



2022 WuXi AppTec Investor Day

# WuXi ATU: A Global CTDMO

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WuXi ATU CEO

## Forward Looking Statements

This presentation may contain certain “forward-looking statements” which are not historical facts, but instead are predictions about future events based on our beliefs as well as assumptions made by and information currently available to our management. Although we believe that our predictions are reasonable, future events are inherently uncertain and our forward-looking statements may turn out to be incorrect. Our forward-looking statements are subject to risks relating to, among other things, the ability of our service offerings to compete effectively, our ability to meet timelines for the expansion of our service offerings, our ability to protect our clients’ intellectual property, unforeseeable international tension, competition, the impact of emergencies and other force majeure. Our forward-looking statements in this presentation speak only as of the date on which they are made, and we assume no obligation to update any forward-looking statements except as required by applicable law or listing rules. Accordingly, you are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. All forward-looking statements contained herein are qualified by reference to the cautionary statements set forth in this section. All information provided in this presentation is as of the date of this presentation and are based on assumptions that we believe to be reasonable as of this date, and we do not undertake any obligation to update any forward-looking statement, except as required under applicable law.

# WuXi ATU – A Globally Integrated CTDMO

“Enabling DNA to BLA”

– Discovery & Early Development ————— Development, Manufacturing, & Testing —————



Three business engines fueled by global platforms

Advanced technologies, manufacturing and testing solutions for cell and gene therapy innovators

## Viral Vectors

AAV | LVV | HSV | Adeno | Plasmids

## Cell Therapies

CAR-T | TIL | MSC

## Testing

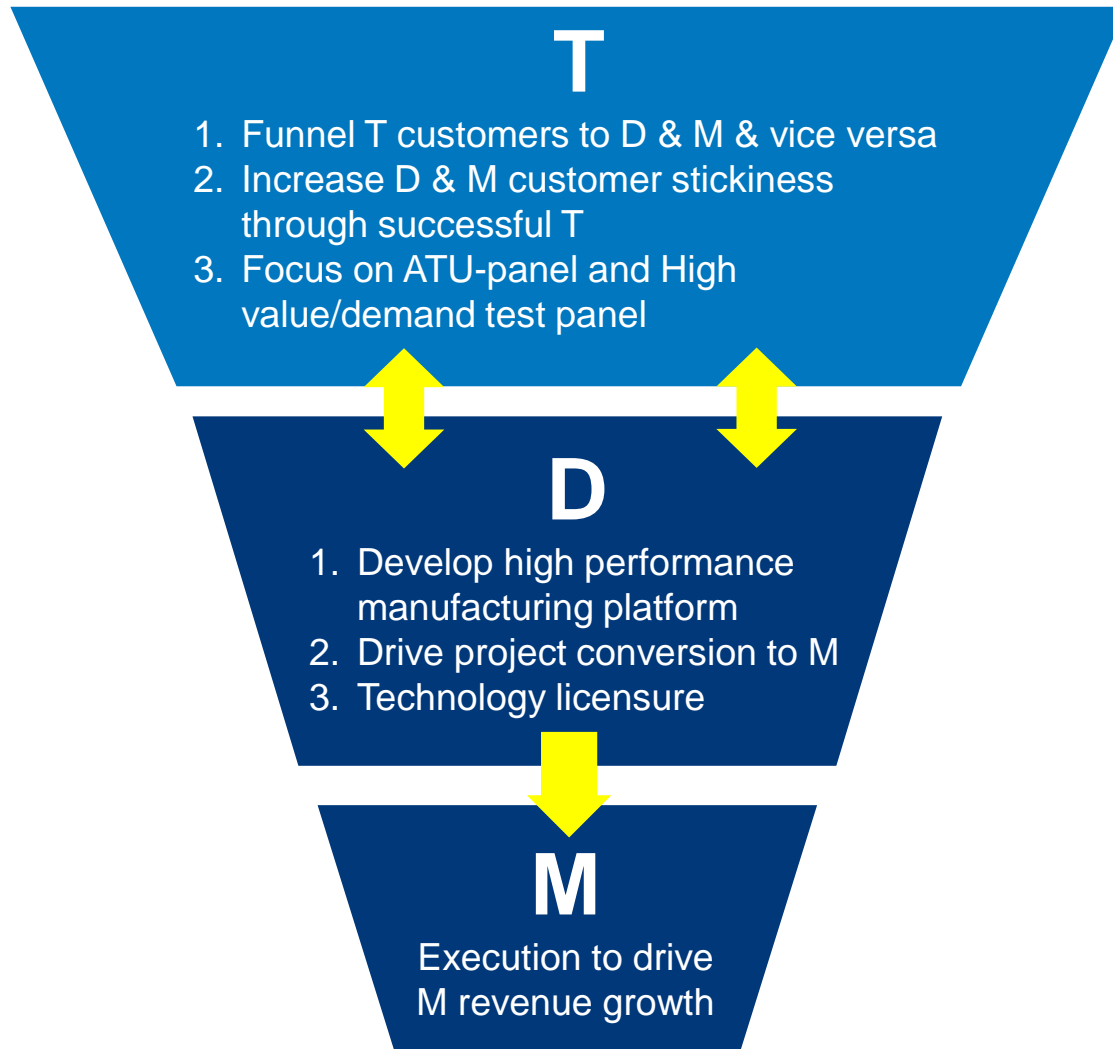
Integrated and standalone advanced therapy and biologics testing

5 sites across 3 continents | 75k+ m<sup>2</sup> facilities | 1,300+ employees

Over 2200 VV and cell therapies GMP lots released

# ATU CTDMO Business Model

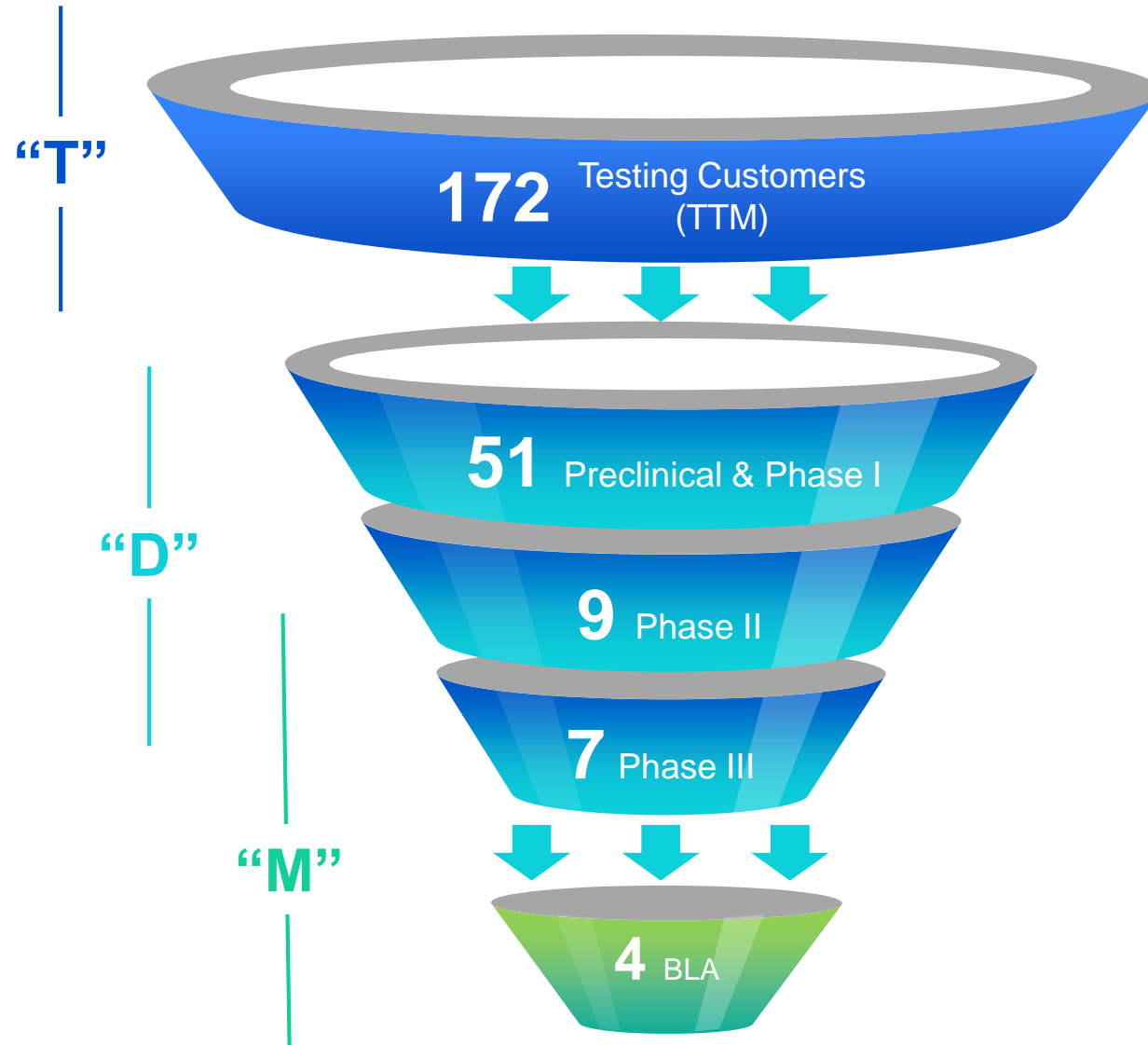
## Integrated C T D M O



## Business Directions

1. Engage customers at all different dev. stage and drive to T D M
2. Differentiate each site's unique competitiveness and drive cross-site collaboration to serve T D M
3. Acquire customers at "T" stage and drive through D & M.
4. Integrate effective T with D & M to enhance customer stickiness

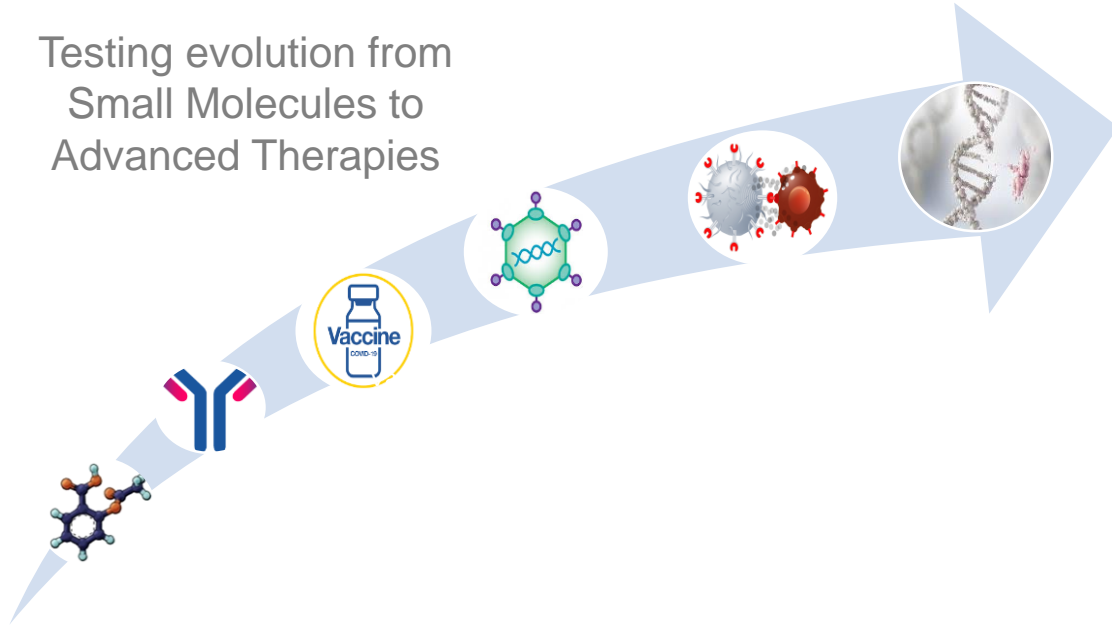
# Expanding CTDMO Pipeline Drives Sustainable High Growth



WuXi ATU C“T”DMO

# Testing Poses Complexity and Challenges to CGT Industry

Testing evolution from  
Small Molecules to  
Advanced Therapies



## Testing Platforms for CAR-T Products

### Product specific release tests:

- CAR Expression by Flow Cytometry
- Integrated Copy Number (GOI specific)

### General characteristics:

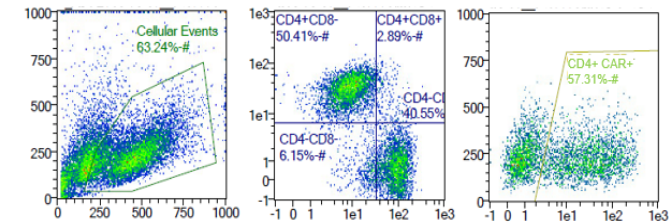
- Cell Count and Viability by NC-200
- Identity by Flow Cytometry
- Cellular Impurities by Flow Cytometry

### Safety Testing:

- Sterility, Endotoxin, Mycoplasma
- Replication Competent Virus

### Additional Capabilities (as needed):

- Potency Assays (product specific)
- T-cell Memory Phenotype by Flow Cytometry
- T-Cell Activation by Flow Cytometry
- T-Cell Exhaustion by Flow Cytometry
- In Vitro and PCR based adventitious agents
- Residual Viral DNA



## • Small Molecule Testing

- Simple chemical/physical characterization
- Conventional instruments in traditional QC labs

## • Advanced Therapy Testing

- Complex biologics, viral and cell characterization
- Advanced instrumentation in development labs
- Broadly used cell based assays (potency assays)

# Ramping Up Operations at New Testing Facility in Philadelphia Site

Fully operational and licensed in 2022 w/ **3X** capacity increase



WuXi ATU Opens New Facility in Philadelphia, Tripling Testing Capacity to Support Global Customers

Nov 15, 2021

New state-of-the-art advanced therapies testing laboratories provide additional capacity for the growing cell and gene therapy industry. November 15, 2021 - Philadelphia. WuXi Advanced Therapies (WuXi ATU), a wholly owned subsidiary of WuXi AppTec, announced the...

WuXi Advanced Therapies Testing Facility To Receive EMA GMP Certificate for New Philadelphia Facility

Jan 7, 2022

January 07, 2022 - Philadelphia. WuXi Advanced Therapies (WuXi ATU) announced it has successfully completed a remote European Medicines Agency (EMA) inspection for its advanced therapies testing facility at 400 Rouse Boulevard in its Philadelphia Navy Yard Campus, and...

"The newly constructed 140,000 sq. ft. testing facility provided WuXi ATU with additional space for expansion of testing operations and enabled the company to meet business demands."



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

"The laboratories had implemented a quality management system that was designed to meet the requirements of the PIC/S Guide to GMP." and "The quality of the work was of a high standard"



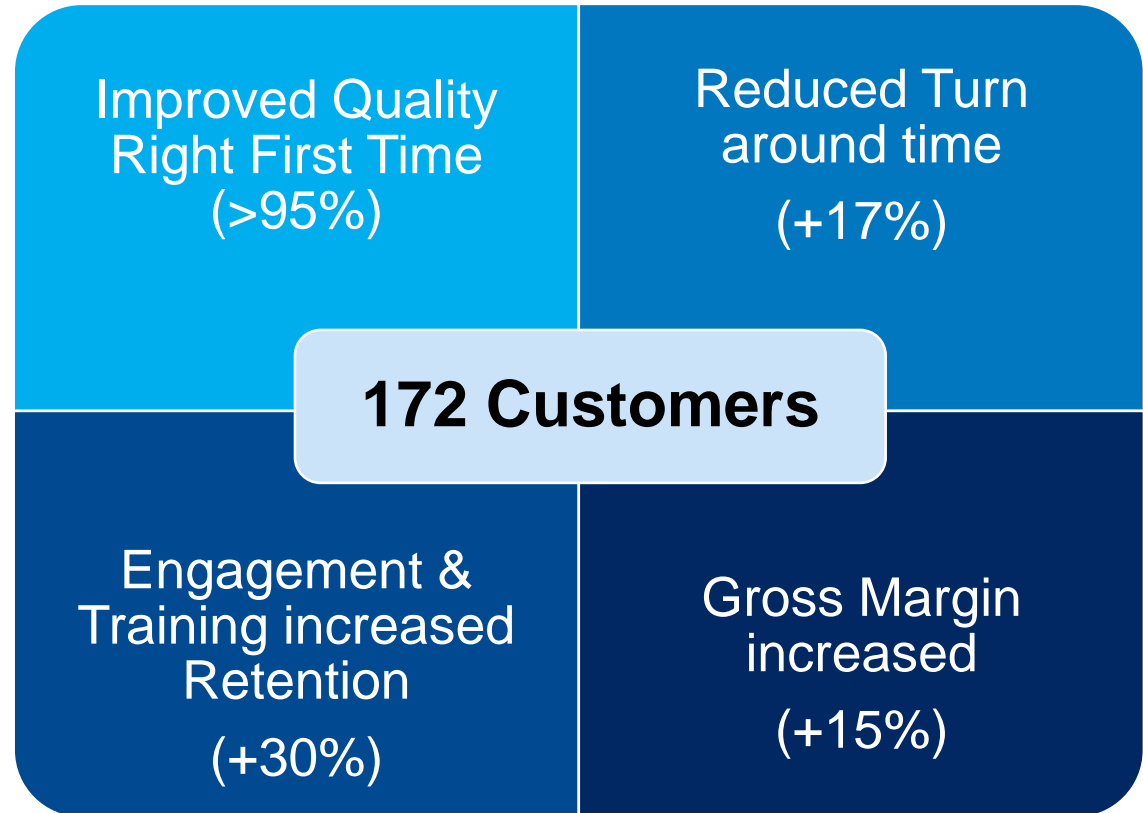
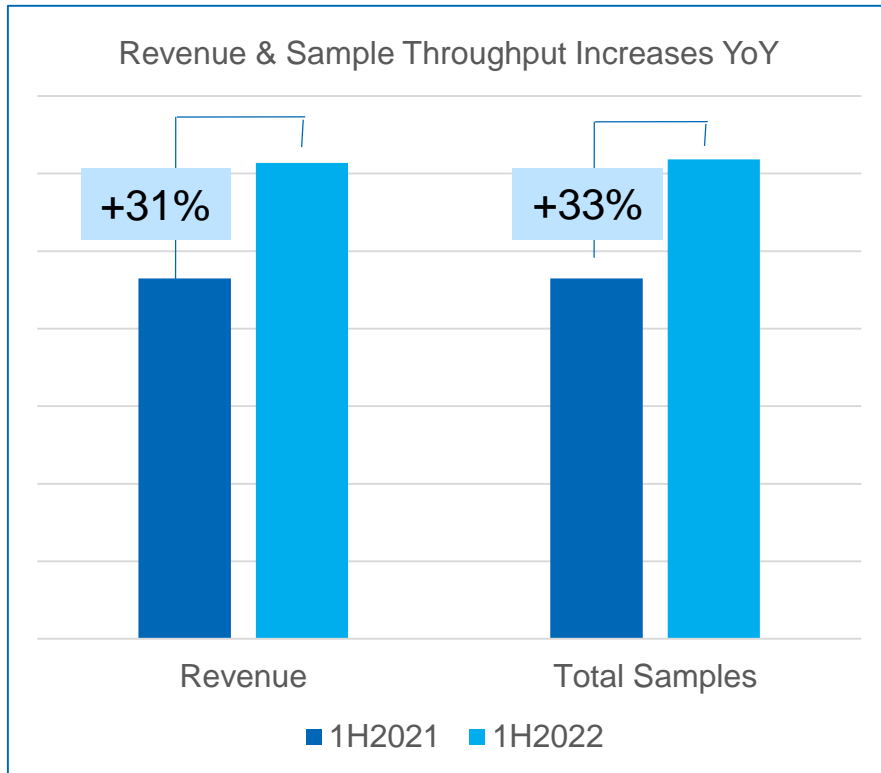
Australian Government

Department of Health  
Therapeutic Goods Administration



# Testing: 1H 2022 Business Performance

## CGT Market Focused Testing Offerings w/ Industry-Leading “ATU Testing Panel”



**Service Growing CGT Market with Ready-Now Testing Capacity and Industry-Leading Analytical Technical Capability**

WuXi ATU CT“D”MO

# WuXi ATU Manufacturing R&D Roadmap

**Defining CGT Future  
Manufacture Standard**

## **Manufacture or License**

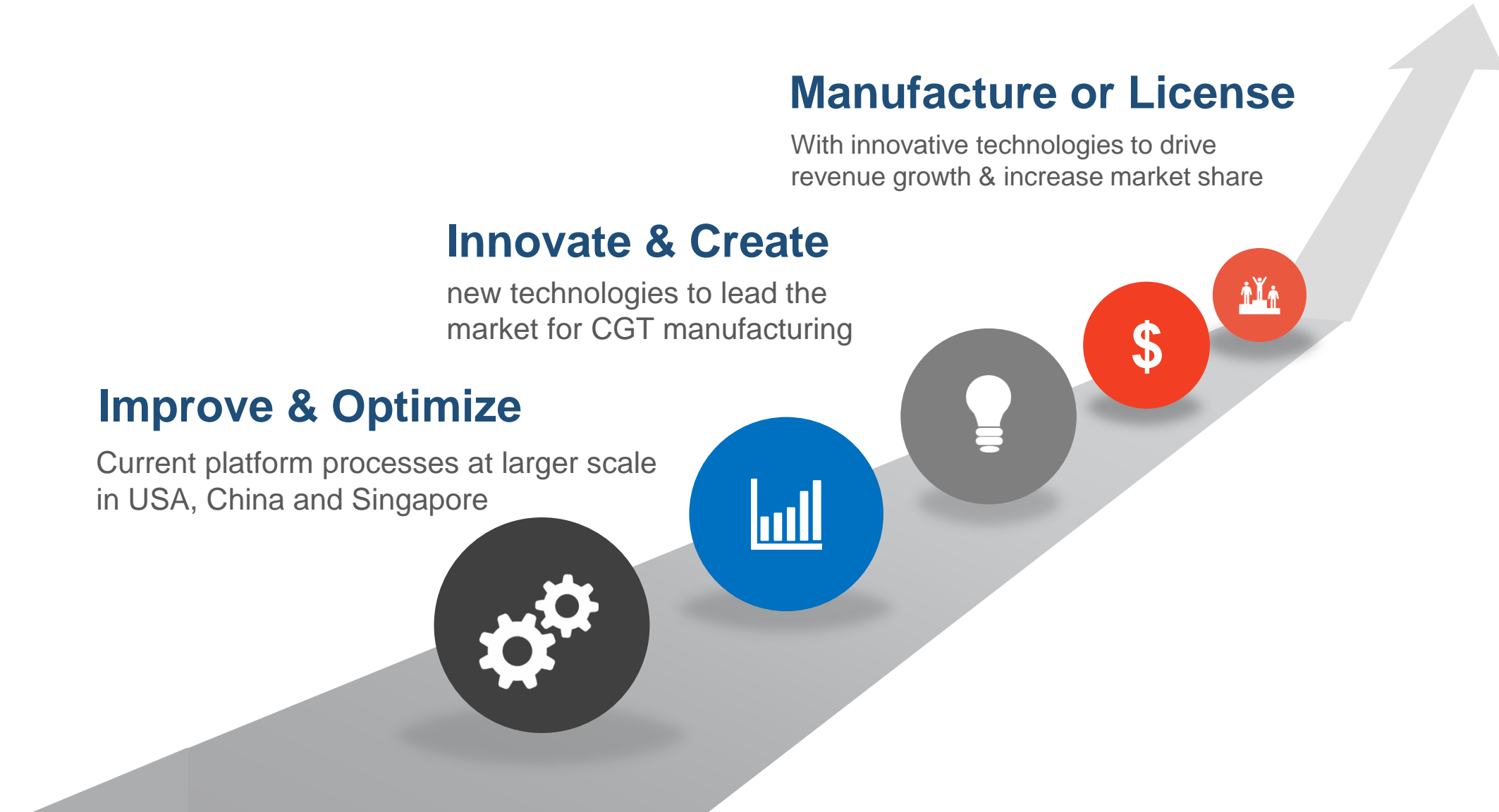
With innovative technologies to drive revenue growth & increase market share

## **Innovate & Create**

new technologies to lead the market for CGT manufacturing

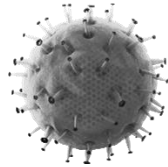
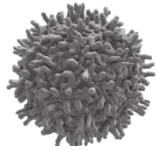
## **Improve & Optimize**

Current platform processes at larger scale in USA, China and Singapore



# Manufacturing R&D Strategy

Improve & optimize industry standard manufacturing platforms



WuXi ATU Platform

AAVEX™ Plasmid Transfection Platform

LentiVEX™ Plasmid Transfection Platform

Cell Therapy (TIL & CAR-T) Platforms



R&D Objective

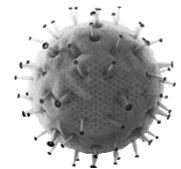
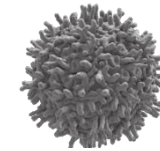
Optimize and standardize plasmids and VV processes to improve yield, quality and operation

Optimize processes to improve yield, quality and operation

R&D Outcome

**Industry-leading** manufacturing performance with current industry standard platforms

Innovate & create new CGT manufacturing platforms



TESSA™ Technology for AAV Vectors

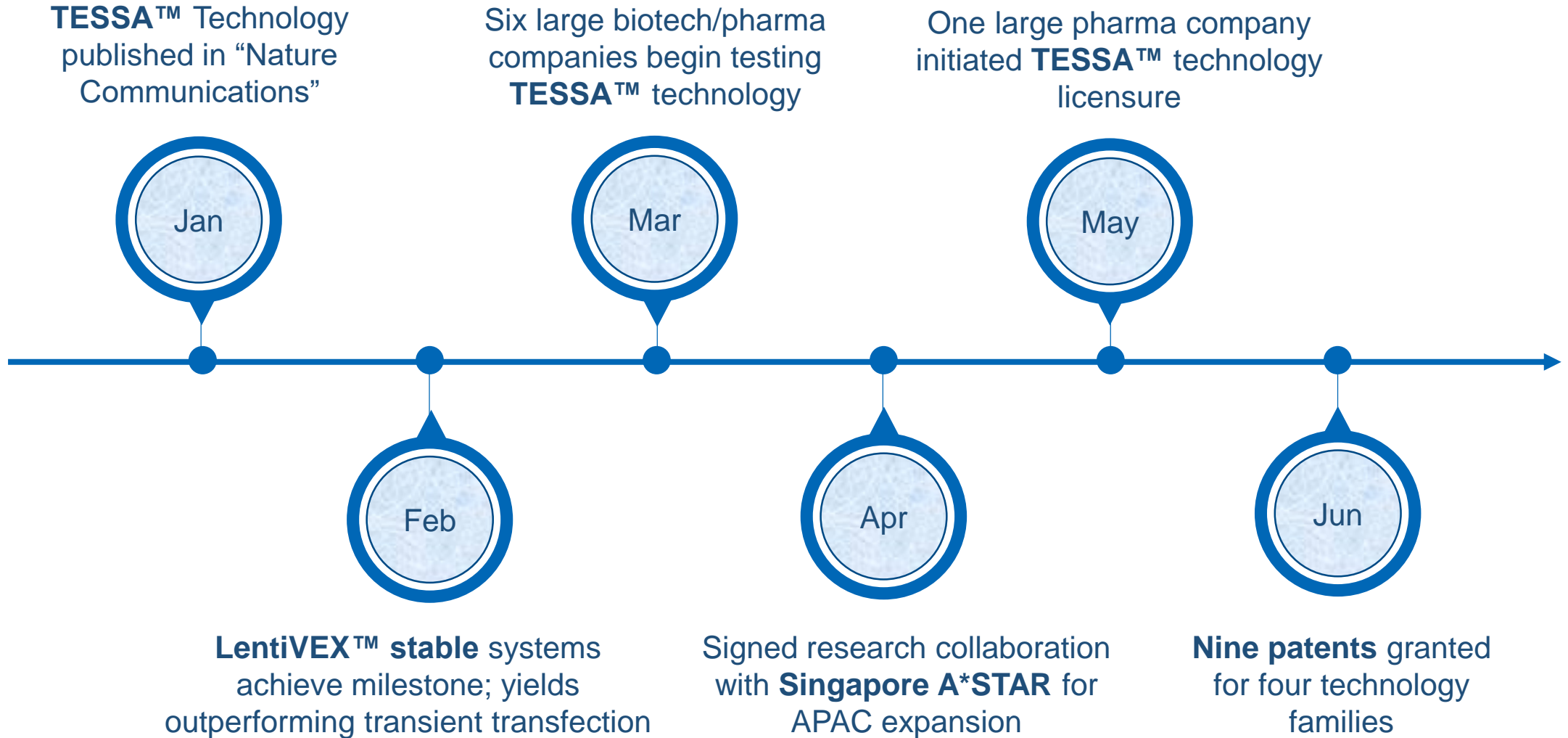
LentiVEX™ Stable for Lentiviral Vectors



Validate new technologies at scale and support customers transition to new platforms

**Transforming** manufacturing performance with innovative new platforms

# 1H 2022 MFG R&D Performance Highlights

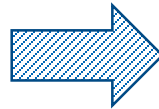


# The Future of Viral Vector Manufacturing Standard Is Here!

- Current viral vector manufacturing approaches require large quantities of expensive plasmids
- Current methods struggle to scale above 200L



200L Bioreactor



1000L Bioreactor

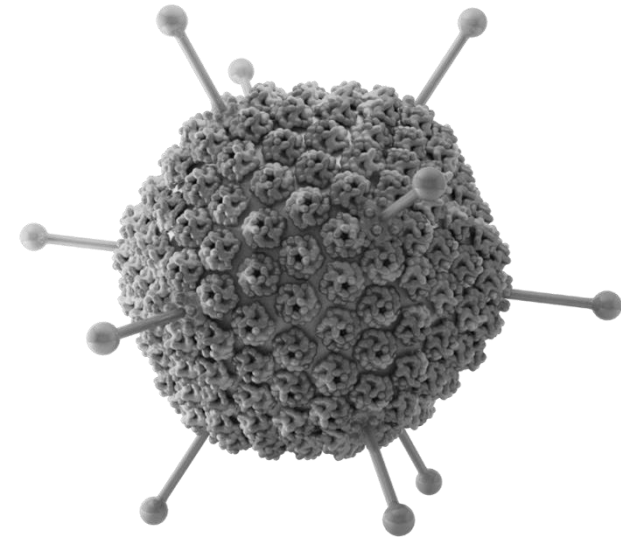
Plasmid-Free, Fully Scalable  
Manufacturing of  
*Adeno-Associated Virus (AAV)*  
&  
*Lentiviral Vectors (LVV)*

- Our technologies remove the need for plasmids to reduce the costs of manufacturing
- Our new technologies can be scaled >2000L
- Produce superior quality of viral vectors

# Innovate: TESSA™ Technology

## Our Vision

- Develop a fully scalable AAV manufacturing platform that improves AAV yield and quality



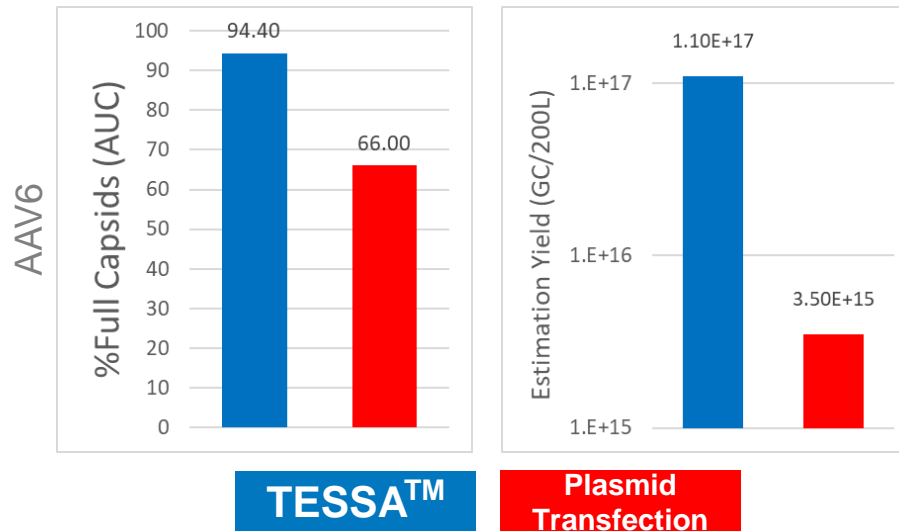
TESSA™ (Tetracycline enabled self silencing adenovirus)

# TESSA™: Transforming AAV Manufacture Through Innovation

## Turning to nature: using adenovirus to make AAV

To manufacture AAV with engineered TESSA™ adenovirus to significantly increase titer and purity w/o adenovirus contamination

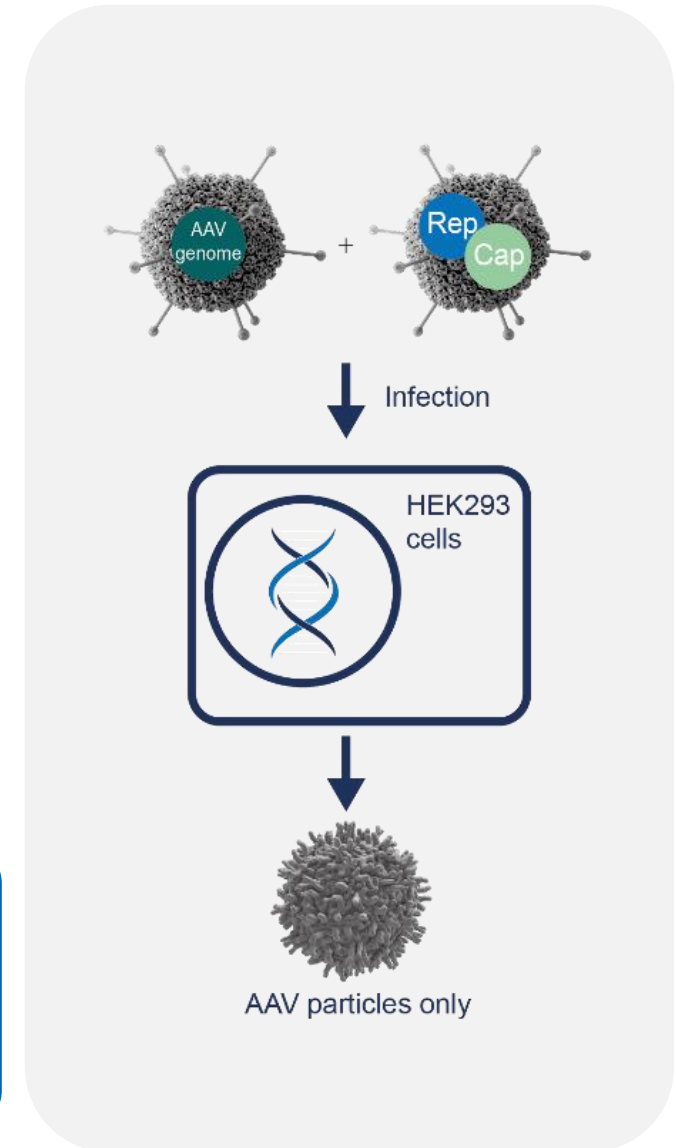
**>95%**  
Full capsid



**30-40X**  
more AAV

## Scalability, High Yield, High Quality and Applicability

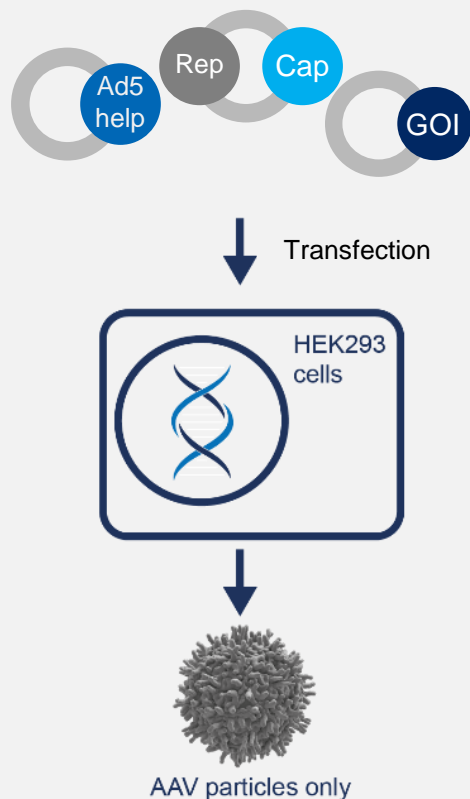
- Scaled TESSA™ AAV sera 2 and 6 to **200L** bioreactors, increasing productivity by **30-40 folds** with **full capsid >95%**
- Significant improvements also in **all other AAV sera types** at lab scale



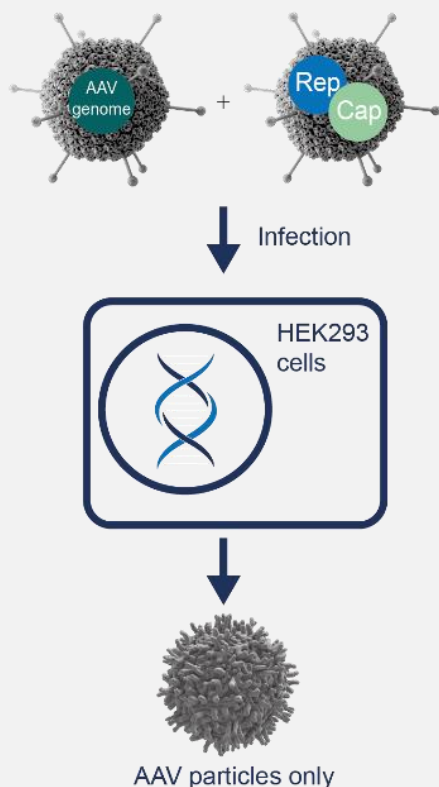


# TESSA™: Enhancing Patient Access to AAV Gene Therapies

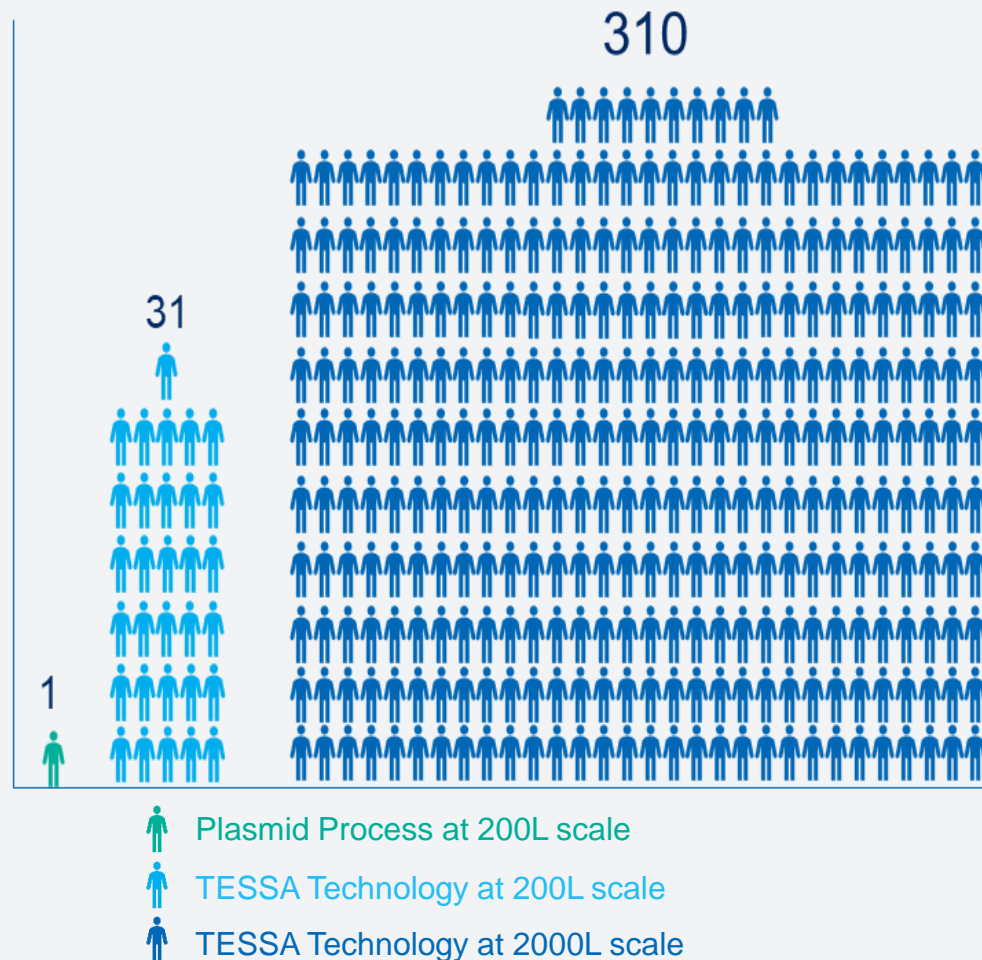
## Plasmid Transfection Process



## TESSA Technology



Minimum number of patients treated per manufacturing run



# TESSA™: Significant Reduction of Costly Starting Materials

- AAV manufacturing requires input materials e.g. plasmid or TESSA™ vectors
- Producing adenovirus (TESSA™) and plasmid in the same size bioreactor is not significantly different, however, the amount of AAV that can be made using that material is very different
- The same volume of input material manufacture can enable 13-40X more AAV production

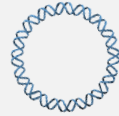
## Plasmid Transient Production



Plasmid production at  
200L scale



Produces approx. 3-5g  
plasmid DNA



Enough to run 15-25 x  
200L AAV bioreactors



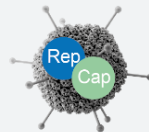
## Adenovirus TESSA™



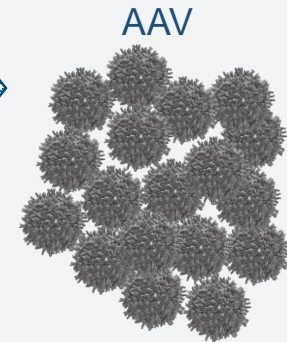
Adenovirus TESSA  
production at 200L scale



$2 \times 10^{14}$  -  $1 \times 10^{15}$  TESSA  
Adenovirus particles

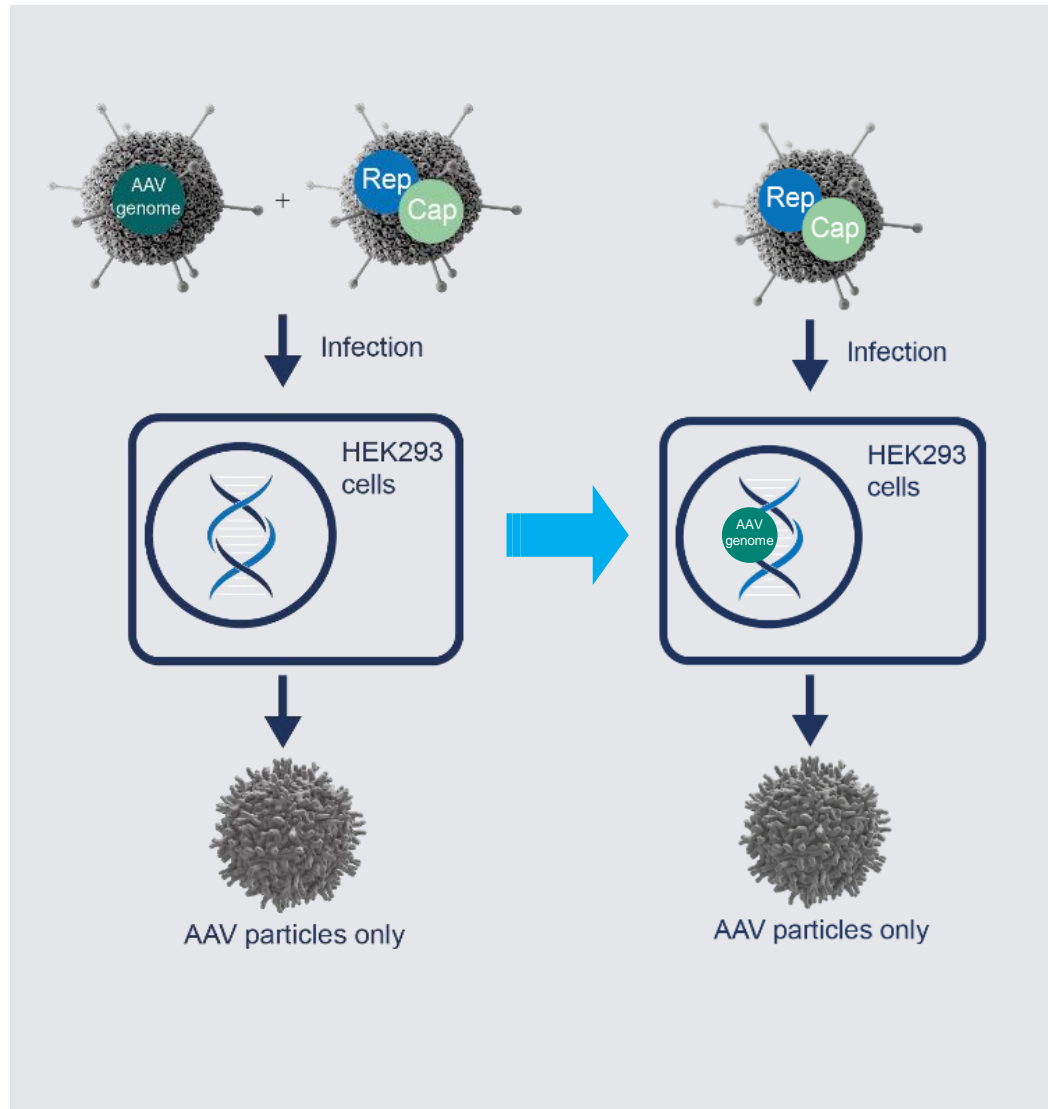


Enough to run 200-  
1000 x 200L AAV  
bioreactors!



**10-40X** Reduction of costly starting material demand

# TESSA™: Improvement and Full Deployment in 2H 2022



R&D and GMP mfg. of TESSA™ AAV vectors in Oxgene, US, China and Singapore



Expedite client TESSA™ experience through ATU and client in-house evaluations



Real life demonstration in disease models



# TESSA™: Strong IP Position and Positive Market Feedback



- 28 international patent filings in 6 families to give TESSA™ technology very strong protection
- In H1 2022, new patents granted in Japan and Australia

“AAV titres were 1 log higher”  
– large pharma. **Licensing discussions underway**

– large Pharma

All of this was way better than helper free triple transfection in the same experiment, which gave us **26-180 times less** yield



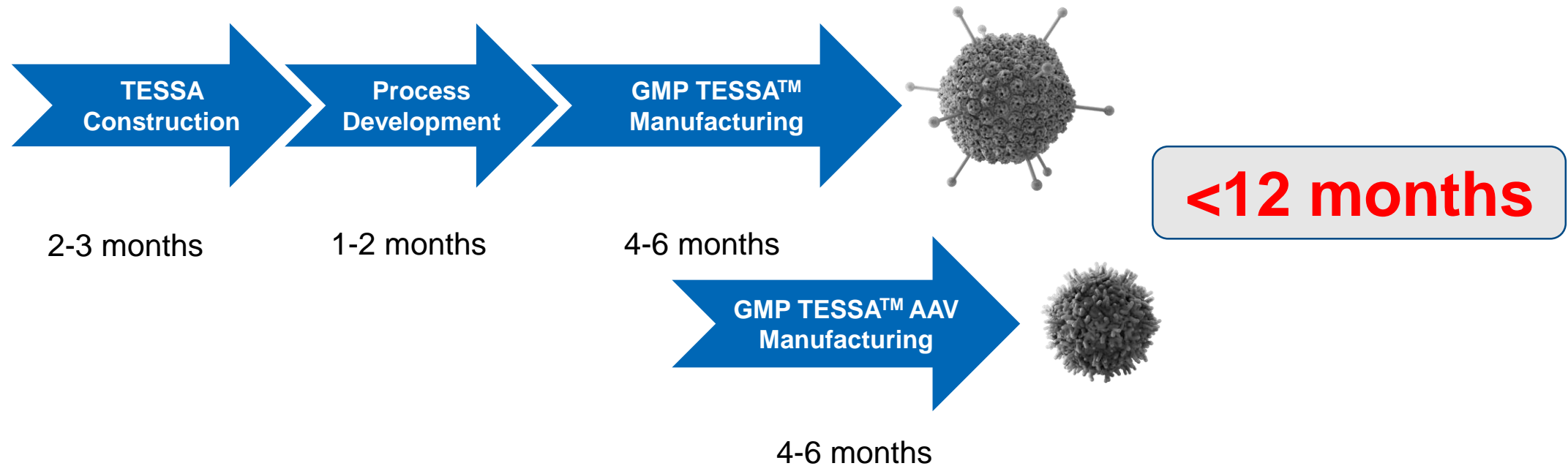
“TESSA™ enables us to test new constructs **much faster and cheaper** now, which is why we like to keep using it”

– renowned university

30 evaluation projects (17 are on-going) including 6 large biotech/pharma

# TESSA™: Enabling Rapid AAV Production

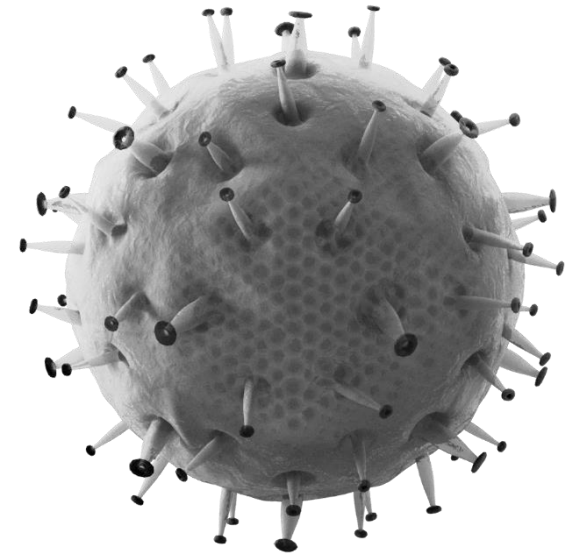
- Customers can test TESSA™ in their own laboratory with TESSA™ kits
- Customers can contract OXGENE to construct their TESSA™ GOI vectors, this can then be transitioned to GMP manufacturing
- WuXi ATU will be producing the standard TESSA™ -RepCap serotypes (1-9) as in stock reagents to be used by customers



# Innovate: LentiVEX™ Stable Technology

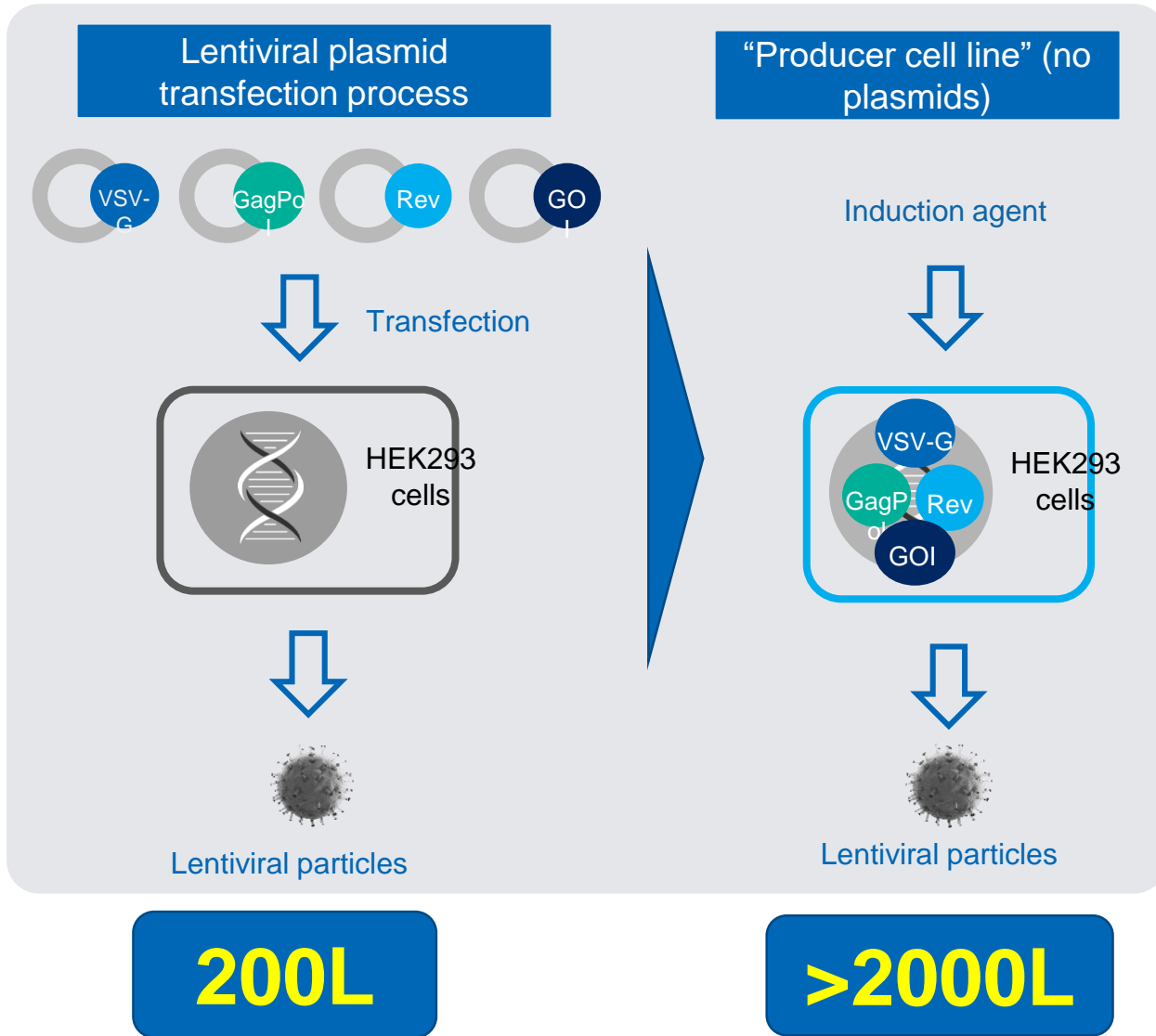
## Our Vision

- Develop a lentiviral manufacturing platform that can be easily scaled and reduces the COGS

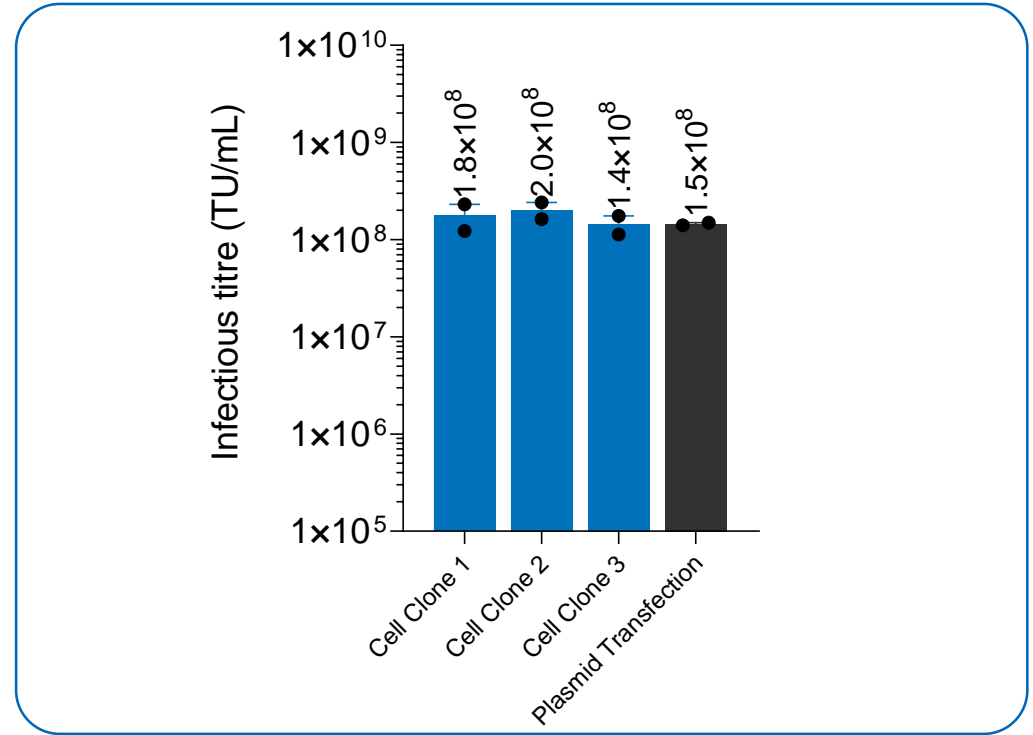


# LentiVEX™ Stable Platform

## The Cost-Effective, Scalable Solution to Lentiviral Vector Manufacturing



- 40-50% of all bioreactor run costs are from lentiviral plasmids transfection process
- LentiVEX™ stable producer technology requires no plasmid transfection, hence reduces COGS
- Fully scalable lentiviral manufacturing at > 2000L



**Comparable Titers**

WuXi ATU CTD “M” O



# A Global Footprint to Support Cell and Gene Therapy Testing, Development and Manufacturing

## United States, Philadelphia, PA



LI1 7,600 m<sup>2</sup>

**D** **M**



CC3 5,100 m<sup>2</sup>

**D** **M**



LI2 14,000 m<sup>2</sup>

**D** **M**

Expand GM-CT



R400 13,000 m<sup>2</sup>

**D** **T**

Standalone testing laboratories

## China



Huishan, Wuxi, Jiangsu 13,200 m<sup>2</sup>

**D** **M** **T**

Plasmids



WGQ, Shanghai 610 m<sup>2</sup>

**D**



Lingang, Shanghai 21,500 m<sup>2</sup>

**D** **M** **T**

## United Kingdom



Oxford, UK 2,400 m<sup>2</sup>

**D**

## Singapore



(D) 3,000 m<sup>2</sup> + (M) >10,000 m<sup>2</sup>

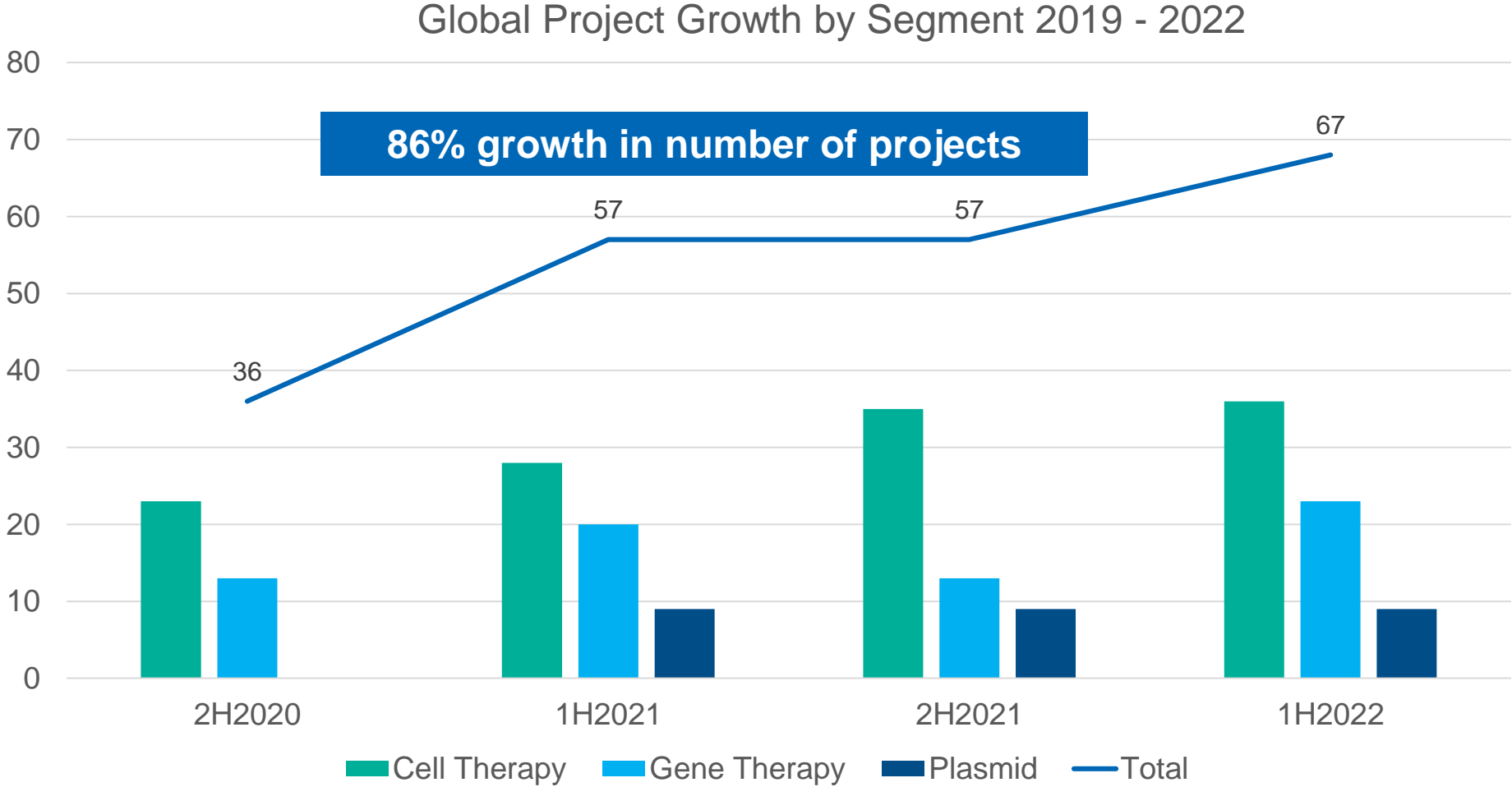
**D** **M**

**T** Testing 3

**D** Development 9

**M** Manufacturing 6

# Global Manufacturing Project Growth



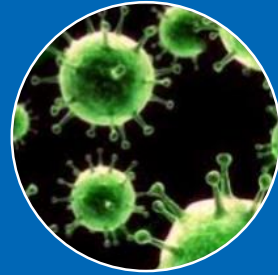
**Ready-now manufacturing capacities in US & China**

# Execution of CTDMO for Commercialization



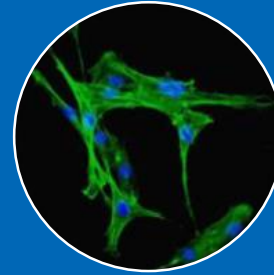
## TIL: IND to BLA (US)

- ✓ 2015 initiated clinical mfg
- ✓ 400+ Clinical Batches
- ✓ 1000+ Potency Tests
- ✓ Commercial Supply at +300 batches / year starting 2023



## Plasmid & LVV: IND to BLA (CN)

- ✓ 2018 initiated clinical mfg
- ✓ 8 mon from Sign to IND
- ✓ 100% success for 12 Clinical Plasmids and 10 Clinical Batches of LVV
- ✓ Commercial Supply starting 2023



## MSC: Testing Funnel to D / M Services (US)

- ✓ 2015 initiated testing
- ✓ Potency Assay Dev with 900+ Executed Results
- ✓ 2021 initiated clinical mfg
- ✓ Commercial Supply at 80 Batches / year starting 2024



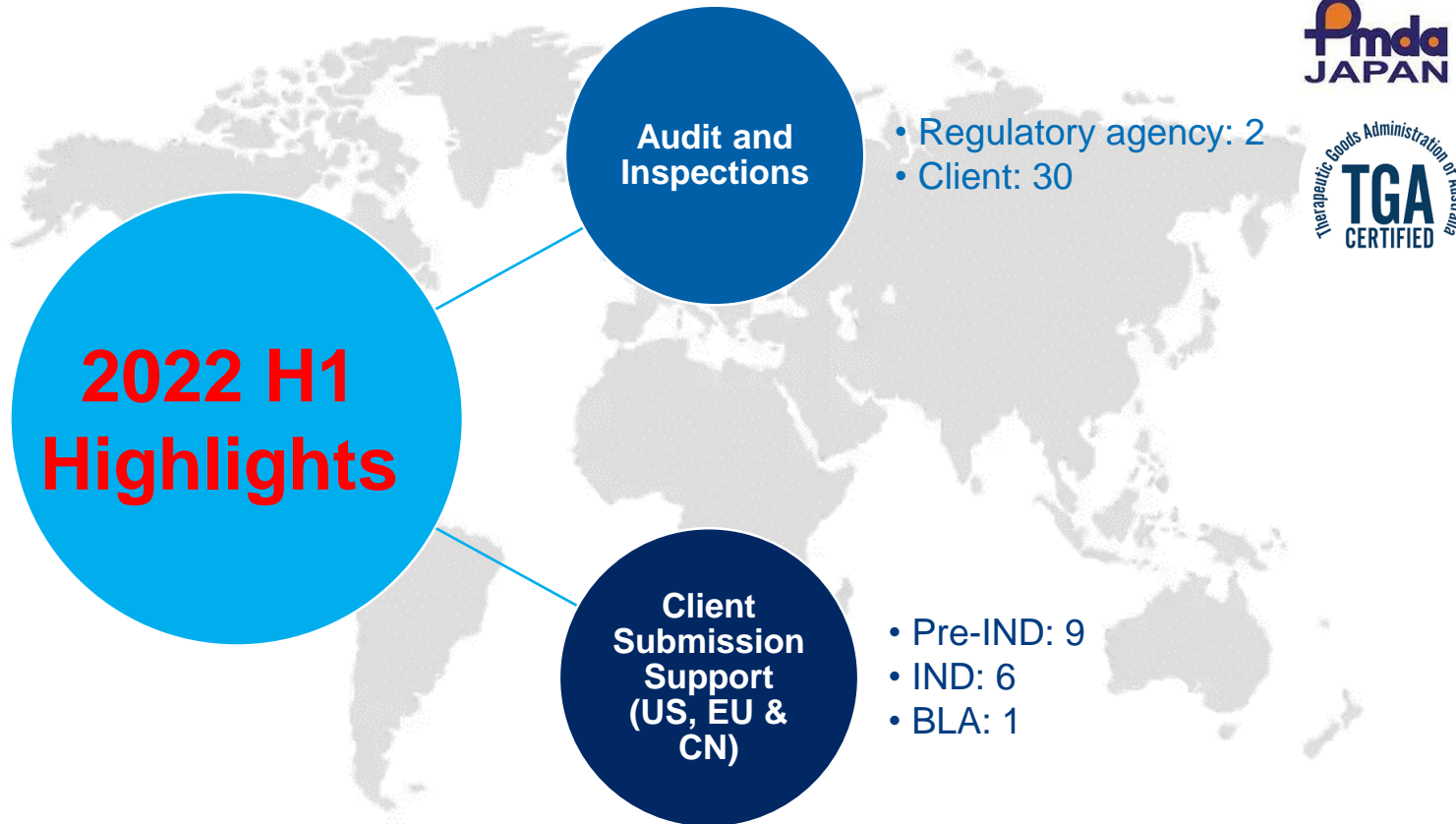
## LVV: Regionally Executed, Globally Supply (US & CN)

- ✓ 2020 initiated TT
- ✓ CN: 1<sup>st</sup> Gen PPQ 2022; Commercial supply at 40-120 Batches / year starting 2023
- ✓ US: 2<sup>nd</sup> Gen PPQ 2023; Commercial supply at 30 batches / year starting 2024

Full Regulatory Support for IND/BLA Filing; PLI (Inspection) Readiness Leading to Commercialization

# WuXi ATU Quality and Regulatory

Consistently Deliver Quality Compliance & Regulatory Services



## Recent Inspection/Certification

March 2022; TGA (Australia) GMP Inspection

December 2021; EMA GMP Inspection

June 2021; USDA Inspection

February 2021; ISO 17025 Re-certification

January 2020; FDA GMP Inspection

December 2019; EMA GMP Inspection

March 2019; TGA (Australia) GMP Inspection

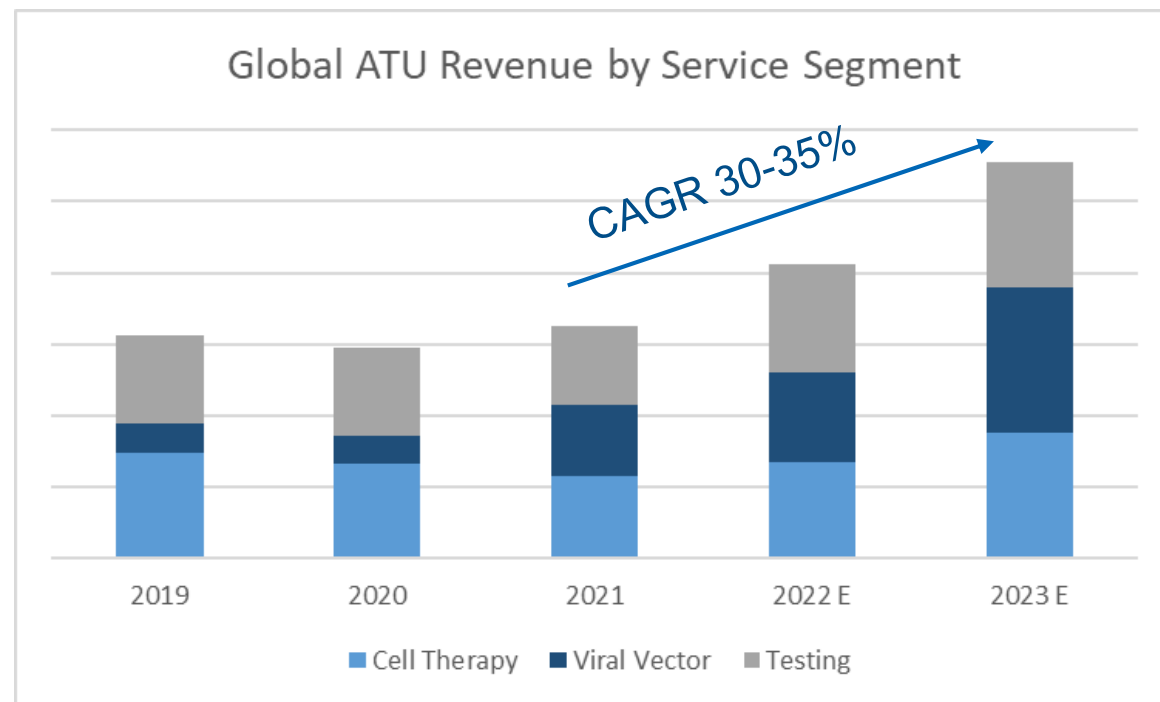
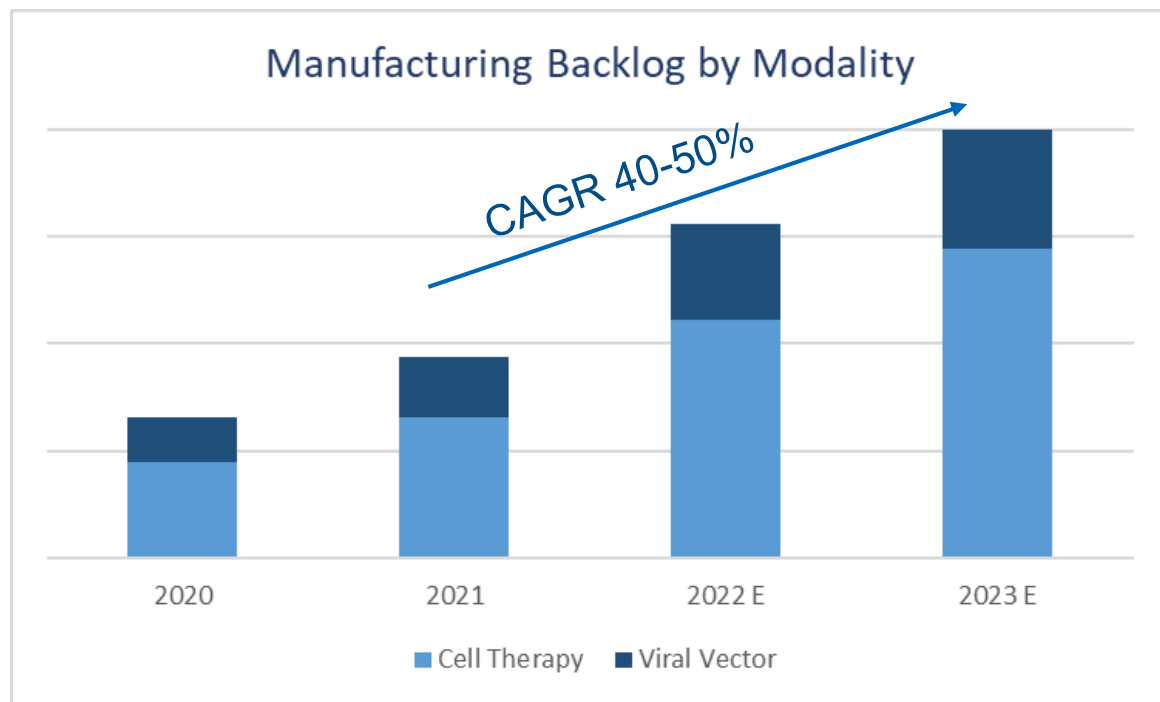
March 2019; PMDA (Japan) GCTP Inspection

**FDA U.S. FOOD & DRUG ADMINISTRATION**

- US Philadelphia FEI #1000122198; Active Type V DMF for all four facilities
- China Huishan FEI #3017796768

# Financials

# Strong Growth in CTDMO Global Backlog & Revenue



# CTDMO Model & Transformational Technologies Enable Innovative CGT Companies to Clinical & Market Globally

