



*Ori Biotech Recognized for*

**2021**

**Enabling Technology Leadership**

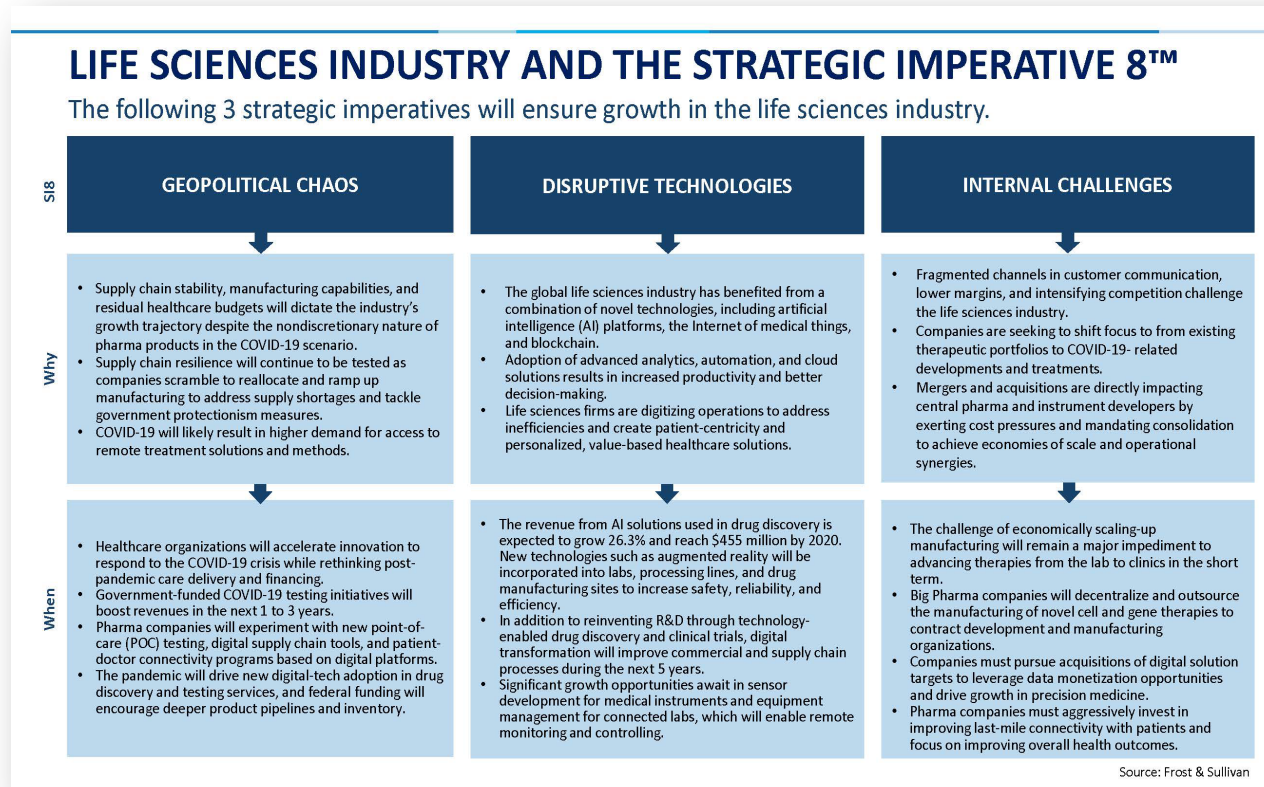
Global Cell and Gene

Therapy Manufacturing Industry

*Excellence in Best Practices*

## Strategic Imperatives

Frost & Sullivan identifies three key strategic imperatives that impact the life sciences industry: geopolitical chaos, disruptive technologies, and internal challenges. Every company that is competing in the life sciences space is obligated to address these imperatives proactively; failing to do so will almost certainly lead to stagnation or decline. Successful companies overcome the challenges posed by these imperatives and leverage them to drive innovation and growth. Frost & Sullivan’s recognition of Ori Biotech is a reflection of how well it is performing against the backdrop of these imperatives.



## Best Practices Criteria for World-Class Performance

Frost & Sullivan applies a rigorous analytical process to evaluate multiple nominees for each award category before determining the final award recipient. The process involves a detailed evaluation of best practices criteria across two dimensions for each nominated companies. Ori Biotech excels in many of the criteria in the Cell and Gene Therapy Manufacturing space.

AWARD CRITERIA	
<i>Technology Leverage</i>	<i>Customer Impact</i>
Commitment to Innovation	Price/Performance Value
Commitment to Creativity	Customer Purchase Experience
Stage Gate Efficiency	Customer Ownership Experience
Commercialization Success	Customer Service Experience
Application Diversity	Brand Equity

***Ori Biotech***

Founded in 2015 and headquartered in London, Dr. Farlan Veraitch and Professor Chris Mason started Ori Biotech (Ori) to manufacture cell and gene therapy (CGT) products. The company developed a market-disruptive, customizable, and proprietary manufacturing platform to meet the vital clinical and commercial manufacturing needs of CGT developers, enabling them to usher a new generation of life-saving precision medicine therapies for the patients. The novel platform capabilities address CGT's complex manufacturing challenge and allow Ori to automate and standardize CGT manufacturing, thus enabling biotechnology companies to scale-out production from clinical to commercial manufacturing seamlessly.

***Automating CGT Manufacturing to Increase Throughput, Improve Quality, Scalability, and Lower Cost***

Genetically-engineered cell therapies comprise the extraction and isolation of patient cells for (most frequently, viral vector-based) genetic modification and often their expansion. The treatment then involves the re-introduction of the engineered cells into the patient's body. The most widely used cell therapy approach is the chimeric antigen receptor (CAR) T-cell therapy. CAR T-cell therapy is a highly complex process requiring multi-step technologies and logistics. These processes involve risk and manufacturing concerns such as non-adherence to quality and regulator-defined manufacturing standards, affecting CAR T-cell therapies' commercialization prospects. In turn, uncertain commercial viability impacts advanced treatment development.

Consequently, many of the currently approved cell therapies are first-generation CAR T-cell products treating hematological malignancies. However, the CGT development industry realizes the need for next-generation technologies. The increasing focus on research over broad indications of solid tumors, such as lung, pancreatic, and ovarian cancers, report several hundred thousand patients annually, beyond just niche categories (liquid tumors) with fewer patients.

Even today, most cell therapy manufacturing across the globe depends on a highly manual process setup, which severely affects the turnaround time, process replicability, and manufacturing costs. As a result, scaling up for commercial production to suffice the demand of several thousand patients a year,

remains highly challenging.

To address these challenges, Ori has embarked on the vision to automate CGT manufacturing to fully realize the unprecedented potential of CGTs in delivering high clinical value. The company developed a one-of-its-kind automated platform catering to the industry's need for clinical and commercial-scale CGT manufacturing. The platform increases throughput, improves quality, and decreases manufacturing costs, aligning with Ori's mission to enable patient access to new generations of CGTs.

CGT represents the next big frontier in medical science due to the enormous promise of treatment, curability, and high clinical efficacy, especially in treatments such as immunotherapies. However, CGT manufacturing's biggest challenge encompasses increasing production yield for wide treatment availability, enabling therapeutics developers to seek reimbursement coverage, and streamlining the supply chain for a timely delivery. Current supply chain issues, i.e., complicated and high-cost processes, result in first-generation therapies priced as high as \$500,000, leading to last line coverage designation and limited access for patients.<sup>1</sup> Hence, the high price of earlier developed autologous (CAR) T-cell treatments, such as Yescarta and Kymriah, lowered patients' accessibility to these therapies.

In addition, the hospital and care costs drive CGT therapy to an extraordinarily high level as reimbursement for highly-priced cell and gene therapies is a hurdle. To that end, Ori's primary focus is substantially reducing the cost of goods sold (COGS). By developing affordable CGTs, the company enhances treatment access and availability to a larger patient population. Automation-enabled manufacturing that reduces treatment costs will improve patients' reach to life-saving therapeutics and improve care. The company estimates that its automation-enabled closed manufacturing platform can

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**- Supriya Lala, Best Practices Research Analyst**

lower COGS for autologous cell therapies by between 60%- 80%.

Reducing costs substantially would potentially allow for the introduction of these therapies earlier into the treatment pathway reducing the overall cost-of-care, such as hospital visits and other therapies, e.g. chemotherapy, transplant, and tests, so that patients can benefit from these next-generation treatments with curative potential earlier in their disease progression .

Other commercial platforms incorporate only one technology element to solve specific challenges in the

CGT manufacturing process. In contrast, Ori envisions CGT manufacturing's future, creating a solution that addresses time, cost and quality issues holistically across the entire CGT development pathway and has established key collaborations to deliver on this.

Hence, Ori offers a one-of-a-kind flexible end-to-end platform that takes a deep dive into end-user requirements to focus on scale, high throughput manufacturing, high-quality, and batch consistency.

<sup>1</sup> *Competitive Landscape Analysis of Recent Cell and Gene Therapy Innovations*, (Frost & Sullivan, July 2020)

### ***CGT Expert-designed Platform for Flexible, Modular, and Distributed Manufacturing***

Ori's automated platform is unique as CGT experts designed it specifically for CGT manufacturing, unlike several first generation, commercial platforms that have been repurposed and retrofitted from their original uses in stem cell or biologics manufacturing. The company's featured design focus was on high throughput production (with a target of going up to 100,000 doses annually), introducing automation into the manufacturing line to drive quality improvements and cost savings.

The process for developing cell therapies is different from antibody based treatments in that it involves inherently variable, patient starting material but requires a consistent end-product quality every time. These truly personalized medicines also introduce additional safety, scientific, and clinical challenges in the manufacturing process. Ori is well-placed to leverage its automated cell processing system, fluid handling and data platform to enable repeatable high quality, low-cost manufacturing processes.

The company partners with industry-leading suppliers for CGT product development. For instance, Germfree and G-Con, both experts in designing cleanroom technologies for particular applications based on a tractor-trailer and/or modular pod based platforms. Such collaborations can help enable fully integrated, closed system manufacturing in a smaller footprint, producing thousands of doses per year in one defined and efficient cleanroom footprint versus extensive (150,000+ sq.ft.) stick built facilities. This innovation will lower upfront investment requirements for the manufacturing facility by nearly 75%.<sup>2</sup> Shrinking facility size, reducing the risk, time, and human involvement for need-based manufacturing, and the shift from fixed batch to continuous production at low cost allows Ori to bring next-generation personalized medicines to patients at scale.

Additionally, to optimize supply chain capabilities, Ori partners with software firms like TrakCel to add supply chain monitoring technology to its data platform. The collaboration will enable clinicians and customers, i.e., CGT developers, academic medical centers as well as contract development and manufacturing organizations (CDMO), to have complete visibility throughout the supply chain, allowing them to monitor the manufacturing processes in real-time. The company also partners with crucial global input providers to address customers' supply chain hassles. For example, Ori has announced a collaboration with CellGenix, a global raw and ancillary materials supplier for CGT and regenerative medicine. The partnership helps reduce process bottlenecks and costs, improve throughput, eliminate manual handling, and build a closed-system preparation and formulation environment aided by CellGenix's media and growth factors for CGT manufacturing. Frost & Sullivan notes that by leveraging these collaborations (media, supply chain, clean room, etc.), Ori is well-positioned to provide a comprehensive automated manufacturing platform specifically designed for cell and gene therapy.

*"Innovation around the integration of high quality raw and ancillary materials from CellGenix into the Ori full-stack platform is another step toward enabling our customers to have a fully-closed manufacturing process from end-to-end with no bottlenecks in formulation, preparation, and process flow." -Farlan Veraitch, co-founder and CSO, Ori Biotech<sup>3</sup>*

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<sup>2</sup> <https://oribiotech.com/news/ori-biotech-and-germfree-to-collaborate-in-modular-facility-integration-automation-and-scale-out-for-cell-and-gene-manufacturing>

<sup>3</sup> [https://www.contractpharma.com/contents/view\\_breaking-news/2020-05-13/ori-biotech-and-cellgenix-collaborate/](https://www.contractpharma.com/contents/view_breaking-news/2020-05-13/ori-biotech-and-cellgenix-collaborate/)

### **Enabling Multiple Ex Vivo CGT Applications Development**

Currently, Ori supports cell therapy and gene-modified cell therapy that involves genetic modification of a patient's cells through viral vector transduction or other transfection methods and re-introducing the

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genetically modified cells into the patient's body. Ori's manufacturing platform flexibility lies in its ability to adapt to the requirements of a given process (without the need for tubes, bags, pumps, manual interventions) and the larger, more involved parts of these processes to be able to support several CGT applications.

The platform design establishes compatibility with several process aspects to hasten transduction and cell activation/expansion with minimal human input and allows real-time monitoring to help optimize process development more quickly and ensure that GMP manufacturing processes are consistent. The platform

lends itself to either centralized or distributed manufacturing, taking manufacturing closer to the treatment point to enable on site manufacturing in the hospital setting in the near future.

With distributed manufacturing, the company emphasizes the importance of maintaining a superior quality system, best practices, and highly controlled processes that are repeatable and safe to produce high-quality products at scale, leveraging highly comparable technologies across all manufacturing sites.

Ori seeks to assist in manufacturing different cell types and processes, focusing on seamless scalability, adaptability, flexibility, and manufacturing efficiency to shorten CGT's time-to-market. While it has initially focused on CAR-T cell therapies in a partnership with Minaris Regenerative Medicine (formerly HCATS), the company has also recently announced a collaboration with Achilles Therapeutics. This innovative biotech firm is evaluating Ori's platform for its proprietary clonal neoantigen T-cell (cNeT) therapy manufacturing process. In addition, Ori plans to expand its focus into allogeneic and adherent cell cultures in the next year.

The company has held recent discussions with the Food and Drug Administration, which supports developing technology companies, like Ori, who are trying to solve the challenges associated with CGT manufacturing. The known challenges surrounding product quality and batch to batch consistency drive the regulatory body to support innovative companies like Ori to help advance next-generation solutions.

Ori closed a \$30 million Series A round in August 2020 with investment from US-based VC Northpond Ventures as well as some of the United Kingdom's leading venture investors, such as Amadeus Capital Partners, Octopus Ventures, Delin Ventures, and Kindred Capital, underscoring its platform's promising potential in enabling fully automated CGT production at scale.

Frost & Sullivan notes that Ori strives to build a CGT manufacturing ecosystem to holistically address CGT manufacturing issues. Through its best-of-breed full stack manufacturing platform, the company can seamlessly plug into various other CGT technologies and positively impact the lives of millions of patients by helping to enable widespread access to life saving cell and gene therapies.

## Conclusion

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Manufacturing is the major bottleneck for cell and gene therapy (CGT). Challenges relate to variable quality, low throughput and high manufacturing costs resulting in increased treatment costs and low CGT accessibility for patients.

Ori Biotech has pioneered the development of a patented, end-to-end, flexible, and automated platform that meets clinical and commercial-scale CGT manufacturing needs. It increases throughput, maintains high-quality batch consistency, and decreases manufacturing costs. Powered by hardware and software capabilities, the novel platform promises to allow CGT developers to shorten time-to-market for life-saving CGTs and lower production costs significantly. Hence, the company hopes to enhance patient access to a new generation of low-cost, life-saving CGT therapies, potentially earlier in the treatment pathway, to significantly lower the overall cost-of-care.

With a focus on enabling distributed manufacturing in the future, the Ori platform will need to ensure well controlled processes that are repeatable and safe while standardizing CGT manufacturing across multiple manufacturing sites to produce high-quality products at scale.

With its strong overall performance, Ori Biotech has earned Frost & Sullivan's 2020 Global Enabling Technology Leadership Award in the cell and gene therapy manufacturing industry.

## What You Need to Know about the Enabling Technology Leadership Recognition

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Frost & Sullivan's Enabling Technology Leadership Award recognizes the company that applies its technology in new ways to improve existing products and services and elevate the customer experience.

### Best Practices Award Analysis

For the Enabling Technology Leadership Award, Frost & Sullivan analysts independently evaluated the criteria listed below.

#### *Technology Leverage*

**Commitment to Innovation:** Continuous emerging technology adoption and creation enables new product development and enhances product performance

**Commitment to Creativity:** Company leverages technology advancements to push the limits of form and function in the pursuit of white space innovation

**Stage Gate Efficiency:** Technology adoption enhances the stage gate process for launching new products and solutions

**Commercialization Success:** Company displays a proven track record of taking new technologies to market with a high success rate

**Application Diversity:** Company develops and/or integrates technology that serves multiple applications and multiple environments

#### *Customer Impact*

**Price/Performance Value:** Products or services provide the best value for the price compared to similar market offerings

**Customer Purchase Experience:** Quality of the purchase experience assures customers that they are buying the optimal solution for addressing their unique needs and constraints

**Customer Ownership Experience:** Customers proudly own the company's product or service and have a positive experience throughout the life of the product or service

**Customer Service Experience:** Customer service is accessible, fast, stress-free, and high quality

**Brand Equity:** Customers perceive the brand positively and exhibit high brand loyalty



