

Contract Services Make a Comeback

Jim Miller

PharmSource-Pharmaceutical Technology Breakfast

November 15, 2010

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Overview

Agenda

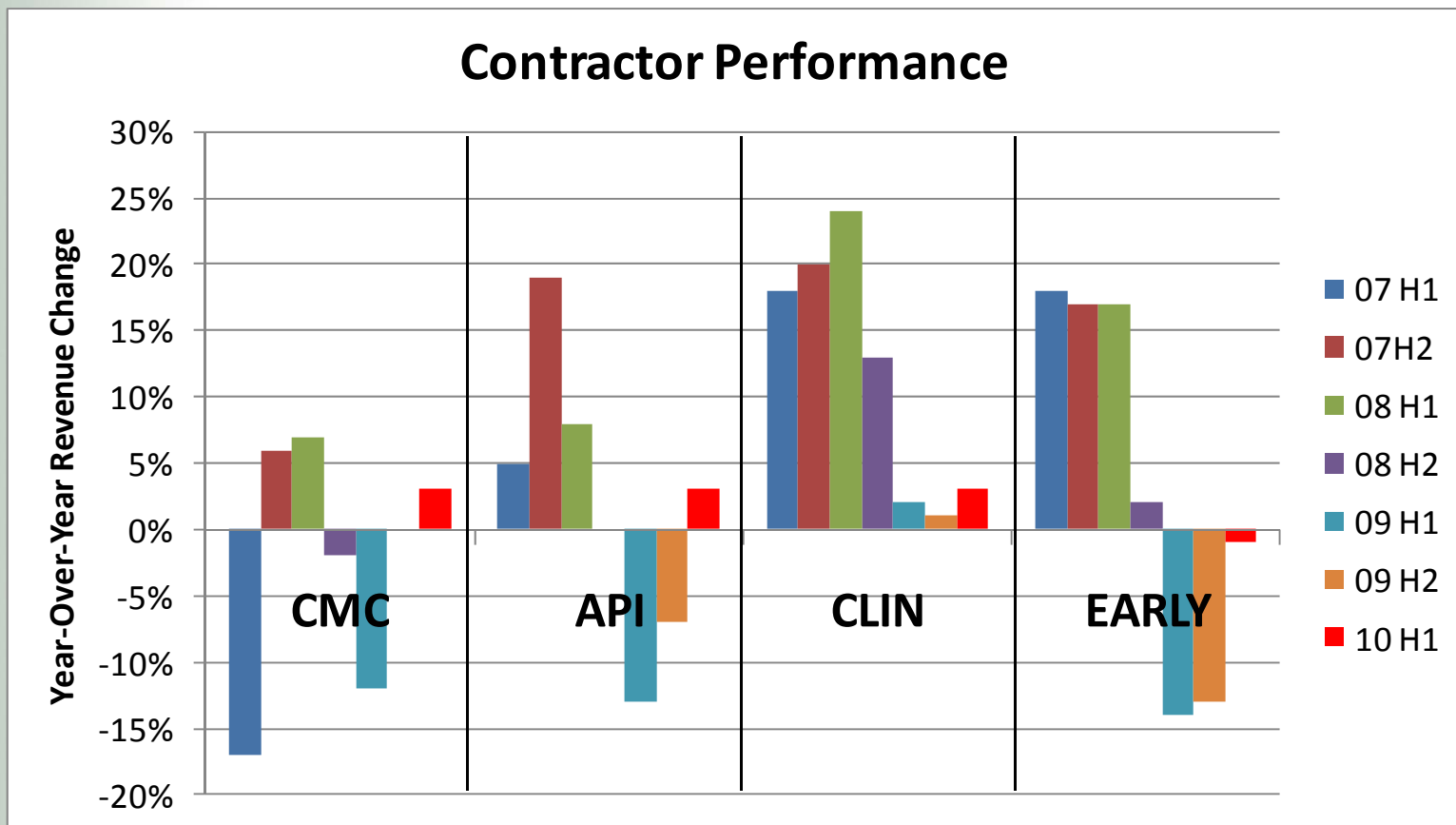
- Industry performance
- Performance drivers
- Industry consolidation
- Final thoughts

Key points

- Gradual but choppy improvement in business
- Supply base consolidation under way
- Industry becoming more intensely competitive

Industry performance

Some recovery, but early development lags



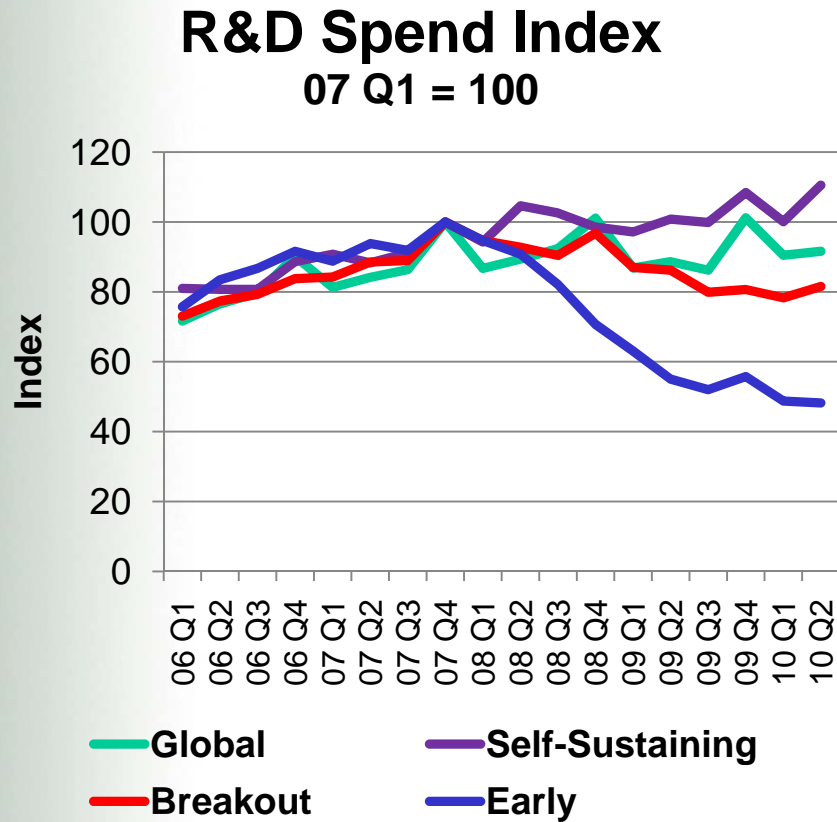
Industry performance

Early development – Early Warning?

- Too much capacity
 - Pharma in-house & CRO
 - Pharma keeps work in
 - Prices down \leq 30%
 - Clients delaying high value studies
 - 20% fewer compounds entering development
- “Pig in the python”
 - Fewer preclinical compounds means less CTM and approvals
 - Facility closings and layoffs presage similar CMC challenges

Performance drivers

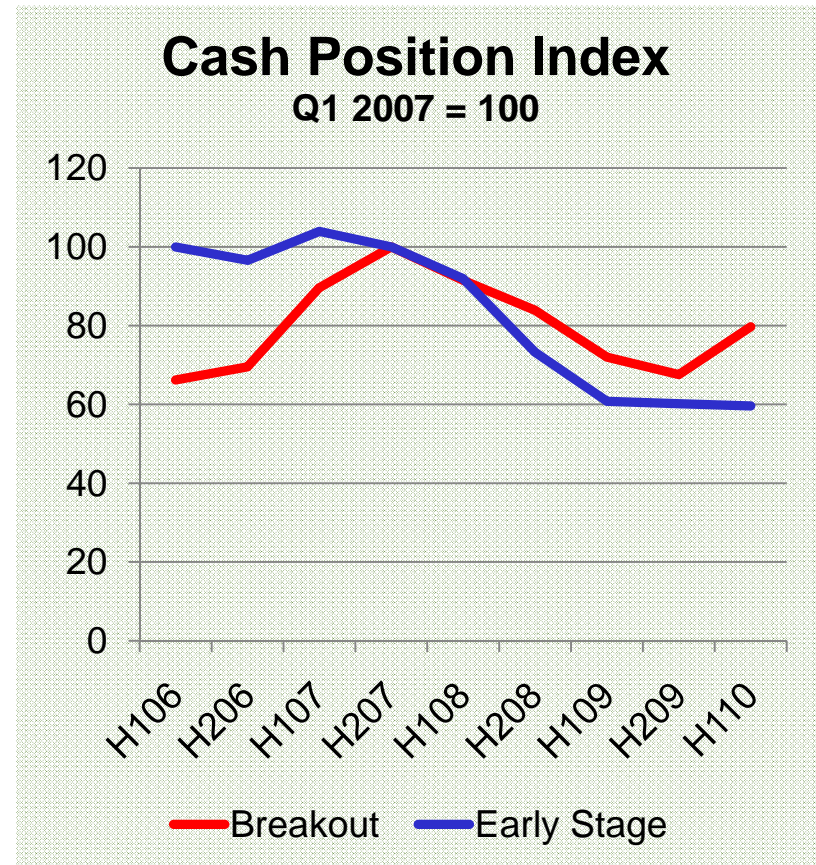
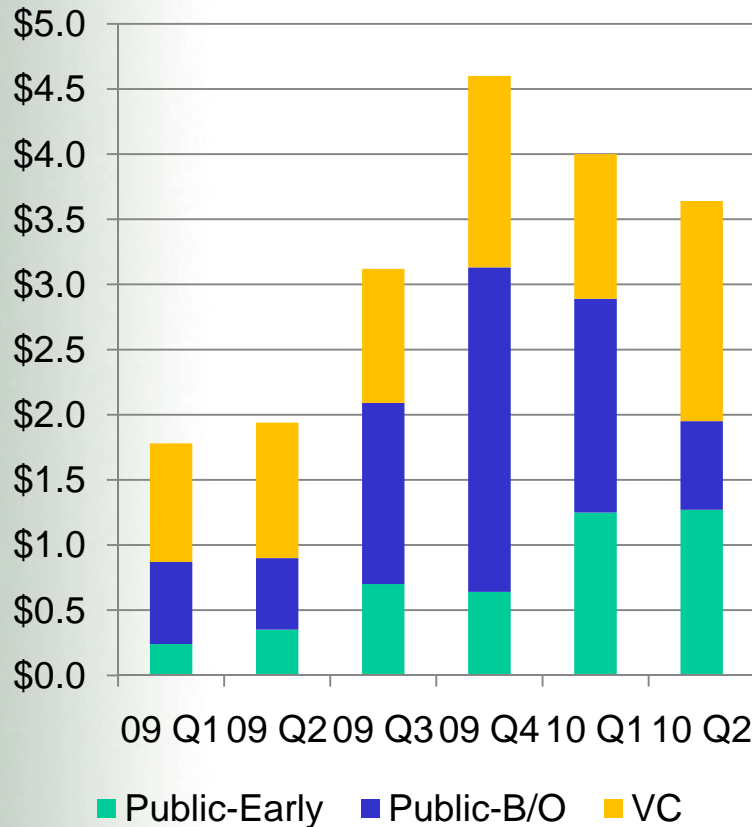
R&D spending is flat



- External finance-dependent companies not recovering
 - Breakout
 - Early
- Global pharma better
 - Suspect less goes to products vs. partners
 - More outsourced
- Note: Q4 spend bumps due to stock option/bonus expense

Performance drivers

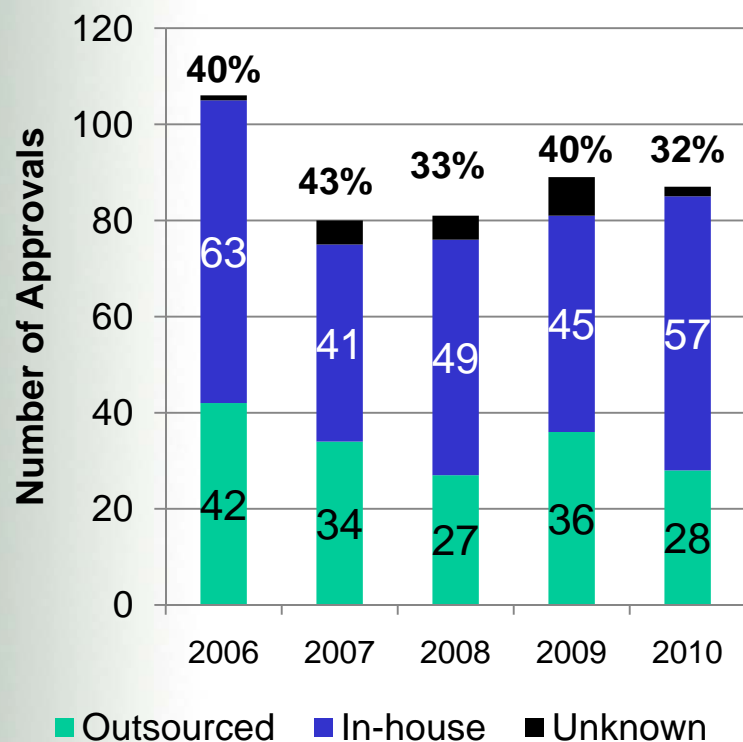
New funding directed toward late stage



Performance drivers

Low NME approvals hurt CMO industry

NDA Approvals by FDA



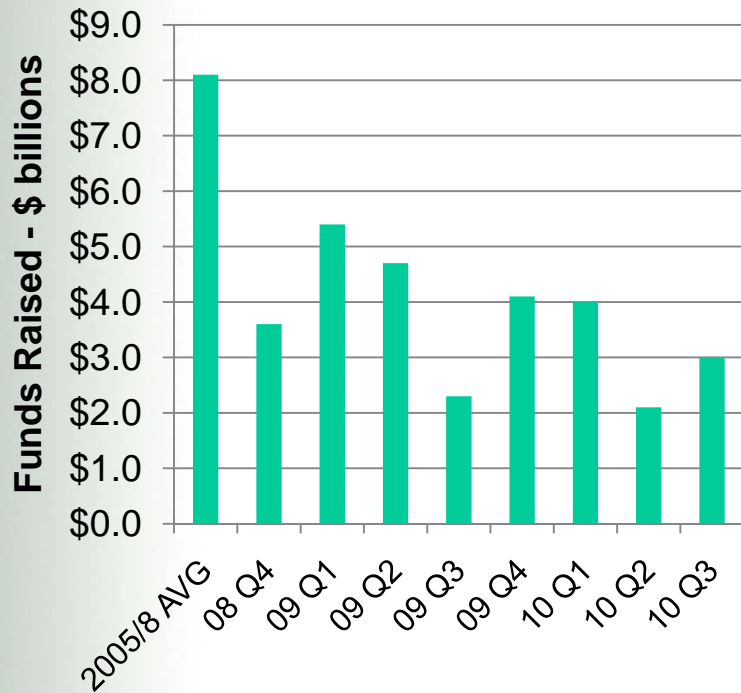
- High % of older APIs among 2010 approvals
 - Generics companies manufacture in-house
- High safety and efficacy barriers for NME approvals

•% above bar is % of approvals outsourced.
•Source: FDA data, PharmSource analysis

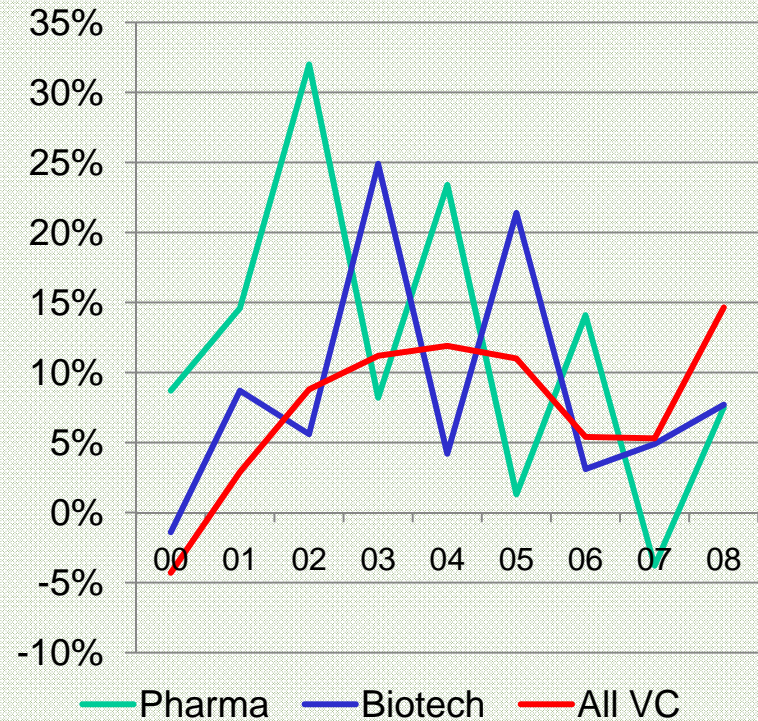
Performance drivers

Poor returns threaten VC availability

VC Fundraising Quarterly



Returns on VC Investment

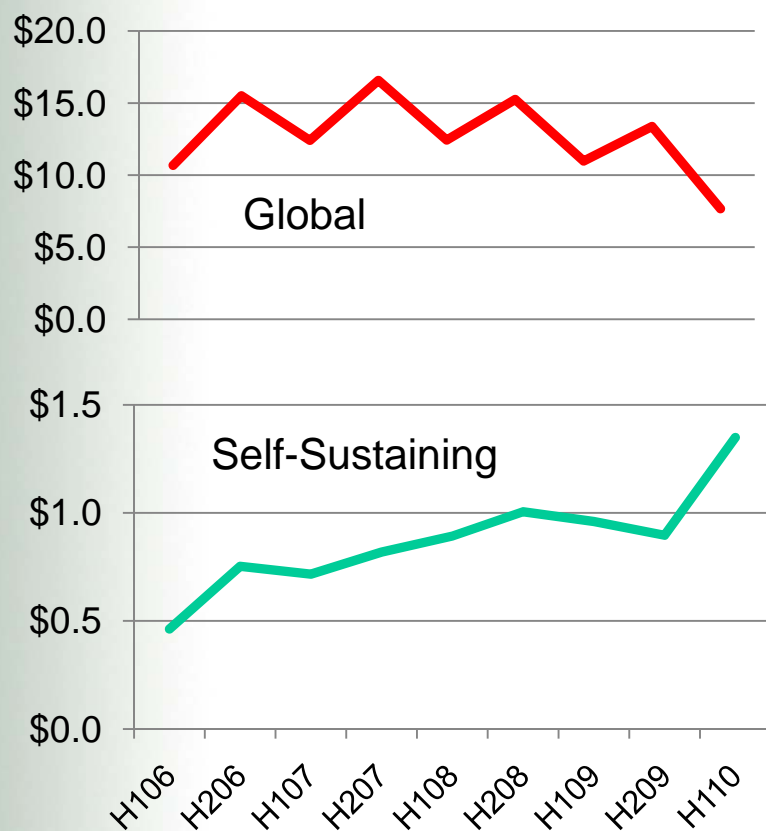


Source: National Venture Capital Association, Cambridge Associates

Performance drivers

Global pharma capex declining

Capital Expenditures



- Global pharma capex decline suggests more outsourcing in future
 - PharmSource analysis indicates more outsourcing of small molecules
- Mid-size companies more willing to invest

Performance drivers

Factors affecting future outlook

Positive factors

- General economic recovery
- Positive industry growth
- Exchange rates
- Global pharma investments in early stage companies
- Global pharma commitment to outsourcing

Negative factors

- Restructuring of pharma pipelines
- Difficult approval environment
- Government spend cutbacks in EU and US
- Reduced availability of VC finance

Supply base consolidation is major trend

“We want to work with a smaller number of suppliers”

Richard Spoor, SVP Global Procurement, Merck & Co.,
DCAT Sourcing Summit, November 3, 2010

Perceived benefits of reduced supply base

- Improved pricing
- Better governance
- Tighter integration
- Continuous improvement and innovation
- Reduced sourcing and oversight OH expense

Industry consolidation

Clinical research initial focus of consolidation

Pharma	CRO	Service
sanofi	Covance	P1-P4, lab, preclin
Lilly	Covance	P1-P4, lab, preclin
Lilly	Quintiles	Site mgmt-Americas
Lilly	Icon	Site mgmt - Europe
Lilly	Icon	Data mgmt – Europe
Lilly	i3	Data mgmt - US
Lilly	Parexel	Site mgmt - Asia
GSK	Parexel	Multiple CR services
GSK	PPD	Multiple CR services
BMS	Icon	Multiple CR services
BMS	Parexel	Multiple CR services
Eisai	PPD	Multiple CR services
Otsuka	Covance	Multiple CR services

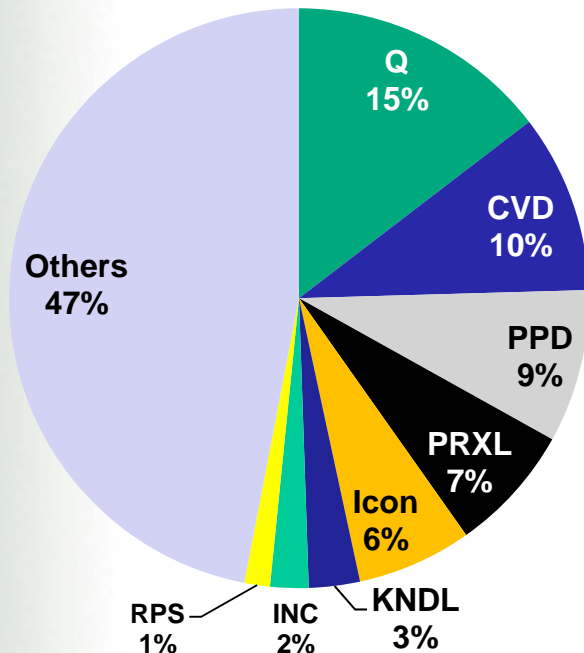
■ Why focus on clinical?

- Few hard assets; mostly staff
- Fluctuations in resource demand
- In-house inefficiency/poor operating skills
- Globalization of trials
- Need for IT skills
- Longer history of outsourcing and CRO relationships

Industry consolidation

CRO industry is consolidating

CRO Market Share
\$14 B Market



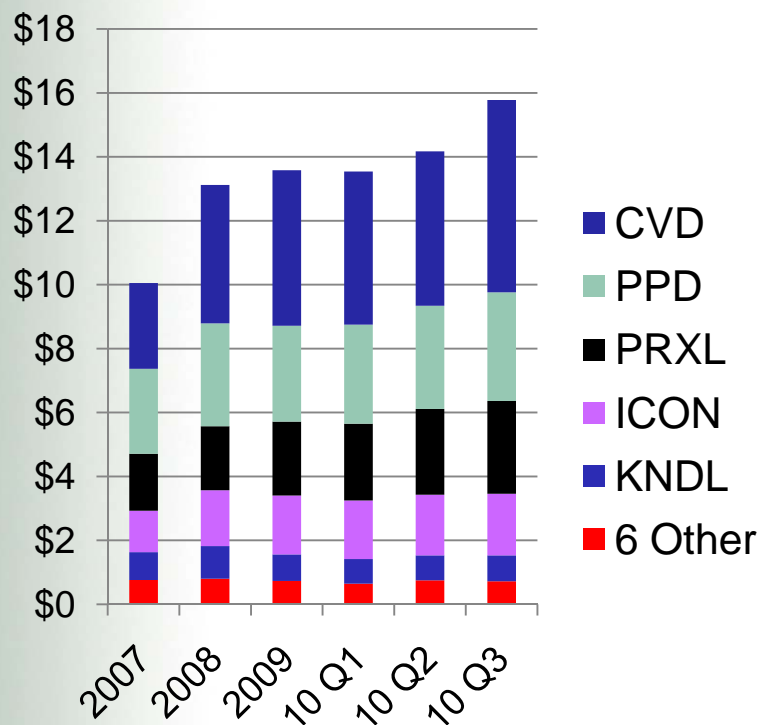
- Top 6 companies account for 50% of industry revenues
- Largest CROs gaining momentum at expense of mid-size companies
- A sign of industry maturity

Source: public financial reports, PharmSource estimates

Industry consolidation

Backlog growth reflects consolidating share

CRO Backlog

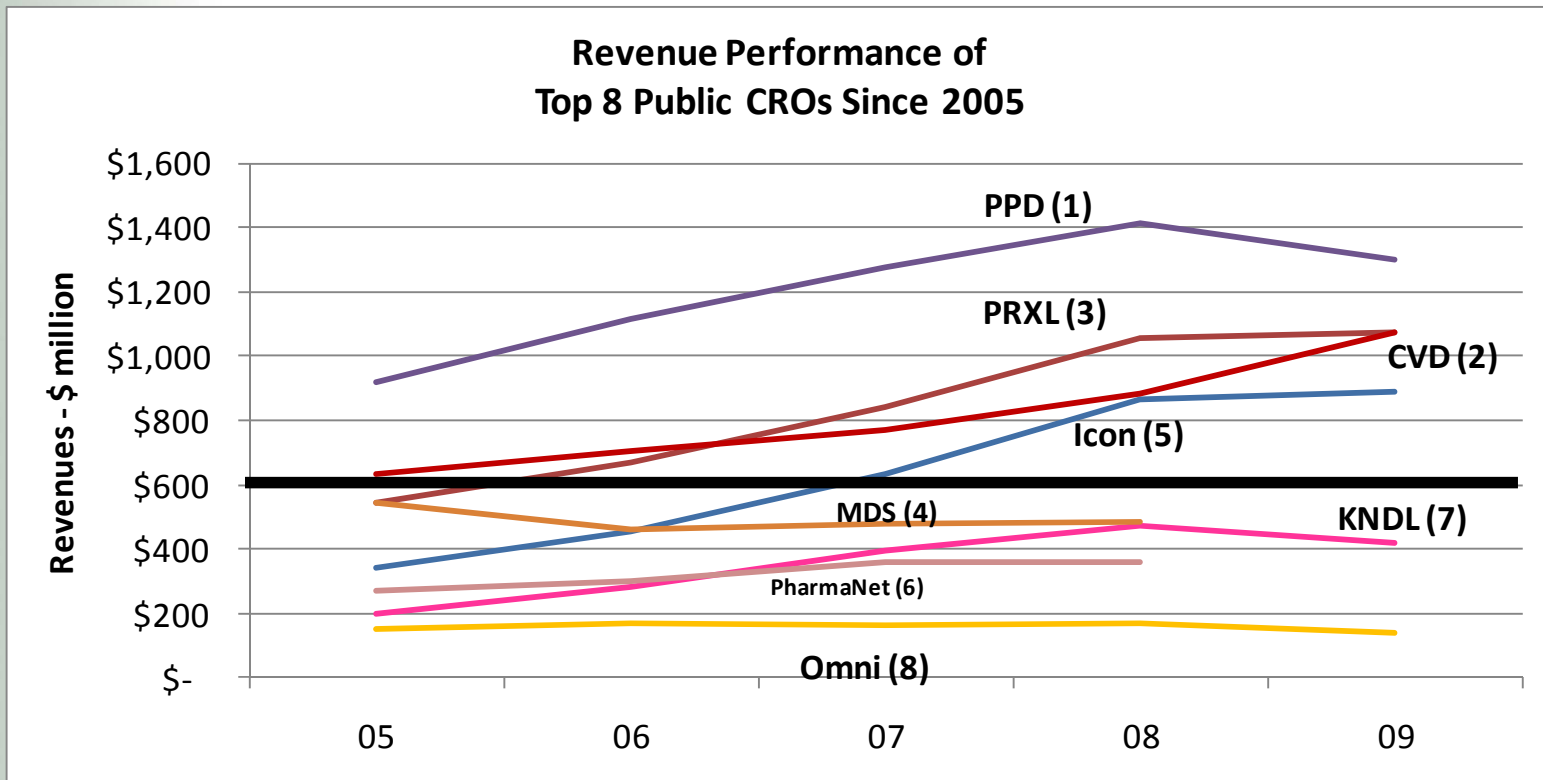


- Largest CROs enjoy greatest backlog growth
 - Multi-year strategic deals
 - Preferred providers
 - Larger studies
- Smaller CROs treading water
 - Some leaving altogether, e.g. MDS

Source: public financial reports

Industry consolidation

Top 5 CROs gaining market share vs. next 5 CROs



Note: Quintiles (# 1 overall) and PRA (#7 overall) went private 2006-7
Source: public financial reports

Industry consolidation

Covance: the power of scope and scale

sanofi-aventis

- Acquired 2 sites for \$25 million
- Received take-or-pay contracts worth \$1.2 billion
- Named sole source for central labs – worth \$1 billion

Lilly

- Acquired 1 site for \$50 million
- Received take-or-pay contracts worth \$1.6 billion

Why Covance?

- Scope of services
 - Preclinical
 - Clinical
 - CMC
- Scale of operations
 - Largest player in preclinical & central labs
 - Global site network
- Performance record in existing relationships
- Financial strength

Industry consolidation

Contract manufacturing faces big hurdles

Demand side impediments

- Supply chain risk fears
- Large fixed asset base
- High cost of closing facilities
- Emerging markets expect local presence
- Technologies viewed as strategic

Supply side impediments

- CMO capabilities limited relative to needs
 - Technologies
 - Logistics & IT
- CMO financial stability and strategic commitment
- Networks not sufficiently global

Lab and clinical supply services face fewer impediments

Final thoughts

- Don't expect big pipeline-driven improvements
 - Funding, portfolio restructuring will limit pipeline growth
- More outsourcing by global pharma will drive industry opportunity
 - But that will favor larger companies with broader capabilities
- Gradual but steady shift toward emerging markets
 - Following the revenue growth
- No longer a “nice little business”
 - Entering an aggressively competitive phase

Industry performance

Asian CMOs/CROs have suffered

Asian Contractor Performance

