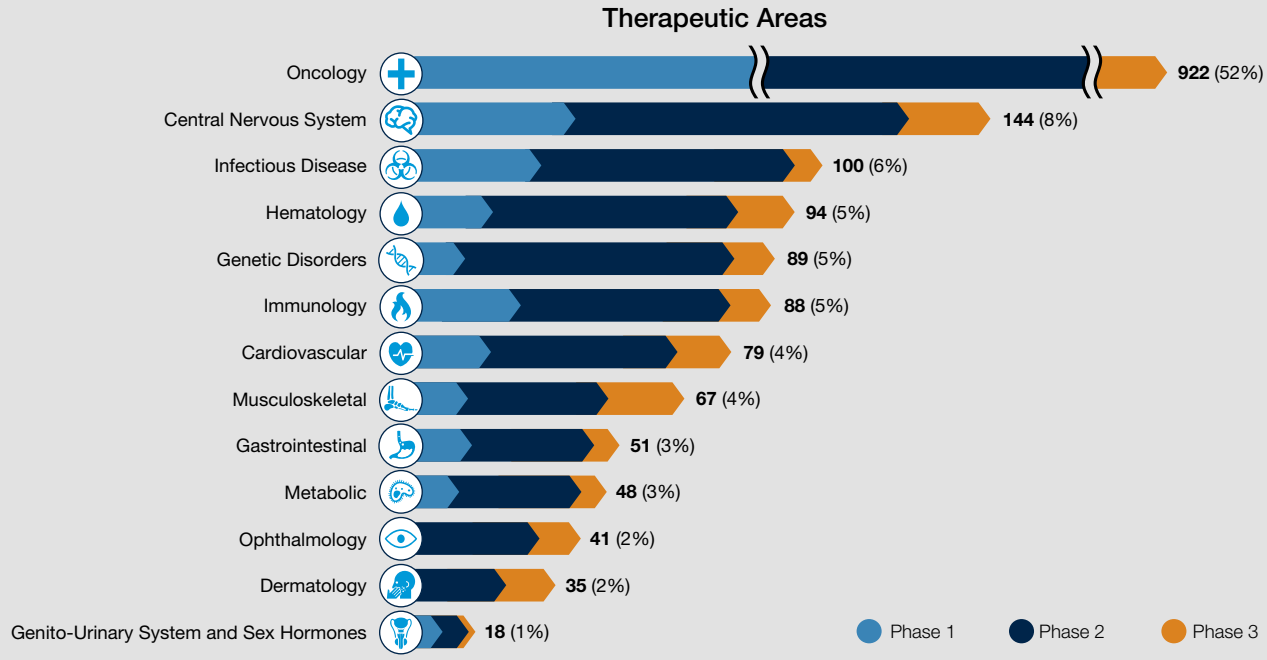
HEALTHCARE & LIFE SCIENCES

Pharma's New Frontier: Identifying Investment Opportunities in Cell and Gene Therapies

Cell and gene therapy (CGT) – a technique that in essence replaces diseased cells with healthy versions – is one of the most promising new frontiers in life sciences today. Research in the field has experienced a resurgence with over 1,200 active trials[1] underway to treat life-threatening diseases such as cancer and rare genetic disorders.

More recently, a string of high-profile drug approvals in the U.S. and in Europe have taken these therapies a step closer to marketability. A recent landmark decision by the Food and Drug Administration (FDA) authorized the world's first gene therapy to treat adults with hemophilia B. As dozens more products obtain the green lights from regulators in the next few years, the market size for CGT is expected to reach $94 billion by 2030.[2]



1. Percentages (%) based on trials with known therapeutic areas; 317 trials with area unknown or unclassified
2. Unlisted areas include known areas with small numbers (<10) of CGT trials including mouth/dental, ear-nose-throat, and unspecified male/female disorders

Source: Alliance for Regenerative Medicine, "Regenerative Medicine: The Pipeline Momentum Builds", September 2022

This progress has attracted the interest of big pharma and investment firms alike. Despite a recent slowdown in the wider M&A market, and following two-record breaking years, investment in CGT is likely to land between $9.8 billion and $13.5 billion in 2022. For pharmaceutical giants, the new therapies are an attempt to refill their pipeline as patents for many of their top-selling drugs expire. Meanwhile, financial buyers are looking into the sector's growth and value creation potential.

1. https://www.statista.com/statistics/1249776/number-active-trials-cell-gene-therapies-by-trial-phase-worldwide/
2. https://www.globenewswire.com/news-release/2022/11/30/2564827/0/en/Cell-and-Gene-Therapy-Market-Size-to-Surpass-USD-93-78-BN-by-2030.html

Ecosystem of companies behind CGTs offers significant market potential

As the sub-industry matures into a large-scale commercial market, CGT companies will need significant assistance in overcoming the challenges associated with the development, manufacturing, supply, pricing and sale of these drugs. This presents a significant opportunity for vendors and service providers – as well as for investors looking to get involved in CGT, without immediately diving into a business area that they don't know well.

The usage of Contract Development and Manufacturing Organizations (CDMOs) is one case in point. Because many of the small biotechs do not own manufacturing facilities, contract manufacturers will be key partners in helping scale up production. CGT companies may also look to outsource their R&D activities to avoid having to build capital-intensive labs, thereby paving an opportunity for Contract Research Organizations (CROs) to provide their specialized services.

Another bottleneck lies in the industry's complex supply chain and logistics. Storage and transport, for example, are often costly and intricate due to the products' narrow viability windows and strict quality controls. Logistics and transportation businesses bringing innovative solutions to these issues are especially attractive in this context.

Recent transactions involving these niche providers include EQT Private Equity and Mubadala Investment Company's €2.8-billion acquisition of Envirotainer, a global provider of cold chain transportation for biopharmaceuticals, and EW Healthcare Partners' buyout of Germfree Laboratories, a solution provider for biopharma and advanced therapy manufacturing.

Global 2022 H1 Quick Facts

	North America	Asia-Pacific	Europe
Developers	**651** +2% vs. 2021	**453** +10% vs. 2021	**230** 0% vs. 2021
Clinical Trials	**808** INDUSTRY 472 ACADEMIC /GOV'T 336 -15% vs. 2021	**640** INDUSTRY 294 ACADEMIC /GOV'T 346 -15% vs. 2021	**329** INDUSTRY 178 ACADEMIC /GOV'T 151 -14% vs. 2021
Investment	**$5.6B** 53 DEALS -68% YoY	**$675MM** 23 DEALS -69% YoY	**$398MM** 13 DEALS -88% YoY

1. 188 industry trials, 22 non-industry trials active in multiple regions
2. 214 industry trials, 224 non-industry trials with region unknown/unspecified

Source: Alliance for Regenerative Medicine, "Regenerative Medicine: The Pipeline Momentum Builds", September 2022

Investors should also be looking at suppliers of specialty materials and equipment. For instance, in highly manual autologous cell therapy manufacturing operations, kitting the materials needed for each step of the process can make the overall cost of the manufacturing less expensive, meaning vendors can provide value in that area too.

Focusing on the providers within the wider ecosystem rather than just on CGT developers has several advantages. First, it allows investors to capitalize on the industry's momentum without being exposed to the binary risks of trial outcomes. CDMOs and CROs in particular can provide the financial transparency that many financial buyers require, as well as significant potential for consolidation.

Finally, for middle-market investors to whom biotech companies may be out of reach due to high valuations, investing in these alternative areas is a creative way to stay in the game.

Conclusion

Entering the CGT space requires more careful strategic planning than with the more mature small molecule and biologics therapies. The technology and operational components are changing rapidly, and it is important not to get locked into an investment that serves only a small part of the industry or a technology that may become obsolete in a few years.

However, as seen above, providers or investment partners to the industry don't have to jump into the deep end of the pool. Despite the challenges and bottlenecks, there are many ways to participate and gain experience while providing valuable products and services to the CGT pioneers. As the sector matures further, these "early-days" investors will be well-placed to capitalize on the opportunities and outlook of this promising field.

How can A&M help?

A&M has the specialized industry, process improvement, strategic advisory, operational, M&A and private equity experience to help make your CGT venture successful. Our experience assisting clients in the space includes:

Strategy: assessment of size of market opportunities, designing pricing model, assessing technology, developing operating model to assist with the CGT initiatives among others.

Operations: analysis of supply chain processes, evaluation of business' ability to scale up, manufacturing strategies, including the management of the build-out of contract networks, and manufacturing facilities and other services to autologous and allogeneic therapy companies alike.

M&A: includes development of inorganic strategy, market landscape assessment for investment strategy, due diligence, tax implications and structuring and other transaction related services. Through our operational heritage and results-driven mindset, we can deliver a successful transaction and implementation end-to-end.

Due Diligence: financial, operational, and commercial due diligence is especially critical for life sciences acquisitions and can have a significant impact on strategies for future value creation.

Digital: operational support to organizations throughout the entire digital journey, including on digital strategy, data analytics, AI & intelligent automation and cloud services.

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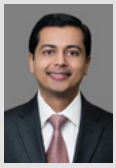

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