

Cambridge Major Laboratories

Strong Growth; Innovative Manufacturing Business

“CML is a Global Leader in Drug Development and Manufacturing, Providing Advanced Chemistry Services to the Pharmaceutical and Biotechnology Industries”

Company Snapshot

3 facilities in US and Europe

- Small-scale to multi-ton drug manufacture
- >20% revenue growth rate since inception
 - Fastest growing pharma manufacturer in the western world
 - 2010 sales growth near 20%
- Quadruple number of employees since 2005
 - 180 employees (50% of chemists hold a Ph.D.)
- 30x increase in square footage - past 5 years
- Company has consistently outperformed the market.
- Company's investment strategy is focused on investment in Western (US/Europe) based assets

Overview

- ◆ Cambridge Major is a R&D and manufacturing partner to pharmaceutical and biotechnology companies, producing Active Pharmaceutical Ingredients (“API’s”).
- ◆ Founded 1999 from merger of two companies with combined thirty years experience. The company has averaged >20% growth per year since inception.
- ◆ Recent expansion in Germantown brings the company’s total Wisconsin footprint to almost 300,000 sq ft of state-of-the-art R&D and manufacturing space. The company’s new facility is THE premier Pharmaceutical Manufacturing site in North America.
- ◆ The company has a dynamic and aggressive approach setting it apart from its competition. 50% of the company’s scientists hold a Ph.D. in chemistry making it’s capabilities unparalleled in the industry.

Recent Milestones

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- Sept 1999: Company founded
 - 2007
 - FDA Inspections
 - Acquisition of facility in Weert, Netherlands.
 - 2008: Multi-million dollar investments in the US and Europe:
 - Additional plant and labs in Weert, The Netherlands, facility
 - Commence construction of large scale facility in Wisconsin
 - Winner of Frost and Sullivan North American Fine Chemical Company of the Year
 - 2009
 - Opened New \$40MM Large-Scale Manufacturing Facility in Wisconsin
 - FDA Inspections
 - Certified Compliant with ChemStewards® Program for EHS&S
 - 2010
 - Large Scale Manufacturing underway and currently the largest growing segment at CML
 - Commercial Manufacture of Cardiovascular and Anti-cancer API's
 - Introduced Chemistry Playbook® in the US and Drug Development Cluster in Europe
 - 2011
 - Announced Solid State Chemistry center of excellence at CML-Europe
 - Flow chemistry at CML-Europe
 - Supporting 3-4 commercial launches in CML's Wisconsin assets

Employees

Job Type	Employees
Manufacturing	35
Research and Development, 50% Ph.D.	90
Regulatory/Quality Control/Quality Assurance	32
SG&A	18
Total	180

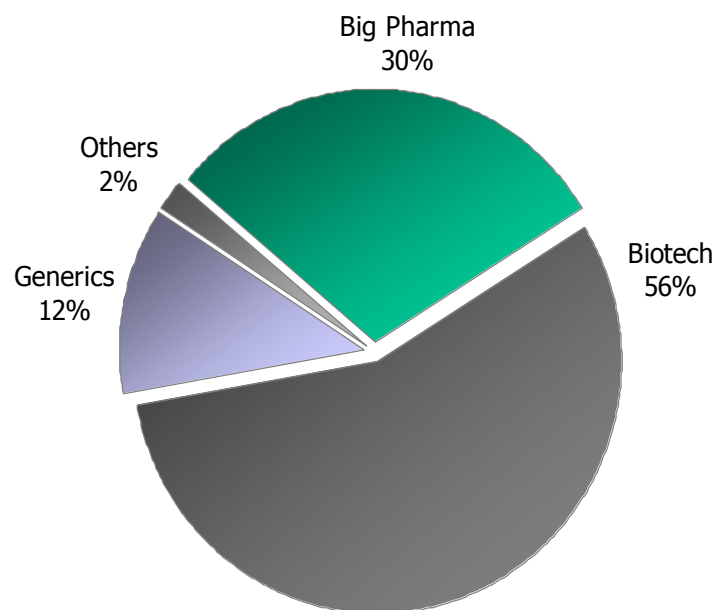
Company Revenue Mix

*“Mutual fund” approach to customer
Diversity brings added stability*

2010 Business at a Glance

- ◆ >110 total customers
- ◆ ~ 400 new drugs developed or manufactured
- ◆ Active and growing Generic Drug manufacturing business

Percentage of 2010 Revenues



*2 Facilities in Southeastern Wisconsin;
1 Facility in Europe*

Washington Dr; Germantown WI



Grant Dr; Germantown, WI



Weert, Netherlands



Network of facilities designed for small scale to large scale manufacture of pharmaceuticals



CML-Washington Dr. USA; grams to 100's kg's



*CML-Weert, Netherlands
Grams to 10's of kg's*



CML-Grant Dr. USA; 100's kg's to ton scale

*CML has successfully
performed multiple internal
technical transfers
(US/Europe)*

Chemical Development Powerhouse

- >150,000 sq. ft. of laboratory and pilot plant space
- 14 cGMP kilo laboratory suites (>50 hoods)
- >40 hoods in R&D laboratories
- 50% of scientists hold a Ph.D.
- 34 reactors ranging from 50 gallon to 500 gallon
 - Glass lined, stainless, cryogenic (-100C), hydrogenation
- State of the art analytical capabilities
 - HPLC(>50), LC-MS, GC-MS, headspace, ICP, NMR, DSC, TGA, XRPD
 - ICH Stability
- Computer-assisted Design of Experiments (*Design Expert*™)
- Complete Hazard Evaluation (*Thermal Hazard* unit, TGA, DSC)

Among the largest chemical development capabilities in North America!

New Large-Scale Manufacturing Facility

- ◆ New facility Dedicated July 2009
- ◆ Large scale drug manufacture
- ◆ Fulfills the need for high quality US-based large scale Manufacturing
- ◆ Extension of CML's growing late-stage clinical drug business
- ◆ Largest growing segment of CML's business; in 2010 the facility generates >20% of CML's revenues after only 1 full year in operation!



Western “Value” Proposition

- Average cost of from development candidate nomination through end of Phase I clinical trial - \$15 million
- Average cost of active pharmaceutical ingredient – \$0.5 million
- % of API cost compared to overall program cost: 3.33%
- Average “cost” saving by using non-Western providers: 1% of total development cost
- Cost of missing Program milestones driven by missed API delivery date: “priceless”
- Focus on “Value” vs. “Cost”

Snapshot of a US-based emerging pharma company

- Fewer than 40 persons
- Totally virtual business model (all outsourced)
- <\$50MM in available cash
- *1-2 compounds drive 90+% of company valuation*
- Off-shoring development/manufacture of such compounds is too risky
- Big pharma deals with emerging pharma companies are at unprecedented levels
 - Big pharma is pouring \$ billions into emerging pharma for new compounds.
 - Big pharma valuations of emerging pharma are based, in part, on the quality of development/manufacturing data
 - Emerging pharma risks millions in valuation by off-shoring to regions with questionable quality standards.



CML is a well-positioned partner to the US emerging pharma/biotech sector

Service Offering Also Includes Early Development Chemistry

Provide early stage synthetic chemistry services to advance drug discovery programs from lead optimization to development candidate nomination.

“Portfolio Value Creation” by providing cost efficient, speedy and high quality synthesis of

- Building blocks
- API's for early toxicology/ADME and PK/PD studies
- Metabolites
- Impurities
- Reference compounds
- Limited SAR compound sets

Why Choose CML?

- *Industry Leading Expertise*
 - *Market Leader Process Development services leading to customer confidence for GMP manufacturing up to Metric Ton scale.*
 - *Defined programs that de-risk and accelerate drug development*
 - *Proven history of innovation and value creation*
- *Responsiveness*
 - *We leverage size to our advantage providing personalized attention*
 - *Dedicated project management, direct access to technical staff*
 - *Multiple Flexible Business models*
 - *Unique project team structure feels like an extension of client facility*
- *Quality-First Focus*
 - *Six successful FDA audits since 2001, PAI and General.*
 - *Low staff turnover*

*Shorten the time to value inflection points and milestones
by taking CMC issues off of the critical path*

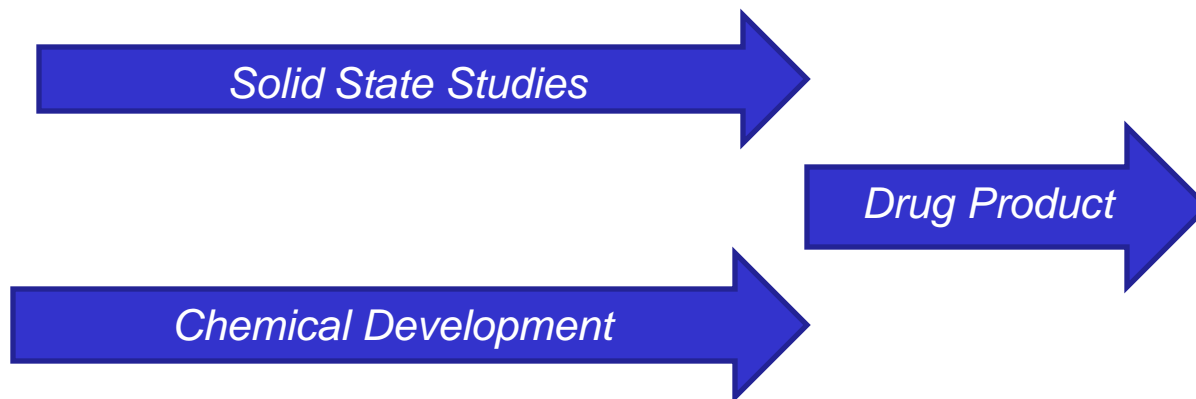
New Solid State Chemistry Capability

CAMBRIDGE MAJOR
LABORATORIES **INC.**
CHEMISTRY THAT WORKS®



CML's Solid State Studies

The CMLE solid state team are crystallization experts: by applying their experience, supported by state of the art tools, we de-risk the choice of physical form to take into development. By integrating solid state studies with the chemical development process, results are available quicker and at less cost.



This is not a high-throughput data driven approach: it considers the physical properties of the compound, the production environment and the intended delivery & likely to provide enough information to facilitate a rapid decision regarding the appropriate form to develop.

Capabilities

- *Material characterization*
- *Solubility and stability study*
- *Temperature dependent solubility / meta-stable zone width determination*
- *Salt formation screen*
- *Co-crystal screen*
- *Polymorph screen*
- *Scale-up of selected form to gram scale*
- *Stability study (hygroscopicity / temperature / competitive slurry / hydrate formation)*

...and an experienced team headed by crystallization expert Dr Edwin Aret. Provides guidance/optimization ahead of plant scale manufacture.

Equipment

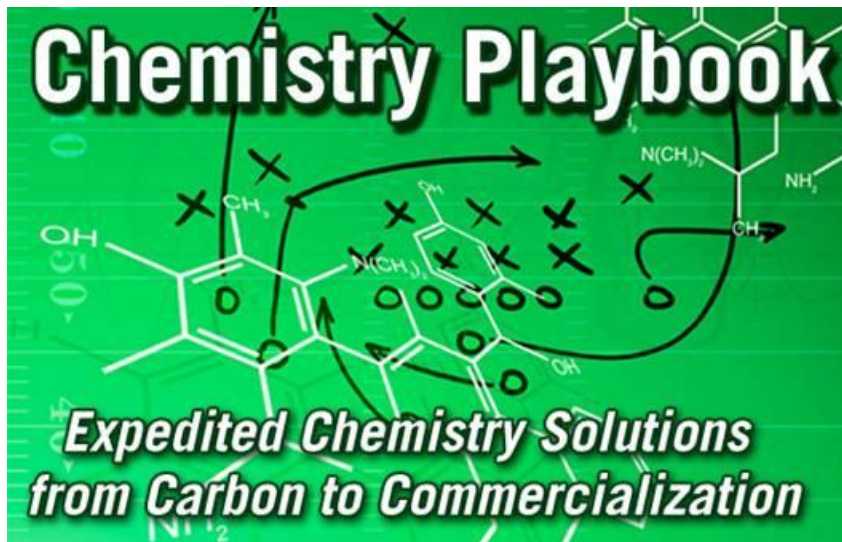
- Crystal 16 (R)
- Symyx Crystallization platform
- Radley's parallel crystallizers
- Mettler Toledo *LabMax*
- XRPD (characterization / peak list)
- DSC
- Particle size
- Melting point
- TGA
- KF
- HPLC (purity and solubility)
- ¹H-NMR
- FT-IR
- Optical microscopy
- DVS
- SEM
- Dissolution rate



Initial Screening - Technical Approach

Task	Weeks -->								
	1	2	3	4	5	6	7	8	9
Physicochemical Characterisation of the API	Light Blue								
Solubility of the API		Light Blue							
Salt Screen			Blue	Blue	Blue				
Polymorph Screen						Dark Blue	Dark Blue	Dark Blue	Dark Blue

Innovative Business Partnerships fuel further growth



- Chemistry Playbook™ is a Drug Development and Manufacturing Partnership Spearheaded by Cambridge Major
- Provides full spectrum services to the Pharma and Biotech industries through a “Virtual One-Stop-Shop” approach comprised of a series of companies performing complimentary services.
- Innovative, first-of-its-kind, business model
- Integrated project management and quality systems between Chemistry Playbook partners ensures seamless approach.