

Oribiotech

Manufacturing Brighter Futures

Fraunhofer Institute for Cell Therapy and
Immunology

31 May 2022



A new generation of **personalized,**
living medicines have been **clinically proven** to
have **curative potential.**



Yet their life-saving potential has been **drastically limited** to <1% of the patients who could benefit from them



Manufacturing problems threaten the future of CGTs

Therapy developers and regulators continue to feel the pain of manufacturing challenges

Cost of Goods Is Crucial for the Future of Regenerative Medicine: CAR-T Cell Therapy Provides a Case Study in Perspective

Manufacturing Delays Set Back Autolus' CAR-T Programs by Five Months

Breakthrough Cancer Therapy Stalls in Manufacturing Bottleneck

Novartis still hasn't solved its CAR-T manufacturing issues

Gilead's Second CAR-T Treatment Suffers the Same Issues as Yescarta

Gene therapy costs, manufacturing keeping CBER head 'up at night'

Delays in CAR T-Cell Treatment Cost Patients, Society

Bluebird delays gene therapy launch to 2020, citing manufacturing tweaks

Bluebird Bio delays Zynteglo launch as manufacturing trips up another gene therapy

Pfizer, Novartis lead \$2 billion spending spree on gene therapy production

Manufacturing difficulties arise for Novartis' CAR-T therapy

For CAR-Ts to be successful, figuring out manufacturing is key

Team That is Delivering the Ori Vision

Leadership team has extensive CGT manufacturing and healthcare business building experience



Farlan Veraitch PhD
Chief Scientific Officer, Co-Founder

Farlan is an Internationally-recognised scientific expert on cell and gene therapy manufacturing -- with more than 30 publications -- and over 15 years of experience as a leading academic at University College London.



Chris Mason PhD
Co-Founder, Non-Executive Director

Chris is a clinician-scientist with over 25 years of CGT experience. He is a Founder and CSO of AVROBIO (NSDQ: AVRO) and Professor of Cell and Gene Therapy in the Advanced Centre for Biochemical Engineering, UCL.



Jason C. Foster
Chief Executive Officer, Executive Director

Jason has held leading operating roles in healthcare and technology companies for over 20 years, including Indivior PLC, (LSE: INDV) which he exited in a £2.5B listing in December 2014.



Jason Jones
Chief Business Officer

Jason has 17 years of experience with Miltenyi, a leader in cell and gene therapy devices and consumables. Jason led Miltenyi's efforts in the UK and east coast US establishing partnerships with leading companies like GSK and Autolus.



Kevin Gordon
Chief Data and Operating Officer

Kevin has 20 years' experience creating information technology solutions for biopharma. Recently launched a digital manufacturing platform for CAR-T and viral vector manufacturing, integrating MES, LIMS, EMS, and QMS systems for eMBRs.



Stuart Milne, PhD
Chief Technology Officer

Stuart has launched nine IOT enabled products in CGT, with clear understanding of the unique security, regulatory, manufacturing and supply chain considerations required for successful scale-up. Sold Asymptote to GE in 2017.



Thomas Heathman, PhD
VP of Commercial Operations, NA

Tom has over 10 years' experience in CGT manufacturing and previously led the North America business for Minaris Regenerative Medicine where he managed the business relationships with key therapy developers.



David Smith, PhD
VP of Technical Operations, NA

Dave has over 10 years' experience in CGT, previously leading the research and development team at Minaris Regenerative Medicine where he manage client development services and implemented new technologies



Lindsey Clarke, PhD
Director, Business Development

Lindsey has over a decade of experience in development and launch of CGT tools and technologies with companies like Miltenyi and Bio-Techne. She has a PhD and post-doc experience in immunology & bioengineering.

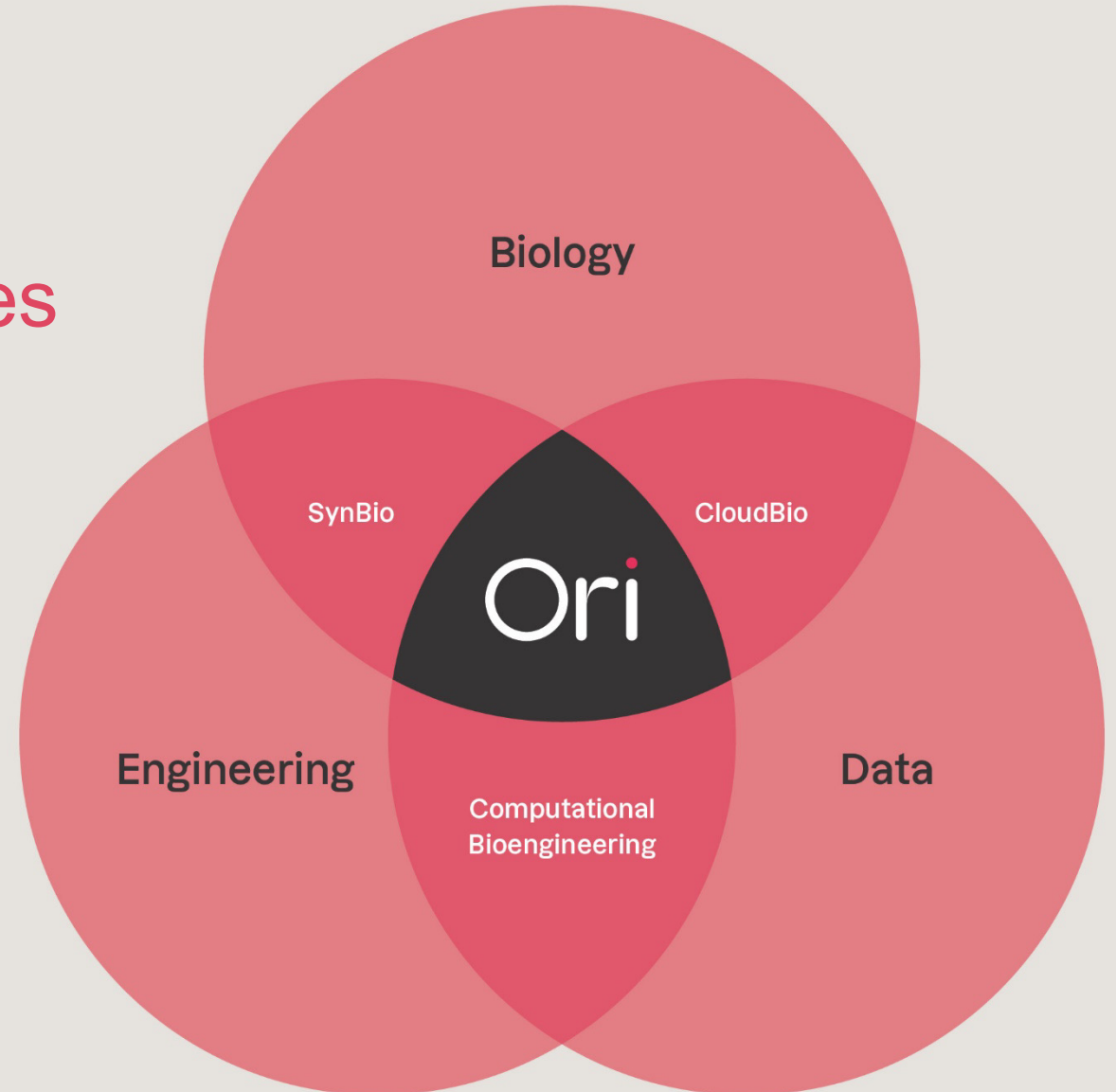


Courtney LeBlon, PhD
Technical Director

Courtney has over 10 years of experience in the field of cell and gene therapy and has led process development programs for 15+ developers and conducted 30+ technology transfers.

Ori is bringing together a full stack platform combining **Biology Engineering and Data** to **Industrialize Precision Medicines**

The current model of fragmented, inflexible, disconnected hardware solutions **will not** solve this challenge



Current solutions available are not fit for purpose

Ori technology is designed to enable a future state of high throughput cell and gene therapy manufacturing

From the Status Quo of Manufacturing



Large, expensive facilities that are heavily under utilized and require individual regulatory approvals



Highly skilled workforce performing multiple manual fluid transfers and sterile connections



Technology borrowed from other industries that is unscalable and inflexible to the needs of CGT products



No data integration with paper-based manufacturing execution and manual batch release



Production of 30 doses simultaneously per 1000ft², seamless tech transfer



Consumable is fully automatable and designed for full robotic manipulation



Ori bioreactor platform is flexible and can be used across many process steps



Secure connectivity to the Ori Cloud allows real-time process data utilization

To the Future State of Manufacturing

Smaller, cheaper, highly utilized facilities with network approval and standardized technology transfer between sites

Fewer, cheaper people monitoring processes with fully automated sterile connections and fluid handling

Flexible manufacturing technology adapting to the needs of multiple products from clinical to commercial scale

Digital integration across cloud native platform enabling full product traceability and continuous process validation

Where are we today!

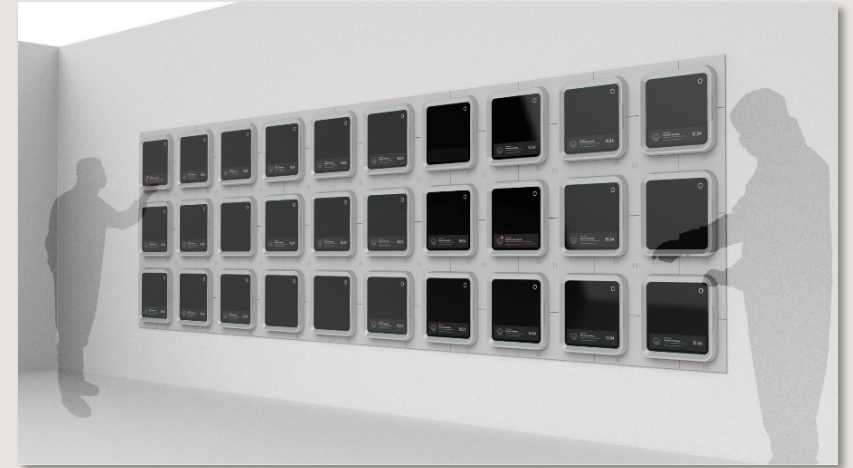
Platform commercial launch will be towards end of 2023

Series B funding - \$100m in Jan 22 will allow us to bring the Ori platform to the market

Currently working with a small number of “lightspeed” partners for early access to the platform to input into our development and access our data generated

Opportunity for new partners to join early access programs

Next steps – CDA and technology deep dive





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