

Univercells | Quantom Biosciences
WHO/MPP mRNA Technology Transfer Programme

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Cape Town – 18 April, 2023

A biotechnology **Group of Affiliates** on a common mission



Since 2013: **Biologics for All**
Proven track record in **scaling production** and **bioprocessing**

Technology-driven affordability to support access and promote sustainability
Addressing the needs of the **health value chain**

500
people

From 40
nationalities

+250
million EUR

In equity & non-
dilutive funding



//Adjuvant
Capital

KKR

BILL & MELINDA
GATES foundation

3 interconnected business models to make biologics available to all



Technology

- Cutting-edge, scalable technology portfolio to enable partners to achieve **low cost, low footprint, high-quality and high-performance production**
- Applications in **viral production, RNA and DNA** from **R&D to commercial**



 **UNIVERCELLS**
Technologies




Quantum
Biosciences

CRDMO

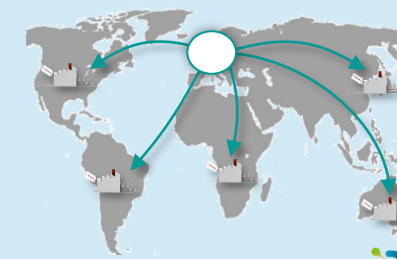
- From **pre-clinical to commercial GMP capabilities** and product development expertise for **viral products** and **nucleic acids-based vaccines and therapies**
- Designing and operating bespoke **bioproduction hubs with state-of-the-art technology**



 **exothera**

Advisory

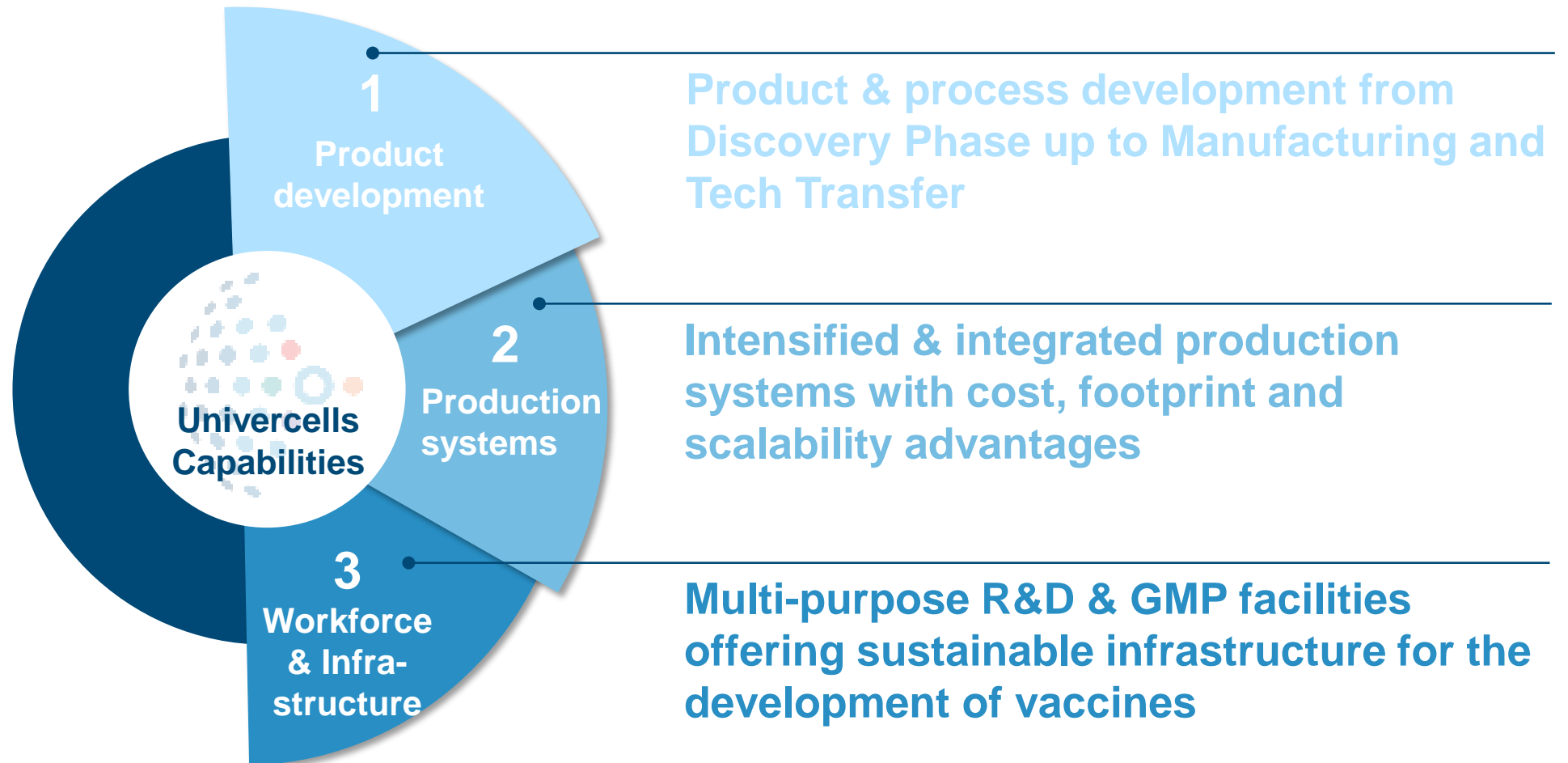
- Turnkey services to **support emerging players** wherever biologics can make a difference, making **local bioproduction a reality**
- Offering spans **from design to operations** of bioproduction sites, incl. **tech transfer, workforce development, and regulatory**



 **unizima**

 **RLM consulting**

Univercells has a **unique set of capabilities** under one roof



Univercells as a **trusted partner** on the vaccine development journey

35+

Projects

DRUG DISCOVERY

PRE-CLINICAL

CLINICAL DEVELOPMENT

COMMERCIAL

- In vitro & in vivo non-clinical devt
- Network of CROs

- Process devt & Characterization
- GMP manufacturing
- Analytical devt + QC
- Regulatory Support

- Drug product & substance manufacturing (incl. F&F)
- Process Industrialization & Validation

mRNA Discovery Workflow

Antigen Discovery

Antigen Definition

Constructs Design

Constructs Screening

Candidate Screening

Formulation Screening

In vivo studies

- Target Antigen Profile

- In silico design of complete RNA construct

- DNA templates synthesis, assembly, clonal selection & amplification
- mRNA IVT & purification
- Analytical testing

- Production of DNA templates
- Production of mRNA's
- Analytical testing

- Optimization via DoE & machine learning

- Design of *in vivo* strategy
- Support for CRO selection

Several tens of candidate

Up to 32 High-throughput

Up to 8 High-throughput

75 diff LNP/week

Biomanufacturing technologies developed by Univercells based on proven Intensification & Chaining fundamentals

UNIVERCELLS ENGINEERING APPROACH



INTENSIFICATION
for high performance
operations



CHAINING
of unit operations for
automated, integrated
& continuous processing

R&D *Scale-up* → GMP *Scale-up* → Commercial

VIRAL

Scale-X™ + NevoLine™ - fixed-bed bioreactor and upstream platform for scalable viral production



[scale-X cell collect]

Streamlined bioreactor-to-bioreactor seed train



[carbo]

Low-footprint, intermediate-scale process development and GMP production



[hydro]

Small-scale production for early-stage process development



[nitro]
NevoLine™ Upstream

Late-stage clinical trials and commercial scale manufacture system

DNA / RNA

Nfinity™ platform - Technologies and reagent pre-mixes to deliver formulated RNA from DNA at all development stages



Ntensify™ Mini

R&D system
Dual application for drug discovery and pre-clinical phase



Nplify

Cell-free DNA production



Ntensify™ Midi

Clinical Phases & annual production



Ntensify™ Maxi
Clinical Phase III &
Commercial Production

OUR DESIGN PRINCIPLES FOR mRNA



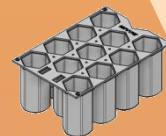
Optimized IVT with single-step purification

Redesigned and optimized for above-standard yields and product quality



Ready-To-Use Reagent Pre-mixes

Contain all the process know-how for maximized output performance



Disposables at max 20mL scale

Enable the operations at small scale for massive capacity



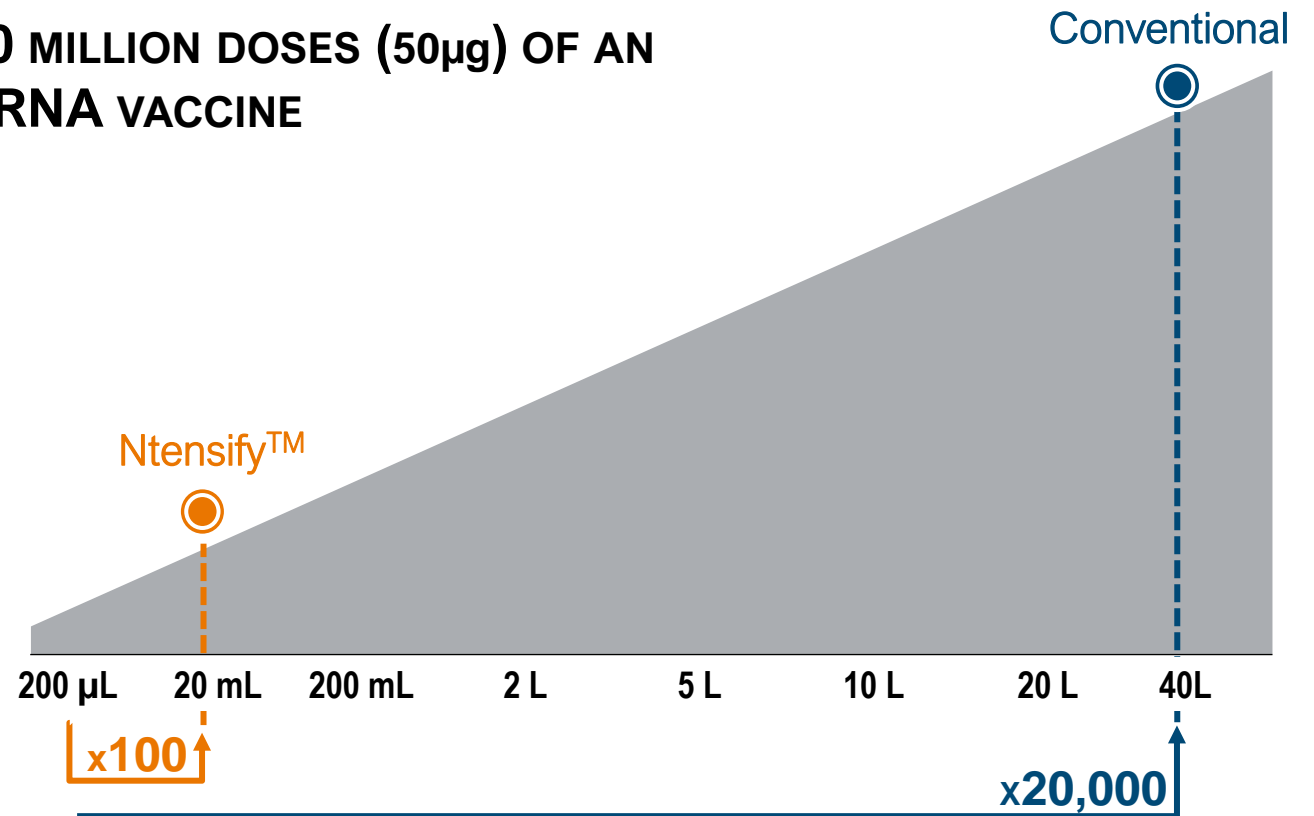
Integration in an automated system

Automates process step operations for high scalability

NO SCALE-UP NEEDED

- Final scale is 20mL, no further process development required
- No need to invest in raw materials and FTE to demonstrate scale-up to 40L
- Product development acceleration, reduced time to market

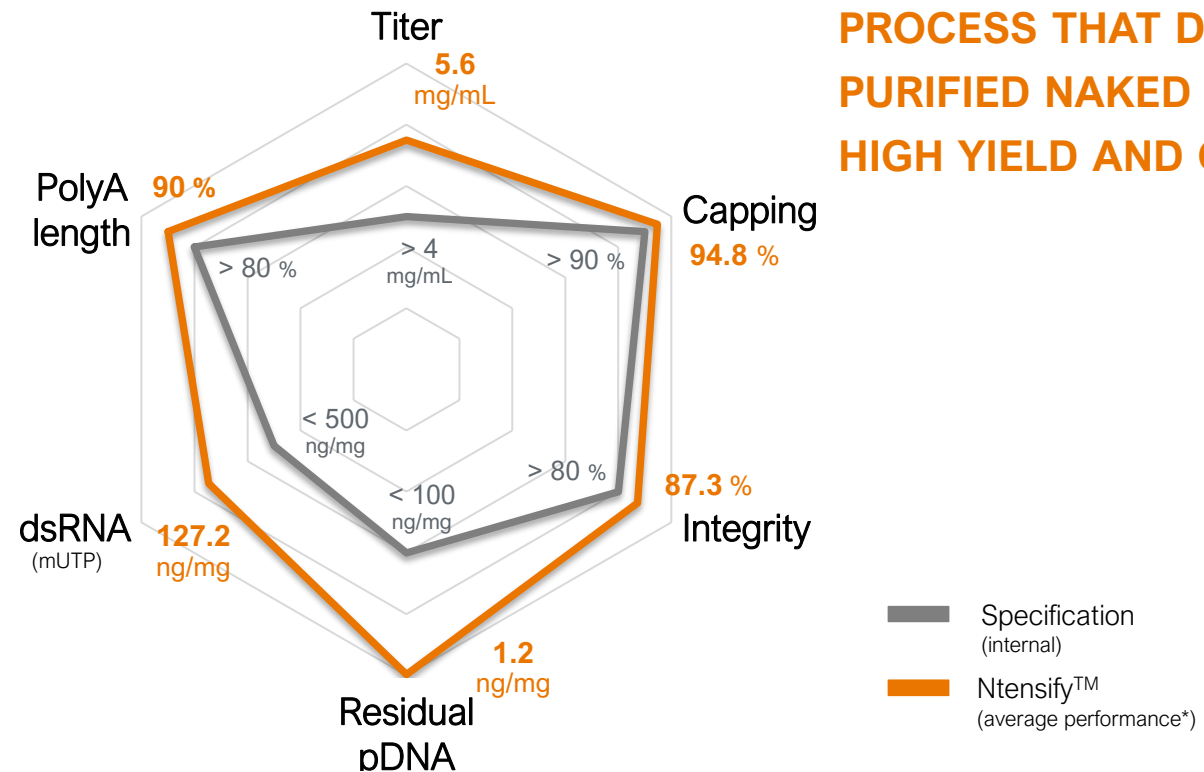
FOR AN ANNUAL PRODUCTION OF 50 MILLION DOSES (50µg) OF AN mRNA VACCINE



DE-RISKED MRNA CONSTRUCT-AGNOSTIC PROCESS

- One process optimized through 250 reactions, tested on 45 constructs from 998nt to 10,865nt
- Quality by Design IVT to eliminate the need for complex purification
- Optimum between productivity and impurities with a single-step purification

**CONSTRUCT-AGNOSTIC
PROCESS THAT DELIVERS
PURIFIED NAKED RNA WITH
HIGH YIELD AND QUALITY**

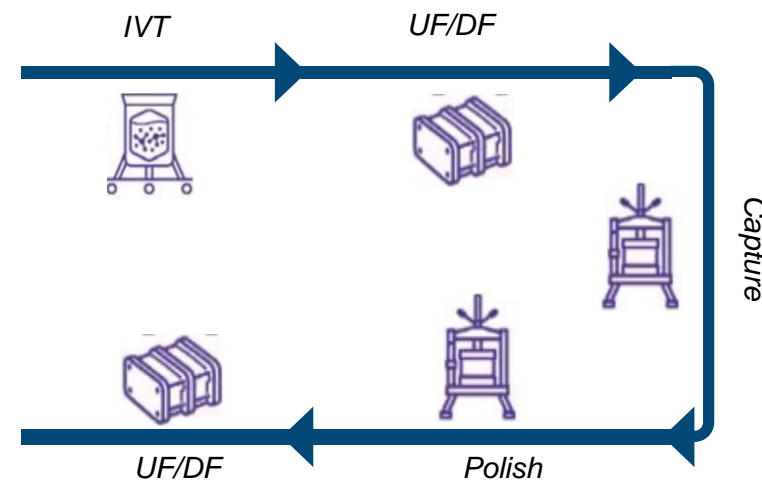


* Not all parameters were tested on every run ; Constructs up to 10,865 nucleotides

SIMPLIFIED & AUTOMATED WORKFLOW

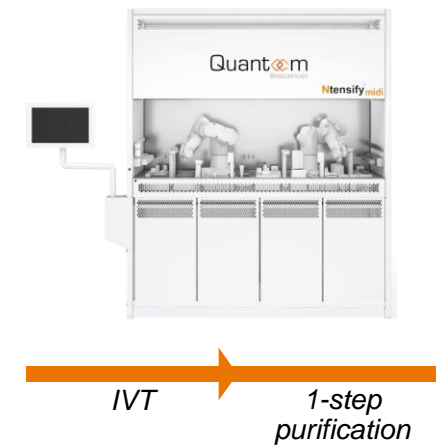
- Both IVT and purification steps integrated in a one fully automated system
- Low footprint facility with a Box-in-a-box (container-based) lab compatibility
- Direct impact on the level of capital investment (CAPEX)

Conventional



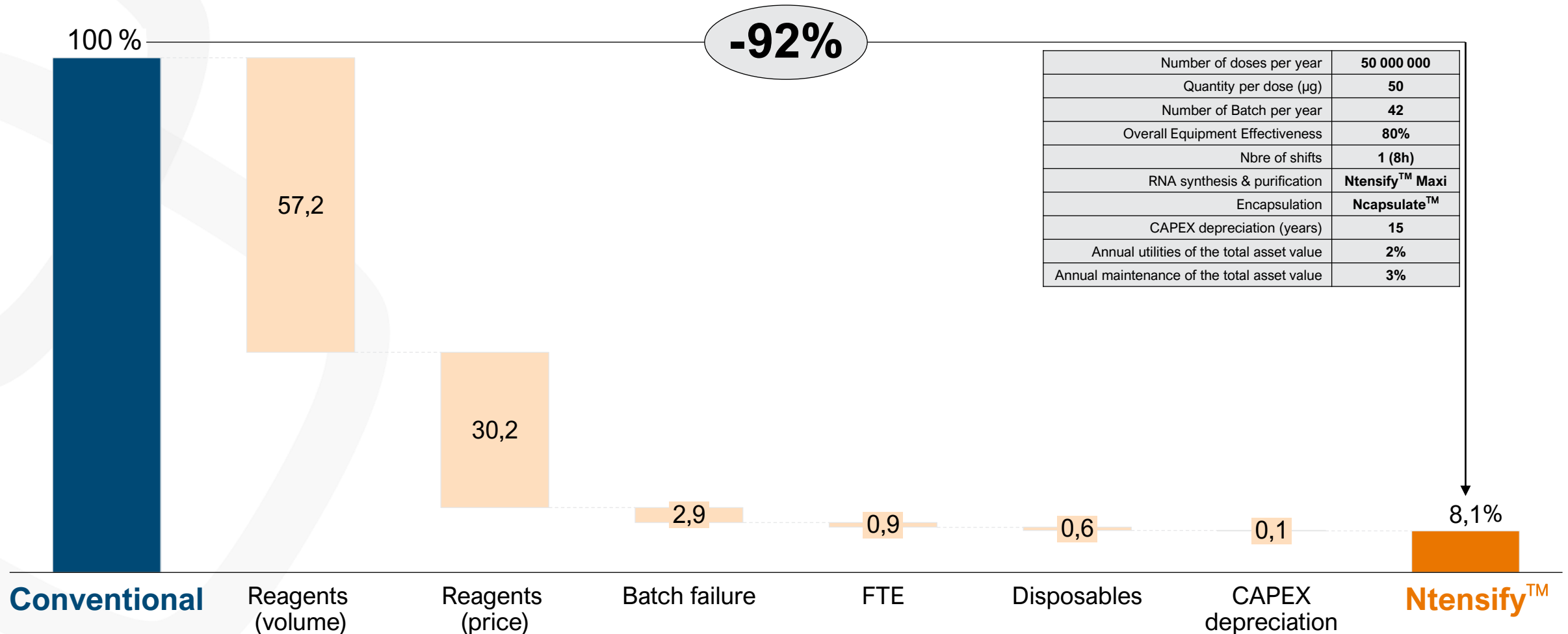
Ntensify™

- 1 fully automated system
- 1 optimized process
- 1 purification step



EXPECTED SAVINGS WITH OUR APPROACH

FOR AN ANNUAL PRODUCTION OF 50 MILLION DOSES (50µg) OF AN MRNA VACCINE



Ntensify™

A DE-RISKED, FAST
AND COST-EFFICIENT
SOLUTION TO MRNA
MANUFACTURING

Ntensify™ Midi INSTALLED AT AFRIGEN



**Thank you
for your attention!**

