



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.

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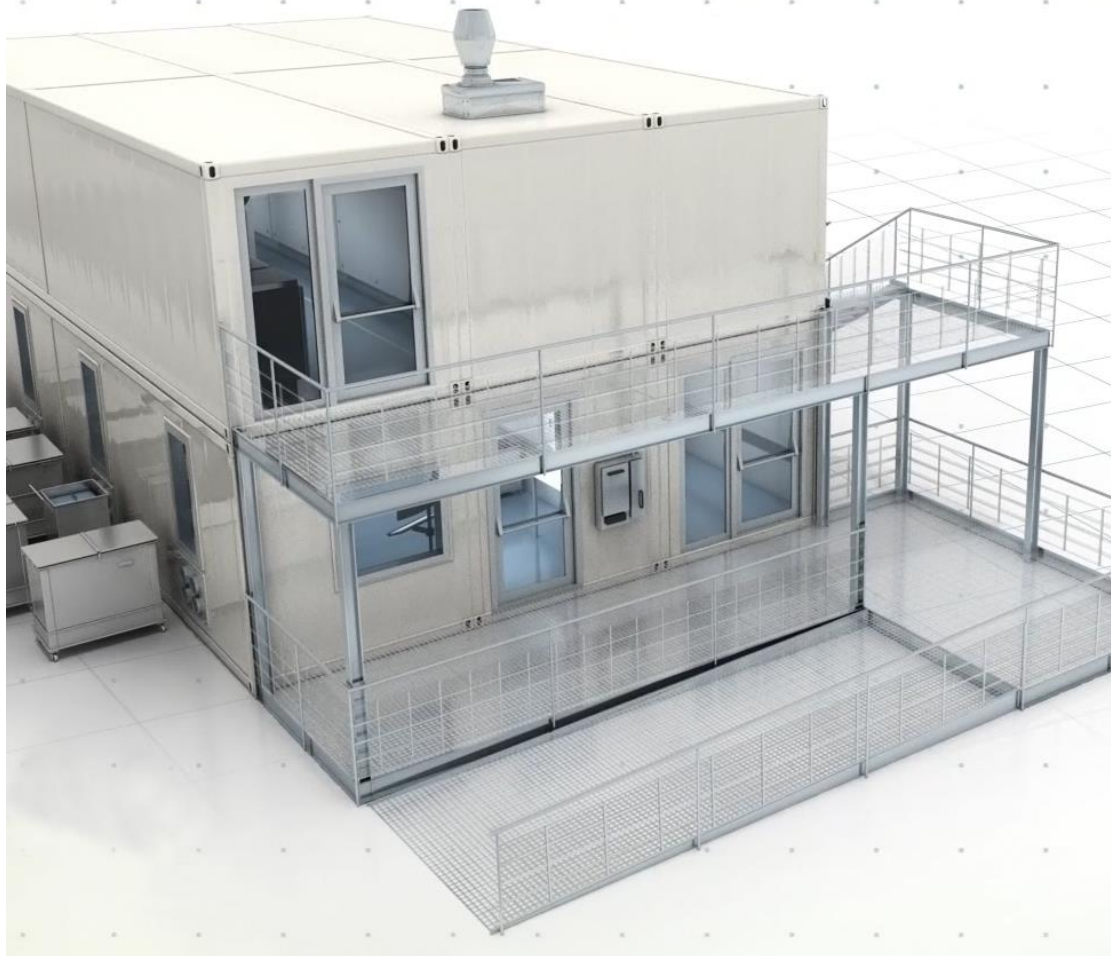
BioNTainers: Introduction of a turnkey, scalable solution



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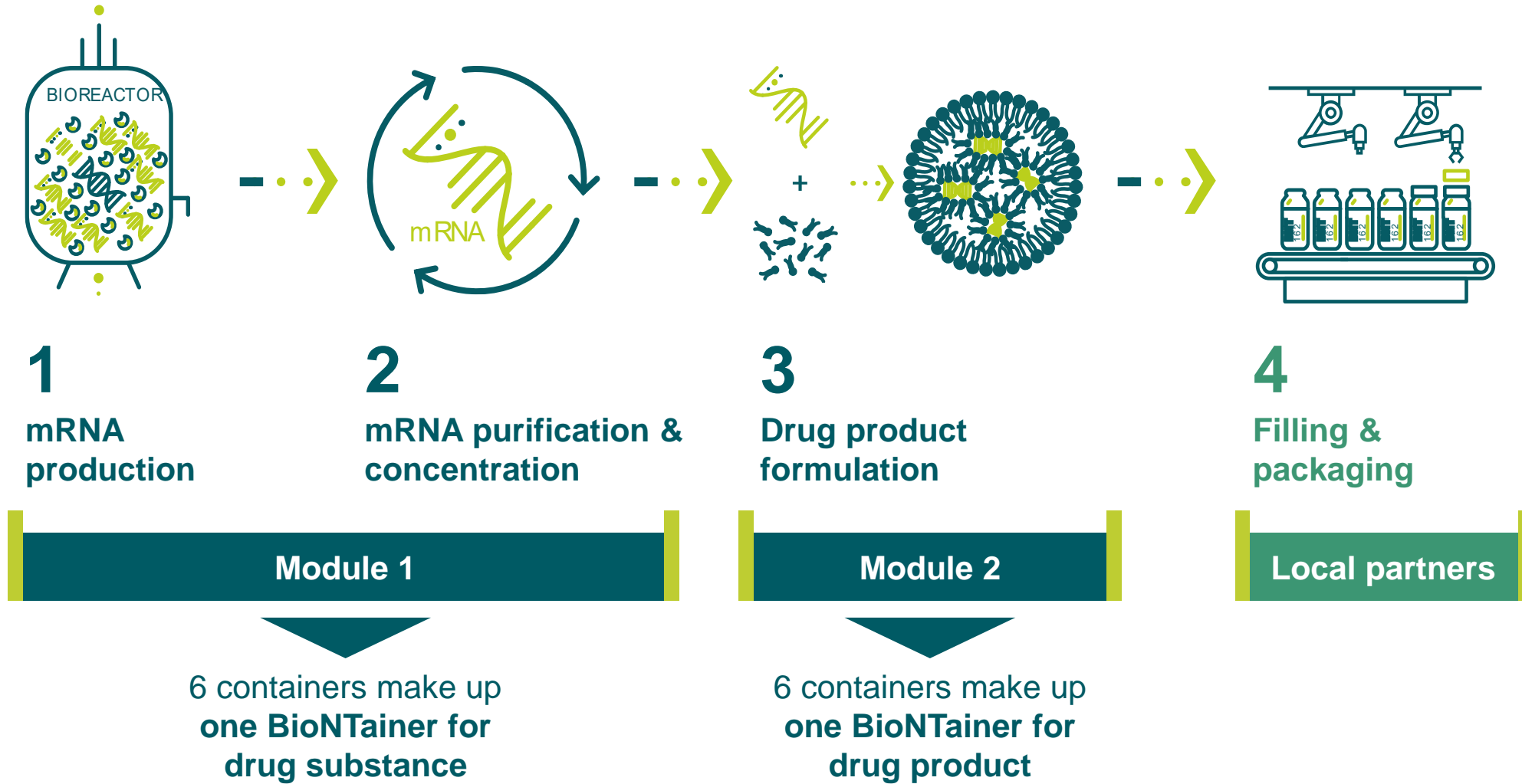
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Key facts on BioNTainer set-up in Africa



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



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