Cell and Gene Therapy Tools: Trends and Opportunities

May 2, 2022
How Big is the Cell and Gene Therapy Tools Market?

Total Cell & Gene Therapy End Market Sales (1)

<table>
<thead>
<tr>
<th>Year</th>
<th>Cell Therapy</th>
<th>Gene Therapy</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021E</td>
<td>$4Bn</td>
<td>3</td>
<td>$4Bn</td>
</tr>
<tr>
<td>2024E</td>
<td>$18Bn</td>
<td>7</td>
<td>$18Bn</td>
</tr>
<tr>
<td>2026E</td>
<td>$41Bn</td>
<td>25</td>
<td>$41Bn</td>
</tr>
</tbody>
</table>

Cell & Gene Therapy TAM (2026)

<table>
<thead>
<tr>
<th>Year</th>
<th>TAM Cell Therapy</th>
<th>TAM Gene Therapy</th>
<th>Total TAM</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021E</td>
<td>$40Bn+</td>
<td></td>
<td>$40Bn+</td>
</tr>
<tr>
<td>2025E</td>
<td>$80Bn</td>
<td></td>
<td>$80Bn</td>
</tr>
</tbody>
</table>

Cell & Gene Therapy Tools Addressable Market

<table>
<thead>
<tr>
<th>Year</th>
<th>TAM</th>
<th>CAGR</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021E</td>
<td>$47Bn</td>
<td>14%</td>
</tr>
<tr>
<td>2025E</td>
<td>$80Bn</td>
<td></td>
</tr>
</tbody>
</table>

Notes:
1. Includes projected worldwide sales for all active cell therapy, gene-modified cell therapy, and gene therapy programs from clinical to commercial.
2. Represents expected global number of revenue generating Cell & Gene Therapy products by respective year; individual products can treat multiple indications.
Putting this in Context: Mirroring Monoclonal-antibody Therapy

Cell and Gene Therapy is Still in the Early Innings of Growth

<table>
<thead>
<tr>
<th></th>
<th>Cell and Gene Therapy (Today)</th>
<th>mAb (20 Years Ago)</th>
<th>mAb (Today)</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAM</td>
<td>$4Bn (59% 5-Year Forward CAGR)</td>
<td>$5Bn</td>
<td>$123Bn+</td>
</tr>
<tr>
<td>Market Capitalization (1)</td>
<td>$39Bn</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cumulative Capital Raised (5 Year Trailing)</td>
<td>$74Bn+</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: Pitchbook, Thomson Reuters, Evaluate Pharma, Alliance for Regenerative Medicine, Pitchbook

Notes:
1. Includes cell and gene therapy and editing companies with primary business of developing innovative drug candidates. Excludes companies where primary drug development focus is not cell and gene therapy
Cell and Gene Therapy – Accelerating Toward a Therapeutic Revolution

Chronology of Key Developments

1990
First clinical trial using viral vector

1993
First generation CARs developed

1998
Second generation CARs developed

2002
First effective CAR T cells developed

2003
First regulatory approval of Gene therapy product (China)

2010
First clinical data using CAR T

2012
Approval of first Gene therapy in E.U.

2013
Development of CRISPR / Cas9 technology

2017
FDA approval of first CAR-T cell therapy

2017/2019
First in vivo gene therapies approved in U.S.

2021
FDA approval of CD19 CAR-T therapy

United States
- Iovance Melanoma
- Gamida Cell Blood Cancer + HSCT
- Janssen/Legend Multiple Myeloma
- bluebird bio Beta thalassemia

Europe
- Bristol Myers Squibb B cell Lymphoma
- Atara Bio EBV+ PTLD

FDA approved Cell Therapy Products (1)

Upcoming 2022 Cell Therapy Milestones

Source: Wall Street Research, Genehome, American Society of Cell and Gene Therapy, Alliance for Regenerative Medicine, FDA

Note:
1. As of March 2022
Capital Inflow to Cell and Gene Therapy Continues to Accelerate

Cell and Gene Therapy Fundraising over Last 3 Years

$Bn

<table>
<thead>
<tr>
<th>Year</th>
<th>$Bn</th>
</tr>
</thead>
<tbody>
<tr>
<td>2019</td>
<td>$9.8Bn</td>
</tr>
<tr>
<td>2020</td>
<td>$19.9Bn</td>
</tr>
<tr>
<td>2021</td>
<td>$23.1Bn</td>
</tr>
</tbody>
</table>

Capital inflows in Cell and Gene Therapy Have Increased Significantly post-COVID Outbreak

Public and Private Investors Actively Participating

Capital Raised by Transaction Type, $Bn

<table>
<thead>
<tr>
<th>Transaction Type</th>
<th>2021</th>
</tr>
</thead>
<tbody>
<tr>
<td>VC</td>
<td>9.8Bn</td>
</tr>
<tr>
<td>IPO</td>
<td>4.8Bn</td>
</tr>
<tr>
<td>Follow On</td>
<td>3.7Bn</td>
</tr>
<tr>
<td>Private Placement / PIPE</td>
<td>2.3Bn</td>
</tr>
<tr>
<td>Corporate Partnerships</td>
<td>1.9Bn</td>
</tr>
<tr>
<td>SPAC / Other</td>
<td>0.6Bn</td>
</tr>
</tbody>
</table>

• Current dislocation in capital markets funding cycle should be transient in overall Cell and Gene Therapy investments

• Current biotechs have 2+ years of cash runway
Volume and Stage of Clinical Activity Suggest Pace of Innovation Will Only Increase

Growth in Cell and Gene Therapy Trials
Cell & Gene Therapy Pipeline (# Programs)

New Innovation Leading the Way, with Preclinical and Phase 1 Activity Tripling

Source: clinicaltrials.gov
Cell and Gene Therapy Innovators Outsource More than Other Modalities

Small Biotechs Account for Increasingly Greater Proportion of Therapeutic Innovation

Outsourcing Integral to Business Model of Biotech Innovators in Cell and Gene Therapy

Constraints of Biotech Models

Cell and Gene Manufacturing Outsourced in Greater Proportions

% of FDA Approvals

% of Clinical Stage Manufacturing Outsourced

Biotechs Among the Most Active Innovators and Most Likely to Outsource

Limited Balance Sheet Capacity

Limited Capital Outlay Firepower

Desire to Focus on Therapeutic Innovation

Limited Scalable Production Capacity

Biologics

Small Molecule

Cell & Gene Therapy

Source: Wall Street Research

Note:
1. Represents small molecule finished dose outsourcing
What’s Holding Cell and Gene Therapy Back?

Commercialization Impeded by Complexity and Cost

Need for More Efficient and Cost-Effective Manufacturing Model

**COSTS**
CGT Affordability is Key

**Current Price Tags are Difficult to Absorb**

- Yescarta: $0.4M
- Luxturna (per eye): $0.4M
- Kymriah: $0.5M

**SCALABILITY**
A Major Barrier to Wider Adoption

- **Manufacturing capabilities represent one of the main barriers to entry**
- **New processes required to meet demand for larger, scaled clinical trials and commercial production**

**LOGISTICS**
Increased Complexity

- **Evolving Cell and Gene therapy market requires innovative manufacturing technology**
- **Personalized CGT products require periodic enhancements**

Source: BioInformant, PA Consulting
# Cell and Gene Therapy Technology is Inherently More Complex

<table>
<thead>
<tr>
<th></th>
<th>Small Molecule</th>
<th>Protein</th>
<th>Viral Vector</th>
<th>Cell Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>API Required</strong></td>
<td>Small (&lt; 0.2 nm)</td>
<td>Small (5 nm)</td>
<td>Medium (20 - 300 nm)</td>
<td>Large (&gt; 5,000 nm)</td>
</tr>
<tr>
<td><strong>Stability</strong></td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
<td>Very Low</td>
</tr>
<tr>
<td><strong>Handling / Distribution</strong></td>
<td>Easy</td>
<td>Temperature controlled</td>
<td>Complex - infectious materials</td>
<td>Complex - genetically modified cells</td>
</tr>
<tr>
<td><strong>Regulatory</strong></td>
<td>Established</td>
<td>Established</td>
<td>Developing</td>
<td>Developing</td>
</tr>
<tr>
<td><strong>Manufacturing Specifics</strong></td>
<td>Same product for all patients</td>
<td>Same product for all patients</td>
<td>Same product for all patients</td>
<td>Individualized; Cell processing required</td>
</tr>
<tr>
<td><strong>Dosing</strong></td>
<td>Often / chronic</td>
<td>Monthly / chronic</td>
<td>Single dose to several over lifetime</td>
<td>Goal of single treatment</td>
</tr>
</tbody>
</table>

**Least Complex**

**Most Complex**
Biologics Enabling Tools Providers Face Significant Challenges in the Workflow
Not Yet Solved by Influx of Capital and Innovation

**Increasingly Complex Technological Requirements**
- Multiple sequential steps and processes required
- Cost of failure
- Time consuming process with multiple bottlenecks

**Expensive Technology**
- Up to $110,000 estimated manufacturing COGS for one dose
- Labor-intensive process
- Lack of automation

**Quality Control Labor and Equipment Constraints**
- Limited availability of trained professionals with specialized skillsets
- Long lead times required for inspection equipment

**Long Wait Times for Contracted Production Capacity**
- Average 16+ month wait time for manufacturing capacity

**High Switching Costs**
- Costly to recertify new suppliers
- Opportunity cost of manufacturing delays

**Regulatory Pressures**
- FDA approval risk
- Regulatory inspections time consuming
- Compliance costs

**Limited Viral Vector Capacity**
- Shortage of manufacturing capacity limiting output
- Investment required to secure additional capacity

**Limited Alternatives to Viral Vectors**
- Few commercially viable alternatives given technical complexity
- Lack of demonstrated safety / efficacy of alternative technologies

Source: Wall Street Research
...and Remain Elevated Amidst Persistent Capacity Constraints

Innovation Outstrips Manufacturing Capacity
IND Application Filings

Commercial Viral Vector Capacity Highly Concentrated
# of Manufacturers by Stage of Clinical Development

Capacity Constraints and Other Challenges Unlikely to Abate over Near to Medium Term

Source: Wall Street Research
How to Play Across the Cell and Gene Therapy Value Chain

R&D
- Raw Materials
- Plasmid Manufacturing
- Collection, Isolation, Culture
- Transfection
- Harvest

Upstream
- Filtration
- Concentration
- Purification
- Concentration
- Sterile Filtration

Downstream
- Formulation and Fill
- Cryopreservation

Fill / Finish

Life Science Tools / CDMO Players
- ThermoFisher Scientific
- Catalent
- Charles River
- TEKNOVA

Other Bioprocessing Focused Players
- PPD
- BioEnabling Technology Providers

Analytical Tools
- Agilent

Analytical Testing / Development
- BioPharms
- QiAIA

BioEnabling Technology Providers
- Kytopen
- Aventis
- Biocart
- Bionet
- Bionet
- Biopac
- CellFE
- SciLife
- Xcellbio
- 64x Bio

Cell Line Development
- BD
- Merck
- Fujifilm
- Lonza
- ACG Biologics

Cell Culture
- REPLIGEN
- SARTORIUS
- BD
- Biotrace

Harvest and Clarification
- eppendorf
- 3M
- Merck
- Maravai

Purification
- REPLIGEN
- SARTORIUS
- BIO RAD
- SARTORIUS

Formulation
- BD
- Schott
- Aptargroup
- SG Stevanato Group

Fill-Finish
- BD
- Schott
- Aptargroup
- SG Stevanato Group
**Analytical Tools in Viral Vector Manufacturing**

<table>
<thead>
<tr>
<th>Quality Measured</th>
<th>Attributes</th>
<th>Analytical Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Identity</strong></td>
<td>Vector presence and identity</td>
<td>SDS-PAGE, MS, Western Blot, NGS, PCR</td>
</tr>
<tr>
<td><strong>Potency</strong></td>
<td>Physical viral titer</td>
<td>DNA hybridization, real-time PCR, optical density, nanoparticle visualization, HPLC</td>
</tr>
<tr>
<td></td>
<td>Functional viral titer</td>
<td>Plaque-forming assay, IFA, end point dilution assay, flow cytometry</td>
</tr>
<tr>
<td><strong>Purity</strong></td>
<td>Process-related impurities</td>
<td>MS, Chromatography, TEM</td>
</tr>
<tr>
<td></td>
<td>Host cell-related impurities</td>
<td>PicoGreen, DNA threshold assay, qPCR, ELISA, cryo-EM</td>
</tr>
<tr>
<td></td>
<td>Capsid Content</td>
<td>Cryo-EM, AUC</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>Sterility</td>
<td>Standard sterility tests</td>
</tr>
<tr>
<td></td>
<td>Endotoxin</td>
<td>LAL Method, rabbit pyrogen assay</td>
</tr>
<tr>
<td></td>
<td>Mycoplasma</td>
<td>PCR, cell culture-based assays</td>
</tr>
<tr>
<td></td>
<td>Replication content virus</td>
<td>Southern blot, qPCR</td>
</tr>
<tr>
<td></td>
<td>Aventitious agents</td>
<td>In vivo and in vitro assays</td>
</tr>
<tr>
<td><strong>Stability</strong></td>
<td>pH</td>
<td>Potentiometry</td>
</tr>
<tr>
<td></td>
<td>Osmolality</td>
<td>Osmometry</td>
</tr>
<tr>
<td></td>
<td>Aggregate formation</td>
<td>Light microscopy, DLS, SEC-MALS, cryo-EM, AUC, FFF-MALS</td>
</tr>
</tbody>
</table>
Cell and Gene Therapy Tools Provide Mission Critical Support to Innovators Throughout Development Lifecycle

Products
- Cytokines and Growth Factors
- Plasma-Derived Products
- Media and Media Supplements
- Filtration Products

Services
- Protein and Nuclease Development & Manufacturing
- Collection, Isolation & Purification
- Media Development & Manufacturing
- Transfection & Transduction Reagents

Used throughout the Cell and Gene Therapy Workflow

Products and Services Entrenched in Critical Workflow

Revenue Pull Through from Clinical Progression

Customer Spend Increases Exponentially throughout Clinical Development

- IND Enabling: ~$20K+
- Early Clinical: ~$100K+
- Pivotal / Registration Trial: ~$500K+
- Early Commercial: ~$2.5MM+
- Late Commercial: $5MM+

Range of Customer Spend per Program by Phase

Base Customer Spend

Relative Customer Spend by Phase
Key Open Questions, Challenges and Milestones for the Future of Cell and Gene Therapy Manufacturing

**Scaling Bottlenecks**
- Cost of reagents
- GMP plasmid production
- Use of adherent cells vs. suspension cells
- Purification issues and regulatory differences / guidelines across different geographies

**Delivery of Technology and Its Impact on Therapeutic Performance**
- Efficacy / level of gene expression needed to drive functional response
- Durability profile
- Potency, particularly for solid tumors

**Safety Profile**
- Particularly for AAV-based therapies
- Regulatory pathway for new technology generations

**Disease Applicability**
- Gene therapy viability beyond rare diseases
- Role of gene editing

**Education & Training of Human Capital**
- Ability to hire, and associated costs

**Reimbursement Framework**
- Tension between value- / outcome-based framework and underlying manufacturing cost
- Financial complexity / affordability
Biopharma Has Shifted Focus to New Modalities and Technology Platforms, Driving M&A Trends

Deal Volume (>$1Bn) $Bn

2003 – 2009
Significant earnings from small molecule blockbusters creates patent risk

2010 – 2016
Scale viewed as critical for M&A
Strategic shift in focus to Biologics
Limited SMID-cap / development stage opportunities

2017 – 2022
Importance of “science” deals and building platforms / new modalities
Proliferation of SMID-cap biotechs as targets
Transformational deals vs. string of pearls

Source: Refinitiv as of March 2022
The Market Rewards High Growth Expectations in Life Sciences

Notes:
1. Market data as of 4/21/2022
Investors Have Shown Persistent Support for Outsourced Biopharma and Tools Players

De-Risked Pharma Exposure Highly Attractive (1)
Last 5 Year Price Performance

Notes:
1. Market data as of 4/21/2022
2. Large Cap Pharma Index includes: AbbVie, AbbVieZymo, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Eli Lilly, Merck, Pfizer, Novartis and Roche
3. Life Science Tools include: Agilent, Avantor (included at IPO on May 16, 2019), Bio-Rad, Bruker, Danaher, Illumina, Merck KGaA, Mettler Toledo, PerkinElmer, Qiagen, Tecan, Thermo Fisher Scientific and Waters
4. CRO Index includes: CharlesRiver, ICON, IQVIA, Medpace (included after 9/6/2016), PAREXEL (until announced acquisition by Pamplona Capital on 6/20/2017), PPD (included after 2/5/2020), PRA Health Sciences (included after 11/13/2015 and until announced acquisition by ICON on 2/24/2021) and Syneos
5. CDMO Index includes: Avid Bioservices, Cambrex (until announced acquisition by Permira on 8/7/2019), Catalent, Consort Medical (until announced acquisition by Respharm on 11/14/2019), Celsion, Horizon Pharma (included after IPO on 3/3/2016), Lonza, Peloton, placed after research initiation after IPO on 10/28/2016 and until Thermo Fisher Scientific announcement on 5/15/2017), Lonza, Peloton, placed after research initiation after IPO on 10/28/2016 and until Thermo Fisher Scientific announcement on 5/15/2017, Recipharm (until announced acquisition by Permira on 8/7/2019), Thermo Fisher Scientific and Waters
7. Median AV / NTM multiple

Trading Multiples Increasing Over Time (1)(7)
AV / NTM EBITDA

CDMO: +4.4x
CRO: +5.5x
LST: +4.4x
Biologic Enabling: +7.0x

% Δ 2022 YTD:

<table>
<thead>
<tr>
<th>Index</th>
<th>XBI (28%)</th>
<th>Large Cap Pharma</th>
<th>Life Science Tools</th>
<th>CRO (22%)</th>
<th>CDMO (22%)</th>
<th>Biologic Enabling</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>19%</td>
<td>81%</td>
<td>146%</td>
<td>170%</td>
<td>227%</td>
<td>241%</td>
</tr>
</tbody>
</table>

Notes:
1. Median data as of 4/21/2022
2. Large Cap Pharma Index includes: AbbVie, AbbVieZymo, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Eli Lilly, Merck, Pfizer, Novartis and Roche
3. Life Science Tools include: Agilent, Avantor (included at IPO on May 16, 2019), Bio-Rad, Bruker, Danaher, Illumina, Merck KGaA, Mettler Toledo, PerkinElmer, Qiagen, Tecan, Thermo Fisher Scientific and Waters
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7. Median AV / NTM multiple

% Δ 2022 YTD:

<table>
<thead>
<tr>
<th>April 2017</th>
<th>April 2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>CDMO (3)</td>
<td>10.5x</td>
</tr>
<tr>
<td>CRO (4)</td>
<td>11.2x</td>
</tr>
<tr>
<td>LST (3)</td>
<td>15.7x</td>
</tr>
<tr>
<td>Biologic Enabling (6)</td>
<td>18.9x</td>
</tr>
<tr>
<td></td>
<td>14.9x</td>
</tr>
<tr>
<td></td>
<td>16.7x</td>
</tr>
<tr>
<td></td>
<td>20.1x</td>
</tr>
<tr>
<td></td>
<td>25.9x</td>
</tr>
</tbody>
</table>
Valuation Gap to Market Has Widened and Proven Resilient Amidst Recent Pullback

Last 10 Years

AV / NTM EBITDA (1)(2)(3) x

<table>
<thead>
<tr>
<th>Multiples Over Time</th>
<th>Current</th>
<th>1 Yr. Avg.</th>
<th>3 Yr. Avg.</th>
<th>5 Yr. Avg.</th>
<th>10 Yr. Avg.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bio-Enabling</td>
<td>26.7x</td>
<td>35.7x</td>
<td>33.3x</td>
<td>29.0x</td>
<td>22.0x</td>
</tr>
<tr>
<td>S&amp;P</td>
<td>12.6x</td>
<td>13.7x</td>
<td>13.2x</td>
<td>12.2x</td>
<td>10.6x</td>
</tr>
</tbody>
</table>

Source: Capital IQ

Notes:
1. Market data as of 4/21/2022
2. CRO index includes PPD (pre-take private and post-IPO), Covance, Charles River, Medpace, ICON, PAREXEL, Kendle, IQVIA, PRA Health, Syneos / INC Research and Wuxi; Biopharma-Enabling index includes BioTechne, Sartorius and Abcam; CDMO index includes ThermoFisher, Catalent, West, Lonza and Siegfried
3. PPD and PRA included through respective unaffected dates and flattened at pre-announcement multiple thereafter

Synthesis of the previous narrative into a concise summary:

The Valuation Gap to Market has widened and proven resilient amidst recent pullback. The AV / NTM EBITDA multiples over time for the Bio-Enabling and S&P 500 indices are shown, with a focus on the historical data from 2012 to 2022. The table highlights the current and averaged multiples over 1, 3, 5, and 10 years, demonstrating the market's valuation trend over the past decade. The source is Capital IQ, and the notes provide additional context on the data collection and methodology.
### Outsourced Biopharma and Tools Amid Convergence in Business Models

<table>
<thead>
<tr>
<th>Acquiror</th>
<th>Recipharm</th>
<th>CDP</th>
<th>Charles River</th>
<th>Thermo Fisher</th>
<th>Catalent</th>
<th>Thermo Fisher</th>
<th>Thermo Fisher</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CDMO</td>
<td>LST</td>
<td>CRO</td>
<td>LST</td>
<td>CDMO</td>
<td>LST</td>
<td>LST</td>
</tr>
<tr>
<td></td>
<td>Biologics Enabling</td>
<td>Biologics Enabling</td>
<td>Biologics Enabling</td>
<td>CRO</td>
<td>Biologics Enabling</td>
<td>Biologics Enabling</td>
<td>Biologics Enabling</td>
</tr>
<tr>
<td>Size</td>
<td>N/A</td>
<td>$9.6Bn</td>
<td>$1.2Bn (1)</td>
<td>$20.9Bn</td>
<td>$1.2Bn</td>
<td>$1.7Bn</td>
<td>$21.4Bn</td>
</tr>
<tr>
<td>Rationale</td>
<td>Additional exposure to high growth cell and gene therapy / biologics markets</td>
<td>Establishes leading presence in plasmid DNA manufacturing through highly revenue- and cost-synergistic vertical integration</td>
<td>Expands capabilities in high-growth cell and gene therapy sector across development, testing, and manufacturing, from research / discovery through cGMP production</td>
<td>Establishes Thermo Fisher as a global leader in the attractive high growth clinical research service industry</td>
<td>Enhances biologics business and grows presence in gene therapy manufacturing</td>
<td>Access to gene therapy viral vector CDMO market</td>
<td>Best-in-class bioprocessing technologies complements biologics workflow solutions</td>
</tr>
</tbody>
</table>

Note:
1. Reflects aggregate purchase consideration; Vigene and Cognate purchase price of $293MM and $875MM, respectively
Growth Trajectory Remains a Key Driver of Valuation

Acquisition Multiples Have Risen Over Time as Growth Expectations Continue to Increase and Drive High Valuations

- Biologics / CGT Median: 30.0X
- Outsourced Pharma Median: 13.6X
- Life Science Tools & Diagnostics Median: 23.9X

AV / LTM EBITDA (x)
Thank You!

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