International Review of Business Research Papers
Vol. 3 No.4 October 2007 Pp.146-151

Bioinvesting for the Future: New Models for Making Biotech and Investors Work Better Together

Chinmay Girish Kukade* and Monishankar Prasad**

Perhaps no other industry of late has been so hyped and 'sold' as the Biotech industry – scarcely does a day pass without its 'potential' and 'promise' being thrust at investors. Accordingly, investors have pumped huge sums into the industry but with negligible benefit – the vast majority of Biotech firms, as of December 2006, make no profit. They commonly have only single product portfolios, overwhelming dependence on funding agencies and almost endemic risk – which only adds to the existing uncertainty and further exacerbate already excessively long drug development timelines. The paper attempts to examine the possibilities for investors and Biotech start-ups to develop a mutually rewarding relationship to further the success of all those involved in the growth of the Biotech industry, with the premise being the structural models Biotech is likely to adopt in the near future.

Field of Research: Finance, Investment Environment

1. Introduction

In the last 30 years of Biotech's existence, 300 billion dollars have been poured in with the assumption being that this new science would bring about a revolution in drug therapy. Biotech, however, remains profitless. This news is gloom for an investment community hoping that biotech would reap the same dividends as the semiconductor or the IT industry. The Biotech industry does have huge potential to change lives of people as Biotech with its arsenal of Biopharma, Bioagriculture and Biofuels can make an impact holistically across these segments and in synchronization - a massive business opportunity for the biotech industry and its paymasters - but it requires an investment model suited to its special needs. New and innovative business models are essential, particularly those based on the structural environment not of the present day but the near future.

2. Literature Review

Although Biotech has seen spectacular revenue growth in the last decade, there has not been an extensive study of why Biotech still fails to deliver net profitability to investors, and why the industry as of 2006 still remains largely unprofitable. Literature on the subject has thus been limited and confined largely to speculative and unclear data.

*Chinmay Girish Kukade, Birla Institute of Technology, Mesra, India
email: chinmaykukade@yahoo.com
**Monishankar Prasad, Birla Institute of Technology, Mesra, India
email: monishankar_prasad@yahoo.com

Recently, Pisano(2006) has attempted to examine the state of the Biotech industry and analyse the causes for its below-par performance; his research, as well as the Burrill & Co. annual reports on the 'state of the Biotech industry' served as valuable research input.

3. Methodology and Research Design

The study aimed to firstly assess the reasons for the overall lack of profitability and other investment-performance related issues faced by the Biotech industry, and whether they were structural or functional in nature. Furthermore the study focused the main categories of structural models used by the Biotech industry, to identify those currently in use and how appropriately they served the industry. Again, given the fact that extensive literature does not exist on the subject, the study aims to provide more of a conceptual and model-based solution model to the issues facing Biotech.

4. Discussion of Findings

The key to profitability in biotechnology sector and thus to its parent investors is that the biotech entity should be allowed to do cutting edge research that when converted to products and thus sold ultimately to the market. Most biotech companies have single product lines which are susceptible to failure in clinical trials. The stock market valuation of such companies usually goes bust when such a bad piece of news comes in from the USFDA. Investment and Innovation is a chicken and egg thing: Investors have to tie up with professional managers and the scientific fraternity to choke out a viable business model for the particular biotech product platform based entity, for e.g.: A biotech company might be having a separate business model which particularly deals with generics than a firm dealing with clinical research outsourcing in India. Biotechnology companies have potential revenue lag times of more than five years versus IT firms that have 1-3 years revenue lag times. The Business Success Rate of biotech companies is 5.7% versus 11.3% in software and communications. If one goes by the US experience, primary life science technologies rise from government funded laboratories like the National Institute of Health and product commercialization is carried out by private firms. Private equity funding is primarily sourced towards the latter stages of the drug discovery development process where the risk factor is considerably devalued than the early stage of the drug development process. The fundamental error that is being made on the part of investor community is that biotech is not the same as the information technology industry that had startups operating out of the garages - Biotechs need sophisticated, multi-disciplinary approaches that require core scientific research, business acumen, and regulatory compliance (IT does not need a regulator) and complete support from the investment community(both governmental and private equity) Furthermore, it must be recognized that while both IT and BT are innovation-led businesses, it is Biotech that is, uniquely, a Science-based business as well. Science and Business are fundamentally different fields requiring fundamentally different approaches –

while Science sticks to methods and processes, business demands utility; while Science thrives on uncertainty, it can be the death knell for a business. Biotech has been tangled up with intellectual property rights disputes between the various components of the biotech value chain- Pharma, biotech and contract research firms that deplete precious few financial resources available in legal disputes. The Investment community can play a vital role in devising a new revenue model and in turn a cohesive business model for the biotech industry as it has the influence and power to leverage decision making in the industry. Another major factor for the depressing state of finances of the biotech sector is its inability to break out of the shackles of the 'Pharma master', which provides funding for biotech startups to produce innovation and that very innovation and those very product lines are incorporated into the Pharma value chain, thus not permitting the Biotech industry to grow on its own strengths and permanently consigning it to a 'parent-child' relationship that holds only one-way benefits for the Pharma master and turns out to be a legal, financial, infrastructural and IP trap for Biotech instead.

The investment community has to play the role of a catalyst in ensuring the success of the biotech industry via its expertise in corporate restructuring and raising capital for various sectors. It is well established that smaller biotech companies are far more competent at churning out innovations at a faster rate than Big Pharma, owing to their flexibility and willingness to adapt. Biotech has the capacity to reduce gestation periods, drug discovery timeframes and half costs in R&D. Medication for almost 90% of the world's diseases is nonexistent as they are located in the developing world and the Pharma companies are not permitted to focus on these markets owing to their vested interests and lack of interest in low-return businesses. While the traditional Pharma mindset will be to look at those who can and cannot pay, Biotech, with its flexibility, single-product focus and hunger for new markets to build its businesses in areas where Pharma has little or no sway can use the Third World as its strongest business opportunity. Multilateral financial bodies like the International Finance Corporation or the Asian Development Bank can help fund the biotech industry in order to save millions of lives. The Singapore Govt. via its investment arm-Temasek Holdings has invested in biotech companies in India. Other vital strategies in the innovation value chain such as funding university research labs and fellowships and providing expertise in product commercialization and scaling up processes will help solidify Biotech's capabilities.

Biotech companies can help use instruments available with the help of the investment community apart from the conventional capital markets like the Alternative Investment Market which is managed by the London Stock Exchange. It has lower listing requirements and it is lightly regulated in comparison to regular exchanges. This is advantageous to Biotech companies that have a low capital base and most of the times it does not make good enough money to meet even operational costs. Reverse IPOs, Private Investment in Public Equity (PIPE) and Special Purpose Acquisition Vehicle (SPAC) can be used to raise capital for biotech firms which have unique needs and unique financial instruments like the one mentioned above can be used for the same. RIPOs have distinct pluses over conventional

IPO's. Public listing can be done faster than conventional IPOs and less management attention is required versus an IPO.

5. Alternative Revenue Model

The investment community can tie up with biotechnology industry bodies facilitated by local government to set up biotech Special Economic Zones, parks to incubate innovation ecosystems that have the entire value chain under the same roof like the upcoming Biotech park spearheaded by Indian financial powerhouse ICICI - ICICI Knowledge Park in Hyderabad, India. Bioclustering need not be geographical - it can be virtual - a Product oriented Biocluster with R&D taking place in the USA, clinical trials in India, manufacturing in China and the funding provided by a global consortium of government-private investors is very much possible in this age of globally distributed work. This virtual product oriented Biocluster is cost effective; a synergy of the very best in the sense that total integration is possible by the coming together of the constituent firms, right from the start without individual firms having to attempt to develop skill sets and enter areas that are not their core competence. IPR issues can be eliminated with predetermined activities assigned to various biotech companies of the Biocluster with fixed baseline remuneration plus royalties upon commercial success of the product.

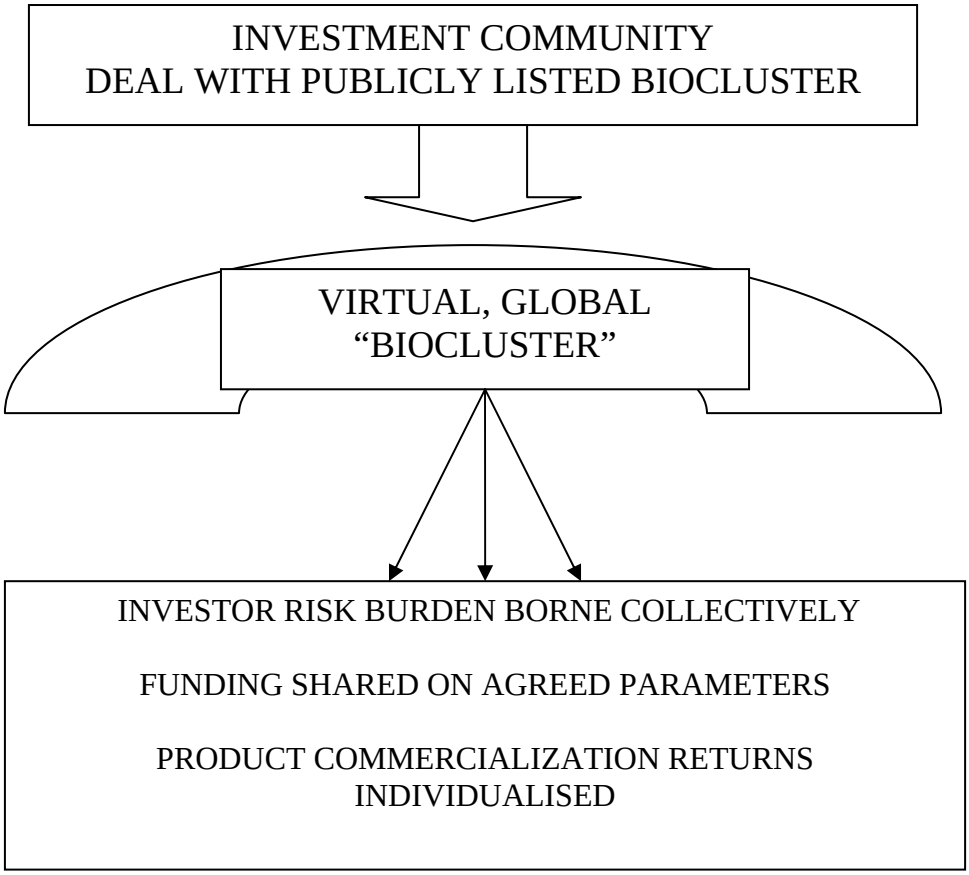

Fig. 1 - A model for creation of a Virtual Biocluster

Thus two sources of funding are established; one fixed, the other variable; thus providing both financial security and the motivation for risk-taking, the

two problems that have plagued Biotech. Once risk-taking becomes affordable, product platforms will multiply and so will investment options. A virtual product oriented Biocluster or a geographical Biocluster can help address the asymmetrical divide between the developing and the developed world.

Localized Bioclusters can help address local diseases with biotech expertise plus help traditional medicine remedies to be commercialized. The Biocluster can be listed on the capital markets to raise cash for the respective entities in the Biocluster in order to pursue their core activities whether research or services in order to meet the desired aim of the Biocluster. The Biocluster will be managed by a holding company whose shares will be floated in the capital market in return for cash. A venture capital firm or an investment bank can be the managing company of the Biocluster as an asset management company is.

6. Restructuring

Venture capital or a private equity placement can help a Biopharma company accelerate drug development process from the commercial inflection point “phase 2a”, from the early stage to the advanced stages of drug development without equity dilution in the parent company in return for royalties or strategic rights. A struggling Pharma or a biotech company can be restructured into marketing entity and a services firm that does R&D and manufacturing with the expertise of the investment community. In this process, shareholder wealth is created by this demerger, derisking the marketing firm by concentrating the risk in the services part of the demerged entity. The two firms become stand alone entities thus making it an imperative for both companies to develop their own USP and increase their profitability thus creating wealth for the investors of the company.

7. Future Investment Potential

There are new frontiers in life science technology that can revolutionize every aspect of human existence. Investments in emerging areas of the life science can accelerate this trajectory to its planned conclusion. Bioagriculture has enormous potential in feeding the hungry in the developing world. Monsanto and DuPont are success stories in this particular niche of biotechnology. Biofuels are the need of the day in this age of $60+/barrel. Brazil and Cuba are world leaders in this area of Biofuels derived from sugarcane. Industrial Biotechnology applications can be used to cut carbon emissions in this age of global warming and carbon trading exchange based in Chicago. Personalized therapy will be the order of the day in the future. Biotechnology has huge application in the medical devices space. The above applications are of huge potential to the investors, as the prospective returns are great. Investors can invest in prospective startups that sell themselves later to bigger multinationals for a huge profit – Biotech multinationals, hopefully emergent by then, as opposed to the current Pharma multinational buyers.

Thus the investment community has a plethora of options in the life science technology sector – all of which can be brought to fruition only if the primary

partnership model between Biotech and its financiers holds strong. The majority of the cash of the investors still goes to firms in North America and Europe as IPR is safeguarded and the supply chain is laid out. But the future lies in the Asian powerhouses of 'Chindia': China and India. Successes like Biocon and the Serum Institute of India which is one of the largest producers of recombinant vaccines in the world are a testament to the value still to be unlocked by investors in these sorts of markets where the consumption market is readily available along with a low cost R&D and manufacturing base plus a massive and low-cost life sciences human resource pool. The production of generics and contract research services have become the niche of life science companies and attempts are being made to scale up such copycat start-ups to centres of innovation with the help of international venture capital firms like Burrill & Co. and Chrys Capital. The investment community must also have a portfolio comprising of a balance of interests between companies in emerging markets and established entities in the developed countries - Shantha Biotech, one of India's promising companies in the life sciences space, had a 60% share buyout by Merieux, a major in vitro diagnostics, which gave it access to developing markets and a wide array of vaccines.

8. Conclusion

If the biotech industry and the investment community establish a synergy via their association with each other, it will be an opportunity for both for wealth and knowledge creation and to use the enormous potential of the science of biotechnology for the resource poor section of humankind; however, it must be recognized that Biotech is a unique industry operating at the interface of science and business and attempting to simultaneously fulfil the requirements of both; as such, new structural models are required to realize Biotech's capabilities; and new financial models must follow those structural models. As a science-based business, it is critical that models develop a flawless IP sharing structure to prevent the fracturing of relationships between Biotech and investors and within Biotech entities like the Biocluster mentioned above themselves. As a business characterized by massive uncertainty, it is critical that risk be shared among Biotechs in a clustered structure like the one mentioned above, which also enables virtual integration of capabilities right from the start. Once risk is lowered, funds from the investment community will flow and so will results from the other end.

References

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