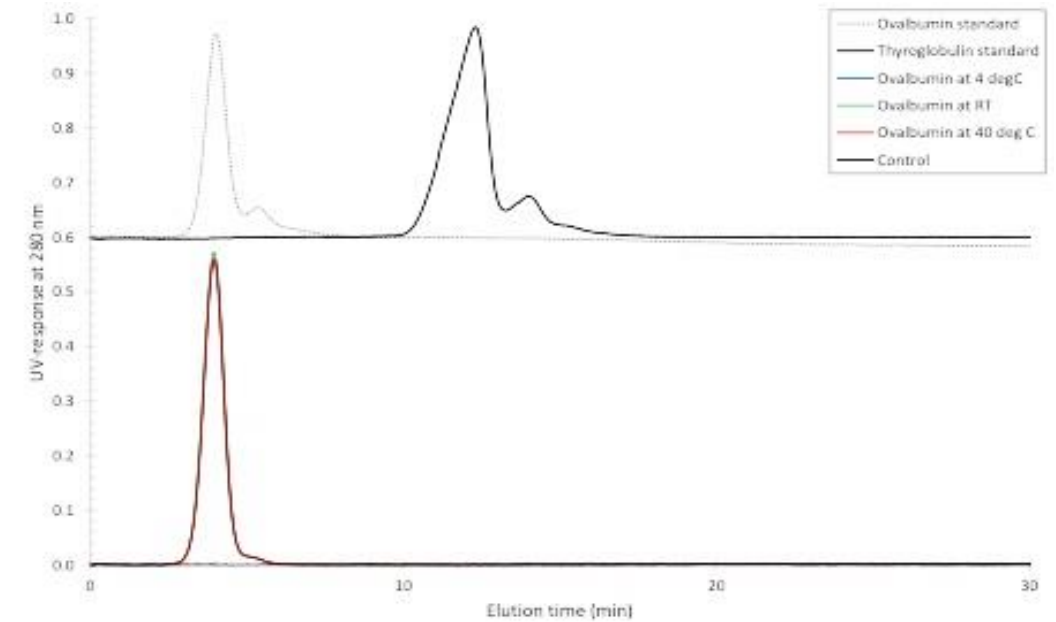
- Inactivated vaccines
- Live attenuated vaccines
- Viral vectors
- Sub-unit vaccines
- LNP (mRNA)
- VLP
- New adjuvants technologies

Stability assessment of spray dried formulation containing Ovalbumin:

Thermal shift assay:



AF4/MALS:



Good stability for at least 360 days at 40°C and no aggregation after reconstitution.

Business model



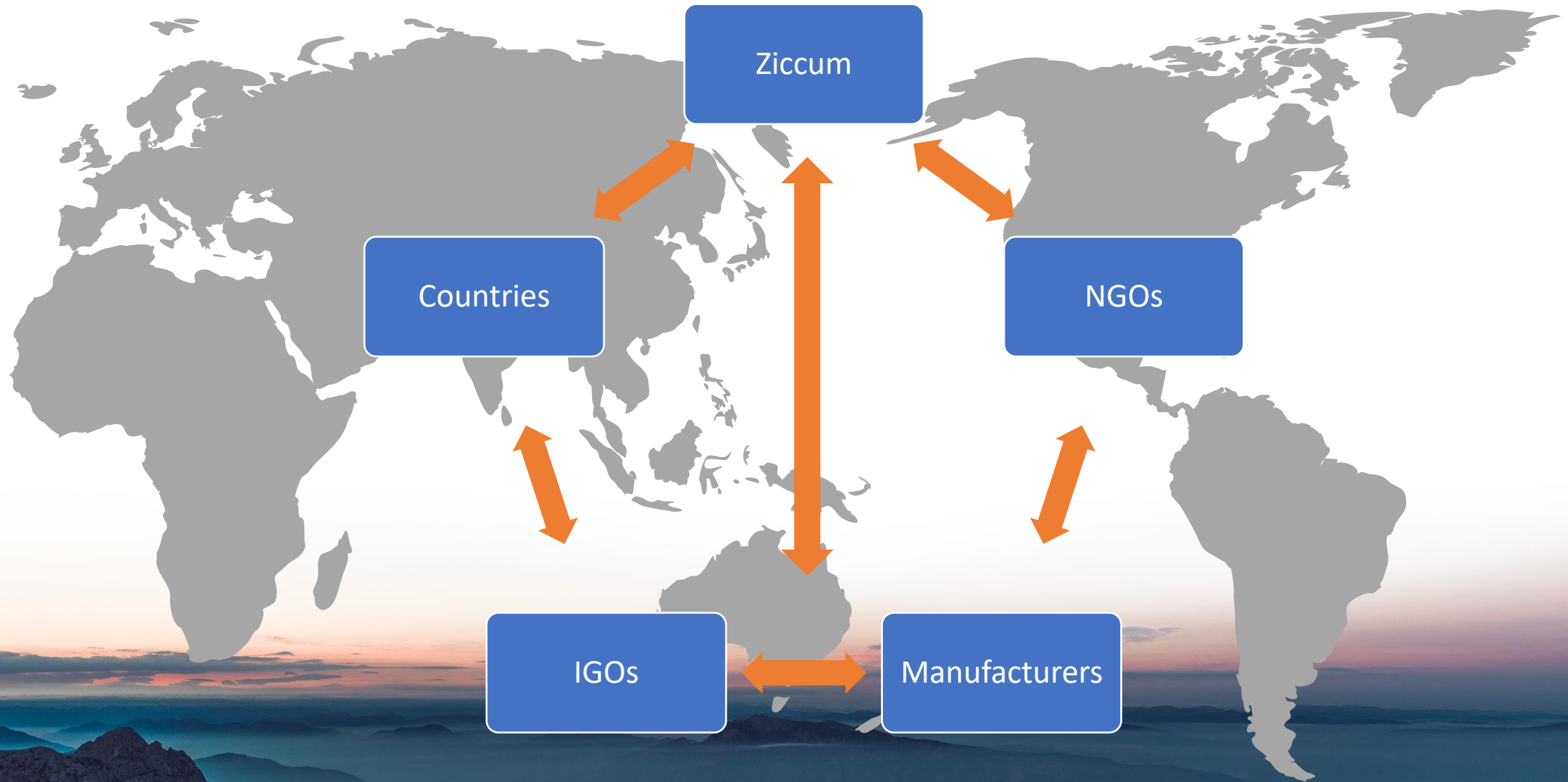
Plant

- Expanded revenue stream
- Expanding WW Fill & Finish capacity
- Equitable access to vaccines

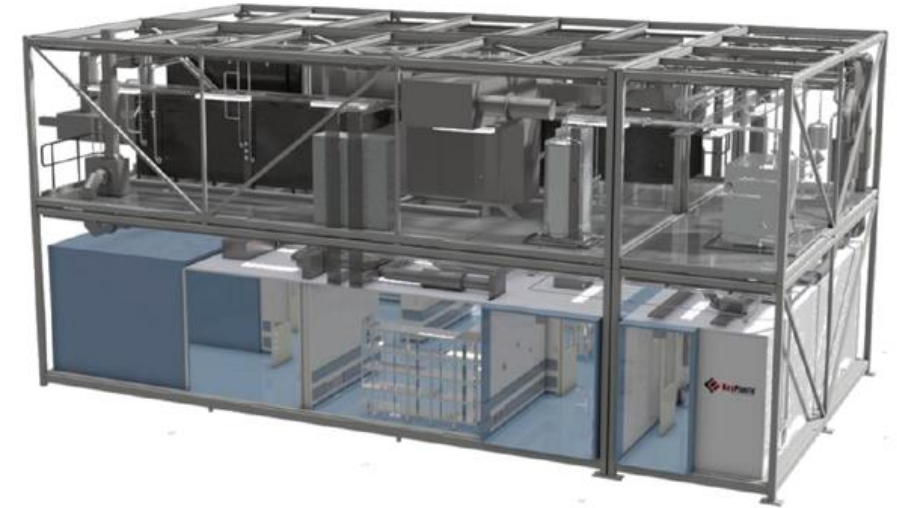
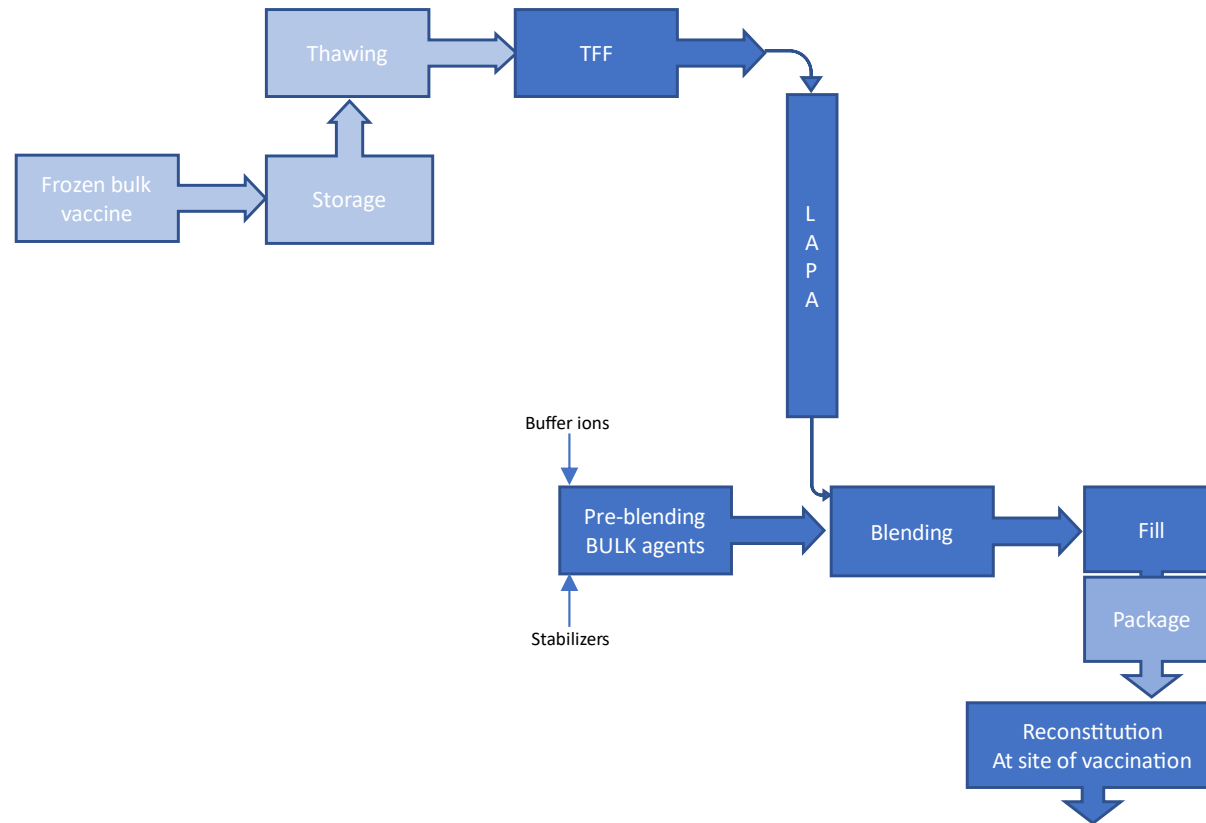
Licensing

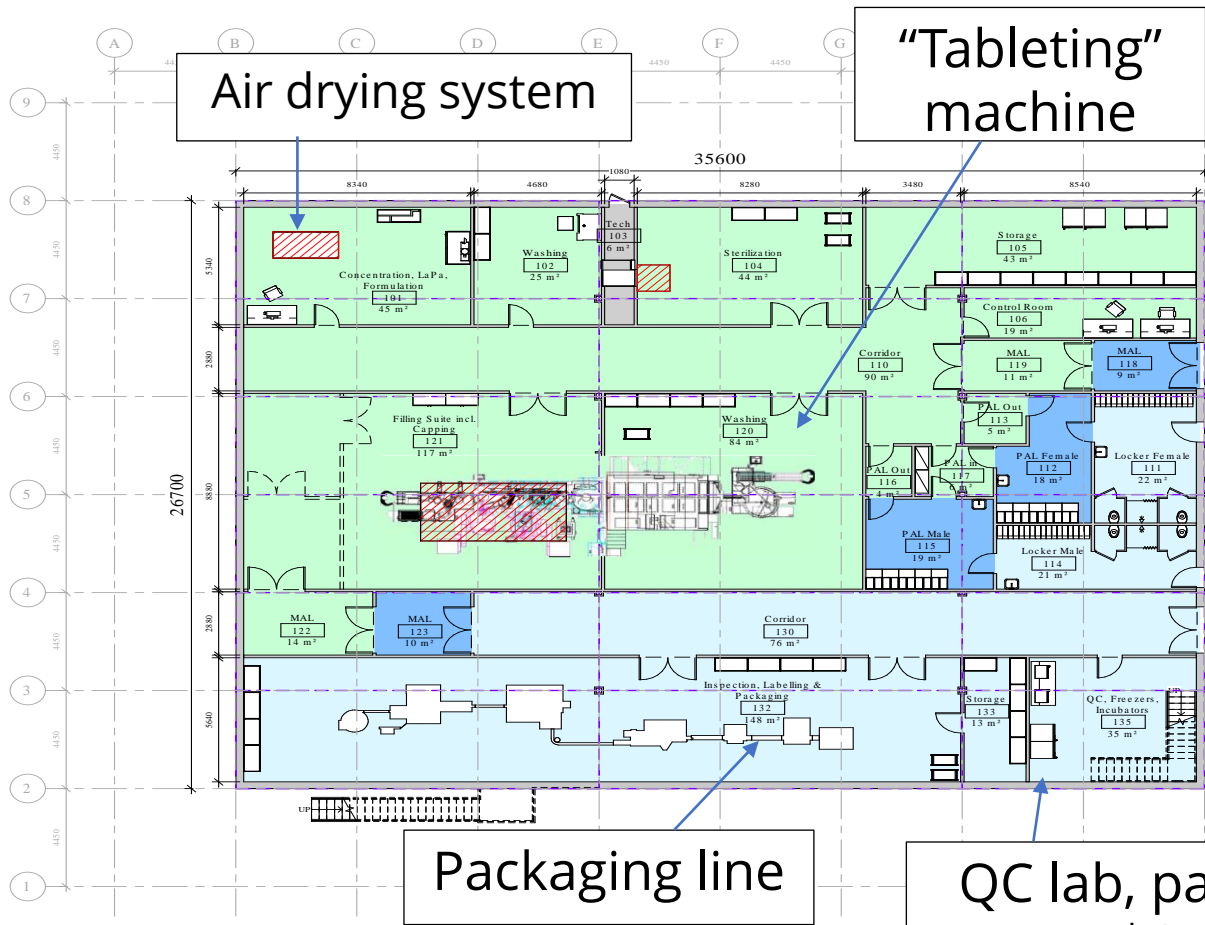
- Basic model
- Several Patent and patent applications

New temperature stable vaccine – requires a collaborative effort



Fill and finish concept





CLEAN ROOM CLASSIFICATION
ISO 14644 **EU GMP** **FDA**

	In operation	At rest	Operation
CLASS 5	CLASS 5	GRADE A	CLASS 100
CLASS 7	CLASS 5	GRADE B	CLASS 10 000
CLASS 8	CLASS 7	GRADE C	CLASS 100 000
NOT DEFINED	CLASS 8	GRADE D	NOT DEFINED
CONTROLLED NOT CLASSIFIED			
UNCLASSIFIED			

CLEAN AIR PROTECTION

101	102	103
104	105	106
107	108	109
110	111	112
113	114	115
116	117	118

First Floor: 18 modules

CLIENT: **ZICcum**

KeyPlants®
 Lilla Rosengården 15, SE-111 23 Stockholm, SWEDEN

PROJECT NAME:
Fill & Finish

PROJECT NO:
SE499C

CLIENT DRAWING NO:

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DATE: 2020-07-06 DRAWN BY: KRL CHECK BY: ASJ APPROVED BY: KJJ

DRAWING TYPE:
Equipment Layout Level 1

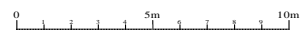
DRAWING OBJECT:
**FILL & FINISH
 PROCESS FLOOR**

DOCUMENT STATUS:
CONCEPTUAL DESIGN

DRAWING NO:
SE499-A-DWG-0003

SCALE:
A1 1 : 100

REVISION:
1.0



Modular concept for Fill & Finish Plant

- Ziccum commissioned KeyPlants AB for a Conceptual Design of a Fill & Finish plant using bulk drug substance
- Key findings in comparison with lyophilisation:
 - 80% reduction of energy
 - 67% reduction in OPEX
 - 50% reduction in CAPEX
- 20 – 30 million vials per year and plant
 - 1 – 10 doses per vial => 20 – 300 million doses/year and plant
- Foot print of plant: 26 x 37 m \approx 1 000 m² in 2 floors
- Estimated costs: \approx 40 – 50 MUSD
- Estimated timeframe to establish first plant: \approx 26 months
- Ref, please read our White Paper and visit KeyPlants web site:
 - <https://ziccum.com/resources/>
 - <https://keyplants.com>

Peace time – War time

Peace Time

- Children's vaccines
- Stock piling
- Training and educational site
- Tech transfer

War Time

- Switch to F&F of Pandemic vaccines
- Process design and development
- Clinical materials



The Company

- Listed on Nasdaq First North GM
 - Ticker: ZICC
- Cash: 4,8 MUSD (Q12021)
- Company established 2017 with the core technology, LaminarPace air-drying, as a spin-out from Inhalation Sciences AB
 - Refocusing the core technology from inhalation of small molecules drugs to formulating temperature stable dry powder vaccine
- ≈ 10 people in total
- 3 industrial collaborations
 - Janssen
- Approved and valid IP on LAPA, several new patent applications submitted
- The company is focusing on developing an industrial, aseptic system for GMP use
- 1 academic collaboration Aix-Mediterranean University, Marseille, France
- Located in Lund, Sweden



The board



Andreas Pettersson



Kristian Kirkegaard



Mikaela Bruhammar



Fredrik Sjövall, Chairman



Mattias Münnich



Thank you!

