Executive Summary

Business Concept/Elevator Pitch: Continuous glucose monitors (CGMs) are a great tool for managing Type 1 diabetes, but wearing them can be uncomfortable, expensive, and may not always read blood glucose levels accurately. At Con-Sense, we're developing an RFID (radio frequency identification) microchip that is non-invasive, cost friendly, and more accurate. We are seeking \$100,000 to complete development and prepare for clinical trials.

Company: Con-Sense is a medical device startup focusing on improving the equipment that diabetics use to manage Type 1 diabetes. Headquartered in Stillwater, OK, the team consists of Oklahoma State University researchers and students to advance glucose monitoring technologies.

Problem/Opportunity: Presently, CGMs operate alongside insulin pumps which are both affixed and worn on a diabetic's person. They are attached by an adhesive patch that must be replaced every ten days, on average. Not only do these devices lack accuracy in reading blood glucose levels, but the patch units are also expensive, costing up to \$22,000 in healthcare costs per year and more than \$300 per month for the patient themselves.

Solution: Con-Sense is developing a CGM that is more accurate and will be surgically inserted below the skin to remain in place for years, therefore reducing the costs of continuous glucose monitoring. The CGM chip transmits the readings wirelessly to a smartphone application via Bluetooth for analysis and communication with the insulin pump.

Business Model: Our business model is an R&D company with an exit strategy to a large medical corporation. The preliminary chip pricing is estimated to be \$10,000 with a monthly subscription service of \$10 per user to gain access to enhanced blood glucose data, analysis, and transfer of data to doctors and family.

Market Potential: The market potential of CGM devices is expected to reach \$1.01 billion by 2024 with a CAGR of 13.7%, largely due to the growing numbers of obese individuals in the United States. The competition includes CGMs made by Medtronic and Dexcom which have made smartphone connectivity commonplace. They are large players with many technologies solely devoted to managing diabetes.

Sales Approach: The sales approach features the embedded microchip consumer purchase and a monthly subscription service. Con-Sense will promote our technology following FDA approval in diabetes magazines, television commercials, and speaking and presenting at medical conferences.

Management Team: The management team consists of Beau Blanchard as CEO, Stuti Mehrotra as Vice President of Operations, and Lucas Utley as Vice President of Engineering. The team is seeking to add a Vice President of Marketing and Sales after obtaining the technology patent.

Required Funding and its Use: Con-Sense is seeking \$100,000 to develop the technology and perform clinical trials prior to submitting for FDA approval of this Class III medical device.

Abbreviated Income Statement:

Exit Strategy: The exit strategy is acquisition by a large medical company as the company is performing the research and development of a single technology for diabetic use.

I. Company Description

Elevator Pitch: Continuous glucose monitors are a great tool for managing Type 1 diabetes, but wearing them can be uncomfortable, expensive, and may not always read blood glucose levels accurately. At Con-Sense, we're developing an RFID (radio frequency identification) microchip that is non-invasive, cost friendly, and more accurate. We are seeking \$100,000 to complete development and prepare for clinical trials.

Mission Statement: Bringing twenty-first century common sense to continuous blood glucose monitoring.

Objectives: Con-Sense's objective is to offer a non-invasive and modern solution that eliminates the need for uncomfortable catheter insertions and manual finger sticks. The current goal is to prove the concept of using RFID microchips as a superior alternative to current offerings. Value generation will be determined by a planned merger or acquisition by a large medical device company such as Medtronic or Dexcom.

Business Model: Con-Sense will serve as a research and development company with a planned exit to a large medical device company. Grants will serve as the primary revenue driver during the first five years.

The pricing of the RFID chip will ultimately be decided upon acquisition; however, even at a preliminary pricing strategy of \$10,000, we will be saving diabetics about \$90,000 over the five-year life of the product. A monthly subscription of \$10 per user can serve as recurring revenue for the smartphone application. Additional family members can be added to the plan in order to view the blood sugar levels of their loved one for an additional \$5 per month.

Summary of Activity to Date: The Con-Sense team has conducted interviews and researched the present issues with continuous glucose monitoring. Interviews have been conducted with hospital administrators, angel investors, and Type 1 diabetics. Type 1 diabetics were extremely interested in the non-invasive and hassle free solution that Con-Sense is developing. The team has established a relationship with Tracey Poole, who invested capital into a RFID Sensor Company and is negotiating a partnership.

Current Stage of Development: Con-Sense is conducting negotiations with Oklahoma State University researchers to develop a method of measuring blood sugar through an implantable device. Dr. Gopan Krishnan, a chemistry professor at Oklahoma State University, is a member of the Bioanalytical and Biomedical Research Group. He specializes in carbon nanotube biosensing applications and has previously invented a volumetric sensor to diagnose a form of diabetes. As stated earlier, Tracey Poole is willing to connect us with a company that he invested in that has developed RFID Sensors that do not require batteries to operate. Con-Sense hopes to leverage both resources to create a better method of monitoring blood glucose levels.

Competencies: The Con-Sense core team consists of entrepreneurs and engineers. Beau Blanchard has five years of healthcare experience and is committed to improving the patient experience. Beau served as a medical assistant for the physician practice that received the number one ranking on Medicaid's Comprehensive Primary Care Initiative. The patient population that benefitted the most from this initiative were diabetics. It is Beau's commitment to improving the patient experience and his ability to leverage connections that will take Con-Sense from concept to reality.

Keys to Success: Con-Sense's key to success will be leveraging customer feedback with Oklahoma State University research. Involving diabetics in the product design process has enabled us to build a strong foundation for success. As we progress from research and development to launch, management will utilize our relationship with the American College of Healthcare Executives and the Project Echo Team to help promote our modern/innovative solution to customers. The American College of Healthcare Executives is a national network of healthcare administrators, researchers, and caregivers. Project Echo is a new initiative that connects rural physicians with specialists who provide information, research, and standardized care.

Locations and Facilities: Con-Sense is currently headquartered in Stillwater, OK at the Spears School of Business. The Endeavor Makerspace at Oklahoma State University will be utilized for

rapid prototyping and research and development. Con-Sense expects to move into a larger facility at 36 Degrees North in Tulsa, OK within the next six months.

II. Problem or Service

Problem/Opportunity: Continuous glucose monitoring (CGM) works in conjunction with insulin pumps or periodical insulin injections that Type 1 diabetics use to manage their blood sugar levels. The CGM is a device intended to replace finger-pricks for measuring a diabetic's blood sugar levels. The finger-pricks are painful and inconvenient but offer the most accurate readings. CGMs receive readings from a catheter implant which is essentially a needle that has been implanted in a diabetic's belly fat. Sensors are connected to the catheter and must be replaced every seven to ten days. The diabetic patients that we interviewed all agreed that CGMs are uncomfortable, require constant replacement, and are often inaccurate versus finger-prick readings. This can lead to improper insulin doses and complications such as ketoacidosis (low insulin levels leading to acidic blood), diabetic comas, and death. Additional complications include cardiovascular disease, nerve damage, and kidney damage.

Researchers at the University of Chicago Medicine found during a six month study that the healthcare costs of using a continuous glucose monitor are around \$11,032 per patient or roughly \$22,000 per year.

According to one interview, the sensors are the largest expenditure for diabetics. Not only are the sensors expensive, (upwards of \$300 per box), but last about a month. The CGM offers many advantages, but it also comes as a second separate unit that must also be worn on one's person in addition to the insulin pump.

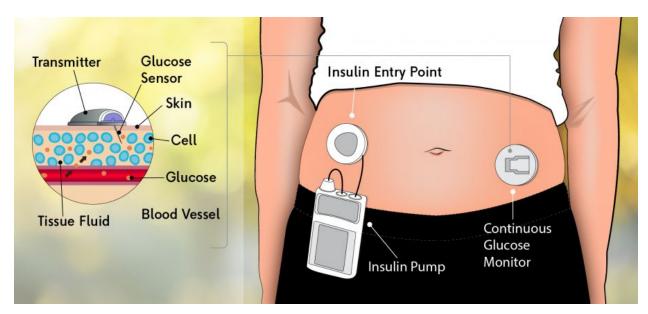


Image courtesy of OnTrack Diabetes; CGMs work with insulin pumps to manage diabetes.

Solution: By selling a CGM that is more accurate and in the form of a tiny unit that remains under the skin for years, patients can be confident in reading their blood sugar levels and better manage diabetes. It will offer connectivity with a patient's smartphone to monitor blood glucose levels. Because the monitor will be embedded under the skin this addresses an inconvenience customers face with wearing this kind of equipment or finger pricks for glucose testing/monitoring.

Technical/Operational Description: RFID technology features a two-part system with a passive tag that does not require a battery to wirelessly communicate with a reader. The RFID sensor package is embedded underneath the skin of a diabetic and can sense blood glucose levels without an active power supply. The sensor package is read by a small patch attached to the skin that contains a Bluetooth chip for wireless communication via smartphone app. The app compiles this data from the CGM and can be sent to either a smartphone or an insulin pump for automatic insulin doses. The app can also send all glucose information to family members or their doctor.

Benefits to the Customer: Current offerings can be over \$1000 for a starter package and cost \$300-\$500 monthly for the monitor patches that must be swapped every seven to ten days. Hence the current monitors are expensive and require frequent replacements. With the embedded CGM that Con-Sense is developing, a one-time insert will last years at a lower overall cost, requiring only an affordable monthly app subscription.

Differences from Current Offerings: Con-Sense eliminates the need for an uncomfortable catheter implant and the expensive expenditure on monthly sensors. Most CGMs today already utilize Bluetooth connectivity with a smartphone to study glucose level trends, but their accuracy can falter. This falter can lead to complications such as blood sugar spikes or lows. The current monitors not only come at a high financial cost but also have an inconvenient patch that requires replacement on a weekly or bi-weekly basis. Con-Sense's CGM will bring heightened accuracy at a lower cost without the discomfort or inconvenience of current systems.

III. Industry Analysis

Industry Overview: According to the American Diabetes Association (ADA), 1.25 million Americans have Type 1 diabetes, which is about 5% of all diagnosed cases. It is estimated that 40,000 people are diagnosed each year. While some type 2 diabetics may utilize continuous glucose monitors, insurance frequently does not cover its use, and they are too expensive to afford out of pocket for most diabetics. Diabetes is an enormous market with a total cost of diagnosed diabetes in the US upwards of \$327 billion, with \$237 billion from direct medical costs, according to the ADA. Diabetes is a condition that is affecting increasing numbers of Americans and improved solutions are necessary to ensure diabetics manage diabetes safely and comfortably.

The largest companies supplying diabetic equipment are Medtronic, Dexcom, and Tandem Diabetes. This equipment can include insulin pumps, blood sugar readers, and continuous blood glucose monitors. Diabetic equipment can be very expensive even with insurance, so insurance providers are key players in making diabetes management more affordable.

Drivers of revenue for diabetic equipment include the initial cost of insulin pumps and the recurring cost of glucose monitors, as these must be replaced every 1-2 weeks. Both of these are highly convenient, and have even been lifesavers to diabetics, and the benefits of the equipment far outweighs the price for most. Despite the high costs to customers of replacing glucose monitors, diabetics deem the technology as worthwhile and necessary.

Supply and Distribution: Diabetic equipment suppliers such as Dexcom have their own teams of sales and customer service. They handle sales and distribution themselves with customers buying directly from them. The sales teams work with insurance companies to offset the high cost of managing diabetes for their customers.

Manufacturing tends to remain domestic, with production in California and Arizona for Dexcom and Tandem Diabetes, for example. This could be due to FDA requirements for medical equipment manufacturing. Because these devices are so common and in high demand among diabetics, there are no significant lead times observed between a customer placing an order with the company directly and receiving it via mail shortly thereafter depending on shipping times.

Technological Factors: Improved sensing devices with smaller computational chips indicate the application to CGMs. RFID is not a new technology, but its application to monitoring blood glucose levels is being studied.

Wearable technology is seeing increased use in modern society including smartwatches, fitness trackers, and glasses. The public perception is becoming more favorable of technology entering more parts of their lives, and positive introduction of medical devices is also showing rapid interest. With that, improved perception of under-skin sensing devices could enable this RFID glucose monitoring technology to enter the consumer market.



Image courtesy of TrioTree. Graphic indicates smart device connectivity with wearable tech.

Seasonality: There is no seasonality to managing diabetes and glucose monitoring.

Economic Influences: Fluctuating healthcare as provided by the federal government can have an impact on the availability of managing diabetes. Since diabetes is affecting more and more Americans, the federal government may be inclined or must intervene and impact the use of diabetic equipment. It is difficult to project these healthcare options and changes with varying political presences, but it will certainly play a role in the future.

Some diabetics are concerned by the financial commitment of beginning with a continuous glucose monitor, and if a national economic recession is present, they may be even less inclined to make the investment.

Entry Barriers: Obtaining FDA approval is the most significant regulatory issue. This process can take years for Class III devices, which the CGM is expected to be. There is a prototype stage, premarket approval, and FDA device review.

Public perception is also an area of concern. Surgically inserting a microsensor, while small and low profile, can be an unwanted procedure for many.

Regulatory Issues: The final step in FDA approval is a post-market device safety monitoring in which the FDA continues to study potential safety concerns even after the device has been approved. These programs include MedWatch (FDA's adverse event reporting program) and Medical Product Safety Network (MedSun) that reports medical device problems that result in injury or death.

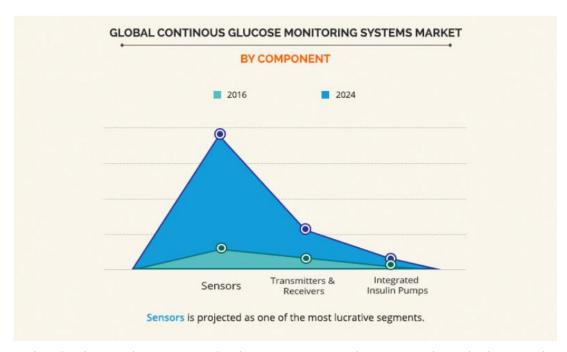
IV. Market Analysis

Definition of Overall Market: Any Type 1 diabetes patient and their doctors.

Market Size and Growth: The global continuous glucose monitoring (CGM) devices market size is expected to reach USD 1.01 billion by 2024. The market is estimated to register a CAGR of 13.7% over the forecast period (2018-2024).

Market Trends: Obesity is believed to be one of the foremost factors leading to diabetes in individuals. According to WHO, in 2014, over 1.9 billion people were identified to be overweight, of which, around 600 million people were obese. Growing cases of diabetes, due to obesity, sedentary and unhealthy lifestyles, and several other factors, is expected to drive demand for diabetes devices over the next few years. Growing cases of diabetes is anticipated to propel market growth, with increasing number of patients opting for simplified CGM devices.

Market Segments: Market segments within the CGM market are separated between Transmitters & Receivers, Sensors and Integrated Insulin Pumps when we see the market segments by components. The market is segregated by the end user into Diagnostics/Clinics, ICUs, and Home Healthcare segments.



Graphic displaying the CGM market by component, with sensors taking the largest share.

Target Segment: Con-Sense will primarily target the sensor segment of the continuous glucose monitoring market with a focus on clinics and Home Healthcare customers.

Customer Needs: Con-Sense has interviewed both patients and doctors. Patients have expressed interest in a device that is wireless and more accurate. The size of the device makes it uncomfortable to wear and using invasive glucose monitors can lead to bruising and skin infections. Some patients have also raised concerns about the price of the product and how often it needs to be replaced.

Purchasing Decision Process: CGMs are prescribed by doctors to the patients, and therefore, those patients with Type 1 diabetes are the main target market. Apart from public awareness, the doctors need to be made aware of the product as well. They have the power to influence what the patient's buy. The best way to reach out to these doctors is through medical representatives, medical journals and magazines. Medical conferences related to the topic are also a good source of generating awareness about the product among doctors.

Product Positioning: Continuous glucose monitors are valuable for managing diabetes, but current offerings have their drawbacks. Over the course of just a year or two, Con-Sense's device will be cheaper than the regular CGMs available in the market today, as it costs just \$10/month and does not require replacement for several years.

V. Competition

Profile of Industry Leaders: Diabetes care is dominated by a few large players. Medtronic's diabetes division recorded roughly \$2.1 billion in revenue in 2018. The introduction of their Guardian Sensor 3, a continuous glucose monitoring device, contributed 26.3% growth in revenue. This was due in large part to the European market adopting CGM technology. While Medtronic's diabetes division includes revenue from insulin delivery, medication, and continuous glucose monitors, Dexcom is focused directly in the continuous glucose monitoring market. Dexcom had approximately \$715 Million in sales during 2017, up 25% over 2016.

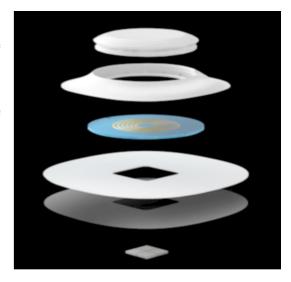
Both companies' products utilize a catheter inserted into the body fat of their customers.

Profile of Primary Competitors: A few companies are conducting research and development to develop continuous glucose monitors that do not require a catheter insert. The problem to date has been accuracy. Google, Sano, SugarBEAT are developing wearable technology that are direct competitors to Con-Sense.

Google: Is developing a contact lens with microchips and embedded electronics to measure blood sugar through the liquid that is naturally found in the eye. The potential for complications that could lead to blindness are significant.



Sano: Is developing a low-profile patch, much like a bandaid to measure blood sugar. The patch utilizes the microfluidics that form between skin cells and relays that information to a mobile app where an algorithm calculates blood sugar levels. The patch will need to be replaced frequently, leading to higher customer costs.



Sano has raised over \$19 Million in start up equity from a number of angel and venture capital firms.

SugarBEAT: Very similar to Sano, SugarBEAT sends an electrical current through the top layer of skin to attract small glucose molecules. The SugarBEAT patch relays information to a smartphone application every 5 minutes and must be replaced every 24 hours. SugarBEAT has raised roughly \$12 Million in funds and has completed approximately 1,000 days of clinical studies.

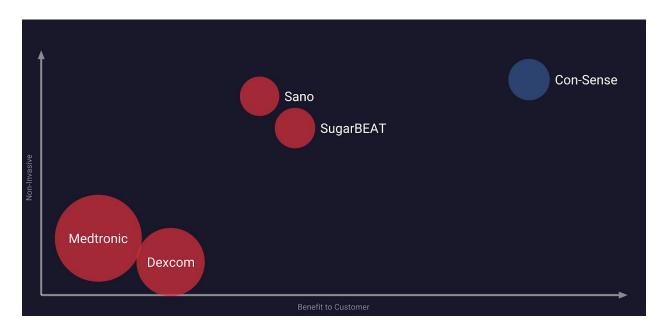




Comparison Chart: Con-Sense is differentiated from the competition on two major components. Con-Sense customers pay for one device that lasts five years and a monthly subscription translating to a roughly 50% in cost savings in year one, and over 90% savings throughout the life of the product. The competition; however, offers patches/sensors that must be replaced every 24 hours: leading to more higher costs and more product purchases.

Company	Features									
	Smart Phone Connectivity	Non Invasive	Accurate	Cost Friendly	One Time Use					
Con Sense	/	/	1	/	/					
Sano	/	/	/	×	×					
Sugar BEAT	1	1	1	X	X					

Product Positioning Chart: Below is a product positioning chart that evaluates the Con-Sense CGM on two criteria: Non-Invasive and overall Benefit to Customer.



Benefit to customer vs Non Invasive chart

VI. Marketing and Sales

Market Analysis: Con-Sense is pursuing an improved CGM because of the growing numbers of diabetics in the United States and the improvement in small, wireless sensing technologies including RFID (radio frequency identification). Current glucose monitoring options are expensive and need constant replacement while lacking accurate readings. To tackle this issue, Con-Sense is utilizing advanced technology to provide a long-term solution to reading glucose levels with utmost accuracy. Rather than targeting high monthly or annual costs like the diabetic equipment of competitors, we want to offer a high initial cost with much lower recurring costs to build a glucose monitoring system with the lowest overall price to customers over the course of multiple years.

Products Offered: The continuous glucose monitor itself is a microchip with glucose-sensing RFID technology that is inserted below the skin. It wirelessly communicates with a smartphone to transmit data for use with the insulin pump and for doctor's records as necessary.

Additionally, the smartphone application that receives data, analyzes it, and makes it available for use by insulin pumps, the user, and the doctor. The application operates on a monthly subscription basis.

Other CGMs today transmit data wirelessly but are tremendously expensive and need replacement every week or two. Con-Sense will excel with a more affordable CGM that can operate for years at a time.

Pricing Strategy: The sales price of the RFID CGM will have a selling price of \$10,000 that will remain in place for an estimated 5 years. The best CGMs on the market can cost roughly \$6,000 with an additional \$18,000 of healthcare costs spent per year on sensors, patches, and finger sticks. The diabetes market is rapidly growing and expected to reach \$1.01 billion by 2024. The monthly subscription service will be \$10 to utilize the Con-Sense smartphone app. The subscription price was determined by other common monthly subscription services that customers use (cell phone, television, internet, streaming services, etc), so that their monthly diabetes management price aligns with other common subscriptions costs.

Distribution (**Placement**): Our CGM product is purchased online following a doctor's prescription and an appointment is made for the CGM to be surgically inserted. We are selling it online because it is ultimately up to the individual whether they wish to utilize this technology. Other CGMs and diabetic equipment is purchased online following a online insurance verification and sales representative. Dexcom and Tandem Diabetes handle CGM and insulin pump purchases this way, respectively. Because diabetics are familiar with purchasing such equipment online, Con-Sense will strive to match this purchasing model for continuity across these equipment options.

Promotion: Con-Sense intends to run advertisements in diabetic magazines such as Diabetes Forecast and Diabetic Living. These are read by diabetics themselves that feature people's stories and meal preparations, for example. Additionally, commercials will be aired on television on channels where drama and news shows are common such as TNT, AMC, FX, CNBC, CNN, and Fox News. According to an article by Joanne Kaufman of the New York Times, pharmaceutical companies are airing increasing numbers of commercials on news and drama television channels.

Additionally, doctors who can prescribe the monitor will be informed of our technology at medical conferences by networking and presenting.

Sales Force: Con-Sense expects to be acquired at the end of year five. However, we have included a sales force plan in lieu of an exit. At the beginning of year six, Con-Sense will begin a

a regional campaign in the midwest. Con-Sense will hire one sales professional to visit doctor's offices throughout Oklahoma to obtain referrals for the RFID Chip. Con-Sense has negotiated contracts with two individuals to offer industry expertise.

- Jack Allen is well connected in Oklahoma and serves on the Project Echo committee.
- **Dr. John Williams** is a primary care physician in Oklahoma who offers exceptional care. Dr. Williams medical practice, Internal Associates of Medicine has won Medicaid's Comprehensive Primary Care Initiative.

Sales Approach: Con-Sense's RFID CGM reduces healthcare costs for diabetic care from \$24,000 a year to a product that costs \$10,000 and lasts five years. According to this model, insurance companies will reduce their five year expenditures per diabetic by \$114,000. Con-Sense salesmen will call insurance companies and highlight the extensive savings that they will incur by having their diabetic customers switch to our product.

Diabetics will be inclined to ask their primary care physician to switch to Con-Sense's RFID CGM because the cost savings will flow through the insurance companies to an overall reduction in the premiums that they are paying.

The purchase of the chip is made at this point, and the specifics of the surgery are handled by the doctor's office and the patient. Following installation, the customer can subscribe to the Con-Sense smartphone app to begin reading glucose levels and analyzing data.

Sales Forecast (Bottom's Up): The Bottom Up Sales Forecast represents Year 6 Sales depending on a five year regulatory pathway to FDA approval. Two salesmen will make one sales call per week to insurance companies. This will involve the initial telemarketing call and a follow on meeting. Assuming a 20% close rate with insurance companies who then have a 10% close rate with their 10,000 diabetic customers, roughly 20,000 units will be sold in Year 6. Translating to \$100 M in revenue per employee.

VII. Operations

Product Development: The intellectual property that Con-Sense plans to utilize has completed a proof of concept phase. The company is currently working with Dr. SadaGopan Krishnan, who developed the technology, to see if it can be used in our product. After Con-Sense receives authorization to move forward, the company will work with the Oklahoma State University Patent Office to file our intellectual property. After the patent authorization and negotiations with OSU have been finalized, Con-Sense will move towards FDA Approval.

Team: The team is currently led by a group of Oklahoma State University students who have experience in business development, product design, database management, and coding.

Costs: The most significant cost associated with taking a medical device to market is the regulatory and FDA processes. According to a group of Oklahoma State University students, the best way to navigate this is to hire a Contract Research Organization for clinical trials and to hire a FDA Consulting Organization like Emergo.

Timeline: The company is currently conducting feasibility analysis, market research, and product design. The next eighteen months will be used to develop a minimal viable product. After completing a minimal viable product, the FDA approval process will begin. Following FDA approval, Con-Sense will begin hiring salesmen to generate revenue.

Lawsuits: Con-Sense is expecting a lawsuit from a large medical device company over patent infringement. We hope to mitigate this risk by filing the patent through the Oklahoma State University Patent Office. If Con-Sense is sued, Oklahoma State University will help take the suit to court

The lawsuit will determine the validity of Con-Sense's patent. If Oklahoma State University is successful in protecting the intellectual property, then Con-Sense has the authority to commercialize

However, if the courts determine that there is a patent infringement, Con-Sense and Oklahoma State University will sell our software code to the major insulin pump manufacturers.

Valley of Death: The most significant risk that Con-Sense will face is the long timeline before revenue generation. Con-Sense will require a large amount of upfront capital in order to take the insulin pump to market. To mitigate this risk, Con-Sense will stage investments in three funding rounds based on the completion of developmental milestones.

Manufacturing: Con-Sense will partner with Qingdao Hiprove Medical Technologies Co., Ltd to manufacture insulin pumps. We will import all machines to our headquarters and assemble in-house. At this point, we will integrate our software with the insulin imported insulin pumps.

Key Suppliers: Con-Sense has identified Qingdao Hiprove Medical Technologies Co., Ltd as the main supplier of insulin pumps. Qingdao Hiprove Medical Technologies Co., Ltd is located in China and will help to lower manufacturing costs.

Product Delivery: Con-Sense will ship product to customers after they have been approved through their insurance provider and diabetes manager. Patients will need to check with their insurance provider to determine if they have Durable Medical Equipment coverage. Many endocrinologists and diabetes educators have demo insulin pumps in their offices and will provide information on all the available pumps to their patients.

Customer Service and Support: A Con-Sense Customer Service Representative will be present at each initial pump installation. Upon installation, the Customer Service Representative will call each customer after a week of wearing the pump to determine how if the patient's blood-glucose management has improved. Con-Sense will have a customer service center that will reach out to each customer quarterly to determine product reliability and ask questions on how to improve.

Human Resource Plan: Con-Sense currently has four full time founders who are preparing the company to produce the first minimal viable product and begin the FDA approval process. As FDA approval comes to a close, Con-Sense will hire four salesmen to conduct a regional sales initiative.

Facilities: Con-Sense is headquartered in Stillwater, Oklahoma at the Spears School of Business. Within the next eighteen months, Con-Sense expects to move into a larger office space at the 36 Degrees North Startup Incubator in Tulsa, Oklahoma.



36 Degree North Startup Incubator, Tulsa, OK

Con-Sense has partnered with Dr. Gopan Krishnan, an Associate Professor in the Department of Chemistry to bring this RFID technology to life. Dr. Sadagopan is funded through the National Institute of Diabetes and Digestive and Kidney Diseases. His research interests align with clinical biosensors/arrays and novel drug screening arrays.



VIII. Management and Organization

Beau Blanchard: is the CEO and founder of Con-Sense. Beau has extensive experience in the healthcare industry and is committed to improving the experience of diabetic patients. Beau has volunteered for hospitals around the Dallas/Fort Worth area and has attended the annual American College of Healthcare Executives. Beau also has experience working under a doctor who received the number one ranking in Medicaid's Comprehensive Primary Care Initiative. Hence his background has equipped him to understand the issues diabetic patients face. Also, his business degree has given him the vision required to lead the company.



Stuti Mehrotra: is the Vice President of Operations at Con-Sense. Stuti has over 3 years of experience in customer insights and analytics. She also has experience streamlining the internal process to increase profitability. Getting feedback from customers and incorporating them into the design of medical equipment is one of the main goals of Con-Sense. Being a startup, Con-Sense must be cost-efficient with its internal processes.



Lucas Utley: is the Vice President of Engineering for Con-Sense. Lucas has extensive experience in mechanical engineering. His expertise has helped Con-Sense come up with the revolutionary design for the insulin pump. His deep understanding of the dynamics and functioning of

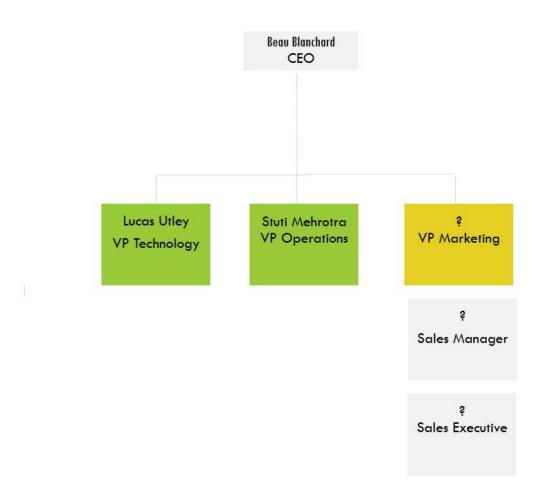


the pumps gives Con-Sense the technical edge over others.

Open Positions: Con-Sense does not have any open positions currently, as it is yet to receive a patent. However, following that patent, the company will be looking for a Vice President of Marketing and Sales, and management and sales executives in the future.

Board of Directors: Con-Sense is looking for a board of five directors who are enthusiastic about the business and would help guide the company towards success. One of the 5 spots will be for the CEO. Con-Sense is looking for two industry experts and two investors to fill the board of directors positions. They will meet once a month every year and will be compensated for each meeting.

Organizational Chart:

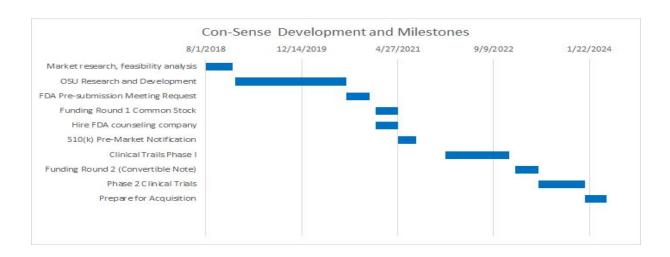


IX. Development and Milestones

Con-Sense is already working towards completing initial feasibility analysis by January 2019 which will allow for a final intended pump design that allows engineering to work towards patent authorization. During the development of the pump technology, Con-Sense is targeting its first funding round to allow for prototype design and testing. The second funding round provides for costs associated during the FDA approval period including payroll and design work and testing as needed during the evaluation. The third round will be near the end of FDA approval as the company moves towards manufacturing and sales.

In engineering and product technology development, the largest objective is securing patent authorization for the design. It will be the first of its kind to primarily be controlled via smartphone, and the smaller package will be totally unique. During this time, the pump accuracy and monitoring will be fine-tuned, and the first prototype built by mid-2019. Testing of the unit for flow rate, accuracy, versatility, and software connectivity will be conducted throughout 2020 in junction with submission for FDA approval at the end of the 2019 calendar year. Following clearance by the FDA, manufacturing and trial periods will run for eighteen months, with release and trial periods immediately following. There will be additional software updates to include new features, improved accuracy, and other tweaks that are independent of hardware after release. The majority of hardware design engineering will be complete at the full-scale release. As manufacturing is being outsourced, that is not a significant engineering concern.

As previously mentioned, patent authorization and FDA approval are two legal milestones that affect the company. Patent authorization is expected to take between 18 and 24 months after finalizing the pump and monitoring technology. FDA approval is estimated to take 3 years, although that could take more or less time.



Gantt Chart displaying milestones and their dates.

X. Risks and Contingencies

Increased competition: Our current competitors are Medtronic and Dexcom. They both sell CGMs that are most common in the market today. Tandem Diabetes sells insulin pumps and have introduced touchscreen technology and bluetooth connectivity. Con-Sense is developing a continuous glucose monitor which is more accurate and utilizes smartphone connectivity for real-time monitoring in a smaller package.

Liability: There is a liability of the patient relying on the insulin pump in case of life threatening situations. But our deice will be prescribed by the doctors hence the liability will be shared under such circumstances

Suppliers failure to meet deadlines: Con-Sense understands that supplier failures can have a far-reaching impact on the business and brand value. As supply chains continue to become more interconnected, their vulnerability to failure and disruptions also increase. To counter these risks Con-Sense will have a proper risk management program which will assess risks and have methods in place to mitigate them. Knowing the supplier and the supply chain is an important part of this process. Assessing a supplier for ISO 13485 or ISO 9001 compliance is one of the first steps in getting to know the supplier. A failure mode and effect analysis (FMEA) will be used to identify areas of significant risk due to suppliers and to determine what needs to be done to ensure the risk stays low with them. Heavy penalties on failing to meet the needs of business and a rigorous selection procedure based on compliance to ISO standard, past failures to comply and FMEA analysis will help mitigate risk.

Regulatory: Getting an FDA approval is a big hurdle for Con-Sense. To mitigate this risk Con-Sense plans to leverage help from FDA consultants.

Privacy Concerns: Data privacy of the user is one of the top concerns of Con-Sense. But the users information will be available only on the users device and the mobile device the user wants to connect it to. The user has the freedom of sharing the information with other people if he/she wishes to do so. Service-level security and device-level security will work together to protect the device from unauthorized data transmission. Security methods include authorization and identification procedures that limit the use of Bluetooth services to the registered user and require that users make a conscious decision to open a file or accept a data transfer. A user can also simply switch his Bluetooth mode to "non-discoverable" and avoid connecting with other Bluetooth devices entirely.

Surgery: There is a risk in placing the device under the skin and the material irritating the tissue inside the customer. The risk will be mitigated by rigorously testing the device material to be safe for use. It will be built similar to etonogestrel implants that go under the skin since they are already FDA approved.

Technology: There is a risk of the technology not functioning to its optimum. To mitigate this risk Con-Sense will have iterative testings procedures in place to ensure the quality and safety of the product.

XI. Capitalization and Structure

Legal Structure of the Company: Con-Sense will file as a C-Corporation in Stillwater, Oklahoma. This will enable Con-Sense to have an appropriate legal structure to conduct funding rounds with venture capital firms.

Present Equity Positions: Con-Sense stock is currently held at a 50% majority by the lead principle, Beau Blanchard. The remaining 50% is split equally between the two remaining principles, Lucas Utley, and Stuti Mehrotra. An option pool of 50% is planned for key personnel such as a Chief Executive Officer, Chief Science Officer, a Chief Financial Officer, and a R&D investment from a medical device company such as Medtronic.

Deal Structure: Con-Sense is currently seeking to raise \$300,000 through a common stock offering with subsequent convertible note of \$500,000 with a 12 month life and a 25% discount rate. The current interest rate on the convertible note is 10%. Depending on how successful Con-Sense is with meeting developmental milestones, a Series A investment of \$3 Million and a following Series B investment of \$7 Million is planned.

Exit Strategy: Similar continuous glucose monitor companies have required returns between \$207 Million and \$250 Million. Con-Sense will seek to be acquired by a large medical device company such as Medtronic or Dexcom at a planned exit value of \$250 Million.

XII. Financial Projections

Assumptions:

- Oklahoma State University Research and Development will cost \$150,000 to develop a working prototype.
- The Con-Sense RFID CGM will receive a Class III classification.
- The regulatory process for a class III medical device will take five years and cost roughly \$10 Million in outsourced consultant/research fees.

• Con-Sense will not be able to sale any product until FDA approval in year six.

■ Year 6 - 2 salesmen - \$92,000 salary

• Taxes and Benefits: 30%

• Clinical trial costs are based on animals and non diabetic patients. Approximately \$22M

RFID CGM Sales: \$10,000 per unit
A monthly subscription fee: \$10

• RFID COGS: \$50

Financial Summary and Statements:

Financial Summary

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Grant Revenue	\$150,000	\$650,000	\$625,000	\$500,000	\$500,000	\$0
Product Revenue	\$0	\$0	\$0	\$0	\$0	\$200,000,000
App Revenue	\$0	\$0	\$0	\$0	\$0	\$2,400,000
Total Revenue	\$150,000	\$650,000	\$625,000	\$500,000	\$500,000	\$202,400,000
Total Expenses	\$316,100	\$1,122,600	\$1,282,000	\$2,438,000	\$7,875,200	\$23,441,200
Net Income	\$ (172,766.67)	\$ (490,933.33)	\$ (680,333.33)	\$ (1,963,000.00)	\$ (7,400,200.00)	\$97,865,423

Income, Cash Flow statement and Balance Statement are attached in the appendix.

Financial Strategy: Con-Sense will seek to capitalize on taking a Class II Medical Device from concept through Phase II Clinical Trials on grant revenue and outside investment that is outlined in the Capitalization and Structure section.

XIII. Summary and Conclusions

Con-Sense is seeking financial support to develop, manufacture, and sell a new continuous glucose monitor (CGM) for patients with Type 1 diabetes. CGMs today, like their insulin pump counterparts, can be cumbersome to wear and yield inaccurate readings which is where Con-Sense wishes to further innovation by building a more accurate, long-lasting monitor that also utilizes wireless connectivity via smartphone to achieve a final product that is smaller, more accurate, and technologically advanced.

The team consists of CEO Beau Blanchard, Vice President of Operations Stuti Mehrotra, Vice President of Engineering Lucas Utley, and Product Designer Hong Kai Long. They have been conducting interviews to understand the issues diabetic patients face when managing diabetes and how an improved CGM could positively impact their lives.

Two major milestones include obtaining a patent for the monitor-specific technology and securing FDA approval of the product. This process takes in excess of a year, but following approval, manufacturing, sales, and distribution are clear to proceed.

The market for insulin pumps and CGMs is expected to experience significant growth in the next decade as obesity is the driving factor of more people developing diabetic conditions. The market is projected to reach USD 35.5 billion by 2024.

Con-Sense is seeking to utilize this growth opportunity to not only grow as a company, but also improve the lives of those who live and cope with Type 1 diabetes with our continuous glucose monitor.

Appendices

Figure 1. Income Statement

-	ated Financial Mo Proforma Income S					
	Totolilla ilicollic (Statement				
	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Revenues:						
Grant Revenues	\$150,000	\$650,000	\$625,000	\$500,000	\$500,000	\$0
RFID CGMs	\$0	\$0	\$0	\$0	\$0	\$200,000,000
CGM Software	\$0	\$0	\$0	\$0	\$0	\$2,400,000
Total Revenues	\$150,000	\$650,000	\$625,000	\$500,000	\$500,000	\$202,400,000
Cost of Good Sold	\$0	\$0	\$0	\$0	\$0	\$1,000,000
Gross Profit	\$150,000	\$650,000	\$625,000	\$500,000	\$500,000	
Gross Profit Margin	100%	100%	100%	100%	100%	100%
Operating (Overhead) Expenses:						
Clinical Trials (Animal/Patient) Related						
Animal Trials Related	\$0	\$320,000	\$166,500	\$0	\$0	\$0
Patient Trials Related	\$0	\$0	\$0	\$675,000	\$3,750,000	\$17,500,000
Lab Research	\$0	\$75.000	\$0	\$0	\$0	\$0
Outsourced External Experts	7.	7.0,000				
FDA Consulting	\$120,000	\$230,000	\$280,000	\$35,000	\$280,000	\$75,000
CRO Related	\$0	\$200,000	\$250,000	\$1,000,000	\$3,000,000	\$5,000,000
OSU Research Support	\$150,000	\$75,000	\$50,000	\$50,000	\$0	\$0
Corporate Overheads:				. ,		
Corporate Salaries	\$0	\$87,000	\$318,000	\$418,000	\$518,000	\$518,000
Employee Taxes & Benefits	\$0	\$26,100	\$95,400	\$125,400	\$155,400	\$155,400
Office Rent	\$0	\$5,000	\$7,500	\$7,500	\$7,500	\$7,500
Travel	\$12,000	\$24,000	\$36,000	\$36,000	\$48,000	\$48,000
Telephone/Internet	\$3,600	\$3,600	\$5,000	\$7,500	\$7,500	\$7,500
Office Supplies	\$1,200	\$3,600	\$3,600	\$3,600	\$4,800	\$4,800
Insurance - Business	\$2,500	\$2,500	\$5,000	\$10,000	\$10,000	\$10,000
Legal - General	\$5,000	\$36,000	\$48,000	\$42,000	\$60,000	\$75,000
Accounting (CPA) - Financial/Taxes	\$4,800	\$4,800	\$12,000	\$18,000	\$24,000	\$30,000
Grant Writter	\$12,000	\$25,000	\$0	\$0	\$0	\$0
Miscellaneous/Other	\$5,000	\$5,000	\$5,000	\$10,000	\$10,000	\$10,000
Total Operating Expenses	\$316,100	\$1,122,600	\$1,282,000	\$2,438,000	\$7,875,200	\$23,441,200
EBITDA	(\$166,100)	(\$472,600)	(\$657,000)	(\$1,938,000)	(\$7,375,200)	\$177,958,800
Depreciation	\$6,667	\$18,333	\$23,333	\$25,000	\$25,000	\$21,667
Interest Expense	\$0	\$50,000	\$0	\$0	\$0	\$0
Pre-Tax Income	(\$172,767)	(\$490,933)	(\$680,333)	(\$1,963,000)	(\$7,400,200)	\$177,937,133
Taxes	\$0	\$0	\$0	\$0	\$0	\$80,071,710
Net Income	(\$172,767)	(\$490,933)	(\$680,333)	(\$1,963,000)	(\$7,400,200)	\$97,865,423

Figure 2. Balance Sheet Statement

	Integra	ted Financ	ial Model								
Proforma Balance Sheet											
	Beg. Year 1 Year 2 Year 3 Year 4 Year 5										
Cash	\$0	\$108,290	\$141.892	\$2,472,106	\$540,161	\$235,478	Year 6 \$98,333,762				
Accounts Receivables	\$0	\$0	\$0	\$0	\$0	\$0	\$0				
Inventory - Materials	\$0	\$0	\$0	\$0	\$0	\$0	\$0				
Total Current Assets	\$0	\$108,290	\$141,892	\$2,472,106	\$540,161	\$235,478	\$98,333,762				
Lab/Research Equipment	\$0	\$25,000	\$75,000	\$75,000	\$75,000	\$75,000	\$75,000				
Office Furniture/Computers	\$0	\$5,000	\$10,000	\$25,000	\$35,000	\$40,000	\$45,000				
Accumulated Depreciation	\$0	(\$6,667)	(\$25,000)	(\$48,333)	(\$73,333)	(\$98,333)	(\$120,000)				
Net PP&E	\$0	\$23,333	\$60,000	\$51,667	\$36,667	\$16,667	\$0				
Total Assets	\$0	\$131,624	\$201,892	\$2,523,772	\$576,828	\$252,144	\$98,333,762				
Account Payable	\$0	\$4,390	\$15,592	\$17,806	\$33,861	\$109,378	\$325,572				
Interest Expense - Accrued	\$0	\$0	\$50,000	\$0	\$0	\$0	\$0				
Total Current Liabilities	\$0	\$4,390	\$65,592	\$17,806	\$33,861	\$109,378	\$325,572				
Convertible Note	\$0	\$0	\$500,000	\$0	\$0	\$0	\$0				
Total Liabilities	\$0	\$4,390	\$565,592	\$17,806	\$33,861	\$109,378	\$325,572				
Equity - Common	\$0	\$300,000	\$300,000	\$300,000	\$300,000	\$300,000	\$300,000				
Equity - Preferred	\$0	\$0	\$0	\$3,550,000	\$3,550,000	\$10,550,000	\$10,550,000				
Retained Earnings	\$0	(\$172,767)	(\$663,700)	(\$1,344,033)	(\$3,307,033)	(\$10,707,233)	\$167,229,900				
Total Equity	\$0	\$127,233	-\$363,700	\$2,505,967	\$542,967	\$142,767	\$178,079,900				
Total Liabilities & Equity	\$0	\$131,624	\$201,892	\$2,523,772	\$576,828	\$252,144	\$178,405,472				
Check Balance	\$0	\$0	\$0	\$0	\$0	\$0	(\$80,071,710)				

Figure 3. Cash Flow Statement

Int	tegrated Financ	ial Model								
Proforma Cash Flow Statement										
	Year 1 Year 2 Year 3 Year 4 Year 5									
Net Income	(\$172,767)	(\$490,933)	(\$680,333)	(\$1,963,000)	(\$7,400,200)	Year 6 \$97,865,423				
Plus: Depreciation	\$6.667	\$18,333	\$23,333	\$25,000	\$25,000	\$21,667				
Operating Cash Flow	(\$166,100)	(\$472,600)	(\$657,000)	(\$1,938,000)	(\$7,375,200)	\$97,887,090				
Working Capital Requirements:										
Change in Accounts Receivables	\$0	\$0	\$0	\$0	\$0	\$0				
Change in Inventory-Materials	\$0	\$0	\$0	\$0	\$0	\$0				
Change in Accounts Payable	\$4,390	\$11,201	\$2,214	\$16,056	\$75,517	\$216,194				
Change in Accrued Interest Expense	\$0	\$50,000	(\$50,000)	\$0	\$0	\$0				
Subtotal Working Capital Requirements	\$4,390	\$61,201	(\$47,786)	\$16,056	\$75,517	\$216,194				
Investment Capital Requirements:										
Change in Equipment	(\$25,000)	(\$50,000)	\$0	\$0	\$0	\$0				
Change in Furniture & Equipment	(\$5,000)	(\$5,000)	(\$15,000)	(\$10,000)	(\$5,000)	(\$5,000				
Subtotal Investment Capital Requirements	(\$30,000)	(\$55,000)	(\$15,000)	(\$10,000)	(\$5,000)	(\$5,000				
Funding Sources:										
Change in Convertible Note Debt	\$0	\$500,000	(\$500,000)	\$0	\$0	\$0				
Change in Equity-Common	\$300,000									
Change in Equity-Preferred	\$0	\$0	\$3,550,000	\$0	\$7,000,000	\$0				
Subtotal Funding Sources	\$300,000	\$500,000	\$3,050,000	\$0	\$7,000,000	\$0				
Total Cash Flow	\$108,290	\$33,601	\$2,330,214	(\$1,931,944)	(\$304,683)	\$98,098,284				
Beginning Cash	\$0	\$108,290	\$141,892	\$2,472,106	\$540,161	\$235,478				
Ending Cash	\$108,290	\$141,892	\$2,472,106	\$540,161	\$235,478	\$98,333,762				

Figure 4. Capitalization Table

								Con-Se	nse- Mu	ultiple I	unding R	ounds								
Total # Founding Shares		1,000,000	Pre-Money:		Common Pre-M	loney Valuation	1	\$2,000,000	Convertible N	lote#1		\$500,000	Series A Pre-Mo	ney Valuation	0	\$10,000,000	Series B Pre-Mo	ney Valuation		\$50,000,000
			Stock Options	50.0%	Common Stock	Raised		\$300,000	Interest Rate			10%	Series A Capital	Raised			Series B Capital			\$7,000,000
			Pool		Common Post N	Money Valuatio	n	\$2,300,000	Note Term in	Months		12	Convert. Note C	onversion ino	Series A	\$687,500	Post Money Val	uation		\$57,000,000
					Common Inves	tor(s) % Equity		13.0%	Discount			25.0%	Post Money Val	uation		\$13,687,500	Series B Investo	or(s) % Equity		12.39
									Series A Value			\$550,000	Series A Investo	or(s) % Equity		21.9%				
					Common Inves	tor per Share P	rice	\$1.0000	Series A Value	w/Disc		\$687,500	Series A Investo	or(s) per Share	Price	\$4.6467	Series B Invest	or(s) per Share	Price	\$16.1626
	Initial	Total	Total	Total	Common	Common		Total	Conv. Note	Conv. Note		Total	Series A	Series A		Total	Series B	Series B		Total
Shareholders:	Shares	% Equity	Shares	% Equity	\$ Investment	#Shares	Total Shares	% Equity	\$ Investment	Shares	Total Shares	% Equity	\$ Investment	#Shares	Total Shares	% Equity	\$ Investment	#Shares	Total Shares	% Equity
Beau Blanchard-Team Lead	600,000	50.0%	600,000	30.0%			600,000	26.1%			600,000	26.1%			600,000	19.4%			600,000	17.0%
Lucas Utley-Research Lead	200,000	25.0%	200,000	10.0%			200,000	8.7%			200,000	8.7%			200,000	6.5%			200,000	5.7%
Stuti Mehrota-Operations Lead	200,000	25.0%	200,000	10.0%			200,000	8.7%			200,000	8.7%			200,000	6.5%			200,000	5.7%
Option Pool																				
CEO-Hire			300,000	15.0%			300,000	13.0%			300,000	13.0%			300,000	9.7%			300,000	8.5%
CSO-Hire			150,000	7.5%			150,000	6.5%			150,000	6.5%			150,000	4.8%			150,000	4.3%
CFO-Hire			100,000	5.0%			100,000	4.3%			100,000	4.3%			100,000	3.2%			100,000	2.8%
Diabetic Company			200,000	10.0%			200,000	8.7%			200,000	8.7%			200,000	6.5%			200,000	5.7%
Unallocated			250,000	12.5%			250,000	10.9%			250,000	10.9%			250,000	8.1%			250,000	7.1%
Common Stock Investor(s)					\$300,000	300,000	300,000	13.0%				13.0%			300,000	9.7%			300,000	8.5%
									\$500,000			0.0%		147,953	147,953	4.8%			147,953	4.2%
Convertible Note																				
Series A Investor(s)													\$3,000,000	645,614	645,614	20.9%			645,614	18.39
Series B Investor(s)																	7,000,000	433,099	433,099	12.35
Total	1.000.000	100.0%	2.000.000	100.0%	\$300,000	300,000	2,300,000	100.0%	\$500,000	-	2,300,000	100.0%	\$3,000,000	793,567	3.093.567	100.0%	7,000,000	433,099	3,526,667	100.05

Figure 5. Liquidation Preferences

					\$250,000,000		
Liquidation Preference Structure: Non-Participating = 0 & Full Participation = 1							
	Dividend	Years	Liquidation	Total			
	Rate	To Exit	Multiple	\$ Preference			
			1.5	\$4,500,000			
	5.0%	4		\$600,000			
ticipating					\$0		
rticipation					\$5,100,000		
			1.0	\$7,000,000			
	8.0%	2		\$1,120,000			
ticipating					\$0		
ticpation					\$8,120,000		
Distributable Equity Value (balance) to Common Equivalent					\$236,780,000		
	ticipating rticipation ticipating ticpation	Dividend Rate 5.0% ticipating rticipation 8.0% ticipating ticipation	Dividend Years Rate To Exit 5.0% 4 ticipating rticipation 8.0% 2 ticipating ticpation	Dividend Years Liquidation Rate To Exit Multiple 1.5 5.0% 4 ticipating rticipation 1.0 8.0% 2 ticipating ticipating	Dividend Years Liquidation Total		

Figure 6. Exit Multiples

Shareholder Equity Distributions	Total Liq.	% Common	Investor	ROI Multiple	
& Returns:	Preferences	Equivalent	Return		
Common Stock Investors	\$0	\$20,141,966	\$20,141,966	67.14	
Series A Preferred Investors:	\$5,100,000	\$43,346,453	\$48,446,453	16.15	
Series B Preferred Investors	\$8,120,000	\$29,078,246	\$37,198,246	5.31	
Beau Blanchard	\$0	\$40,283,932	\$40,283,932		
Lucas Utley	\$0	\$13,427,977	\$13,427,977		
Stuti Mehrota	\$0	\$13,427,977	\$13,427,977		
Option Pool	\$0	\$0	\$0		