SparkBiotech
the spark of life™

Business Plan

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Table of Contents

1 Executive Summary

Spark Biotech is focused on developing oral formulations of biologic drugs such as insulin. The Company's anchor asset is a biopolymer-based encapsulation technology (SparkCoral™) that facilitates oral delivery without modifying the therapeutic molecule. Early clinical development will focus on well-established, low-risk, high market potential drugs such as insulin, human growth hormone and monoclonal antibodies. Spark Biotech's oral formulation of insulin (Sparkulin™) is also glucose sensitive and delivers insulin on demand when glucose levels are low. Spark Biotech plans to expand the pipeline to include oral formulations of other commercially marketed and biologic therapies.

SparkCoral™ technology will satisfy an unmet need for the oral delivery of a broad range of biologics and alleviate the pain associated with the current delivery method -- injection. The ease of administration of therapeutic molecules with SparkCoral™ technology will result in increased patient compliance and improved treatment efficacy. Sparkulin™ -- the oral, glucose-sensitive, on-demand formulation of insulin -- promises a pain-free, self-regulating form of insulin that will radically improve glycemic control in diabetics. Spark Biotech will realize revenues through early sales in India followed by milestone and royalty payments from sales partnerships with large biopharmaceutical companies in the US.

Spark Biotech's technology is based on extensive research by Dr. PanduRanga Rao Koritala, an internationally recognized scientist with over 40 years of experience in biopolymer science and more than 160 publications in peer reviewed journals. Spark is following a risk-reduced path to commercialization by initially focusing on currently marketed and highly successful therapeutics. Spark's drugs are initially being developed in India due to lower cost of development and faster regulatory approval cycles. The fast commercialization in India reduces the developmental risk because Spark can leverage the Indian data for USFDA approval.

Spark Biotech is seeking $4.9 million in seed/series A funding (tranches of $1.4 and $3.5 million) to finance growth, perform pre-clinical and Phase I clinical trials, file the IND with the USFDA, and develop key partnerships to commercialize Spark's lead targets, oral insulin and hGH. Future rounds will fund clinical trials and expand Spark's pipeline. Spark Biotech anticipates an IPO in 2009 for funding future development and growth. Spark will also seek M&A opportunities to maximize value through synergies.

2 Company

Spark Biotech, Inc. is a Delaware corporation founded for the purpose of creating oral formulations of biologic drugs. Ownership is divided between Dr. PanduRanga Rao Koritala and S. Bobby Koritala, the founders. Currently, all research and development activities are conducted in India by a wholly owned subsidiary, Spark Biotek, Pvt. Ltd., India. To date, the founders have funded all the expenses related to the company. Recently, an angel investment of $30,000 and a $30,000 investment by Carnegie Mellon University as a result of Spark Biotech winning the "McGinnis Venture Competition" were structured as convertible notes (with warrants for the angel).

Spark Biotech's technology is based on 20 years of pioneering research conducted by Dr. PanduRanga Rao Koritala in this field. Exhibit 2 illustrates the history of Spark Biotech's evolution.

3 Market

Currently there are approximately 84 macromolecule drugs marketed in the United States and more than 350 are in clinical studies worldwide. Sales of biologic drugs are estimated to be $50 billion by 2010. Nearly all biologics are delivered through an injection. SparkCoral™, Spark Biotek's technology for oral formulation can potentially be used for many biologics in the market. However, Spark Biotech will initially focus on insulin, human growth hormone (hGH) and monoclonal antibodies, in that order.

Spark Biotech is currently conducting pre-clinical animal tests in its Indian labs on its oral insulin (Sparkulin™) and will bring this to the market in 2 years in India. In parallel, Spark will pursue development of Sparkulin™ in the US, leveraging data from the Indian trials. In India the diabetes market is estimated to be about 32 million people (growing to 57 million in 2025) and Spark will assemble a sales force to address the Indian market.

In the US, Spark Biotech will partner with larger biopharmaceutical companies to develop and market oral biologics, including insulin. Revenue from these partnerships will be in the form of milestone payments from partners associated with the completion

of each phase of clinical development and royalties from the sales of the drugs upon FDA approval.

Spark Biotech offers a compelling value proposition to its US partners beyond the obvious advantage of oral delivery over injections. Some of these benefits include:

- Extension of patents – this has significant implications, especially for blockbuster medications with sales in excess of $ 1 billion per annum. The oral reformulation of the biologic will allow a new patent to be filed that will protect the partner from competition with generics for several years, reaping significant profits.
- Market growth – increased efficacy, convenient capsule form, and advantages over competing injectable technologies will drive greater market penetration for the partner firm. Significantly advantageous formulations like the orally delivered biologics will enjoy pricing power over other formulations.

3.1 Market Analysis

Biopharmaceutical companies are increasingly focused on developing novel therapeutic proteins to treat a variety of disorders. The therapeutic protein market was $34 billion in 2004, growing to $52 billion in 2010 and is expected to continue outpacing the conventional pharmaceutical market in the coming years. [1]

Insulin, growth hormone and monoclonal antibodies (initial focus areas for Spark) have significant market potential. The market opportunity in these segments is outlined below.

Insulin:[2] The global sales forecast for insulin is ~$10.3 B in 2008, with a CAGR of 16.2%. Novel insulin products are projected to have increased physician uptake due to better patient compliance and ease of administration. The total addressable market versus total current insulin penetration suggests that convenient and patient-friendly delivery of insulin would greatly increase utilization. Additionally, early data indicates that the delivery of insulin into the portal vein via the GI route may decrease hypoglycemic complications and prevent the development of insulin resistance. A new delivery formulation would allow an insulin supplier to differentiate itself in the diabetes market and command greater share and higher margins than competitors.

Growth Hormone:[3] In 2001, worldwide human growth hormone (hGH) sales were ~1.5 B with a CAGR of 8%. According to a DataMonitor report, easy administration of hGH is a key factor in driving uptake, especially among the pediatric patient population. Although the hGH market is highly competitive, with more than five players, competition is not based on product pricing. Companies developing innovative needle-less systems enjoy significant competitive advantage. A new oral formulation would allow a smaller player to leapfrog the competition or a dominant player to redefine the market, increase market share and establish a new price point.

Monoclonal Antibodies: The monoclonal antibodies market is exploding, almost reaching $7 billion in revenues in the US. The FDA has approved 17 monoclonal antibody (MAb)-based drugs to date – and hundreds more are in clinical development. As monoclonal therapies are studied in chronic disease markets, oral delivery may improve their ability to penetrate these chronic markets more extensively than injectable delivery.

3.2 Partners

Target partners for oral insulin and hGH include: Eli Lilly, Aventis, Genentech, Sorrono, Savient, Ferring and Novo Nordisk. Spark is currently in discussions with Genentech, who is evaluating Spark's technology for oral delivery of its biologics. A distinguished research scientist at Eli Lilly seeking to further understand Spark's technology has also contacted Spark Biotech. In addition, the business development teams working with the R&D teams at Novo Nordisk and Takeda Pharmaceuticals are evaluating Spark's technology. Spark Biotech is in discussions with Johnson and Johnson regarding Sparkulin™ and oral EPO. The business development activities at Spark will further expand to actively pursue partnership with other target partners very shortly.

3.3 Competitive Differentiators

Among competing oral delivery technologies, direct competitors to Spark are Emisphere Technologies, Nobex Corporation and BioSante Pharmaceuticals. Spark Biotech's oral formulation technology differs from the competitor products in three very significant ways:

- Unlike most competitive systems Spark Biotech's system does not alter the therapeutic molecule, thus reducing the toxicity profile.
- Spark Biotech offers better loading efficiency to ensure that the necessary dosage of the therapeutic drug is delivered in one to two capsules.
- Spark Biotech offers a unique glucose-sensitive, on-demand release mechanism in the case of insulin. Sparkulin™ will release insulin only when glucose levels in the bloodstream are higher than normal, potentially removing the need for repeated testing of blood sugar levels.

While these companies represent the direct competition to Spark Biotech, larger pharmaceutical and biotechnology companies, as well as other delivery methods, represent potential future threats. The advantages mentioned above for Spark's patented SparkCoral™ technology constitute a next generation drug formulation technology when compared to potential competitors.

In terms of development time, Spark Biotech enjoys a significant advantage over our competitors because our discussions with Indian regulators indicate that we can bring our formulations to market in India in 2 years, on average. This allows us to perform the necessary clinical development at a much more accelerated pace, get much needed validation in a market with large patient populations, and generate revenues, while leapfrogging over our competitors.

4 Products and Technology

4.1 Technology

Spark Biotech has a portfolio of natural polymer-based technologies that can be customized for the oral formulation of each biologic drug.

Spark's drug formulation technology is based on proprietary biodegradable polymer microspheres/nanoparticles that serve as carriers for the drug. These carriers encapsulate therapeutic proteins and peptides, and facilitate oral delivery and bioavailability. Spark Biotech has over six technologies that can be applied to the range of biologic drugs. The

size and properties of the active ingredient help determine the effectiveness and loading efficiencies of the different technologies. A capsule containing these nano/microspheres is coated with a proprietary biopolymer and is ingested by the patient. The capsule containing the drug-loaded nano/microspheres then passes through the stomach without denaturing. The capsule travels intact to the small intestine where it breaks apart due to the pH in the small intestine and disperses the microspheres/nanoparticles, which then attach themselves to the mucosal surface of the small intestine. The nano/microspheres are engineered to penetrate the mucosal wall through transcellular and paracellular pathways. The nano/microspheres are protected with a proprietary biopolymer that enables them to resist lysozomal degradation in the transcellular pathway and in the bloodstream. The hydrogel matrix of the spheres interacts with the tight junctions of the mucosal wall allowing the spheres to squeeze through the paracellular pathway. The cocktail of nano and microspheres and the dual routes of absorption through the transcellular and paracellular pathway ensure sufficient bioavailability of the molecule. The nano/microspheres and any drug molecules that are already released into the bloodstream are then transported to the liver through the portal vein. For insulin, this is the physiologically natural pathway followed by endogenous insulin as well.

4.2 Drug Targets

Spark Biotech is focusing on oral formulation of insulin and human growth hormone as the lead drug targets. Oral insulin - Sparkulin™, will have the unique attribute of being formulated as a glucose-sensitive, on-demand release system, which will deliver insulin when there is above-normal glucose in the blood stream. This is a significant development and could be considered a second-generation offering of an oral insulin formulation, thus leapfrogging the competition. Human growth hormone will be formulated to enable the oral delivery of hGH to the pediatric and adult populations.

Spark Biotech is also evaluating other drug candidates, including monoclonal antibodies, and will seek to develop more commercially marketed drugs and new biologic entities to keep its pipeline full. Spark's goal is to partner broadly with numerous biologic drug

companies through the development stages in order to create oral formulations of their drugs.

4.3 Development Status

Spark Biotech's technology has evolved over a period of 20 years through Dr. Rao's work in the area. Studies have been conducted on the oral formulation of numerous drugs using various technologies to protect the drug as well as the carrier from gastric acidity, proteolytic degradation, and to enhance drug absorption and promote successful drug delivery. In Vivo and In Vitro studies using the biodegradable polymer encapsulation technology have revealed positive results. Building off earlier success with the technology, oral delivery systems for vaccines such as tetanus and diphtheria toxoids using natural polymeric microspheres such as gelatin, chitosan, and alginate were developed. The viability of these systems as an oral vaccine delivery system was proved using animal models.

Since the formation of Spark Biotech, several improvements have been made to the biopolymer delivery platform used in the earlier studies. Some of Spark Biotech's improvements include: the ability to provide glucose sensitive release of insulin from proprietary biopolymers, enhanced muco-adhesive properties, elimination of the need for Trypsin Inhibitor, enhanced absorption through the mucosal membrane of the small intestine, and the ability to fine-tune the size of the proprietary biopolymer-based microspheres and nanoparticles. Six different proprietary biopolymer microsphere-based delivery systems have been developed for various applications. These latest improvements and developments of the platform technology constitute the intellectual property that Spark Biotech is protecting and leveraging.

Spark Biotech has studied the behavior of Spark's carrier device (gelatin capsule coated with a proprietary biopolymer), used to deliver drug-loaded nano/microspheres through the stomach and into the small intestine, in humans. Results of human gastrointestinal studies clearly indicate that Spark's biopolymer coated carrier device is resistant to the acidic environment of the stomach, thus enabling effective delivery of the

microspheres/nanoparticles to the small intestine. Exhibit 4 shows in-vitro and in-vivo study results of drug delivery.

Spark Biotech's development timeline going forward is to focus on the pre-clinical and clinical development of Sparkulin™, followed by pre-clinical studies on the oral hGH product. Spark Biotech is currently conducting rat model experiments and preparing for human trials of Sparkulin™ in its Indian facility. The anticipated commercial launch of Sparkulin™ in India is 2008. We anticipate that this will allow Spark Biotech to achieve a faster regulatory approval cycle from the USFDA because Spark is not modifying the original drug molecules. Other drugs in its pipeline will follow a similar pattern with accelerated development and commercialization in India, with data leveraged for USFDA approval. Exhibit 1 describes the developmental timeline that Spark Biotech will follow to develop the various drug candidates in its pipeline and the revenues Spark will derive from these activities.

Most of the pre-clinical and clinical development is performed at our Indian laboratories. This will be supplemented by any additional work the USFDA requires to be done in the USA at our US laboratory (which we will establish when it is needed). We are entering into a cooperative research and development agreement with Argonne National Laboratory (US DOE National Laboratory) to use their sophisticated equipment such as SEM (scanning electron microscope) and TEM (transmission electron microscope) to characterize the nano and microspheres. Spark Biotech retains exclusive rights to inventions created under the agreement.

Spark Biotech is in a unique position to develop this technology due to Dr. Rao's leadership and expertise in this area. In addition to his experience, Spark has employed scientists (Dr. Rao's PhD students) who have been trained by Dr. Rao in SparkCoral™ technology. Once Spark secures the necessary funding, the team will grow to include more scientists, clinical development specialists and business development / sales professionals.

4.4 Technology Advantages

Significant advantages of Spark's unique platform technology include:

- Formulation flexibility, which includes the ability to control the rate of drug release. Biopolymer release characteristics can be modified by making the particles stimuli-sensitive. This ensures that the appropriate amount of drug is available under the appropriate conditions. For example, when there is glucose in the blood, insulin is released from Spark's nanoparticles and microspheres
- Using biodegradable and natural biopolymers, thus reducing the toxicity profile.
- Unmodified drug molecules reduce the possibility of unintended side effects. Unlike the other oral delivery systems in development Spark does not use covalent bonds and conjugates which could potentially alter the drug molecule.

The various advantages of Spark's technology include the fact that it is cost effective and uses safe and inexpensive, readily available ingredients. This, in addition to the ability to scale operations, allows Spark to offer our partners the technology to effectively build out manufacturing capacity. Spark's technology achieves effective loading efficiency for incorporating the drug, leading to maximum therapeutic effect. The biopolymer particle size can be controlled to accommodate various kinds of drug molecules. SparkCoral™ can also incorporate the necessary volume of active drug in just one to two pills. Enhanced adhesion and permeation capability of the delivery system leads to improved bioavailability of the drug.

4.5 Intellectual Property

Spark Biotech's pending patent covers several areas, including biopolymer composition, mechanism of action and the manufacturing method for SparkCoral™ formulation technology. The IP is unique and revolutionary and constitutes a formidable barrier to entry. Dr. Rao has applied his significant expertise and experience to develop this technology over a period of 20 years. Spark Biotech's strategy is to file numerous other patents, several more of which are already being written, to establish a significant IP portfolio to effectively protect its platform technology.

5 Business

5.1 Business Model

Spark Biotech will pursue a risk-reduced path to revenues by first concentrating on commercially successful biologics. Spark Biotech will develop the new formulations by forming development partnerships with commercial manufacturers. Spark will gain value from the partnerships by capitalizing on the partner's trial development expertise. The partner will bear the development costs and US market commercialization responsibilities. Spark Biotech will derive revenues through direct sales in India and development milestones and sales revenue royalties in the US.

Transforming approved therapeutics into oral therapies will create exceptional value for the current manufacturers of these therapies. These manufacturers face increasing therapeutic competition, potential bio-generics and generally thin pipelines. They recognize that sustaining a product through effective life cycle management increases revenues while significantly reducing risk. Spark Biotech delivers a sought-after technology that improves a manufacturer's product lifecycle management.

Reformulated products provide value to the originator company through five key drivers:

- **Extension of Patents:** This has significant implications, especially for blockbuster medications with sales in excess of $1 billion per annum. The oral reformulation of the biologic will allow a new patent to be filed that will protect the partner from competition with generics for several years. Given that these partner firms have already incurred the cost of developing the core molecule, the patent protection from the reformulation will greatly increase the lifetime profits on the drug.
- **Improved efficacy and safety:** Increased patient compliance and improved outcomes increase product utilization. Spark Biotech's oral insulin (Sparkulin™) will provide on-demand release, which promises to reduce hypoglycemic events, improving safety and efficacy.
- **Increased market penetration:** Oral therapies will increase the market penetration of the product by increasing treatments in the currently eligible but untreated patient

population. Human growth hormone has significant growth opportunities in the adult market. The injectable route of delivery is impeding growth in this market.

- **Pricing Power:** The market entry of a novel delivery mechanism is analogous to the entry of a new drug entity. Entry provides an opportunity for the establishment of a new value-pricing strategy.[4]
- **Additional indications:** Many biologics have potential activity in new disease states, but limitations associated with the injectable route of administration prevents these drugs from being used in those novel areas.
- **Off-Label use:** The ability of a physician to prescribe an oral therapy increases the opportunities for that agent to be used in off-label areas, resulting in increased market size.

The revenues gained from improved lifecycle management significantly offset the costs associated with development of a reformulated therapy. Spark Biotech will capture a share of this value through milestone revenues, Indian sales, US sales revenue royalties and reduced development costs. Spark Biotech anticipates development costs beyond formulation and pre-clinical trials, to be borne by the development partner. For each development candidate, this relationship will be determined based on maximum value capture with appropriate risk reduction. The exception to this is our oral insulin, which we intend to develop through Phase II clinical development in the US and full clinical development in India. Insulin is well suited for additional development prior to handing off because insulin is a relatively low cost therapy and efficacy measurement can be determined in relatively short trials.

Spark will primarily seek a milestone-royalty revenue model with partners. Revenue from partnerships with early-stage companies will be driven primarily by royalties, while pre-clinical candidates from larger commercialized companies will be based on milestones and royalties. These deal structures are intended to realize revenues early and mitigate risk. As Spark Biotech grows and becomes product diversified, it will shift revenues out

in time by developing its drugs farther through the clinical trial process hence capturing more upside value from the commercialization of the drug.

5.2 Strategy

5.2.1 Partnership Strategy

Spark Biotech will select partnership companies based primarily on drug characteristics but additionally on characteristics that include corporate drug commercialization capabilities, market power, demonstrated project commitment and transferability of SparkCoral™ technology to other products in the company's portfolio.

Spark Biotech will also pursue opportunities to partner with drug discovery companies during pre-clinical testing. Many pre-clinical biologics are better suited to enter the market as oral formulations. Oral formulation is particularly important for biologics that will compete with oral small molecule drugs. Furthermore, biologics that are going to be late to an injectable market and lack significant clinical differences can effectively compete in the market as an oral formulation.

5.2.2 Product Strategy

Spark Biotech selects candidates based on product, market and partner characteristics. The characteristics of an ideal drug candidate include: potential for clinical improvements (reducing hypoglycemic events with insulin), large current and potential market size (unmet medical need), chronic or long-term therapy, ability to establish pricing power and biologics in a poorly differentiated market.

Spark Biotech is pursing a pipeline build-up characterized by an initial reduced risk strategy, and progressing toward a higher-value, higher-risk strategy in later years. Spark will lead with insulin, followed by hGH. Spark will seek to develop additional molecules at a growing rate each year. The additional development candidates will initially be focused on commercially approved drugs. A growing number of novel biologic entities will be added in future years. This development pipeline will provide Spark with a diversified and rapidly growing development portfolio. Spark Biotech's development pipeline is outlined in Exhibit 1.

The clinical development for most of these drugs will initially be conducted in Spark Biotech's Indian laboratories. This has the obvious benefit of lower cost of development. More importantly though, clinical development timeframes in India on average are 2 years as opposed to 8 years in the US. This allows Spark Biotech to drastically reduce its time to market in the Indian context. It provides the company an invaluable opportunity to leverage the data and experience in the Indian market as it pursues parallel clinical development in the US, potentially speeding up time to market in the US as well[5]. This is consistent with the trend where numerous large pharmaceutical companies such as Novo Nordisk, Aventis, Novartis, GlaxoSmithKline, Eli Lilly and Pfizer have conducted clinical drug trials across various Indian cities (Exhibit 10)[6]. The USFDA has indicated that it will accept foreign clinical study data that is conducted under an IND (Investigational New Drug) application and follows GCP (Good Clinical Practice), which is now mandated by Indian law as well.[7]

SparkCoral™ technology also holds the promise of unleashing novel therapeutics currently not being pursued. An example of this would be the combination of two therapeutic entities in separate micro/nanospheres that are then incorporated into one biopolymer coated capsule. Upon absorption, the two agents would give a synergetic therapeutic effect that would yield a novel therapeutic which is highly desired in certain disease conditions.

While Spark Biotech is not the first to enter the oral biologic drug space, SparkCoral™ is a unique technology platform that is an improvement over current technologies in development. SparkCoral™ technologies provide a patent-protected foundation upon which Spark Biotech will continue to innovate.

6 Management

6.1 Management Team

Spark Biotech's management team includes biotech and management professionals with excellent track records. The breadth of experience includes R&D, Drug and Product Development, Sales and Business Development, Marketing and, Project Management,

Operations and Startup experience. The team also has a depth of experience ranging from 12 to 40 years.

Over the last two years Dr. Rao has been working full-time as the scientific and strategic leader of Spark Biotech. Bobby Koritala recently left his position as a Director in Blue Cross Blue Shield to join Spark Biotech full time. Several scientific staff have been employed in our Indian laboratory. All the other team members are involved in the enterprise part-time with a commitment to come on-board at the appropriate time. Spark Biotech has a hiring plan in place where the recruitment of clinical development, regulatory specialists, product managers and other essential personnel has been planned. The Spark Biotech team includes:

Dr. PanduRanga Rao Koritala (founder), Chairman and Chief Executive Officer, is an internationally known leader in several areas of novel drug delivery and biotechnology research. He has worked in this area for over 40 years and is widely published in over 160 scientific publications, including books. He has worked at Indian National Labs and universities in the UK, Germany and USA. Dr. Rao is a proven entrepreneur and has successfully brought ridge augmentation and guided tissue regeneration biotech products to market in India. His leadership and ability to create novel drug delivery systems and biotechnology applications will be critical in Spark's creation of products and technologies that will pose a formidable technological barrier to Spark's competitors. As the CEO, Dr. Rao provides essential strategic leadership guiding Spark Biotech in the right direction.

S. Bobby Koritala (founder), Chief Operating Officer and President, has 13 years of management experience directing and managing the implementation and operations of several major technology projects. He has worked in successful startups including one that was acquired by a major software firm, in which he started at a very early stage as the 9th employee and helped grow the firm to over 150 people. Most recently he was the Director of Information Technology at Blue Cross and Blue Shield. He is currently completing his MBA at the Kellogg School of Management, Northwestern University. His experience with startups, management and excellent communication skills make him

a strong business leader with a clear vision for Spark. Bobby will manage the operations and business development activities of Spark Biotech.

Ron Richmeier, responsible for Business Development, has 17 years of pharmaceutical experience. Ron is a sales manager with Genentech, where his experiences include managing a sales team, developing a go-to-market strategy for a new drug introduction and collaborating with Marketing and Business Development to analyze new business deals. Prior to Genentech, Ron was with Upjohn for 10 years, where he held 7 positions, including Managed Care Account Management, and Health Science Associate. Ron has significant experience in the diabetes market. He is currently completing his MBA at the Kellogg School of Management, Northwestern University.

Anand Janardhan, responsible for Product Development, obtained his MBA degree from Northwestern University's Kellogg School of Management. Anand was a Business Intern at Pequot Ventures, where he analyzed emerging trends within the life sciences industry and identified drug delivery as a focus area with attractive investment potential. He evaluated the market and commercialization potential of novel drug delivery technologies in Oncology, Pain and Inflammation, CNS, and Respiratory therapeutic areas. He has managed cross-functional drug development project teams supporting new product introductions at Pharmacia Corporation (currently Pfizer, Inc.) for 8 years.

Matthew Kenning, responsible for manufacturing and process development, has several years of plant management and process development experience. Matthew is currently a Plant Manager for a chemical manufacturing and recycling company where his experiences include the start up of a new manufacturing plant, the expansion of an existing plant, and the orchestration of a number of turnarounds at struggling facilities. Prior to his role as a Plant Manager, Matt held a number of process and project engineering roles at different chemical manufacturing sites in the US and Canada. He earned his bachelors in Chemical Engineering at the University of Illinois and is currently completing his M.B.A at the Kellogg School of Management, Northwestern University.

Advisory Board - Spark Biotech has assembled business and scientific advisory boards with thought leaders in drug delivery, entrepreneurship, health industry management and

clinical expertise (Exhibit 11).

6.2 Organizational Development

In order to execute its initial growth strategy, Spark Biotech will focus on growing the Research and Development organization. At the same time Spark will also focus on business development and marketing activities to actively develop partnerships that will generate revenue and fund the ongoing clinical development of its drugs.

In India Spark Biotech will seek to initially outsource a significant portion of its sales and marketing operations with the goal of gradually building up an internal sales and marketing organization.

7 Financial Summary

Spark Biotech's business relies on a revenue model including sales revenues in India and partnership based milestone and royalty on sales in the US. Initial revenues are realized from an upfront payment at the time of partnering. Subsequent revenues are in the form of milestone payments for completing each phase in clinical development and royalties as a percentage of future product sales. Table 7.1 (a) and (b) show the expected revenues from lead compounds insulin and hGH. Table 7.2 represents the financial projections for Spark Biotech based on the commercialization and financing strategy outlined above.

7.1 Assumptions[8]

Development Assumptions:

Spark Biotech will complete clinical development of Sparkulin™ in India and pre-clinical, Phase I and Phase II trials in the US for Sparkulin™. Oral hGH will be partnered in the pre-clinical stage. In the US, Spark Biotech anticipates an upfront payment from establishing a partnership, and milestone payments upon completion of the Phase I and Phase II clinical trials. For hGH, we plan on seeking a partnership upfront milestone payment upon completion of significant pre-clinical work.

Table 7.3 represents the cost estimates and related assumptions regarding patient numbers, number of studies and US study costs for the phase I and II clinical development that Spark Biotech intends to perform.

Market Assumptions:

The US insulin total accessible market (TAM) is estimated to grow at 15% through 2010, 8% through 2015 and 6% after that[2]. Spark's penetration of this market reaches 10%, a year after introduction and rises to 30% over 4 years, which is typical of novel drugs that meet a strong unmet need. US adoption rates for Sparkulin™ are similar to estimates for newer formulations of insulin such as Exubera™(Pfizer) and Oralin™[2]. Pricing in the US assumes a 3 times price premium, which is consistent with willingness to pay studies[4] and is within the norm of significant price premium for new formulations that provide significant benefits[1,2,3]. Today's price per patient is $800 per annum and our pricing is at $2400 per annum[2]. The 3 times number is based on the fact that insulin is a commodity market which has driven the cost to very low levels. The improved Sparkulin™ will be value priced and will command a significant premium above the standard insulin cost. The multiplier is cautious given that branded therapies routinely cost $2,400 a year and with the pharmaco-economic savings that tighter glycemic control will yield, the cost of therapy will be significantly offset by the savings in complications and hospitalizations.

The Indian insulin TAM is estimated to grow at 15% through 2015 and 8% after that[11]. Indian adoption rates for Sparkulin™ are similar to Wosulin™ and Insugen™ reaching 10% a year after introduction, growing at 50% for 2 years and then growing at a slower 15% in 4 years[11, 8]. Cost of sales in the Indian context is 17% of sales, which is typical for new drug entities in India[6, 11]. Drug sales are extremely competitive in India and hence we price competitively to capture market share at slightly below the market price of Rs. 126 (~$3) for a 40 iu, 10ml dosage[6, 11].

Other Financial Assumptions:

Other pertinent financial assumptions include a tax rate of 35%, depreciation of 25%, inflation factor of 3%, ramp-up factor (annual growth factor used in cost estimates) of 5% and a personnel burden (benefits, insurance, etc.) of 20%.

7.2 Funding Requirements

Based on growth and cost projections over five years (Exhibits 5 thru 8), Spark Biotech is seeking venture capital funds to support the business. Spark will require an initial infusion of $4.9 million in seed/series A funding (tranches of $1.4 and $3.5 million). These funds will be used for the following:

- Grow the Indian laboratory and purchase additional essential laboratory equipment and supplies
- Lease office and laboratory space in the US for US clinical work
- Complete pre-clinical studies and clinical trials for oral delivery of Spark's lead drug – oral insulin (Sparkulin™) in India
- File IND (Investigational New Drug) application with the USFDA for Sparkulin™
- Support business development, to actively seek partnerships for Spark's lead drugs – oral insulin (Sparkulin™) and oral hGH and subsequently other commercially marketed drugs and new biologic entities (including monoclonal antibodies) to grow Spark Biotech's pipeline.
- Personnel expenses for the CEO, COO, three scientists and one business development person in the first year. In the following year the additional personnel planned include two scientists, one regulatory, clinical development, manufacturing, business development and product management persons.

In 2007, Spark Biotech plans to raise $15 million in Series B funding to support Phase I and II clinical trials for Insulin and hGH in the US. In addition, these funds will be used to add other drug candidates to the R&D pipeline.

Spark Biotech plans to continue its development through additional rounds of venture funding and an initial public offering in 2009. Spark will also examine M&A options to

effectively commercialize its technology. The appropriate exit strategy will depend on the accepted market valuation for an IPO and the synergies associated with M&A.

7.3 Milestones

Key milestones that Spark Biotech intends to accomplish over the next year includes:

- Growing the laboratory and operations in India
- Hiring of critical personnel in scientific, business development and other key areas.
- Close seed/series A funding
- Complete pre-clinical studies with for oral delivery of Spark's lead drugs – oral insulin (Sparkulin™) and human growth hormone
- Initiate partnership negotiations for oral insulin (Sparkulin™) and hGH

8 Future Prospects

In the immediate future, prospects are extremely good because Spark Biotech is focusing on established drugs, thus removing the developmental risk associated with the molecule. The candidates Spark has chosen are blockbusters and have a better chance of partnering and earning positive economic rents.

The long-term prospects are also bright because the number of macromolecular drugs is growing. The need for oral delivery will continue to grow. Spark Biotech's strategy is to start partnering in the drug discovery stage so it can reap more benefits from developmental drugs and widen its market reach. This puts Spark in a position to fully integrate the activities in the drug development value chain and to further explore new drugs. This includes the possibility of developing vaccines, gene therapies, anti-sense therapies and other more nascent drug technologies. The build-up opportunities based on Spark's platform technology are enormous.

8.1 Business Risks

In recognition of the fact that Spark Biotech faces significant risks as an early stage drug company, Spark has accounted for this risk in numerous ways. Most importantly, Spark

believes that the seasoned and experienced management team it has put in place gives us significant flexibility and skill in being able to handle situations and mitigate the risk associated with the business.

In terms of technology risks Spark has focused on accounting for the developmental risk associated with pre-clinical and clinical development of biologic drugs. Even though Spark is working with currently commercially marketed biologic drugs, the USFDA has historically treated new drug delivery formulations of existing drugs as new drug entities and this implies that Spark would have to go through the full clinical development cycle. Spark Biotech has mitigated the risk of long development cycles by focusing on initial drug development in India and achieving approval in about 2 years. Spark will then leverage the data from the Indian trials to accelerate the US development process.

Spark Biotech has applied typical risk factors associated with new drugs going through this developmental cycle to its risk-adjusted revenue predictions in the financials. There is a significant possibility that Spark's assumptions in this area will be overcome because of its focus on current drugs, which removes the risk associated with the drug molecule.

Spark Biotech has also examined the technology risk from substitute technologies like islet transplantation to the insulin market, etc. However, since Spark's business model is based on a flexible and versatile platform technology that can be applied to any biologic drug, there are significant build-up opportunities, which mitigates this risk.

Spark Biotech's moving some of its research and development activities to India provides significant access to a very skilled labor force in addition to a cost savings. In addition to this, the Indian regulatory regime may lead to a quicker time to market for Sparkulin™, shortening the cycle by 4 – 5 years. Spark intends to do everything possible to focus its activities and spend its cash most judiciously.

Finally, Spark Biotech has paid significant attention to market risk and competition. Spark's IP position and the people it has on the team give Spark Biotech significant competitive advantage. Spark Biotech intends to continue to build its IP portfolio and is uniquely positioned to do so with Dr. Rao's significant experience and expertise. Spark's technical differentiators put it ahead of the competition in terms of its offering.

Appendix

9 Tables

Table 7.1(a) – Expected partnership and royalty revenues in US for lead development compounds –[9]

Milestone Revenues

$ Millions	Preclinical/IND 2006	Phase I 2007-08	Phase II 2009-10	Phase III 2011-12	NDA 2013
Insulin	$0.00	$0.00	$20.00	$25.00	$45.00
hGH	$5.00	$5.00	$7.50	$15.00	$20.00

Royalty Revenues[10]

$ Millions	Royalty rate	Royalty on sales 2014	2015	2016
Insulin	7.50%	$ 138.00	$ 564.53	$ 1,196.79
hGH	7.50%	$ 101.48	$ 152.22	$ 197.89

Table 7.1(b) – Expected revenues from Sparkulin™ (oral insulin) sales in India[11]

$ Millions	2005	2006	2007	2008	2009	2010
Insulin sales in India	$0.00	$0.00	$0.00	$7.76	$11.63	$17.45

Table 7.2: Financial Projection

$ Millions	2005	2006	2007	2008	2009	2010
Revenues	$0.00	$2.50	$2.50	$12.76	$11.63	$44.95
Net Income	($0.90)	($0.62)	($2.97)	$4.18	($0.80)	$21.46
Ending Cash Balance	$3.95	$2.20	$14.51	$43.90	$113.25	$134.83

Table 7.3: US clinical developmental cost estimates [12][13]

Developmental Assumptions *Insulin*	Phase I 2006-2007	Phase II 2008-2009
# of patients	50	120
Cost per patient	$12,000.00	$15,000.00
Patient costs	$600,000.00	$1,800,000.00
# of studies	2	3
Study Costs	$1,200,000	$5,400,000
hGH	**2006**	**2007-2008**
# of patients	20	90
Cost per patient	$12,000.00	$15,000.00
Patient costs	$240,000.00	$1,350,000.00
# of studies	2	2
Study Costs	$480,000.00	$2,700,000.00

Exhibit 1: Spark Biotech's development strategy and timeline.

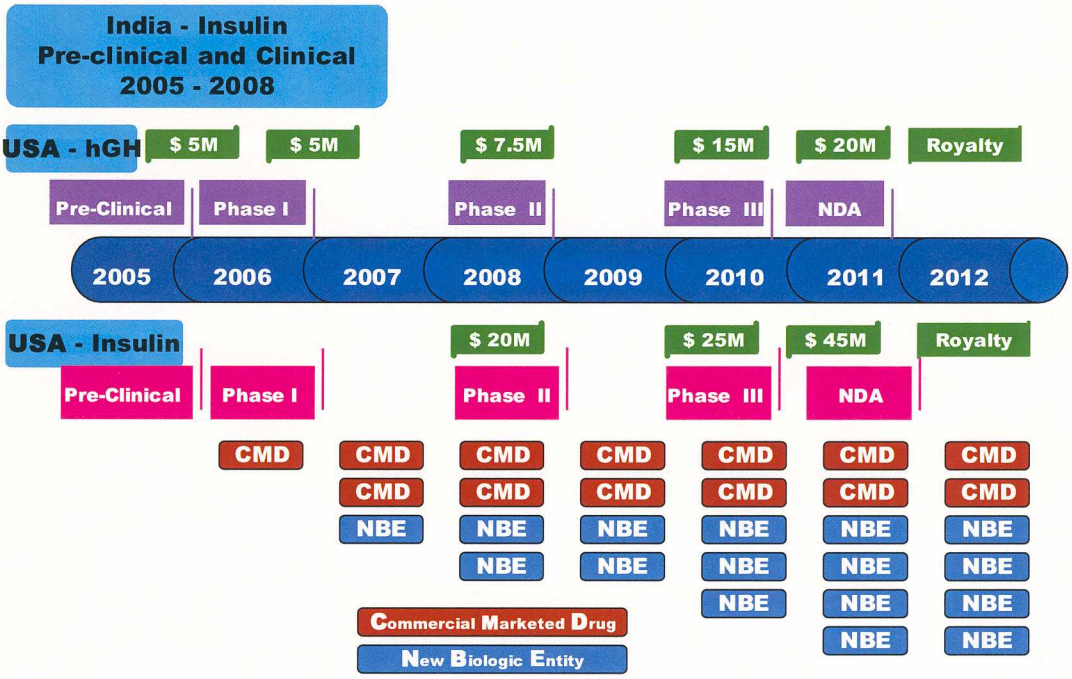

Exhibit 2: Spark Biotech – Historical Milestones

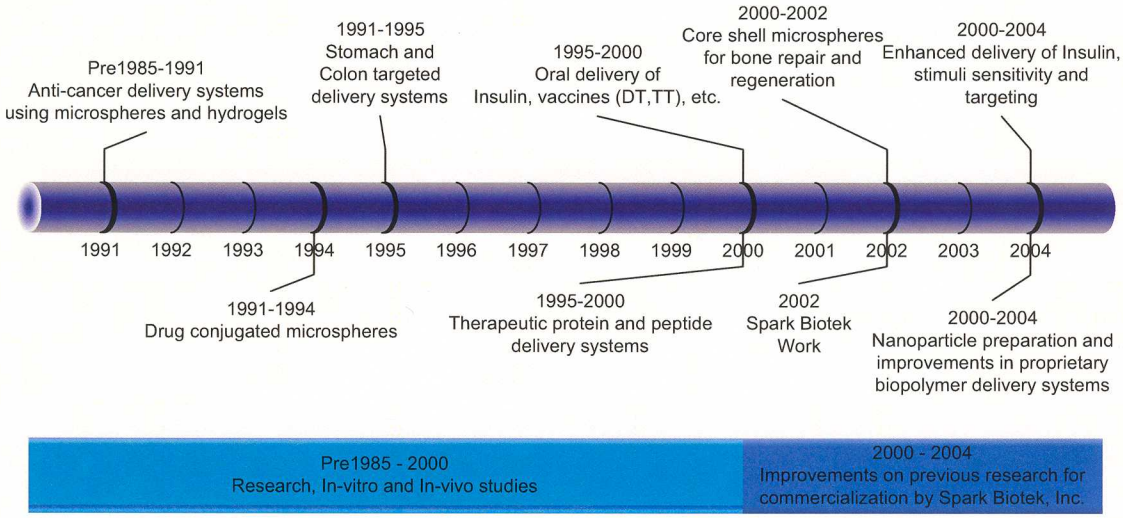

Exhibit 3(a): Spark Biotech's Oral Delivery Technology

Encapsulation of Drug Molecules in Biopolymer Nano and Microspheres

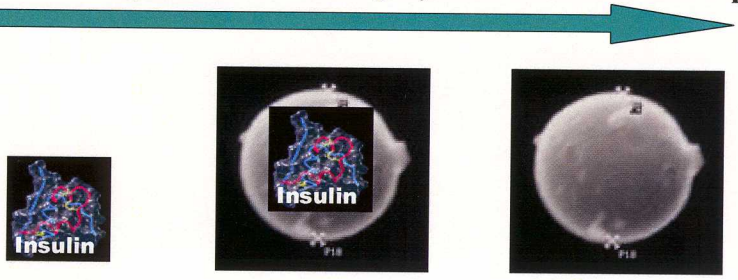

Exhibit 3(b): Spark Biotech's Oral Delivery Technology

Delivery through the Gastro-Intestinal Tract in the Small Intestine (surviving stomach acids)

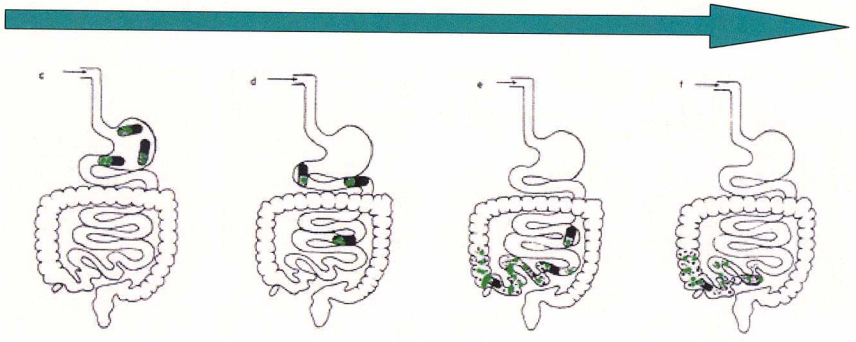

Exhibit 3(c): Spark Biotech's Oral Delivery Technology

Penetration through the intestinal wall – Spark uses (a) transcellular pathway, (b) paracellular pathway and (d) M-cells through Peyer's patches and lymphatic system. In the future we may use (c) Transcytosis with receptor mediation.

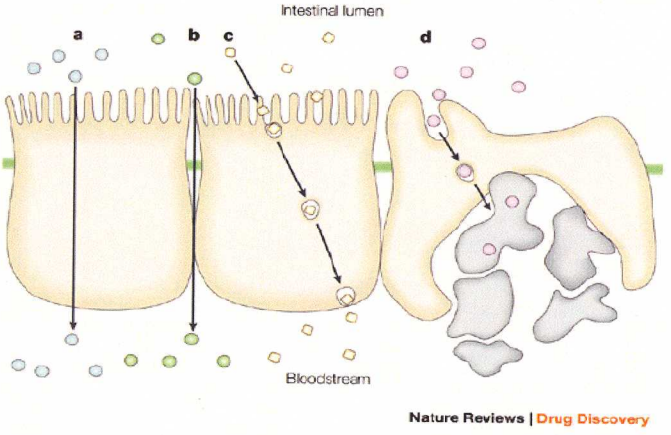

Exhibit 3(d): Spark Biotech's Oral Delivery Technology

Physiologically natural mechanism of delivery through the portal vein, liver and then to the rest of the body through the circulatory system

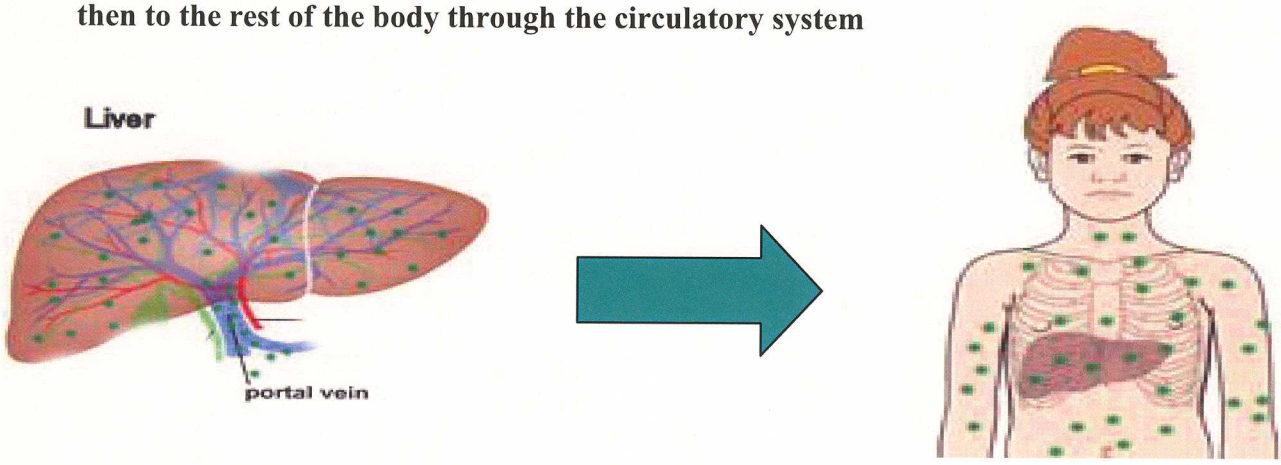

Exhibit 3(e): Sparkulin™ - Glucose sensitive, on demand release

Nano and Microspheres respond to high glucose levels by swelling and releasing Insulin. Once the blood glucose level is normal they shrink and retain Insulin for future delivery.

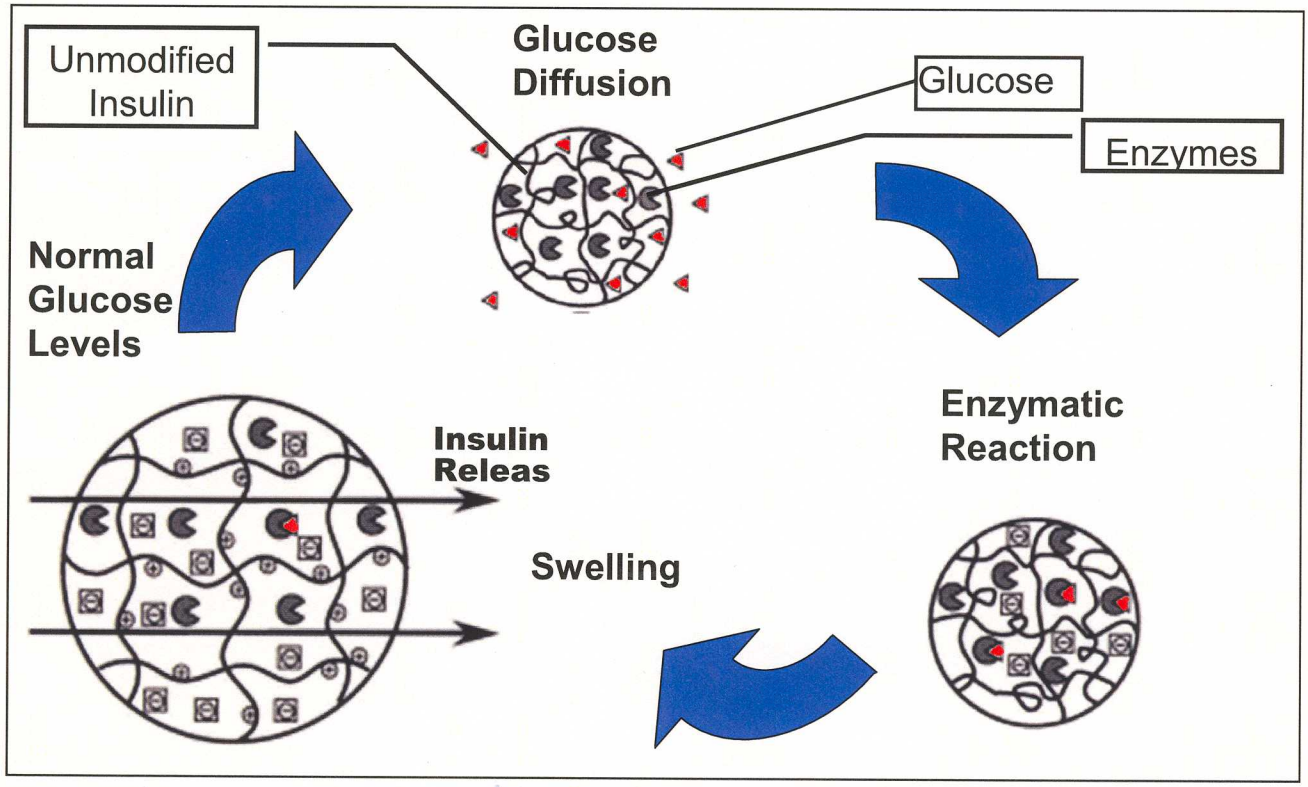

Exhibit 4: Status of Studies performed by Dr. Rao using platform technologies which are the basis for Spark's offering.

Platform Technology	Drugs Tested	Disease	In-Vitro	In-Vivo Model	%Entrapment	% Loading	In-vitro Release Days	In-vitro Release %	In-vivo results
Gelatin Nano/Microspheres									
	Insulin	Diabetes	Release Studies	Rat	80	1 to 5	6	90-98%	Hypoglycemic effect for upto 32 hours
	Model Protein - BSA	Model Protein	Release Studies		60.07	6.01	80	79.5	
	Antigen - DT	Diphtheria	Release Studies	Rat	46.13	0.56	60	90.3	
	Antigen - TT	Tetanus	Release Studies		31.73	0.39	55	88.9	
	Methotrexate	Cancer	Release Studies	Rat	80.5	5.3	9 to 11	97	Intra-tumeral injection. Conjugated MTX worked well.
	5-Fluorouracil	Cancer	Release Studies (Cocktail)		69 to 72	x	7 to 9	97 to 99	
	Type II Collagen	Rheumatoid Arthritis	Release Studies		67.38	2.2	9	87	
	Lysozyme	Model Protein	Release Studies		75	73	172 hours	93%	
	pDNA (plasmid DNA - p-CMV-SPORT-b-gal and p-EGFP)	Anti-sense nucleotide and gene therapies	Release Studies	Mouse	In pDNA data	In pDNA data	In pDNA data	In pDNA data	
Chitosan Nano/Microspheres									
	Model Protein - BSA	Model Protein	Release Studies		60.24	15.06	66	71	
	Antigen - DT	Diphtheria	Release Studies	Rat	85.26	0.39	68	79.6	
	Antigen - TT	Tetanus	Release Studies	Rat	36.6	0.44	16*	73.48*	* - Uncoated
	pDNA (plasmid DNA - p-CMV-SPORT-b-gal and p-EGFP)	Anti-sense nucleotide and gene therapies	Release Studies	Mouse	In pDNA data	In pDNA data	In pDNA data	In pDNA data	
Alginate Nano/Microspheres									
	Model Protein - BSA	Model Protein	Release Studies		85.22	26.54	90	80	
	Antigen - DT	Diphtheria	Release Studies		54.64	1.45	72	79.3	
	Antigen - TT	Tetanus	Release Studies		41.01	1.08	90	80.2	
Protenoid - Polypeptide based - Nano/Microspheres									
	Insulin	Diabetes	Release Studies	Rat	47.2	5.12	72 minutes	97	Hypoglycemic effect for upto 32 hours
	Methotrexate	Cancer	Release Studies		52.00	9.80	70 Minutes	98	
Protenoid - Polyamino acid based - Nano/Microspheres									
	Rifampicin	TB	Release Studies		x	6.8	85 hours	71	
	Nifedipine	Cancer	Release Studies		x	9.2	85 hours	95	
Polycaprolactone PEG Nano/microspheres									
	Levonorgestral	Contraception	Release Studies	Rabbit	x	17-29	15 Months	85	

Exhibit 5: Cash Flow Statement

$ Million	2005	2006	2007	2008	2009	2010
Beginning Cash	$0.00	$3.95	$2.20	$14.51	$43.90	$113.25
Operations						
NOPAT + Depreciation	($0.88)	($0.22)	($2.66)	$4.42	($0.62)	$21.61
Investing						
Capital Expenses	($0.08)	($1.53)	($0.03)	($0.03)	($0.03)	($0.03)
Paid-in Capital (VC funding)	$4.90		$15.00	$25.00	$70.00	
Net Cash Flow	$3.95	($1.75)	$12.31	$29.39	$69.35	$21.58
Ending Cash Balance	$3.95	$2.20	$14.51	$43.90	$113.25	$134.83

Exhibit 6: Balance Sheet

	2005	2006	2007	2008	2009	2010
Assets						
Cash	$3.95	$2.20	$14.51	$43.90	$113.25	$134.83
Capital Assets	$0.08	$1.58	$1.21	$0.93	$0.73	$0.58
Less Depreciation @ 25%	$0.02	$0.40	$0.30	$0.23	$0.18	$0.14
Residual Asset Value	$0.06	$1.19	$0.91	$0.70	$0.55	$0.43
Total	$4.00	$3.39	$15.42	$44.60	$113.80	$135.26
Liabilities						
Paid in Capital	$4.90	$4.90	$19.90	$44.90	$114.90	$114.90
Retained Income	($0.90)	($1.51)	($4.48)	($0.30)	($1.10)	$20.36
Total	$4.00	$3.39	$15.42	$44.60	$113.80	$135.26

Exhibit 7: Income Statement

$ Million	2005	2006	2007	2008	2009	2010
Revenues						
Total Milestone Payments	0.00	2.50	2.50	5.00	0.00	27.50
Total Royalties	0.00	0.00	0.00	0.00	0.00	0.00
Total Indian Sales Revenues	0.00	0.00	0.00	7.76	11.63	17.45
Total Revenues	0.00	2.50	2.50	12.76	11.63	44.95
COGS for Indian Sales (17%)	$0.00	$0.00	$0.00	($1.32)	($1.98)	($2.97)
Operating Expenses						
R&D Expenses	($0.48)	($1.23)	($3.19)	($4.85)	($7.69)	($6.61)
SGA	($0.40)	($1.49)	($1.98)	($2.18)	($2.59)	($2.81)
Total Operating Expenses	($0.88)	($2.72)	($5.16)	($7.02)	($10.28)	($9.42)
EBITDA	($0.88)	($0.22)	($2.66)	$4.42	($0.62)	$32.57
Depreciation	($0.02)	($0.40)	($0.30)	($0.23)	($0.18)	($0.14)
Gross Income	($0.90)	($0.62)	($2.97)	$4.18	($0.80)	$32.43
NOL Utilization	$0.00	$0.00	$0.00	($4.18)	$0.00	($1.10)
Taxable Income	$0.00	$0.00	$0.00	$0.00	$0.00	$31.33
Taxes @35%	$0.00	$0.00	$0.00	$0.00	$0.00	$10.96
Net Profit (Loss)	($0.90)	($0.62)	($2.97)	$4.18	($0.80)	$21.46

Exhibit 8: Revenue Projections

Revenue Projections ($ Millions)

		2005	2006	2007	2008	2009	2010
US Insulin							
Milestone Complete				IND	Phase I		Phase II
Milestone Payments (from Partnerships)		-	-	0.00	-	-	20.00
Projected Revenues for Partnerships		-	-	-	-	-	-
Royalty Payments =	7.5%	-	-	-	-	-	-
Total US Insulin Revenues		-	-	-	-	-	20.00
US hGH							
Milestone Complete				IND	Phase I		Phase II
Milestone Payments		-	2.50	2.50	5.00	-	7.50
Projected Revenues for Partnerships		-	-	-	-	-	-
Growth (Year over Year)		-	-	-	-	-	-
Royalty Payments =	7.5%	-	-	-	-	-	-
Total US hGH Revenues		-	2.50	2.50	5.00	-	7.50
India Insulin							
Sales Revenues		-	-	-	7.76	11.63	17.45
Growth (Year over Year)					-	0.50	0.5
Total Milestone Payments		-	2.50	2.50	5.00	-	27.50
Total Royalties		-	-	-	-	-	-
Total Indian Sales Revenues		-	-	-	7.76	11.63	17.45
Total Revenues		-	2.50	2.50	12.76	11.63	44.95

Exhibit 9: Cost Estimates

Spending Period:	2005	2006	2007	2008	2009	2010
R&D Expense						
Analytical Services	($35,000.00)	($100,000.00)	($200,000.00)	($300,000.00)	($400,000.00)	($420,000.00)
Animal Studies	($350,000.00)	($500,000.00)	($1,000,000.00)	($1,500,000.00)	($2,000,000.00)	($2,100,000.00)
Lab						
Chemicals & supplies	($50,000.00)	($75,000.00)	($85,000.00)	($89,250.00)	($93,712.50)	($98,398.13)
Safetyware	($2,500.00)	($5,000.00)	($5,000.00)	($5,000.00)	($5,250.00)	($5,512.50)
Total Lab Expenses	($52,500.00)	($80,000.00)	($90,000.00)	($94,250.00)	($98,962.50)	($103,910.63)
Salary of critical R&D personnel	($17,640.00)	($529,257.60)	($793,783.53)	($980,301.45)	($1,119,407.99)	($1,263,686.67)
Clinical Study Costs	$0	$0	($1,080,000)	($1,950,000)	($4,050,000)	($2,700,000)
Scientific Consulting Services	($20,000.00)	($20,600.00)	($21,218.00)	($21,854.54)	($22,510.18)	($23,185.48)
Total R&D Expenses	**($475,140.00)**	**($1,229,857.60)**	**($3,185,001.53)**	**($4,846,405.99)**	**($7,690,880.67)**	**($6,610,782.78)**
Capital Expenses						
Laboratory Equipment (Computers, Equipment etc.)	**($75,000.00)**	**($1,525,000.00)**	**($25,000.00)**	**($26,250.00)**	**($27,562.50)**	**($28,940.63)**
SGA						
Patent Filing	($100,000.00)	($100,000.00)	($100,000.00)	($105,000.00)	($110,250.00)	($115,762.50)
Salary of Critical Personnel Includes (Administrative Services)	($222,000.00)	($1,031,568.00)	($1,492,907.52)	($1,666,934.65)	($2,053,489.71)	($2,248,791.09)
Office						
Rent (Lab and Office)	($16,666.67)	($36,000.00)	($50,000.00)	($52,500.00)	($52,500.00)	($52,500.00)
Utilities (Heat and Light) @ $500 a month	($4,000.00)	($8,000.00)	($8,400.00)	($8,820.00)	($9,261.00)	($9,724.05)
Communication @ $600 a month	($4,800.00)	($9,200.00)	($9,660.00)	($10,143.00)	($10,650.15)	($11,182.66)
Operating Supplies @ $500 a month	($4,000.00)	($12,000.00)	($12,600.00)	($13,230.00)	($13,891.50)	($14,586.08)
Lease/Buy Computers/Printers	($5,000.00)	($5,250.00)	($5,512.50)	($5,788.13)	($6,077.53)	($6,381.41)
Account Auditing Services	($10,000.00)	($10,500.00)	($11,025.00)	($11,576.25)	($12,155.06)	($12,762.82)
Total Office Expenses	($44,466.67)	($80,950.00)	($97,197.50)	($102,057.38)	($104,535.24)	($107,137.01)
Liability Insurance	($2,000.00)	($4,000.00)	($4,200.00)	($4,410.00)	($4,630.50)	($4,862.03)
IND Document Preparation and Fees	$0.00	($100,000.00)	($100,000.00)	($105,000.00)	($110,250.00)	($115,762.50)
Legal Services	($10,000.00)	($100,000.00)	($105,000.00)	($110,250.00)	($115,762.50)	($121,550.63)
Travel Expenses	($25,000.00)	($75,000.00)	($78,750.00)	($82,687.50)	($86,821.88)	($91,162.97)
Total SGA	**($403,466.67)**	**($1,491,518.00)**	**($1,978,055.02)**	**($2,176,339.52)**	**($2,585,739.83)**	**($2,805,028.71)**
TOTAL	**($953,606.67)**	**($4,246,375.60)**	**($5,188,056.55)**	**($7,048,995.52)**	**($10,304,183.00)**	**($9,444,752.12)**

Exhibit 10: Clinical drug trials conducted by large pharmaceutical companies in India

Drug Company	Molecules Researched in India
Alcon	Vegamox
AstraZeneca	Merenem
Cangene	Hepatitis B Vaccine
Eli Lilly	Alimta
	Gemcitabine (breast cancer)
	Cialis (erectile dysfunction)
	Xygris (Septicemia)
Glaxo (GSK)	Lamictal
Jannsen	Resperidal
Novartis	Tegaserod
Pfizer	Voriconazole
Roche	Peg-Interferon
Santen	Quixin
Wyeth	Influenza A Vaccine

Exhibit 11: Advisors:

Dr. Leo Henikoff

Former CEO, Rush Prebyterian Hospitals and Rush University.

Prof. Neil B. Graham

Founder PolySystems, Ocutec and SmartTech, Stratchclyde University. Leading authority on hydrogel based systems including drug delivery systems with over 40 years of experience.

Prof. Alan S. Hoffman

Professor of Bioengineering, Univ. of Washington, Seattle. Leading authority on drug delivery systems and biomedical applications with decades of experience.

Prof. Alicia Loffler

Professor of Biotechnology, Kellogg School of Mgmt, Northwestern University.

Prof. Barry Merkin

Professor of Entrepreneurship, Kellogg School of Mgmt, Northwestern University.

Troy Henikoff

Serial Entrepreneur, Founder SurePayroll.

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