The Outlook for Contract Services: Is That Light at the End of the Tunnel?

PharmSource-*Pharmaceutical Technology*

Breakfast at AAPS

November 9, 2009

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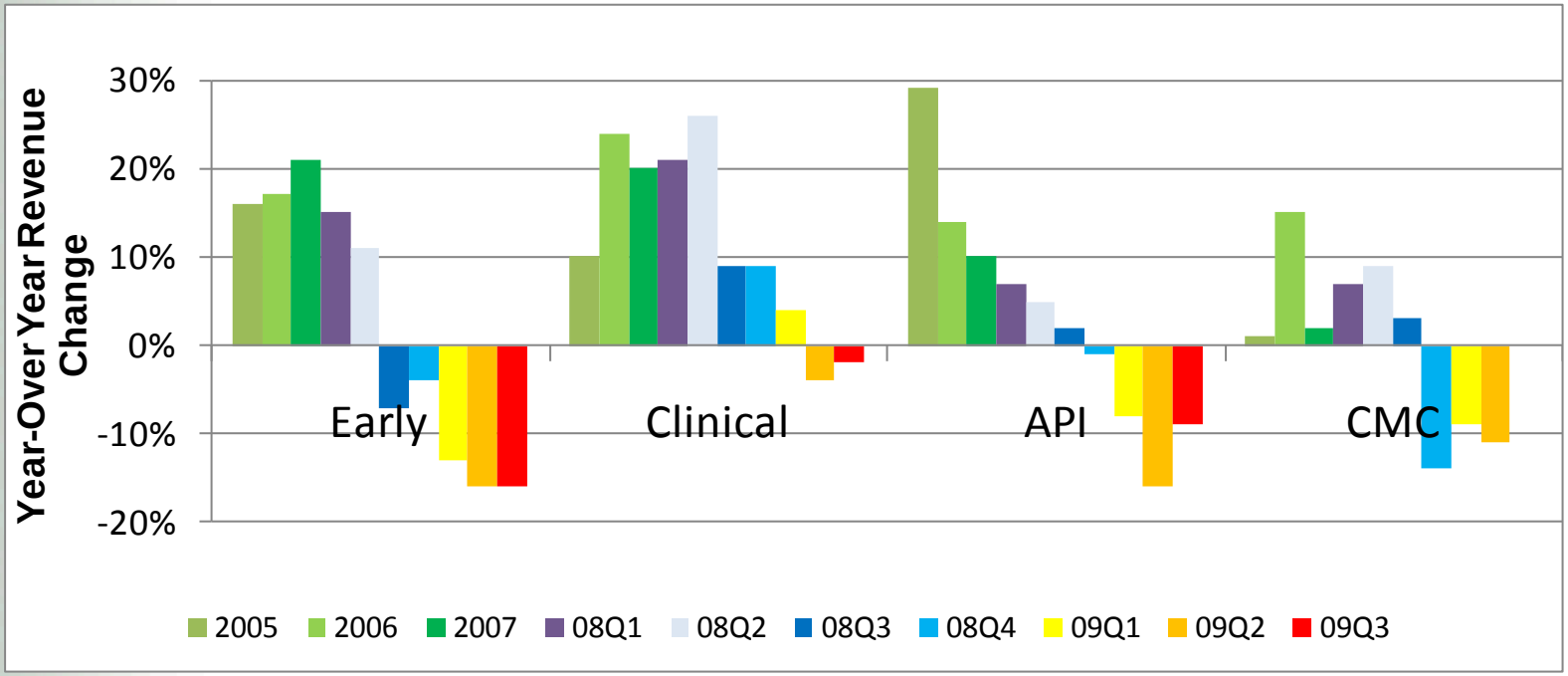
Market conditions

Contractor revenues continue sharp decline



Source: company reports

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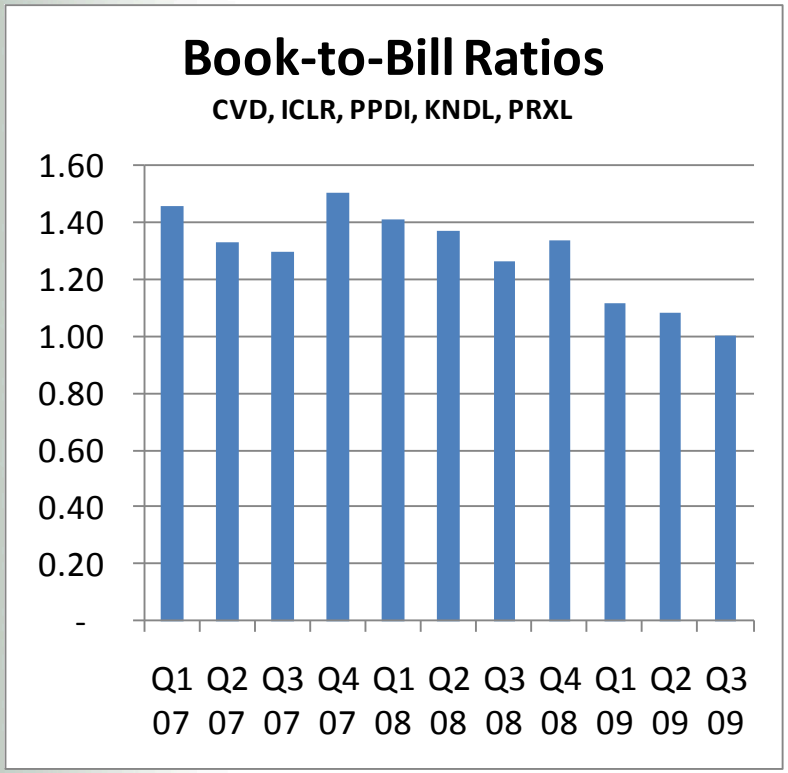
Market conditions

CRO signings down, cancels up



- Book-to-bill decline
  - Higher cancels
  - Delayed decisions
  - Smaller projects
  - Funding shortages
- Previous periods have been worse
  - 99-00: 0!
  - Q2 02: .97
  - Q2 04: .94

Source: company reports, Jefferies & Company

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Market conditions

Outsourced CMC development a $6 billion industry

Total USD millions	Organization Doing the Work			
	Bio/Pharma In-house	CDMO In-house	Contract Lab / CDMO Lab Only	Total
Process/form development	1,177	1,780	-	2,957
Analytical development	659	964	1,406	3,029
CTM manufacture	1,302	2,070	-	3,372
Total	**$ 3,138**	**$ 4,814**	**$ 1,406**	**$ 9,358**
Share of spend	**34%**	**51%**	**15%**	**100%**

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

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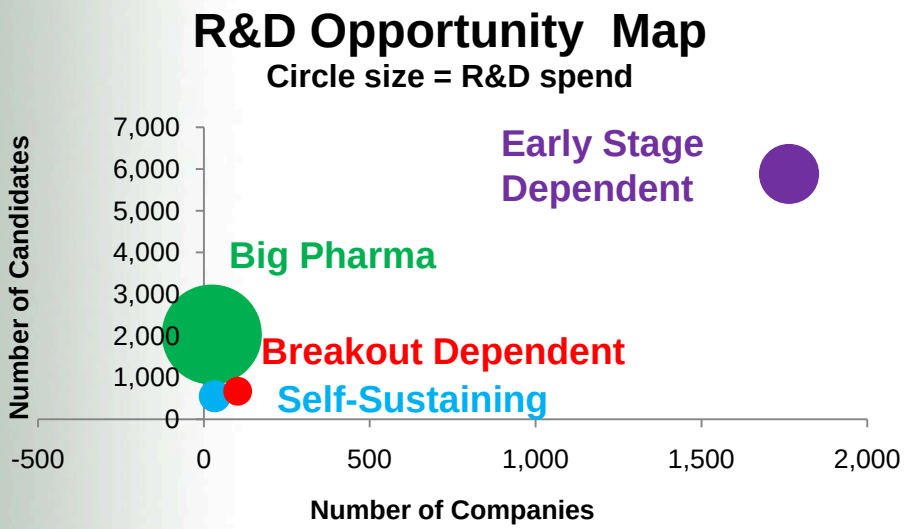
R&D outlook

R&D opportunity highly segmented



Big Pharma: 25 largest bio/pharma
Self-sustaining: revenue-generating, profitable
Breakout dependent: late stage pipeline, need outside financing
Early stage dependent: early pipeline, VC-backed

- 72% of pipeline dependent on outside financing
- <75 companies are self-sustaining
  - 72% of R&D spend
  - 28% of candidates

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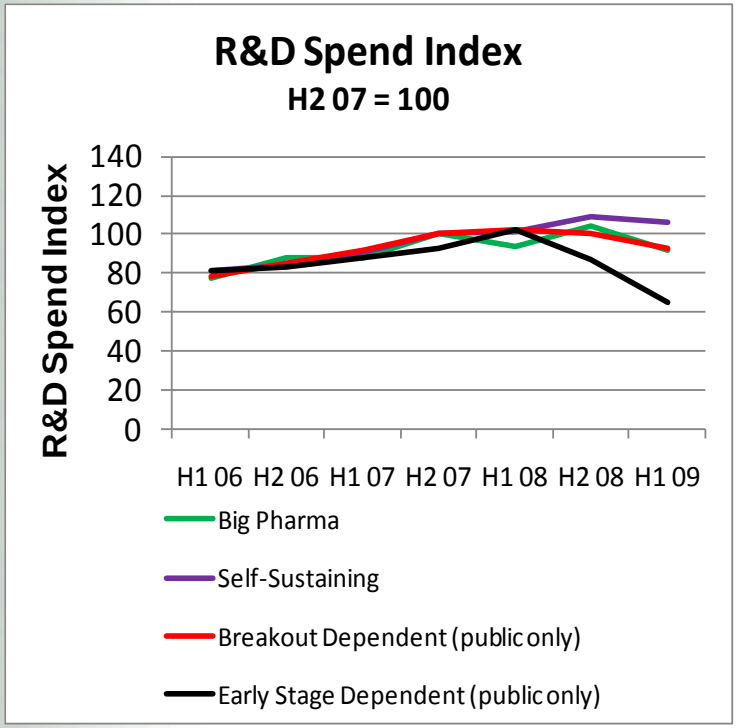
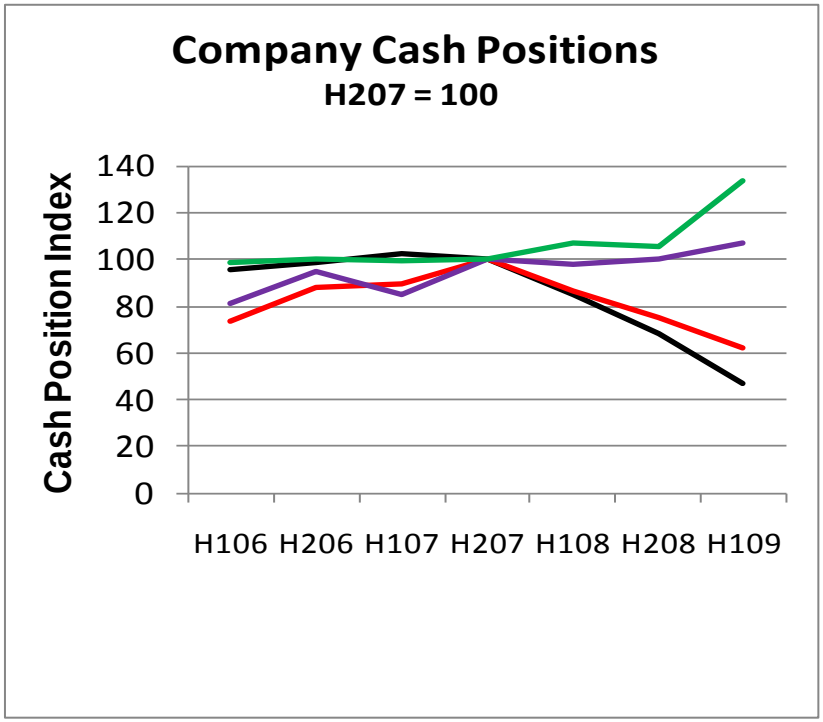
R&D outlook

R&D spending declining





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R&D outlook

Follow the money

2009 YTD	Big Pharma	Self-Sustaining	Breakout Dependent	Early Stage Dependent	Total
VC	$ 0	$ 0	$ 90	$ 2,785	**$ 2,875**
Follow-on	0	500	2,875	2,250	**5,625**
IPO	0	1,065	85	75	**1,225**
Debt	-	1,950	1,380	325	**3,655**
Partnering	32	387	863	1,431	**2,713**
Total	**$ 32**	**$ 3,902**	**$ 5,293**	**$ 6,866**	**$ 16,093**

- Partnering includes known upfront and milestone payments
- IPOs include Talecris (1.065 billion, none to R&D); Omeros; Cumberland
- Excludes $80.4 billion debt raised by Big Pharma

Source: PharmSource Lead Sheet

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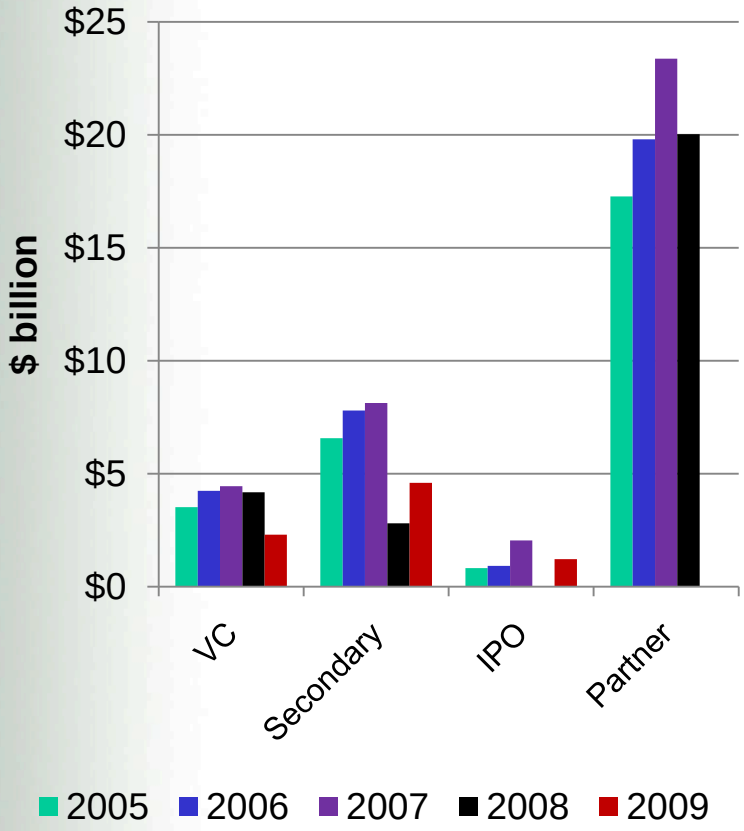
R&D outlook

Follow the money (2)



- Sources for early stage dependents still down
  - VC off sharply, some recovery in Q2/3
  - IPOs still difficult
- Follow-on funding bouncing back
- Partnering terms tougher
  - Less cash up front
  - More of deal depends on milestones, options

Source: PharmSource Lead Sheet

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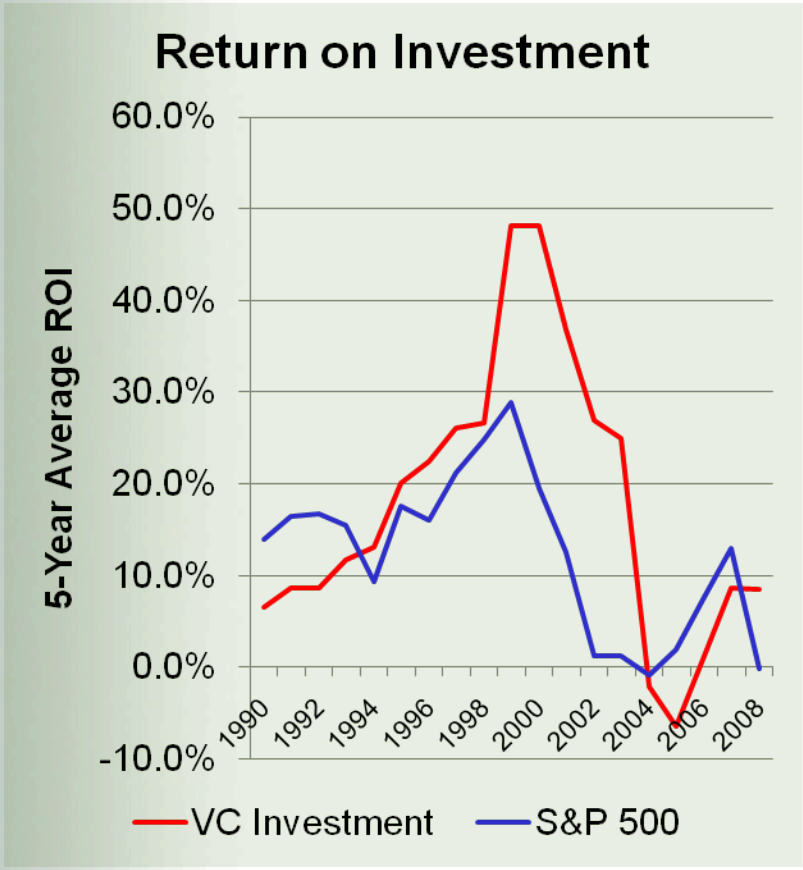
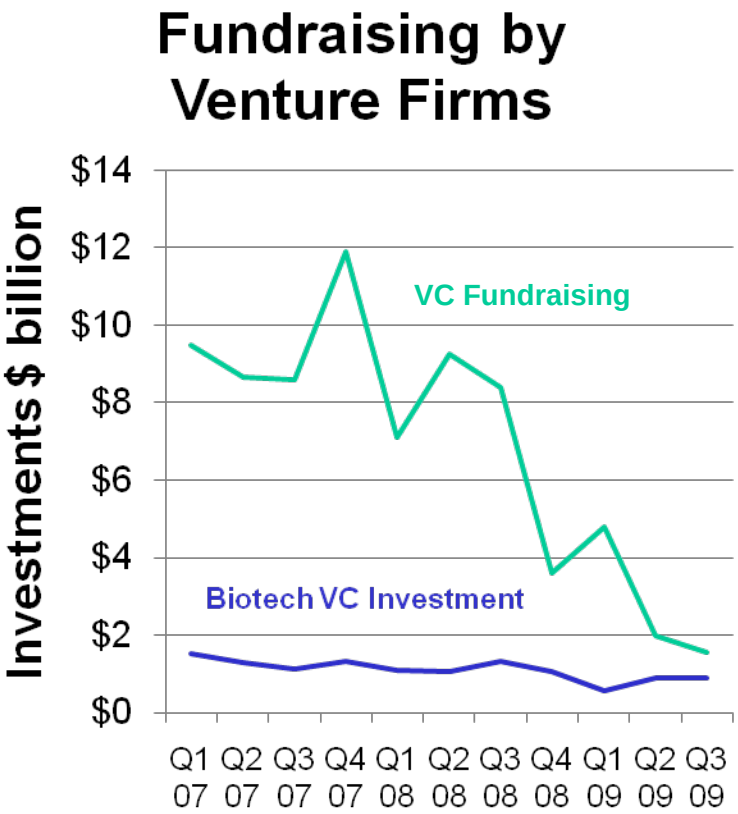
R&D outlook

Early stage dependents face funding shortage





Source: National Venture Capital Association

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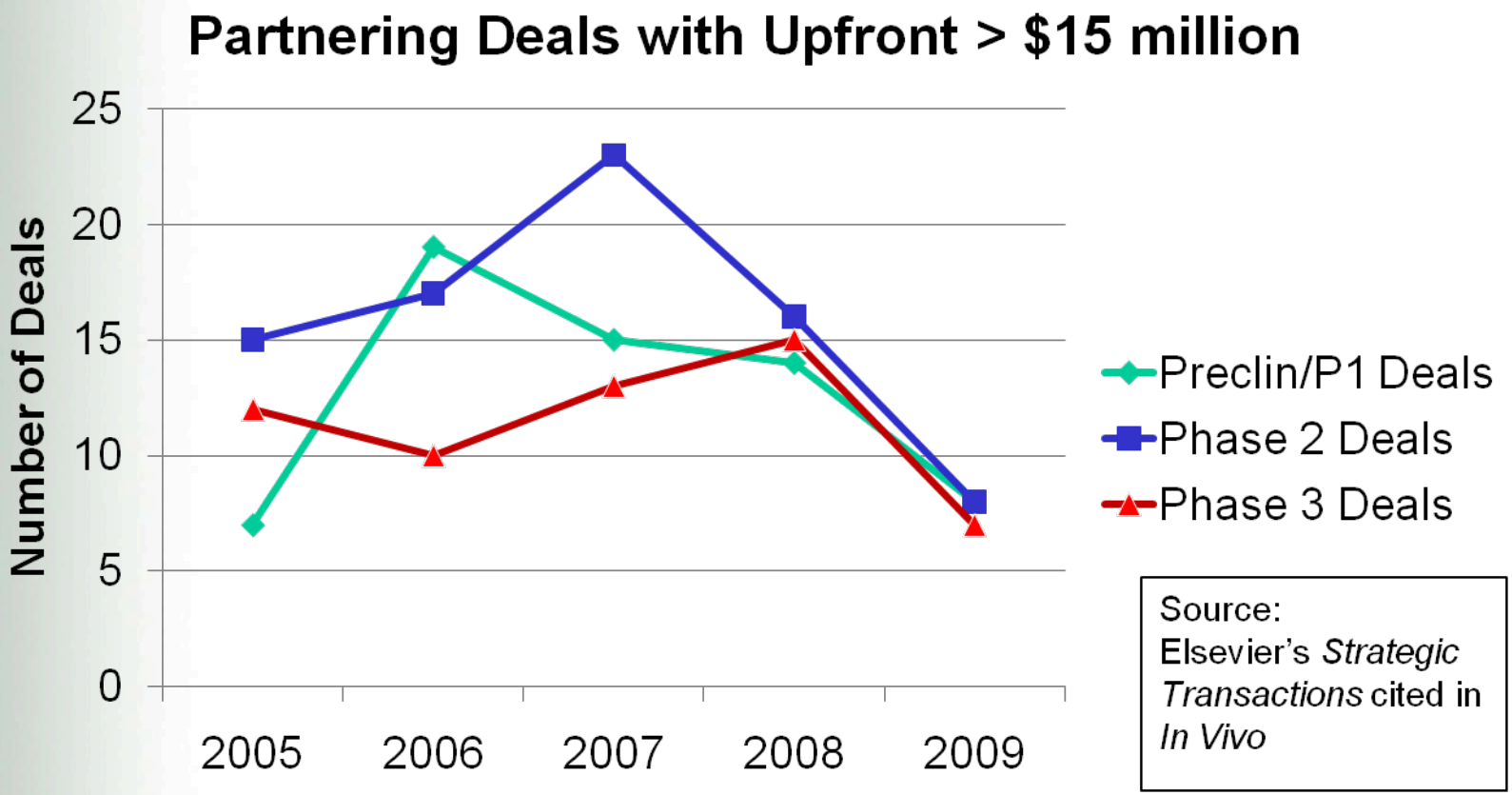
R&D outlook

Partnering deals offer less up front



Source:
Elsevier's *Strategic Transactions* cited in *In Vivo*

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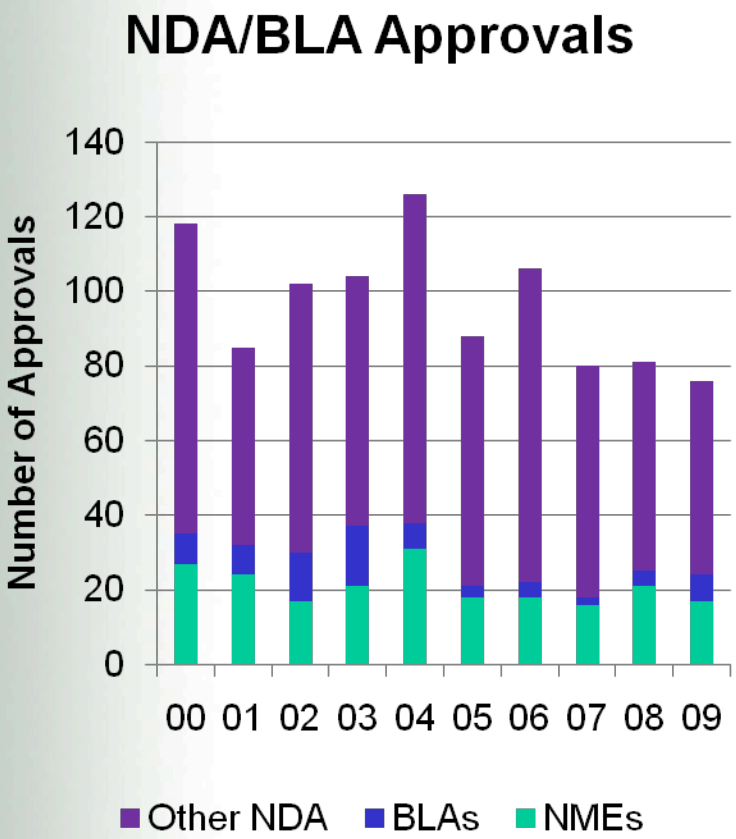
Commercial outlook

Approvals slightly ahead of 2007/8



- Filed NDAs awaiting approval:
  - 107 identified
    - Including. 30 w/CRLs
  - 47 known dose CMOs
  - 39 known API CMOs

Source:
PharmSource Market Intelligence Service

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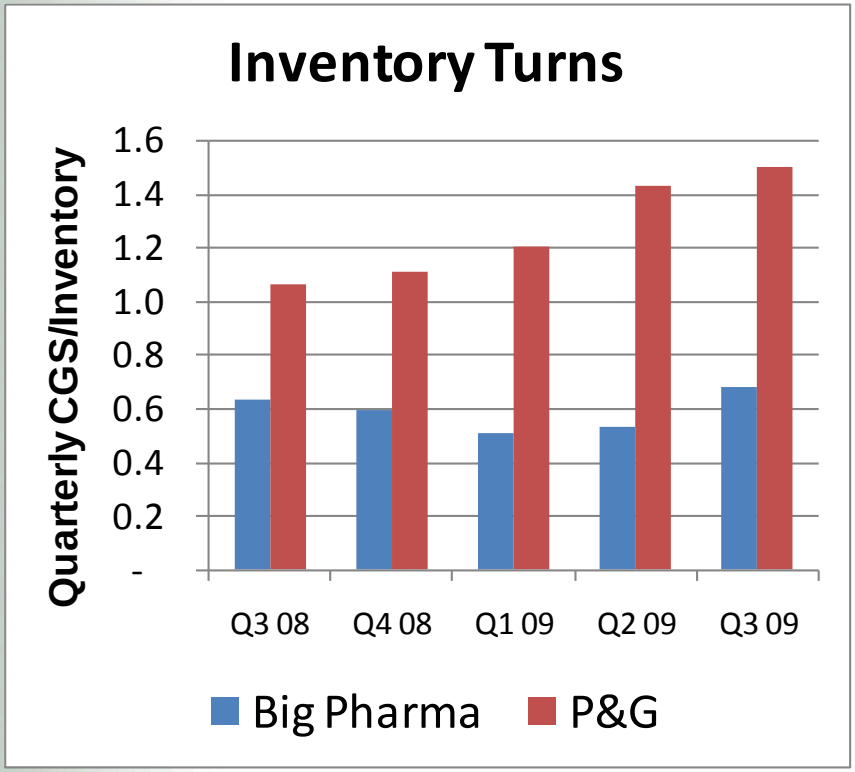
Commercial outlook

CMO order volatility to continue



- Managing working capital to free cash
- Big Pharma still has a ways to go
  - 20-50% reduction in inventory still possible
  - Flat/declining sales worsen problem
- Lonza: "This environment of high volatility is expected to continue for the next few years."

Source: company reports

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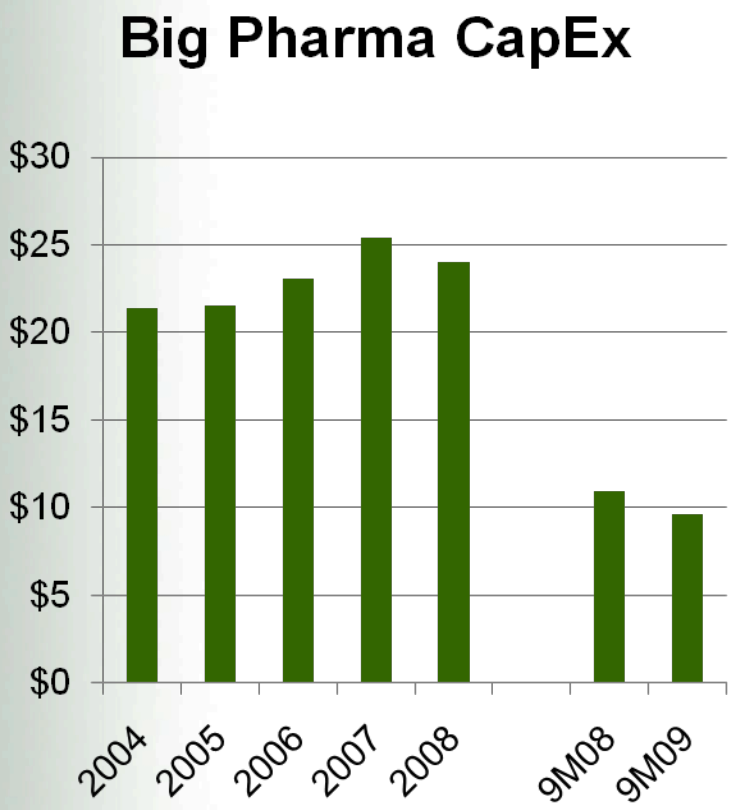
Commercial outlook

CapEx slowing down somewhat



- Down 12% YTD
- Big Pharma continues to invest in strategic manufacturing
  - Vaccines
  - Biologics

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Industry transition dampens 2010 outlook

R&D

- Funding uncertainties continue to hurt early development
- Late development flat to slow growth
- Public CROs expect improvement by Q2 10
- More Big Pharma CMC outsourcing
  - Preferred provider opportunities

Commercial Manufacturing

- Continued volatility as clients adjust operating and financial management
- Positive bump from NDA approvals
- Some opportunity from post-merger restructuring
- More competition from Big Pharma excess capacity

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Managing in uncertain environment

- Embrace uncertainty
  - Scenarios and contingency plans
  - Not static forecasts and budgets
- Fight for market share
  - Increase business development/sales
  - Position as Big Pharma preferred provider
  - Strengthen service offerings
  - Accept you may have to compete on price
- Figure out emerging market opportunity
  - China pharma market to grow 20% p.a. (IMS)

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