




– Kineticos Case Study –  
Diligence Support and Strategy for Global CDMO

# Diligence Support and Strategy for Global CDMO

 **Challenge:** A global CDMO was considering the purchase of a mid-size contract development and manufacturing services company. The client was interested in learning more about the market, key competitors, customer opinion, and ultimately whether to acquire the target company. Thus, Kineticos was tasked to conduct a due diligence engagement of the potential acquisition.

 **Solution:** The first step of the project was to meet with the target company's management team. After the meeting, Kineticos began the data collection process. Kineticos evaluated the following:

- Evaluation of total and addressable market for the target company by geography
- Identification of key market risks and opportunities
- Analysis of top 5 competitors and their strengths, weaknesses and differentiators
- Primary research from industry Key Opinion Leaders, with many KOLs having direct experience with the target company
- Analysis of target company's financials compared to available comparisons.

 **Outcome:** After gathering both primary research and secondary research, in addition to reviewing the target company's financials and meeting the management team, Kineticos ultimately recommended against acquiring the company.

# Diligence Support and Strategy for Global CDMO

## The Current Situation...

- At a minimum, there are 6 strategic and 3 PE firms still in the running for Alta including [REDACTED]
- At [REDACTED] w [REDACTED]
- Process has w [REDACTED] transaction (C [REDACTED])
- The floor for a transaction valuation appears to [REDACTED] actively evaluating although Cambrex is hesitan [REDACTED]
- All active strategic bidders could recognize significant synergy cost savings

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## The CDMO market offers attractive fundamentals

Biologics present best opportunities now and foreseeable future

- The global CDMO market is estimated at \$76.6B with an expected growth rate between 6-10%
- The US is the largest global market with 40% share
- Oral solids comprises 54% of the clinical CDMO market with a slightly lower growth rate of 4-7%
- Biologics offer the fastest growth opportunity with 8-12% growth
- Biologics are expected to be the largest segment of the clinical CDMO market in the next 3-5 years
- The Oncology market, primarily biologics, comprises 40% of the clinical CDMO market by therapeutic area

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## Changes in the biopharma industry are leading to tectonic shifts in the CDMO (and CRO) industries

- The current CDMO and API manufacturing markets are extremely fragmented with over 1000 market participants
- The top five players generate approximately 15% of industry revenues
- Due to generic scrips, the oral solids CDMO and API markets are highly competitive
- Increasing consolidation in the CMO/CDMO sector: global providers and specialty service providers are the target of acquisition efforts to gain market share
- CDMO publicly announced M&A deals increased by approximately 12% per year from 2012-16
- There is a need for specialized development and manufacturing capabilities to keep up with innovation especially in biologics

CDMO Trends

[No Title]

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## Still, the biopharma industry is challenged in fundamental ways

- Cost for developing an approved drug is greater than \$1.5b and rising
- There is significant political pressure on drug pricing globally
- Market access is one the biggest challenges for the pharma industry
- Immuno-oncology has become particularly crowded with 2000+ active trials
- Neurosciences, particularly Alzheimers, has been a difficult target
- Loss of patent exclusivity of blockbuster drugs will continue to trigger strong generic competition increasing pressure on manufacturing margins
- 87% of all scrips in the US are for generic drugs
- More than 50% of all clinical trials do not recruit enough patients
- More than 50% of all clinical trials do not start on time, causing expensive delays

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# Diligence Support and Strategy for Global CDMO

## Unprecedented innovation in biopharma leading to significant opportunities for service organizations

- NCE/NME drug approvals for the last two years have exceeded 50 approvals, all time industry highs
- The greatest innovation in pharmaceutical R&D is occurring in
  - Gene/cell therapy: Treatment that involves modifying a person’s genes to treat or cure disease
  - Gene editing: Group of technologies that give scientists the ability to change DNA. These technologies allow genetic material to be added, removed, or altered at particular locations in the genome. Recent example is CRISPR-Cas9
  - CAR-T: Treatment in which a patient’s T cells are altered so they will attack cancer cells
  - Immuno-Oncology: Using drugs that target the body’s immune system to help fight cancer
  - Precision medicine: Approach for disease treatment that takes into account individual variability in genes, environment, and lifestyle for each person
  - Autologous manufacturing: Manufacturing therapies as a single lot from the patient being treated
- The rise of specialty pharma, but have only 3% of capital, is

Biopharma Trends

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## VOC suggests that REDACTED service offerings are middle

Validated with KOL interviews

### Sterile Manufacturing Services

Company	Rank
REDACTED	1
REDACTED	2
REDACTED	3
REDACTED	4
REDACTED	5
REDACTED	6
REDACTED	7

### Oral Solids and Finished Dose Manufacturing Services

Company	Rank
REDACTED	1
REDACTED	2
REDACTED	3
REDACTED	4
REDACTED	5
REDACTED	6
REDACTED	7
REDACTED	8
REDACTED	9
REDACTED	10

### Packaging

Company	Rank
REDACTED	1
REDACTED	2
REDACTED	3
REDACTED	4
REDACTED	5
REDACTED	6
REDACTED	7

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### Analytical Laboratory

Company	Rank
REDACTED	1
REDACTED	2
REDACTED	3
REDACTED	4
REDACTED	5

### API Manufacturing

Company	Rank
REDACTED	1
REDACTED	2
REDACTED	3
REDACTED	4
REDACTED	5
REDACTED	6
REDACTED	7
REDACTED	8

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## VOC suggests that REDACTED reputation is middle to lower tier

Validated with KOL interviews

Customer Choice

Factor	Importance	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED	REDACTED
Overall Score	N/A	5th	4th	3rd	1st	7th	10th	9th	6th	2nd	8th
Favorable Regulatory Track Record	1st	2nd	6th	4th	5th	1st	10th	8th	7th	3rd	9th
Overall Reputation	2nd	2nd	3rd	7th	4th	5th	9th	8th	6th	1st	10th
Fair Project Costs	3rd	1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th
Technical Expertise	4th	4th	5th	1st	2nd	6th	10th	7th	8th	3rd	9th
Timeliness of Delivery	5th	1st	3rd	6th	2nd	7th	10th	9th	5th	4th	8th
Available Capacity	6th	8th	6th	5th	2nd	4th	10th	9th	7th	1st	3rd
Right 1st Time Metrics	7th	10th	4th	1st	3rd	7th	9th	8th	6th	2nd	5th
Flexibility to adjust schedule	8th	7th	3rd	4th	1st	10th	8th	9th	2nd	5th	6th

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g; valuations appear to be

decreasing after initial diligence

- **Size & Growth:** The CDMO market offers attractive characteristics, particularly biologics
- **Biopharma Industry:** There is unprecedented innovation especially in oncology & immunology
- **CDMO Industry:** Biopharma changes are causing tectonic changes for CDMO competitors
- **Customers:** Customers appear to value transactional relationships with CDMO vendors
- **Competitors:** The CDMO market is highly fragmented and competitive with 1000+ participants
- **Operations:** SG&A expenses
- **Financials:** Baseline earnings power appears to be about mid \$30 million in EBITDA; revenue, earnings and capital expenditure forecasts are at significant risk
- Strategic risk increasing strategic possibilities for CDMO with the exception of the API business

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