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BUSINESS PLAN COMPETITION | EXECUTIVE SUMMARY | SPRING 2013

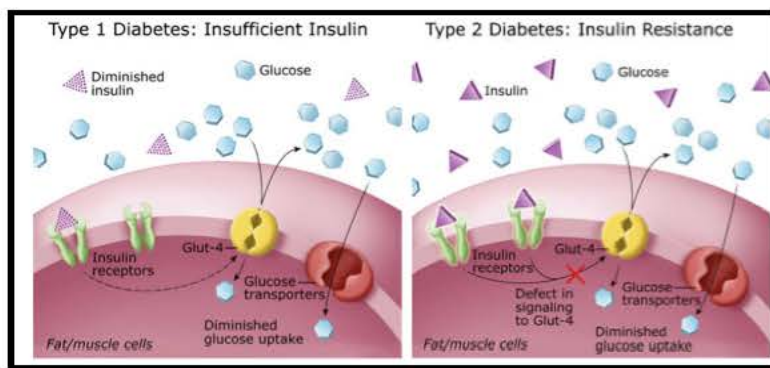
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OVERVIEW

At InsuLenz, we seek to be the leading innovators in polymer-based medical devices for continuous glucose monitoring and concurrent insulin release for at-risk diabetics. By commercializing the prototypes of glucose-responsive, insulin-eluting contact lenses, our company aims to combine existing strategies for glucose monitoring and insulin delivery on **one low-cost platform**, to develop a safety device that is accessible to all at-risk diabetes patients. Unlike our competitors, InsuLenz will provide a completely needle-free platform that is **pain-free and automated**. We believe that the development of the InsuLenz product will introduce a **disruptive technology** that captures significant market share from competitors by reimagining the field of diabetes patient care.

PROBLEM: DIABETES MELLITUS AND DIABETIC KETOACIDOSIS

Diabetes mellitus is a metabolic disease characterized by high blood glucose levels. Currently, diabetes affects more than 20 million Americans and occurs in different etiologies, namely Type 1 and Type 2. Type 1 diabetes results from failure of the pancreas to produce insulin, which is necessary to break down and process glucose. Type 1 diabetes is most often diagnosed in children and teens and comprises ~5-10% of all diabetes cases. Type 2 diabetes results from insulin resistance or the inability of pancreas-secreting insulin to break down glucose. While Type 2 diabetes can be improved with medications and lifestyle changes, Type 1 diabetics are dependent on insulin and generally require more careful glucose monitoring.



When glucose levels become dangerously high (hyperglycemia), a series of physiological changes can lead to retinopathy (eye damage), kidney dysfunction, and nerve damage. One of the more serious complications of severe hyperglycemia (blood glucose >600 mg/dL) is **diabetic ketoacidosis (DKA)**. Insulin plays a critical role in stimulating glucose entry to muscle, fat, and other tissues. As such, when insulin levels are too low, cells become starved of energy. This initiates a cascade of processes in which the body begins to break down fat for energy. However, this process generates harmful ketones or "ketone bodies." DKA occurs when ketones, or toxic acids, accumulate in the body at high levels. If left untreated, DKA often leads to hospitalization or even death. DKA mostly affects Type 1 diabetics and is the most common type of hyperglycemic emergency within the diabetic population. There have been an estimated 135,000 cases annually in the U.S. alone and this complication accounts for nearly half of all deaths in diabetics younger than 24 years of age.¹

The mainstay treatment of DKA often involves immediate insulin administration and intravenous fluid resuscitation after hospital admission. Significant healthcare resources are spent managing DKA. Patient care for DKA episodes accounts for more than \$1 in every \$4 spent on medical care for adult Type 1 diabetics and \$1 in every \$2 in patients with a history of multiple DKA episodes.² The estimated cost of \$17,000 spent for every DKA patient hospitalization highlights the need for better DKA prevention methods than currently available.

CURRENT TREATMENT PROBLEMS

INVASIVE SYSTEMS

Since insulin became commercially available in 1921, treatment for diabetes has consisted of palliative care by insulin administration. Glucose levels fluctuate throughout the day and as such, the dose of insulin varies with the rise and fall of blood glucose levels. Insulin doses must be adjusted to avoid both hypoglycemia and hyperglycemia, which varies between individuals. To determine the necessary dose of insulin, patients use fingerstick glucose meters that sample blood or continuous glucose monitors (CGMs) that sample interstitial fluid. CGMs are needle probes which pass through the skin into tissue where they monitor interstitial glucose levels. These devices are taped to the skin and are changed every few days. In addition to the invasive nature of these devices, which can cause irritation and tissue damage, both glucose monitors and CGMs need to be calibrated on a regular basis to achieve accurate blood glucose level readings.

EXPENSIVE SYSTEMS

The most common insulin delivery systems are insulin syringes or insulin pens, which contain replacement drug cartridges, replacement needles, and a mechanical pumping mechanism. Both of these systems are low cost, but are invasive and painful, dependent on manual administration by users, and are generally inconvenient. Patients may also choose to buy expensive and automated insulin pumps, which contain a needle tipped probe inserted into the abdomen for insulin delivery. The most sophisticated systems consist of fingerprick blood glucose monitors that can wirelessly beam the dose to an insulin pump – many of these systems cost in the range of \$10K.³

LACK OF PATIENT COMPLIANCE

Despite the availability of the above technologies, the complex and often demanding nature of diabetes management commonly results in poor adherence. It has been reported that only 26% of children and adolescents, as well as 40% of adults with Type 1 diabetes, monitor their blood glucose as recommended (3-4 times daily).⁴ Wing et al. has reported that between 30% and 60% of patients have made errors in the timing procedures involved in self-monitoring blood glucose and that 58% of patients have administered incorrect insulin doses.⁵ A separate study by Morris et al. found that 28% of young people with Type 1 diabetes underused their insulin and two-thirds of those with the worst glycemic control were nonadherent to their prescribed insulin therapy.⁶ Overall, lack of adherence to insulin use continues to be a major contributing factor leading to DKA and poor long-term glycemic control.⁷

SOLUTION: "SMART" CONTACT LENSES

To reduce the risk of severe hyperglycemic episodes that can precipitate into DKA, we have conceptualized the development of a novel glucose-responsive polymer that can release insulin in the eye in a non-invasive manner and that can respond to potentially dangerous blood glucose levels (>400 mg/dL). To deliver insulin ocularly in a controlled fashion, we will be using commercially available hydrogel contacts as our delivery platform. The contact lens will be layered with glucose-responsive polymeric hydrogel containing a small dose (2-3 units) of insulin. Since 1 unit of insulin lowers glucose levels by approximately 50 mg/dL, the release of a small dose of insulin as glucose levels exceed the threshold of 400 mg/dL should be sufficient to prevent a severe hyperglycemic episode while minimizing risk of hypoglycemia. We also propose the addition of a polymer layer that undergoes a colorimetric change upon insulin depletion. This will alert the patient that a hyperglycemic episode has been aborted and that glucose levels should be checked for further insulin dosing. This will also indicate the need to replace the contact lens for continued protection.

MANAGEMENT TEAM

EXECUTIVE MANAGEMENT AND TECHNOLOGY DEVELOPMENT TEAM

Nick Au, B.S., Pharm. D., Ph.D. candidate UW Medicinal Chemistry

Nick earned his Pharm.D. from the UW School of Pharmacy in 2009 and is currently a Ph.D. candidate at the UW Department of Medicinal Chemistry. In 2011, he was awarded a competitive ITHS T-L1 Predoctoral Clinical Research Training grant. His research focuses on understanding the genetic and environmental factors that influence coagulability in Native Alaskan Yup'ik people. He also concurrently works as a part-time pharmacist for Group Health Cooperative and serves as the VP of Finance for the UW Science and Engineering Business Association.

Karen Eaton, B.S., M.S., Ph.D. candidate UW Bioengineering

Karen has a Bachelor of Science in Biochemistry & Molecular Biophysics/Molecular & Cellular Biology/Mathematics, as well as a Master of Science in Biochemistry from the University of Arizona. She is currently working toward a PhD in Bioengineering from the University of Washington. Karen has worked in a variety of academic research labs that focus on protein and cellular engineering as applied to metabolism and inflammation. Karen has also worked at Ventana Medical Systems, where she has been exposed to clinical kit design for rapid disease diagnosis.

Caleb Gerig, B.S., UW MBA candidate

Caleb has specific experience in launching new products including marketing, finance, and customer relationship management. He has worked at a few small software companies and is currently a finance data analyst at Microsoft. Caleb's undergraduate degree is from Northwest University and he is currently getting a Master in Business Administration from the University of Washington.

Renuka Ramanathan, B.S., Ph.D. candidate UW Bioengineering

Renuka has a Bachelor of Science in Bioengineering from the Massachusetts Institute of Technology and is currently working on a PhD in Bioengineering from the University of Washington. Renuka has worked at a number of academic labs researching and publishing on novel drug delivery platforms. She was previously employed by Cambridge Polymer Group to develop unique hydrogel formulations and assess their mechanical properties.

BUSINESS DEVELOPMENT TEAM

Dennis Frett, Vice President, Toray Composites

Dennis currently serves as the Vice President, responsible for Production, Maintenance, Supply Chain Management, Information Systems, Safety and Environmental, and Project Engineering. He has held a number of positions in his 15+ years at Toray, most recently the Director of Supply Chain Management where he was responsible for negotiating long term supply agreements with key raw material suppliers and establishing logistics procedures for worldwide distribution of frozen aerospace materials. He has been a key contributor in improving the corporate culture to one that fosters communication, employee involvement and continuous improvement.

Craig McNary, Senior Manager, Global Marketing, Microsoft

Craig McNary began his career agency-side in New York City and has driven integrated marketing strategy and activation for many of the world's premiere consumer brands - including Sony, GlaxoSmithKline, American Express, Coca-Cola, Google and Diageo. He joined Microsoft's Interactive Entertainment Business in 2010, leading global strategy and experience for the Xbox, Kinect and Xbox Live platforms. He is the architect of some of the company's largest experiential initiatives – including the recent global launch of Kinect for Xbox 360.

Mohammed Minhaj M.D., University of Washington/Veterans Affairs, Puget Sound Health Care System

Mohammed Minhaj is an educator and a clinician in the Department of Anesthesiology at the University of Washington. Working primarily at the VA Puget Sound Health Care System, he administers clinical care to patients, is involved in the education of students and residents, and has administrative responsibilities.

MARKET OPPURTUNITY

TARGET MARKET

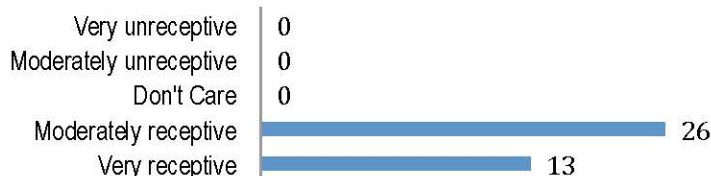
InsuLenz will target Type 1 diabetes patients who are more prone to diabetic ketoacidosis (DKA) and have poor control over their current treatment. There are an estimated 25.8 million people in the US with diabetes, in which 6.3 million of these people use insulin to treat their diabetes. Of the Type 1 diabetics, it has been reported that 60-74% of these individuals do not manage their insulin as advised by their doctor and often have periods of hyperglycemia that may lead to DKA. This represents a total of about 3.3 million diabetics, who are at high-risk for hospital admissions due to poor management of glucose levels. With regard to demographics, DKA is more common in women (specifically young women) compared to men and the most common age (18-44 years of age) accounts for 56% of the total target. Furthermore, it has been reported that 135,000 hospital admissions occur annually as a result of DKA, at an estimated cost of \$2.4 billion or 25-50% of total Type 1 diabetic care costs. A history of poor glucose management and/or insulin discontinuation accounts for more than half of DKA admissions in inner-city and minority populations. Lastly, about 30% of children with Type 1 diabetes receive their diagnosis only after an episode of DKA, so the InsuLenz product can potentially target pre-diabetes patients as well. In all, we believe we can acquire a small niche segment of these persons, between 5-7% in five years, after product launch. This will give InsuLenz an estimated 165,000 to 230,000 end-users.

PRIMARY RESEARCH

PHYSICIANS

InsuLenz was only able to contact 39 medical professionals, as most hospitals try to protect against commercial surveys or questions. However, with the data we did acquire, there seems to be a great interest in an InsuLenz-type product. We first established that current technology is suboptimal by asking how much of an inconvenience current glucose monitoring and insulin delivery devices are. When asked, non-specifically, about devices in general, medical professionals responded quite overwhelmingly with a "large inconvenience" response and all responses conveyed some kind of inconvenience. When asking specifically about syringe, needle, and pump insulin delivery devices, medical professionals conveyed more of an inconvenience for syringes and needles, as opposed to automated pumps. When asked, "who would benefit more from a medical device that could continually monitor blood glucose levels and automatically deliver insulin when needed, as a safety precaution for DKA?", the majority of medical professionals responded that the patient and the doctor would benefit more. This was interesting, as we had expected that they would answer that only the patient would benefit. This might have secondary implications, such as continual re-admittance of diabetics for problems with self-monitoring or self-administration. To establish that there is a need for a product, such as an InsuLenz device, we asked, "In your medical/personal experiences thus far, how would you think the diabetic community would respond to a DKA glucose monitor and insulin delivery safety device, without having to carry around insulin/needles/monitors (also without any pricking or active responsibility to monitor glucose or insulin delivery)?" Every medical professional surveyed responded positively to this question with either a "very receptive" response (87%) or a "moderately receptive" response (13%). When asked how the same community would respond to a "non-invasive ocular device" that could do the same thing, the medical professionals were more likely to respond with a less receptive to even unreceptive answer. However, when we asked how receptive the community would be if this ocular device were "prescription and non-prescription contact lenses," all medical professionals surveyed responded with a "very receptive" to "moderately receptive" answer.

In your medical/personal experiences thus far, how would you think the diabetic community would respond to a glucose monitor and insulin delivery safety device in the form of both prescription and non-prescription contact lenses?



PATIENTS (END-USERS)

InsuLenz was able to contact 24 diabetics through the use of an email survey and online discussion boards. On the surface, the results of these surveys are counter intuitive. People seem to be satisfied with current methods but at the same time highly value a pain-free solution. This seems to suggest that people are comfortable with current options, possibly because there is not a better solution available. We believe that these poll results indicate that the InsuLenz product may be a breakthrough innovation and suggests that if people really understood what InsuLenz could provide, they would be more prone to shift away from needles. The data also shows an overwhelming willingness to attempt a contact solution. The biggest concerns were how InsuLenz would interact with other medications and whether it would be able to handle the dosage amounts required. All of these comments can be reasonably addressed during the first five years of development and testing.

PRIMARY RESEARCH OVERVIEW

Nothing surfaced in consumer research that suggested a lack of market. Our research also did not uncover any major concerns in the first three years of company development. Although the sample size for this analysis is small, research polls support that there is a need among diabetics for a product like the InsuLenz technology. The main focus of this primary research was to validate the concept and gauge the adoption of the idea in the market. More focused primary research will need to be conducted to identify specific product requirements and further refine the marketing strategy.

MARKET COMPETITION AND BARRIERS TO ENTRY

COMPETITIVE PRODUCTS

Current treatment options for insulin-using diabetics involve drug injection by one of three main mechanisms:

- Intermittent injections during the day by the patient based on glucose monitoring (requiring a separate puncture)
- Wearing an insulin pump that is similar to a pager that attaches via a needle to a patient and provides a steady stream of insulin
- “Jet applicators” which are touted to be needle-less but still require a high pressure puncture of the skin in order to deliver insulin (in some patients this is described as even more painful than the needle injections)

Our primary competitors are Medtronic who specializes in injectables, Sanofi-Aventis and Pfizer who focus on inhalables, and Altea Development Corporation who are focused on transdermal patch innovation. The overall result is that these products are either seen as uncomfortable or cumbersome for patient use and thus contribute to non-compliance with insulin therapy. The end-result of non-compliance include worsening of the disease process. This contributes to organ damage (blindness, renal disease, increased risk of coronary artery disease, etc.) or life-threatening emergencies (DKA), which end up costing the patient, insurance companies, and our health care system billions of dollars annually.

COMPETITIVE ADVANTAGE

Our product offers distinct advantages over conventional therapies. The first of these is a less invasive and **needle-free** method to deliver insulin. Many diabetics already wear contact lenses, due to inherent eye complications associated with diabetes. By merely adding an insulin-eluting “smart” polymer to their existing contact lenses, they will have the ability to receive a safety dose of insulin without needles, when their high blood glucose levels trigger an emergency. Additionally, the insulin-eluting smart polymer can be applied to nonprescription contact lenses for patients who do not require corrective lenses. Secondly, the polymer will allow for **better maintenance** of ideal blood glucose levels rather than the peaks and troughs that can be associated with the intermittent needle delivery system. Thirdly, the InsuLenz product has **none of the drawbacks of insulin pumps** which are cumbersome to wear, have higher risk of infection (needles need to be kept clean and changed out frequently), and can curtail some physical activities.

Currently, there are no puncture-free delivery devices available on the market. The jet applicators are limited by the fact that they still require high pressure delivery through the skin, which causes discomfort and pain. There is also concern about the accuracy of dosing via jet applicators when compared to traditional needle injections. Some advancement has been made in nanotechnology research to monitor blood glucose and deliver insulin therapy based on glycemic levels, but this is still in development. Recently, the FDA approved a device that combines the insulin pump (currently produced by Medtronic) with glucose monitoring capability, however this still requires needle injections for insulin and a sensor placed underneath the patient’s skin for monitoring. Epidermal patches as a needle-free insulin delivery system have been trialed but not been proven successful enough to receive FDA approval. Given the limitations of the currently available products, patients’ dislike for needles, and no other proven method of needle-free delivery, the InsuLenz product is uniquely positioned to revolutionize diabetic management.

GO-TO-MARKET STRATEGY

The preliminary go-to-market strategy will be aimed at three key groups:

Medical Providers

Objective: Educate medical care providers on product advantages, benefits, and cost savings.

Activities and Tactics: (1) Full-day conferences to immerse Medical Providers in InsuLenz treatment and potential benefits, (2) Visits from sales reps to communicate long term health and decreased 'emergency' costs

Doctors (physicians and ophthalmologists)

Objectives: Educate and demonstrate the attributes and ease of obtaining the InsuLenz technology, how we are simplifying the patient experience, and how our product is significantly different from other treatment options.

Activities & Tactics: (1) Articles in top medical journals promoting InsuLenz technology and ease of use, (2) Advocacy programs, (3) Custom prescription systems to create seamless integration from doctors to pharmacy to product delivery

Consumers (end-users)

Objectives: Build awareness and drive adoption of the InsuLenz technology, provide an incentive trial, and create an emotional connection to the advantages of our product.

Activities & Tactics: (1) Above the line communications platform featuring TV, Radio, Print and Online, (2) Extensive Public Relations and social media campaign featuring real diabetes patients who have benefited from needle-free treatment, (3) Influencer campaign featuring well-known diabetes patients aimed at youth market, (4) Purchase incentives

COMMUNICATIONS PLATFORM

Positioning Statement: InsuLenz is a safe, reliable and convenient means to prevent diabetic ketoacidosis (DKA). Through a customized 'smart' contact lens and glucose-responsive delivery, it offers needle and pain-free delivery of insulin, and potentially addresses diabetic retinopathy, for both Type 1 and 2 diabetic patients.

Current Perception: Glucose monitoring and insulin delivery is limited to cumbersome, invasive, and inconvenient options

Desired Perception: InsuLenz provides an innovative and effective treatment solution that works with my lifestyle

Campaign Platform: Diabetes treatment, simplified.

Reasons to believe: One platform / Needle- and pain-free / Customized for your insulin needs / Safe, reliable, and easy

Call to Action: Consultation with an InsuLenz specialist / Talk to your Doctor about InsuLenz

Tone: Professional, reliable, dependable

TRACTION

INTELLECTUAL PROPERTY

InsuLenz has performed an initial IP landscape analysis with help from the UW Center for Commercialization (C4C) to make sure there is value in our concept. We have found one patent with the following claim: "drug delivery from a contact lens not in the viewing portion of the lens." Furthermore, our design also involves a colorimetric change that has been patented in contacts. Since our product design involves drug delivery from outside the zone of vision and a colorimetric reaction to indicate insulin depletion, we will be contacting the commercialization offices for these patents to possibly acquire room to work by non-exclusive licensing rights. Lastly, it is necessary for InsuLenz to have enablement of claims before any IP can be secured. We are currently in the beginning stages of development and have no intellectual property; however, there are multiple potential patents that can originate from our concept once enablement has been established.

POTENTIAL USERS/LICENSEES

In relation to potential users, we have conducted primary research to gauge interest on part of end-users and physicians. We believe our preliminary research suggests that there is a need and perceived interest in the end-user population for needle-free solutions for glucose monitoring and insulin administration. Our research also suggested that end-users found it difficult to fully understand our conceptualization of the InsuLenz product, indicating that there may be a barrier to adoption. On the other hand, every physician agreed that diabetic patients would benefit from a device such as InsuLenz. Finally, we are actively scoping out companies that could be potential licensees in the future, which include pharmaceutical companies as well as companies specializing in hydrogel contact lens manufacturing. One candidate company would be Novo Nordisk, whom is a leader in the insulin and insulin delivery market and recently launched a type 1 diabetes research center in Seattle.

FINANCIALS

Year:	0	Phase 1		Phase 2			Phase 3			Commercialization				
		1 (2013)	2 (2014)	3 (2015)	4 (2016)	5 (2017)	6 (2018)	7 (2019)	8 (2020)	9 (2021)	10 (2022)	11 (2023)	12 (2024)	13 (2025)
Yearly Beginning Amount:		\$ -	\$ 200,000	\$ 2,210,000	\$ 12,435,000	\$ 15,235,000	\$ 12,985,000	\$ 15,905,000	\$ 8,223,800	\$ 1,218,800	\$ 54,390,094	\$ 66,394,488	\$ 96,384,894	\$ 173,876,570
Funding (Grants,Partnership,VC)		\$ 2,150,000	\$ 4,000,000	\$ 12,000,000	\$ 5,000,000	\$ -	\$ 15,000,000	\$ 10,000,000	\$ 25,000,000	\$ -	\$ -	\$ -	\$ -	\$ -
Yearly Costs		\$ 1,950,000	\$ 1,990,000	\$ 1,775,000	\$ 2,200,000	\$ 2,250,000	\$ 12,080,000	\$ 17,681,200	\$ 32,005,000	\$ 6,965,000	\$ 9,890,000	\$ 11,390,000	\$ 11,890,000	\$ 12,393,000
Licensing Upfront Fee										\$ 50,000,000				
Ongoing License Fees (\$25/box) ¹		\$ -	\$ -	\$ -	\$ -	\$ -	\$ -			\$ 10,136,294	\$ 21,894,395	\$ 41,380,406	\$ 89,381,676	\$ 136,626,277
Balance Forward		\$ 200,000	\$ 2,210,000	\$ 12,435,000	\$ 15,235,000	\$ 12,985,000	\$ 15,905,000	\$ 8,223,800	\$ 1,218,800	\$ 54,390,094	\$ 66,394,488	\$ 96,384,894	\$ 173,876,570	\$ 298,109,847

¹Licensing Fee based on 1 box of 60 daily contacts

The financial figures suggest that many of the costs in the early development stages are devoted to research personnel, materials and equipment. We recognized the expenses related to research should include a facility and equipment purchases, along with personnel and material expense, and these are reflected in the costs. We will be pursuing a partnership with the University of Washington that can significantly decrease these costs, but we wanted to reflect the true costs of research and development. The funding for Phase 1 of the project would consist of a combination of government and/or foundation grants. We also assumed that it would take approximately 5 years of development and 3 years of clinical trials before the product was ready for licensing. Also implicit in our financial assumptions was that there are biotech, biopharmaceutical or venture capital firms with capabilities and risk seeking portfolios which allow for high leverage medical device companies to pursue device approval after the patent and animal testing phases, even though the costs can be very high and the expected success rate can be low. There are multiple VC companies (HealthCare Ventures, Alta Partners) which fit this risk portfolio and many large biotech companies (Novo Nordisk, Pfizer) that specialize in commercializing medical devices. We recognize that partnerships are very important in this industry and believe that by beginning of Phase 2, after we have a patent, we could attract a large strategic partner or VC willing to provide the capital necessary to take the product to the FDA testing stages.

FUNDING REQUIRED

GRANT FUNDED RESEARCH FOR ENABLEMENT

The proposed InsuLenz technology is currently seeking mechanisms of non-dilutive funding. The founders are seeking partnerships with labs at the University of Washington and in the greater Seattle area to demonstrate technical feasibility and proof-of-principle. In the initial stages of research and development, the founders will apply to various non-dilutive funding mechanisms through the National Science Foundation (NSF), National Institute of Health (NIH), and private foundations funding research in diabetes. We will also pursue Small Business Innovation Research (SBIR) grants. InsuLenz expects to secure enough funding through grant applications to demonstrate feasibility, optimize the technology, and run pre-clinical animal testing of prototype products for the first three years of research and development. Given the initial stages of research are promising, InsuLenz will pursue a patent through C4C at UW and actively seek connections with companies that may license our technology. After securing IP, InsuLenz will seek out risk-seeking VC companies as well as industry partnerships to fund our final years of research, development, and prototyping. To cover the high costs of clinical testing and FDA approval, InsuLenz will continue to apply to non-dilutive grants offered through the NIH specifically for clinical trials. We will concurrently continue to build relationships and seek funding from VC companies as well as opportunities to raise funding from licensees of our technology.

INSULENZ APPROVAL

DEVICE REGULATORY AND STRATEGY

InsuLenz has purposefully planned our development around a phased manner, which will allow us to get our product to market as quickly as possible. Phase 1 will entail development and proof-of-concept animal studies starting as soon as 2013. Phase 2 will entail patent filing of InsuLenz technology based on our developmental work. Phase 3 will involve testing our product in clinical trials and applying for FDA approval. In Phase 3, we will also pursue licensing our patent to potential client companies.

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