NASDAQ: MRVI

# Craig Hallum Bioprocessing Conference

September 19, 2024

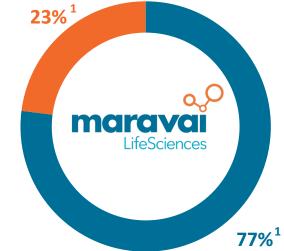


### **Maravai's Business Segments**

### **Biologics Safety Testing**

Critical for process impurity detection and quantification

- Broad applicability across biologic manufacturing
- Driven by growth demand for cell and gene therapy production
- Loyal bioprocessing customer base
- Custom analytical method and assay development programs
- Orthogonal expansion into Mass Spec for bioprocess design
- HCP kits used in 23 out of 23 commercialized CAR-T cell and gene therapies plus the first-ever CAR-T approval in China



### **Nucleic Acid Production**

Highly modified nucleic acids and enzymes for research, therapeutic and vaccine programs

- Specialty in complex nucleic acid synthesis
- Meeting growing customer need for outsourced research-grade to GMP-grade components
- Extensive catalog of nucleic acid building blocks
- New product innovation:
  - CleanCap® M6, most robust cap analog
  - N1-Methyl-Pseudouridine-5'-Triphosphate, critical raw material for mRNA therapeutics
- Alphazyme acquisition adds critical enzyme manufacturing capabilities











MARAVAI SHARED SERVICES ("CORPORATE")

Science & Innovation | Commercial | Finance & IT | HR, Global Operations, and Business Transformation | Legal





### **Exciting Product Portfolio Supports Customer Needs**

CleanCap® Technology



### CleanCap® AG

### CleanCap® 3'OMe

Already in approved vaccine



### CleanCap® AU

Self-amplifying mRNA

✓ Already in approved vaccine
 CleanCap® M6 Potential for 30%+ higher protein production

**NTPs** 



Decades of experience developing and producing modified NTPs



Brings scientific capabilities and innovative chemistry approaches for NTP development and production

Oligonucleotides



Foundational oligonucleotide producer for next-generation sequencing, molecular diagnostics and genomic tools companies



Provides reagents, supports, modifiers and labelling technologies for oligonucleotide synthesis

**Enzymes** 



Provides unique expertise in molecular biology, enzyme scale-up, and production services



### **Leveraging San Diego Manufacturing Capability**









## mRNA and related raw material manufacturing

- 118,000 ft<sup>2</sup> (10,963 m<sup>2</sup>)
- Discovery and GMP mRNA manufacturing services
- CleanCap® technology and NTP and oligo innovation and scale up
- On-site quality control lab

### Analytical and support services

- 54,232 ft<sup>2</sup> (5,038 m<sup>2</sup>)
- Home of the Analytical Sciences Center of Excellence (ASCE)

### **GMP** nucleic acid production

- 32,000 ft<sup>2</sup> (2,973 m<sup>2</sup>)
- CleanCap® technology and NTP production for clinical and commercial use
- On-site quality control lab
- BARDA Award

### cGMP mRNA manufacturing

- 32,000 ft<sup>2</sup> (2,973 m<sup>2</sup>)
- Phase 2 clinical through commercial manufacturing
- On-site quality control lab



### CleanCap® M6 Most Robust Capping Analog Available



# Provides category leading capping efficiency of >95%

- Increased IVT efficacy resulting in high manufacturing yield
- Demonstrates reduced immunogenicity compared to other cap analogs



# New cap structure can produce 30%+ higher protein expression

- Increases potency of your mRNA drug substance
- Allows for lower dosing resulting in higher manufacturing yield

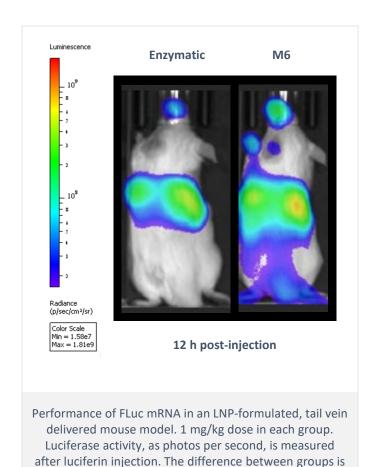


# Maintains the one-pot workflow benefit of CleanCap

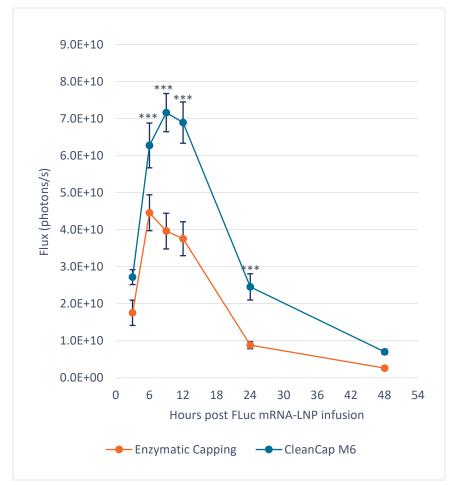
- Simplified manufacturing process, decreasing process risk
- Lowers time, labor, and cost to manufacture

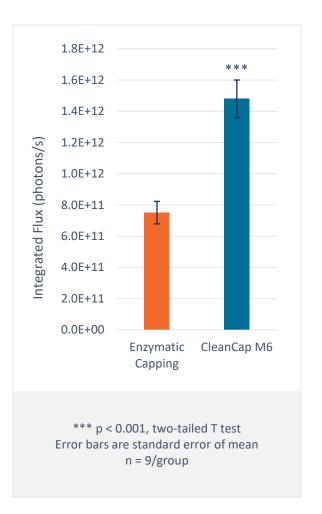


# **CleanCap® M6 makes mRNA more potent** – superior protein expression compared to enzymatically capped mRNA



the capping strategy. All other variables are controlled.





\*\*\* p < 0.001, two-tailed T test. Error bars are standard error of mean. n = 9/group



### **Cygnus Participates Throughout the Drug Development Cycle**



**Initial Process Development** 

**Process Development and Clinical** Manufacturing

Validation

**Quality Control** 

**Preclinical To Phase 1 Clinical** 

New Protein Detection



**Impurities Introduced During Upstream Cell Culture and Downstream Purification Process** 

Process-related impurity detection is required during downstream purification to demonstrate effective impurity removal, downstream process consistency and the final drug substance purity

### Phase 1 & Phase 2

Clinical Manufacturing

and Qualification



**Impurity Assay Development** 

#### Phase 3 To BLA

Purification Process & Analytics Validation for Late-Stage Manufacturing



Is Generic Assay Adequate or

Is Process-Specific Assay Required?

### **Commercial Manufacturing**

**Routine Quality Control** 



**Assay Validation and** 

**Product Release Testing** 

#### **Products**

- Generic HCP **ELISA Kits**
- Host Cell DNA Kits
- Albumin ELISA Kits Insulin ELISA Kits
- Transferrin ELISA Kits
- Protein A Mix-N-Go™ **ELISA Kits**
- EndonucleaseGTP® ELISA
- MockV Kits

#### **Products**

- · Generic HCP ELISA Kits
- Protein A Mix-N-Go™ ELISA Kits
- EndonucleaseGTP® ELISA
- Other Bioprocess Impurity ELISA Kits
- MockV Kits

#### **Services**

- HCP antibody coverage analysis by Antibody Affinity Extraction (AAE) with 2D-PAGE and/or MS
- Assay qualification
- Sample testing by ELISA and orthogonal methods: AAE. AAE-MS™

#### **Products**

- · Generic HCP ELISA Kits
- Protein A Mix-N-Go<sup>™</sup> ELISA Kits
- EndonucleaseGTP® ELISA
- Other Impurity ELISA Kits
- MockV Kits

#### **Services**

- HCP antibody coverage analysis by AAE with 2D-PAGE and/or MS
- Assay qualification: dilution linearity, spike & recovery analysis, precision, accuracy
- · Custom process-specific HCP antibody and assay development

#### **Products**

- Generic HCP ELISA Kits
- Protein A Mix-N-Go<sup>™</sup> ELISA Kits
- EndonucleaseGTP® ELISA
- Other Impurity ELISA Kits

#### **Services**

- Custom process-specific HCP ELISA
- AAE-MS™

