



WuXi ATU

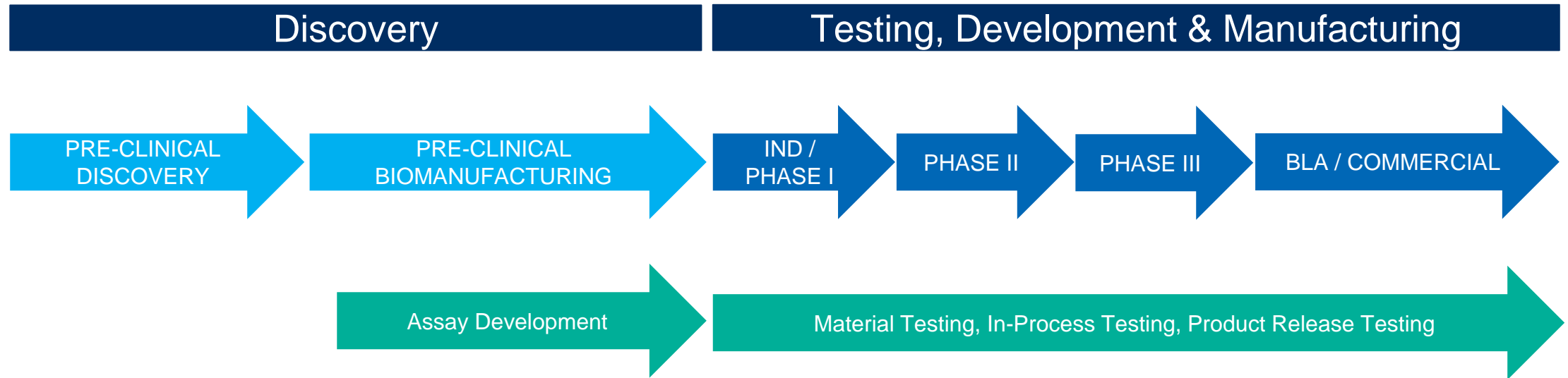
A Global CTDMO

Dr. David Chang 张幼翔 博士
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 – Revolutionary Global CTDMO Model



OxGENE[®]
A WuXi Advanced Therapies Company

 **WuXi
Advanced
Therapies**

 **药明康德
WuXi AppTec**

Global Platform, Global Talents

1,100+
employees

8
global sites

800k+ ft²
global sites

587
Programs worldwide

WuXi ATU Leadership Team



David Chang, Ph.D.

CEO, WuXi ATU

29+ years
of experience



Ryan Cawood, Ph.D.

CSO, WuXi ATU

14+ years
of experience



Jennifer Cheung

VP, QA and RA

28+ years
of experience



Heather Malicki, Ph.D.

ED, AD & Testing

20+ years
of experience



RJ Fitch

GM - US

25+ years
of experience



Angela Chen, Ph.D.

GM - China

19+ years
of experience



Jocelyne Bath

GM - UK

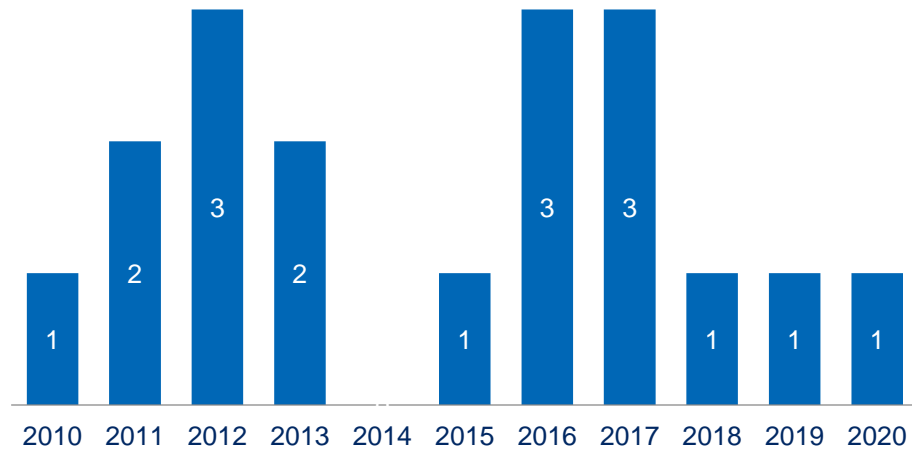
22+ years
of experience



Cell & Gene Therapy Product Development Landscape

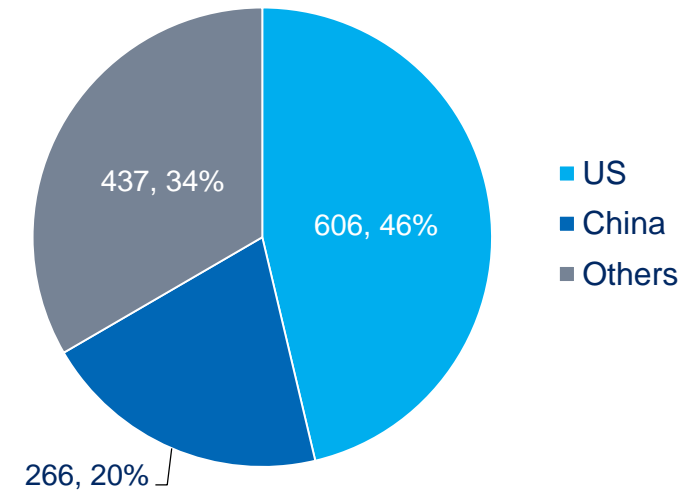
- Cell and gene therapy-related research, development and market in the global will continue to grow at a fast rate. There are currently **1,306 cell and gene therapies** in clinical trials as of the end of 2020 globally.
- As of 2020, there are total **18 FDA-approved** cell and gene therapies (**3 in the last 3 years**). It is expected that cell and gene therapy will make big advances in the next years.
- **46%** of CGT product are developed in US, and **20%** are in China.

FDA Approved Cell and Gene Therapies, 2010-2020



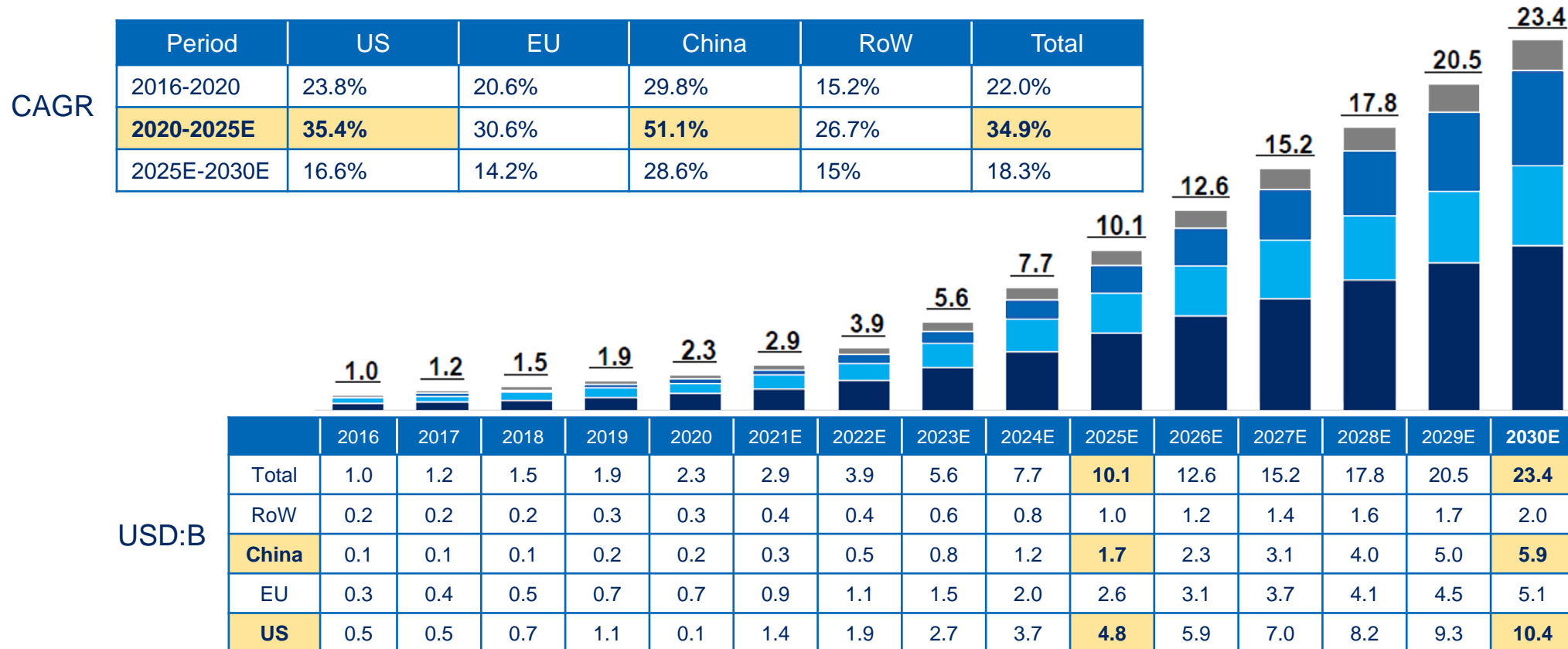
Source: FDA, ClinicalTrials.gov, Frost & Sullivan analysis

Cell and Gene Therapies under Development by Region, 2020



Historical and Forecast Cell and Gene Therapy CDMO Growth by Region

- Global CDMO services market increased at **22.0%** CAGR (2016-2020)
- Global CDMO for cell and gene therapy set to be **USD10.1B** by 2025 (CAGR **34.9%** 2020-2025)
- China CDMO forecast to be the fastest growing market at **51.1%** CAGR (2020-2025)

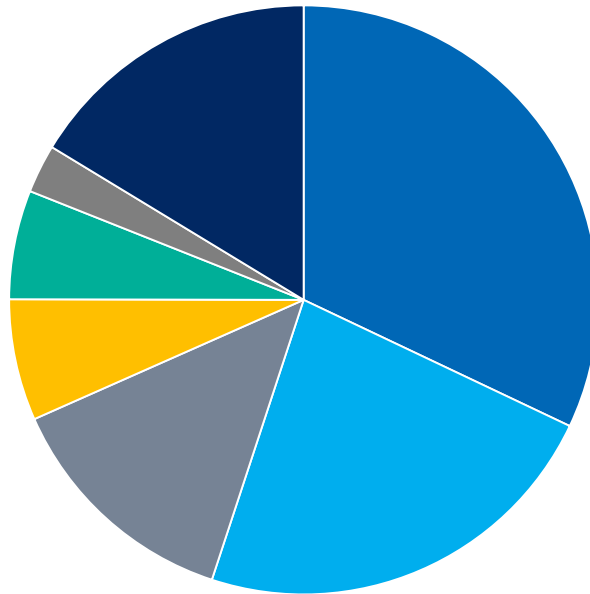


Competitive Landscape of Global Cell and Gene Therapy CMO/CDMO Market, 2020

- Cell and gene therapy CMO/CDMO market is an emerging segment in CMO/CDMO market due to high demand and approved clinical efficacy of cell and gene therapy in clinical. Catalent is the largest market players in global market with a revenue of USD722.8 Million or 32.0% of market share in 2020.
- WuXi ATU ranked 4th by revenue or 6.7% market share in 2020.

Competitive Landscape of Global Cell and Gene Therapy CMO/CDMO Market, 2020

Unit: Million USD



Company	Revenue	Market Share	
■ Catalent	722.8	32.0%	CDMO
■ Lonza	518.8	23.0%	CDMO
■ Thermo Fisher	300.5	13.3%	CDMO
■ WuXi ATU	150.4	6.7%	CTDMO Business Model
■ Charles River	135.0	6.0%	CRO (T)
■ Oxford BioMedica	60.0	2.7%	CDMO
■ Others	368.1	16.3%	

Notes: China-based market includes revenue that companies in China provide and generate revenue in China or global. F&S has estimation for the revenue which does not have public information.

Source: Annual report, Frost & Sullivan analysis

WuXi ATU C“T”DMO

Why “Testing” is So Important from Lessons Learned



Biotech

Mesoblast hit by FDA rejection, request to run another trial

Mesoblast said “assays measuring the **potency** of remestemcel-L will continue to be refined to provide further scientific rationale for its use in severe inflammatory diseases with high mortality risk.”

BRIEF

BIOPHARMA DIVE

FDA delays a biotech's cancer cell therapy once again

FDA is taking a tougher line on gene therapy development in general. FDA asked Sarepta to run another laboratory test using a new **potency assay** and Pfizer recently said it’s working with the FDA to resolve questions about **potency assays** for its own experimental Duchenne treatment.



Iovance Biotherapeutics Faces Another Delay in BLA Submission for TIL Therapy

Iovance said in a statement on Tuesday that it will continue to develop and validate its **potency assays** for the TIL drug, with plans to submit the additional assay data to the FDA in the second half of this year.

What Complex Testing for CGT is All About?

STARTING MATERIALS

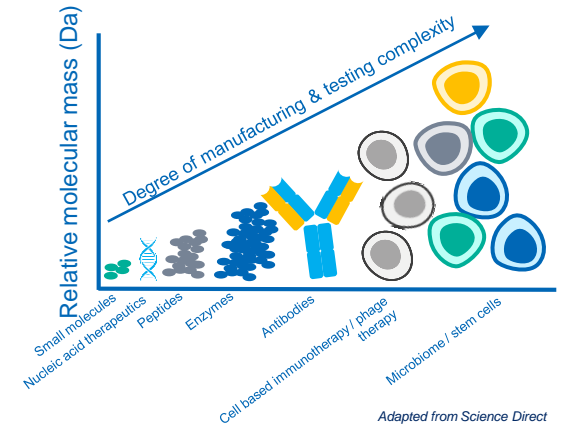
- Cell Bank Testing
- Viral Vector Release Testing
- Animal/human derived raw materials need extensive safety testing
- Heterogeneity of patient cells
- High numbers of complex raw material in CGT program

ASSAY DEVELOPMENT

- Complex cell and molecular based assays (eg potency assays)
- High number of product specific, customized assays
- Specialized technical capability (rare)
- Experience in managing patient heterogeneity

PRODUCT RELEASE

- Extremely short turnaround time for cell therapies (~24-96 hours)
- Very limited sample volumes for assays
- Complex biosafety testing (eg RCL, RCAA, ...)
- Regulatory guidance is still evolving – no clear path to market



- Product companies & traditional CDMO do not possess the internal analytical development and testing capabilities for CGT products
- WuXi ATU internal, integrated testing could address all these challenges in US, China and EU

Testing: Serving the Funnel for Integrated CGT Projects, and Integral Part of the Process Dev and Manufacturing

“WuXi ATU’s 3 Decades of “Testing” Experiences in Cell and Virology Testing”

 **1,700+** Global Submissions

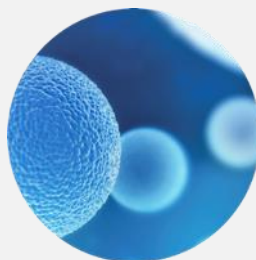


27+

Commercial Lot Release Testing



Strong Assay Development



Biosafety



Virology
Microbiology
Molecular



Viral Clearance



Commercial Lot Release

3x Capacity | CGT Focused | Enhanced Automation | Global Expansion

>90% On-time Delivery | >90% Right First Time | 99% Manufacturing Customer Take Advantage of Integrated Testing

WuXi ATU CT“D”MO

WuXi ATU Acquires OXGENE (March/2021)

OXGENE[®]
A WuXi Advanced Therapies Company

**BE FIRST
IN THE RACE**

TO DELIVER BREAKTHROUGH
CELL & GENE THERAPIES



50 | Technology **Fast 50**
2019 UK **WINNER**
Deloitte.

TOP 10 BRITAIN'S
FASTEST-GROWING
BUSINESSES 2019

WuXi ATU + OXGENE Platform Portfolio

Fully Integrated World-Class CTDMO Platforms

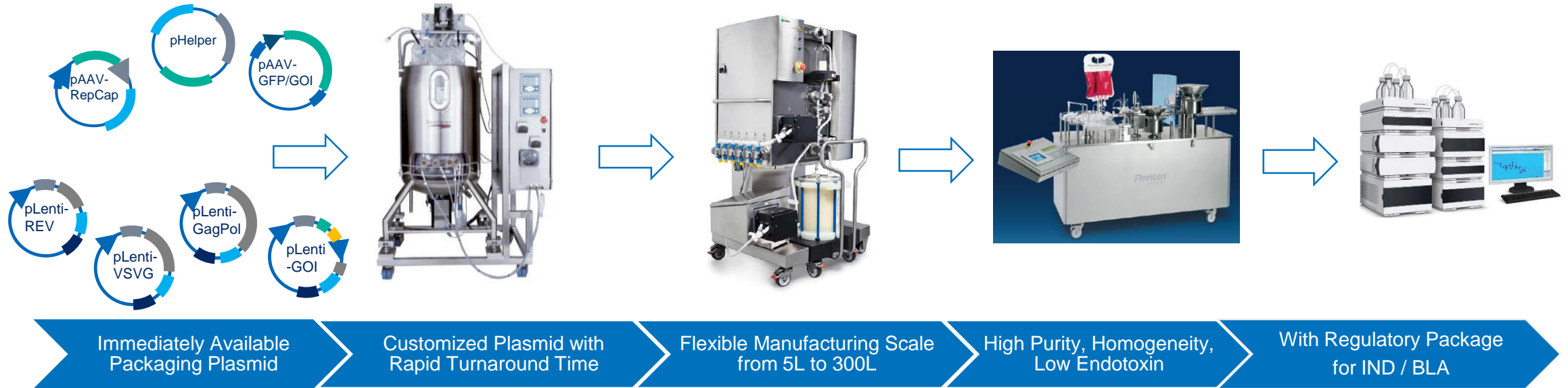
OXGENE	Plasmid DNA	Viral vector	Cell therapy
<p data-bbox="239 539 690 658">Viral vector & cell line development</p> <p data-bbox="239 801 690 919">Innovations in future manufacture platform</p>	<p data-bbox="756 596 1207 772">Research, Clinical and Commercial Grade</p>	<p data-bbox="1261 491 1732 615">XAAV™ ~ AAV platform</p> <p data-bbox="1261 665 1732 789">XLenti™ ~LVV platform</p> <p data-bbox="1261 839 1732 1015">TESSA™ ~Future revolutionary AAV platform</p>	<p data-bbox="1778 546 2249 618">Closed CAR-T</p> <p data-bbox="1778 689 2249 761">TIL / MIL</p> <p data-bbox="1778 832 2249 951">Stem cell & Tissue Engineering</p>
<p data-bbox="428 1103 504 1146">UK</p>	<p data-bbox="856 1103 1110 1146">UK & China</p>	<p data-bbox="1358 1103 1638 1146">USA & China</p>	<p data-bbox="1875 1103 2155 1146">USA & China</p>

Plasmid DNA Production Platform

Off-the-shelf XAAV™ and XLenti™ Plasmids and customized GOI plasmids with Patented Technology

Technology and Process (USP / DSP)

Filling and Testing



- Research, Clinical-GMP and Commercial-GMP grades available
- Antibiotics-free manufacturing process (regulatory friendly, especially in China)
- Delivers consistent high yields (1-10 g) and high quality plasmid in 5 days (thaw to fill/finish)

XAAV™ Suspension Transient Platform

Consistently (10 Serotypes) Delivering High AAV Yields and Reproducible Productivity

Technology and Upstream Process

Downstream and Testing



High Performing Clonal
HEK293 cell line

Patented Plasmid Technology

Scalable Suspension Platform
Up to 200L

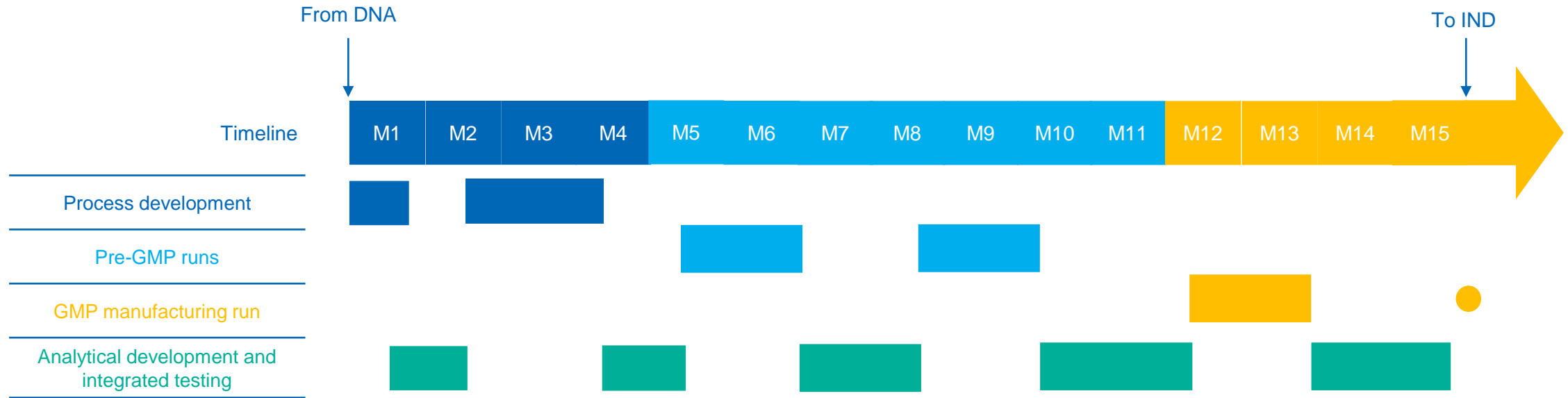
Pre-Validated
Downstream Processes

Validated Integrated and
Release Testing

- Use OXGENE high-performance plasmids (off the shelf)
- Delivers consistent industry-leading AAV yields at harvest (2×10^{10} - 2×10^{11} GC/ml) and high quality in **30 Days** for 200-400L/batch (Thaw to Final Fill/Finish)
- Excellent customer satisfaction of recent **8** AAV clients (eg, ViGeneron)

XAAV™: From DNA to IND in 15 months

An Accelerated, Fully integrated Industrially Leading Customer Journey



* These timelines are reduced/eliminated if customer's GOI is already in an OXGENE backbone

XLenti™ Adherent and Suspension Transient Platform

Consistently Delivering High Lenti Viral Vector Yields and High Quality

Technology and Upstream Process

Downstream and Testing



High Performing Clonal
HEK293 cell line

Patented Plasmid Technology

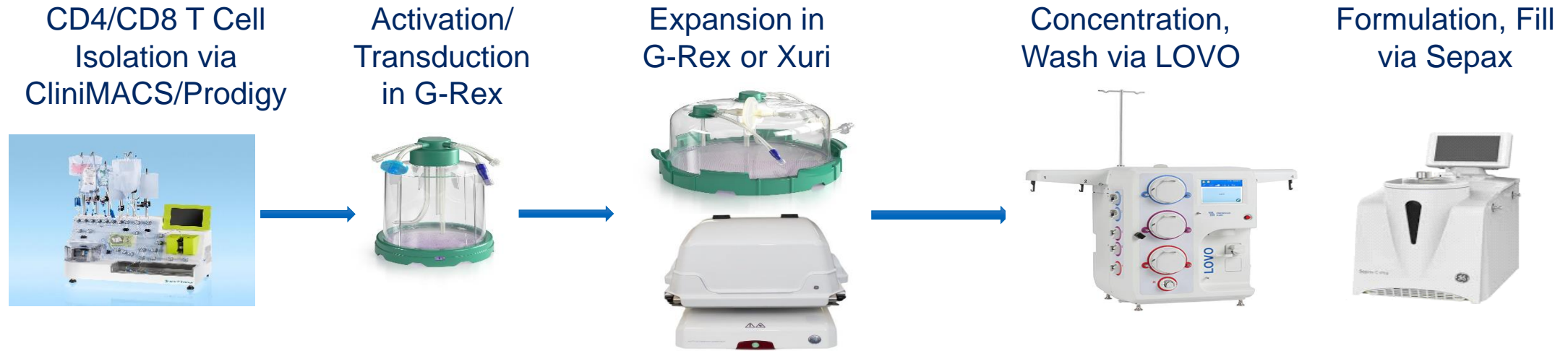
Scalable Platform Up to 24-
48 Hyperstack (adherent) or
200L Bioreactor (Suspension)

Pre-Validated
Downstream Processes

Validated Integrated and
Release Testing

- Use OXGENE high-performance plasmids (order off the shelf)
- Deliver consistent industry-leading Lenti yield at harvest (1×10^7 TU/ml) and high quality in each adherent batch (**100-200L**), or in a **200L** suspension batch in **20 Days** (Thaw to Final Fill/Finish)
- Excellent customer satisfaction of recent **12** Lenti VV clients (2 for global BLA filing).

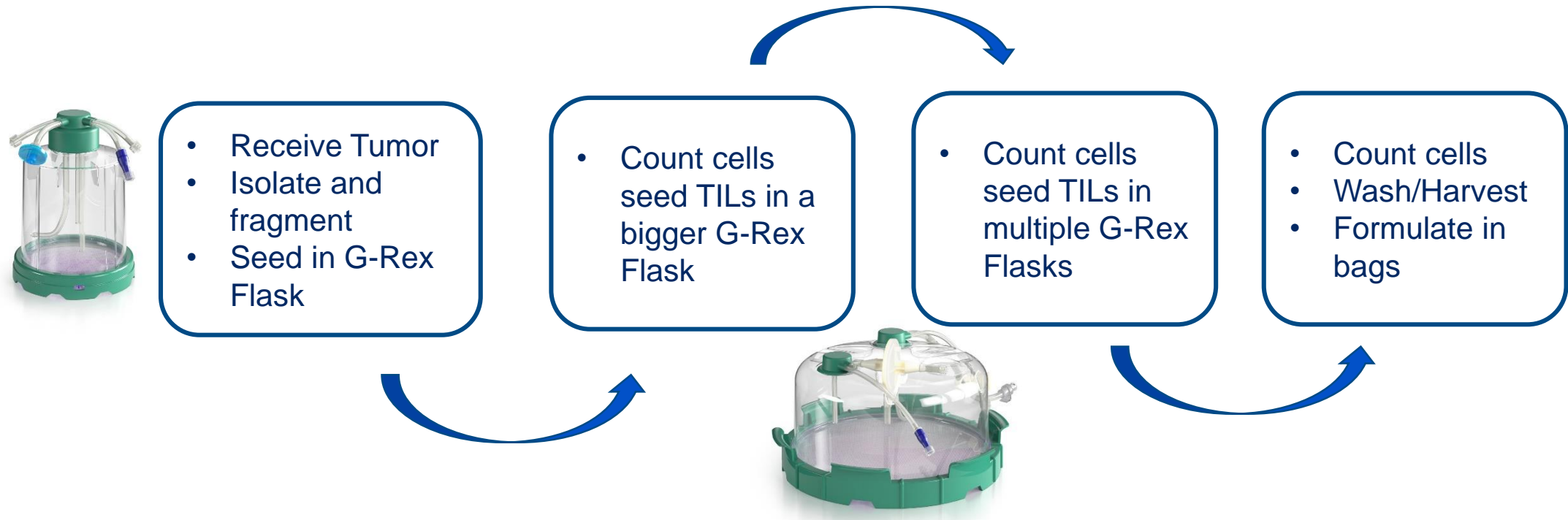
Closed CAR-T Platform: 3 Months from Signature to MFG



Off-the-shelf GMP grade chemically defined media, activator, and cytokines

- The platform includes pre-established equipment, documents, raw materials, testing catalog and specifications -> Enable fast tech transfer to manufacturing.
- Closed CAR-T enables Mfg in lower grade of clean room -> **reduce COGs and increase Mfg throughput**
- **>400** batches of autologous / allogeneic CAR-T experience

Tumor-Infiltrating Lymphocytes (TIL) Platform



Categories of Tumors

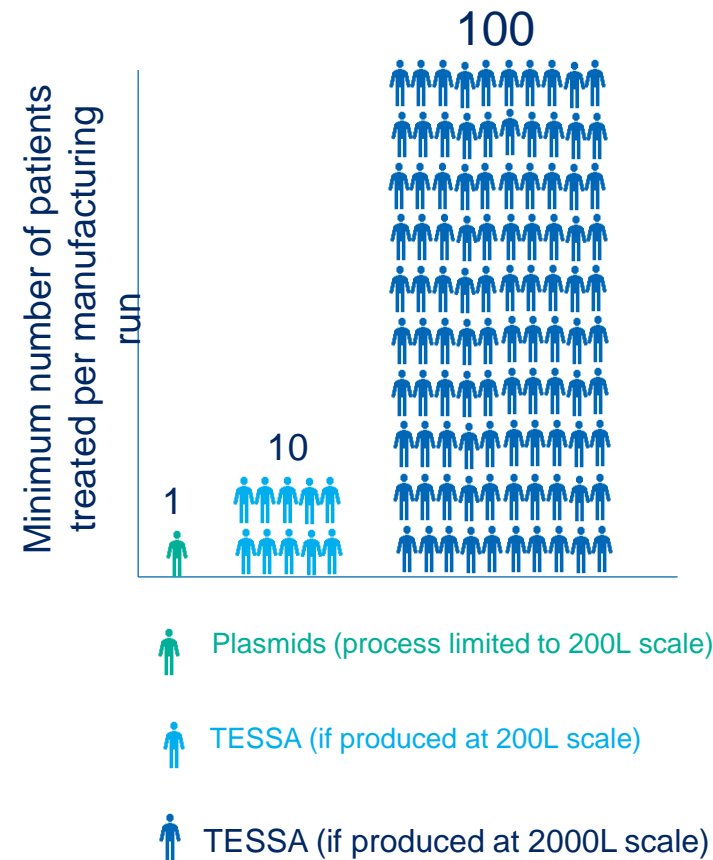
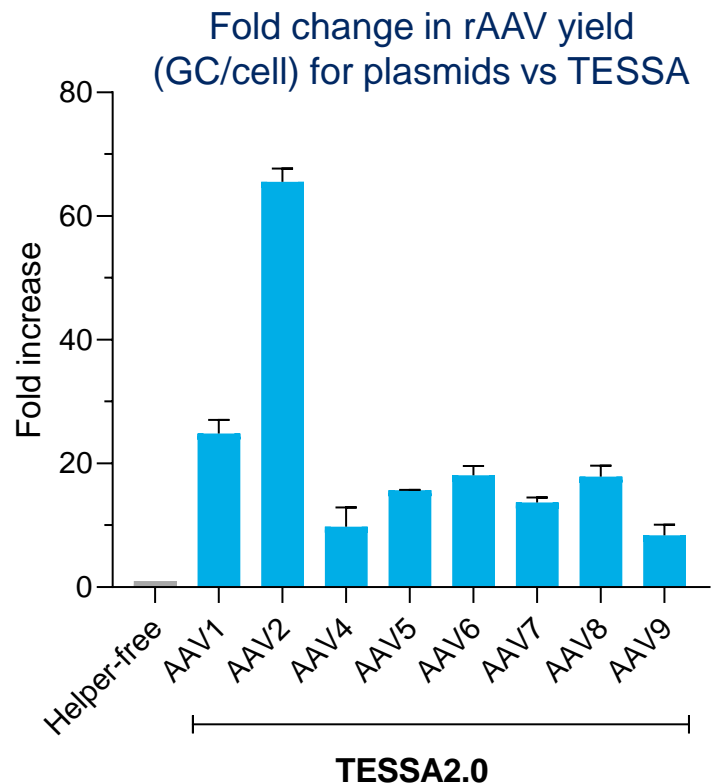
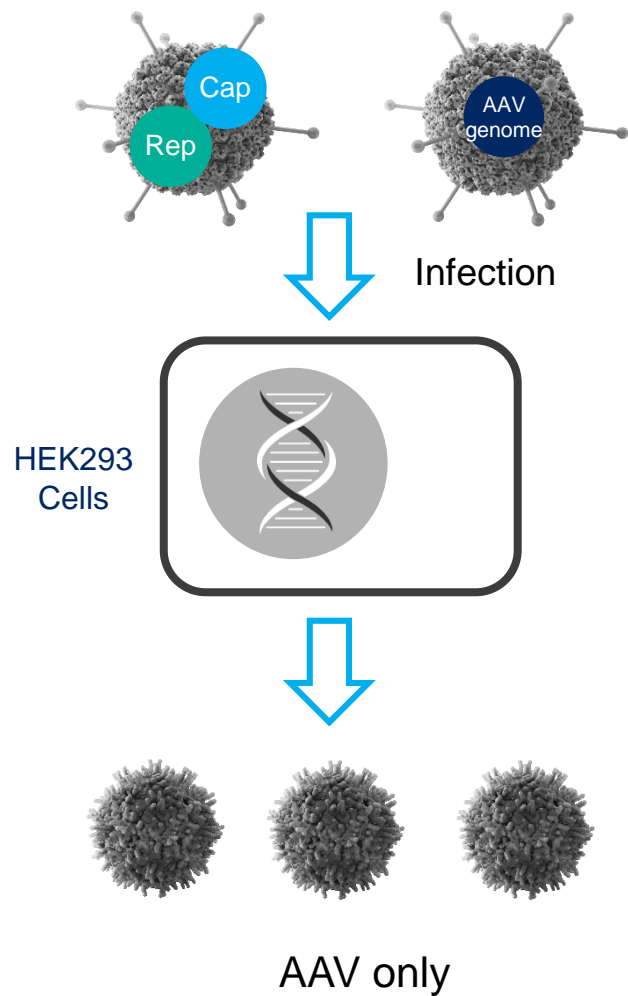
- Melanoma, Metastatic Melanoma
- Cervical, Cervical Carcinoma
- Head & Neck, Head Neck & Shoulder, HNSCC
- Other (Carcinoma, Soft tissue sarcoma, Lung)

Processed Lots

- **> 300** TIL lots processed and released
- WuXi ATU is current industrial leader

TESSA™ AAV Revolutionizes AAV Manufacture

TESSA™ AAV Process



TESSA™ AAV Technology: Current Deployment Status

Early adopters

2 Big pharma **>10** biotech **3** academic

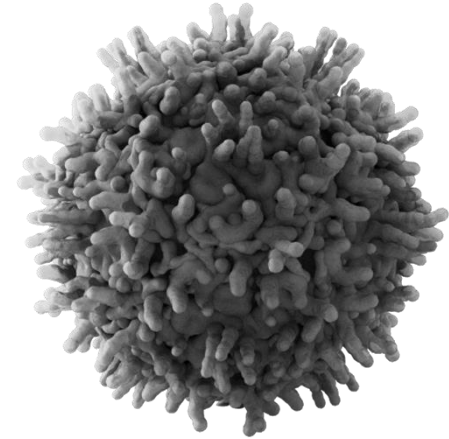
Feedback from early adopters

“AAV titers were 1 log higher” – big pharma

“Significantly better than controls” – big pharma

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

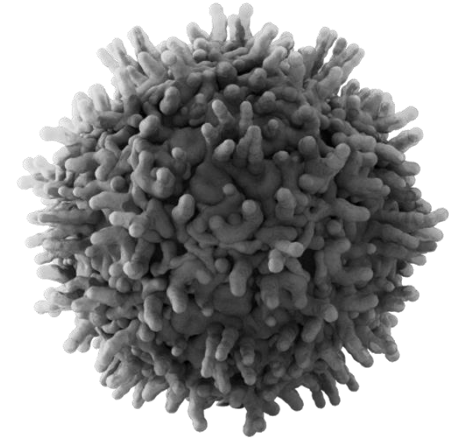
“TESSA™ enables us to test new constructs much faster and cheaper now, which is why we like to keep using it” – renowned university



TESSA™ AAV Technology: An Innovation to Transform and Revolutionize AAV Manufacturing

Transformational Advantages

- Significantly increases AAV particle yields
- Increases AAV particle quality
- Reduces adenovirus contamination by 99.99999999%
- Removes the use of plasmids thus significantly reduce COG
- Significantly improve scalability (> 2000L) and process robustness, and uniform infection of cells, thus further significantly reduce COG



Greatly Increase Market/Patient Access Through Significant Reduction of COGs

WuXi ATU CTD “M” O

CTDMO Model of Manufacturing Lifecycle Management

CELL & VIRAL BANKING

PLASMID MANUFACTURING

CELL THERAPY & VECTOR MFG.



- Dedicated Cell & Viral Banking
- R&D and Commercial Client Banks
- Full on site characterization testing
- On-site & remote long term storage options

- Research, GMP like ad GMP grade plasmid production offering from an antibiotic free process; supporting both CGT and mRNA modalities

- Adherent & 1K L Suspension technologies
- Build to EU & FDA & China Compliance standards
- >95% batch success rate



A Global Footprint to Support Cell and Gene Therapy Programs

United States, Philadelphia, PA



LI1 82,000 ft²

D M



CC3 55,000 ft²

D M



LI2 150,000 ft²

D M



R400 140,000 ft²

D T

China



Wuxi City, Jiangsu 143,000 ft²

D M T



WGQ, Shanghai 6,600 ft²

D



Lingang, Shanghai 231,000 ft²

D M T



Huishan, Jiangsu, 50,000 ft²

M T

United Kingdom



Oxford, UK 26,000 ft²

D

T Testing 4
D Development 8
M Manufacturing 6

WuXi ATU Facilities

USA: 400K+ ft² of Integrated End-To-End Facilities

- Occupy 400K+ ft² in the Navy Yard, Philadelphia, PA
- 800+ highly-skilled scientific professionals recruited from Philadelphia, a major global cell and gene therapy hub
- 30 GMP suites / 3 manufacturing facilities
- All Facilities are US & EU & CHN Compliant
- Clinical and commercial capability
- Dedicated facilities for cell Therapy, gene-mediate cell therapy and vector Mfg.
- Recently expanded testing footprint (3X) to meet increased industry demand



League Island 1 (LI1, 82,000 ft²)
Early Phase Cell & Gene Therapy Clinical Manufacturing



League Island 2 (LI2, 150,000 ft²)
Late Phase/Commercial Manufacturing Gene-Mediated Cell Therapies and Viral Vectors



Commerce Center 3 (CC3, 55,000 ft²)
Late Phase and Commercial Manufacturing Autologous / Allogeneic CT



Rouse 400 (R400, 140,000 ft²)
Testing for ATMPs and Standard Biologics

WuXi ATU Facilities

China: 380K+ ft² – Largest CGT Dedicated CTDMO in China

Huishan Wuxi + Lingang Shanghai + Waigaoqiao Shanghai

- Over 380K + ft² full scale plasmid, viral vector and cell therapy GMP manufacturing
- 250+ skilled work force (>10% domain experts with international background)
- Global standard quality system, compliant with CHN, US, and EU
- Building largest CGT Testing center in Asia
- Dedicated customer project suites and shared platforms
- Commercial suites and space can be reserved for future projects



Wuxi City, Jiangsu
143,000 ft²



WGQ, Shanghai
6,600 ft²



Lingang, Shanghai
231,000 ft²

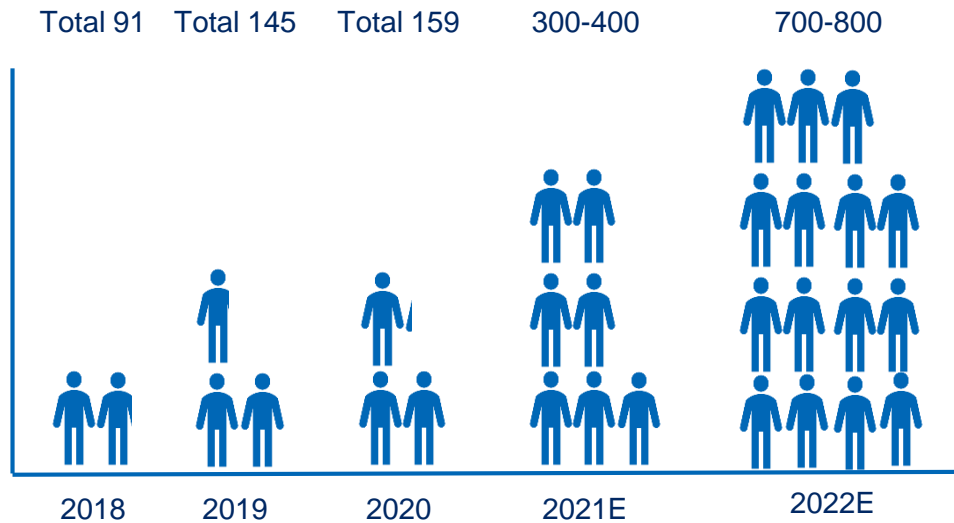


Newly expanded plasmid manufacture facility opening 2022

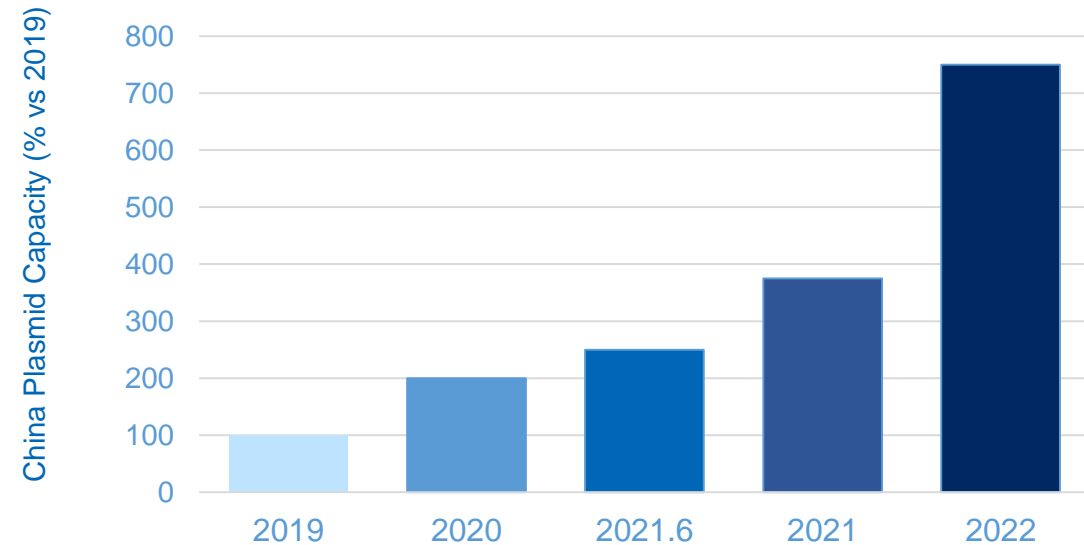
Accelerating WuXi ATU China Growth to Meet Global Demand (Plasmid, CTDMO)

- Opening Lingang Shanghai new facility Q4 2021; largest CGT GMP facility in China, housing end to end CTDMO capability for gene therapy, from testing, to PD, and to manufacturing
- China will have 300-400 employees by end of 2021, and estimate to have 700-800 by 2022
- Expanding plasmid manufacturing capacity in WuXi headquarter (**450** lots/year, triple capacity by 2022)

China Team Expansion to Meet Increasing Demand



China Plasmid Capacity (% increase vs 2019)



WuXi ATU Quality and Regulatory

A Strong Global Track Record of Regulatory Compliance



US FDA Inspections

- December 2019, EMA GMP Inspection (GMP Certificate)
- May 2019, TGA GMP Inspection (GMP Certificate)
- March 2019, PMDA GCTP Inspection
- April 2019, ISO 17025 Re-Certification
- September 2018, AATB Inspection
- August 2018 & March 2019, EU QP GMP Inspection
- October 2014, EMA (Spanish Inspectorate)
- September 2013, Korean FDA (No Observations)
- Jun 20/May 19 USDA (Release Product Intermediate to EU)

Additional Inspections

- January 2020, GMP Inspection (No Actions Indicated)
- April 2015, GMP Inspection (483 with Minor Observations)
- September 2013, GTP/GMP Inspection (No Form 483 Issued)
- August 2012, GMP Inspection (No Form 483 Issued)
- January 2010, GMP Inspection (No Form 483 Issued)

Client Audits

- ~65-75 / year

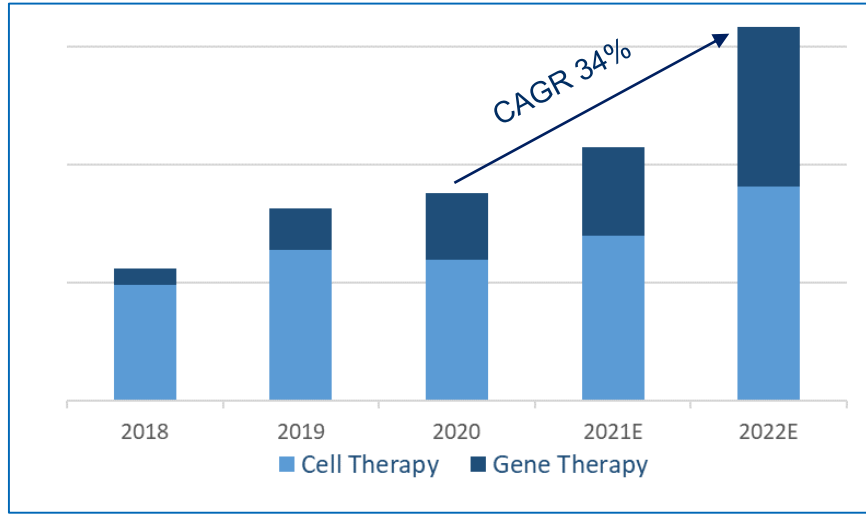
Registrations

- FDA (CBER) #1000122198

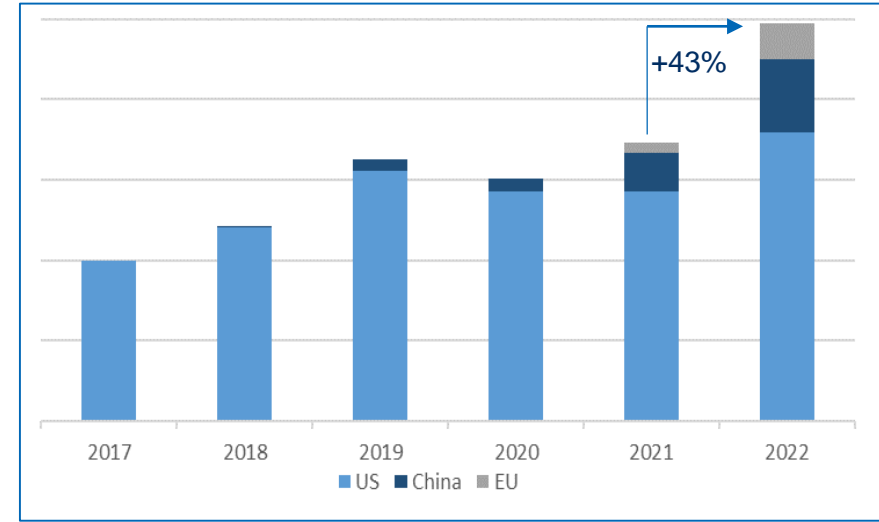


Strong Growth in CTDMO Services and Global Back Log in 2021 and Beyond

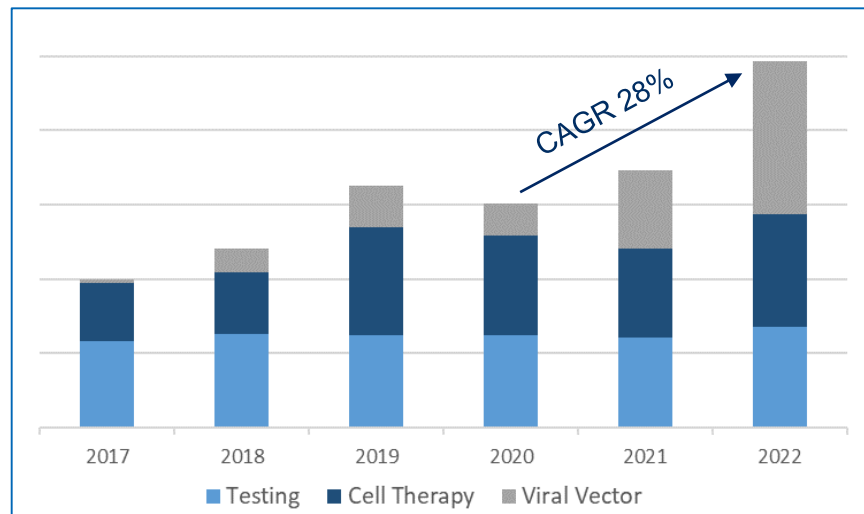
Manufacturing Backlog by Modality



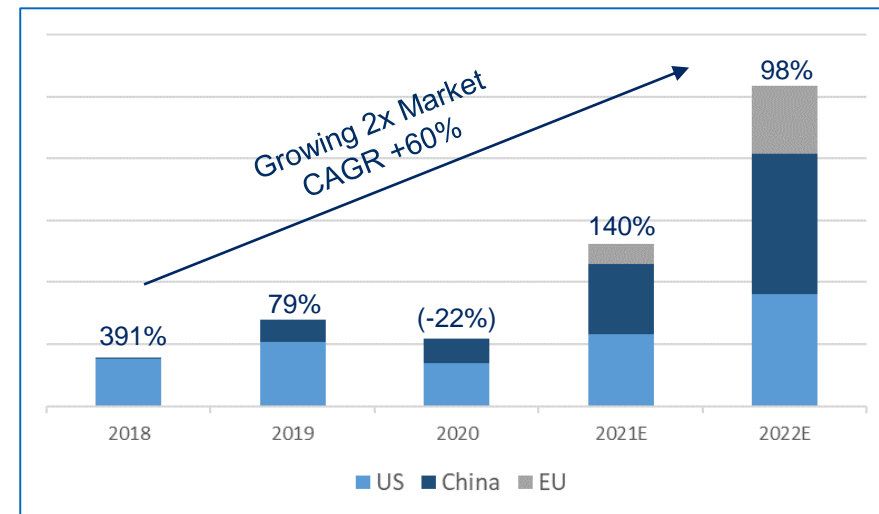
Global ATU Revenue by Region



Global ATU Revenue by Service Segment



Gene Therapy (Viral Vector)



Growth Strategy: Accelerating Time to Clinics & Market for Innovative CGT Companies Globally

WuXi Advanced Therapies

- 1 CTDMO Business Model Leveraging Testing to Funnel Business to “D”&”M”
- 2 Next Generation Platform Technologies ~ TESSA-AAV
- 3 Expand Capabilities and Capacities in US, China & EU to Service Global Markets
- 4 Attract & Retain Highly Skilled Talents