

Cell & Gene Therapy CDMO Services

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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

>25%

Revenue CAGR
expected over
next 5 years



~\$2.5B

Addressable
C>
CDMO sector
(primarily cell therapy,
plasmid DNA &
viral vectors)

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

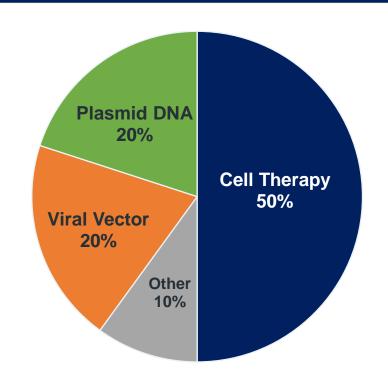


Cognate Business Overview



- ➤ A premier CDMO partner for clients' comprehensive C> development and manufacturing needs
- Cognate has solutions across the major CDMO platforms for C>
 - 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 Revenue Mix by Service Area (2021E)





Cognate's Global Capabilities

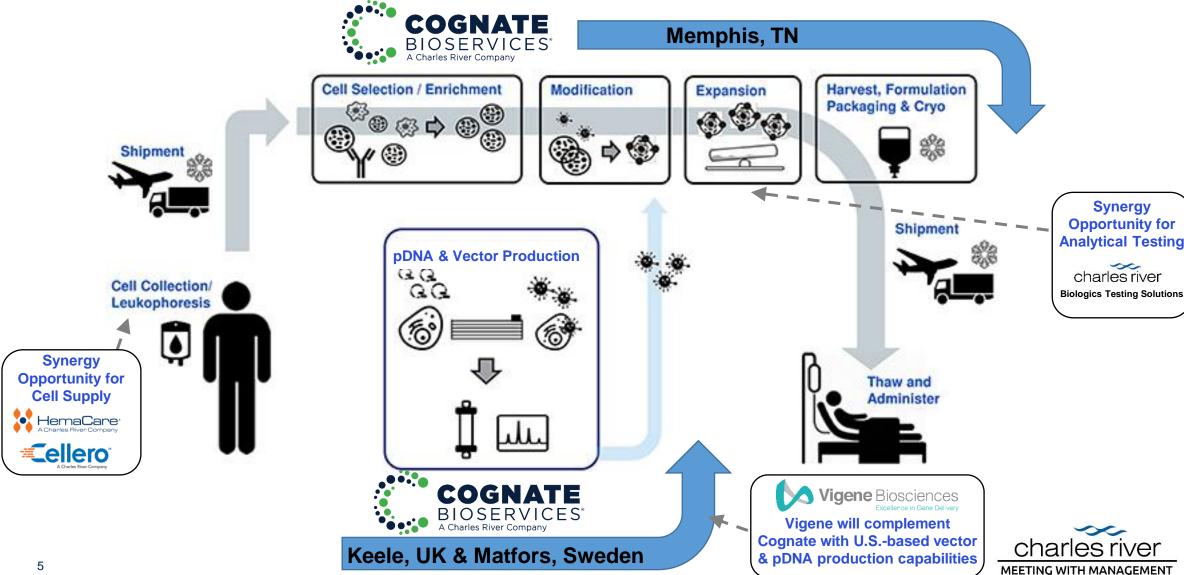
Cognate's global capabilities include C> logistics, regulatory support, and guidance for IND submissions



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



Cognate's Gene-Modified Cell Therapy Workflow



Cognate's Cell & Gene Therapy CDMO Capabilities

Cell Therapy (US)

Gene Therapy (UK/EU)

Memphis, Tennessee & Hanover, MD

- CGMP cell therapy manufacturing
- Current capacity:
 - >10 years of CGMP cell therapy production in Memphis
 - GMP cell therapy operations in 22 suites for US/EU standards
- Future expansion:
 - 9 additional suites by end of 2022
- Other capabilities: Process development, analytical testing, and logistics/supply chain capabilities
- Commercial-ready cell and gene therapy production capacity available

Keele, UK

- Plasmid DNA & Viral Vectors
- Current Capabilities:
 - 20-year track record in gene therapy
 - High-Quality Plasmid DNA
 50L CGMP Plasmid DNA
 - Viral Vector Process
 Development & GMP Production
- Future Expansion:
 - Commercial DNA & viral vector supply

Matfors, Sweden

- Plasmid DNA & Other CDMO Inputs
- Current Capabilities:
 - 20-year track record for clinical/commercial GMP
 - · High-Quality Plasmid DNA
 - Microbiota Process
 Development & GMP 500L
 - Technical proteins
 - Fill/Finish
- Future Expansion:
 - New 50L/300L GMP DNA suite







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



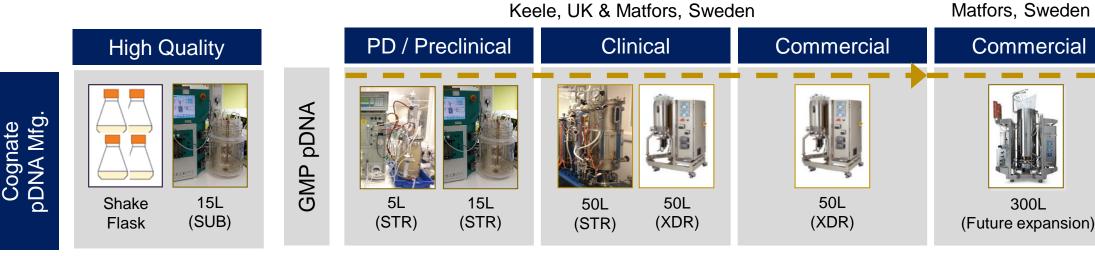
CGMP CELL THERAPY MANUFACTURING:

- MILs
- Dendritic Cells (DC's)
- Natural Killer (NK) Cells
- T-Cells
- Car-T
- BMSC's

- MSC's
- Whole Blood
- Apheresis
- Leukapheresis
- Tumor Isolate
- Stem cells (variety)

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
 - o Near-term expansion to 300L commercial-ready scale
 - Aligned with analytical testing platform for critical quality control (QC) protocols





300L

Cell & Gene Therapy CDMO Capabilities

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> 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

CRL + Cognate: A premier scientific partner for C> development, testing, and manufacturing

