

How Long Will the Good Times Roll?

Jim Miller

Pharmaceutical Technology Breakfast at AAPS

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PHARMSOURCE™

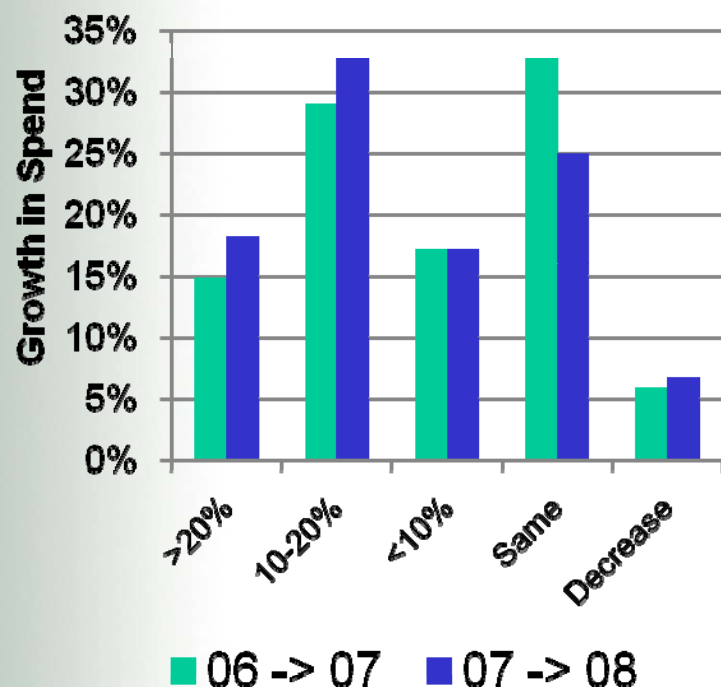
Key points

- Development services and CTM continue to enjoy strong performance, tight supply
- But CROs and CMOs should adopt a cautious view
 - Risky technologies and me-too products not panning out
 - Soaring deal valuations could curtail in-licensing activity and stem VC investment

Market conditions

Pharma expects strong spend growth

Expected Growth In R&D Services Spend
PharmSource-Pharmaceutical Technology Survey

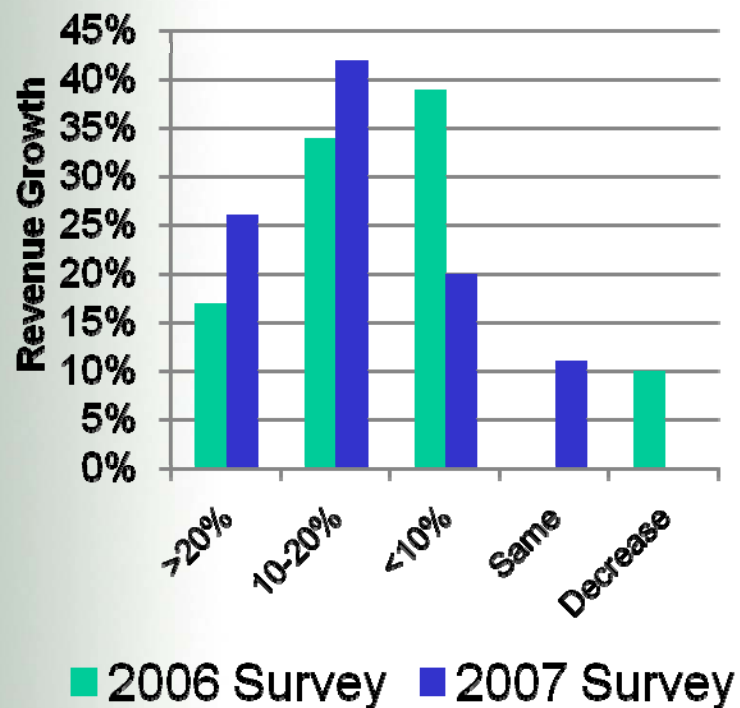


- Big pipeline is driving development spend
- Early candidates progressing to early clinical phases
- Small and mid-size companies dominate pipeline

Market conditions

CROs experience outstanding performance

Expected Growth In Services Revenue
PharmSource-Pharmaceutical Technology Survey



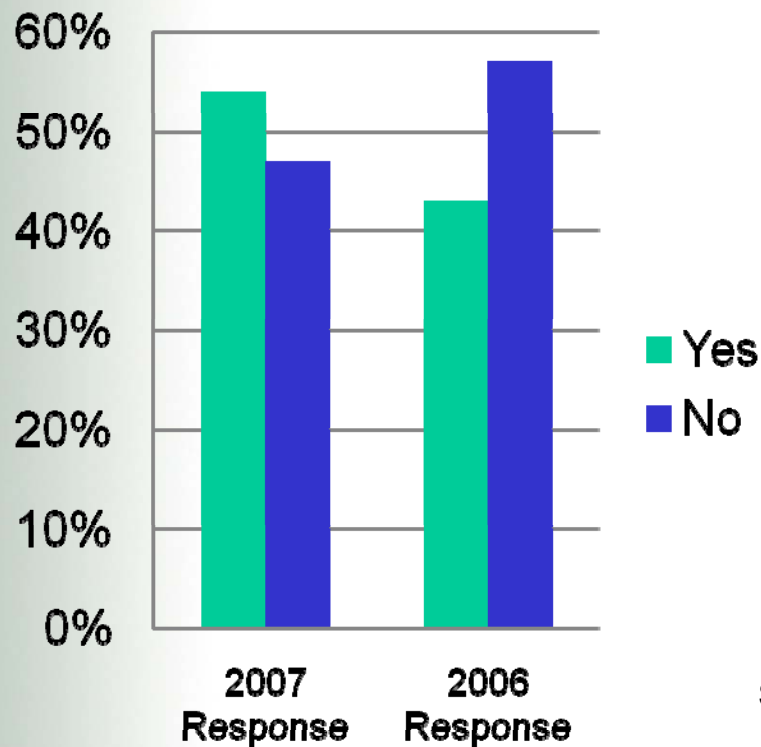
H1 Development Services Results

Company	Segment	H1 Growth
Patheon	Form, CTM	25%
AMRI	API develop	25%
Covance	Preclinical, Phase I	14%
CRL	Preclinical	20%
SGS	Lab, Phase I	5%
PPD	Phase I	25%

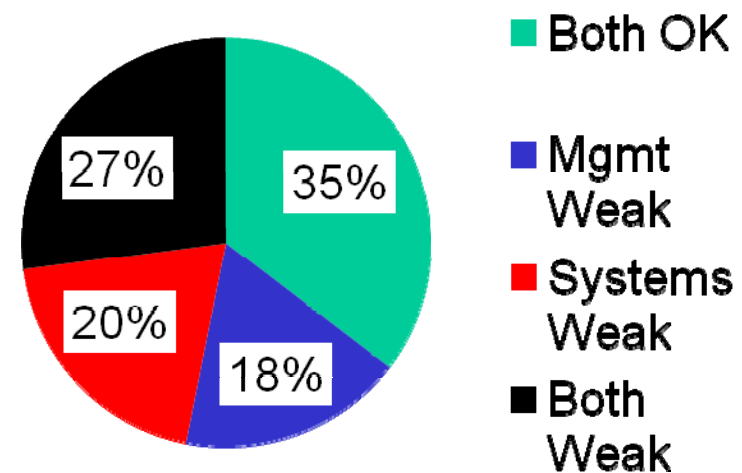
Market conditions

Contractors feel growth stresses

Capacity Constrained?



Able to Grow 20%?



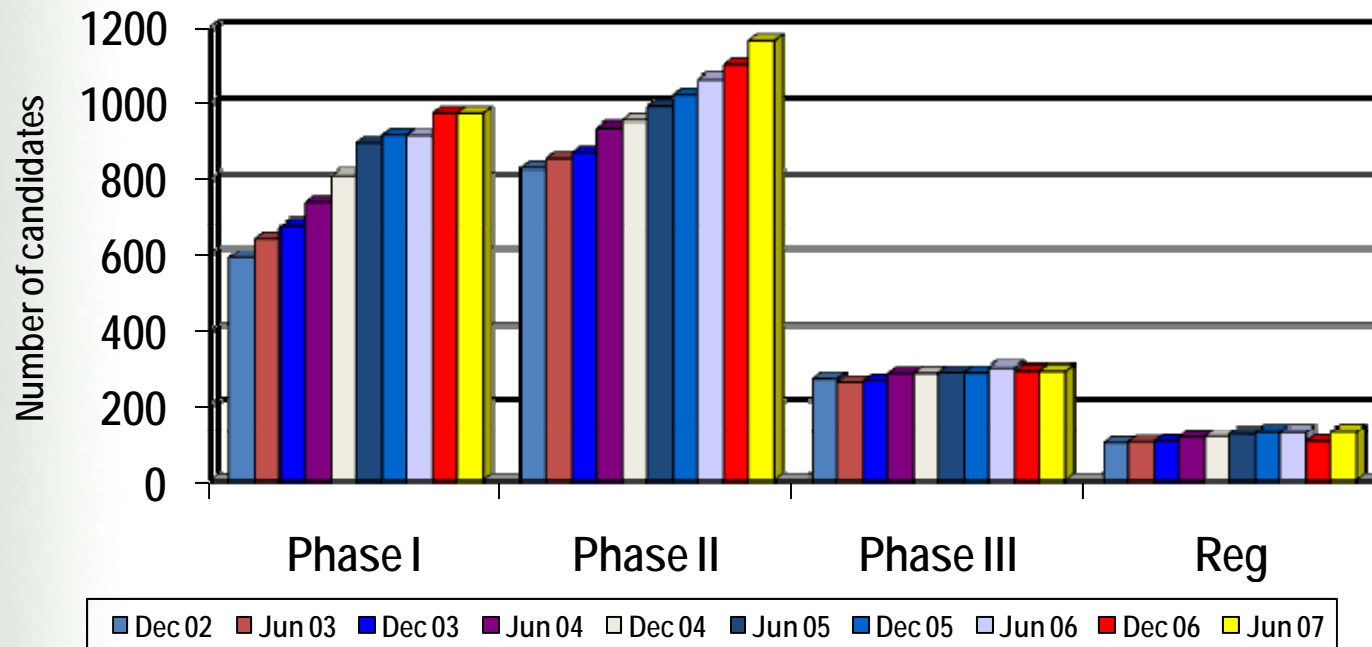
Source: PharmSource-Pharmaceutical Technology Survey

Industry environment

Early pipeline driving CRO/CMO market

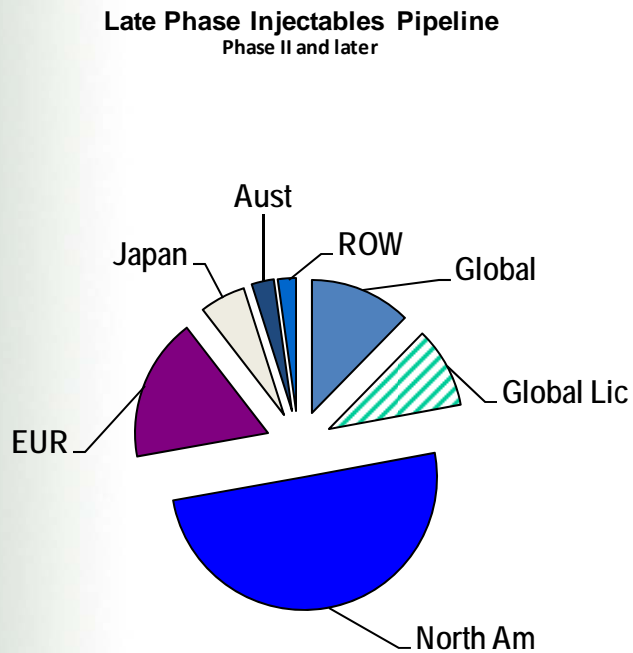
Global Drug Development Pipeline

Source: IMS

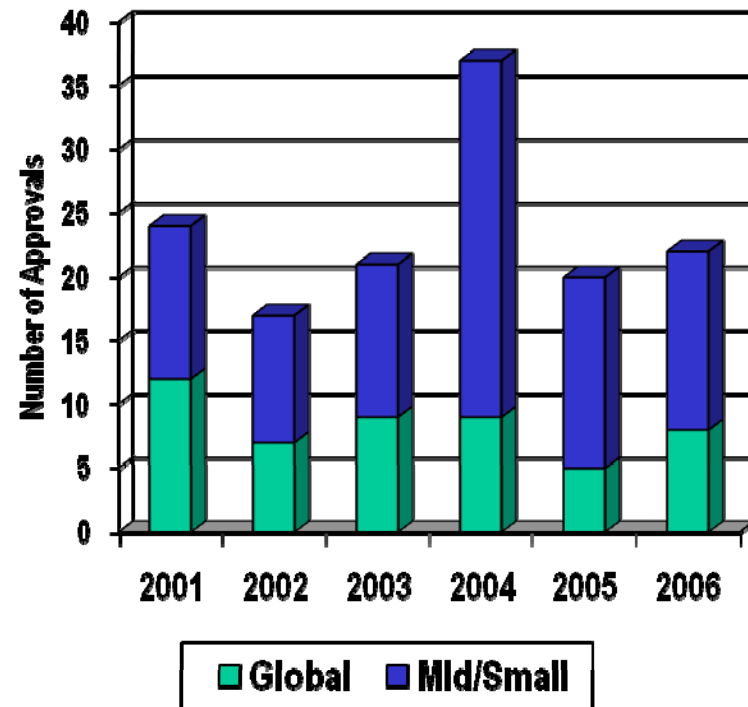


Industry environment

Mid-small bio/pharma = 75+% of pipeline



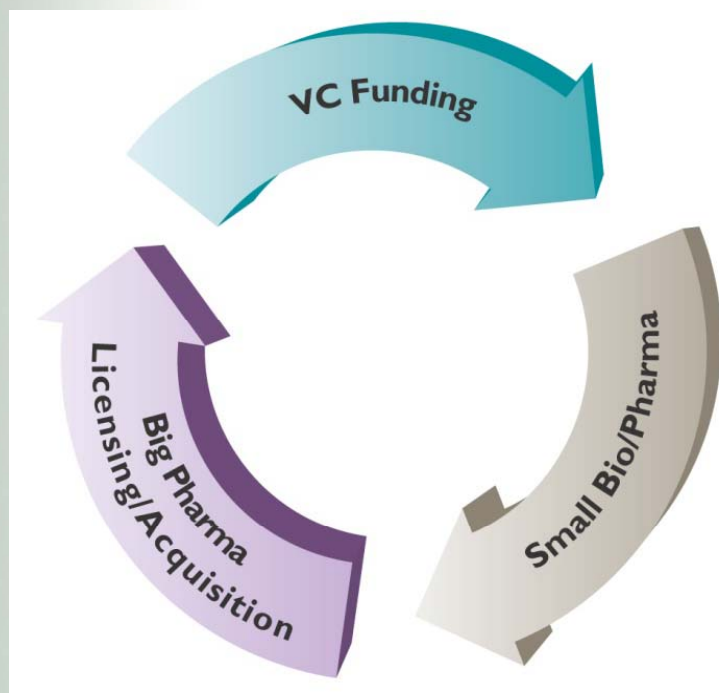
CDER Approvals 2001-2006



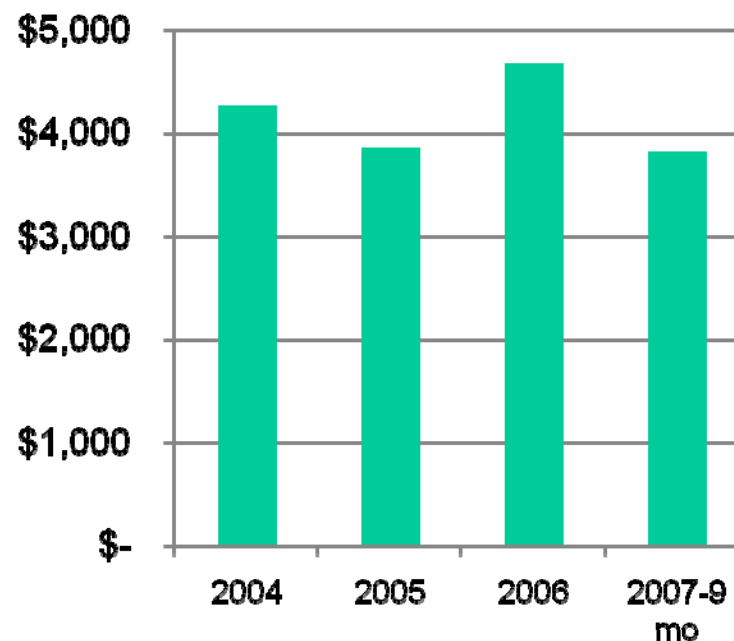
• Source: Pharmaprojects database

Industry environment

Funding cycle has been in high gear



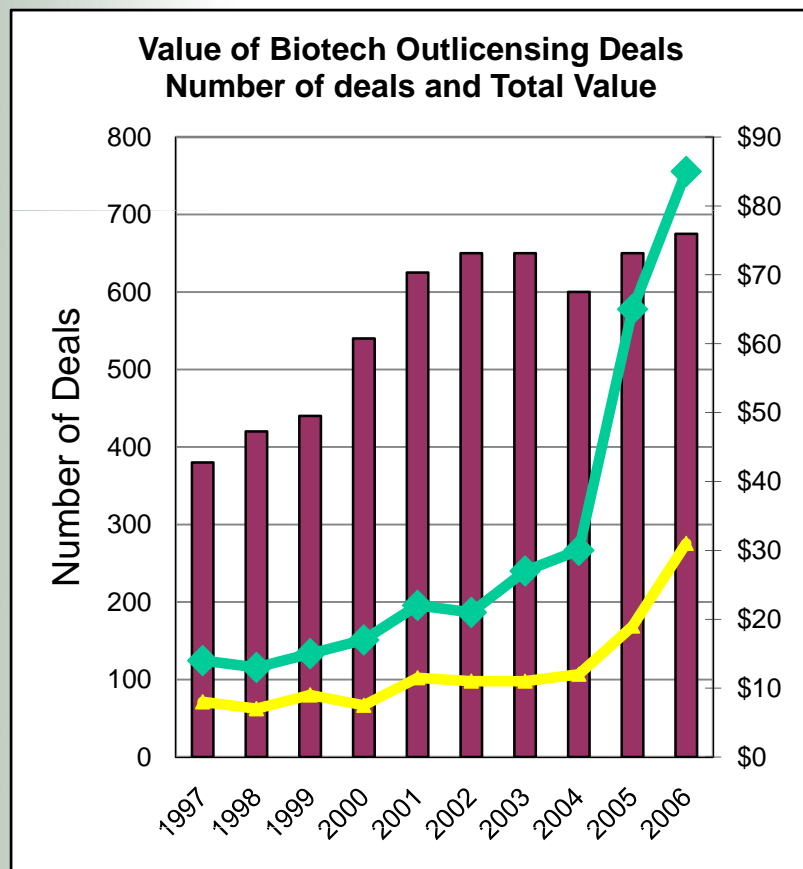
VC Investing in US Biopharma
\$ millions



Will the cycle be unbroken?

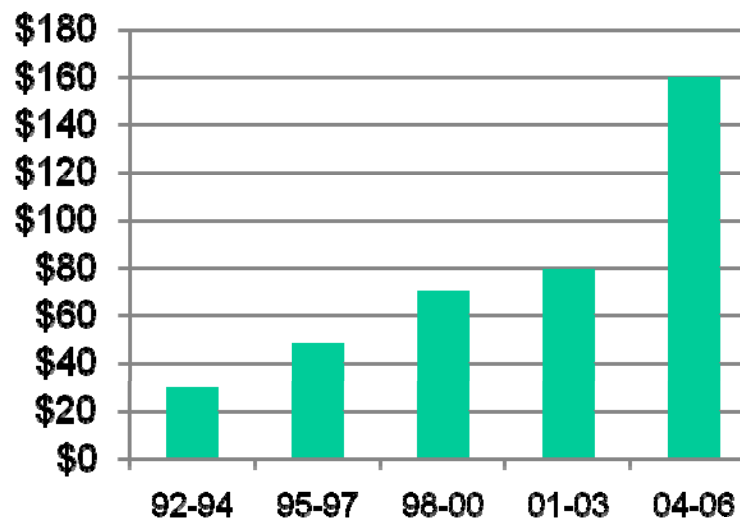
Industry environment

Value of licensing deals is rising rapidly



Average Deal Value for Early Development Candidates

\$ million



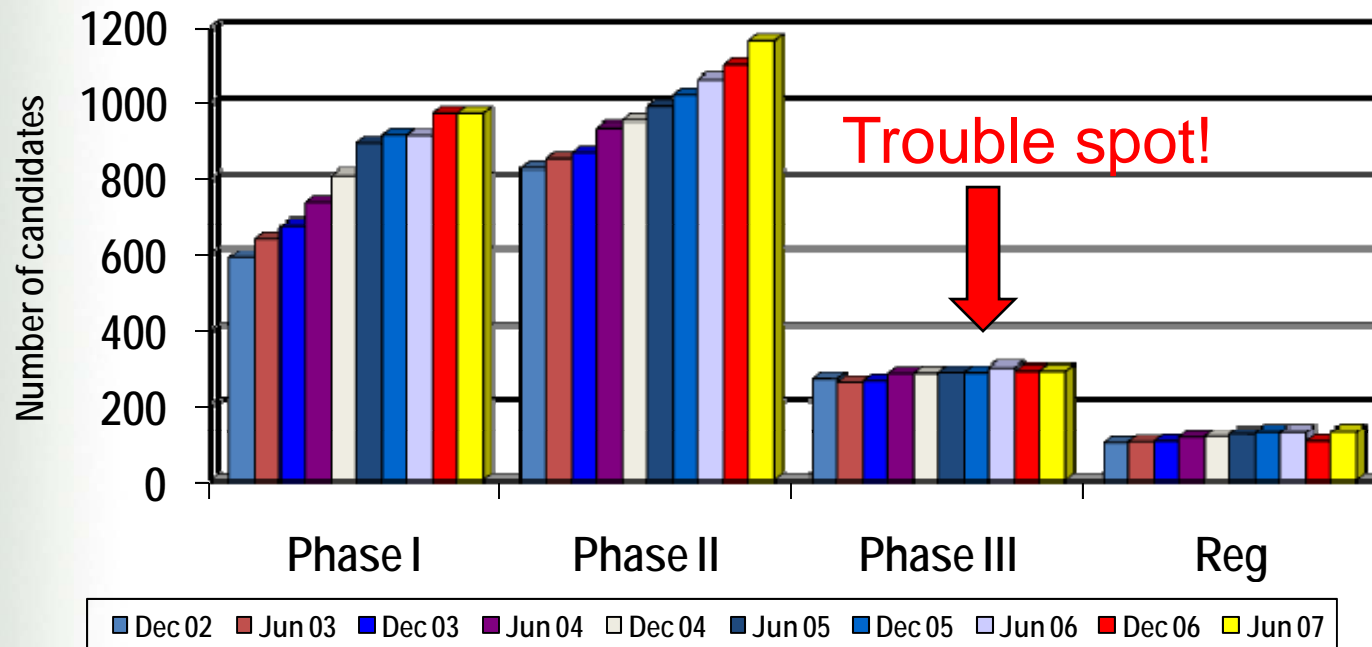
Source: Recap

Industry environment

Early pipeline driving CRO/CMO market

Global Drug Development Pipeline

Source: IMS



Industry environment

Do success rates support investment?

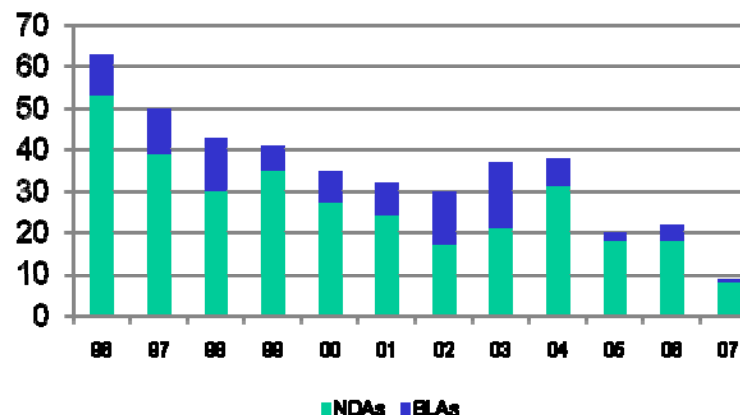
Pipeline Success Rates

	FIM to Approval	Phase 3 to Approval
All candidates (1)	10%	68%
In-house (1)	12%	78%
In-licensed (1)	14%	59%
Oncology (2)	8%	

Sources:

- (1) CMR
- (2) Tufts Center for Study of Drug Development

NME Approvals



Safety and efficacy issues hitting high profile late stage candidates

- Torcetrapib
- Prasugrel
- Merck HIV vaccine

Industry environment

Pipeline composition poses issues

Me-Too Candidates

Indication/Type	Pre-P I	P2 -3
HIV/AIDS vaccine	38	14
Oncology MAbs	255	54
Oncology - small	225	163

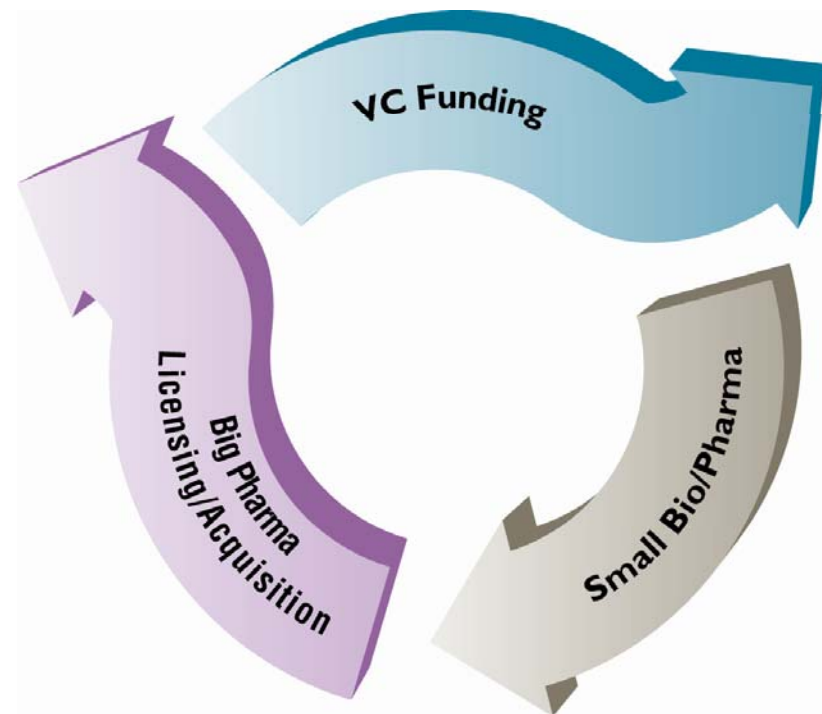
- **Shortage of new targets for MAbs**
- **Everyone chasing oncology**
- **Regulators less open to “no better than” candidates and hard on those with higher risk**

Unproven technologies

- Gene therapy and antisense
- Cell therapy
- Therapeutic vaccines
- Higher potency compounds have greater adverse events

Reasons for caution

- How long will pharma pay big prices for risky candidates that aren't panning out?
- Will VC's continue funding if pharma stop buying?
- Will regulators approve new drugs?
- Will insurers pay for the new drugs?



CMOS & CROs should proceed cautiously

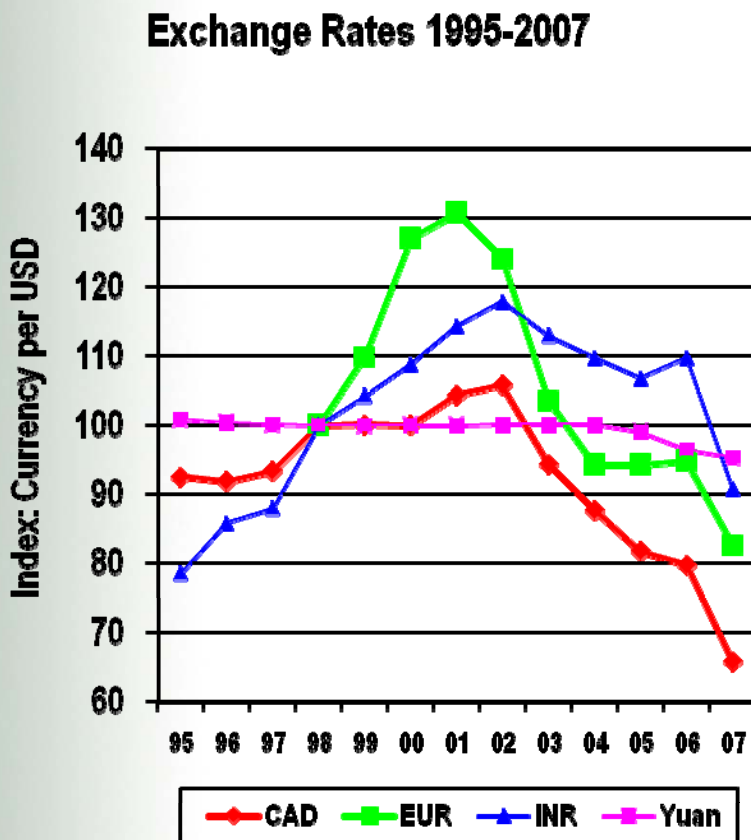
- Careful on new capacity
- Focus on utilization versus price
- Go for market share
- Prepare for the big pharma opportunity

Two more points

- North American providers are in a favorable position
 - Exchange rate making it difficult for Europeans
 - Locus of VC activity and big pharma decision-making
- Asian players starting to sort out
 - Dedicated contract companies versus pharma excess capacity

Market conditions

Dollar devaluation favors U.S. sourcing



- Exchange rates falling sharply and likely to continue
- EU CROs and CMOs looking to U.S. market but less competitive
 - Even Indian suppliers feeling the impact
- Practical implications of importing into EU?
 - Leveraging QP capabilities
- Favors suppliers with global network
 - Ask about creative solutions
 - Lonza, Albany, Dishman, Piramal
 - Patheon, Catalent

LCC Update

Major players coming to the fore

	Contract Revenue	Contract Growth	Contract Share
Jubilant Organosys	\$93.52	54%	60%
Nicholas Piramal	\$86.93	22%	45%
Dishman Chemical	\$35.64	72%	75%
Dr. Reddy's	\$30.48	-29%	9%
WuXi PharmaTech	\$30.24	99%	100%
Biocon	\$18.80	80%	26%
Suven Life Sciences	\$7.07	0%	93%
Shasun Chemicals	\$5.55	115%	17%
Vimta Labs	\$5.09	21%	100%

- Acquisitions impacted Jubilant, NPIL, Dishman
- NPIL , Biocon, Shasun to separate contract and proprietary units
- NPIL moving commercial manufacturing to India, UK for development