UEM 2005
Market Feasibility Analysis

Portable Hepatitis C Diagnostic Device
Final Report

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1. EXECUTIVE SUMMARY

We had identified the growing importance of Hepatitis C as a global epidemic and believed that the solution to this problem was mass screening of the population by healthcare professionals. We understood that it was impossible to implement this solution using existing lab based diagnostic modalities. Our belief was that this problem could only be solved by the availability of a portable, point-of-care Hepatitis C diagnostic device, which would enable healthcare professionals to personally administer the test to all of their patients. We believed that the benefits of instantaneous results, higher efficacy and the ability to make timely treatment decisions would compel healthcare professionals to adopt this device.

We define our mission as: To bring about substantial improvements in the quality and efficacy of disease diagnosis by offering nanotechnology based point-of care portable diagnostic devices that empower healthcare professionals and patients.

In the UK there are an estimated 200,000 people infected with HCV of which only one in six have been diagnosed so far. There were about 4000 new cases during 2001 though this number is expected to decrease at a rate of 12% for the next ten years. Overall, the macro market is favourable as even though the growth rate of the disease in UK is decreasing, the global market is still very large.

As the cost of Hepatitis C drug therapy is £10,000 compared to £68,000 for a liver transplant, we had calculated that if our device was adopted by NHS, it would save them about £50 million every year for a period of 20 years. However, the micro-level market overall is very unfavourable for the idea that we had proposed initially primarily because of customer resistance.

In-Vitro Diagnostics is a mature industry with more than 20 billion blood tests performed annually worldwide. The global market for IVD totalled over $23 billion in 2002, with over 40% of sales in the US. The overall IVD industry is growing at 4-5% annually. In general, the IVD industry is dominated by several large players who have established technology platform standards and control distribution channels. Smaller companies have to work in collaboration with others to remain competitive.

Additional research into the macro-level and micro-level industry has revealed that there are many sub-classes of technology required that span several different industries. There are also a significant number of competitors in the industry (both large and small) developing a variety of testing devices or the necessary components. Each has vast, tightly held patent portfolios for their particular area of expertise. As a result, the industry is significantly more competitive than anticipated and several technologies will need to be licensed. The degree of complexity of many of the necessary component technologies is also very high and manufacturing them requires specialized techniques.

The business model is self-reinforcing once the instruments are sold to medical practitioners. As they become accustomed to using the device and screening high-risk patients, volumes of cartridges sales will increase and become a recurring source of revenue for the company.

Based on our research findings, it now seems an infeasible idea to develop the product as specified. Most of the domains listed below show a negative impact on the company, with only the Macro-Market and Micro-Industry analysis possibly considered favourable. This, taken in conjunction with the high level of competition in the industry has led us to conclude that our idea is therefore not feasible.

2. MACRO-LEVEL MARKET CONDITIONS

2.1. Overall market size and growth rate

According to WHO, 170 million people across the world (3% of the world’s population) are chronically infected with hepatitis C virus (6). It is estimated that the number of infected patients will quadruple to about 700 million by 2015 (6). Of 100 people exposed to the Hepatitis C virus, 20 people clear the virus within 2-6 months while the rest 80 develop chronic hepatitis C (1).

In the UK around 0.4% of the population (200,000) are chronically infected with HCV (2). As the average list size for GPs in the UK is 1745 patients, this equates to about seven patients per GP or about 18 patients per GP practice (3). As HCV infected patients can remain symptom free for as long as 20 years, in order to diagnose all infected cases, the whole
population will have to be screened (UK population 2001: 58,789,194). Although UK, by comparison, is a low prevalence country, the risks of complacency are high. Only 38,000 cases have been diagnoses so far. An estimated five out of every six people with chronic hepatitis C are unaware of their infection (2). Moderate to severe disease can now be treated successfully in up to 55% of cases overall by using a combination of drugs. If chronic infection is left untreated, most people eventually develop symptoms, and one in five go on to develop cirrhosis of the liver or liver cancer after 20 years or more (2).

2.2. Macro trend analysis
Economic: Early diagnosis of Hepatitis C is beneficial as anti-viral therapy costs £10,000 as compared to a liver transplant which costs about £68,000 (2). Cost to treat patients dramatically increases as the disease progresses.
Demographic: The incidence rate of chronic Hepatitis C varies widely across countries with Egypt being on the top with 18% (5). The prevalence is higher in males than in females (2:1) (1).
Socio-cultural: The W.H.O. has declared Hepatitis C a global health problem (7). There is a worldwide focus on stopping what has been called a more dangerous epidemic than AIDS.
Technological: As a result of improvements in technology, HCV diagnostics is becoming more sensitive and more specific. Tests used for anti-HCV (ELISA) and HCV-RNA (Nucleic Acid Testing) presently are very sensitive and specific. Transcription mediated amplification can detect very small amount of HCV RNA – 10IU/ml. ELISA is used for screening and has 99% specificity (8)
Regulatory: The Hepatitis C Epidemic Control and Prevention Act - H.R.3539 was introduced in the US senate in 2003, though it is still pending action. To combat the HCV epidemic in the United States, the Center for Disease Control and Prevention developed the “Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease” in 1998 and the “National Hepatitis C Prevention Strategy” in 2001.

Overall, the macro market is favourable as even though the growth rate of the disease in UK is decreasing, the global market is still very large.

3. MICRO-LEVEL MARKET TARGETS AND TRENDS

3.1. Target market pain and compelling benefits of solution proposed
We had identified the growing importance of Hepatitis C as a global epidemic and believed that the solution to this problem was mass screening of the population by healthcare professionals. We understood that it was impossible to implement this solution using existing, lab based diagnostic modalities as it was impractical to send the whole population to the lab for tests and even if this was somehow made possible, the cost of doing so would be too much to afford. Our belief was that this problem could only be solved by the availability of a portable, point-of-care Hepatitis C diagnostic device which would enable healthcare professionals to personally administer the test to all of their patients. We believed that the benefits of instantaneous results, higher efficacy and the ability to make timely treatment decisions would compel healthcare professionals to adopt this device. We initiated the feasibility study with the aim of confirming these beliefs. Our plan was to target a well defined segment of the healthcare market; the GP practices in UK and we began with the assumption that each practice would probably use only one device.

At the beginning of the study, we considered GPs to be the end-users for our device. Our initial presumption was that in UK, all medical devices were bought centrally by the NHS, who then distributed it to the GP practices. We decided that in order for the NHS to be interested in our device as a customer, we should first find out the views of doctors who would be using the device as we considered their acceptance a significant factor in the adoption of our device. Armed with the feedback from doctors and the results of our financial analysis, we planned to approach NHS in order to explain to them the benefits of our product. As the cost of Hepatitis C drug therapy is £10,000 compared to £68,000 for a liver transplant, we had calculated that if our device was adopted by NHS, it would save them about £50 million every year for a period of 20 years (Appendix 3). This was determined by multiplying the difference between the transplant and therapy costs by the number of HCV cases diagnosed. It assumes that all cases can be treated with therapy rather than liver transplants and that all cases will be diagnosed.

3.2. Target market segment, size and growth rate
Hepatitis C is caused by infection with the Hepatitis C Virus (HCV). In UK there are an estimated 200,000 people infected with HCV of which only one in six have been diagnosed so far. There were about 4000 new cases during 2001 though this number is expected to decrease at a rate of 12% for the next ten years (2). In 2003, there were a total of 10,683 GP practices in the UK. Their number has decreased by 417 in the past ten years as a result of consolidations (3). In the future, it is expected that the number of GP practices will either remain steady or decrease by a small fraction (3).
3.3. Customer willingness to pay
To obtain the opinion of end-users, we personally interviewed a number of doctors in the UK (listed in Appendix 2). As a result of these interviews, we became aware of certain facts, some of which were contradictory to our initial assumptions.

- NHS is not a central supplier of equipments and each GP practice works under a contract as a semi-autonomous institution. The practice is allotted a yearly budget by the NHS and it uses this money for all expenses including buying of equipment from private vendors.
- The customer for the Hepatitis C device is the GP and not the NHS.
- Hepatitis C is not considered a significant health problem by GPs as most GPs have not even seen a case in two to three years time.
- The benefits offered by the device are not considered compelling enough by the GPs as far as Hepatitis C is considered as the difference of a day or two compared to established lab tests is not considered to provide any significant benefit to the patient. None of the doctors interviewed were interested in buying the device.
- Presently, all patients diagnosed to be Hepatitis C positive are not treated with drug therapy. Treatment is started only if there is evidence of liver dysfunction. Treatment of all positive cases is considered expensive and unnecessary.
- If the Hepatitis C device is adopted by GP practices, it will be used by either the nurse or the phlebotomist and not by the doctors.
- Doctors are very protective of their time. If the patient is diagnosed immediately, the doctor will have to spend a much longer period of time during the same appointment in order to explain the implications of the positive result. This makes the whole idea of instantaneous diagnosis of chronic infective conditions an unlikely proposition to the GP.
- GPs would like to have a portable device capable of diagnosing acute infectious conditions especially meningitis.
- Features desired by doctors in a portable medical diagnostic device for these conditions were reliability, sensitivity and cost-effectiveness.

3.4. Options to grow
Few options identified from the study were: a) a device to measure arterial blood gases for use in hospital emergency rooms; b) a device to diagnose a whole number of infectious diseases for use in hospital wards and ICUs (multi-functional devices); c) targeting other countries like Egypt (18% of population infected) or countries like the US (3.6 million patients) where the long-term damage from hepatitis C infections is expected to cost more than $81 billion by 2019 (4). It was recognized that insights obtained from this study could be used to develop better products for the new markets.

Overall, the micro-level market is very unfavourable for the idea that we had proposed initially. Although we identified other markets we could target, their attractiveness depends on the state of the macro-level market and the industry.

4. MACRO-LEVEL INDUSTRY CONSIDERATIONS
4.1. Industry definition
The diagnostics market is broadly segmented into the in vitro diagnostics (IVD) and in vivo diagnostics businesses. In vivo diagnostics is typically viewed as a specialty market with the key players being instrument manufacturers of imaging technology. We envisage these as two completely separate industries and thus define our market as IVD. To be more specific, our product lies in the rapidly growing segment of nucleic acid testing (NAT). As previously described, our device, along with other NAT devices, analyzes DNA or RNA from a patient to identify a disease or the predisposition of a disease. However, to counter the possibility of defining our industry market too small, we will adopt the previous IVD sector as our defined Industry.

The IVD is a mature industry with more than 20 billion blood tests performed annually worldwide. The global market for IVD totalled over $23 billion in 2002, with over 40% of sales in the US. Geographically, approximately 41% of the IVD revenues are generated in the US, while Europe and Japan account for approx 31% and 11%, respectively.

While the overall IVD industry is growing at 4-5% annually, NAT, which is a fast-growing subset of the IVD industry, grew 23% in 2002 and reached $1 billion in sales in 2003. The market for NAT is forecast to continue growing by 20% annually and will have sales exceeding $8 billion in 2008 while the overall IVD market is projected to exceed $25 billion in 2007. In 2002, the total volume of NAT tests performed in the US was estimated at 35 million.

4.2. Five forces
In general, the IVD industry is dominated by several large players who have established technology platform standards and control distribution channels. For example, Bayer/Chiron are market leaders in blood testing and Roche controls a
large part of the NAT markets due to its proprietary position and established standard base of PCR technology. Smaller companies have to work in collaboration with others to remain competitive.

Substitutes: *None*
After having carefully researched the market, we can neither find nor think of any substitutes for portable, Hepatitis C diagnostic testing. However, this is not to say that this will remain the case. With the market dominated by several larger players, it would be naïve to assume that not one of them is currently undertaking R&D in this area.

**Buyer Power: Medium - Low**
Our targeted customers, doctors, represent the ideal buyer under the 5 forces analysis. They are small, numerous and fragmented buyers who at the individual level have little influence over setting terms and conditions. However, they are hard sells due to the level of competition for share of wallet in the healthcare industry in general. Also, switching costs are high as the total cost of ownership of any piece of technology in this field is high. Also, buyers have been gaining bargaining power recently due to the formation of hospital buying groups and large HMOs using the power of scale to choose specific tests and reimbursement levels (this has mostly occurred in the States).

**Supplier Power: Medium**
Suppliers for device platforms command significant margin in this industry, giving rise to strong supplier power for established platforms. They also enjoy the benefits of capitalising on their patents. However, the nature of the industry is such that many routes lead to the same destination; as this industry is still in its initial stages, there are lots of small companies each perfecting their own technology. This means that although these technologies are protected by patents, there are several different processes that could be employed to reach the same desired functionality. Thus suppliers would have a reduced influence in negotiations.

**Threat to Entry: Medium**
Relatively significant barriers to entry exist in the form of on-going R&D, patents and government regulation. However these factors are not too large to pose a significant entry barrier to the industry as can be seen from the 400 or so small companies currently operating in IVD.

**Rivalry: High**
Competition is intense and is focused on cost in the clinical diagnostics area. Alongside the main large players there are also numerous smaller players who are emerging with new technologies. Competition for customer share-of-wallet is high.

4.3. *Is the industry attractive?*
Even though the industry is large and forecast to experience good growth in the future, with the presence of intense rivalry this industry does not look too attractive for a potential new entrant. However, it is possible for an entrant to enter the market with a specific piece of technology and become a successful niche player. If our idea was to succeed, this is how we must position ourselves in the market.

4.4. *Likely changes going forward*
Competition will increase as technology advances. Given the high margins achievable, we would not rule out the possibility of large new entrants coming into the industry e.g. Pharma companies. It is possible that a round of consolidation will likely follow as large companies try and become more vertically integrated.

Even though the industry is large and growing, overall, the macro industry is highly unfavourable due to the level and nature of competition. If we were to enter the market, it would have to be as a small niche player.

5. **MICRO-LEVEL INDUSTRY FACTORS**
At the beginning of the project our research indicated that there were no players in the portable diagnostic testing industry and that sustainable advantage could be developed by securing rights to intellectual property. This suggested that there were two alternative business models: manufacture the product and components ourselves or outsource the development and manufacturing of the product to a company with appropriate expertise.

Additional research into the macro- and micro-industry has revealed that there are many sub-classes of technology required that span several different industries. There are also a significant number of competitors in the industry (both
large and small) developing a variety of testing devices or the necessary components. Each has vast, tightly held patent portfolios for their particular area of expertise. As a result, the industry is significantly more competitive than anticipated and several technologies will need to be licensed. The degree of complexity of many of the necessary component technologies is also very high and manufacturing them requires specialized techniques. In particular, the cartridges/chips require sophisticated manufacturing techniques developed in the semi-conductor industry. Given the complexity of the technologies involved and the patent portfolios, it would be infeasible to develop and manufacture all of the components required. These technologies must be licensed and the non-proprietary components purchased from suppliers.

5.1. Proprietary elements
The proprietary elements of the device stem from research conducted at UCL. These elements consist of a bio-manipulator and other technologies that could enhance the functioning and sensitivity of the device. This intellectual property would be licensed exclusively from UCL and would not be available to competitors. In addition, an application would be made to patent the device in the UK, the US and the EU.

5.2. Organizational processes, capabilities or resources
The structure of the IVD industry and the NAT micro-segment as well as the medical device market is such that extensive licensing and partnership agreements are required to bring a product to market. This is because large established companies have substantial intellectual property portfolios, control distribution channels, have regulatory and clinical trial expertise, and established platforms.

In analyzing the value chain for the molecular diagnostics industry, our proposed venture would not initially possess any specific capabilities in any of the categories – R&D, Raw Materials, Manufacturing, Clinical Trials or Distribution, Marketing and Sales. Thus, we have not identified any organizational elements that would be difficult to replicate other than the integrated nature of the industry makes it difficult for start-ups to enter the industry. This would not prevent established enterprises from easily replicating the model.

5.3. Business model
Design
We design the complete device and outsource the assembly/manufacturing. The device consists of a reusable base and a disposable cartridge containing the reagents and a sensor chip. The design of the device will be completed internally while the integration of the components and development of a prototype will be outsourced.

Licenses
The device incorporates several components (bio-sensor, reagents) which are non-proprietary and the right to use them will have to be licensed (and components purchased) from third party companies that own the intellectual property. The intellectual property for the proprietary elements will be licensed from UCL (bio-manipulator)

Clinical trials
The UK (and most other first world nations) has extensive regulation and testing requirements for medical devices. This is a complex and lengthy process, especially for start-up companies. We will seek to enter into a partnership agreement with an established company with experience in clinical trials for medical devices to expedite the process.

Manufacturing
Outsourcing the assembly of the device itself appears to be the logical step as expertise in production and sourcing techniques is required for rapid and quality production of this type of high-precision device.

Sales and distribution
Sales of medical devices in the UK require an extensive and well-trained sales force. Sales to hospitals, partnerships and practitioners are made individually, not collectively. In order to gain access to the distribution channel and rapidly distribute our product it will be necessary to enter into a partnership agreement with a well-established company.

5.4. Economic viability of the business model
Capital requirements
Milestones such as basic research, feasibility studies, prototype development, securing IP rights, developing contracts and licensing agreements, clinical trials, development of sourcing & distribution, and commercialization are separate and clearly identifiable. Please refer to Appendix 1c for estimates of the cost of each stage. Estimates of each milestone were developed through analysis of similar ventures.\(^{(13)}\)
Revenue forecast
Revenues are derived from sales of both components of the device: the instrument and the cartridges. The revenue forecast outlined in Appendix 1b is highly influenced by four main factors: the roll-out rate in the UK, the partnership penetration rate, the types of patients tested and the cartridge selling price.

Based on the general practitioners interviewed (Appendix A), each sale is likely to be for small amounts as each device will be sold for 500 pounds and each cartridge for 75 pounds initially. Only one instrument is expected to be sold to each partnership. Subsequent purchases of cartridges, even in batch quantities of 50-100, will still represent small sales.

Gross margin forecast
Our product has two components: the instrument and the cartridges. Please refer to Appendix 1b for details of the calculations, assumptions and references.

Instrument
We estimate that the gross margin on the instrument to be approximately 55%. The costs of the components were determined through research of industry selling prices(13) and prior experience with product development at UCL. The decreasing selling price over time will be offset by lower costs through higher volumes and on-going research and development. The selling price of the instrument was estimated using the results of our interviews (customer willingness to pay) and comparison to the selling price of laboratory equipment.(13)

Cartridges
We estimate that the gross margin on the cartridges will be close to zero in year one but will rise to 45% in year three with higher volumes and on-going research and development. The costs of the components were determined through research of industry selling prices and prior experience with product development at UCL.9(10)(11)(12)(13) The selling price of the cartridges was estimated using the costs of the components, comparison to the selling price of laboratory tests (estimated to be 50 to 75 pounds per test by GPs interviewed) and the estimated value created (see below).

Estimate of the value created
It is estimated that more than 50 million pounds per year over twenty years will be saved from using drug therapy instead of liver transplants. The estimated savings were determined by multiplying the difference between the cost of liver transplants (68,000) and therapy for infected patients (10,000) by the number of diagnosed cases of HCV. Please refer to calculations on Page 2. In addition to these direct savings, there is better overall health of patients, more rapid diagnosis and empowerment of the doctor.

Operating expenses
The level of operating expense associated with delivering our products is likely to be significant even though will be able to sign agreements with existing medical supply distributors as gaining access to an established sales force and distribution channel will be expensive. The level of operating expense associated with producing our products such as research and development, licensing costs, and administrative are expected to be quite high. There are several analogous businesses to which we compared our business model. We benchmarked our costs primarily against Affymetrix, a company with a similar business model and development path.13(14) It is expected that R&D, SG&A and licensing fees will require large expenditures that will grow with the business. The level of operating expenses causes the business model to have a negative operating profit margin. This situation is expected to continue to improve as expansion occurs – i.e. the percentage of sales that these costs represent is expected to decrease and stabilize. Please refer to Appendix 1b for details.

Customer acquisition and retention costs
Our product has two components: the base unit used for scanning and the cartridges used for individual tests. The sales of the base unit will a large, coordinated sales effort to significantly penetrate the market. Once our base units are in place, the cartridges will be reordered without prompting as stocks are depleted by end users, creating a self-sustaining business. These are likely to be reordered on a monthly basis with other needed supplies.

Interviews with practitioners and a member of the NHS have determined that the practitioners are responsible for purchases of specialized equipment such as the device we propose. Unlike our previous belief, the NHS does not function as a centralized buyer except for common supplies. As such, we estimate that the time it will take to win each customer’s business will be short and inexpensive. However, in order to reach our customers, we will have to partner with an
established enterprise for sales and distribution or develop our own sales force. Given the nature of the medical care industry, we will have to partner with an established enterprise in order to quickly roll out our device. We estimate that a 5% sales commission will have to be paid on the selling price of each device and cartridge.

Note: It is likely, given the reimbursement of expenses system used by the NHS and the independent budget of each practitioner that we will also have to negotiate with the NHS with regards to standard pricing of the devices and the cartridges. This process is likely to be long and expensive but has the benefit of being able to demonstrate the value created by the device and testing for the entire medical system. As such, it may be possible to have the cartridges and devices subsidized at a central level by the NHS to increase the affordability and frequency of use by practitioners. This was discussed with a member of the Strategic Health Authority (Appendix A) and was considered a possibility given the combined trends of additional investment in medical services in the UK and cost containment. A clear business case demonstrating lower costs for the overall medical system would have to be prepared and presented.

Cash operating cycle

Inventory
The time between completion of assembly by the manufacturer and shipment to customers is likely to be 45 days.

Accounts payable
Our payment terms to suppliers are likely to be 30 days from delivery of goods, which could potentially be stretched to 60 days.

Accounts receivable
Our customers, general medical practitioners, would likely pay on minimum terms of 60 days, with payment received by our company 75 days after delivery on average.

The cash cycle is unfavourable. Under a best case scenario, we would have a funding gap of 45 days. Under a worst case scenario, we would have a funding gap of 90 days. This presents an additional funding requirement that will grow with the business

5.5. Overall assessment of economic viability of the business model
The business model is self-reinforcing once the instruments are sold to medical practitioners. As they become accustomed to using the device and screening high-risk patients, volumes of cartridges sales will increase and become a recurring source of revenue for the company.

Additional information needed to refine the estimates for the cartridges include:
- actual cost of a HCV laboratory test (labour, reagent, delivery)
- biosensor costs for a single test sensor (for HCV only)
- customer willingness to pay and perceived value of the test
- sales commission and distribution percentage
- volume manufacturing cost savings

6. TEAM ASSESSMENT

6.1. Team’s mission, aspirations and propensity for risk
We define our mission as: To bring about substantial improvements in the quality and efficacy of disease diagnosis by offering nanotechnology based point-of care portable diagnostic devices that empower healthcare professionals and patients.

We summarize our aspirations as follows: To build a fast growing and profitable nanotechnology company that would:
- change the way healthcare professionals diagnose epidemic diseases;
- enable patients patients to self-diagnose diseases;
- enlarge the base of diagnosed patients.

There are two aspects of our propensity for risk that we consider highly significant. First, we would prefer to retain control of our business. However, we recognize the high cash needs of our type of business would make it unlikely to retain complete control. Second, since we have not identified enough market potential for fluid-based testing, we are not prepared to risk a secure salary or personal savings. It would rather be more beneficial to invest time in assessing whether
slight modifications to the current proposal (i.e., portable HCV diagnosis device) would show better prospects (e.g., what about HIV portable diagnosis devices?).

6.3. Team’s ability to execute on the CSFs in this industry
We identified three main CSFs in our industry:
  1. Finding ways to reengineer research outcomes according to the market. It is essential that our research plans are driven by real needs in the field of medical diagnosis and adapt to fast changes in both medical and nanotechnology research fields.
  
  2. Setting up partnerships with key suppliers. Both research and technology integration benefit from key partnerships. Our applied research requires the cooperation of research institutes in the areas of medical diagnosis and nanotechnology. Reliable suppliers in each technology are vital for the successful production of our device that integrates different types of technologies.

  3. Building efficient sales and distribution networks. Each single GP/hospital makes the purchasing decision. As a consequence, we need medical sales forces. In addition, distribution networks are also required because orders need to be delivered to each single GP/hospital.

Our team can partly execute on the second CSF. As part of his appointment at the London Centre for Nanotechnology of University College London, Ajith Jinnil has managed different research contracts with companies providing nanoparticles, has contacts with companies providing instrumentation solutions and also has the necessary contacts in UCL to license out the biomanipulator technology on favourable terms.

Given our inability to execute on the remaining CSFs, we propose to fill out our team with:
  
a. Head of Product Development, responsible for executing on the first CSF.
  
b. Well-connected Health Care Sale professional, responsible for executing on the third CSF and partly on the second CSF enhancing our network of partnerships.

6.4. Team’s connectedness up, down and across the value chain
Our team has strong connection with

  1. London Centre for Nanotechnology: For nanotechnology solutions and R&D
  
  2. Jeff Skinner, Director, UCV Ventures: For licensing needed technologies from UCL
  
  3. Henry Clemente, Clemente Associates: Supplier of customized nanoparticles
  
  4. Instrumentation solution providers (names cannot be disclosed)

7. IN CONCLUSION

As highlighted above, only the Macro-Market and Micro-Industry analysis can be considered favourable. This, taken in conjunction with the fact that the customer is unwilling to buy a portable Hepatitis C device and there exists a very high level of competition in the industry, leads us to the conclusion that our initial idea is not feasible.

However, this is not to say that the general idea wouldn’t work without some modifications. Through our research we identified several areas in which to refine our product offering in the future including:

  1. Turning the device into a multi-function product for hospitals that is able to test for several different diseases (probably by utilising different cartridges): Not technically feasible at present.
  
  2. Develop the product as a low cost, throw away item, similar to current pregnancy tests: Not feasible to develop a cheap device unless micro-level industry dynamics change
  
  3. Develop a Hepatitis C device for countries with high prevalence of infection like Egypt: The cost of device is considered a barrier for a device targeted at Africa and moreover, at present it is difficult to estimate the needs of geographically distant customers.

Each of these modifications is truly worthwhile investigating if the associated problems can be surmounted.
8. Appendices

Appendix 1a – Sales and Gross Margin Forecast

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<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
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<tbody>
<tr>
<td><strong>Devices</strong></td>
<td></td>
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<tr>
<td>Revenues from device sales</td>
<td>160,700</td>
<td>201,250</td>
<td>375,911</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>72,379</td>
<td>90,003</td>
<td>166,623</td>
</tr>
<tr>
<td>Gross margin on devices</td>
<td>88,321</td>
<td>111,246</td>
<td>209,289</td>
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<tr>
<td>Gross margin % on devices</td>
<td>55%</td>
<td>55%</td>
<td>56%</td>
</tr>
<tr>
<td><strong>Cartridges</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Revenues from cartridge sales</td>
<td>6,131,610</td>
<td>11,080,648</td>
<td>35,017,325</td>
</tr>
<tr>
<td>Cost of goods sold</td>
<td>5,747,362</td>
<td>8,023,972</td>
<td>19,351,112</td>
</tr>
<tr>
<td>Gross margin on cartridges</td>
<td>384,248</td>
<td>3,056,676</td>
<td>15,666,212</td>
</tr>
<tr>
<td>Gross margin % on cartridges</td>
<td>6%</td>
<td>28%</td>
<td>45%</td>
</tr>
</tbody>
</table>

Appendix 1b – Net operating margin forecast

<table>
<thead>
<tr>
<th></th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operating costs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>2,456,005</td>
<td>3,497,388</td>
<td>7,786,512</td>
</tr>
<tr>
<td>Selling, gen &amp; admin</td>
<td>3,838,309</td>
<td>4,964,035</td>
<td>7,432,580</td>
</tr>
<tr>
<td>Licensing fees - UCL</td>
<td>564,616</td>
<td>814,995</td>
<td>1,250,000</td>
</tr>
<tr>
<td>Licensing fees - Biosensor</td>
<td>562,923</td>
<td>612,819</td>
<td>853,932</td>
</tr>
<tr>
<td><strong>Total operating costs</strong></td>
<td>7,421,853</td>
<td>9,888,337</td>
<td>17,323,024</td>
</tr>
<tr>
<td><strong>Net operating margin</strong></td>
<td>-6,949,284</td>
<td>-6,720,415</td>
<td>-1,447,523</td>
</tr>
</tbody>
</table>

Appendix 1c – Capital requirements analysis

Assumptions: Appendix 1a

1. Roll-out devices to London practices year 1, cities > 100,000 year 2, England year 3.
2. Each partnership will have a unit but only 20% of partnerships will order one as only large partnerships in urban areas with medium to high risk patients will likely by.
3. Only high risk patients will be tested and they will be tested once a year.
4. Based on results of interviews with general practioners, nurses and member of the NHS.
5. Cost of components
6. Assembly & Manufacturing estimated to 30% of cost of components
7. Sales commission estimated to be 5% of gross revenues
8. Shipping & packaging estimated to be 10% of costs
9. Costs per unit are estimated to decrease by 20-30% per year with volume and experience

Assumptions: Appendix 1b

10. On-going R&D will be the following % of sales: Year 1 - 39%; 2 - 31%; 3 - 22%  
11. SG&A will be the following % of sales: Year 1 - 61%; 2 - 44%; 3 - 21%

Assumptions: Appendix 1c

12. Stages 1 to 3 start-up costs estimated
13. Sufficient funding available to meet cash requirements of expanding business

Appendix 2

List of Doctors interviewed:

1. Dr Rangaswamy Mothukuri  
   House Surgeon (Ex GP), Royal Gwent Hospital, Wales
2. Dr Pranav Kumar  
   SHO Medicine (Ex GP), Royal Gwent Hospital, Wales
3. Dr Thomas Estcourt  
   Paddington Green Health Centre, 4 Princess Louise Close
4. Dr Ronmil Bavishi  
   London Business School
5. Dr Anthony Lehman
Appendix 3

Population infected 200,000

CURRENT STATUS

<table>
<thead>
<tr>
<th>Status</th>
<th>Count</th>
<th>Drug Treatment Cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Early treatment</td>
<td>110,000</td>
<td>£ 10,000 x</td>
</tr>
<tr>
<td>Chronically infected</td>
<td>72,000</td>
<td>£ 10,000 x</td>
</tr>
<tr>
<td>Liver transplant</td>
<td>18,000</td>
<td>£ 68,000 x</td>
</tr>
</tbody>
</table>

Total £ 3,044,000,000

WITH EARLY DIAGNOSIS

Population infected 200,000

<table>
<thead>
<tr>
<th>Drug Treatment Cost (£)</th>
</tr>
</thead>
<tbody>
<tr>
<td>£ 10,000 x</td>
</tr>
</tbody>
</table>

Savings £ 1,044,000,000

9. References:

(1) NHS Briefing paper – “Hepatitis C – Essential information for professionals”, 2002
(3) Profile of UK Practices, RGGP information sheet No2, June 2004
(4) American Association for the Study of Liver Diseases (AASLD) meeting on Hepatitis C, 09 November 1999
(5) Hepatitis C support project: http://www.hcvadvocate.org/hepC/Wakil-1.html
(9) http://www.clementeassociates.com/
(11) http://www.usask.ca/events/news/articles/20000531-1.html
(12) http://www.investindk.com/textversionII/default.asp?artikelId=11600
(13) Annual reports and websites of Randox Laboratories, Infineon, Affymetrix, Biomerieux, Roche, Acrogen, PerkinElmer, Ciphergen Biosystems and Agilent Technologies