FEASIBILITY STUDY: PROJECT *BigDNA*

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Contents

1. Introduction

The purpose of this feasibility study is to assess the long term suitability for investment of the company BigDNA.

Project Big DNA as an investment opportunity has been assessed in six main areas in the following pages: user benefits, potential markets, competition, human factors, project and development issues and IP protection. A Risk Analysis (Section 9) has also been carried out in order to identify any concerns and recommend further studies.

BigDNA is a spin-out company of the Moredun Research Institute (MRI).(1) MRI is sponsored by the Scottish Executive Environment and Rural Affairs Department. Commercially sponsored research is channelled through the Institute's affiliated company Moredun Scientific Ltd.(2)

The main profile of the Company is built around a new vaccine delivery technology. (3) Their innovative procedure is based on using whole bacteriophages (virus of bacteria) as delivery vehicles of DNA vaccine against viruses. (4) The vaccine DNA is packaged into the phage, transferred into the host, where it is engulfed by antigen presenting cells (APC). Based on the DNA, vaccine proteins are expressed on the APC cell surface. (3) The concept of the host immunising itself by vaccine proteins (antigens) is not new. DNA vaccines have already been tested. Vaccine DNA codes proper antigens, which induces antiphage antibodies that can eliminate pathogenic viruses. (5) However, previous tests only dealt with "naked DNA", contrary to DNA packaged into phages, which has been proved more efficient. (6)

The company is seeking £160,000 from private equity investors for managing their patent portfolio and to support business development for up to 18 months. (4)

2. Identification of User Benefits;

2.1 Reported Developments and Issues	**Likely impact on project - action required?**
2.1.1 Compared to conventional vaccine techniques, phages are easy and cheap to produce. It requires simple technology and minimal equipment. Conventional techniques include killing or weakening pathogens, produce non-pathogenic strains or purify non-pathogenic fragments of the microorganisms. All of these techniques require sophisticated facilities and highly trained staff. (3)	This can prove to be a major selling point and must be stressed during negotiations.
2.1.2 Phages have large capacity. More DNA can be transferred than using "naked DNA" technique. (3) This means smaller doses and eliminate the need for multiple injection. (7)	Vaccine manufacturers must be approached whether they would consider using it.
2.1.3 Phage housing can also be targeted to a specific cell type. It can also contain multiple type of vaccines for different diseases. (7)	Further investigations on how safe it is to use more vaccines together. It could trigger a severe immune reaction. Is it cheaper than using the same vaccines separately?
2.1.4 Phage delivered vaccines are also highly stable. They can be stored in powder form, which enables them to be taken orally. (3)	What safety measures have to be implemented? Pills can be mixed up. How much would it cost to implement a reliable identification system?
2.1.5 The technique is environmentally friendly. Bacteriophages cannot reproduce outside the laboratory. (7)	

2.2 Further Comments

Saving money is one of the most important aspects of the project, which will appeal to most customers.

For existing DNA vaccines, this can provide a better alternative to their existing technique (injection).

The specificity of the technique can lead the way to personalized vaccines. HIV patients often have multiple diseases, that could be handled by a single vaccine, personalized for a single patient.

Injections and needles are associated with high risks and potential hazards. Biohazard cleanup also means a substantial amount and difficulties at vaccinations (especially when large groups of children are involved). In developing countries, vaccination poses a huge problem. If vaccines could be taken as pills, there would be no need for cold storage, or supply of needles. Charities and parents could be very supportive and help with the public acceptance of the new technique.

Genetic research and foreign DNA introduction has always been a target for environmentally conscious people and groups. This could be a set back for the project, unless the benefit of being environmentally safe is emphasised.

3. Potential markets for the project;

3.1 Reported Developments and Issues	**Likely impact on project - action required?**
3.1.1 In the last 2 decades, the pharmaceutical industry, including the vaccine industry, has been narrow. (8) However, due to the evolution in technology, in the last few years it has been expanding. (9) In 1999, the global vaccine market was worth $3.6 billion. By 2004, it was $9.9 billion. (11) Today, it is expected to top $16 billion (4) at the end of 2007 and $23.8 billion by 2012. (14)	The market is definitely growing and it is easier to position the company in a growing market.
3.1.2 Because the large company dominance, there was no competition and vaccine shortages are common. (12) The Big DNA technology can seize a market segment of the big companies as well.	The dissatisfaction regarding global vaccine shortages are affecting the national health systems and governments. Their support is likely and desirable in an investment.
3.1.3 Tropical diseases account for 5 million deaths per year. There are no preventive vaccination for the top 5 tropical disease.(10)	WHO could be a potential distributor for new vaccines.
3.1.4 Increasing level of international travel and urbanization also expands the potential market. (10)	Fast and convenient vaccinations can mean higher pricing. Businessmen and upper/middle class could afford it.
3.1.5 The same technology can be used in animal vaccines. (Avian Flu)	
3.1.6 The threat of bioterrorism created a growing market for vaccines.	There are possibilities for substantial government orders.

3.2 Further Comments – Markets

R&D in the pharmaceutical market (including the vaccine market) is very costly. It takes many years and hundred millions of pounds to launch a new product. (8) Due to increasing costs and strict regulatory healthcare systems, there have been several acquisitions and merges in the industry.(8) In 2002, 5 company dominated the preventive vaccine market, by being responsible for 80% of the sales revenue. Vaccine manufacturing was a low return and high risk business and there was no driving force to develop new products. Between 2000 and 2005 there were only 3 new vaccine products, and three consecutive years without one.(9) However, new technologies have caused a resurgence in new companies and new potential products. (11) In the cancer vaccine pipeline 80% of the companies are small biotechnology firms. The remaining proportion includes six large pharmaceutical companies (9%) and seven research institutes (11%). (15)

According to BigDNA:

"The key market for the technologies is the human and animal vaccines market, estimated to be worth around $16 billion (annually) and growing more rapidly than any other part of the pharmaceuticals sector."

The "bioterrorism vaccines" have already resulted in huge orders and financial backing from the US government. According to a report, in 2002 "for example, VaxGen was awarded an $80 million contract for anthrax vaccine, and is reported to expect to achieve sales of $2.8 billion in 10 years. Acambis accelerated its development of smallpox vaccine, bringing its Massachusetts facility online more rapidly than the late 2003 date originally planned after the $343 million contract to supply 40 million doses was placed. Dynport has received $350 million in bioterrorism related vaccine work." (13)

4. Potential Competition

3.1 Reported Developments	Likely impact on project
4.1.1 There are a growing number of small biotech companies and research institutes.	The technology must be superior in order to seize a profitable market segment.
4.1.2 BigDNA wishes to compete in the vaccine delivery market. Currently there are a few other options for vaccine delivery. Anti-viral medicine can be produced in transgenic plants. (16) The method is tested, and working. However, there are difficulties with the cultivation and is strongly opposed by green movements and several governments.	This could mean a set-back for the whole conventional vaccine industry. However, the legitimisation of this project cannot be expected soon.
4.1.3 There is a new method on delivering vaccines intranasally. The package contains a viral envelope subunit with a glycoprotein complexed with a lipid. (17)	This method is not a comprehensive method, contrary to BigDNA's method.
4.1.4 Russia's Influenza Research Institute recently completed a preclinical study on an intranasal influenza vaccine, using a novel adjuvant technology, with plans to develop what could become the first tablet flu vaccine formulation.(18)	This is a very recent study. Similarly, it has only been tested on flu viruses.

4.2 Further Comments – Competition

The vaccine market is very competitive. However, new technologies are only emerging, and with the right financial background and with protected IP it is the right time to establish a place in the market.

5. Potential Human Factors

5.1 Reported Developments and Issues	**Likely impact on project - action required?**
5.1.1 BigDNA has close ties with MRI. MRI is an internationally recognised research institute, with many successful research project in different areas.	The team at the Institute is a well-organized group, with strong leadership and motivation.
5.1.2 Vaccines that are based on transferring foreign DNA in an organism might evoke opposition from many people.	There must be further studies done on long-term effects of foreign DNA insertion.

5.2 Further Comments – Human Factors

The fact, that the Company is a spin-off of a respectable research institute, is a good starting point for the investor. This means, that the people at BigDNA have experience in research and business as well.
Vaccines are not a new concept. People will accept new technologies more easily, contrary to transgenic organisms, that are completely new, and without precedent.

6. Potential Project and Development Issues

Reported Developments	Likely impact on project
6.1.1 The business model is based on service. The income will be through development support charges and licensing the technology. (3)	All IP must be protected.
6.1.2 Development will be carried out in partnerships to reduce costs.(3)	Good partnership deals, strong legal team.
6.1.3 The company can introduce new technologies due to its links to MRI.(3)	The company will not be outdated in the ever changing environment of vaccine research.
6.1.4 There are spin-off possibilities in wildlife management.	Investigate possibilities.

6.2 Further Comments

The proposed business model is sensible. For a relatively small research company the cost for developing and testing a completely new product would be very high and unprofitable. Also, these products require rapid market entry. This can only be done with huge capital investment or outsourcing. Partnerships can minimise investment and lost revenue. (12) For combining technologies and vaccines collaborations can be very useful and profit oriented step. License will also provide an ongoing income.

7. Intellectual Property

Reported Developments	Likely impact on project
7.1.1 The company has 1 patent granted and 2 filed. (3)	All IP must be protected. More possibilities have to be investigated.

7. Risk Analysis

7.1 'Project-termination' Factors

Factor	Comments
7.1.1 BigDNA has not tested its vaccine delivery technology on humans. However, the company is very confident that it will work. (7)	Testing has to be done, and a due date established. Without positive testing, the will not last.
7.1.2 Many people are concerned with the side effects of medicines. (80%) (8)	There must be a positive publicity prior to the release, with appropriate supporting data.
7.1.3 The life cycle of new pharmaceutical products are short. (8)	There must be several continuous development projects at all time.

7.2 'Project Scale-down' Factors

Factor	Comments
7.2.1 Most of the vaccine research deal with cancer (60.6%) This can overshadow other developmental areas. (9)	
7.2.2 Research money concentrates in small biotech companies. (15)	

8. Conclusion/Next Steps;

BigDNA has a very promising technology with a well organised team and leadership. The market for vaccines is growing, and due to political and socio-economic trends new markets are created. As a research company, their portfolio is capable of renewal, an advisable feature in a competitive market. There are also possibilities for spin-off companies (wildlife management and diagnostics). The company could be considered for investment, however, a few more investigations should be carried out.
Testing on humans should be completed and product delivery date must be set.
I would also like to investigate to annual reports of the company, to establish their financial situation in the present. Most of their investment money came in the form of reimbursable grants. Since in partnerships and in licensing deals the legal background is very important, it would be advisable to take a look at their deals so far, and the ones under negotiation. The company should take on only minimal financial responsibilities, in case of lawsuits.
I would also strongly suggest to check all the vaccine regulatory processes for discrepancies with company policies.

Appendices

8.1 APPENDIX A – BIBLIOGRAPHY

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