

# Accelerate Biotechnology

Rapid response, low-cost manufacturing of viral vaccines  
against emerging infectious disease threats

21 September 2023

Batavia Biosciences


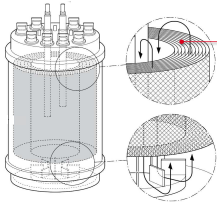
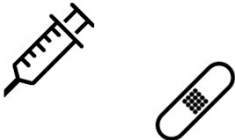


## HIP-Vax® Technology

- **Batavia Biosciences**
  - Centre of Excellence biopharmaceutical CDMO with facilities in the Netherlands (Leiden) and USA (Woburn, MA)
  - 14 years of experience in process development and clinical manufacturing
  - HIP-Vax® established for viral & vector vaccines using \$60m in grants and contracts since 2016 from Gates Foundation, CEPI, DTRA
- **HIP-Vax® delivers low CoGs: <\$1 per dose for vaccines**
  - High cell density production based on innovative fixed-bed bioreactors (scale-X)
  - Reduced facility footprint (CAPEX)
  - Reduced labor and consumables (OPEX)
  - Reduced bioprocessing timelines
  - Commercial manufacturing at lab scale (1000L output in 50-100L harvest)
- **Technology applicable to multiple product modalities**
  - Viral & vector vaccines (e.g. based on Vero and MRC-5)
  - Virotherapies, such as gene therapy or oncolytic vectors (e.g. based on HEK293)
  - Recombinant proteins (based on CHO)



## HIP-Vax® highly intensified manufacturing technology



				
<p><b>Biological materials</b></p> <ul style="list-style-type: none"> <li>• <b>GMP Cell substrates:</b> Vero MRC-5 HEK293</li> <li>• <b>GMP vaccine seeds:</b> Measles EZ Rubella Wistar WHO Sabin Polio type 1 WHO Sabin Polio type 2 WHO Sabin Polio type 3</li> </ul>	<p><b>Highly intensified manufacturing</b></p> <ul style="list-style-type: none"> <li>• Based on innovative, fixed-bed manufacturing equipment</li> <li>• Achieves ~20-fold increased process intensification compared to current technologies</li> <li>• Output at 50L scale equivalent to 1000L</li> </ul>	<p><b>Platform approach</b></p> <ul style="list-style-type: none"> <li>• Generic platform processes developed for multiple vaccine modalities (eg: VSV, MV, Adeno)</li> <li>• Reduces time to clinical POC to &lt;6 months and to commercial manufacturing in &lt;10 months</li> </ul>	<p><b>Low COGs</b></p> <ul style="list-style-type: none"> <li>• Production in small footprint, low-cost facility reduces CAPEX and hurdle to manufacture</li> <li>• High yields, short production times &amp; low FTE requirement reduces OPEX</li> <li>• COGs below 1 Euro per dose</li> </ul>	<p><b>High output</b></p> <ul style="list-style-type: none"> <li>• High vaccine output per year (hundreds of millions of doses)</li> <li>• Flexibility to deliver multiple vaccines from single facility &amp; respond quickly to outbreak threats</li> </ul>

Cells, virus seeds, and process available for partners through licensing

A low cost manufacturing process for technology transfer

## **Available for inactivated Polio, Measles and Rubella and Rota**



- Technology developed under global access commitment
  - Licensed to developing country vaccine manufacturers
  - Obligation to deliver % of manufactured product to GAVI and UNICEF agencies at defined price
- Technology Transfer include
  - Process know-how
  - Biological materials (GMP cell lines and GMP seeds), for Rota and Rubella a license agreement with respectively Wistar and MCRI needed
  - Safety and containment (for Polio) documentation
  - Equipment and consumables provided by Univercells. For Rota initial process developed using CF's, initial data using Scale-X bioreactor is available

# New clinical & commercial manufacturing facility in 2024

## Facility located in Leiden, NL (12,000m<sup>2</sup>, 5 Floors)

- Design, engineering & permitting completed, constructors engaged and procurement ongoing
- Construction to start early Q2 2023
- Expected facility qualification completed H2 2024

## Manufacture of Viral Vaccines and Virotherapy Products

- 6 Drug substance manufacturing suites (2 clinical, 4 commercial)
- Clinical and commercial drug product aseptic filling & packaging, warehouse, QC, goods in/out
- Up to 20 clinical batches, 88 commercial batches (150-200M doses) per year
- Based on scale-X / HIP-Vax at 600M<sup>2</sup> scale, with capability for standard 1000L scale STR manufacturing





## Take away points

- HIP-Vax intensifies the manufacturing of vaccines
- Cost of Goods less than \$1 per dose
- Robust and scalable platform
- Cell substrates and Virus seeds available for partners through licensing
- Commercial manufacturing facility ready at the end of 2024

# Thank you for your time



## Feedback

We value your input and would like to hear your thoughts on the presentation,



## Next steps

Let's take a moment to discuss and map out the next steps towards our shared goal.



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