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Value from Innovation

INSIGHT BRIEF

# Fast-Tracking Development of MSC-Based Cell and Extracellular Vesicle Therapies Through a Strategic Partnership

**DANIEL DeVIDO, PhD,** Director of Strategic Business Development, FUJIFILM Biotechnologies

The therapeutic potential of mesenchymal stem cells (MSCs), particularly for the regenerative medicine space, has generated significant attention in clinical research. These cells, which can be derived from bone marrow, adipose tissue, or the umbilical cord, among others, are isolated and cultured and have been shown to restore cellular function and repair injured tissue across a range of disease states. They are also one of the more encouraging sources for exosomes, which hold promise in supplanting traditional nanocarriers for drug and gene delivery.

Yet, just as with many of the novel modalities being explored in the cell therapy space, MSC development is accompanied by several challenges related to adequate characterization, regulatory adherence, and balancing upstream and downstream development considerations. As developers work to scale MSCs and MSC-EVs, the value of identifying a contract development and manufacturing organization (CDMO) with the incumbent expertise, capacity, and supporting partnerships to fast-track these crucial modalities is key to advancing their therapeutic potential and regulatory acceptance.

## Addressing Complexity and Accelerating Development: RoosterBio and FUJIFILM Biotechnologies

For many cell therapy companies, the ability to focus their expertise on the foundational clinical science surrounding an MSC asset versus the complexity of their manufacture is crucial to the development of these therapeutics. Having manufacturing partners with specialized and complementary expertise in process development, cGMP manufacturing, including scale-up, and quality control standards of MSCs and EVs can be key to achieving the timely delivery of these lifesaving medicines to the patient. Vetting a potential CDMO partner for more novel cell therapy modalities like MSC-based and EV therapeutics often requires an evaluation of an organization's experience with both relevant technologies and related advanced therapies. Likewise, evaluating the CDMO's partnering capability, particularly when it comes to establishing an end-to-end development and commercialization paradigm, can help close the loop to secure the expertise necessary for seamless scale-up.

To achieve this accelerated development, FUJIFILM Biotechnologies and RoosterBio have partnered to link optimized process development and analytical workflows via seamless technology transfer to scale up and cGMP

## Extracellular Vesicles Partnership with Strong Collaboration Flow

RoosterBio®
Radically Simplifying Use of MSCs

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| RoosterBio MSC technology & manufacturing | RoosterBio product and process development | FUJIFILM Biotechnologies led transition to cGMP manufacture | FUJIFILM Biotechnologies cGMP manufacture | |
|---|---|---|---|---|
| • Source human tissue and cell isolation<br>• MSC culture and exosome collection<br>• Master and working cell banks<br>• RUO and GMP media and processing protocols | • Upstream / downstream process development<br>• Genetic engineering of cell banks<br>• Bioprocess roadmap to commercial scale<br>• MSC and exosome analytics | • Process review and evaluation<br>• Facility fit activities<br>• Analytical method transfer | • cGMP manufacture of cell bank<br>• cGMP manufacture of drug substance<br>• cGMP drug product manufacture |  Cell-based therapies<br>  Engineered tissues<br>  Extracellular vesicles (EVs)<br>  Cell-based gene therapies |

**Streamline Process Development** | **Allocate Resources Efficiently** | **Reduce Costs & Risks** | **Accelerate Path to Clinical & Commercial**

manufacturing. RoosterBio, a leading supplier of technology for biomanufacturing of MSCs and MSC-exosomes, has established an interconnected and comprehensive portfolio of products that spans cell sourcing, culture media, isolation technology, and banking services, as well as raw materials, media, gene editing technologies, and analytical assays. This specialization, when combined with FUJIFILM Biotechnologies' global advanced therapy manufacturing network and full-service preclinical-to-commercial capabilities, has served to establish a workflow optimized for these highly bespoke, highly valuable therapeutics.

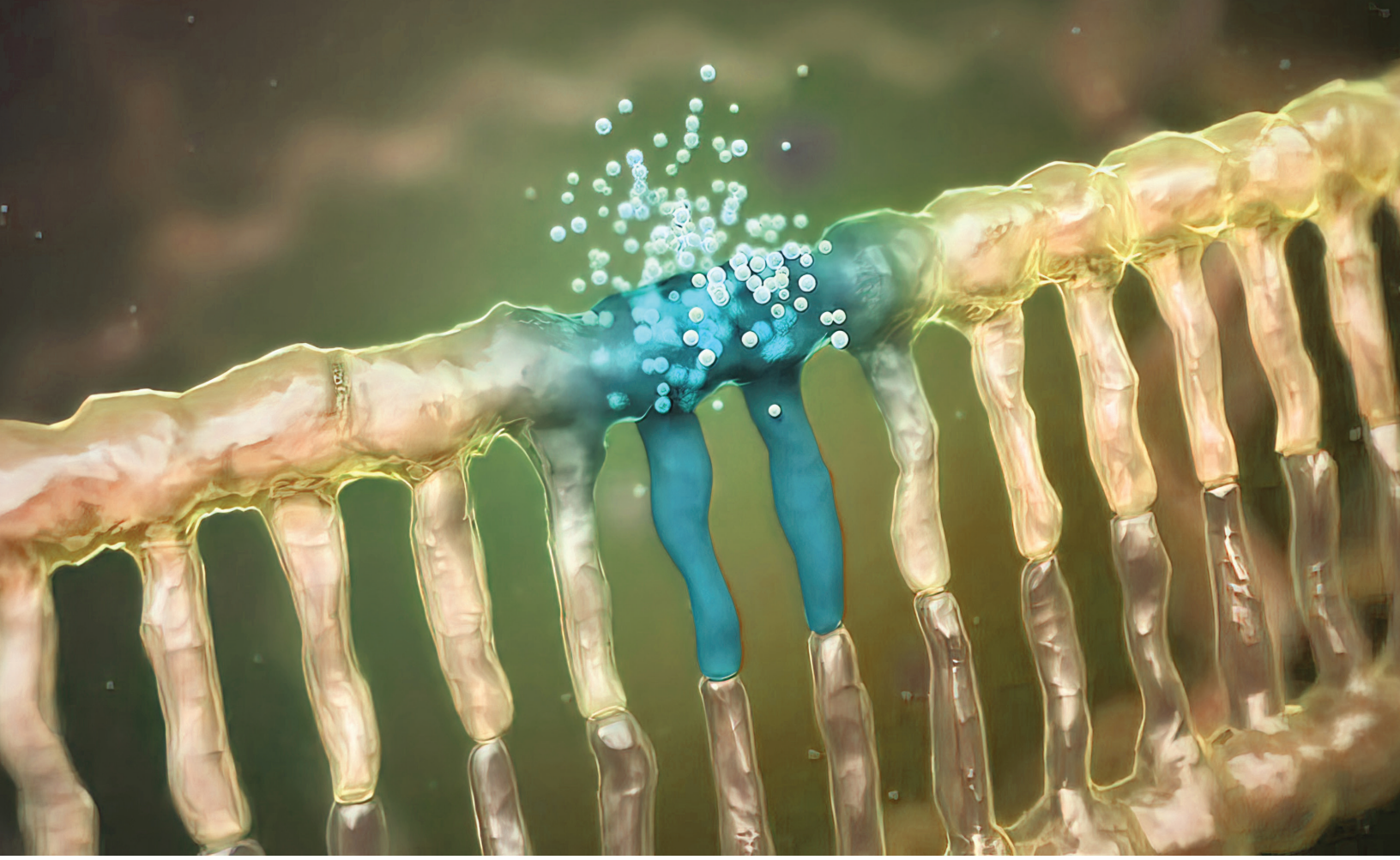
Through its extensive process and analytical experience, RoosterBio offers:

- Quality, well-defined raw materials (cGMP cells and media backed by FDA Type II Master Files)
- Optimized, scalable processes
- Experienced teams in MSC and MSC-EV product, process, and analytical development
- Consistent CMC-compliant protocols (with "CMC-ready" documentation available)

Through its long-standing tech transfer and GMP manufacturing experience, FUJIFILM Biotechnologies offers:

- 30+ years' experience in cGMP manufacture
- Skilled teams in dedicated workflows
- Quality track record
- End-to-end capabilities

RoosterBio can do much more than provide raw materials to its clients — its capabilities span process and analytical development to offer companies as much support as necessary to optimize their clinical asset. Likewise, FUJIFILM Biotechnologies has positioned itself to work with both RoosterBio and its clients collaboratively to ensure that the tech transfer process and subsequent scale-up are performed as efficiently and cost-effectively as possible. This starts with achieving familiarity with RoosterBio's established processes via transfer of the technology and extends to facility fit for each individual client process. Along the way changes to equipment and consumable materials are evaluated to consider supply chain, forecasting, and scale.



## A Streamlined Partnership for Quality and Risk Mitigation

Advancing MSC-based cell therapy products into clinical trials requires highly specialized process and analytical development as well as expertise in cGMP manufacturing. Through its collaboration with RoosterBio, FUJIFILM Biotechnologies' aim is to achieve greater efficiencies in scaling these unique therapeutics and for collaborative innovation in an emerging and evolving space. FUJIFILM Biotechnologies has leveraged unit operations from decades of experience in biologics and advanced therapies to produce MSCs and MSC-based EV products. Its global quality system is also well-suited to MSC production, and its project management experience, which spans cell-based therapies, engineered tissues, EVs, and cell-based gene therapies, is well-positioned to offer the flexibility and speed necessary to accelerate MSC product development and commercialization.

## CDMO Partner for Life

FUJIFILM Biotechnologies' "Partners for Life" strategy represents a transformative approach to biopharmaceutical development and manufacturing, emphasizing relationships founded on trust and transparency — founded in people-centric values, transformative science and innovation, and unprecedented delivery.

Learn more about our **Advanced Therapy** capabilities.

**Contact us** to learn how we can accelerate your MSC-Based Cell and Extracellular Vesicle Therapies.

# Partners for *Life*

CDMO LEADERSHIP AWARDS2024

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**Contact us to discuss your science — get the latest updates on our network and capabilities.**


**USA**

**College Station, Texas**
3940 Fujifilm Way
College Station, TX 77845
+1 979 431 3500

**Holly Springs, North Carolina**
100 Biotechnology Avenue
Holly Springs, NC 27540
(Coming online 2025)

**Research Triangle Park, North Carolina**
101 J Morris Commons Lane
Morrisville, NC 27560
+1 919 337 4400

**Thousand Oaks, California**
2430 Conejo Spectrum Street
Thousand Oaks, CA 91320
+1 805 699 5579

**DENMARK**

**Hillerød**
Biotek Allé 1
3400 Hillerød
+45 7741 6000

**UNITED KINGDOM**

**Teesside**
Belasis Avenue
Billingham, TS23 1LH
+44 1642 363511

**JAPAN**

**Tokyo**
R7 Building, 7-12-2 Roppongi
Minato-ku, Tokyo 106-0032
+81 3 6871 7736

**FUJIFILM Biotechnologies**

fujifilmbiotechnologies.fujifilm.com

**Email:** contactfdb@fujifilm.com


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