CMOs and CROs as Business Solutions Providers:

A New Strategy for Contract Services Providers

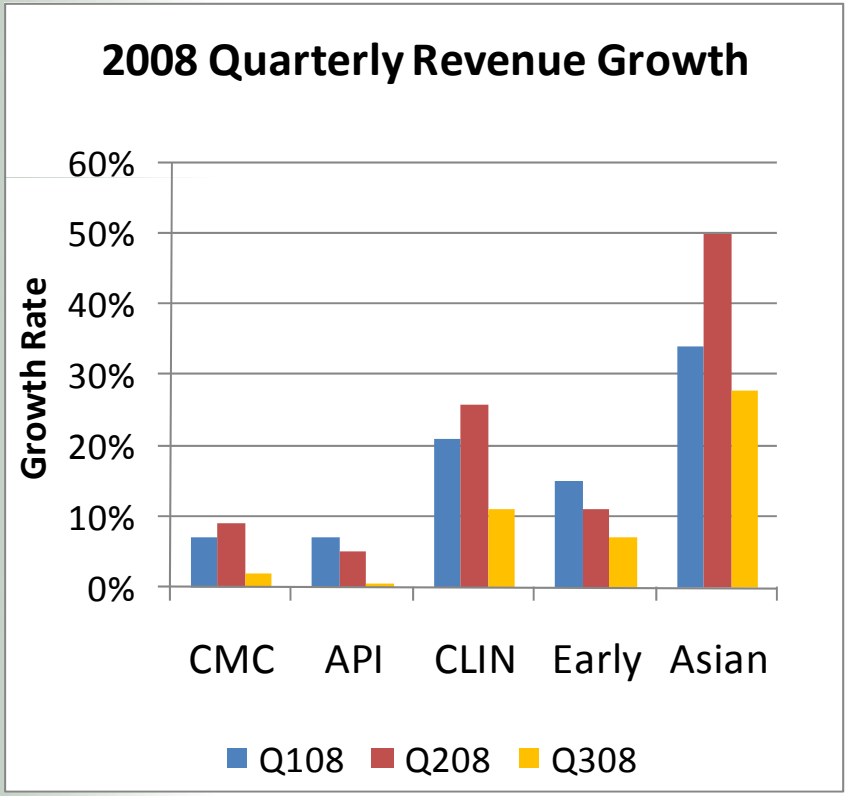
Jim Miller

Pharmaceutical Technology Breakfast at AAPS

November 2008

Market conditions

Top line growth down sharply in Q3 2008



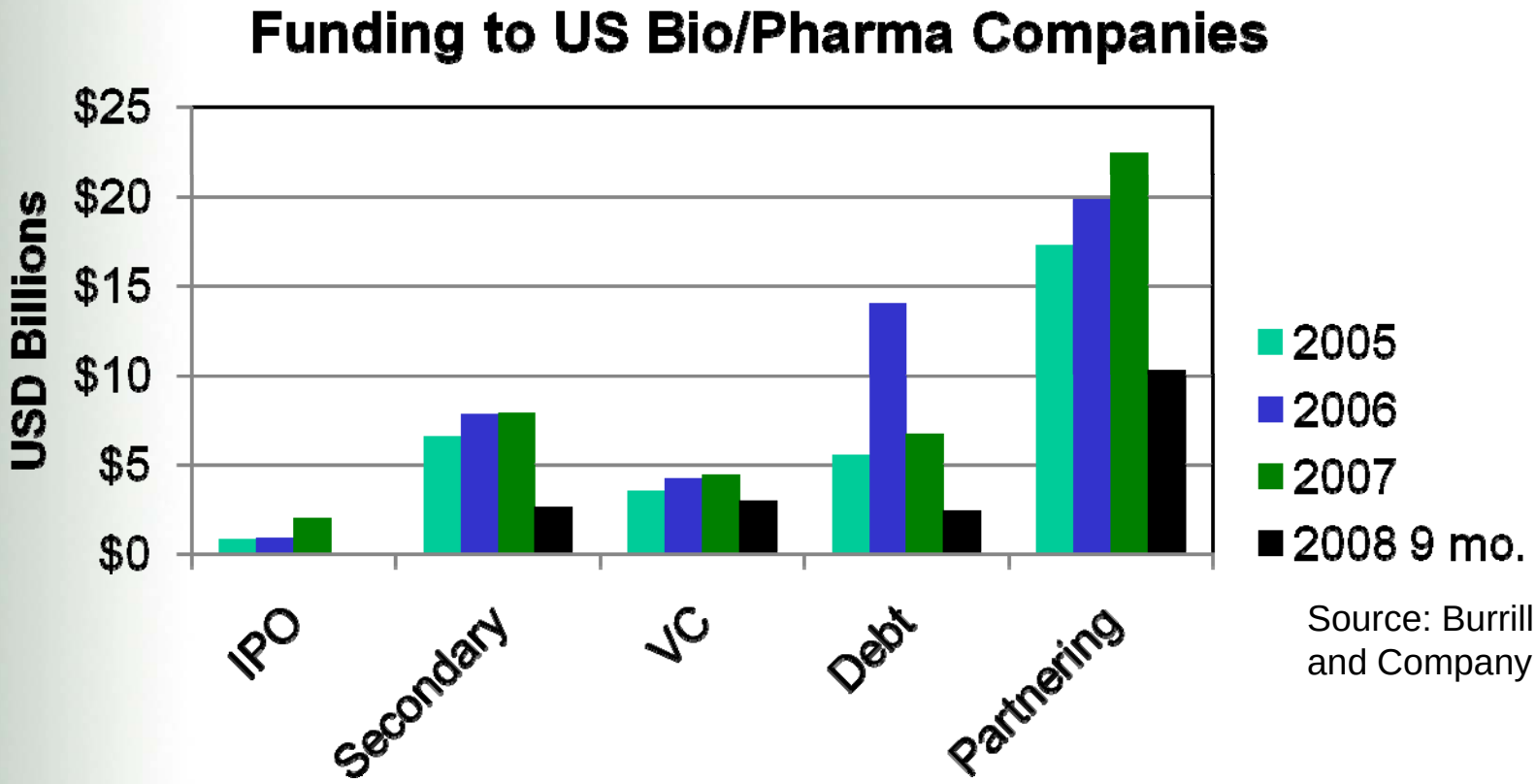
Asian companies mostly APIs, intermediates and dose manufacturing

CROs and CMOs report major demand drops

- Toxicology, clinical pharmacology, process development
- Includes Charles River, Lonza, SAFC, Cambrex
- Late development seems to be holding up

Market indicators

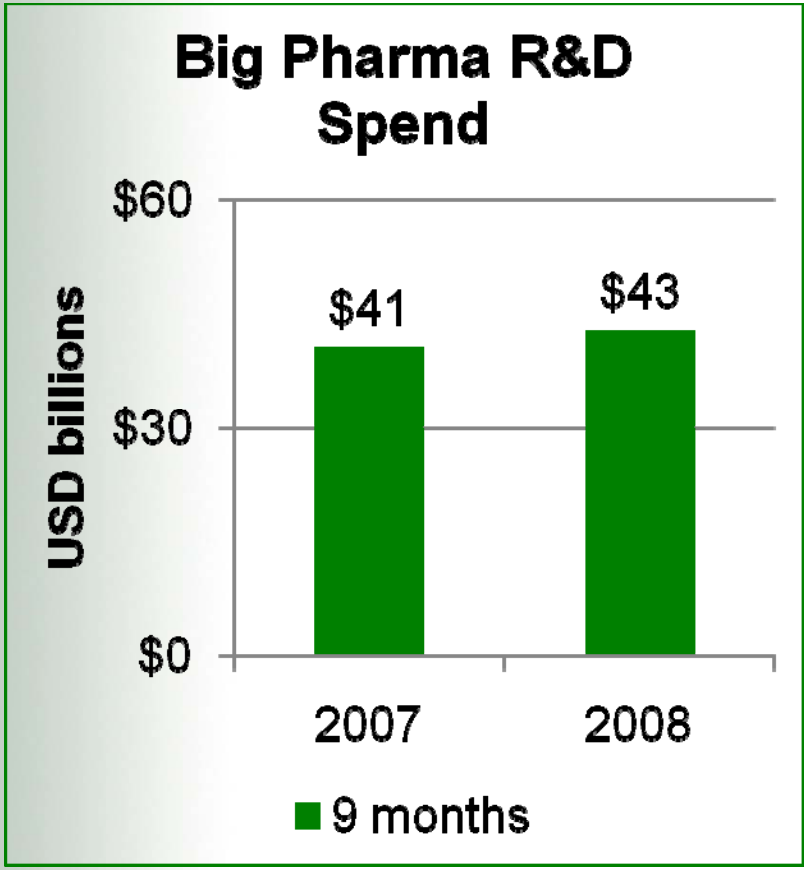
Bio/pharma funding down sharply

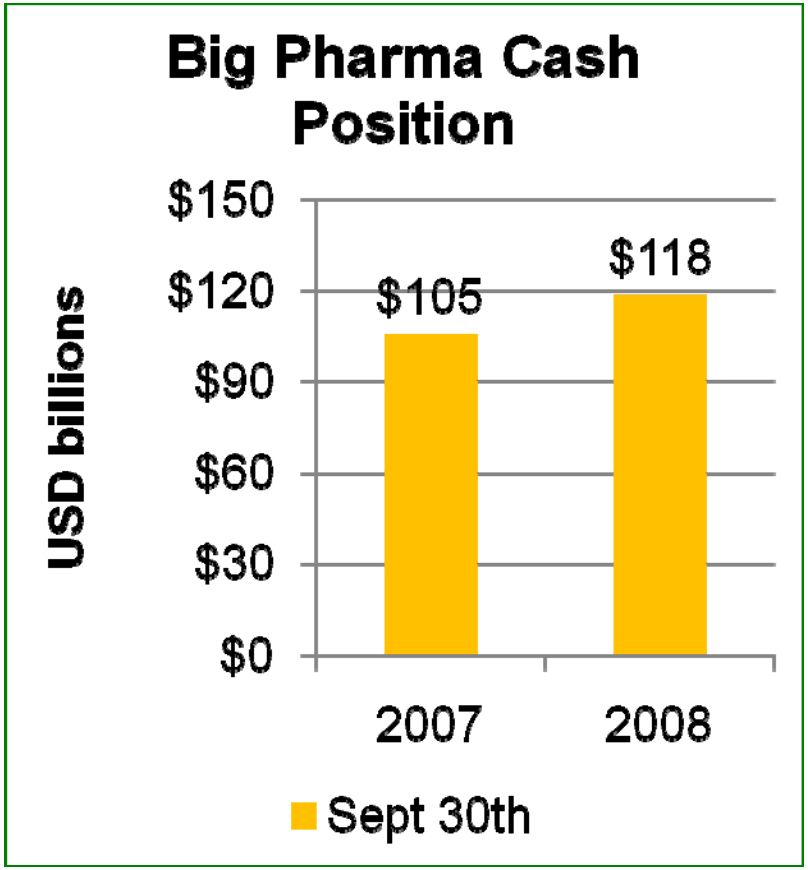


Source: Burrill and Company

Market indicators

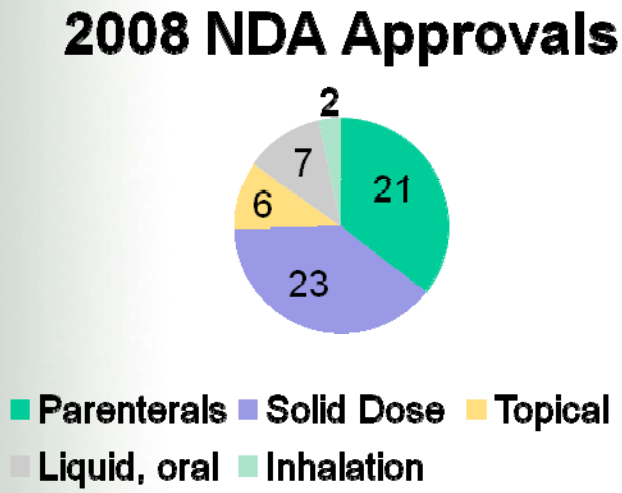
Big Pharma holding up



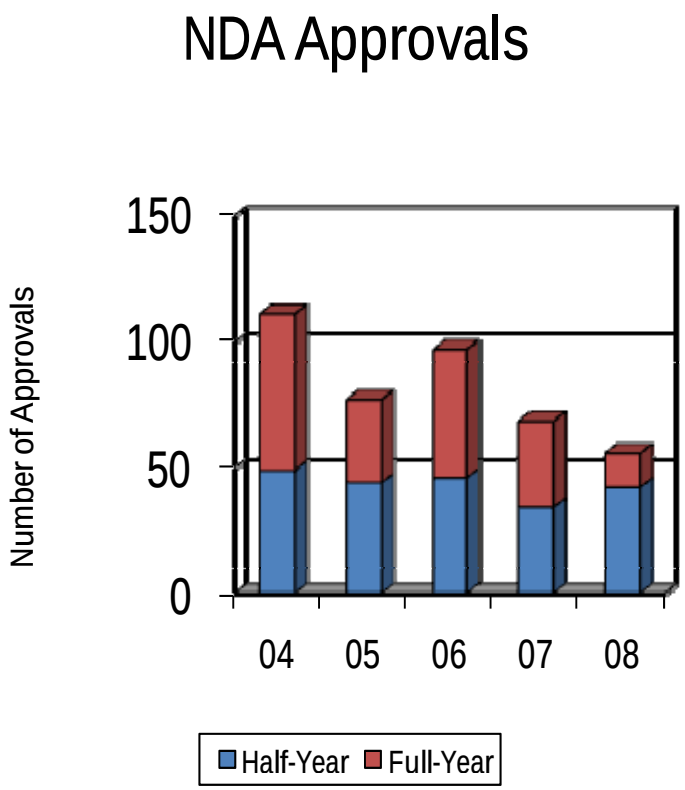


Market indicators

FDA approvals on track with past years



- 57 Total
- 14 NMEs
- 33 global pharma
- 23 small/mid pharma



Data through September 2008

Market conditions

How long will downturn last?

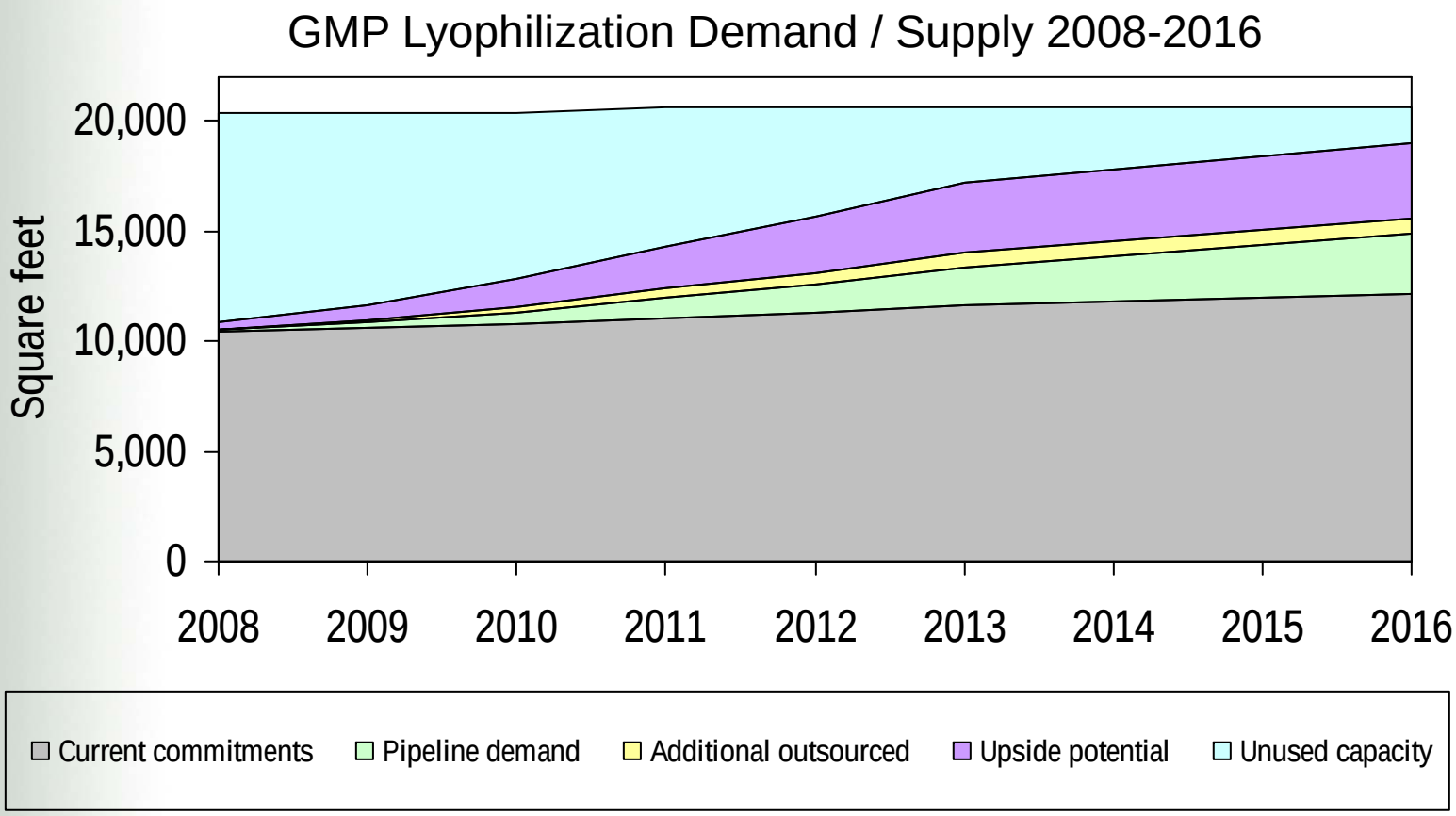
- Big Pharma could be window dressing 2008 results
  - Delayed projects should move in 2009
  - Phase II/III studies contracted, cancellations not high
  - But portfolio restructuring is permanent
- VC downturn could be a year or more
  - Focus on ensuring funding for portfolio companies
  - Europe worse than US

CMOs and CROs as solutions providers

- GMP capacity is a commodity
  - Although some CMOs still get in regulatory trouble
- Pharma is in survival mode
  - Looking for broader solutions than just capacity
- Providers must move beyond capacity
  - Recast offerings as a solution to broader business problems
  - New capabilities + positioning

CMOs and CROs as solutions providers

GMP manufacturing capacity is a commodity

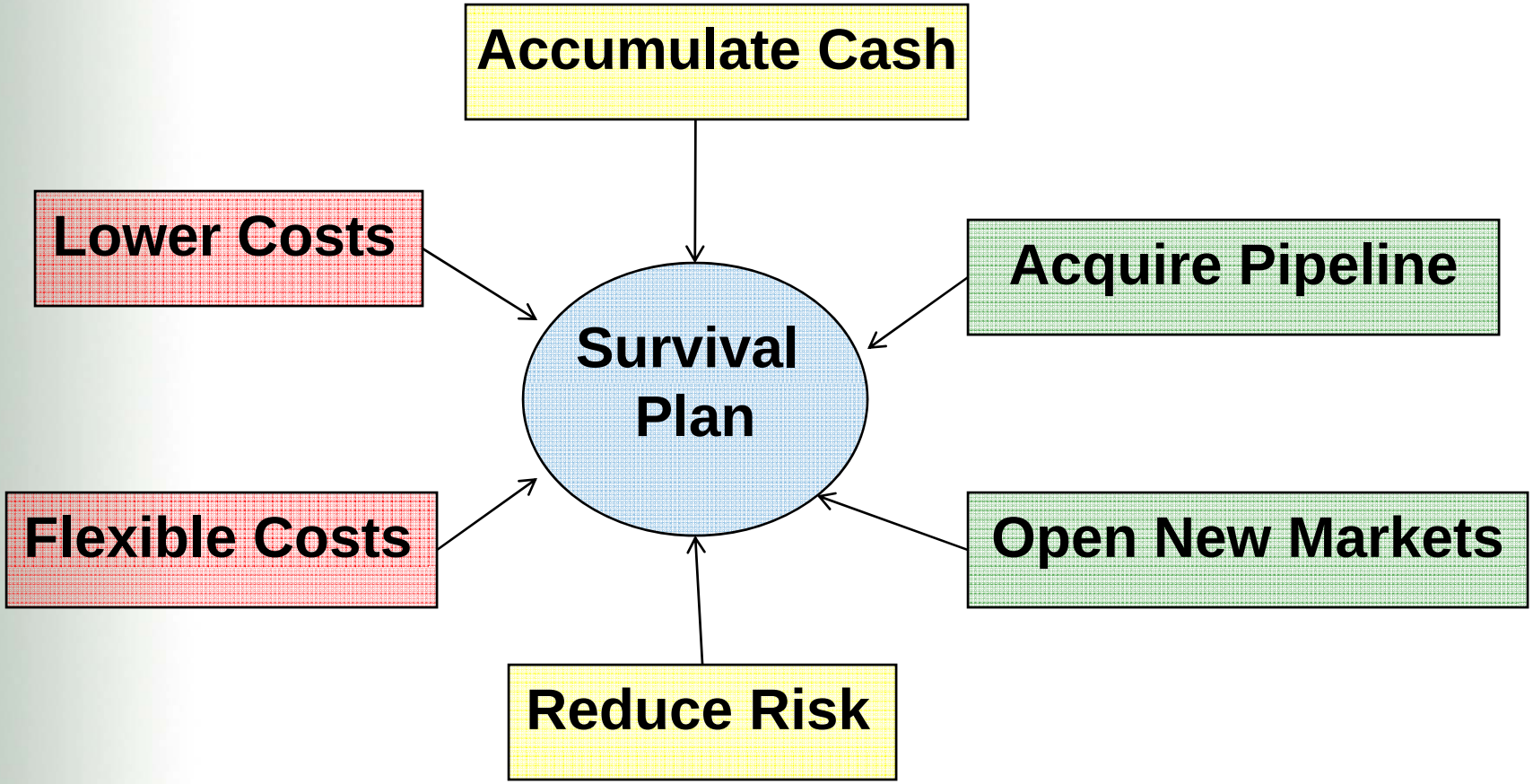


Source: PharmSource model

PHARMSOURCE™

CMOs and CROs as solutions providers

Pharma is in Survival Mode



CMOs and CROs as solutions providers

Pharma adopting alternative strategies

Examples

- Proof-of-concept
- M&A and in-licensing
- Discovery partnerships
- Venture capital
- Generics
- Offshoring
- Functional outsourcing
  - Central labs, data management, monitoring
  - Space reservation at preclinical facilities

Lilly-Covance deal

- Covance buys Lilly research facility for $50 million
- Covance gets:
  - $1.6 billion 10-year services contract
  - New technologies
  - Experienced staff
- Lilly gets:
  - $50 million cash
  - Lower fixed costs
  - Best-in-class performance

CMOs and CROs as solutions providers

Manufacturing decision is very complex

Make or Buy?

- Unit cost
- Global supply
- IP protection
- Security of supply
- Product approvals
- Plant closure & labor laws
- Acquired products
- Technology
- Facility utilization
- FOREX exposure
- Gov't subsidies
- Tax planning

CMOs and CROs as solutions providers

Globalization complicates manufacturing decisions

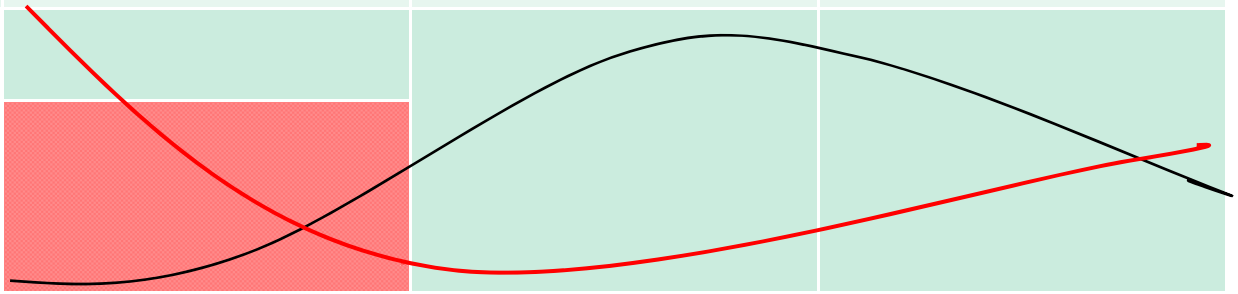
Global Products									
North Am Regional Products		Europe Regional Products		South Am Regional Products		Asia Regional Products		Africa Regional Products	
Country Products	**Country Products**	**Country Products**	**Country Products**	**Country Products**	**Country Products**	**Country Products**	**Country Products**	**Country Products**	**Country Products**

How to balance cost and compliance?

- Large batch economies
- Labor rates
- Exchange rates
- Shipping costs
- FDA/EU versus local GMPs

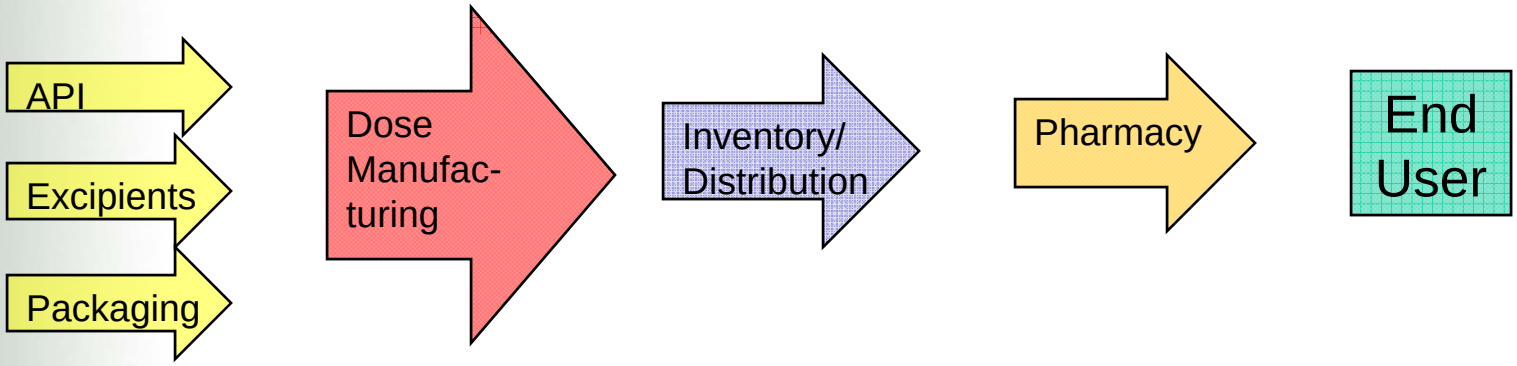
CMOs and CROs as solutions providers

CMO's greatest value may be reducing risk

	Launch	Maturity	Decline
Innovator Risk	Very high	Very low	Moderate
Innovator objective	• Regulatory approval • Market acceptance • Reduce sunk costs	• Build and defend market share • Reduce CGS	• Harvest profits • Very low CGS
Volume **CMO value**			
CMO Value	• Absorb risk • Flexibility • No capital expense	• Process expertise • Delivery technology	• Low cost production inc. offshore

CMOs and CROs as solutions providers

Pivotal to solving supply chain issues



- Extended supply chains
- Inventory management

- Asset utilization

- Globalization
- Security/ counterfeiting
- Cold chain
- Inventory management

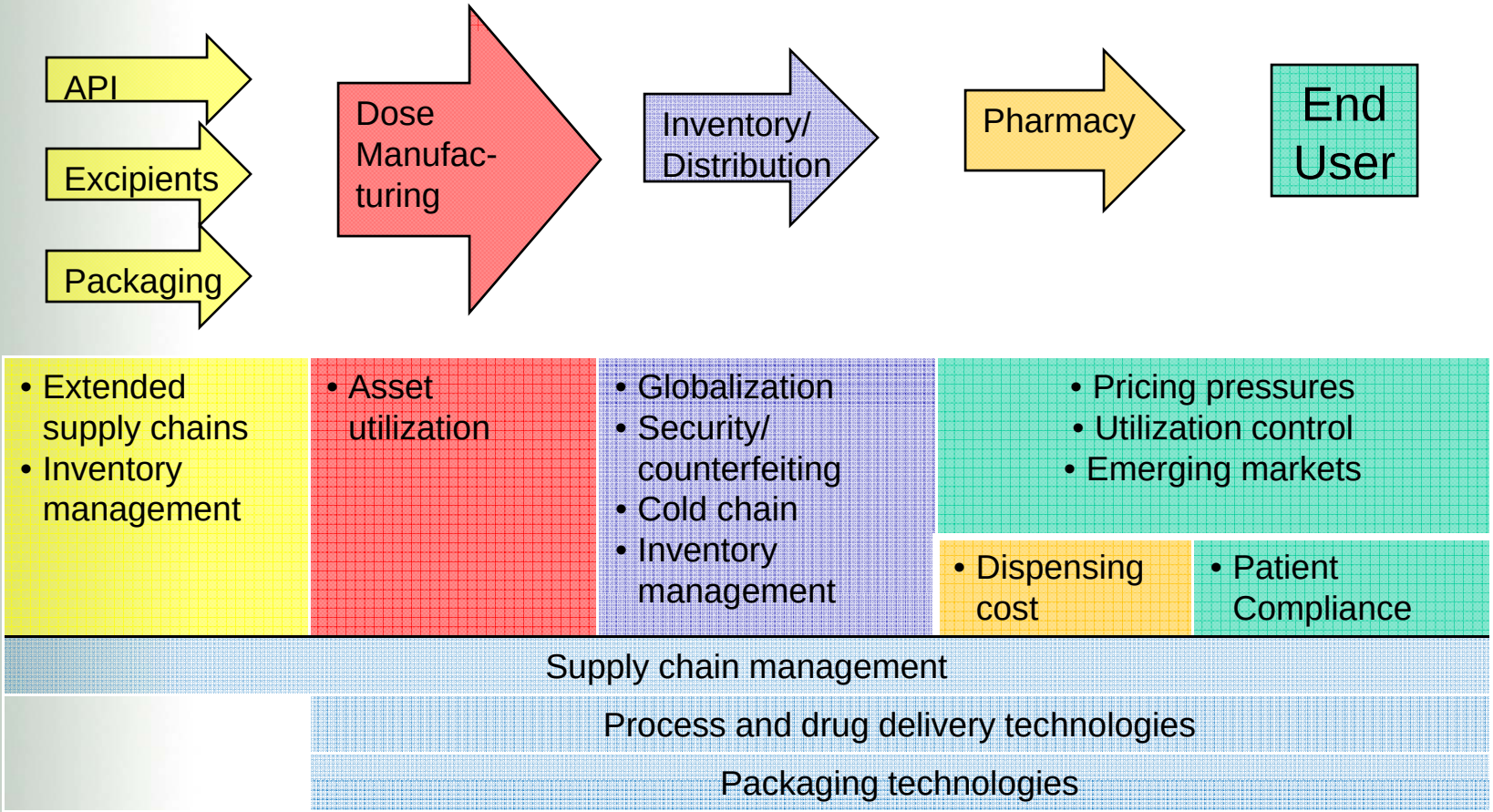
- Pricing pressures
- Utilization control
- Emerging markets

- Dispensing cost

- Patient Compliance

CMOs and CROs as solutions providers

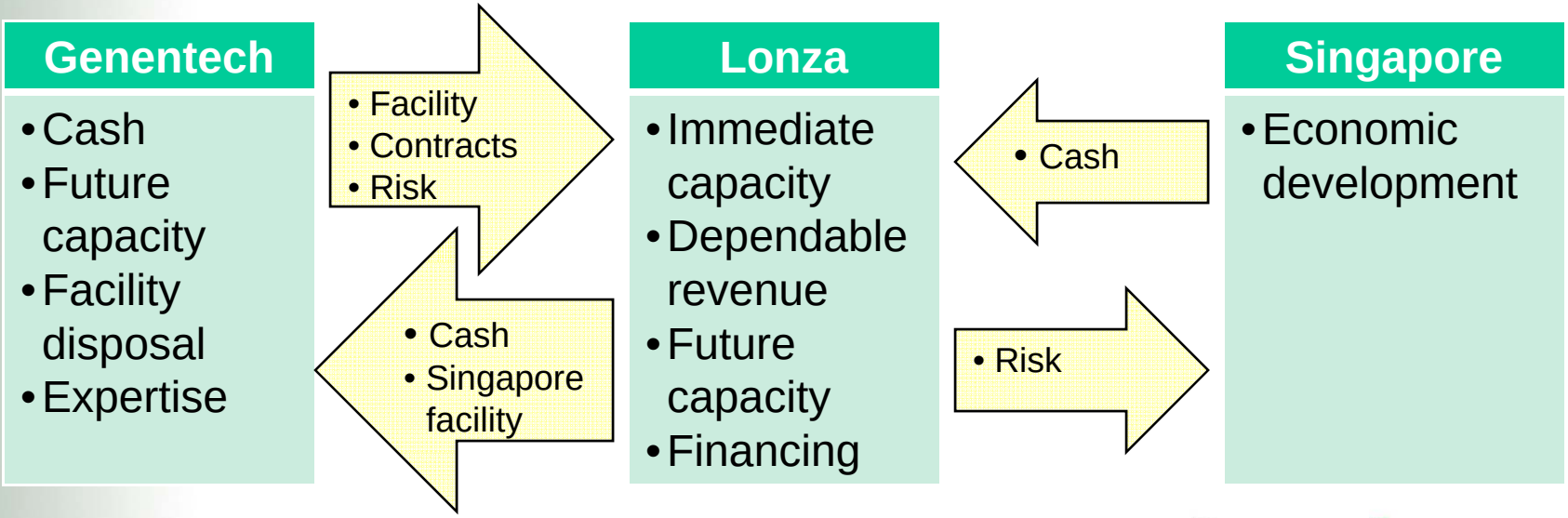
Pivotal to solving supply chain issues



CMOs and CROs as solutions providers

Lonza-Genentech deal transfers risk

- **Key elements**
  - Lonza buys Genentech MCC facility in Spain w/contract
  - Lonza builds MCC facility dedicated to Genentech in Singapore
  - Singapore agency contributes investment
  - Genentech option to acquire facility



CMOs and CROs as solutions providers

Lonza – Novartis deal: risk + technology transfer

10+ year deal for biopharmaceutical development

Service	Value to Novartis	Source of Value
• Process development • CTM manufacture • Launch manufacture • Facility design & engineering	• Faster development • Better performance • CAPEX avoidance • Risk mitigation	• 20 years experience and expertise • Investment in GS expression system • Diversified project/ product portfolio • Manufacturing assets • Clever deal making

Closing thoughts

- Manufacturing will become part of broader business solution
  - Think IBM, UPS, FEDEX
- Changing environment providing important new sources of value
  - Risk mitigation and arbitrage
  - Supply chain management
  - Global manufacturing networks
- New skill sets required
  - Marketing (segmentation and positioning)
  - Financial engineering
  - Global logistics
  - Just-in-time manufacturing operations