Do Financial Markets Support Innovation or Inequity in the Biotech Drug Development Process?

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Introduction

Table 1. Publicly-listed biotechnology companies, by geographic region, 2009

	Global	USA	Europe	Canada
Public company data				
Revenue, US$b	79.1	56.6	16.6	2.2
R&D expense, US$b	22.6	17.2	4.7	0.4
Net income (loss), US$b	3.7	3.7	(0.4)	(0.1)
Number of employees	176,210	109,100	49,120	6,930
Number of companies				
Public companies	622	313	171	64
Private companies	na	1,386	1,619	260

Source: Ernst & Young, *Beyond Borders: Global Biotechnology Report, 2010*

Being public: A US phenomenon

Introduction

Table 2. Public biotech companies in USA and Europe, average per company revenues, R&D expenses, net income, and employees, 2001-2009

	2001	2002	2003	2004	2005	2006	2007	2008	2009
USA									
Revenue, US$m	71.3	95.2	114.2	129.5	145.3	165.1	219.6	177.9	180.8
R&D expense, US$m	33.4	51.2	43.2	47.6	48.6	68.1	82.4	61.8	55.0
Net income, US$m	-14.2	-30.6	-10.3	-13.1	-6.5	-10.3	-7.0	1.1	11.8
Employees	368	449	465	416	na	389	349	329	349
EUROPE									
Revenue, US$m	72.4	81.0	77.8	78.9	80.2	73.6	71.5	85.8	97.1
R&D expense, US$m	40.8	48.9	44.1	42.4	26.8	23.3	25.2	26.9	27.5
Net income, US$m	-5.8	-27.1	-5.7	-4.9	-15.9	-7.2	-9.3	-7.1	-2.4
Employees	329	327	338	262	na	255	264	271	287

Source: Ernst & Young, *Beyond Borders: Global Biotechnology Report, 2010*

Europe < US on average

Introduction

Table 3. Sources of investment capital for US and European biotech companies, 2001-2009

	2001	2002	2003	2004	2005	2006	2007	2008	2009
USA									
Venture capital, US$m	2,392	2,164	2,826	3,551	3,328	3,302	5,464	4,445	4,556
Initial public offering, US$m	208	456	448	1,618	626	944	1,238	6	697
Follow-on and other, US$m	5,330	6,080	11,131	11,810	10,740	16,067	14,689	8,547	12,782
EUROPE									
Venture capital, US$m	1,374	1,155	3,551	1,447	1,738	1,907	1,604	1,369	1,102
Initial public offering, US$m	175	26	0	359	691	907	1,010	111	144
Follow-on and other, US$m	723	108	1,602	1,596	1,577	3,069	4,880	1,115	2,771
Ratio EUROPE:USA									
Venture capital	0.57	0.53	1.26	0.41	0.52	0.58	0.29	0.31	0,24
Initial public offering	0.84	0.06	0.00	0.22	1.10	0.96	0.82	18.50	0,21
Follow-on and other	0.14	0.02	0.14	0.14	0.15	0.19	0.33	0.13	0,22

Source: Ernst & Young, *Beyond Borders: Global Biotechnology Report, 2010*

US >> Europe

Introduction

Why has so much money flowed into an industry with such a long history of unprofitability?

Solution to this “Pisano puzzle”:

A combination of government funding and the speculative stock market

Lazonick and Tulum (2009)

Introduction

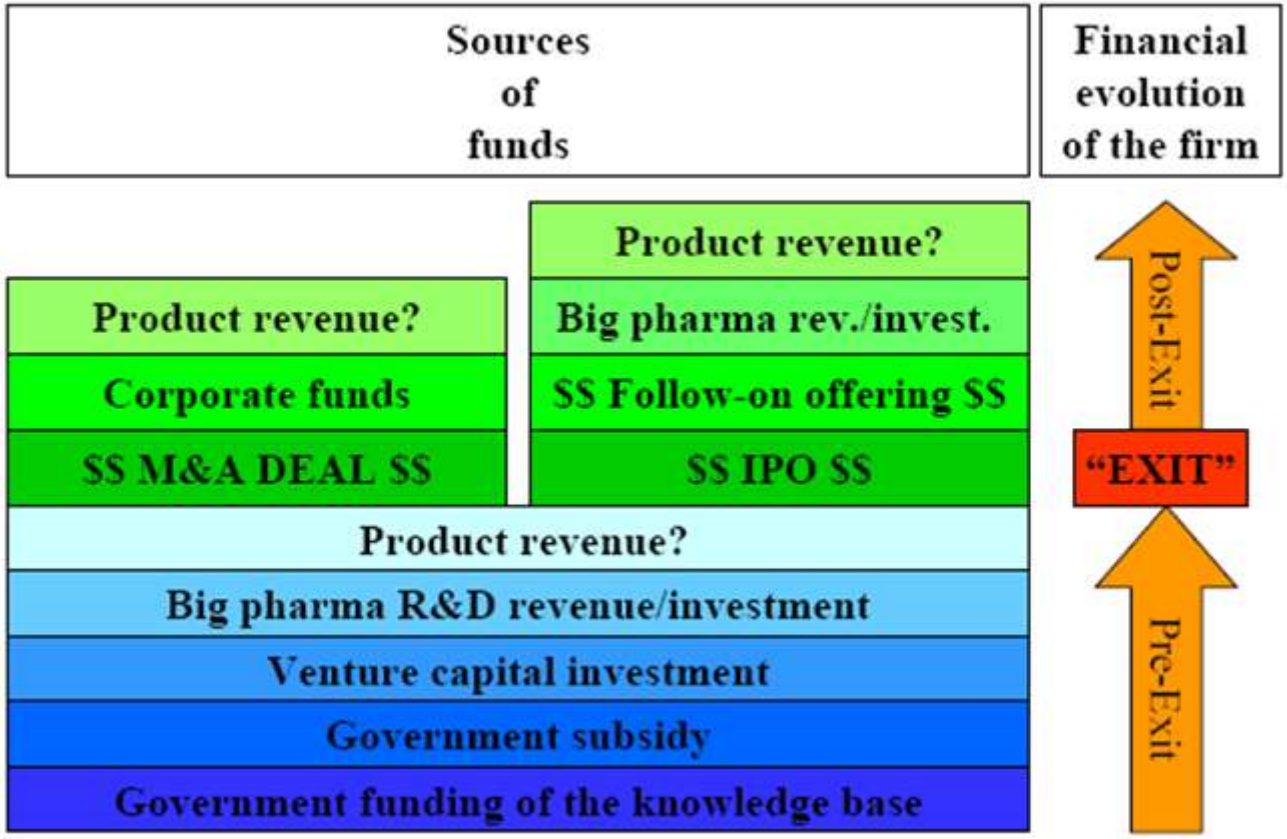
- How important have the government-funded knowledge base and government subsidies been in financing the drug development process?
- To what extent has the equity finance that has flowed into the biotech industry actually funded drug development?
- If this equity finance did not fund innovation, then how was it used and where did it go? Put differently, what is the relation between value creation and value extraction in a biopharmaceutical firm?

Methodology

- To develop a model of the phenomenon that captures the essence of the real-world experience of biopharmaceutical companies
- To understand the financial evolution of the firm – that is, its sources and uses of funds
- To understand the impacts of this financial evolution on value creation and value extraction
- To understand the dynamics of value creation/extraction for the sake of building databases for industry studies and policy analyses

Methodology

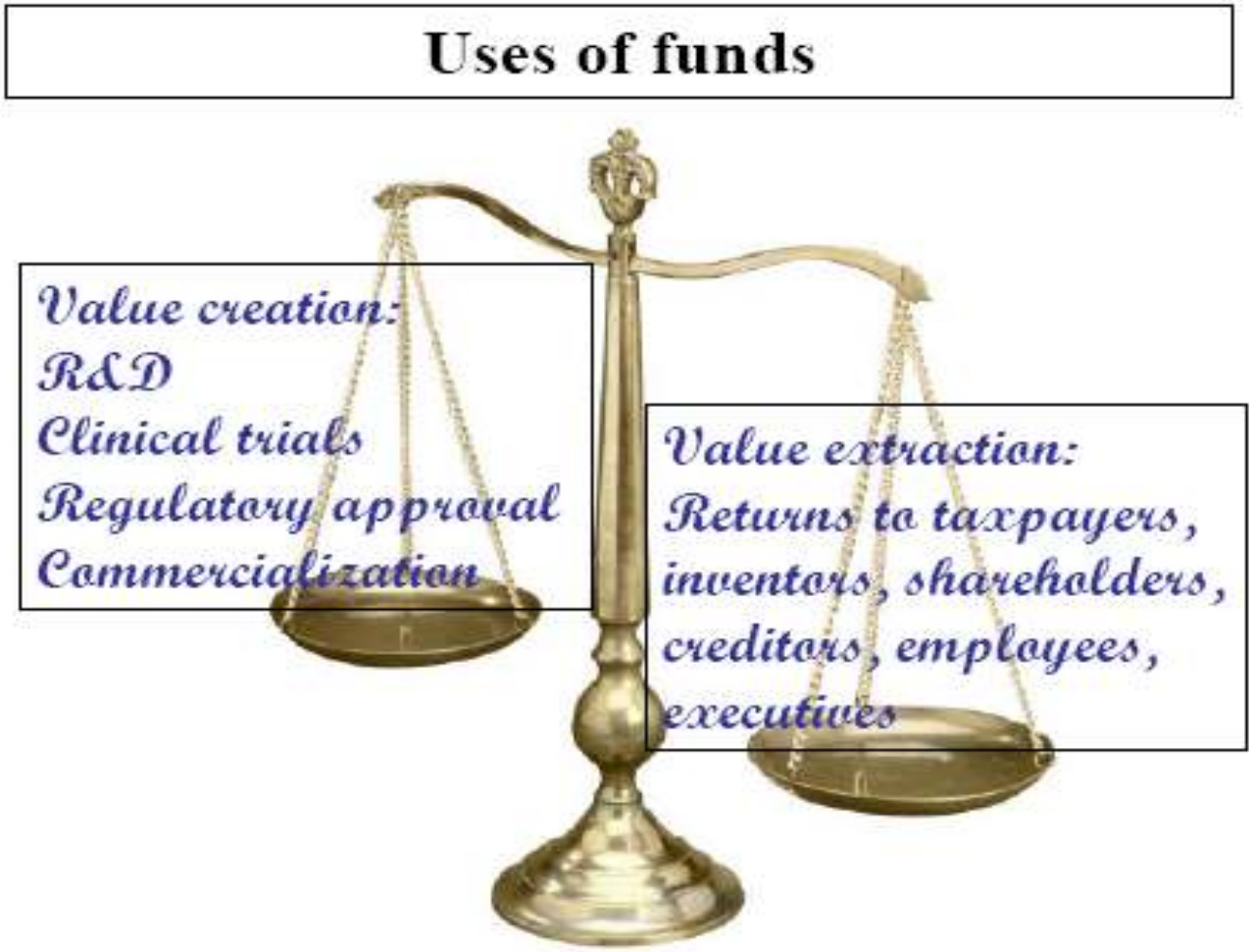
Figure 1. The financial evolution of the firm in terms of the sources of funds



Source: Adapted from Lazonick and Tulum 2009

Methodology

Figure 2. The financial evolution of the firm in terms of the uses of funds

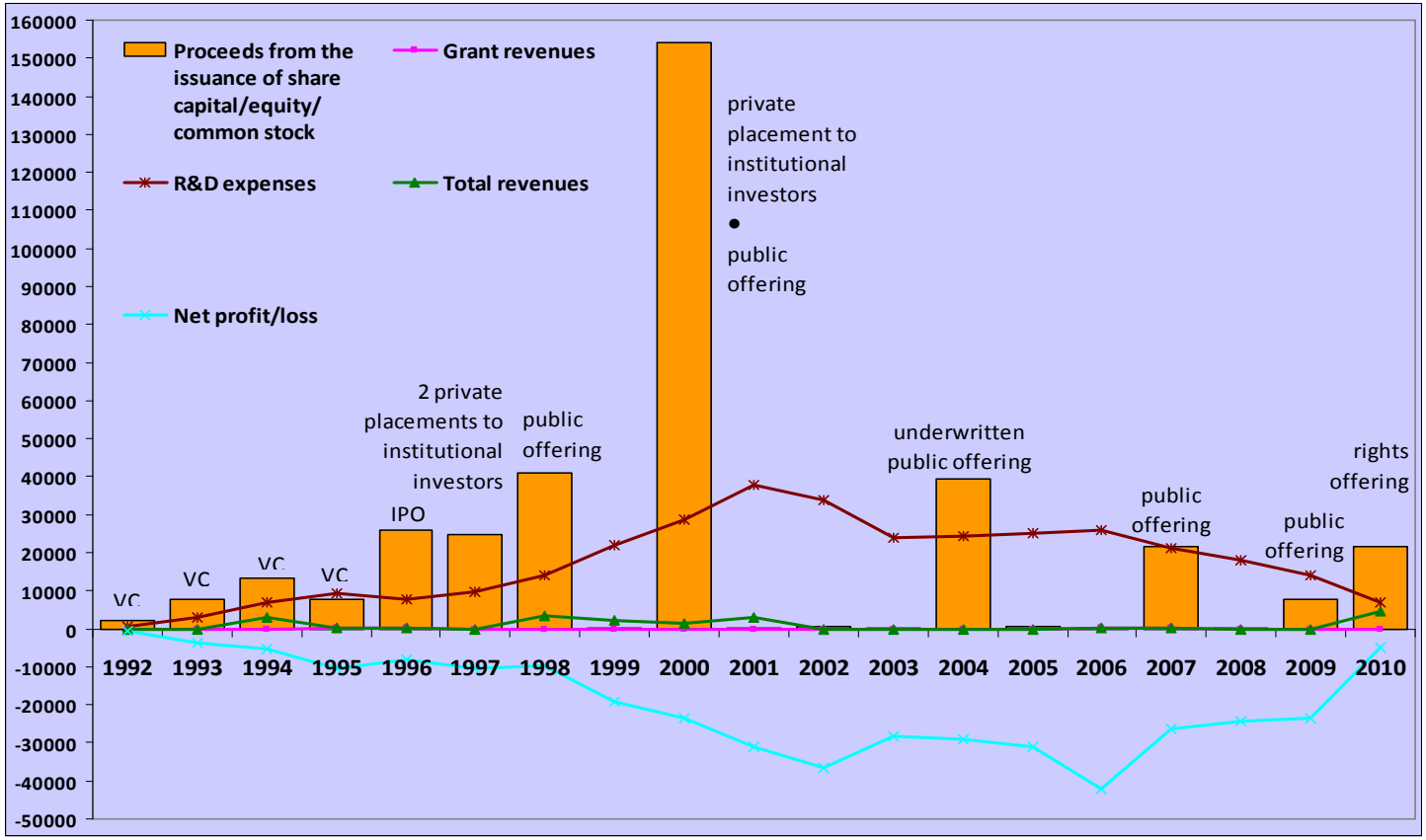


Case Study #1: Pharmacyclics

- Founded in Sunnyvale CA in 1991
- Raised $25.8 million in IPO in 1995 while the most advanced drug candidate was in its Phase I/II clinical trials
- The candidate reached Phase III in 1998

Case Study #1: Pharmacyclics

Figure 3. Pharmacyclics finance and revenue recognition/expense, June 1991-December 2009



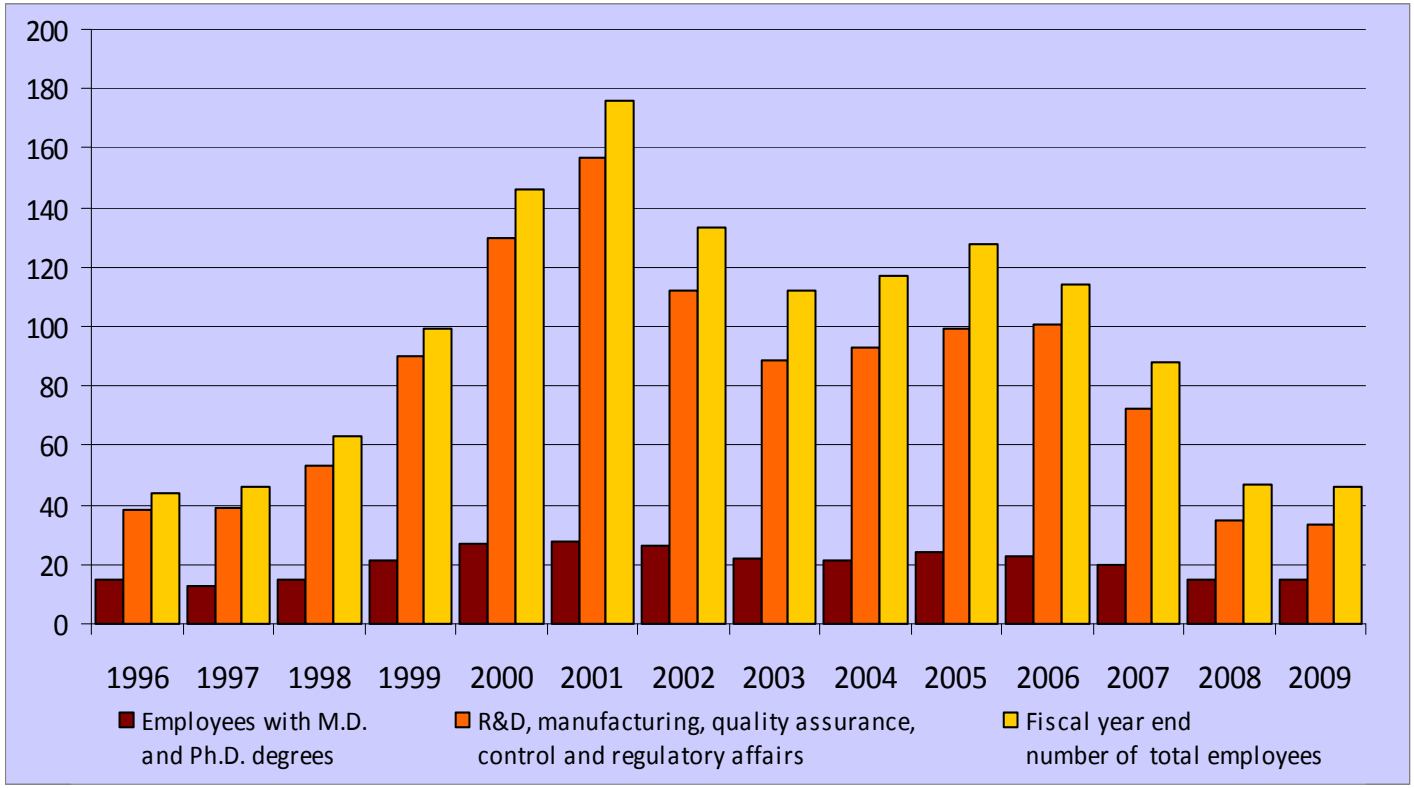
Fiscal years end June 30th. 2010 values consist only of six months between July and December 2009. US$ thousands

Case Study #1: Pharmacyclics

- Formation over in-licenses from UT
- Critical support of NCI
- Unsophisticated partnership structure
- Highly fluctuated ownership structure
- Moderate turnover of executives
- Utilization of stock options as a form of compensation exceptionally
- Rise and fall of employment

Case Study #1: Pharmacyclics

Figure 4. Pharmacyclics employment, 1996-2009



Case Study #1: Pharmacyclics

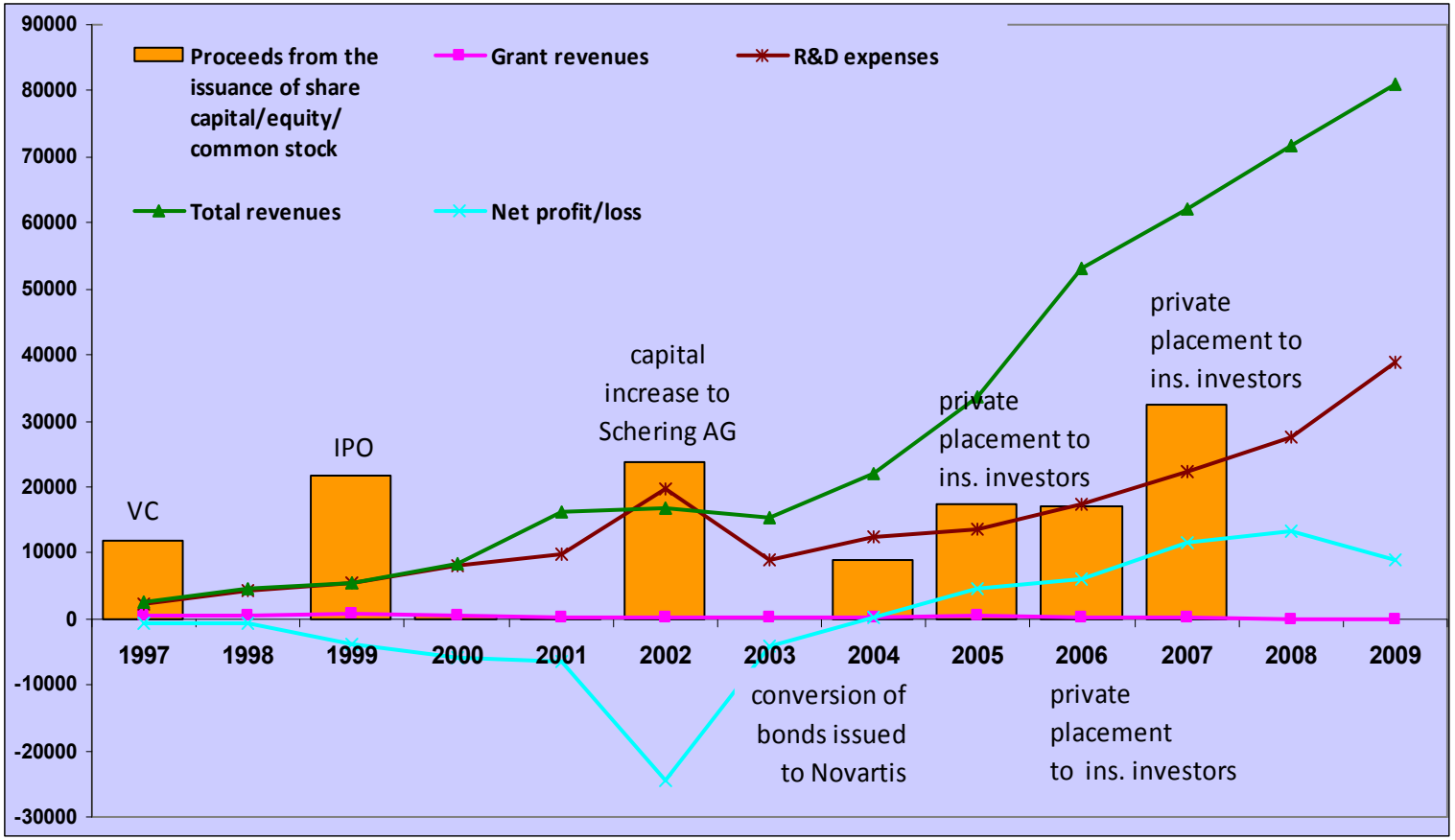
- FDA rejections
- Continuing NCI support
- Restructuring in 2009
- Lifesaver partnership in 2009
- NASDAQ notification

Case Study #2: MorphoSys

- Founded in Martinsried near Munich in 1992
- Raised €25.8 million in IPO in 1999 without any drug candidate in clinical trials
- The first drug candidate reached Phase I in 2005

Case Study #2: MorphoSys

Figure 5. MorphoSys finance and revenue recognition/expense, 1997-2009, € thousands

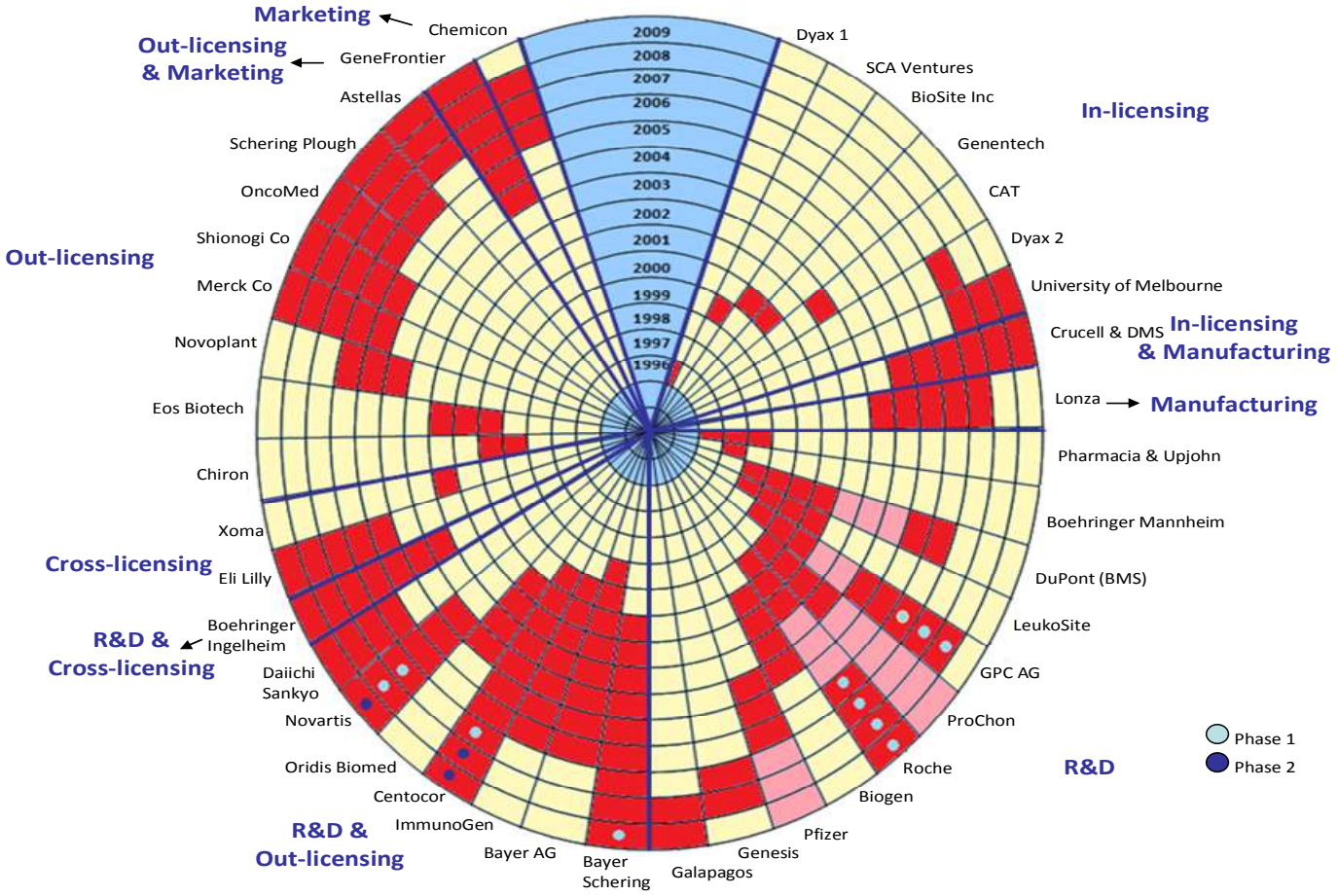


Case Study #2: MorphoSys

- Resolution of patent dispute with Cambridge Antibody Technology in 2002
- Two major acquisitions in 2005 and 2006
- Substantial change in ownership since 1992
- Continuous increase in workforce
- Very stable executive committee
- Rising stock option exercises along stable stock price after 2004
- Vivid partnership activity

Case Study #2: MorphoSys

Figure 6. MorphoSys Partnerships, 1996-2009



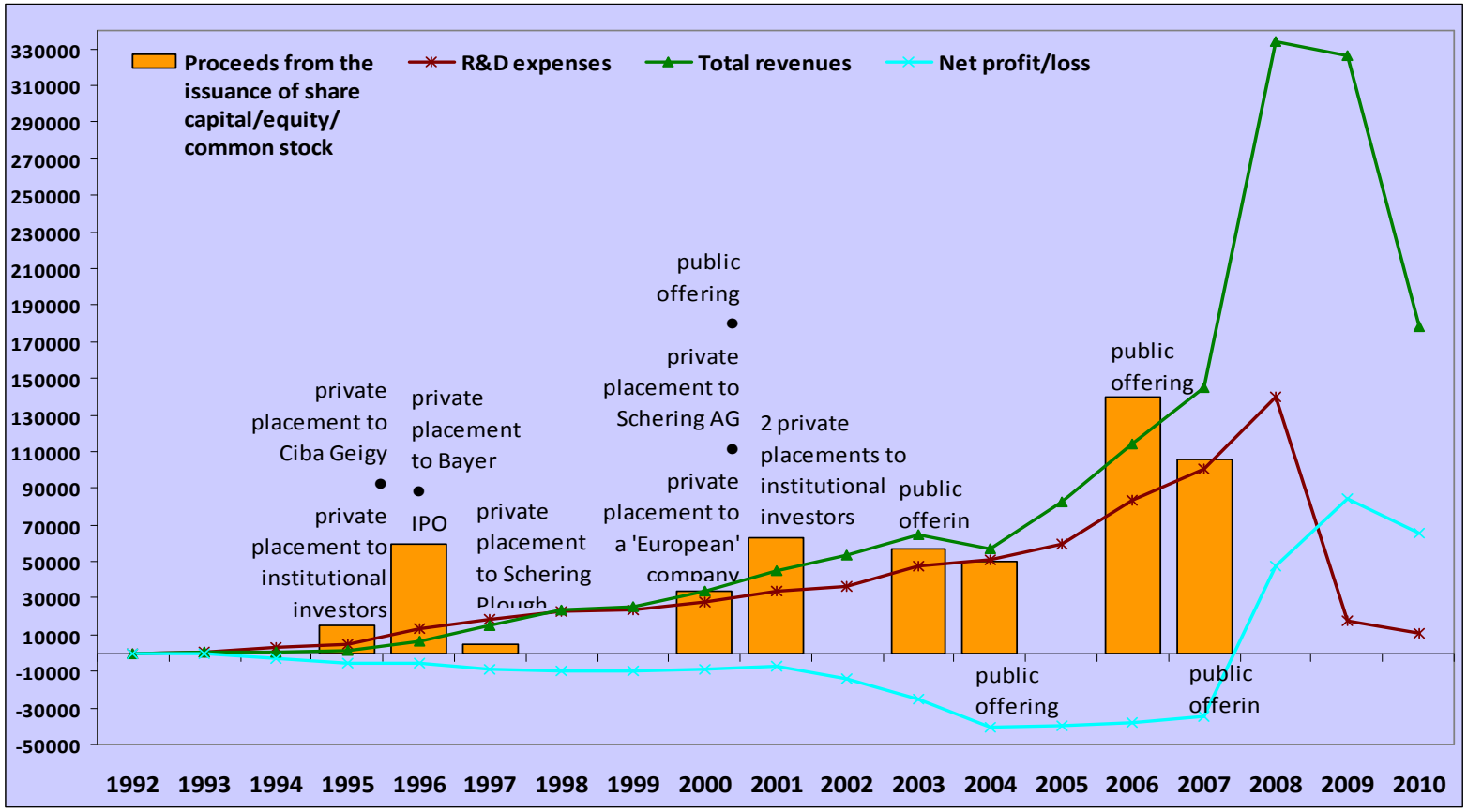
Red and pink areas indicate active and dormant years of collaboration respectively. Yellow areas indicate non-collaborative years.

Case Study #3: Myriad Genetics

- Founded in Salt Lake City UT in 1991
- Raised $49 million in IPO in 1995 without any product
- The launch of first product in 1997
- First drug candidate (in-licensed) reached Phase II in 2001

Case Study #3: Myriad Genetics

Figure 7. Myriad Genetics finance and revenue recognition/expense, June 1991-December 2009



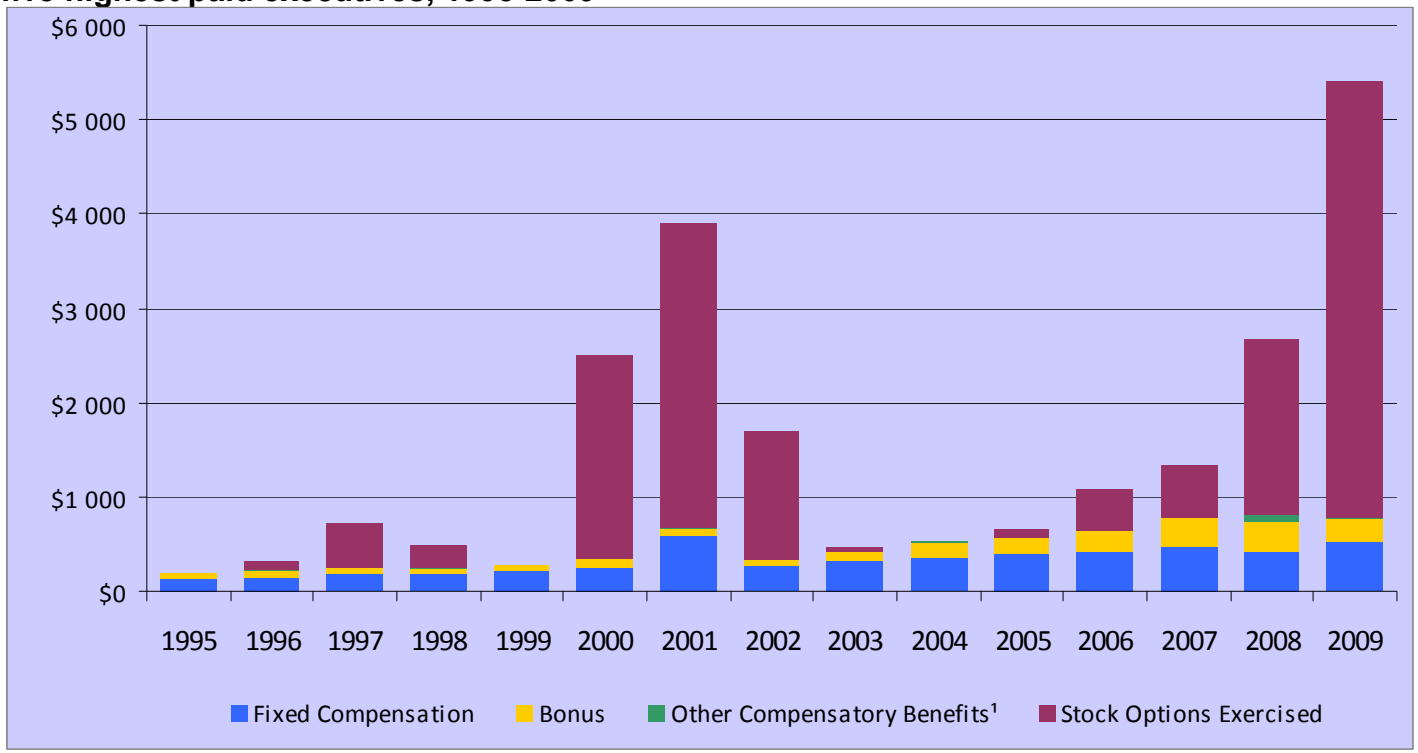
Fiscal years end June 30th. 2010 values consist only of six months between July and December 2009. US$ thousands

Case Study #3: Myriad Genetics

- Quest for patents
- Attraction for investors
- Remarkable growth of workforce
- Moderate turnover in the executive committee
- Stock options and bonuses
- High volume stock trade

Case Study #3: Myriad Genetics

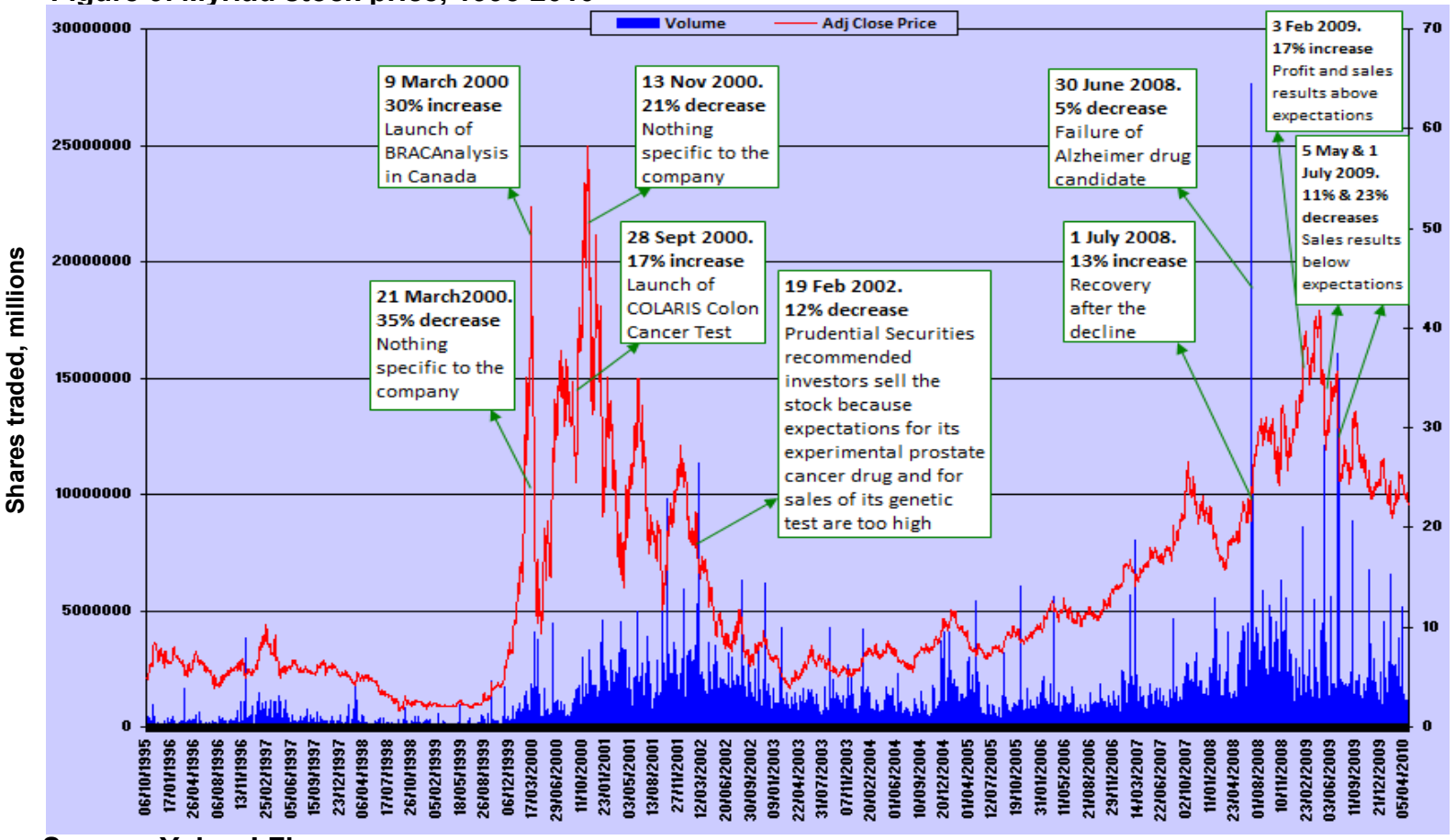
Figure 8. Myriad Genetics, average total compensation and it components, five highest paid executives, 1995-2009



Top three in 1995, top four in 1996 and 1997 and top six in 2008. Numbers are in thousands
¹Include life insurance payments, 401(k) contributions, and a payment with respect to a resignation agreement for 2008

Case Study #3: Myriad Genetics

Figure 9. Myriad stock price, 1995-2010



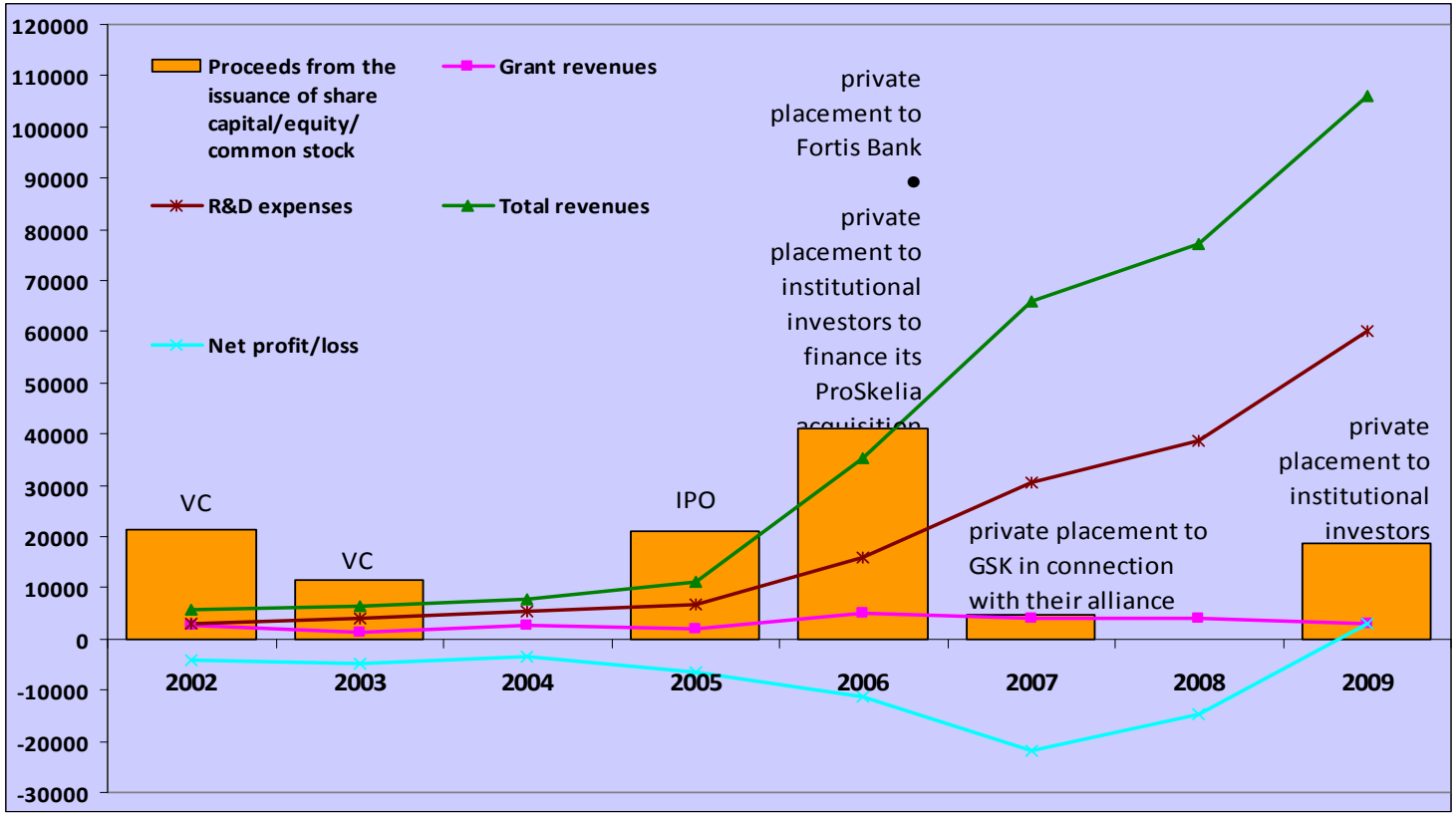
Source: Yahoo! Finance

Case Study #4: Galapagos

- Founded in Mechelen, Belgium in 1999
- Adopted a hybrid business model
- Raised €22.4 million in IPO in 2005 without any product
- The first drug candidate (in-licensed) reached Phase II in 2006

Case Study #4: Galapagos

Figure 10. Galapagos finance and revenue recognition/expense, 2002-2009, € thousands

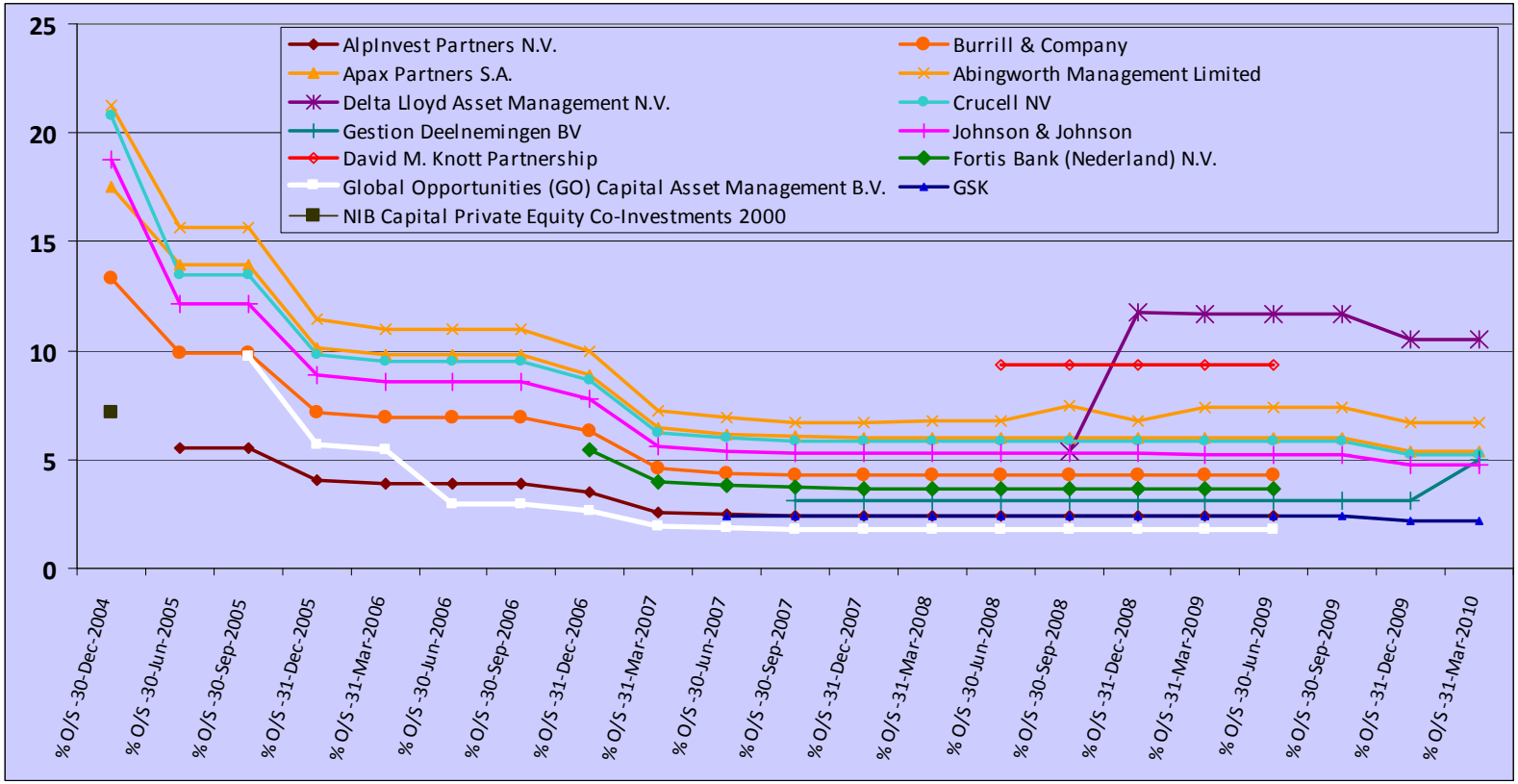


Case Study #4: Galapagos

- Rapid acquisitions after IPO
- Cooperation with governmental organizations
- Complex partnership structure
- Workforce growth after acquisitions
- Utilization of stock options
- Very stable ownership structure

Case Study #4: Galapagos

Figure 11. Ownership of more than 3 percent of Galapagos shares, December 2004-March 2010



Source: Thomson Reuters and company reports

Preliminary Findings

- Equity investors view biopharmaceutical companies as sources of speculative gains. Especially after the IPO, there is a strong tendency toward value extraction even for companies that still require years to reap the fruits of their research
- Different firms pursue different financial strategies in the face of varying alternative sources of finance
- Access to government funding is critical for companies to develop their proprietary technology. This funding may take the form of research grants to founders through universities or direct grants to the company

Preliminary Findings

- The content of proprietary technology, therapeutic research area, and/or coverage of patents also has a major impact on the development of the company's financial strategy
- Whatever a company's business and financial strategy, compensation through the exercise of stock options becomes important to executives and employees after the IPO, with short-term stock-price fluctuations providing them with windows of opportunity to reap the gains. This focus on the possibilities for short-term financial gain stands in stark contrast to the inevitably long-term and sustained investments that the companies must make to research and develop innovative products

Further Research

- Detailed analyses of the importance of government funding for the drug development process, including not only the amount and forms of finance (research grants and financial subsidies) but also the extent and form of organizational integration of the publicly-funded knowledge-creation process with product development by the business enterprise
- Detailed analyses of the ways in which short-term financial gains from stock-option exercises may conflict with the long-term financial requirements of product development
- Comparative analyses of partnerships, focusing on the purpose and importance of alliances for the different partners

Further Research

- Detailed mapping of the various scientific and financial contributions to the development of biopharmaceutical products by parties such as scientists, research institutes, early investors, and founders of start-ups to determine the relation of these contributions to the ultimate sharing of the gains from innovative enterprise
- Methodological specification of how to collect information about the drug development process required for this type of research, how to compare and integrate qualitative and quantitative data derived from a variety of sources, and why it is critical to have a dynamic theory of innovative enterprise as an integrative analytical framework

Further Research

Thank you for your attention