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Challenges of Scaling Up Cell Therapy to New Geographies

Content for this article was contributed by the EVERSANA Asia Pacific team.

Cell therapy has emerged as one of the most promising disruptive innovations in the pharmaceutical industry. However, despite its commercial promise, companies developing cell therapies have not been able to take full advantage of its massive potential.

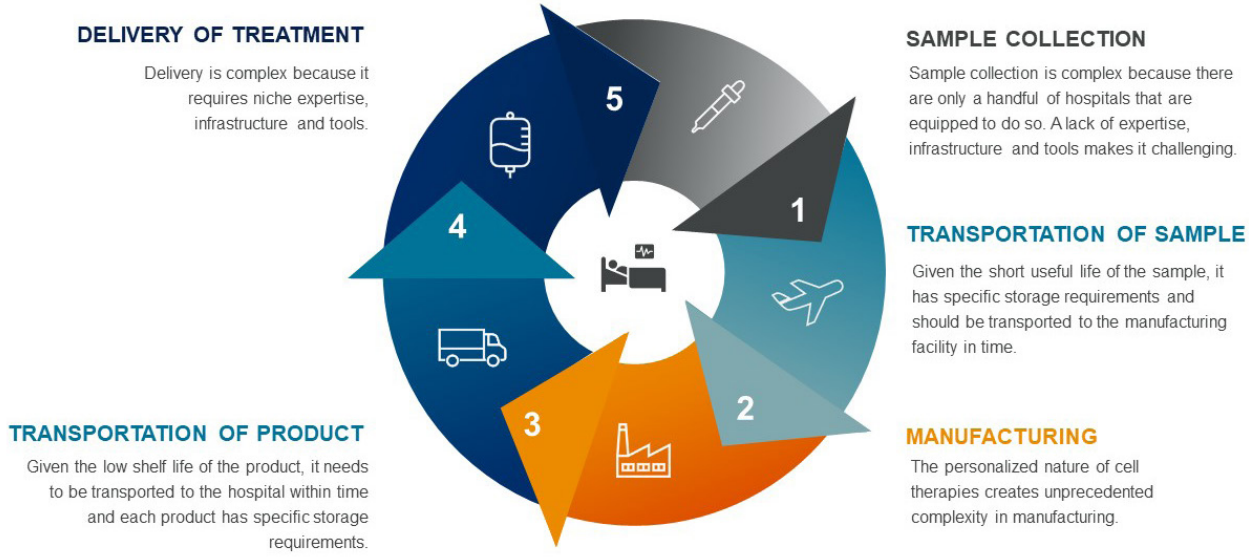
Cell therapies offer a massive commercial opportunity

In 2021, the cell and gene therapy (CGT) market was valued at $5.2B and is expected to increase at over 30% per year, reaching $25B by 2027. Globally, there are 56 cell therapies approved for clinical use. CGT products account for ~12% of the pharma industry's clinical pipeline and ~16% of its preclinical pipeline. Further, there are 816 cell therapies in development accounting for 22% of the pipeline of gene, cell and RNA therapies. Of the cell therapies in development, oncology and rare diseases are the top targets and account for ~60% of the products in the pipeline. 20% of clinical trials are being conducted in China, while the US and EU account for 35% and 20% respectively.

Cell therapy is different from traditional pharma products

Cell therapy, unlike traditional pharmaceutical products, involves multiple stakeholders right from the development stage to the delivery of the therapy making it inherently more layered, complex and high risk. The deeply personalized, patient-centric and emergency nature of cell therapies require companies to rethink the way they deliver their offering. Some companies have made the mistake of directly applying traditional approaches that are not as patient centric.

Figure 1: Cell Therapy Treatment Process



Over 20 companies across the globe have commercialized CGTs. While products like Kymriah and Yescarta have shown increasing revenues and gained significant market share, products like MACI by Vericel and Glybera by UniQure failed to scale up in Europe.

Major obstacles to successful CGT commercialization are the complexities associated with R&D, market access and reimbursement, manufacturing, and supply chain operations.

1. **R&D:** Rare indications targeted by these regimens and a lack of funding pose a big risk in terms of conducting clinical trials. Recruiting patients and longer follow up requirements make conducting clinical trials difficult and escalates treatment costs.
2. **Market access and reimbursement:** Unclear data requirements from regulatory authorities makes it difficult for companies to gain approval. Accelerated approval exists in many countries, but reimbursement remains an issue due to the high cost of the therapies.
3. **Manufacturing and supply chain operations:** Due to the specialized manufacturing requirements and limited patient populations, setting up manufacturing is costly. Many companies opt for outsourced business models to avoid setting up infrastructure while still achieving early market entry. Demand for services of CROs, CDMOs, CSOs and CPOs in this therapy area has exceeded capacity. Autologous regenerative medicines have a short shelf life, necessitating fast delivery time with complex storage requirements, driving up costs.

Scaling up

Commercial success results from two factors: product innovation and building delivery capabilities across the product life cycle. At the product level, CGT companies must develop a clinically superior product addressing a strong unmet need. Companies are investing heavily in R&D, as shown by the number of products under development. Companies have made little to no investment on building their capabilities across the product life cycle, evidenced by companies outsourcing their operations and leading to an acute service supply shortage. The decision to outsource operations is often driven by the high investment required to run operations in-house, and the desire to enter the market early.

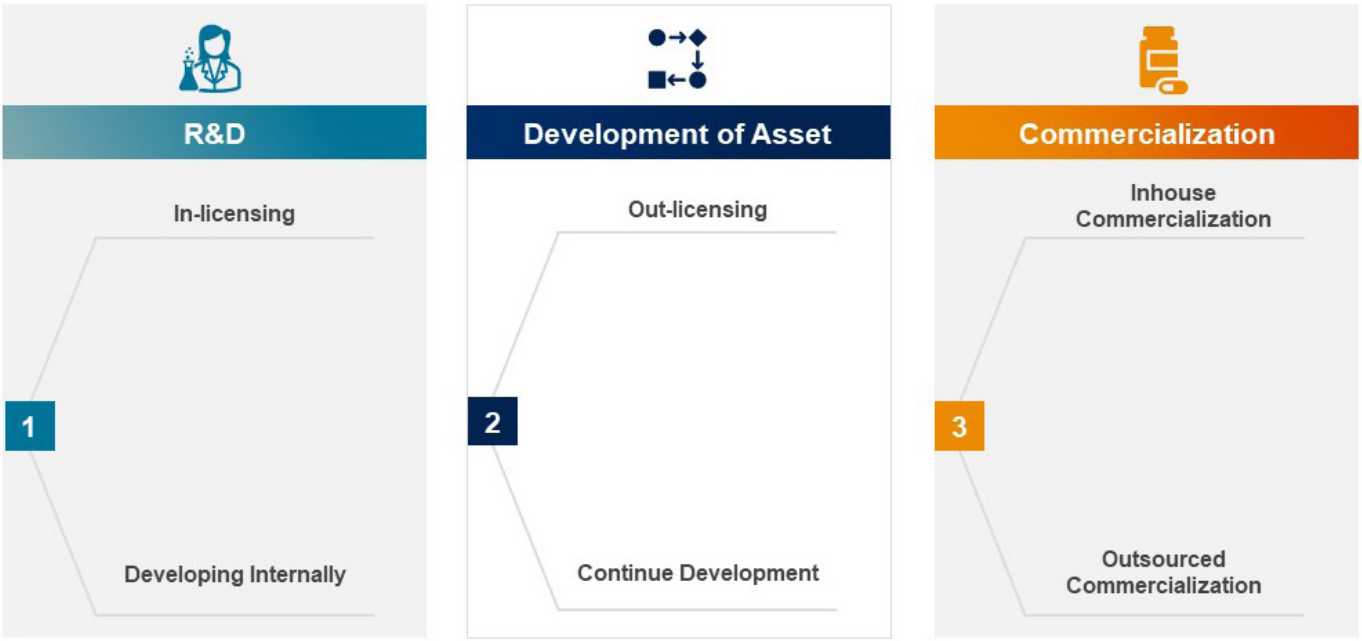
With numerous challenges to scaling up, companies must decide on the level of investment they can commit to maximise returns across the product life cycle and not just at the product level. They can then allocate these resources between R&D and capability development. Risk exists in both investments, and we have supported clients in making strategy decisions by helping them understand the trade-offs and return on investment.

Developing a go-to-market strategy for regenerative medicine

In one recent engagement, a client was exploring the option of expanding their regenerative medicine business into foreign markets and required a deep understanding of the U.S., European, Canadian and Australian markets. The client also wanted to evaluate business models to arrive at a go-to-market strategy. The engagement required us to prioritize the markets by attractiveness in terms of size, regulatory dynamics, and reimbursement pathways.

We arrived at a go-to-market strategy for each market by evaluating alternate business models, including a financial assessment of running operations in-house vs. outsourcing, keeping in view the client's vision and strengths.

Figure 2: Go-to-market strategy decision approach



EVERSANA has the unique experience of having worked with clients in the regenerative medicine space across the value chain and we have developed a deep understanding of this space. Our engagements have helped clients take high quality decisions on the regenerative medicine strategies. Further, EVERSANA also has operational and commercialization experience, which help clients implement strategies.

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