

## Bio-pharma: A financialized business model

Tord Andersson  
Pauline Gleadle  
Colin Haslam\*  
Nick Tsitsianis

Tord Andersson, Colin Haslam and Nick Tsistianis  
Centre for Research in Finance and Accounting  
University of Hertfordshire  
Hatfield, UK.

[t.andersson@herts.ac.uk](mailto:t.andersson@herts.ac.uk)  
[c.j.haslam@herts.ac.uk](mailto:c.j.haslam@herts.ac.uk)  
[n.tsitsianis@herts.ac.uk](mailto:n.tsitsianis@herts.ac.uk)

Pauline Gleadle  
Accounting and Finance Research Unit  
Open University  
Milton Keynes  
UK

[M.P.R.Gleadle@open.ac.uk](mailto:M.P.R.Gleadle@open.ac.uk)

Corresponding author  
Colin Haslam  
[c.j.haslam@herts.ac.uk](mailto:c.j.haslam@herts.ac.uk)

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## Abstract

In this paper, we construct a complementary financialized business model of SME bio-pharma that reveals how the product innovation and development process conjoins with speculative forces in capital markets. To conceptualise this descriptive business model we employ three organising elements: *narratives* about pipeline progress that may (or may not) lead to additional funding from equity investors or other investing partners, *capital market conditions* that impact on the supply of funding and market valuations and the *variable motivations of equity investors* who are not in a development marathon but a relay race anxious to pass on ownership and extract higher returns on invested capital through realised market value. Bio-pharmas are, in effect, constituted as investment portfolios of innovations where products in pipeline and firms trade for shareholder value. In this speculative innovation, capital market liquidity business model complementary narratives and favourable capital market conditions are required to keep it all going.

Key Words: bio-pharma, financialization, business model, shareholder value.

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## 1. Introduction

Investment in the creation of knowledge based assets through innovation and a high level of R&D spending is generally viewed as the key to maintaining relative corporate and national competitiveness, often summarised as closing the ‘innovation gap’. The critical literature on financialization is concerned with how the demands of the capital market modify strategic priorities and corporate governance in an era of shareholder value creation where management and shareholder interests align (Froud et al., 2003; Andersson et al., 2007; Lazonick, 2008). This literature exposes tensions and contradictions between the ‘expectation’ that innovation can transform corporate, industry and national economic performance, and ‘outcomes’ that tend to be more disappointing. Lazonick (2008) argues that in a financialized economy the short-run priorities of the capital market hold sway over productive and financial transformation because firms are encouraged to maximize their short-run returns to shareholders rather than re-invest in innovative new product development for future competitiveness. Froud et al., (2006) are concerned with how, in a financialized economy, the role of management becomes that of structuring narratives that flatter the outcomes of R&D spending to maintain the confidence of analysts and investors, and thus improve market valuations of firms’ equity on the stock market in the absence of financial transformation.

Lazonick and Tulum (2008) develop their general financialized account of ‘downsize and distribute’ more specifically in their paper on the US Bio-pharma (BP) industry.

“Since the 1980s the US business community, the BP industry included, has embraced the ideology that the performance of their companies and the economy are best served by the ‘maximization of shareholder value’ ...”

“It is an ideology that, among other things, says that any attempt by the government to interfere in the allocation of resources can only undermine economic performance. In practice, what shareholder ideology has meant for corporate resource allocation is that when companies reap more profits they spend a substantial proportion of them on stock repurchases in an effort to boost their stock prices, thus enriching first and foremost the corporate executives who make these allocative decisions” (p.4).

Froud et al., (2006), in their case study of GlaxoSmithKline (GSK) observe that the pharma business model has less to do with R&D and product innovation and more to do with defensive mergers, corporate restructuring and narratives promising research productivity that ‘has not yet come through in the numbers’ (p.11). Gleadle & Haslam, (2010) note that narratives, in an R&D intensive medical diagnostics firm, are concerned with how R&D ‘must pay for itself’ and generate a return on investment to support analyst opinions about the share price.

The objective of this paper is to construct an alternative but complementary financialized account of the bio-pharma business model. Our alternative account departs both from productionist understandings of the potential of R&D and the perspective of Froud et al (2006). Specifically, we argue that bio-pharma is an industry dependent on the capital market for funding because it is cash hungry until,

and if, products in pipeline<sup>1</sup> become commercially viable and generate positive cash flow from revenues. The productive phases of drug development run from conception, laboratory stage, clinical development, patient testing (phases I to III) towards final regulatory approval. In this business model, R&D spending (expensed or capitalized) is deployed to meet agreed milestones, for example, completing development, obtaining results from patient clinical testing and submitting a product for regulatory approval and possible commercialisation. Favourable milestone reports about product in pipeline will help increase the chances of securing additional funding which may be crucial not only for continued survival but also positively influencing analysts' opinions about stock market valuation for equity investors and incidentally helping to boost executive bonuses tied to the value of stock options. These options are more likely to be 'in the money' if a drug's development does progress from one phase to the next and towards final regulatory approval for the market. Positive milestone reports move products along the pipeline towards regulatory approval reducing the risk of failure and mitigating investor losses on their equity investments.

Milestone reports are also (but not always) opportunities for a firm's existing investors to exit and new investors to enter because market values tend to adjust favourably after milestone announcements creating better conditions for buy and sell side transactions to be executed. As a result, individual investors tend to focus on different pipeline phases for their portfolio investments. Venture capital investors, for example, can exit via an initial placement offer (IPO), which results in a public listing on the stock market or they may sell on to a partner, such as a Big-Pharma<sup>2</sup> or a

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<sup>1</sup> Pipeline here refers to how pharma products progress from laboratory into clinical development and testing (known as Phases I, II to III) towards final regulatory approval and commercialization.

<sup>2</sup> By Big-Pharma, we mean the international pharmaceutical giants such as Pfizer, Merck and GSK. This is in direct contrast to much smaller bio-pharma companies, the focus of this paper.

private equity partnership seeking a potential return on investment. In this financialized business model, the investor is not participating in a marathon but instead, competing in a relay where handing the baton on to the next investor secures a (possible) realised gain on invested equity funds. Bio-pharma investment is a speculative bet on scientific discoveries and is similar, in this respect to oil, gas and mineral exploration where Federal Drug Administration (FDA) regulatory approval is like striking oil or finding the seam.

In this paper we employ an innovation, capital market liquidity conceptual framework to organize our understanding of the Financialized bio-pharma business model. This conceptual framework emphasises how complementary narratives about pipeline progress conjoin with capital market conditions and demands. Favourable milestone reports coupled with capital market liquidity help to inflate analyst's expectations about market valuations and promote entry and exit opportunities for equity investors looking to extract a positive return on speculative investment. We explore the operation of this financialized business model in three UK small, medium enterprise (SME) bio-pharmas.

## **2. Constructing a financialized bio-pharma business model**

Both government policy documents and the academic literature identify the potential of the creative and innovative sectors to transform economic growth and national competitiveness. (Porter, 1990; Prahalad & Hamel, 1990; Barney, 1991; DCMS 1998, 2001; Lazonick & O'Sullivan, 2000; Carpenter et al., 2003; Mazzucato & Dosi, 2006; Lazonick, 2008). The general argument is that productive investment in innovation

can strengthen corporate financial performance and thus transform industry and national economic competitiveness. Investment in knowledge development and commitment to high levels of R&D spending are essential to maintaining competitiveness and closing the ‘innovation-gap.’

“Investment in research, leading to innovation and productive benefit to the economy, is a major concern for governments around the world, and a high priority for the European Union. Currently, the EU has considerable strengths, yet invests about a third less than the US and the innovation-capital market gap has not narrowed in recent years”.

<http://www.eirma.org/f3/showthread.php?t=613>

Against this background, more generally a central objective of UK industrial policy is to support the development and sustainability of creative knowledge intensive small and medium enterprise (SME) industry sectors to promote long-term economic growth and competitiveness.

“This country’s success ultimately depends on a strong skills base and dynamic R&D both driving an innovative and competitive economy.”

Lord Paul Drayson, Minister of State for Science and Innovation-capital market [May 2009]

[http://www.innovation-capital market.gov.uk/rd\\_scoreboard/?p=1](http://www.innovation-capital market.gov.uk/rd_scoreboard/?p=1)

An earlier House of Commons report (HC 87 2002-3 UK Bio-pharmacology Industry) observed that:

“Red (*pharmaceutical*) bio-pharmacology is a prime example of the sort of knowledge-driven industry that the government has been so keen to encourage and the lessons drawn here will be relevant to other high-technology industries making products with long gestation periods” (p.5).

Over the last thirty years, global bio-pharma has attracted more than \$300 billion in capital funds (Pisano, 2006a) into a science based business model. This business model according to Pisano(2006b, p.116), is epitomised by Genentech established in 1976 to exploit recombinant DNA technology, a technique for engineering cells to produce human proteins. Genentech, Pisano observes, was a business model for monetizing intellectual property (IP) that has shaped the bio-pharma industry in three inter-related ways. Firstly, technology transfer from universities to the private sector takes place through the creation of new entities, rather than by selling directly to existing companies. Secondly, venture capital and private equity investors provide funding and management support at critical phases and reward the founders (scientists, universities and seed-investors) for risks taken. Finally, a viable market for know-how is created in which newly established firms provide their IP to established companies in return for funding or exit to capital markets via an Initial Placement Offer (IPO), partnered or acquired by Big-Pharma firms like Merck, Pfizer and GlaxoSmithKline (GSK).



The SME bio-pharma sector became an investment opportunity for venture capital and private equity investors because Big-Pharma ultimately needs to develop new products either in-house or procure products developed externally to replenish their pipelines as many existing products are coming out of patent. Ernst and Young (2009) estimate that, for the period 2007 to 2012, \$67bn of Big-Pharma revenue is vulnerable to price competition that arises when drugs lose patent protection (p. 3). Avis Bridgers (Nerac Analyst, 2009) observes that:

“Large pharmaceutical companies seek that next successful business model which supports both scientific innovation and speed to market. The recent economic downturn has hastened these efforts. Dwindling development pipelines, increased regulatory pressures and spiralling healthcare costs have put extra strain on an old and once-successful corporate model that supported the development of blockbuster drugs. The emerging business model combines continued acquisition of smaller companies with constant reorganization of the parent, to preserve shareholder value and provide the flexibility to capitalize on rapidly-evolving science, global expansion of markets and changing regulations” (p.1).

<http://docs.google.com/gview?a=v&q=cache:bNHLXj01C4J:www.nerac.com/download.php%3Fid%3D175+bio+pharma+business+model&hl=en&gl=uk>

The SME bio-pharma business model has been further legitimised because Big-Pharma has started to emulate small cash strapped bio-pharma companies and introduce a venture capital approach to their product portfolio and pipeline investment, Bloomberg columnist Trista Kelley observing:

“In July, Witty (*GSK’s Chief Executive*) began requiring drug-discovery divisions to compete for funding. He brought in an investment board that included venture capitalists and bio-pharmacology executives to review researchers’ proposed projects. The board applies three-year business plans to the scientific process, mimicking the do- or -die environment in small, cash-strapped bio-pharmacology companies. Previously, a research unit’s funding wasn’t dependent on meeting deadlines and goals”.

<http://www.bloomberg.com/apps/news?pid=20601109&refer=home&sid=apc1eXm6xaGc>

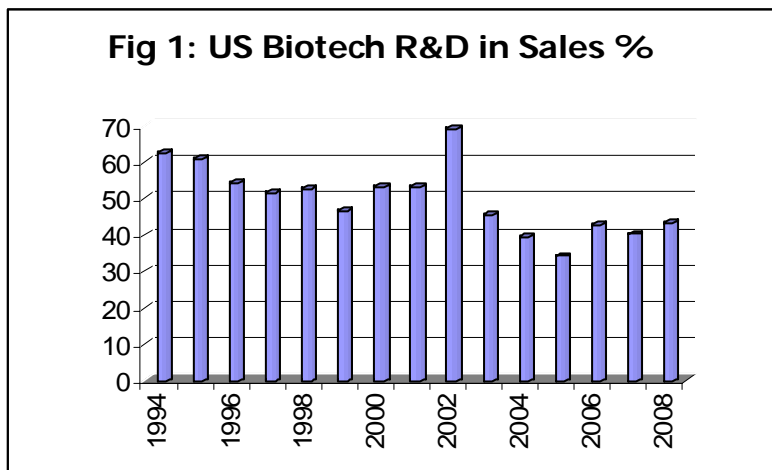
In the 2008 annual report and accounts Andrew Witty (GSK’s) new chief executive, argued that large-scale acquisitions absorb too much organizational effort on integration at the expense of innovation and creativity. GSK is rebalancing its product portfolios to take advantage of new market opportunities offered by biopharmaceuticals.

“During the year we rebalanced our Drug Discovery organisation to improve efficiency and focus on the areas of new science that we believe are most likely to lead to new medicines” (p.8).

“Biopharmaceuticals will play an increasingly important role in our future portfolio. Offering a worldwide market of approximately £40 billion with projected compound annual growth of 18% over the next five years, biopharmaceuticals are compounds capable of being manufactured by living organisms, usually cultured cells” (p.8).

<http://www.gsk.com/investors/reps08/GSK-Report-2008-full.pdf>

The SME bio-pharma sector has benefited from government funding into universities (McMillan et al., 2000) through knowledge transfer, company spin offs and R&D tax credits. In some cases, the commercial ventures established retain links to medical research centres and universities through a strategic alliance or else contractual arrangements that out-source the R&D work back to the university (Robinson and Stuart, 2001; Standing et al., 2008). Venture capital (VC) partnerships and private investors, sensing financial opportunity, have channelled significant funding into SME bio-pharma. Bio-pharmas that do manage their innovation process, to create new product from their technical platform(s) and either move towards or achieve regulatory approval, can increase the probability of leveraging returns on invested capital. This is because the perceived financial risk, and thus investors' required return on investment, is reduced as milestones are met along the route to regulatory approval.

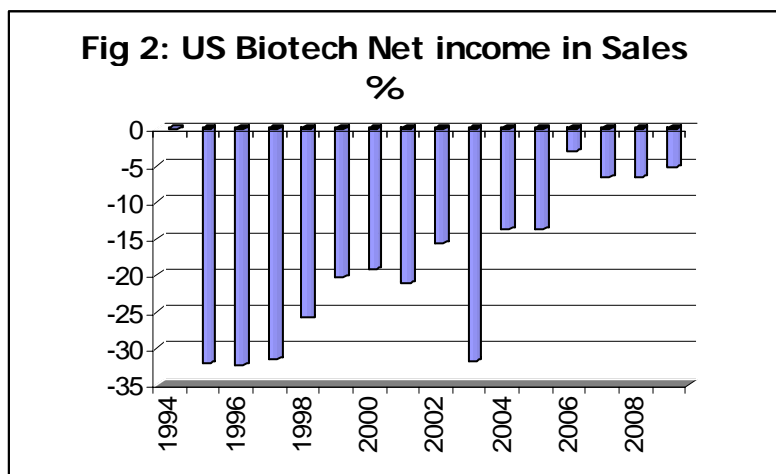


Source:

[http://www.ey.com/Publication/vwLUAssets/Beyond\\_borders\\_2009/\\$FILE/Beyond\\_borders\\_2009.pdf](http://www.ey.com/Publication/vwLUAssets/Beyond_borders_2009/$FILE/Beyond_borders_2009.pdf)

In the US, the bio-pharma industry (comprising 1754 firms) accounts for three quarters of the global bio-pharma industry by sales revenue and roughly eighty percent of total global R&D spend. This group of firms deploys roughly 40 percent of revenue into R&D although this has fallen from a high of over 60 percent in the late 1990s (see fig.1). Although the average US bio-pharma firm is research-intensive, Ernst and Young (2009) observe that profit is elusive and that with the exit of Genentec, acquired by Roche in 2009, this sector is unlikely to be back in profit in the near future.

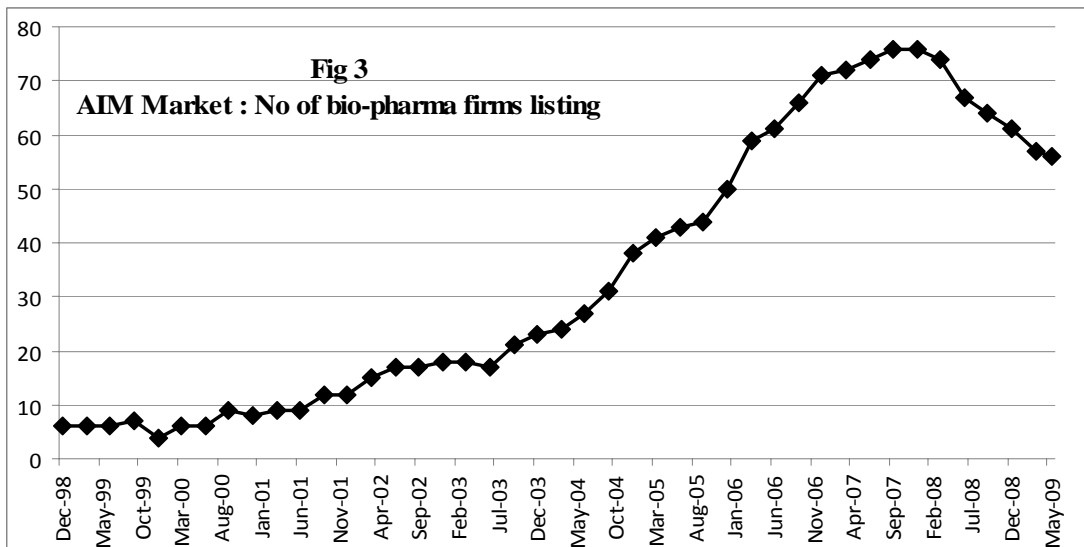
“In 2008, the sector finally reached aggregate profitability with aggregate net income of US\$0.4 billion. Alas, this accomplishment will likely turn out to be short-lived, given Roche’s acquisition of Genentec in 2009” (p.25).



Source:

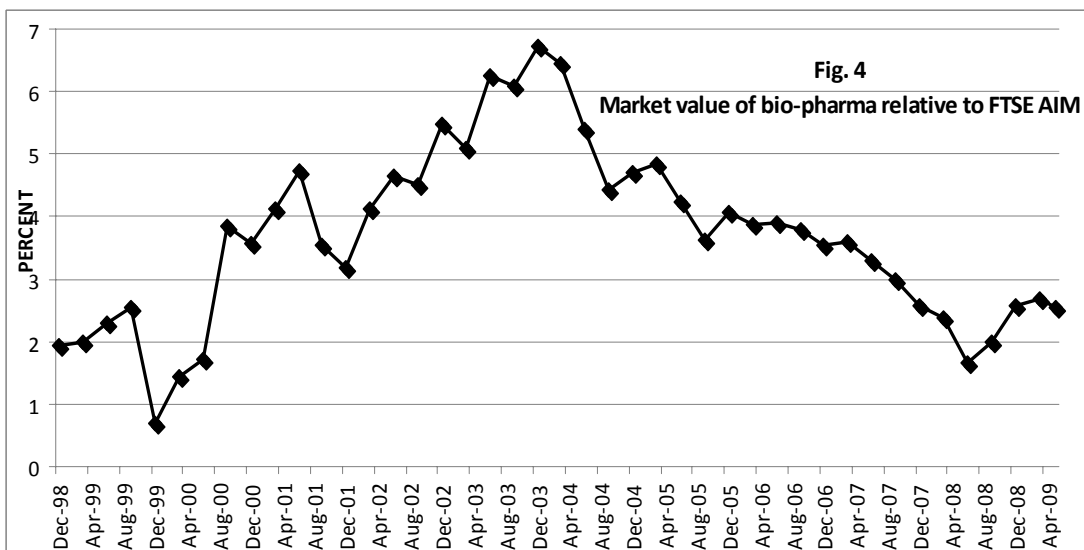
[http://www.ey.com/Publication/vwLUAssets/Beyond\\_borders\\_2009/\\$FILE/Beyond\\_borders\\_2009.pdf](http://www.ey.com/Publication/vwLUAssets/Beyond_borders_2009/$FILE/Beyond_borders_2009.pdf)

During the period 2001 to 2007, the number of bio-pharma companies listed on the London Alternative Investment Market (AIM) increased from ten to over seventy (see fig 3) and at peak, the sector accounted for seven per cent of all AIM listed firms market value (see fig 4)



Source:

<http://www.londonstockexchange.com/companies-and-advisors/aim/aim/aim.htm>



Source:

<http://www.londonstockexchange.com/companies-and-advisors/aim/aim/aim.htm>

It is possible to construct a ‘productionist’ business model of SME bio-pharma, one that places emphasis on the importance of R&D and innovation as part of a resource based view (RBV) of the firm where the object is to transform R&D spending and

acquired knowledge into unique intangible assets to enable an above average financial return. (Porter, 1990; Prahalad & Hamel, 1990; Barney, 1991; DCMS 1998, 2001; Lazonick & O'Sullivan, 2000; Carpenter et al., 2003; Mazzucato & Dosi, 2006; Lazonick, 2008). In this productionist bio-pharma business model, the development of ethically approved drugs requires a combination of: technical ingenuity, financial resource and patient shareholder investment because product development takes place over decades not years (see Hopkins, 2007).

Alternatively, it is possible to construct a complementary financialized business model of SME bio-pharma, one that emphasises the tension between innovative possibilities, cash burning firms, capital market liquidity and investors' quest for realised shareholder return. Our bio-pharma financialized business model incorporates three organising elements: a) narratives about productive performance and how these act as a substitute for commercially driven financial numbers, b) capital market conditions and c) the variable identities and motivations of equity investors where the scope for arbitrage and financial gain from exit matters.

In start-up SME bio-pharmas, narratives about productive achievement take on increased importance in the absence of commercially driven financial information about revenue, expenses and return on capital. These narratives relate to a specific drug development outcome, trial and patient test results communicated in the form of milestone reports. Favourable reports might encourage equity investors to provide additional follow-on funding or result in payments from partners relating to milestone agreements. Positive narratives may also inflate analyst expectations about future cash funding and thus the market value of shareholder equity (see Newberry and Robb,

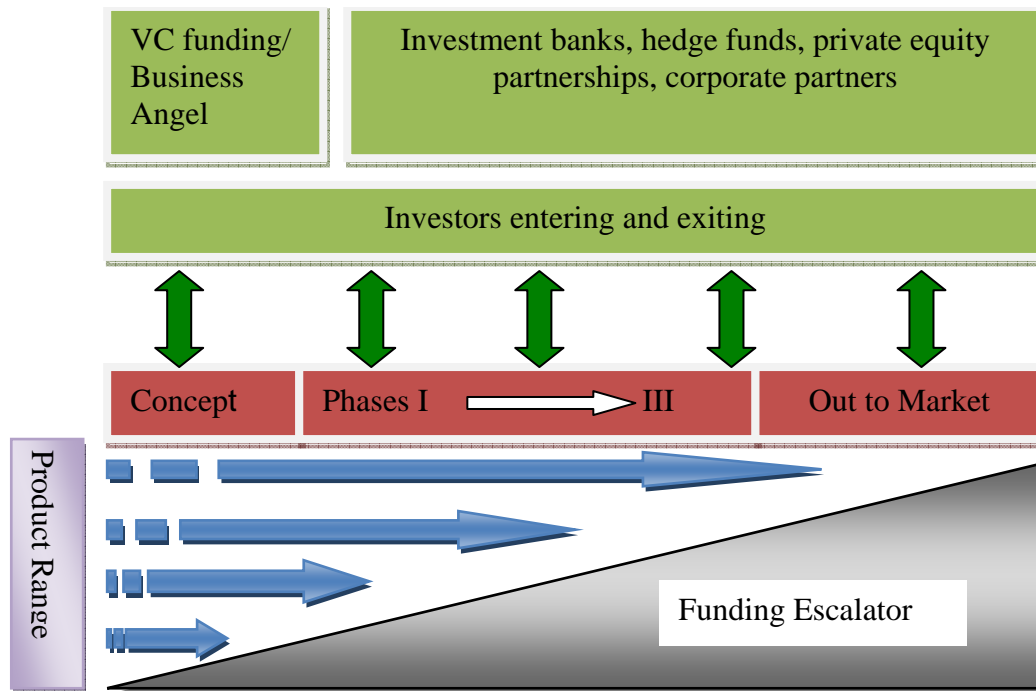
2008). It is very much a speculative business model where narratives about potential discovery operate as a substitute for actual discovery in setting stage payments and establishing the basis for market expectations and perception of market value.

Capital market conditions matter especially with regard to maintaining the flow of follow-on equity funding into a financial value chain that is fragmented and the calculations and motivations of investors, variable. For example, there are complex trade off's between raising additional follow-on equity funding and the dilution of existing equity stakes. The average bio-pharma firm is perhaps best viewed as a portfolio of products at various phases of development where a funding deal can attach to individual products or firms. Obtaining financial support for specific products in the pipeline may not underwrite firm-level financial stability if the investor's strategy is to fund a portfolio of products at various stages of development, rather than to invest in a particular firm.

If funding is complex and fragmented (see Fig 5), exit strategies for equity investors are also variable and depend on the extent to which investment is in the firm as a whole or attached to specific products. It may be more difficult to exit if the investment is in the firm rather than a specific product contract and is not helped if capital market liquidity and the market valuation of a firm's equity deteriorate. Partnering agreements and payments linked to specific products may boost a firm's market value but this may not be sufficient to encourage investor exit if realised market value is still below the value of the accumulated equity investment made in the firm. Capital market valuations are volatile and may either inflate or depress IPO funding, and put a brake on the supply of debt finance to private equity and hedge

funds that depend on leveraging holding gains on the market value of equity investment relative to debt finance.

Fig 5: The financialized bio-pharma product development chain



Source: Authors

The bio-pharma innovation, capital market liquidity business model reveals the tension between the flow of funding, progress of product pipeline and the variable motivations of investors who are entering and exiting at various points along the product development value chain. Winners that invest in bio-pharma have lottery tickets stamped 'FDA approved'. Equity analysts assume that final approval even at phase III offers at best a 50-60% chance for a bio-pharma (Ernst & Young, 2008) and that



“the success rate of companies that are truly commercially successful and sustainable is well below 10%” (p.38).

In the following section, we employ our innovation, capital market liquidity Financialized bio-pharma business model to explore failure and success in three SME's: Ardana, Vernalis and Antisoma.

### **3. Bio-pharma SME cases: illustrating the innovation, capital market liquidity, business model**

Of our three SME bio-pharmas, Ardana ceased trading in June 2008 going into administration, Vernalis downsized and restructured its business, backing a number of its products into partnerships to fund product in pipeline towards regulatory approval and Antisoma whilst carrying an accumulated deficit, is now running with a surplus as partnership milestone agreements start to pay off. Collectively our three firms reported accumulated losses of £684 million on equity investments of £767million and all have struggled to generate a positive return on invested capital for equity investors.

#### **3.1 Ardana: up for sale but no buyers**

The Board of Ardana has taken these steps after it became apparent that a possible refinancing or a possible sale or merger under discussion could not be completed within a timeframe during which the Board believed the Company would have sufficient cash reserves to continue trading. All discussions were terminated by the afternoon of Friday 27 June.

The Company has over recent months been in a number of licensing discussions for individual development products, however the Board have also concluded that these potential transactions could not be completed within the time available before exhaustion of the Company's cash resources.

<http://www.ardana.co.uk/>

Ardana was floated on the London Stock Market at a price of 128p not the 153p expected by management in March 2005. The funding raised from the IPO utilised to finance the development and approval of a range of products for male reproduction, prostate cancer and growth hormone deficiencies. Ardana had by 2007 three products with regulatory approval: Emselex, Striant and Invicorp (see table 1). These products were sold and marketed in the UK and near European countries through joint distribution arrangements but this success did not translate straightforwardly into strong financial performance because revenues from distribution deals were negligible and the company was rapidly burning balance sheet cash reserves.

**Table 1: Ardana product pipeline**

Product	Indication	Phase I	Phase II	Phase III	In market
Striant SR	Male Hypogonadism				✓
Invicorp	Non oral erectile dysfunction				✓
Emselex	Over active bladder				✓
Testo Cream	Male Hypogonadism		✓		
Oral GHS	Endocrinology diagnostic	✓			
Teverelix LA	Prostrate cancer		✓		
Teverelix LA	BPH		✓		
Teverleix LA	Endometriosis	✓			
Terbutaline	Infertility		✓		
Oral GHS	Endocrinology therapeutic	✓			
Testo Cream	Female Indication	✓			

Source: Annual Report, 2007, page 13.

Without additional follow-on funding in 2005 and 2006, the company would have run out of cash and analysts initially reacted positively to the additional funding marking-up the share price. Beyond 2006, Ardana was slow to move product along the pipeline into phase III especially its Testo Cream product and analysts reacted negatively, marking down the market value of the company from £70 to £4 million. With the share price and stock market value tumbling, Ardana was not able to raise additional follow-on equity funds and progressively ran down balance sheet cash reserves.

**Table 2: Ardana financial data 2004 to 2007**

	Revenues £mill	EBITDA £mill	Cash Balances £mill	Market value £mill
2004	0.09	-15.5	11.1	2.1
2005	0.08	-9.2	29.2	1.1
2006	0.49	-8.8	19	70
2007	0.26	-12.2	16.6	70
2008				4

Source: <http://www.ardana.co.uk/reports.html>

In these circumstances, shareholders had few (if any) exit possibilities and in a desperate final move, Ardana advertised on its web site the following message: “Ardana prides itself on its flexible, focussed approach to creative deal making.”

Ardana is also interested in co-developing strategic products with partners who bring supplementary resources and expertise to accelerate their development. Ardana is currently seeking either licensing or co-development partners for the products listed below.

<http://www.ardana.co.uk/ardanaoffer.html>

Despite some interest, no buyers were forthcoming and the company continued on its cash burn trajectory going into voluntary administration on June 27<sup>th</sup> 2008 with share capital valued at £4 million after £72 million of equity funding had been put into the company.

### 3.2 Vernalis: Cash burn, downsizing and a last minute rescue package

Vernalis was formed in 2003 by the merger of British Biotech, Ribo Targets and Vernalis Group with one product approved and marketed (Frovatriptan) and a number of other products in pipeline for the treatment of strokes and Parkinson's disease at phase II and phase I respectively. Both before and after its formation, Vernalis continued on to burn cash such that the accumulated value of equity funding of £609 million more or less straightforwardly translated into accumulated operating losses amounting to £602 million in 2008.

**Table 3: Vernalis financial data 2003 to 2008**

	Revenues £mill	EBITDA £mill	Cash Balances £mil	Market value £mill
2003	12.9	-30	24	83
2004	15.2	2.9	33	137
2005	14.1	-14	68	190
2006	16.3	-30	37	196
2007	19.8	-17	21	20
2008	10.2	3.8	14.6	12

Source: <http://www.vernalis.com/ver/ic/>

During the period 2003 to 2008, Vernalis's net cash requirements were £85 million, supported by additional equity financing in the form of follow-on funding but in 2008, Vernalis (in partnership with ENDO) lost its FDA approval for Frova, a preventative menstrual migraine product.

To quote Vernalis executive chairman Peter Fellner:

“It was clear that because we did not get Frova approved by FDA we had to make some radical changes. We had to reduce cash burn, which we have from £20m a year to less than £10m” (Jonathan Russell, Telegraph: 21 February 2008)

If the drug had been approved, Vernalis would have received a \$40m (£20m) milestone payment from Endo Pharmaceuticals, its US partner. However, in a reversal of fortune, Vernalis now owed Endo \$50m, paying \$7 million in cash and agreeing to forego future royalties on US sales of Frovatriptan, and divesting product in pipeline to further slow its cash burn.

Vernalis said it would seek to divest Apokyn, its drug for Parkinson's disease, and of its US commercial operations. Analysts said share price movement indicated Vernalis was a strong takeover target.

(Marianne Barriaux, Guardian: 21 February 2008)

<http://www.guardian.co.uk/business/2008/feb/21/pharmaceuticals>

**Table 4: Vernalis product pipeline end 2008**

Product	Indication	Phase I	Phase II	Phase III	In market
<b>Priority Programmes</b>					
V3381	Neuropathic Pain	✓			
V2006	Parkinson's Disease		✓		
V85546	Inflammatory Disease	✓			
NVP-AUY922	Cancer	✓			
HSP990	Cancer	✓			
V158866	Pain	✓			
V158411	Cancer	✓			
<b>Progress through partnering</b>					
V1512	Parkinson's Disease		✓		
V10153	Ischaemic stroke		✓		

Source: <http://www.vernalis.com/ver/av/>

The loss of FDA approval compounded already weak financial performance, accelerating defensive restructuring to limit cash burn but after a successful financing round in May 2009 the company revealed it now had sufficient cash resources to keep it going until March 2010. As at the end of 2009, the market value of the company was £20 million, down from a peak of £200 million in 2006 (see table 3) leaving investors with little in the way of exit options. Yet during 2009, Vernalis successfully negotiated two partnership agreements with Servier and GlaxoSmithKline to fund two products in pipeline towards regulatory approval.

The deal is structured as a risk-sharing agreement, with Vernalis responsible for drug discovery activities and GSK for pre-clinical development. Upon IND filing, GSK will have the option to license all collaboration compounds and if this is exercised, will then be responsible for all future development and commercialisation activities.

<http://www.vernalis.com/ver/nc/latestreleases/releases2009/2009-08-06a/2009-08-06a.pdf>

In the interim statement for June 2009, the Executive Chairman observed that:

The Company ended the half year with £27.8 million in cash and has secured a further \$7.5 million since the end of the period from Novartis and GSK. The Company is positioned well to continue rebuilding substantial shareholder value.

<http://www.vernalis.com/ver/nc/latestreleases/releases2009/2009-08-06/2009-08-06.pdf>

In response during 2009, the share price recovered and the market value of the firm's equity reached £58 million in September 2009 improving exit options for equity shareholders. This market value represents just one-tenth of the overall accumulated investment made by equity investors in Vernalis and in 2008 annual report still revealed twenty-eight risk factors that could still frustrate investor returns.

### **3.3 Antisoma: towards a viable bio-pharma business model?**

Antisoma plc, founded in 1998, was first listed on the European Nasdaq market before transferring to the London Stock Exchange in 1999. The 2003 annual report and accounts reveal that the company has a number of treatment therapies at various stages of development for the treatment of cancer. The company discloses in its 2002 annual report that the strategy is to search and acquire promising early stage products and take these through towards regulatory approval

“Our ‘search-and-develop’ business model is based on acquiring promising early stage product candidates from academic and commercial institutions. We then add value to these agents by designing and implementing effective programmes for pre-clinical development and the initial phases of clinical development. As our product candidates progress to late-phase trials, we actively seek pharmaceutical industry partners to complete clinical development, file for regulatory approval and carry out marketing activities”.

<http://www.antisoma.com/asm/ir/reports/rep2002/2002ar/2002ar.pdf?t=popup>

To finance acquisitions and progress product along the pipeline, Antisoma has regularly sought follow-on equity funding increasing issued share capital from 141 million to 835 million shares to raise roughly £100 million of additional equity finance.

**Table 5: Antisoma product pipeline end 2008**

Product	Indication	Phase I	Phase II	Phase III	In market
ASA404	Lung prostrate secondary cancer			✓	
AS1413	Secondary Leukaemia			✓	
Oral fludarabine	Lymphocytic Leukaemia				✓
AS1411	Renal cancer		✓		
AS1402	Breast cancer	✓			
AS1409	Renal cancer	✓			
P2045	Lung cancer	✓			

Source: <http://www.antisoma.com/asm/ir/reports/rep2002/2002ar/2002ar.pdf?t=popup>

In 2008, one product nearly ‘in market’, oral fludarabine, was awaiting FDA regulatory approval for use in the US market and was obtained as a result of the acquisition of Xanthus.

Another important asset from the Xanthus portfolio is oral fludarabine. This is a tablet formulation of a widely used chemotherapy drug for CLL, which is currently only available in the US as an intravenous formulation. A marketing application for oral fludarabine is being considered by the FDA.

<http://www.antisoma.com/asm/ir/reports/rep2002/2002ar/2002ar.pdf?t=popup>

Antisoma continues to ‘search, acquire and develop’ new products for its pipeline where the objective is to limit R&D spending risk to equity investors, that is, avoiding investment in drug discovery but focusing instead on the development of promising



prospects. As product moves along the pipeline, it is then possible to back these into partnership agreements that tend to generate ‘lumpy’ and erratic revenue patterns when milestones are met (see table 6).

**Table 6: Antisoma financial data 2000 to 2008**

	Revenues £mill	EBITDA £mill	Cash Balances £mill	Market value £m
2000	1.5	-8	4.4	
2001	3.3	-9.2	9.1	
2002	2.2	-12.7	18.9	78
2003	11.8	-5.2	2.4	115
2004	18.1	-2.7	16.4	58
2005	6.2	-10.3	25	192
2006	1.6	-19.4	14.9	123
2007	7.9	-13.5	51.4	144
2008	39.5	10.6	33.9	300

Source: Annual reports, various years  
<http://www.antisoma.com/asm/ir/reports/>

Total revenues for the year ended 2008 were £39.5 million, compared with £8.0 million last year. The difference mainly results from the increase in revenues relating to recognition of the upfront and milestone payments received from Novartis.

<http://www.antisoma.com/asm/ir/reports/rep2008/ar2008/ar2008.pdf?t=popup>

As milestones agreements result in additional revenue, analysts revise their narratives about the share price.

Antisoma, the cancer drug developer, took on 5 per cent to 31½p after analysts said a value gap had opened up against its peer group.

US oncology specialists have gained 89 per cent this year, compared with Antisoma's 38 per cent gain, PiperJaffray said. It saw the performance as anomalous given Antisoma's promising test data this year. (FT.Com September 18 2009)

<http://www.ft.com/cms/s/0/edf336ba-a3ea-11de-9fed-00144feabdc0.html>

#### **4. Summary**

The productionist bio-pharma business model describes a long-term financial commitment by equity investors because the R&D spending process is driven by scientific discovery and clinical testing and development takes place over decades. This productionist stereotype is used by policy makers and deployed by academics to describe innovation-led business models and how they might transform firm, industry and national competitiveness. The critical literature constructs an alternative financialized view where according to Lazonick (2008), in an era of shareholder value, there is a tendency for firms to downsize and distribute rather than sustain R&D investment in innovation for firm and national competitiveness. Froud et al (2006) in their financialized account of strategy at GSK argue that managerial narratives promoted the promise of transformation from R&D spending and helped to boost analysts' short-run opinions about the share price. The financial numbers disclosed in GSK's annual report and accounts are used by Froud et al to construct an alternative narrative about the lack of financial transformation and productivity from R&D spending in an era where strategy is directed towards value creation for shareholders.

## **5. Discussion and conclusions**

In this paper, we construct a descriptive financialized bio-pharma business model and utilise this to explore how narratives about innovation and the productive outcomes of R&D spend conjoin with capital market conditions and demands of equity investors. Our descriptive financialized bio-pharma business model is structured using three organising conceptual elements: narratives about performance, capital market conditions and the variable motivation of equity investors, where entry and exit possibilities matter.

Narratives about pipeline progress are important in the absence of sensible financial information (Froud et al, 2006) because this helps secure refinancing and increase the probability of follow-on funding from equity investors and receipts from partnership agreements in the form of milestone payments. Narratives about milestone achievements are also communicated to investment analysts who make recommendations about the firms share price and hence market value. Capital market conditions now take on added significance both in terms of the supply of funding, liquidity and market valuation because this facilitates entry and exit for equity investors. The identity of investors involved along the product pipeline changes from the original academics/university spinout equity holders to venture capitalists, partnership firms, private equity funds or Big-Pharma. The motivations of equity investors are variable, involving investment in the firm or into individual products that are at various stages of development along the pipeline, complicating market valuations because contractual arrangements are fragmented and complex.

The financialized bio-pharma business model shares many of the characteristics of other highly speculative sectors and tellingly The Times on 24<sup>th</sup> January 2009 observed that the biotech sector is that corner of the stock market that most closely resembles a casino. The chances of success of an early-stage drug are unpredictable and financial loss is the most likely outcome. Pisano (2006b, p.119) observes that this is due in no small part to the ‘profound and persistent uncertainty rooted in a limited knowledge of human biological systems and processes, mak(ing) drug R&D (a) highly risky’ process. The biotech business model that we describe in this article is a speculative innovation, capital market liquidity business model that depends on complementary narratives, capital market liquidity, risk appetite and appreciation of market values to facilitate entry and exit possibilities for equity investors to keep it all going. In contrast to more traditional productionist perspectives, we argue that this is not simply a business model capable of delivering productive transformation for the competitive economy.

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