Oribiotech

Unlocking the full potential of CGT.

ISCT 2025 Oribiotech Global Showcase
Jason C. Foster, CEO

The cell therapy industry is facing a crisis of confidence, with investors and partners questioning whether ex-vivo approaches are commercially viable.

Globally, **less than 5%** of patients who could benefit from approved therapies have been able to access them.

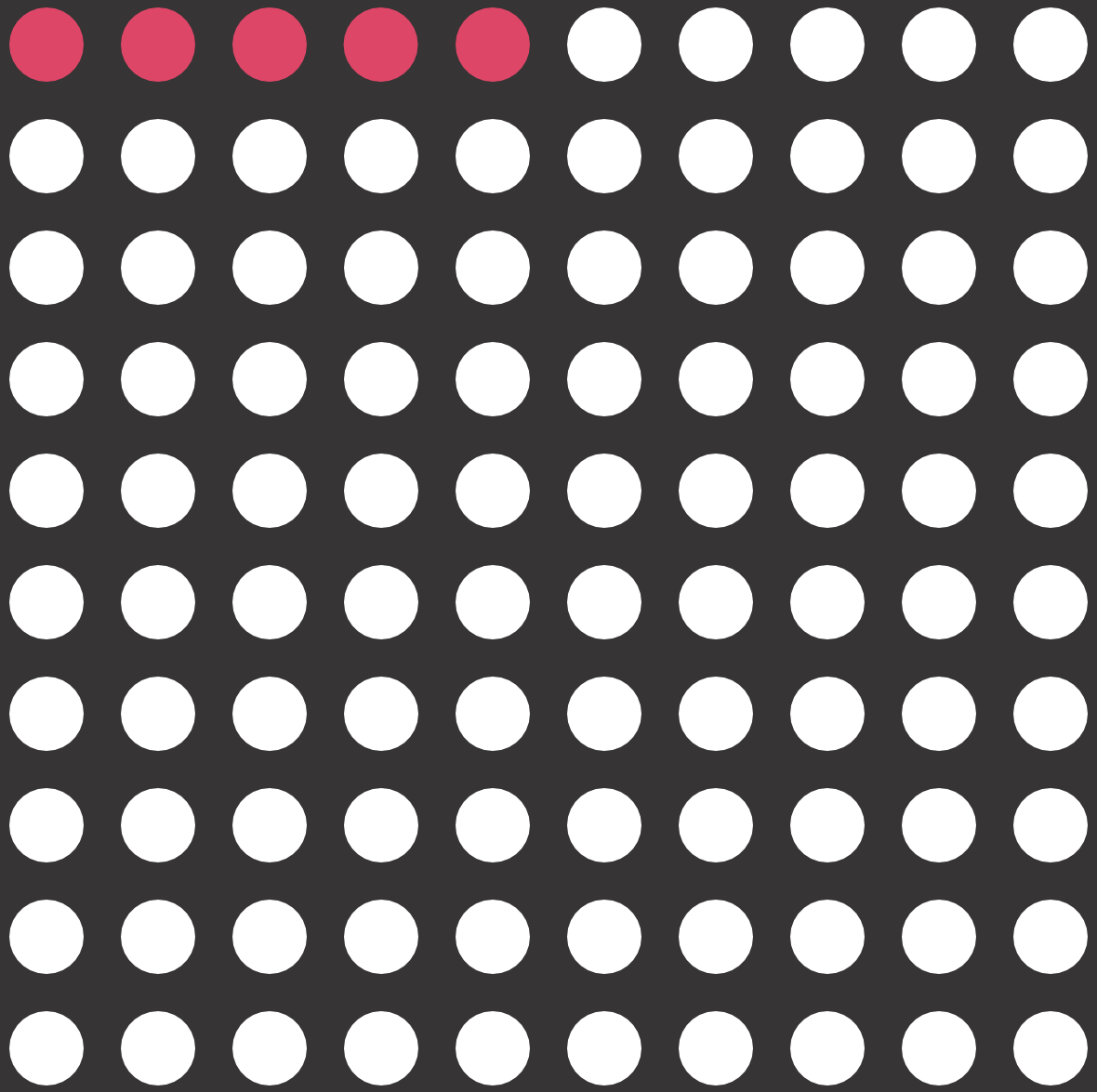
900K*

Addressable Patient Population

~36K

Total Patients Treated

Post 2016 approved products across CAR-T, TCR, and TIL



*Projected : Includes ALL, DLBCL, Multiple Myeloma, CLL and FL. Source: McKinsey, Statnews.
Source: Ori Biotech Internal Research at www.oribiotech.com

Patient Access Reality.

Patient access to these life-saving therapies is currently limited, stemming from manufacturing challenges

Therapy Name	2017	2018	2019	2020	2021	2022	2023	2024	Cumulative Patients Treated by Therapy
KYMRIAH®	13 (Aug 2017)	162	588	999	1,238	1,131	1,072	934 (-13%)	**6,137**
YESCARTA®	19 (Oct 2017)	711	1,225	1,511	1,865	3,111	4,018	3,707 (-8%)	**16,167**
TECARTUS®				119 (Jul 2020)	474	803	996	918 (-8%)	**3,310**
ABECMA®					393 (Mar 2021)	927	1,127	970 (-14%)	**3,417**
BREYANZI®					214 (Feb 2021)	447	815	1,534 (+88%)	**3,010**
CARVYKTI®						290 (Feb 2022)	1,076	2,073 (+93%)	**3,439**
AMTAGVI®								203 (Feb 2024)	**203**
TECELRA®								2 (Aug 2024)	**2**
AUCATZYL®								- (Nov 2024)	**-**
Total Patients Treated per Year	**32**	**873**	**1,813**	**2,629**	**4,184**	**6,709**	**9,104**	**10,341**	**35,685**

Annual Patients Treated with Approved Cell Therapies per Year

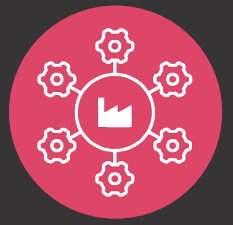
Source: April 2025 Ori Data Analytics

"The **status quo** in cell and gene therapy for most patients today **represents death or serious disability**."

Tim Hunt

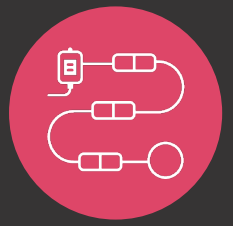
Chief Executive Officer,
Alliance for Regenerative Medicine (ARM)

What's Holding CGT Back?



Too hard to manufacture

Too expensive to make widely available



Not commercially viable due to **high COGS, low throughput,** and **low reproducibility**

Outdated tools
built for research

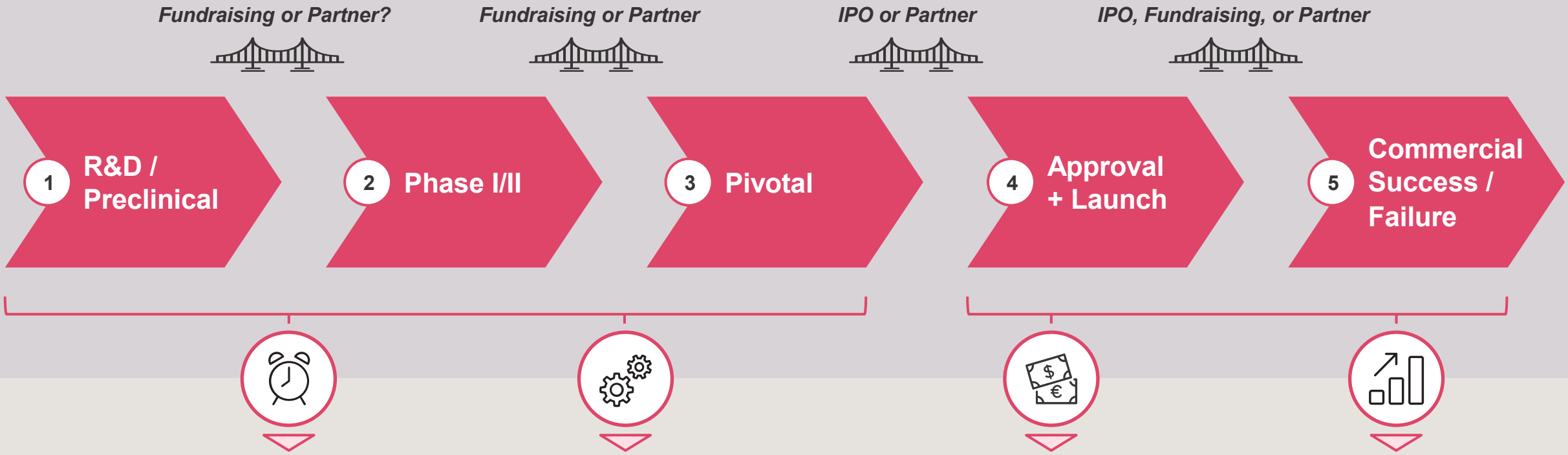
Manual processes

Repurposed legacy
automation

CGT Industry Has Not Kept Pace with Innovation.

We Are Still Using…

Typical Biotech Playbook.



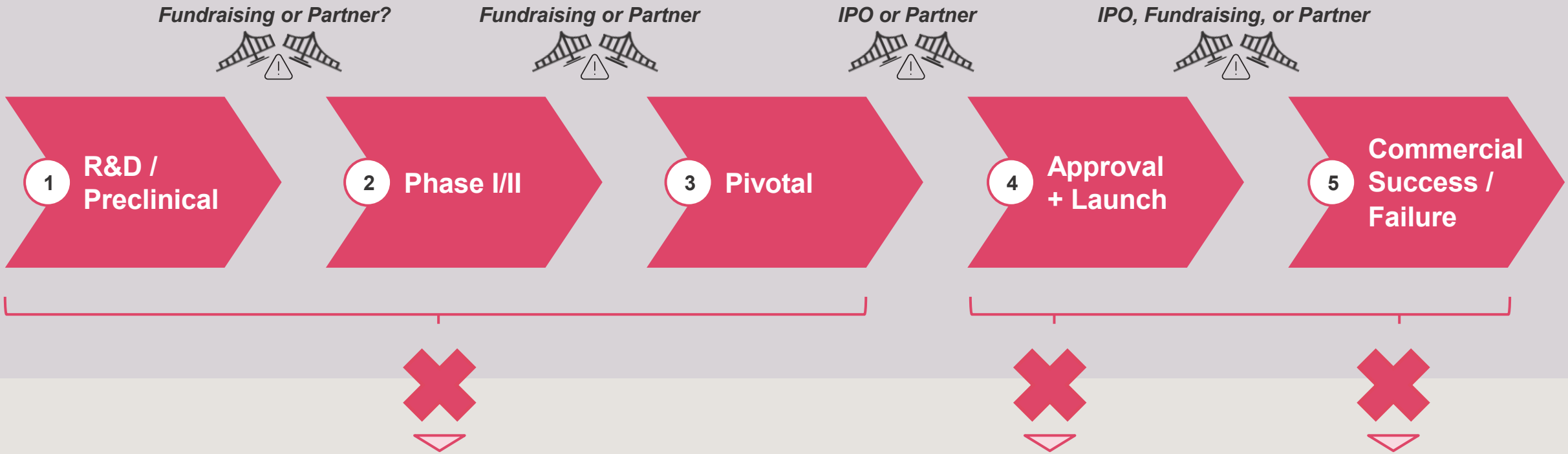
Developers **rush through the clinical process,** racing for **approval** and **launch**

Process optimization is often executed while the **product is already in the clinic**

Major infrastructure investment is required to support commercial MFG

Automation & scale-up are both evaluated **after commercial approval**

Applying This Playbook to Cell Therapy Has Been an Abject Failure.



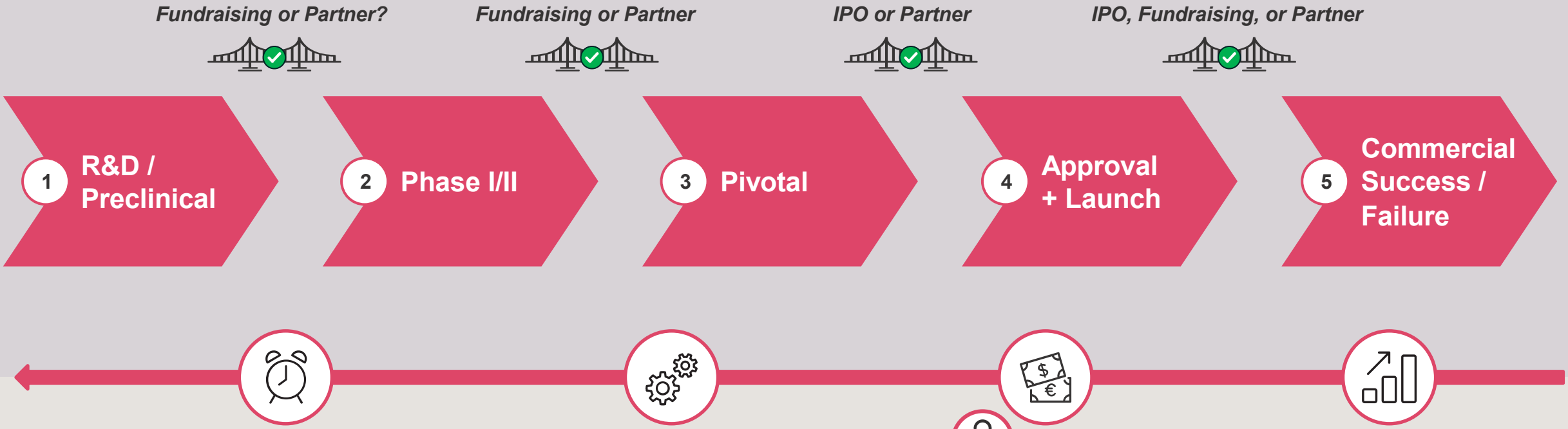
VCs & Investors are observing scale challenges and are **unwilling to fund early-stage developers without a clear path to scale**

Even with clinical results, **Pharma is unwilling to invest in assets that cannot scale**

Adding **retrofitted automation** post-approval **does not work. Unscalable products fail**

It’s Time for a New Playbook.

Therapy developers must optimize and automate simultaneously early in development



Plan and prepare for commercial viability from the **beginning, implementing automation in R&D/PD** to shorten time to clinic and establish a credible path to scale for investors/ partners

Unlocking Key Benefits

- Shorter time to clinic
- Easier attraction of funding/partners
- Derisked path to commercial viability

It’s Time for a New Playbook.

Therapy developers must optimize and automate simultaneously early in development

1	2	3	4	5
R&D / Preclinical	Phase I/II	Pivotal	Approval + Launch	Commercial Success / Failure
Fundraising or Partner?	*Fundraising or Partner*	*IPO or Partner*	*IPO, Fundraising, or Partner*	

Plan and prepare for commercial viability from the **beginning, implementing automation in R&D/PD** to shorten time to clinic and establish a credible path to scale for investors/ partners

Unlocking Key Benefits

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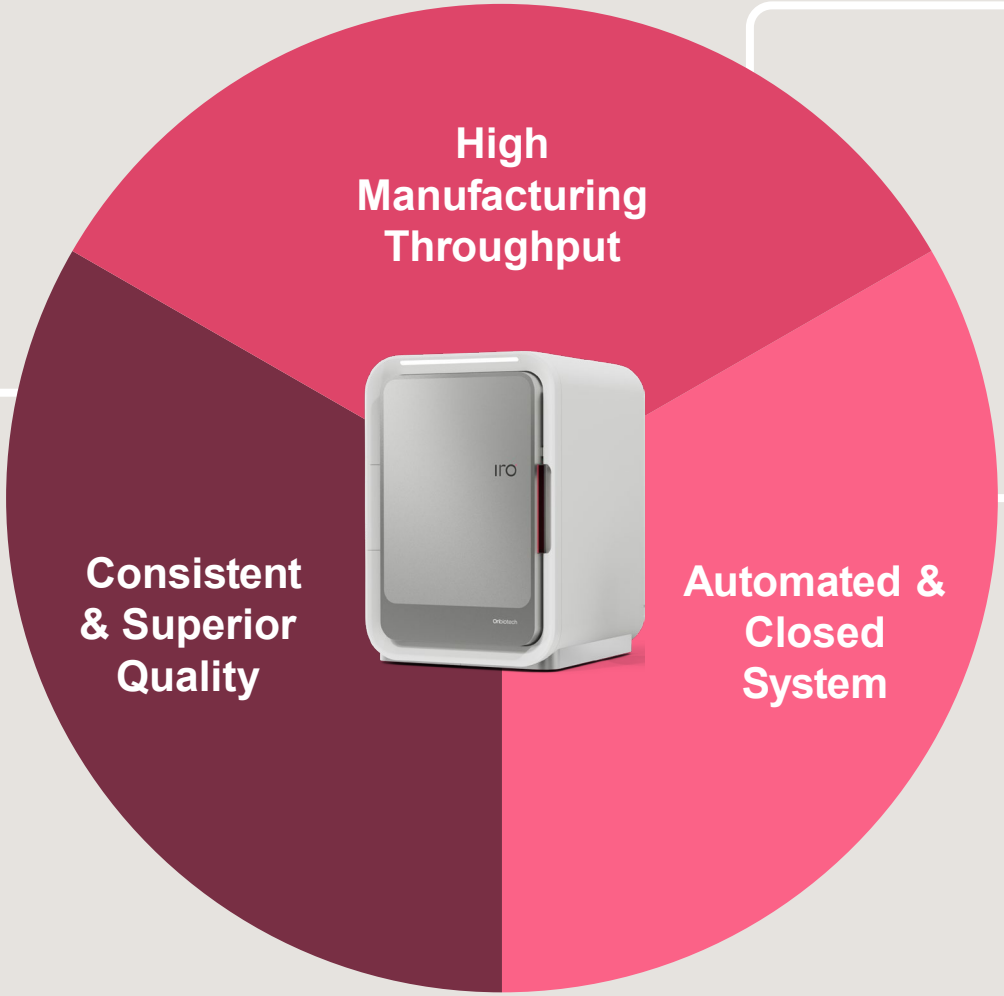
“It used to be too hard and too expensive to develop your process on an automated platform. Not anymore.”

-PD Team of Ori Big Pharma Partner with a Commercial CAR-T Product

IRO®: The New Standard of Cell Therapy Manufacturing.

IRO **directly addresses** the core requirements in **CGT manufacturing**



Enables **10-50x throughput increase** in the same manufacturing footprint

- Provides ~1000 doses/yr in 1000 sq. ft.
- Lowers COGS 30-50%

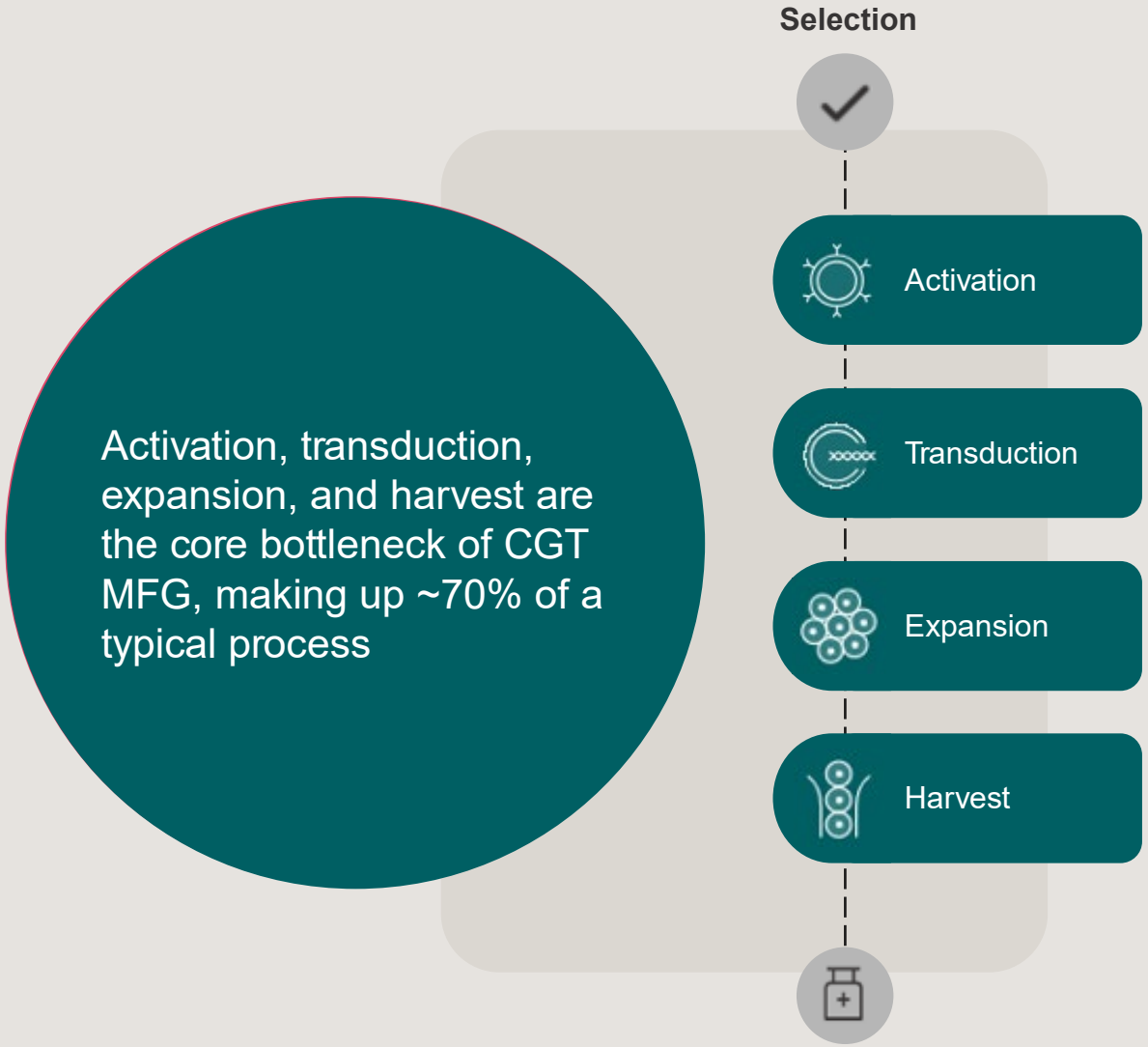
Delivers **higher cell quality, higher cell yield,** AND **higher transduction efficiency**

- Shorten process times by 25%
- Lower out-of-spec(OOS) rates to ~5%
- Shorten product development by ~3 years

Automates the most manual part of the workflow, sterile fluid transfer, and representative sampling within a **closed system**

- Reduces human interactions and errors
- Operates in Grade C/D
- Removes all tubing, bags and flasks from your process

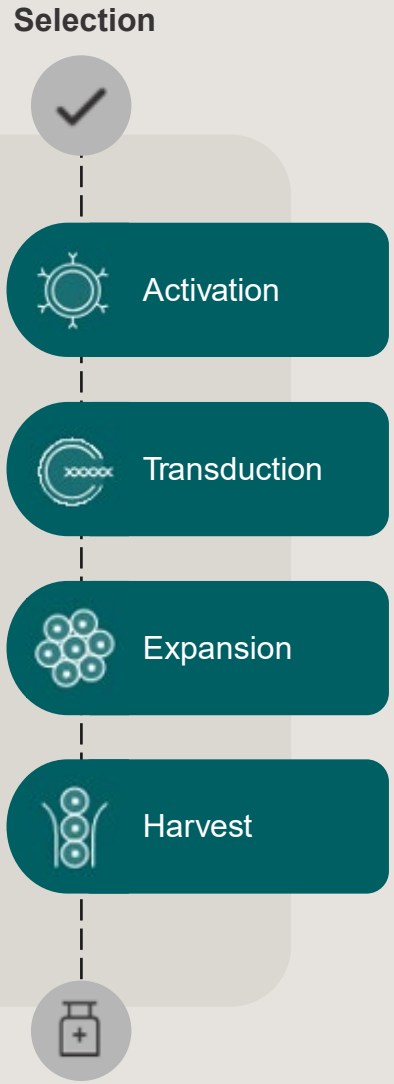
Identifying the Primary Bottleneck in CGT Manufacturing.



Removing the Primary Bottleneck in CGT Manufacturing.

Automating the CGT Bottleneck

IRO automates the longest, most manually intensive part of the CGT workflow, including activation, transduction, expansion, and harvest.



IRO provides a means to unlock CGT MFG by:

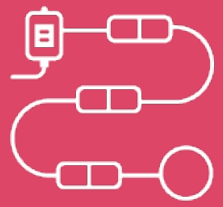
- Automating the majority of the CGT MFG process
- Providing a solution designed for robotic integration
- Offering improvements in product quality
- Enabling shorter vein to vein times
- Allowing higher throughput AND lower COGS

Design With the End in Mind.

Transition seamlessly from R&D into the clinic and then to commercial scale manufacturing

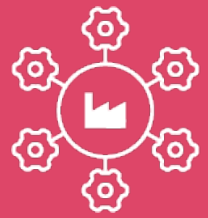
R&D and PD

Develop the process, test it, and make sure it works biologically



Clinical

Prove the process works in small volume, human trials, testing safety and efficacy



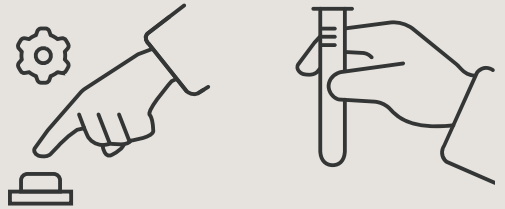
Commercialization

Scale process up to gain market access and meet patient demand

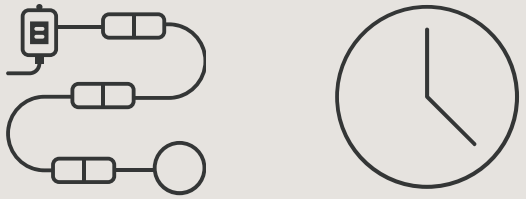
“We recommend that any extensive manufacturing changes be introduced prior to initiating clinical studies that are intended to provide evidence of safety and effectiveness in support of a BLA.” - U.S. FDA

IRO Was Designed To…

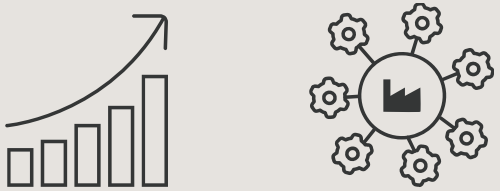
Automate Better Biology™



Accelerate Product Development



Scale Your Impact™



Automating Better Biology™

> 900 Runs

Characterization runs completed (in house and at partner sites in NA and UK)

> 70 Donors / Patients

Testing platform's ability to address donor and patient variability, showcasing the robustness of system outputs across different starting material

11 Unique Processes

Different processes including CAR-T, TCR-T, TILs, CD34+, with CAR-M and others on the horizon

12 Partners

5 therapy developers, 5 CDMOs, and 2 AMCs like MD Anderson, ElevateBio, CTMC, Kincell, and Charles River

50ml to 1L

Flexible operating volume range allows activation, transduction, and expansion in one platform

12B Cells

Maximum cell yield observed from bioreactor (~170x fold expansion)

You used to have to trade off biological performance for automation. **Not Anymore.**

IRO consistently outperforms first generation manual and automated tools demonstrating strong biological performance alongside the benefits of automation.

IRO is for both R&D and GMP – shortening time to clinic and smoothing the transition to scale

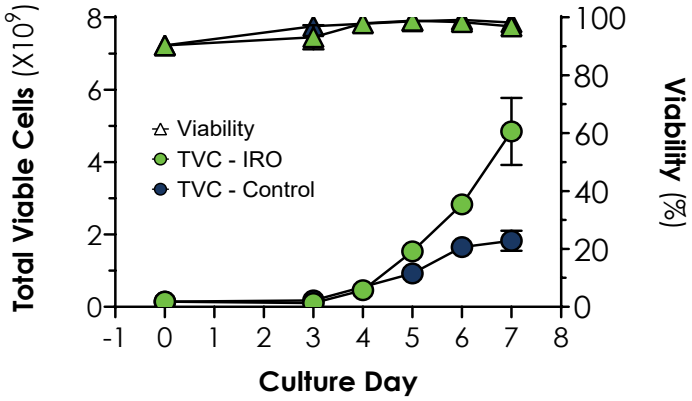
"I expected automation, I expected more process insights, **but I never expected better biological performance right out of the gate.**"

Jason Bock
Co-Founder and Chief Executive Officer, CTMC – A Joint Venture Between Resilience + MD Anderson Cancer Center

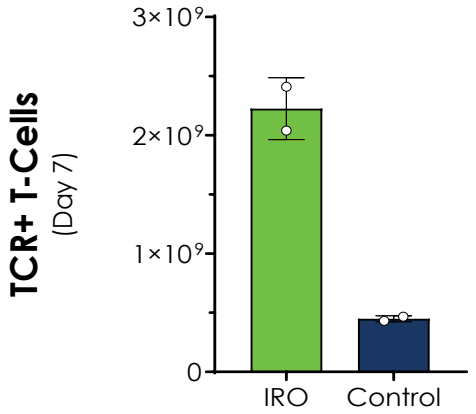
IRO® Evaluation by ElevateBio: Key Results.

- ElevateBio performed TCR runs comparing the IRO to an industry standard control at their site.
- After just 3 hours of training, the ElevateBio team was able to successfully operate and execute the protocol on the IRO platform.
- The IRO data generated by ElevateBio showed significantly Higher cell yield and Transduction efficiency (~46.3% IRO) compared to the control (~24.7%).
- All other analytical results were comparable (viability, activation panel, memory panel, CD4/CD8 ratio, and exhaustion panel).

Total Viable Cells
IRO vs Static Control



Transgene+ T-Cells at Harvest
IRO vs Static Control



"The IRO's intuitive design streamlines training and operation, **enabling rapid adoption and immediate productivity.**"

Jeff Cram
Senior Director, Cellular Process Development

Flexibility to Support Early Development.

- Activation, Transduction, and Expansion
- Large Working Volume Range
- Dynamic and Static Culture
- Automated Fluid Handling with Representative Sampling
- Remote Monitoring

Scale to Meet Patient Demand.

- Digitally Connected
- Full Robotic Integration
- Multiplex Capability
- Clinical / Commercial Comparability
- Supports Rapid QA / QC and Release by Exception

The New Economics of Cell Therapy.

Quantifiable Benefits for Manufacturers and Their Partners

Cost Savings

~60–90%

Labor cost reduction

~60–80%

Equipment / facilities cost reduction

~30–80%

Cost to manufacture reduction

Time Savings

6 months

Tech transfer time reduction

1–2 years

Shorter time to market

~50%

Operator touch time reduction

Quality Benefits

Real-Time Monitoring and Control

+

Predictive Analytics

+

Insight Generation (AI / ML / MVDA)

=

Shorter Development Times/
Reduced Batch Failure Rates

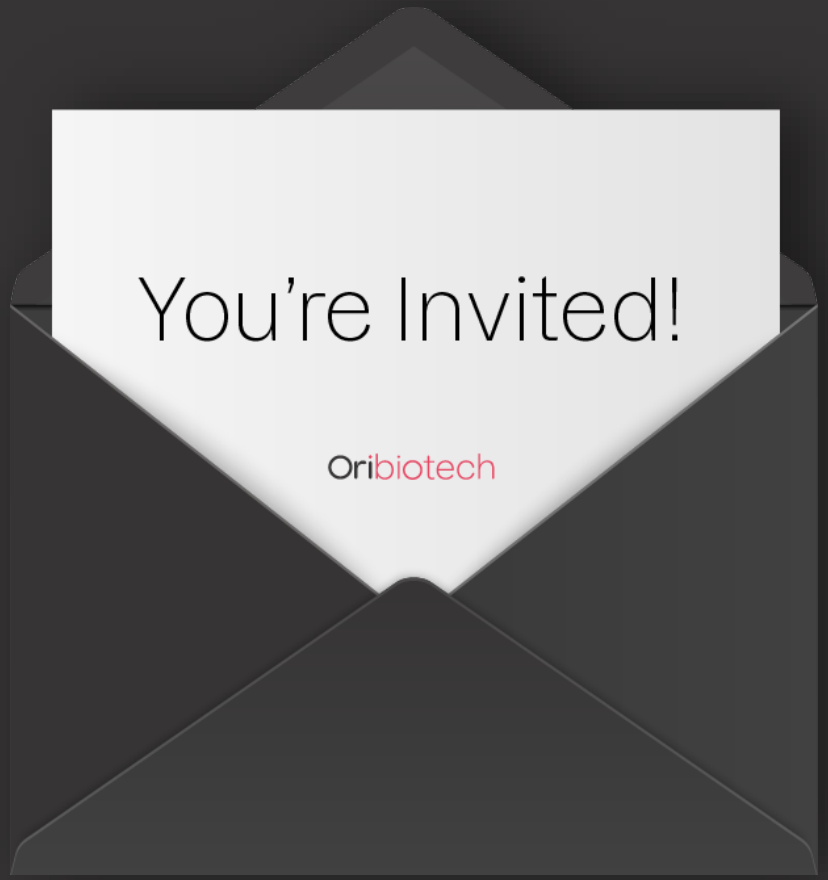
Note: Scale of benefits is process dependent

In Summary: What we are doing as an Industry is insane…

We are doing the same thing over and over again, expecting a different result

- If you are using first generation automation or manual flasks/bags, you are designing to a dead end, which will cost more time and money in the long run
- Automation technology, like IRO, is not just for scaled GMP manufacturing… it should be used to optimize your process during R&D/PD and derisk the path to scale
- IRO can shorten time to clinic and overall development time by up to 3 years
- Developing on an automation platform like IRO can increase the likelihood of attracting venture funding and/or finding a licensing partner
- Trying to scale an inefficient process by adding robotics to a manual flask/bag-based process doesn't solve (enough of) the problem
- Trying a new platform like IRO isn't as risky as using the same old technologies that have proven their inability to scale over the last decade

Discover IRO today to achieve the commercial impact you want and the access patients need



Want to learn more?

- Book a demo here at ISCT
- Connect with our team
- Visit our labs

We're looking forward to helping you enable widespread patient access to life saving cell and gene therapies.

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Let’s Manufacture Brighter Futures Together.

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Join our mission to enable widespread patient access to life saving cell and gene therapies

Manufacturing
Brighter Futures.

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Patient Access Table

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