Oribiotech

Manufacturing Brighter Futures

Experience IRO® - The New Standard of CGT Manufacturing

September 17, 2024

Boston, MA

Jason C. Foster

Chief Executive Officer at Ori Biotech

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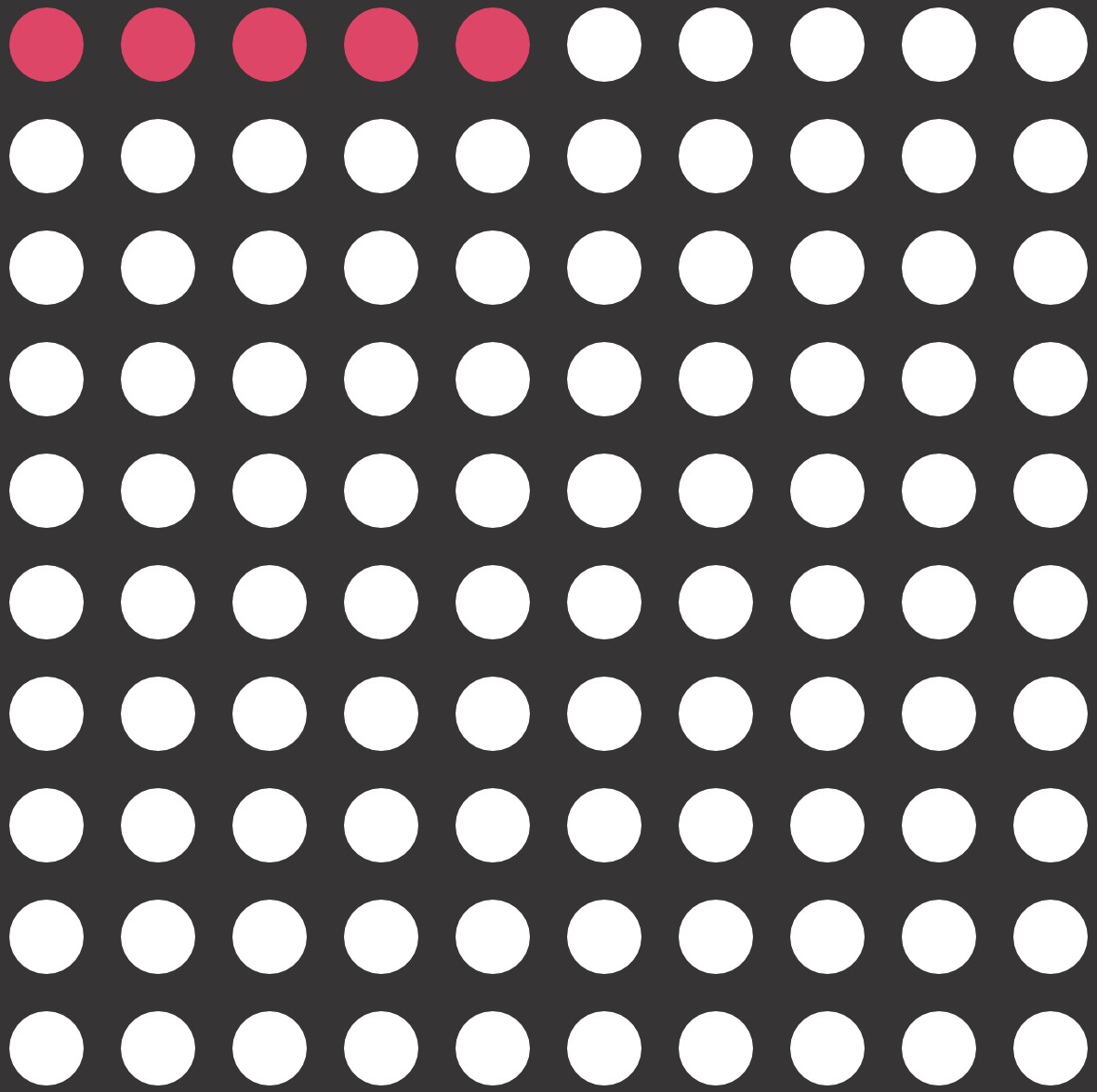
Globally, less than **5%** of patients who could benefit from approved CAR-T therapies have been **able to access them**

900K*

Addressable Patient Population

~30K

Total CAR-T
patients treated



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

Annual Patients Treated with Approved CAR-Ts per Year.

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

Therapy Name	2017	2018	2019	2020	2021	2022	2023	Q2 2024	**Cumulative Patients Treated by Therapy**
KYMRIAH®	13 (Aug 2017)	160	586	998	1,236	1,129	1,070	491	**5,683**
YESCARTA®	19 (Oct 2017)	708	1,223	1,510	1,864	3,110	4,017	2,129	**14,580**
TECARTUS®				118 (Jul 2020)	472	802	995	555	**2,942**
ABECMA®					391 (Mar 2021)	925	1,126	422	**2,864**
BREYANZI®					213 (Feb 2021)	444	888	634	**2,179**
CARVYKTI®						289 (Feb 2022)	1,076	738	**2,103**
AMTAGVI®								25 (Feb 2024)	**25**
Total Patients Treated per Year	**32**	**868**	**1,809**	**2,626**	**4,176**	**6,699**	**9,172**	**4,994**	**30,376**

Source: August 2024 Ori Data Analytics

"

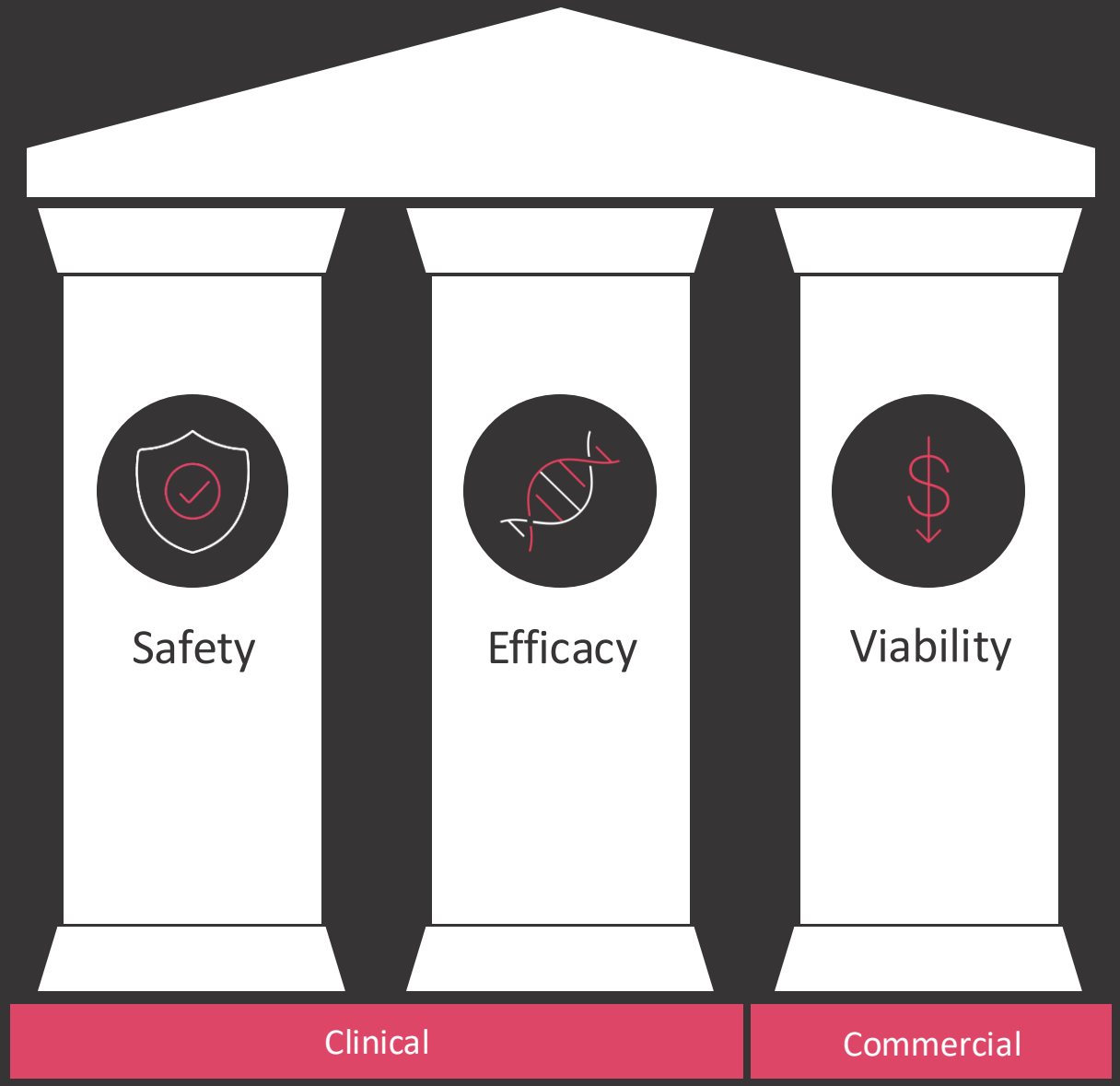
The **status quo** in cell and gene therapy for most patients today **represents death or serious disability**

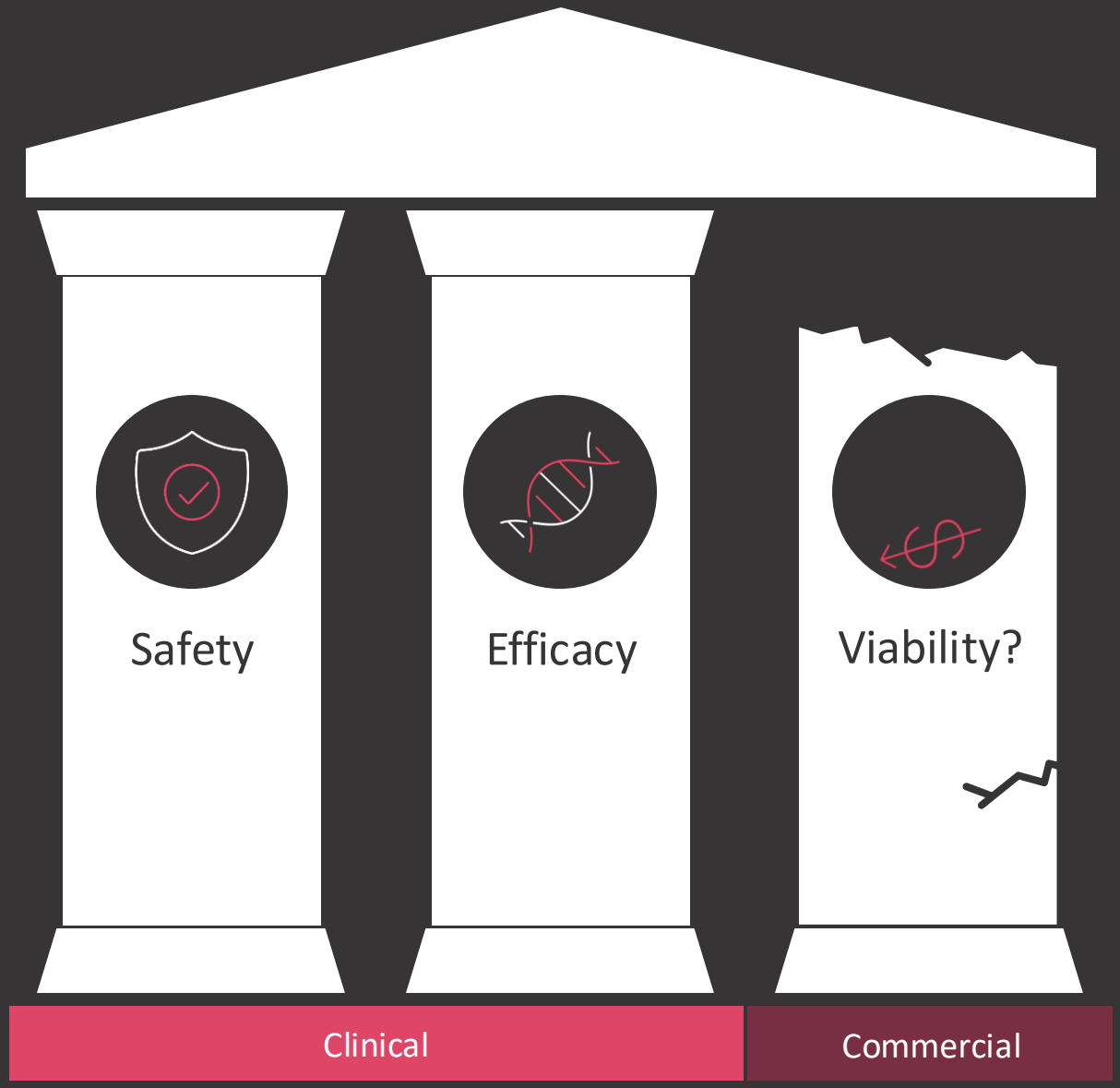
"

Tim Hunt
Chief Executive Officer,
Alliance for Regenerative Medicine (ARM)

Small molecules and biologics

If we develop safe and effective products, we can assume they will be commercially viable





Cell and gene therapy

Developing safe and effective products is not enough to ensure that cell and gene therapies will be viable

Launch of the IRO® Platform

Launched at ISCT in Late May

- Unveiled the IRO platform for the first time
- Highlighted superior head-to-head data
- Conducted >50 live demonstrations
- Deployed with 2 pharma partners
- Target deployment of 10 partners in 2024

> The IRO is the ***easiest*** thing I've ever worked with." – Big Pharma Partner PD Team

IRO® Platform: Instrument, Bioreactor, LVC, SVC, and OriConnect™

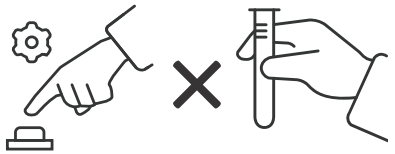
IRO® Platform Technology: Bioreactor, LVC, SVC, and SC

IRO® was designed to…

Automate Better Biology

Accelerate Product Development

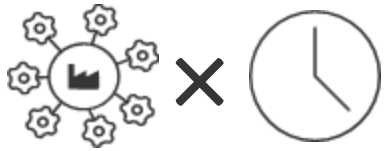
Scale Your Impact



Automate Better Biology™

- Automates the key manufacturing bottleneck -- activation, transduction, expansion, and harvest in one platform
- Achieves higher cell yields and transduction efficiencies than the "gold standard"
- Reduces manufacturing process times by up to 25%

- Begin with ~50M cells and yield up to ~12B cells
- Supports different cell suspension culture types and workflows
- Delivers cells with >95% viability and potent cancer killing activity
- (Delivers) 170x fold expansion with no signs of exhaustion
- Delivers target cell yield with a 50% reduction in MOI



Accelerate Product Development

- Getting products into the clinic faster by reducing process development and tech transfer time
- Reduces batch variability and failure rates to hit target dose more consistently
- Eliminates the need for comparability during scale up, shaving years off development timeline

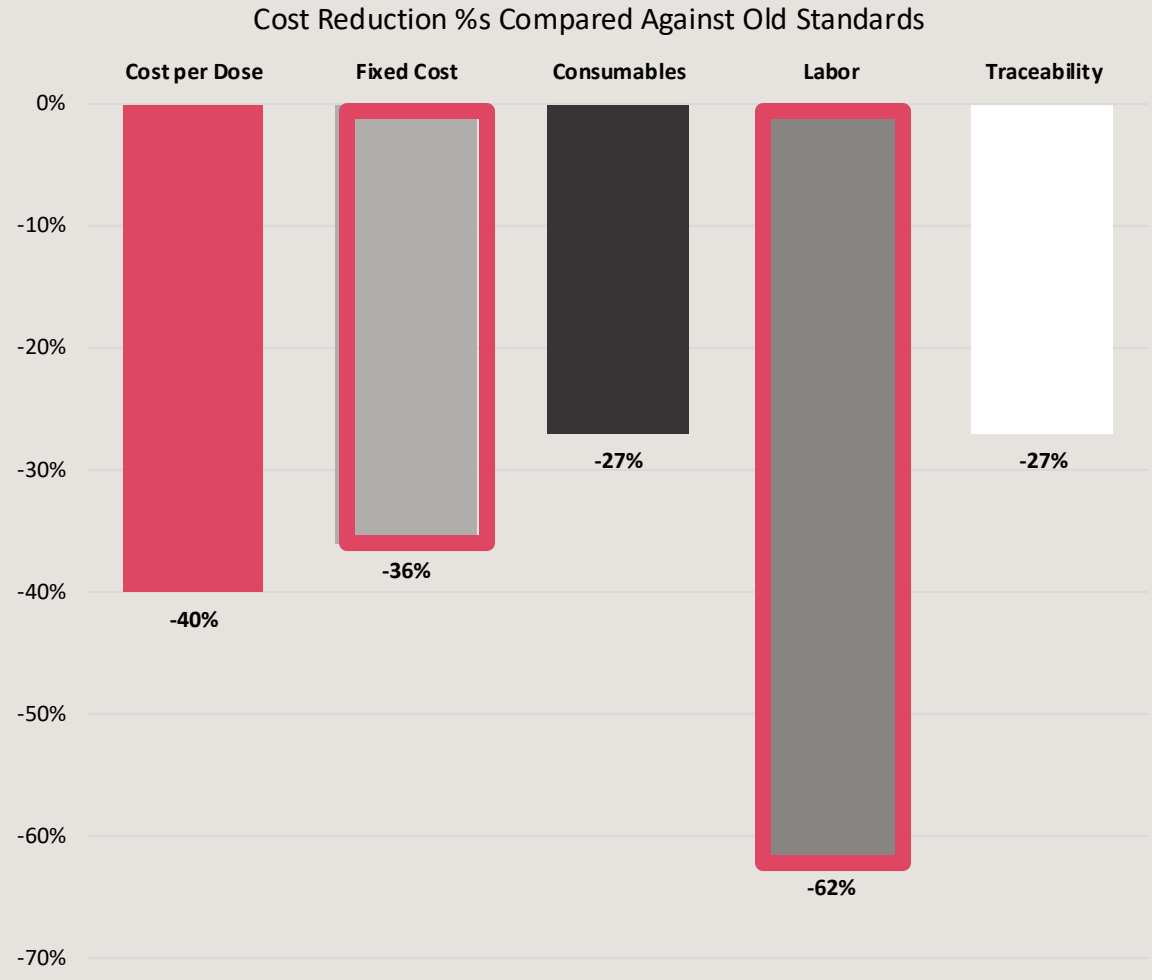
- Enables a seamless transition from R&D into the clinic and from the clinic to commercial scale manufacturing
- Empowers your scientists, offering them the freedom to optimize and the flexibility to innovate
- Helps you reach your next value inflection point more quickly
- Puts control back in the hands of your expert scientists via customizable software
- Enables complete product traceability via our digital, cloud native platform

Scale Your Impact™

- Increases throughput to ~1,000 doses per year in 1,000 sq ft
- Reduces manufacturing costs by 30-50%
- Unlocks multi-site manufacturing capability

- Enables manufacturing in less expensive, lower grade (C or D) cleanrooms
- Designed to support full robotic automation and advanced analytics (AI, ML)
- Reduces labor costs by ~60%
- Delivers a > 50% reduction in manufacturing facility footprint
- Integrates with industry leading software (e.g. EBMR, ELN, SCADA etc.) via APIs with ISO 27001

Initial Benefits of Automation: Cost per Dose and % of Savings by Category



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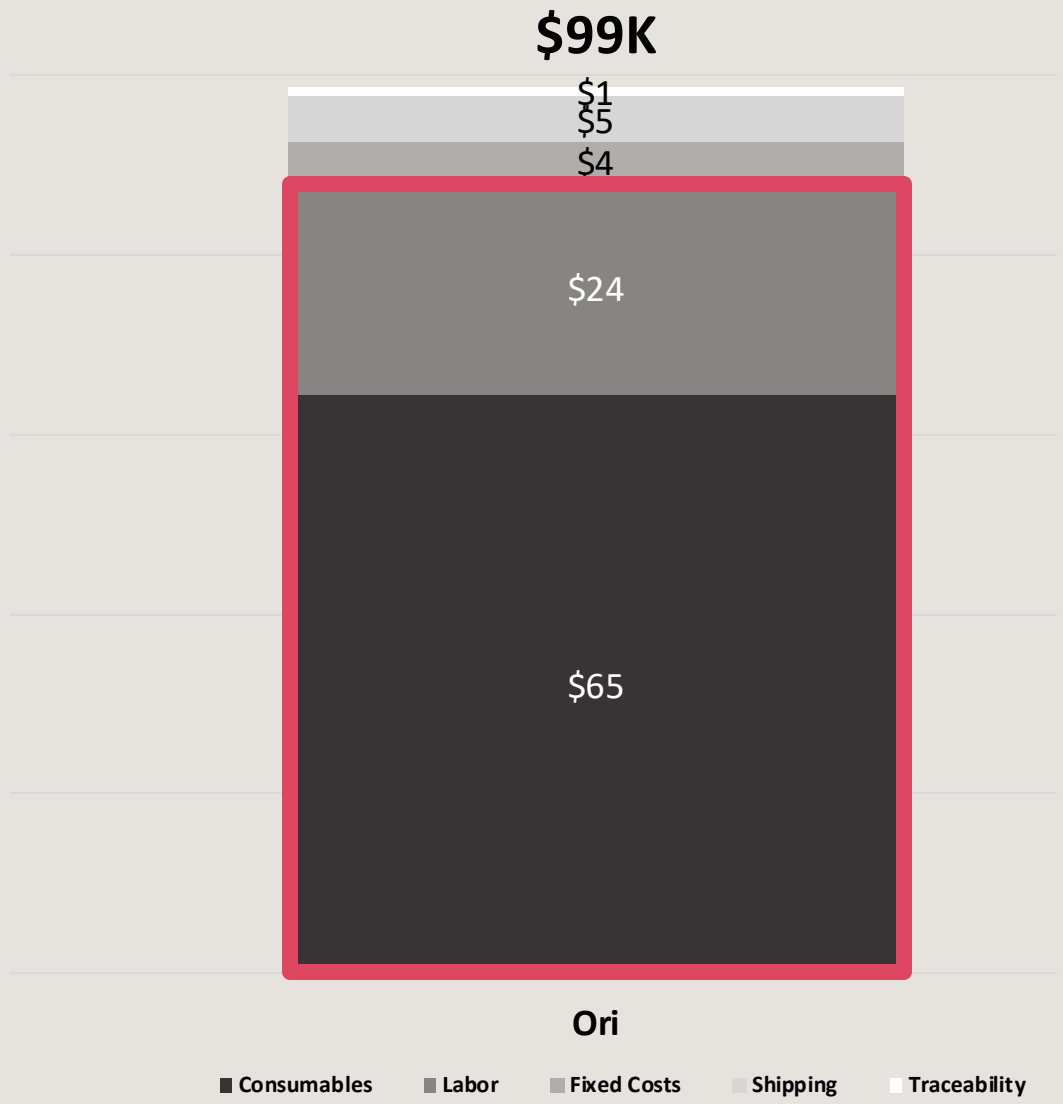


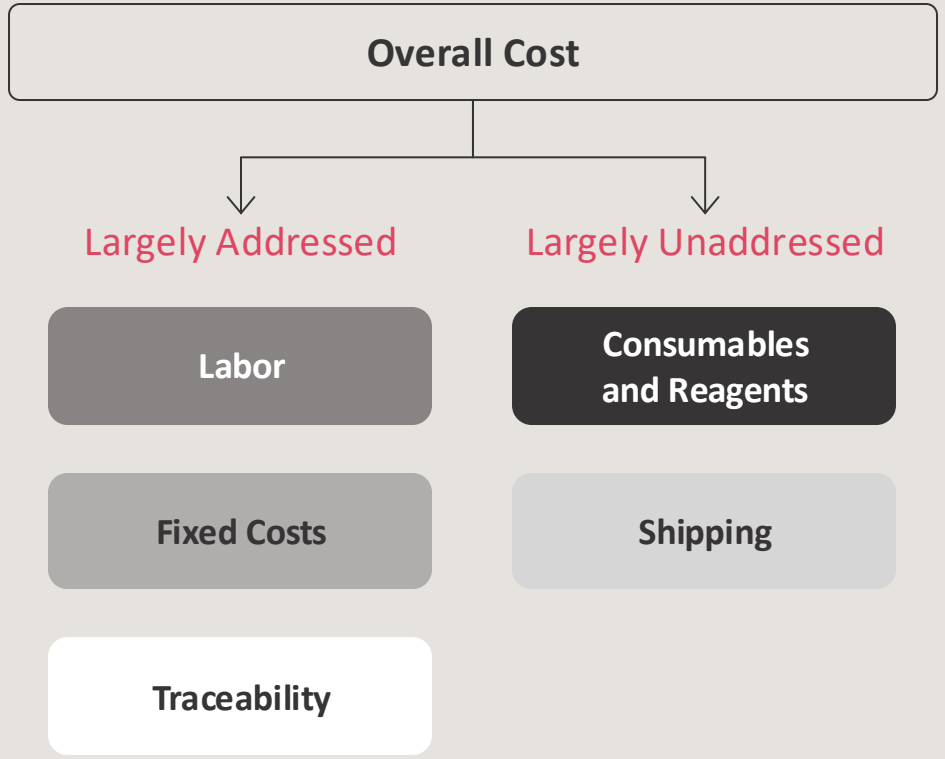
While initial automation brings down the cost per dose of consumables and labor significantly, they remain the primary cost drivers post
initial automation

What's Left? Addressing Remaining Cost Challenges

With labor and fixed costs largely addressed, consumables and shipping are the largest opportunities remaining

Automation Enabled Future State

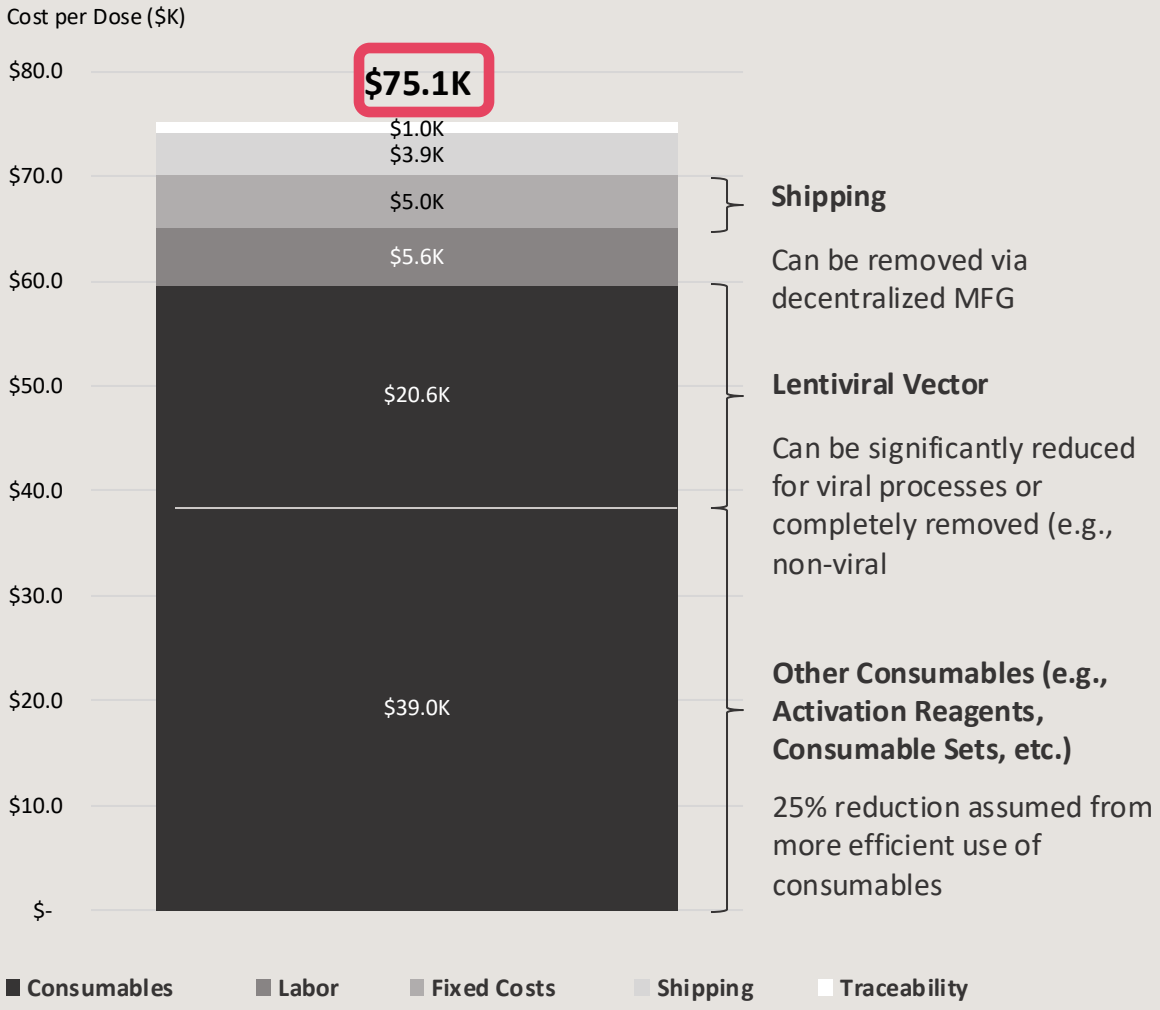
Cost Breakdown



Beyond Automation: Opportunities to Improve Cost per Dose

Our industry can take further steps to reduce cost per dose to ~$40K, including non-viral and decentralized manufacturing

Automation Enabled Future State



Shipping

Can be removed via decentralized MFG

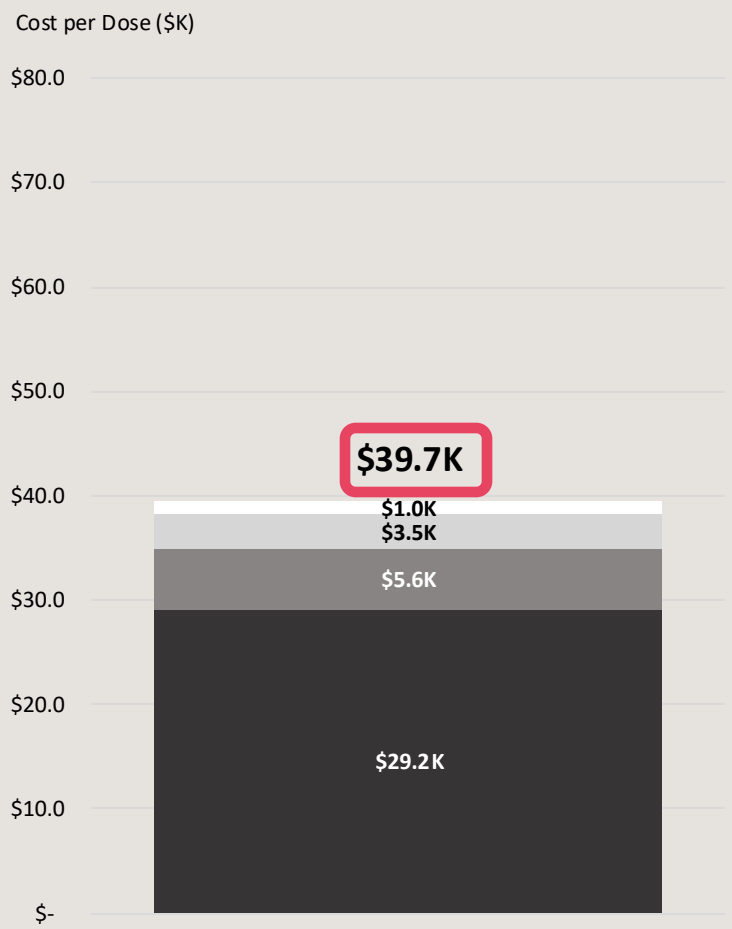
Lentiviral Vector

Can be significantly reduced for viral processes or completely removed (e.g., non-viral

Other Consumables (e.g., Activation Reagents, Consumable Sets, etc.)

25% reduction assumed from more efficient use of consumables

Industry Target Future State



Manufacturing Problems Threaten the Viability of CGT Products

Manufacturing challenges have limited the patient's ability to access these lifesaving products

GOLD STANDARD

Scientific Wins

NOVARTIS

Kymriah approved for ALL as first cell based gene therapy

Kite A GILEAD Company

Yescarta approved for certain types of B-cell lymphoma

Bristol Myers Squibb™

Breyanzi approved for large B-cell lymphoma

LEGEND BIOTECH

Johnson&Johnson

CARVYKTI approved for multiple myeloma

IOVANCE BIOTHERAPEUTICS

Amtagvi approved as first TIL product

Manufacturing Problems Threaten the Viability of CGT Products

Manufacturing challenges have limited the patient's ability to access these lifesaving products

Manufacturing Setbacks

NOVARTIS

"Novartis, still struggling with Kymriah manufacturing, is providing some out-of-spec doses to patients who ask"

Kite A GILEAD Company

"Gilead to lay off staff at cell therapy unit Kite"

Bristol Myers Squibb™

"Manufacturing success rate holds back sales of Bristol Myers' CD19 CAR-T cell therapy"

LEGEND BIOTECH

Johnson&Johnson

"Johnson & Johnson shelves Carvykti's UK launch amid manufacturing shortfalls"

IOVANCE BIOTHERAPEUTICS

Only "~10-15% of 'enrolled' patients have been infused with commercial Amtagvi in the full first quarter since approval"

What’s Next: Advanced Manufacturing Technology Designation

Customer benefits of IRO gaining AMT designation

Faster Time to Market

With expedited FDA review, IRO customers can expect quicker regulatory approvals when referencing our AMT in their submissions.

Reduced Risk in Filings

Having an FDA-designated AMT in their supply chain increases confidence in compliance and safety during regulatory reviews.

Improved Adoption Rates

Our AMT status demonstrates that we use cutting-edge technology, making our solutions more attractive to customers seeking reliability and innovation.

FDA Guidance on AMT Designation

The FDA recognizes **AMT under its Emerging Technology Program**, offering:

- Expedited review of applications utilizing AMT
- Dedicated support for regulatory filings
- Faster approval timelines

*“The **AMT designation** highlights a supplier’s commitment to innovation and regulatory alignment, encouraging adoption by pharmaceutical and medical device companies.”*

Let’s Manufacture Brighter Futures Together.

Jason C. Foster

Chief Executive Officer

jason.foster@oribiotech.com

M: +44 7920278334

Thomas Heathman, PhD

Chief Commercial Officer

thomas.heathman@oribiotech.com

M: +1 (201) 962-6447

Marianna Mavropoulou

Business Development Executive

marianna.mavropoulou@oribiotech.com

M: +44 7771197035

Kale Feeter

Director, Business Development

kale.feeter@oribiotech.com

M: +1 (707) 718-6129

Sarah Meeks

Business Development and Strategy

sarah.meeks@oribiotech.com

M: +1 (612) 202-6805

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Patient Access Table

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