



BIONTAINER

by BIONTECH

Introducing a scalable manufacturing solution for Africa

Press Conference

16 February 2022

This slide presentation includes forward-looking statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include, but may not be limited to, direct or indirect statements concerning: the ability of BioNTech to produce, deliver and install mRNA container manufacturing facilities for the African continent, including the ability to meet all necessary infrastructure, technology and regulatory requirements; the ability of BioNTech to reach an agreement with potential collaboration partners in Africa to establish an end-to-end manufacturing network in Africa; the development of quality assurance capabilities to remotely support manufacturing sites in Africa; the scale-up of local know-how and training in Africa; BioNTech's malaria, tuberculosis and other infectious disease vaccine development programs; timing for selecting clinical candidates for these programs and the commencement of a clinical trial, as well as any data readouts; the nature of the collaboration with the African Union, the Africa CDC, and the WHO; the development of sustainable RNA vaccine capacities, production and supply solutions on the African continent and the nature, timing, and feasibility of these solutions; the potential safety and efficacy of the product candidates; and BioNTech's anticipated market opportunity and size for its product candidates the rate and degree of market acceptance of BioNTech's investigational medicines, if approved; BioNTech's efforts to combat COVID-19; the collaboration between BioNTech and Pfizer to develop a COVID-19 vaccine (including qualitative assessments of available data, potential benefits, expectations for clinical trials, supply agreements and the timing of delivery of doses thereunder, efforts to help ensure global equitable access to the vaccine, the anticipated timing of regulatory submissions, regulatory approvals or authorizations and anticipated manufacturing, distribution and supply). Any forward-looking statements in this presentation are based on BioNTech current expectations and beliefs of future events, and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to: discussions with regulatory agencies regarding timing and requirements for additional clinical trials; and the ability to produce comparable clinical results in future clinical trials.

For a discussion of these and other risks and uncertainties, see BioNTech's Annual Report on Form 20-F for the Year Ended December 31, 2020, filed with the SEC on March 30, 2021, which is available on the SEC's website at www.sec.gov. All information in this presentation is as of the date of the release, and BioNTech undertakes no duty to update this information unless required by law.

Marburg is our largest manufacturing site

BioNTech's Marburg site is
one of the largest mRNA vaccine manufacturing sites

Supply of mRNA for more than
1.2 bn doses of the COVID-19 vaccine
in 2021 as part of a European manufacturing network

50% boost in staff planned
in 2022 (+ 250 jobs)

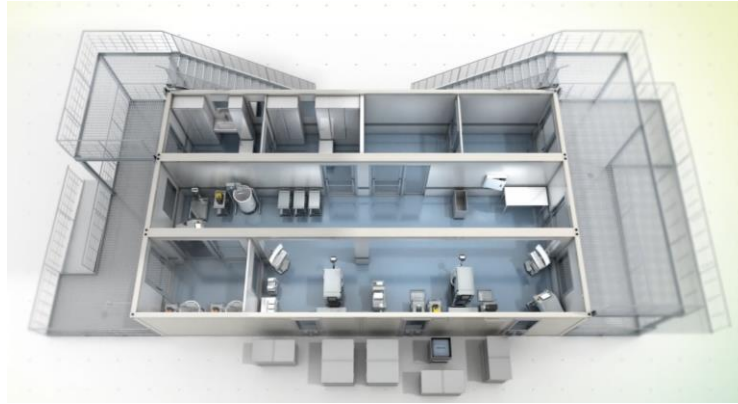
~ EUR 50 million
to be invested in Marburg site in 2022

Manufacturing innovations made in Marburg



Manufacturing Center

State-of-the-art, large-scale GMP-compliant vaccine production



Innovation Center

Development of novel manufacturing solutions



Excellence Center

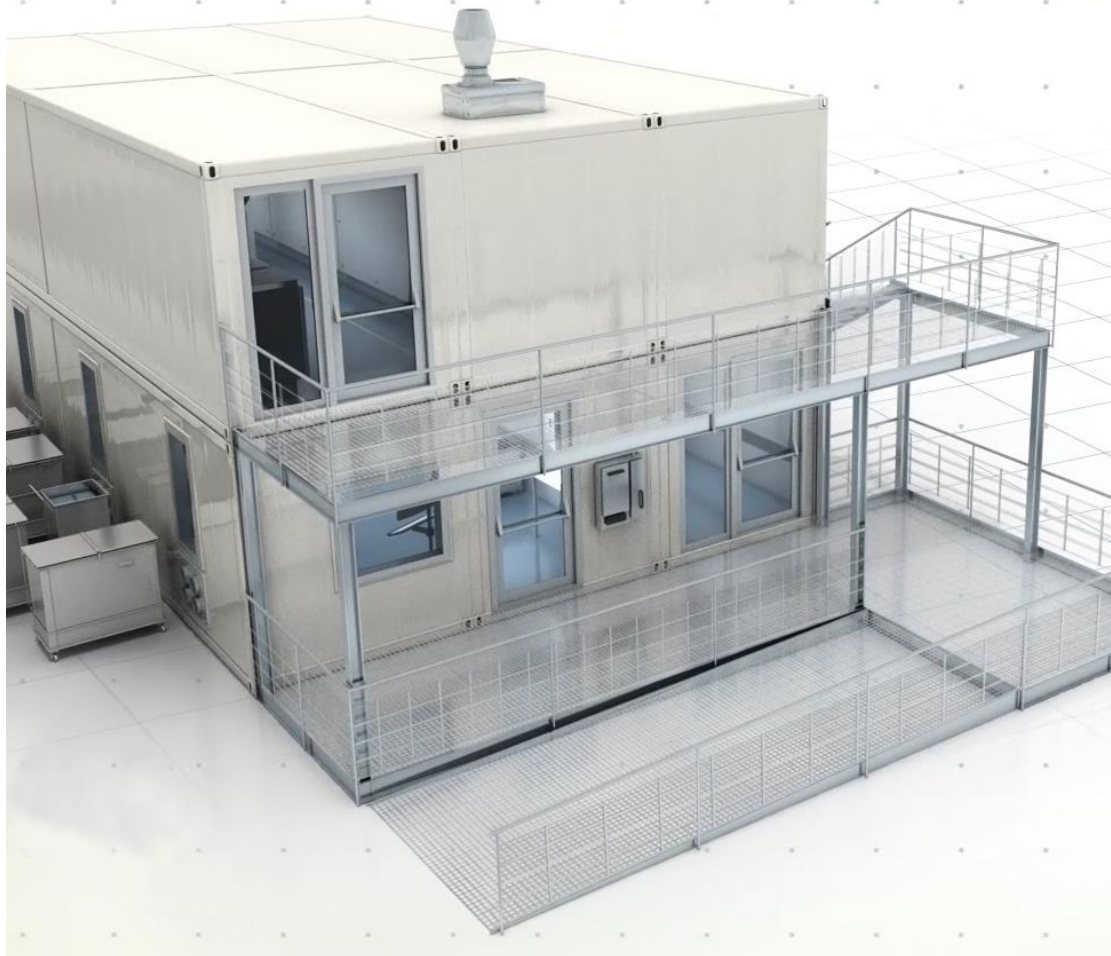
Quality control for remote manufacturing

BioNTainers: Introduction of a turnkey, scalable solution



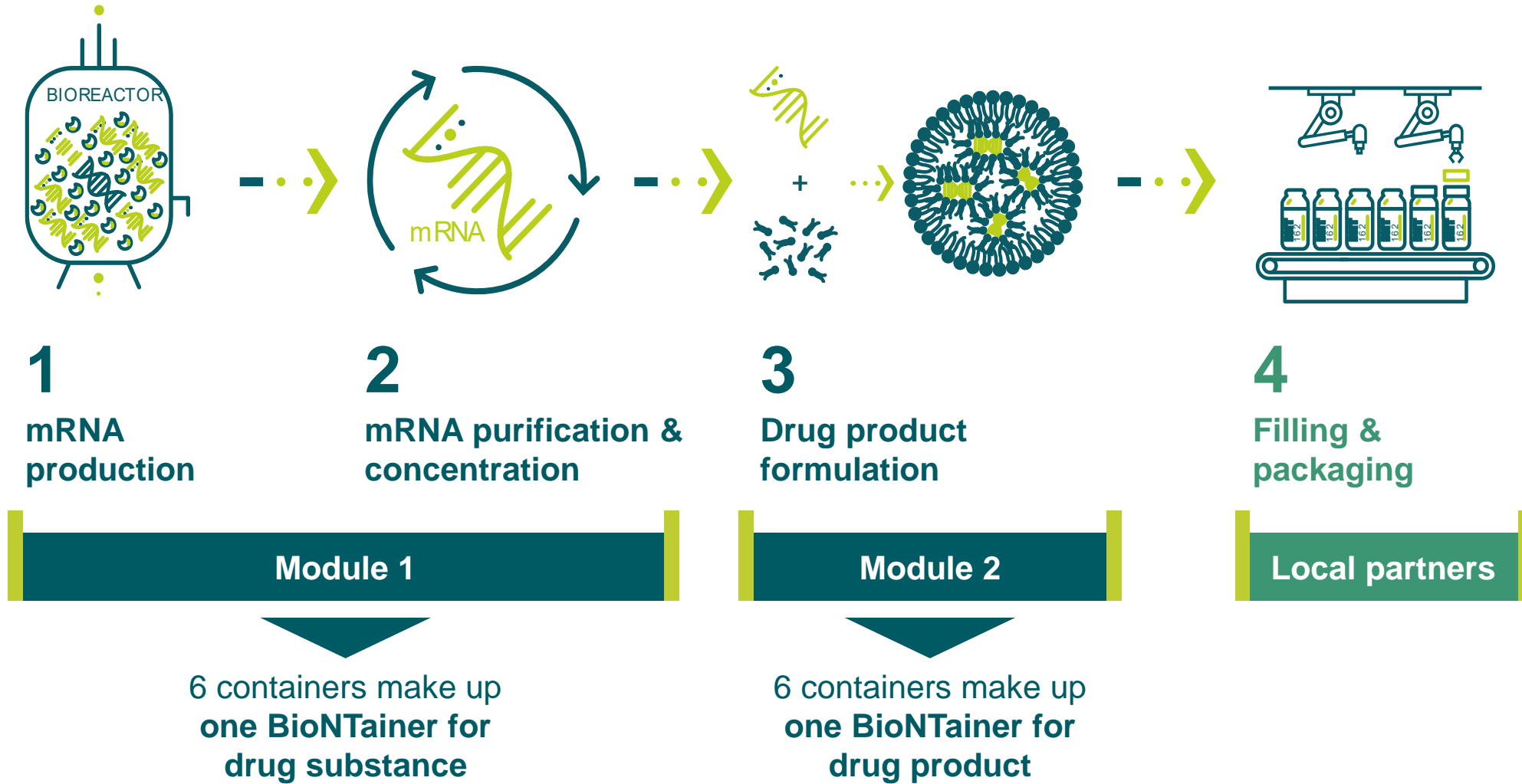
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Key facts on BioNTainer set-up in Africa



Scope	12 containers
Structure	6 containers = 1 module > 1 drug substance (DS) module > 1 drug product (DP) module
Container size	ISO sized (2.6m x 2.4m x 12m)
Shipment	Shipped via freighter, truck and train
Production volume (initial)	E.g. approx. 50 million doses of the Pfizer-BioNTech COVID-19 vaccine
Production	BioNTech jointly with local support
Quality control	BioNTech jointly with local support
Local infrastructure	E.g. logistics, quality control labs, quality control set-up, warehousing, cold and frozen storage
Technical autonomy	Fully self-sufficient
Scope of application	Single to multi-drug production & clinical trials

Two BioNTainers as core of mRNA vaccine production



Key questions and answers

Why now?

What challenges can be addressed?

How is quality control supported?

Why a joint effort?

What is the bigger picture ?

What comes next?

The time is now to facilitate access to mRNA



In a connected world, a **global approach** is required to address public health issues



mRNA is a **versatile drug class** to potentially develop various vaccines



Technology, automation and digitalization allow for new solutions



The pandemic has shown the **power of collaboration** and joint efforts

Learnings from the COVID-19 pandemic

A sustainable solution for mRNA vaccine production

The challenge

Establishing GMP production of mRNA is complex and requires overcoming challenges at many levels

Technical solutions for manufacturing sites must comply with **internationally harmonized GMP standards**

Complex mRNA manufacturing process with **high quality standards**

Highly qualified personnel required to ensure transfer process and system maintenance

The solution

Turnkey package that includes modular production units, GMP-compliant setup and personnel training

Container-based **“Plug & Play”** approach with **modular design, standardized equipment** and **software components**

GMP process implementation and maintenance facilitated by **validation packages, automation, digital solutions**, local and global quality control

Training of local employees with planned hand-over of site to support sustainable supply within African Union as well as development of local biotechnology industry

High-quality vaccine manufacturing is our priority

Approved suppliers to provide raw materials

Transfer of know-how and trained personnel to build manufacturing capabilities in a sustainable and safe way

Local quality control on site to ensure the safety and quality of the production process

Global support by quality control center in Marburg to support the operations of all BioNTainers

280

components from 86 suppliers in 19 countries

50,000

steps from beginning of a Pfizer-BioNTech COVID-19 vaccine batch to bulk filling

40

individual quality control tests for each finished vaccine batch

24/7

support and monitoring of processes

A joint effort to build a mRNA manufacturing network



The BioNTainer solution ensures:

- Acceleration of knowledge and technology transfer**
- Rapid set-up of new mRNA manufacturing nodes for licensed mRNA vaccines**
- Pandemic preparedness & other use cases**
- Sustainability through maintenance and updating**

Partner contribution:

- Utilities**
 Power supply, water connections, wastewater treatment, internet/network
- Access to talent**
 Trainees, technicians, professionals
- Regulatory framework**
 In collaboration with e.g. WHO, Africa CDC/AMA
- Operation permit**
 Legal permission to run production
- Fill & finish capacity**
 Local F&F for end-to-end manufacturing in Africa
- Logistics & supply**
 Enabling manufacturing and dissemination

A solution optimized for quality, speed and sustainability

Quality

- Proven efficacy and safety of mRNA
- **GMP-compliant** facility and processes
- Multiple **quality controls** to release vaccine batches

Speed

- Turnkey facility to **shorten set-up time**
- **Replicable** transfer of processes
- Training and **24/7 support**

Sustainability

- mRNA is a new drug class **suitable for many diseases**
- **Adaptation for future needs** through modular facility design
- Decentralized process **updates and continuous improvement**

What is next in 2022



Finalize the planning and initial assets for the new facility in the African Union



Start of construction of first manufacturing facility in African Union in mid-2022

First BioNTainer expected to be shipped in H2/2022

Regulatory framework in alignment with international standards e.g. WHO and Africa CDC/AMA

Evaluation of additional use cases and products for BioNTainers (clinical trials and regional pandemic preparedness)

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Further media material: [link](#)