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Cell and Gene Therapy in an Evolving Capital Market: Value Drivers to Enable and Elevate a Successful Raise

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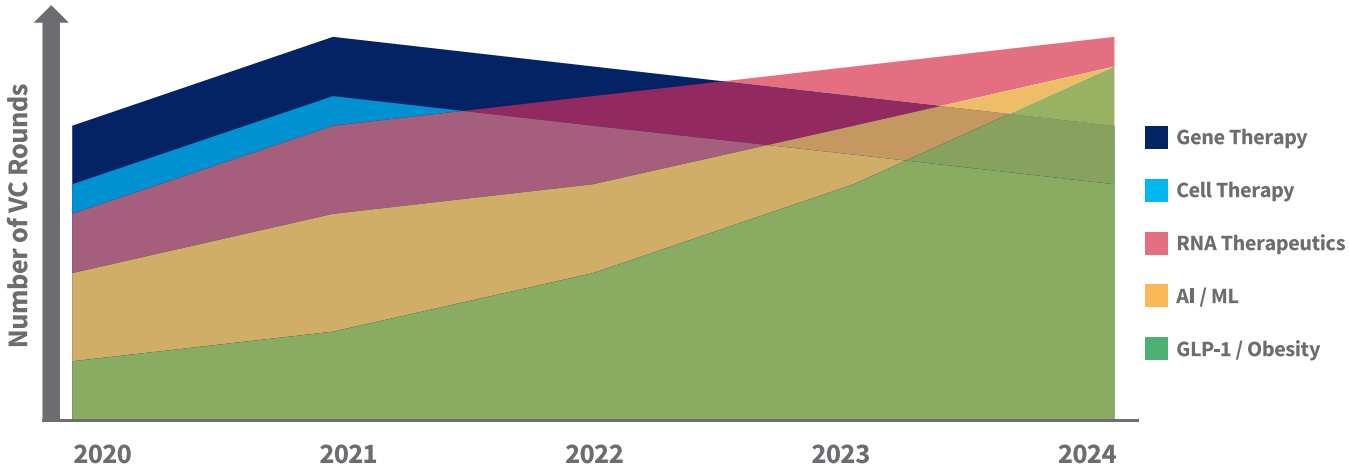
WHITE PAPER

Introduction

The shifting winds in the cell and gene therapy capital market are perhaps unsurprising to those who have been watching since the post-COVID zeitgeist, when market entry of several clinical successes finally came after decades of innovation and development in the field. Slow clinical progress of many cell and gene therapy programs, coupled with a reinvigoration of "large" disease therapies (e.g. GLP-1 receptor agonists) and emergence of new technologies for drug discovery and development (e.g. AI/ML), has led to a shift in early venture capital interest over the past 5 years.

Figure 1: Biopharma VC Raises - Select Technologies



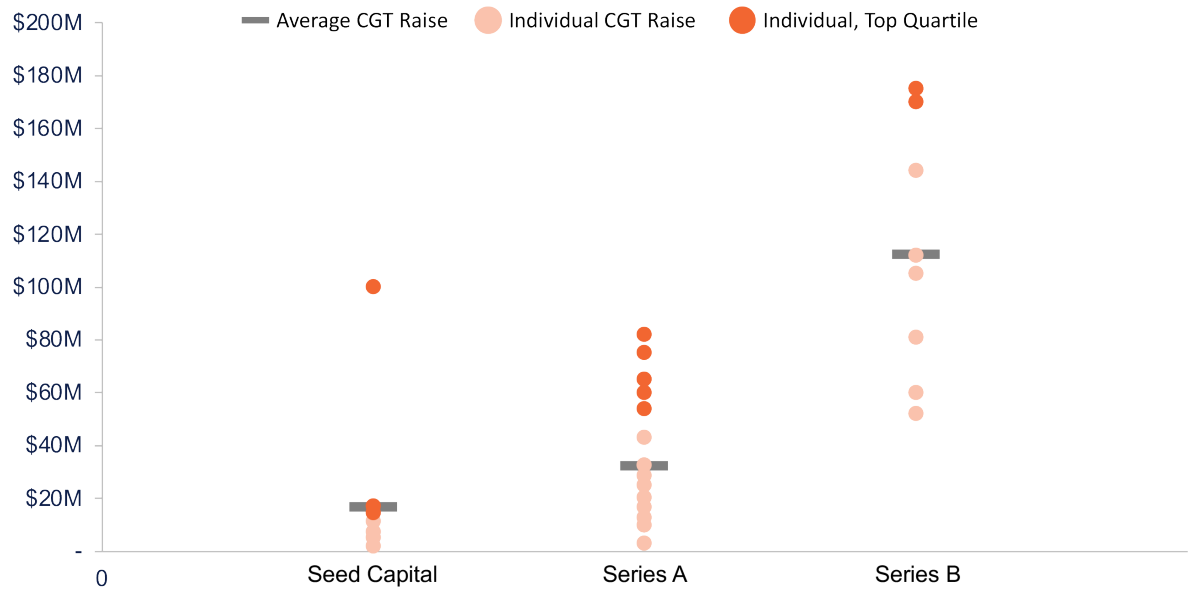
VC raises for cell and gene therapy companies have declined since hitting a peak in 2021. In that time, RNA therapeutics and AI/ML have grown, spurred by the very public successes of mRNA vaccines and AI technology. Unsurprisingly, investment in companies with GLP-1 receptor agonists or related technologies has increased dramatically in recent years. Other major categories (e.g., protein-based therapeutics, digital therapeutics, ADCs) have experienced less dramatic changes and have been omitted for simplicity. Sources: Company press releases and related publications

While seemingly discouraging in the immediate-term, what is important to remember is that the promise of cell and gene therapies hasn't changed. 2024 saw 7 cell and gene therapy approvals, and >40 later-stage topline clinical readouts are expected this year. We are confident that high-profile wins – major clinical milestones for the next paradigm-shifting therapies or landscape-changing acquisitions of innovators – will energize investor interest in the cell and gene therapy space. However, many innovators cannot afford to wait for the world to change.

So, where does that leave cell and gene therapy startups? How does innovation continue to receive funding in this environment, and what will drive the most value in a resource-constrained market?

To provide some perspectives, Triangle Insights Group evaluated the VC raises by cell and gene therapy innovators in 2024 to identify consistent value drivers supporting successful raises. For each round of funding, we evaluated deals in the top quartile compared to peers in the same round to identify the key company- and asset-level characteristics driving higher-than-average value. Beyond basic requirements to draw investor attention, several themes emerged that reveal more nuance about what investors are looking for – and that help to inform steps that the next new innovator can take to refine their fundraising efforts.

Figure 2. 2024 Cell & Gene Therapy Early VC Activity



In 2024, cell & gene therapy innovators raised early VC rounds ranging from $2M to $175M; highlighted deals were in the top quartile within each series. Note: data is limited to 47 companies with cell & gene therapeutics (i.e., does not include supportive services and technologies for cell & gene therapy products) who raised early rounds in 2024 (i.e., Seed, Series A, or Series B). Sources: EvaluatePharma; BioMedTracker; Company press releases

Value Theme 1: Form a Winning Team to Drive Early Investor Enthusiasm

An old adage in the world of VC is that funds invest in the leadership team of a target company rather than the technology itself, and that holds true for cell and gene therapy innovators as well. The qualities that firms highlight in leadership teams tend to steer toward either robust successful leadership experience, deep technical expertise, or both. Several firms raised large rounds in 2024 due in part to management teams with proven background and known leadership in the space. GC Therapeutics was not shy about the role of co-founder George Church, renowned geneticist who pioneered genomic sequencing 40 years ago, in announcing its Series A round. Exsilio Therapeutics raised an $84M Series A round with the notable role of former Moderna CMO Tal Zaks as a temporary CEO.

Of course, not all early-stage companies will be founded or lead by industry heavyweights or world-renowned pioneers of cell and gene therapies, but still have highly promising and credible disruptive technology. In these cases, it's valuable to stress a strong background in the core technology. Waypoint Bio raised a seed round of $14.5M in June 2024 without a defined product candidate, but with a strong story for why the complementary wet and dry lab backgrounds of co-founders Xinchen Wang and David Phizicky would position it for success in developing a highly efficient platform for screening novel cell therapies directly in mouse models.

Complementary to a strong team supporting the scientific backing, additional value can be unlocked if company leadership includes individuals with track records in growing biotechs to successful outcomes. In announcing its $75M series A round, Tr1X Bio highlighted the experience of incoming CEO William Lis and co-founders with decades of experience developing successful therapies and building development-stage companies. As it announced a $17M seed round in late 2024, Tolerance Bio highlighted not only the proven track record of CEO Francisco Leon and the role of co-founder Holger Russ in inventing the core technology, but also the experience of other key members of the team who led the successful $2.9B acquisition of Provention by Sanofi in 2023.

Value Theme 2: Maximize the Existing Data and Define the Path Forward

Given the nascency of the technologies, mixed efficacy results, and recent serious safety signals, it is likely that cell and gene therapy investors will place even more emphasis on the body of evidence supporting the assets and underlying technology. Companies raising Series A rounds, often right around the IND submission and transition to clinical trials, need to build confidence that the technology will work safely in humans. Akamis Bio exemplified the most compelling way to do that when raising a $60M series A round in late 2024, as their intravenous oncology gene therapy lead asset had already generated evidence of safety and signs of clinical potential in phase 1 trials. For firms that have not yet entered human trials, defining a clear plan for an IND submission can build credibility that the preclinical evidence is sufficient to move forward. Both Kenai Therapeutics and Latus Therapeutics highlighted near-term paths to the clinic when announcing Series A rounds.

In earlier Seed rounds, where the investment thesis tends to focus more on the team and the potential of the technology, preclinical data is compelling but does not need to be comprehensive if other elements of the business case are strong. Nvelop Therapeutics touted published in vivo data for just one of its two platform technologies when announcing its sizable $100M Seed round, but it also benefited from association with co-founders David Liu and Keith Joung, who previously started Editas Medicines, Beam Therapeutics, and other startups.

Strong clinical data becomes more of a baseline requirement in later rounds, as exemplified by Beacon Therapeutics' sizable Series B to expand on ongoing clinical trials. However, there can be exceptions to the rule, especially for disruptive technologies - Capstan Therapeutics was able to raise a $175M Series B round to expand its pipeline and develop its lead asset based on robust murine model data supporting its promising in vivo CAR-T approach.

Value Theme 3: Invest in Manufacturing or Overcome Traditional Barriers

Manufacturing is a notable challenge for today's cell and gene therapies. For traditional autologous CAR-T therapies, the insufficient scalability and logistics of sample collection and processing present substantial costs that have yet to be addressed. Allogeneic cell therapies address some of these logistical challenges by enabling greater economies of scale, but manufacturing remains complex and many physiological and scientific barriers continue to be challenges. Even comparatively "simple" gene therapies require specialized manufacturing processes that are far more complex and less scalable than traditional biologics.

Firms that demonstrate early steps toward GMP manufacturing – particularly as they de-risk the core therapeutic technology through pre-clinical research – can improve their access to capital. Before raising a $75M series A in early 2024, Tr1X Therapeutics was able establish a GMP-grade process to enable manufacturing to support their clinical program. However, firms do not need to tackle this burden alone – Kenai Therapeutics established a relationship with CDMO Fujifilm to develop and manufacture their iPSC-based therapy before raising a robust Series A round. Absent any actual manufacturing initiatives, it can still be influential to highlight how the core technology will mitigate traditional manufacturing challenges – as was the case for both Latus Therapeutics, whose technology enables efficacy at low doses that will be easier to manufacture, and GC Therapeutics, whose technology will accelerate development and production of iPSC-based therapies. Each of these firms raised a large Series A round in 2024. Capstan Therapeutics may have derived additional value from an implicit assumption that in vivo CAR-T will significantly reduce manufacturing complexities associated with ex vivo cell therapies today.

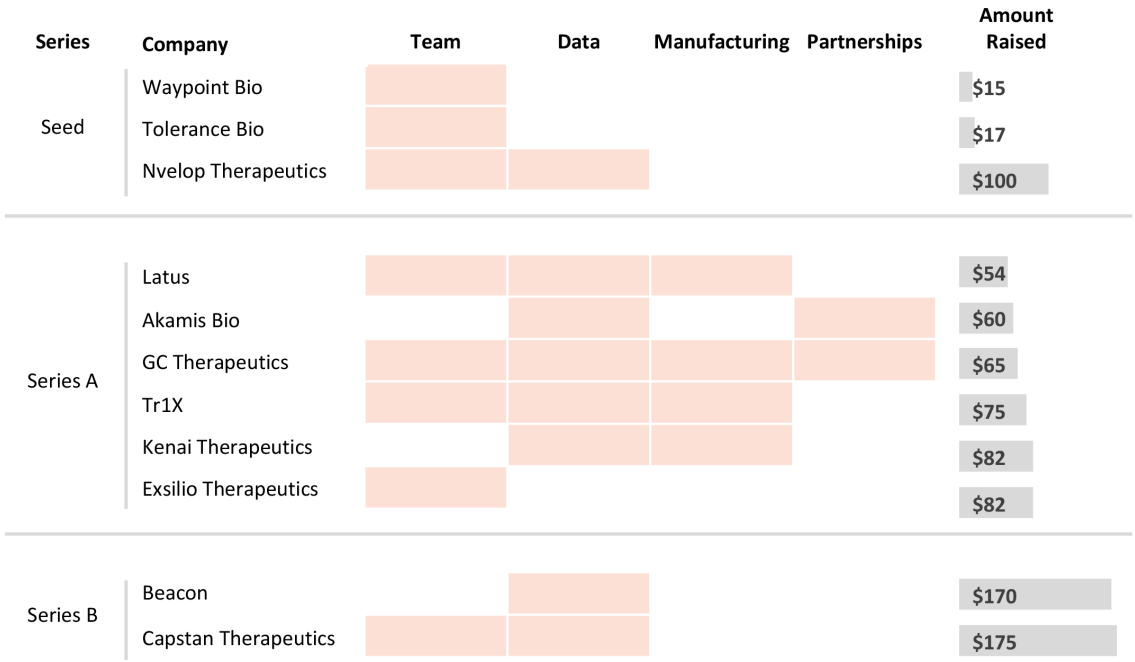
Value Theme 4: Consider Strategic Partnerships to Address Gaps and Build Confidence

While partnerships and strategic collaborations can be seen as risks to an investment thesis – whether co-development deals or geography-specific commercial rights – they can help to build confidence in a challenging environment if structured correctly. In announcing its Series A, Akamis Bio described a licensing agreement granting Xuanzhu Biopharma the Greater China Region rights for its lead asset. Such deals can potentially generate clinical proof of concept data from ex-US trials, provide nondilutive capital, and enable nascent firms to benefit from markets that they otherwise would not have the scale to access for years to come. As firms mature, strategic partnerships can fill various needs to expand efficiently. Outpace Bio, an honorable mention with a large raise just shy of the top quartile in this analysis, highlighted research collaborations with several researchers shortly before announcing its $144M Series B to bring multiple assets into the clinic and build out its pipeline. In an interview with Fierce Biotech, GC Therapeutics described the potential for its cell therapy production platform to support selective industry partnerships to propel the development of some assets.

Lessons for the Next Innovators

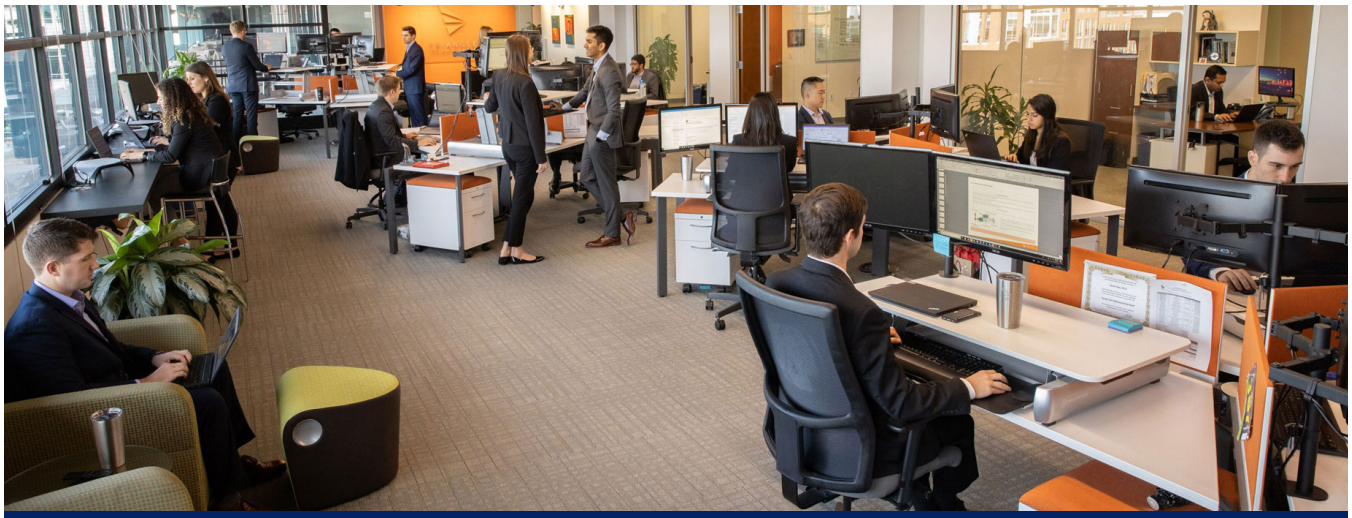
For startups that are wondering how best to build investor confidence while raising capital in 2025, the CGT success stories from last year reveal several themes to consider. It is as important as ever to focus the story on the firm's technology and vision, whether highlighting the contributions of scientific founders to the field or hypothesizing what early preclinical findings suggest about clinical viability. However, building on these themes – data, manufacturing, leadership teams, and partnerships – goes beyond simply retelling a familiar story.

Figure 3. Value Themes Driving Capital Raise (Based on Public Disclosures)



For companies raising early seed rounds, the team/company leadership drives value as other elements may not yet exist. Series A rounds tend to require the greatest variety of proof points to build credibility as companies make the substantial transition from early proof of concept to dosing in humans in a heavily regulated environment. Series B rounds typically hinge on the data, as companies are typically either ramping up for pivotal trials or building out a pipeline after validating the core technology. Sources: EvaluatePharma; BioMedTracker; Company press releases; Triangle Insights analysis

In challenging fundraising environment, what steps can you take today to make the most of the resources available and elevate your investor narrative? Pre-clinical data can be sufficient to establish early proof-of-concept, but a draft IND submission may give additional confidence in the path to clinic. A scalable, GMP-ready manufacturing process may de-risk the development plan substantially, and in lieu of self-owned manufacturing square footage, a committed deal with a CDMO can potentially mitigate investor concerns with scalability and timelines. A seasoned management team that includes the inventor is attractive, but one or two expert hires in select roles – or representation on the board or SAB – can address potential gaps. Across the themes highlighted from last year's stand-out startups, there may be achievable steps that new firms can take to build credibility. Every startup and every investor is different, so it is critical to establish multiple value drivers and consider as many opportunities as possible to secure additional confidence. In these challenging times for cell and gene therapy innovators, the lessons from last year's standout capital rounds shed light on viable paths that could enable the next raise.



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