Cell & Gene Therapy

CDMO Services

Mike Austin
Corporate Vice President, Cell and Gene Therapy CDMO

There information contained herein principally reflects Cognate BioServices, since Charles River’s planned acquisition of Vigene Biosciences has not yet been completed. Any reference to Vigene contained herein would only be relevant when the transaction closes.
Cognate: A Premier Cell & Gene Therapy CDMO

A leading position in cell therapy manufacturing

~150K sq. ft. in the US, UK & EU with planned expansions to support growth

~$140M Cognate’s annual revenue expected for full-year 2021

~$2.5B Addressable C&GT CDMO sector (primarily cell therapy, plasmid DNA & viral vectors)

>25% Revenue CAGR expected over next 5 years

>2,900 C&GT programs in biopharma R&D pipeline

Cognate: A Premier Cell & Gene Therapy CDMO
Cognate Business Overview

➢ A premier CDMO partner for clients’ comprehensive C&GT development and manufacturing needs

➢ Cognate has solutions across the major CDMO platforms for C&GT
  ▪ Primary area of expertise is CGMP cell therapy manufacturing
  ▪ Also has capabilities in the production of plasmid DNA, viral vectors, and other value-added CDMO inputs

➢ Track record of producing various cell types and technologies used in cellular immunotherapy and immuno-oncology, regenerative medicine, and advanced cell therapy

➢ Talented staff of >500 employees across four locations (Tennessee, Maryland, U.K. and Sweden)
Cognate’s global capabilities include C&GT logistics, regulatory support, and guidance for IND submissions.

Vigene has viral vector and plasmid DNA manufacturing operations in Rockville, MD.

- Cell Therapy Manufacturing (Memphis, TN)
- Plasmid DNA Manufacturing (Keele, UK & Matfors, Sweden)
- Viral Vector Manufacturing (Keele, UK)
- Logistics/Supply Chain Warehouse (Memphis, TN)
- Process Development & Analytical Testing (Hanover, MD)
Cognate’s Gene-Modified Cell Therapy Workflow

Memphis, TN

Keele, UK & Matfors, Sweden

Synergy Opportunity for Cell Supply

Cell Collection/Leukaphoresis

Shipmen

Synergy Opportunity for Analytical Testing

Charles River Biologics Testing Solutions

Vigene Biosciences Excellence in Gene Delivery

Vigene will complement Cognate with U.S.-based vector & pDNA production capabilities
Cognate’s Cell & Gene Therapy CDMO Capabilities

<table>
<thead>
<tr>
<th>Cell Therapy (US)</th>
<th>Gene Therapy (UK/EU)</th>
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<tbody>
<tr>
<td><strong>Memphis, Tennessee &amp; Hanover, MD</strong></td>
<td><strong>Keele, UK</strong></td>
</tr>
<tr>
<td>• CGMP cell therapy manufacturing</td>
<td>• Plasmid DNA &amp; Viral Vectors</td>
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<tr>
<td><strong>Current capacity:</strong></td>
<td><strong>Current Capabilities:</strong></td>
</tr>
<tr>
<td>• &gt;10 years of CGMP cell therapy production in Memphis</td>
<td>• 20-year track record in gene therapy</td>
</tr>
<tr>
<td>• GMP cell therapy operations in 22 suites for US/EU standards</td>
<td>• High-Quality Plasmid DNA &amp; 50L CGMP Plasmid DNA</td>
</tr>
<tr>
<td><strong>Future expansion:</strong></td>
<td>• Viral Vector Process Development &amp; GMP Production</td>
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<tr>
<td>• 9 additional suites by end of 2022</td>
<td><strong>Future Expansion:</strong></td>
</tr>
<tr>
<td><strong>Other capabilities:</strong> Process development, analytical testing, and logistics/supply chain capabilities</td>
<td>• Commercial DNA &amp; viral vector supply</td>
</tr>
<tr>
<td>• Commercial-ready cell and gene therapy production capacity available</td>
<td><strong>Future Expansion:</strong></td>
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<td></td>
<td>• New 50L/300L GMP DNA suite</td>
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Vigene’s Gene Therapy CDMO Capabilities

Gene Therapy (US)

Rockville, MD

• Viral Vector & Plasmid DNA

• Current capacity:
  • ~110K sq. ft. state-of-the-art facility
  • 15 GMP cleanroom suites

• Current Capabilities:
  • 10-year track record in gene therapy
  • Major viral vectors being used for gene delivery (AAV, adenovirus, lentivirus, and retrovirus)
  • High-Quality and CGMP Plasmid DNA
  • Viral Vector Process Development & GMP Production
Cell Therapy Manufacturing Capabilities

- Extensive capabilities for scientifically complex, cell therapy development and manufacturing solutions
  - CGMP manufacturing expertise across multiple cell types
  - From clinical phases to commercial-ready production
- Cell therapies are personalized medicines produced in small batches/scales with customization based on client requirements
  - Highly flexible blank slate production suites that are agnostic to equipment manufacturers
    - Accommodates a variety of client processes
  - Process scale from shake flask (<1L each) to 200L bioreactor systems
    - Near-term expansion with flexible suites to accommodate allogeneic and large autologous client programs
  - Aligned with QA/QC for critical analytics and review
Gene Therapy Manufacturing Capabilities

- Gene therapy capabilities to support clients with the production of gene therapies and gene-modified cell therapies from preclinical to commercial-ready scale
  - Cognate’s primary focus area is plasmid DNA manufacturing
  - Also produce other value-added CDMO inputs from viral vectors to technical proteins

- Cognate’s plasmid DNA offering includes:
  - Scalable production platform from high quality to 50L commercial-ready scale
    - Near-term expansion to 300L commercial-ready scale
  - Aligned with analytical testing platform for critical quality control (QC) protocols

### Cognate pDNA Mfg.

<table>
<thead>
<tr>
<th>High Quality</th>
<th>PD / Preclinical</th>
<th>Clinical</th>
<th>Commercial</th>
<th>Commercial</th>
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</thead>
<tbody>
<tr>
<td>Shake Flask</td>
<td>5L (STR)</td>
<td>50L (STR)</td>
<td>50L (XDR)</td>
<td>300L (Future expansion)</td>
</tr>
<tr>
<td>15L (SUB)</td>
<td>15L (STR)</td>
<td>50L (STR)</td>
<td>50L (XDR)</td>
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Keele, UK & Matfors, Sweden

Matfors, Sweden
Cell & Gene Therapy CDMO Capabilities

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<td>Cognate Production Suite</td>
<td>Cognate 200L Bioreactor Production</td>
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<td>Memphis, Tennessee</td>
<td>Keele, UK</td>
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Cell Therapy (US)
Cognate Production Suite
Memphis, Tennessee

Gene Therapy (UK/EU)
Cognate 200L Bioreactor Production
Keele, UK
Charles River + Cognate: Strategic Fit

- Cognate has solutions across the major C&GT CDMO platforms
  - Intend to continue to add capabilities and capacity to accommodate robust client demand
- Cognate is highly complementary to CRL’s existing, non-clinical capabilities
- Cognate’s strategic fit with CRL’s Biologics business enables clients to be able to seamlessly conduct analytical testing, process development, and manufacturing for advanced modalities with the same scientific partner
  - Enables clients to achieve their goals of driving greater efficiency and accelerating speed to market
- Cellular products from HemaCare and Cellero (also in Memphis) can be the starting point for clients’ cell therapy programs