

The Current State of the Market for Contract Services

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Storyline

Outline

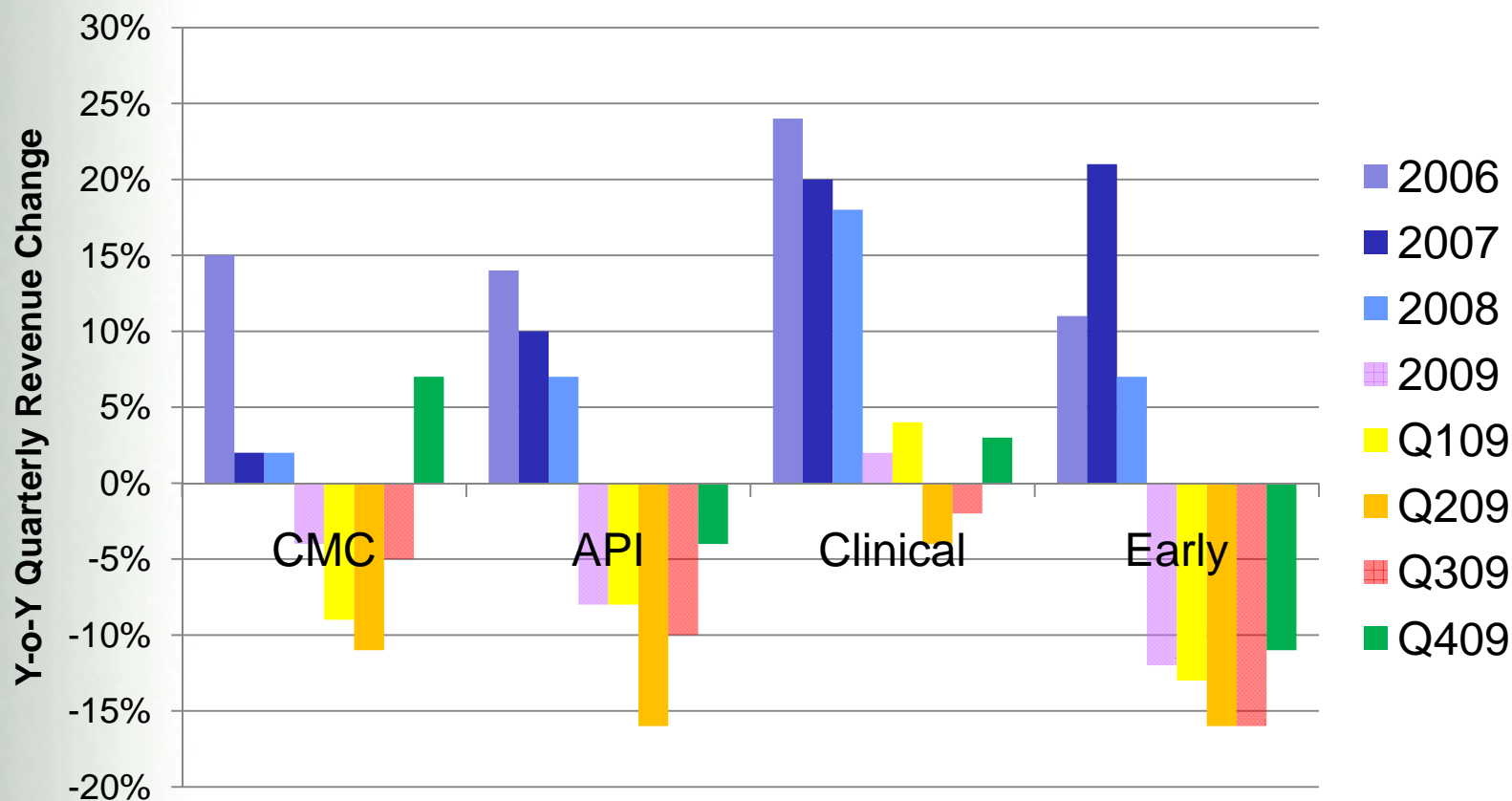
- Recent performance
- Market conditions
- Opportunities and issues
- Final thoughts

Key points

- Demand for development services market slowly improving
- Manufacturing market will be challenged
- Overcapacity plagues industry, will hurt pricing
- Emerging market opportunity expanding
- Need for business model innovation

Recent performance

Contractor industry showed improvement in Q4

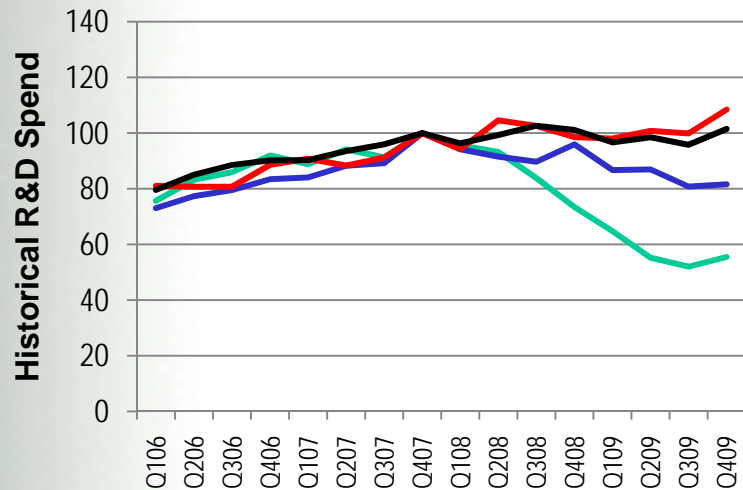


Market conditions

Better finances drove R&D spend in Q4

R&D Spend

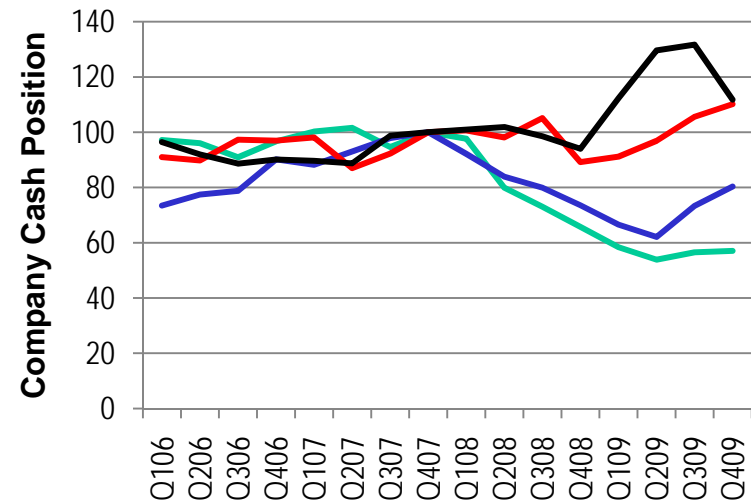
Index: Q407=100



- Early Stage Dependent (public only)
- Breakout Dependent (public only)
- Self-Sustaining
- Global

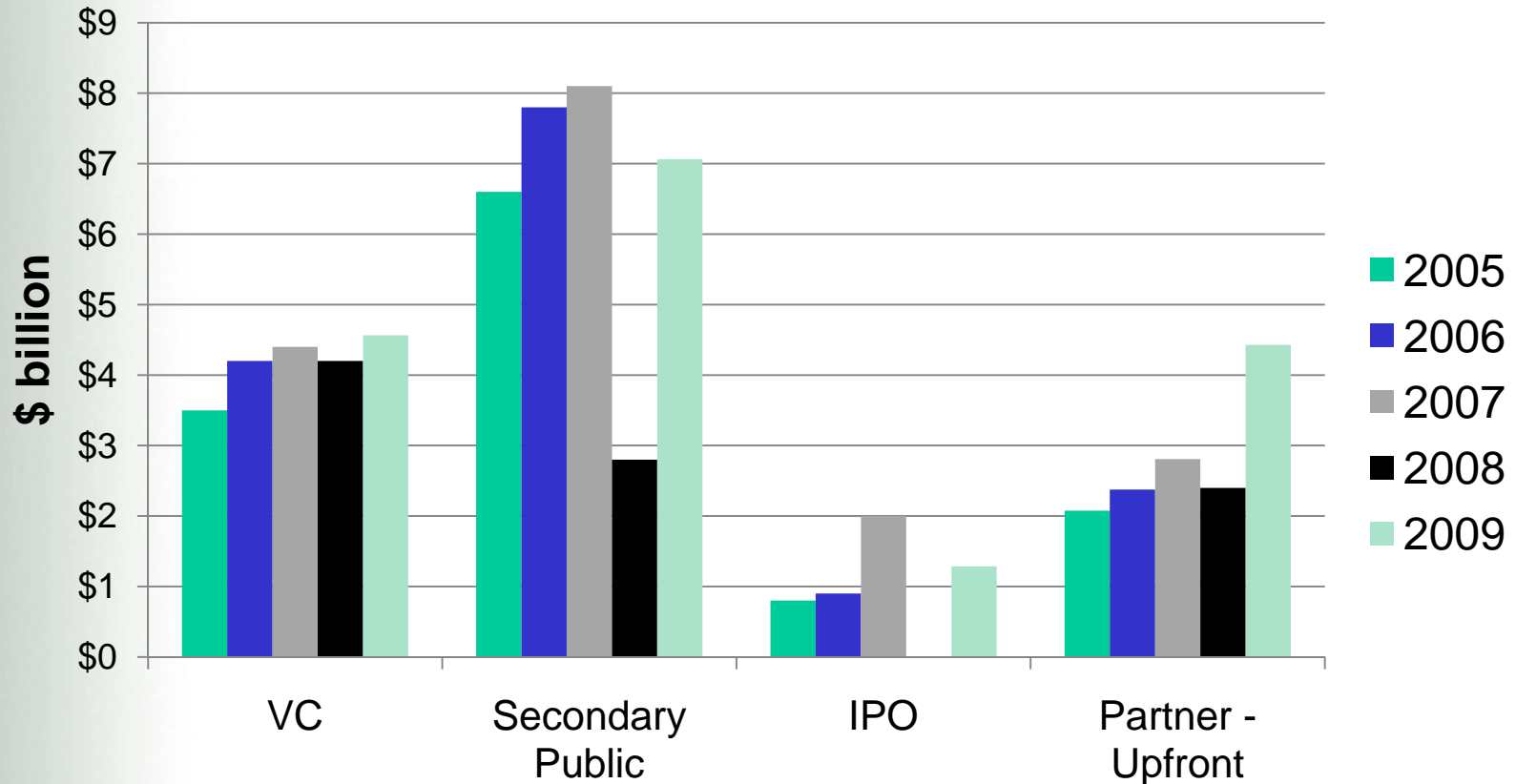
Company Cash Position

Index: Q407=100



Market conditions

2009 funding increased but still volatile

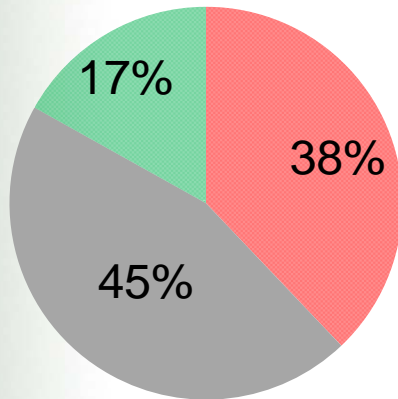


Q1 2010 down from Q4 2009

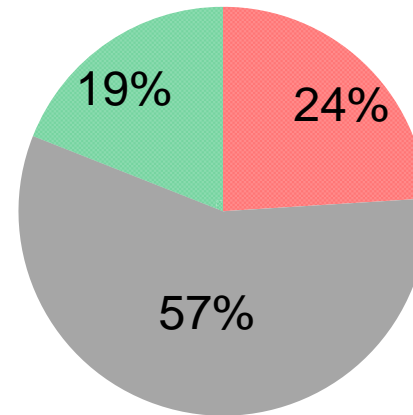
Market conditions

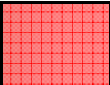


Investors favor companies with late stage products

Phase 1-2 Pipeline



Phase 3+ Pipeline

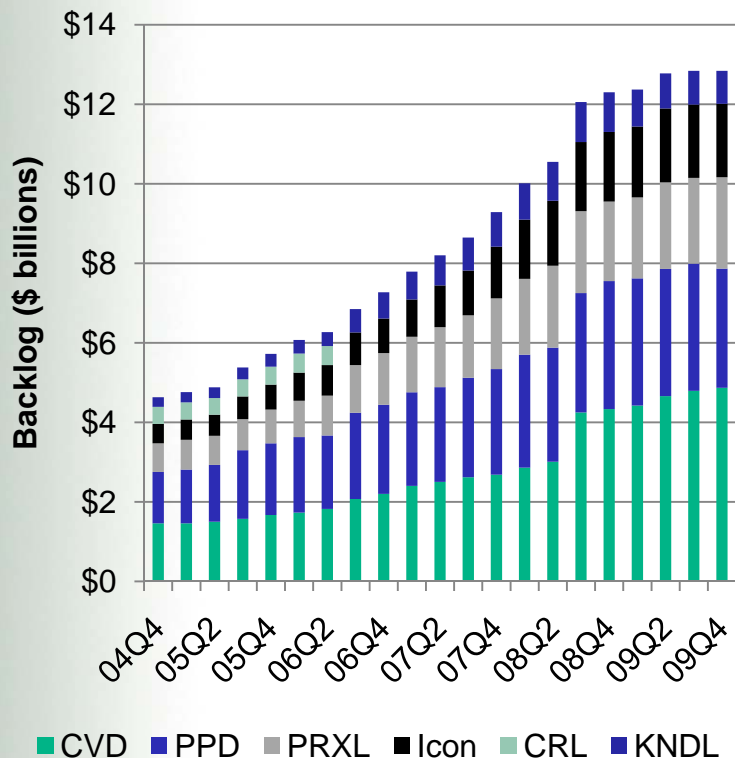


	Products controlled by companies that received no funding in 2009
	Products controlled by global and self-sustaining pharma
	Products controlled by companies that received new funding in 2009

Market conditions

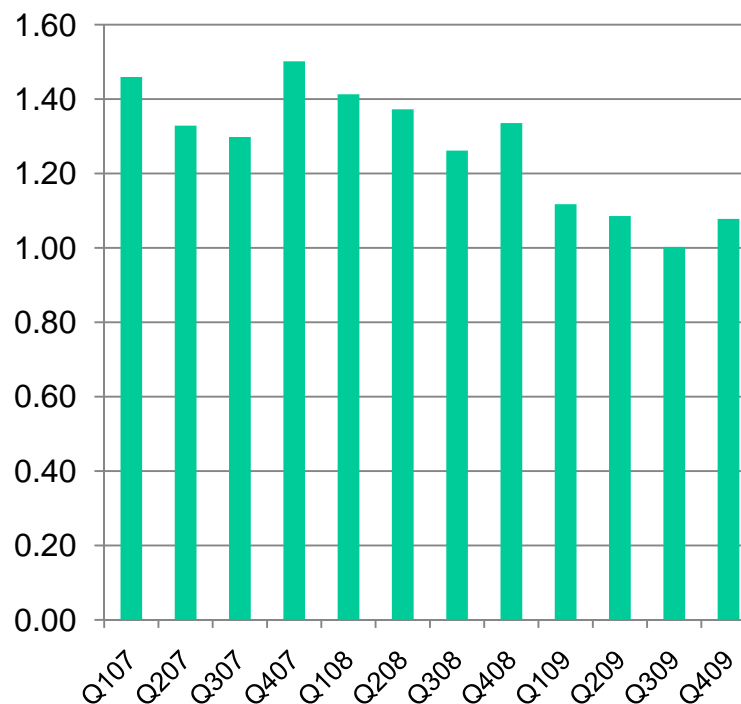
CRO signings reflect late phase demand

Backlog for Top 5 Public CROs



Book-to-Bill Ratio

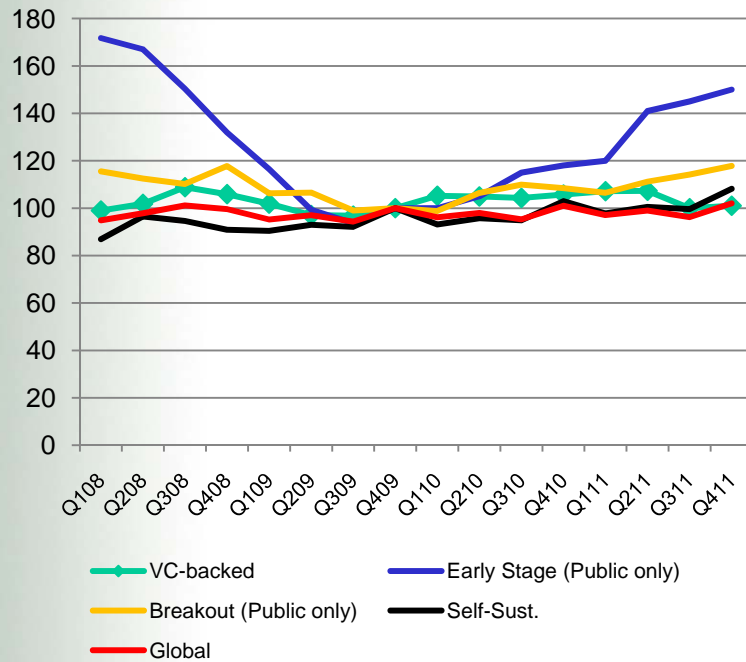
CVD, PPD, PRXL, ICLR, KNDL



Market conditions

R&D spending will rise through 2011

R&D Projections by Company Type
Index: Q409=100

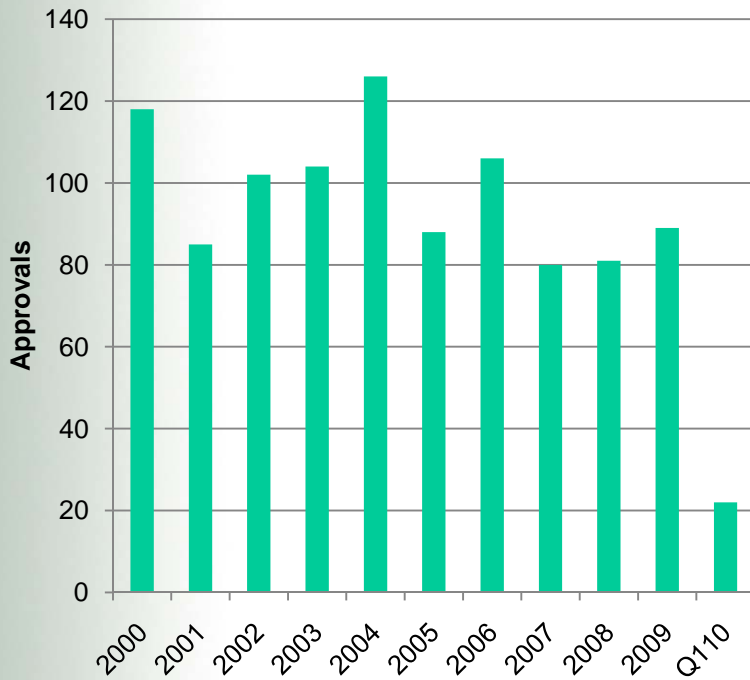


- Finance-dependent bio/pharma will rise but not to re-crisis levels
- Global and self-sustaining will be pretty flat
 - Restructuring, mergers will reduce spend at many companies
 - Share going to products vs. partnering may decline
 - **But share outsourced should grow**

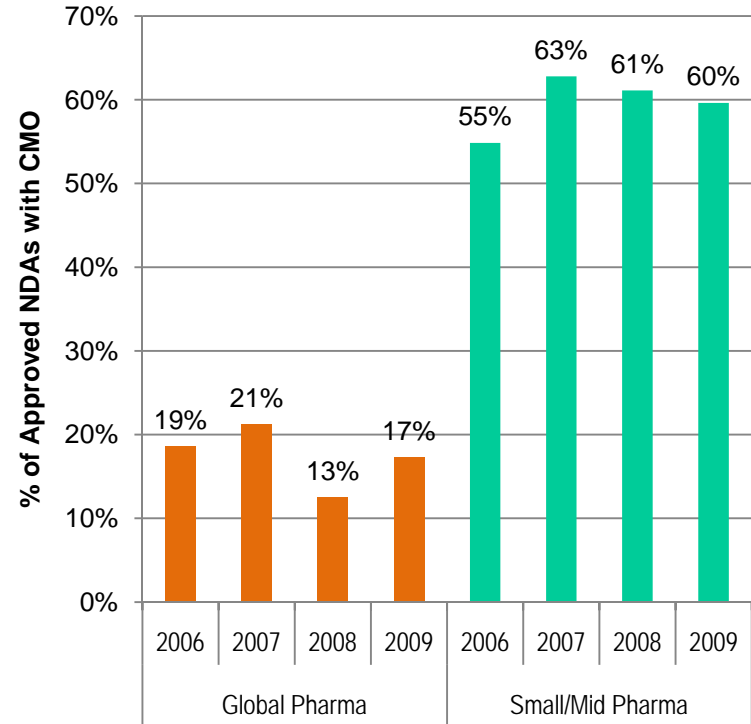
Market conditions

NDA/BLA approvals likely to remain flat

CDER NDA/BLA Approvals

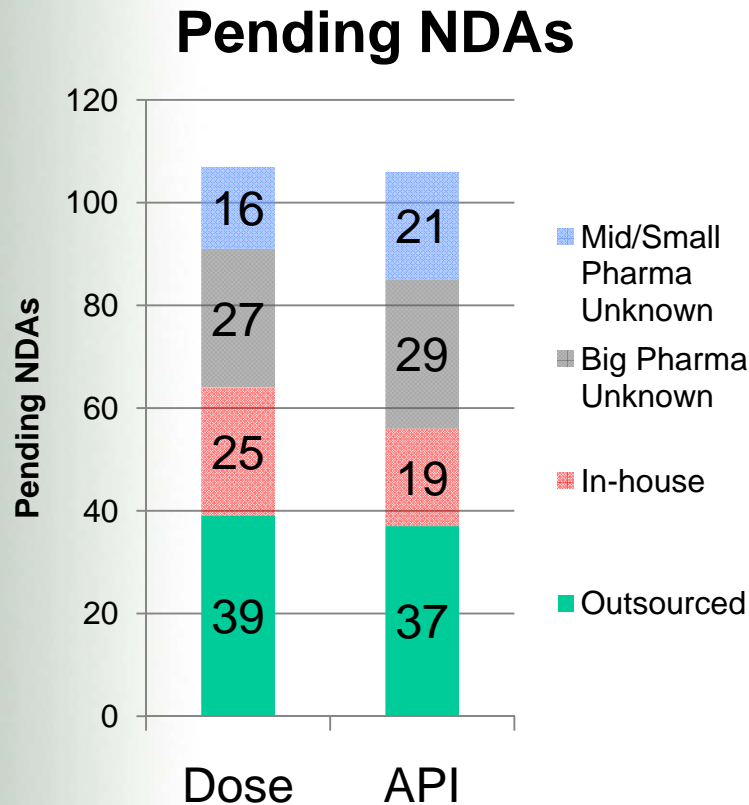


Approved NDAs with Dose CMO 2006-2009 by Year



Market conditions

Pending NDAs continue trend



■ 106 products filed

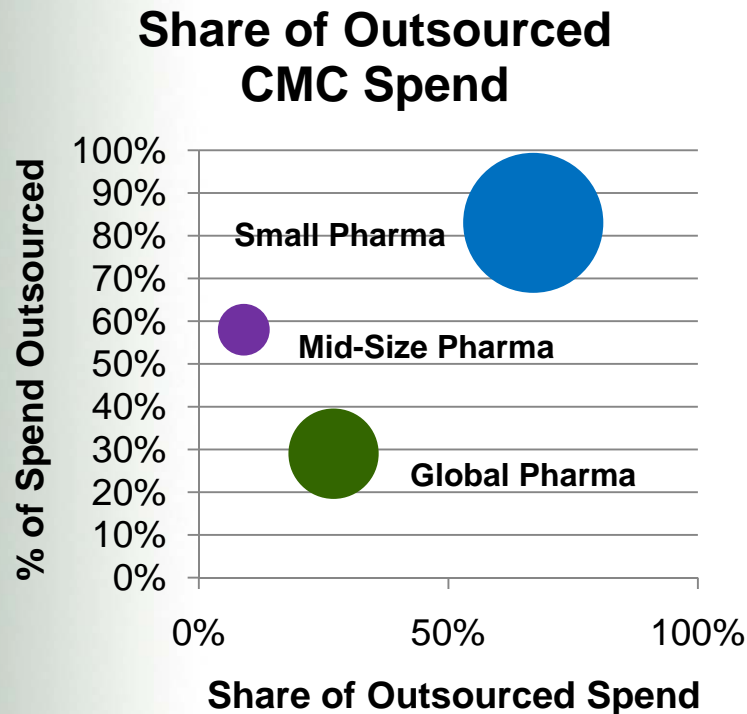
- 38% known CMO
- 23% known in-house
- 39% unknown

■ 39 with CRLs

- CMC/GMP problems in a number of them

Opportunities and issues

Global Pharma will drive CDMO growth



Circle size represents total spend

Source: PharmSource, "The Market for Contract Development and Analytical Services"

- Small Pharma opportunity limited
 - Heavily outsourced
 - Volatile financing
- Increased Global Pharma development outsourcing will add \$500 million to \$1 billion
 - How much will go offshore?
 - Who will get offshore business?

Opportunities and issues

Clinical/preclinical deals establish precedent

Lilly Strategic Sourcing Relationships				
	Discovery	Early Development	Late development	Commercial
Chemistry/Biology	Jubilant Life Sciences			
Toxicology	Covance			
API				Evonik
Dose/CMC development		Fisher Clinical		
Clinical research		Covance		
Clinical research			i3 Statprobe	
Clinical research			Icon	
Clinical research			Quintiles	

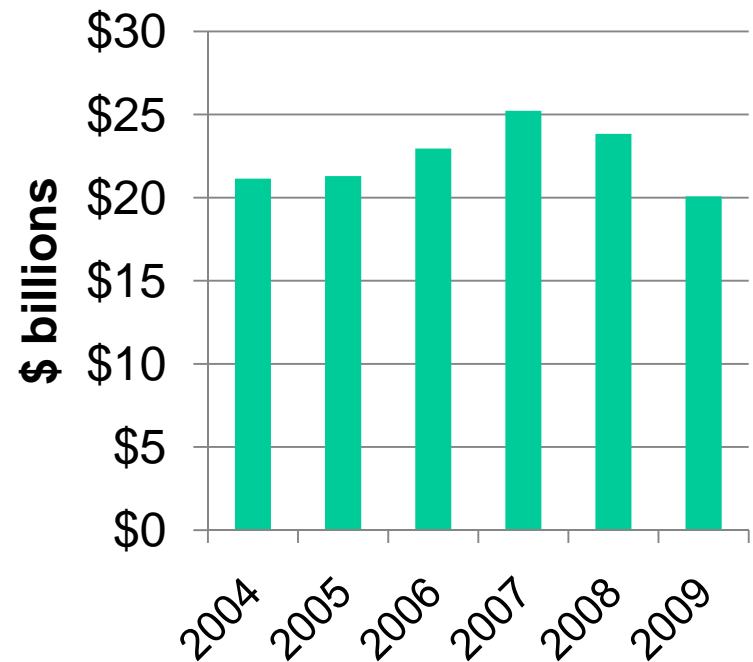
Functional service model winning out over integrated project model

Opportunities and issues

Welcome to the Hotel California

- Once manufacturing capacity enters bio/pharma industry it doesn't leave
- Global bio/pharma shedding assets but new and established CMOs will buy and new capacity being built
- Global bio/pharma expanding excess capacity sales and marketing efforts
- **Price competition is a reality**

**Capital Expenditures
for Top 17 Bio/Pharma**



Opportunities and Issues

Death by a thousand niches

- “If only I had this/that capability I could make my numbers”
 - Being everything to everybody won’t work
 - Low utilization means high costs, low returns, poor quality
 - Few proprietary niches left in the business
 - Equipment, disposables widely available
- Need to alter the inherited CMO business model
 - High fixed cost
 - Low utilization
 - High risk of product failure
 - Overcapacity
 - Embrace high volume, high utilization
 - Focused capabilities
 - What does fully-absorbed OH look like?
 - Need to go to emerging markets?

Opportunities and issues

Risk mitigation is driving pharma restructuring

	Early Development	Late Development - Launch	Commercial
Probability of failure	<ul style="list-style-type: none">• Very high	<ul style="list-style-type: none">• High	<ul style="list-style-type: none">• Low
Risk focus	<ul style="list-style-type: none">• Cost• Late phase failure	<ul style="list-style-type: none">• Clinical failure• Non-approval• Market failure• Cost	<ul style="list-style-type: none">• Supply chain• Pricing
Risk mitigation	<ul style="list-style-type: none">• Option-based partnering• Chorus-type development models	<ul style="list-style-type: none">• Early development• Emerging markets• Function service outsourcing	<ul style="list-style-type: none">• Dual sourcing• Process improvement• Offshoring

Opportunities and Issues

Who is going to service Asia?

- “Looking East, Big Pharma Cuts Prices”
 - *Business Week*, April 15, 2010
- R&D, clinical research well established in India, China, Latin America, Eastern Europe
- Clinical CROs have attacked the opportunity head-on and blanketed emerging markets
 - Sites, central labs, data centers
- CDMOs have largely avoided the opportunity
 - A few API CDMOs, SGS (Labs), Fisher Clinical (clinical packaging)

Final thoughts

Time to get aggressive

- Don't expect a rising tide to lift all boats
 - Competition will intensify, sales/marketing skills will matter greatly
 - Track record, financial stability count for a lot
- Opportunities for business model innovation
 - Understand the new development paradigm
 - Appreciate the pharma manufacturing calculus
 - Understand risk to be able to manage it and accept more of it

PharmSource

- ***PharmSource Lead Sheet***
 - New business opportunities for service providers
- ***Market Intelligence Service***
 - In-depth analysis of market conditions for contract services
- ***PharmSource Advantage***
 - Detailed profiles of contract service providers