[Logo and name]

www. com

Contact: COO
info@ com

PhD, MBA
MS
MBA
MD, MBA
MBA

Executive Summary

One Line Pitch: develops smart wound care devices that aid timely clinical decision-making by providing objective tools to measure wound health. Early identification of non-healing wounds and infections helps reduce amputations in diabetic patients.

Business Summary: Our business includes the research, development, and sale of smart wound devices that monitor wound health in real time, which in turn guide clinical decisions and improve wound prognosis. R&D and marketing is managed in-house while manufacturing and distribution are outsourced to specialized medical device companies to effectively scale the business for the $122 million/year Total Available Market.

Management: MBA, has four years of corporate experience as an Associate Manager at PepsiCo. PhD, brings 10+ years of experience in diagnostic interventions for diabetes and wound healing. MD, is a practicing internal medicine physician with over nine years of clinical experience. MBA, has four years of experience in digital marketing and analyzing ventures for the Desert Angels, a local organized angel investment group. Fanciullo, MS is a Systems Engineer with 12 years of experience and three patents.

Customer Problem: Status quo includes the subjective and inaccurate measurement of 360,000 diabetic foot ulcers in the US, leading to 85,000 (24%) annual lower limb amputations annually. Systemic treatment costs incurred to treat these ulcers amount to roughly $8 billion a year. Social costs include poor quality of life and high mortality rates.

Target Market: Diabetes is the fastest growing health epidemic in the US with 26 million people affected today. The CDC anticipates a third of Americans will have diabetes by 2050. Our Total Available Market is at least $122 million, or $340 in annual revenues from each of the 360,000 annual diabetic patients with foot ulcers. Through initial sales facilitated by early clinical trials at leading wound care centers in AZ and CA, we aim to scale nationally over years 3-5.

Customer Validation: Our preliminary clinical trials to prove medical efficacy and derive specific metrics for CMS coverage will provide us with first customers, facilitating sales to national wound care centers. Our device is designed to objectively measure parameters recommended by the Infectious Disease Society of America (IDSA) and International Working Group on Diabetic Foot (IWGDF). Our product design is guided by current literature and support from key opinion leaders, providing higher likelihood of acceptability in the medical community

Sales/Marketing Strategy: While foundation-marketing materials such as a web presence will be managed in-house, sales and distribution will be outsourced to a national medical device distributor network such as Cardinal Health to facilitate the scaling of our venture. Through engaging and relationship building with a major national distributor, we will achieve high penetration rates into hospitals and wound clinics.

Business Model: Our patentable products will initially be manufactured at a local contract manufacturer, Mastek-InnerStep. A 3rd party distributor such as Cardinal Health will sell to wound care centers nationally at a 30% discount to end-user pricing. Our business model achieves high gross profit margins (88%) at price to distributor.

Competitors: Incumbents include Smith & Nephew, 3M, Johnson & Johnson, KCI, and specifically MC10. These companies, except MC10, produce the status quo simple wound dressings used today. There are no real-time, objective measurement devices associated with the products offered by these companies, except for MC10, who is focused on neonatal vitals monitoring only. Several competing devices by researchers from Northeastern, Fraunhofer Research Institution, and Monash University are in development but are not commercialized.

Competitive Advantage: Our competitive advantage is rooted in our medical expertise and our small organization's ability to rapidly design, develop, iterate, and clinically test patentable products for large markets.

Financial Outlook:

	Year 1	Year 2	Year 3	Year 4	Year 5
Revenues	**$0**	**$420,750**	**$5,856,840**	**$11,713,680**	**$23,427,360**
Gross Income	**$0**	**$370,438**	**$5,156,490**	**$10,312,980**	**$20,625,960**
Expenditures	**$138,223**	**$660,365**	**$4,687,276**	**$8,159,027**	**$13,613,649**
Net Income (Post-tax)	**($138,223)**	**($289,928)**	**$452,978**	**$1,302,280**	**$4,239,643**

Table 1: Financial outlook for over 5 years.

Use of Funds:

Source of Funds	Specific activity	Funds required	Deliverable	Delivery by
Founders' Fund / SBIR Phase I	Continue prototype development, patent filing, expert counsel for reimbursement and trials planning	$150,000	Product prototypes tested in laboratory and clinic. Identify expert counsel for CMS interactions and clinical trials planning.	September, 2015
Sub-Total Initial Funding Required		**$150,000**		
SBIR Phase II	Clinical Trials and FDA 510(k) filing	$500,000	FDA clearance, randomized clinical trial proving technology effectiveness	2015-2018 (Ongoing)
	Product manufacturing & clinical sites liaison		Provide finished product for clinical study and initial sales	2015-2018 (Ongoing)
Working Capital	Series A Funding to facilitate rapid growth phase and CMS liaison	$250,000	Implement distributor network and support company operations.	2016-2018 (Ongoing)
Total Capital Required		**$900,000**		

Table 2: Use of funds description for

Table of Contents

Management

Core Team

has identified a team with a strong clinical, research and business background highlighted by a physician, two engineers and four MBAs.

Advisory Board

Problem Statement

Diabetes - Global Problem View

There are approximately half a million new diabetic foot wounds annually in the United States. Of these almost 360,000 wounds become infected leading to 85,000 amputations. This represents a 24% amputation rate. Stated more simply, one of every four people with an infected foot ulcer will lose their limb. Globally, there is a diabetes related amputation every 20 seconds (International Working Group on Diabetic Foot, IWGDF).

…. a diabetes related amputation every 20 seconds (IWGDF)

Systemic treatment costs of these ulcers are ~$8 billion.[1] Social costs include poor quality of life and high morbidity and mortality rates.[2] The five-year mortality rate for a diabetic amputee is 60%.[3, 4] With diabetes growing at epidemic proportions, we will witness a need for targeted strategies for reducing the number of amputations.[5, 6] Poor wound healing due to uncontrolled inflammation, poor patient compliance and severity of infections leads to wound chronicity, thereby increasing the risks of amputations.[7] Healing wounds by identifying the best treatment options provides the most efficacious means of reducing wound complications and achieving better clinical outcomes. [8]

Inflammation & Infections

Inflammation is a central unifying concept of medicine spanning across the spectrum of pathologies from a simple bruise to cancer. For a diabetic wound, uncontrolled inflammation produces a staggering impact for the patient as well as the healthcare system.[9-12] Currently, there are no objective means of measuring wound inflammation and surprisingly the status quo for assessing diabetic foot wounds is ‘measurements of temperatures using back of the hand’.[10, 13]

…. the status quo for assessments is ‘measurements of temperatures using back of the hand’

Lack of Clinical Research

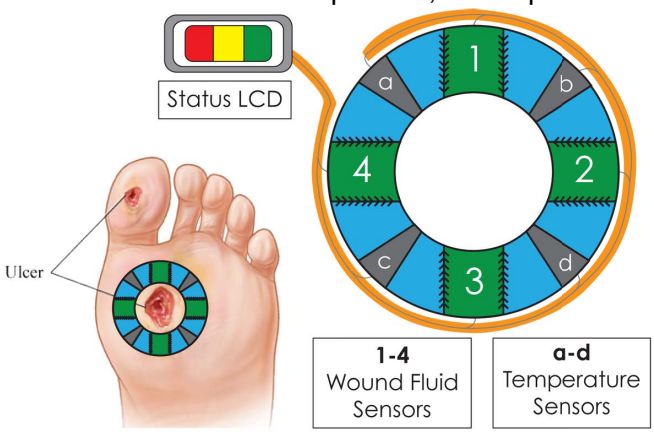
Additionally, while it is well accepted that early manifestations of inflammation are heat and swelling, there is a surprising lack of clinical data or research that defines the threshold temperature delta that indicates the onset of infection. To this end, there are three clinical studies that all suggest a temperature difference between the wound tissue and healthy tissue (delta temperatures) is indicative of infections and/or poor healing outcomes.[11, 14, 15] More specifically, these studies provide a wide range of delta temperatures from 2°F to 10°F, with sensitivity of temperature assessment for infections greater than 90%. In summary, 2°F is indicative of onset of wound infection while 10°F correlates with poor outcomes such as amputations. Therefore, there is a need to refine these thresholds for better clinical decision-making.

Solution

aims to provide objective wound care devices that can measure wound health with the goal of identifying patient healing potential and reducing amputations. The specific metrics include wound tissue temperature and moisture, as recommended by the Infectious Disease Society of America (IDSA)[9] and International Working Group on Diabetic Foot (IWGDF).[16]

i-WARM

first offering, i-WARM - Intelligent Wound Analytics Retrieval Meter, is an innovative wound health assessment tool, based on temperature and moisture, with actionable feedback for patients and physicians. While this is first product, future products will incorporate other assessments of wound characteristics such as moisture, exudate quality and oxygenation levels, all of which are indicative of wound healing potential and progression of infections.



This device can be used in an inpatient or outpatient setting, and is intended to sit on top of the skin under any gauze wrappings that are applied by a health care provider to keep the wound clean.

The device will feature two types of proprietary technology. First, the device will combine the measurement of wound temperature and wound exudate into a seamless system. Second, as the research conducted regarding the threshold of infection regarding the two metrics measured will be proprietary to all predictive algorithms that determine whether an infection is present, or imminent, will also be protected intellectual property.

Once applied, the device will take measurements at regular intervals, tracking the trends over time and displaying, through the simple status LCD, whether the wound is healing appropriately or is at risk of infection and needs further treatment. In an inpatient setting, this status could be interpreted by the health care provider, reducing the severity of infection and increasing the likelihood of healing. In an outpatient setting, this device would trigger the patient to contact their primary care physician for further treatment.

To create this device, it is first essential to complete the clinical testing needed to identify the threshold at which temperature and moisture become an indicator for infection. This research will be completed during the entirety of year one of operations.

Target Market

Our Initial target market encompasses diabetic patients with infected foot ulcers seen at wound care centers as well as hospitals in Arizona and California (approximately 42,000 infected foot ulcers or $14 million market size). We estimate there are 25 wound care centers in Arizona and 150 wound care centers in California approximately. Once our concept has been validated, we hope to help diabetics across the US (360,000 infected diabetic foot ulcers or $122 million Total Available Market), and also seek to expand the scope of our product to people with any infected wounds such as elective surgical incisions, decubitus ulcers, venous ulcers and burns.

Table below summarizes the target market.

	Year 1	Year 2	Year 3-5
Customer Type	Academic Research Institutions	Wound Care Centers in AZ and CA	Wound care centers and hospitals nationally
Specific Details	Southern Arizona Limb Salvage Alliance (SALSA), University of Arizona	Multiple sites across AZ & CA	Distributor Network Dictates Sales Locations and Penetration
Purpose	Preliminary research for FDA 510 (K)	Economic feasibility study for CMS	Product sales
Size (TAM)	350 Wound patients/Yr	350-400 Wound Patients/Yr	360,000 infected ulcers / $122 Million Market size
Sales Strategy	N/A	Direct Sales	Distributor Network

Table 3: Summary of target market for i-WARM technology.

One of the co-founders at PhD serves as researcher and Director of Operations at the Southern Arizona Limb Salvage Alliance (SALSA), at University of Arizona. SALSA is a premier research organization dedicated to reducing the number and severity of amputations that are caused by diabetic foot disease.[*] SALSA's national and international recognition to develop disease classification models, prevention strategies, wound diagnostics and wound therapeutics merits a partnership with to further validate the technology. SALSA will therefore serve as the testing grounds for conducting first feasibility studies beginning Year 1, to kick-start the FDA 510(k) clearance process. This is a standard process to seek regulatory approval for a new device by comparing core functionality to an already existing and approved predicate device with similar features. Once the feasibility clinical study and FDA approval are completed by Year two, will directly market the product to academic research centers and wound care centers in Arizona and California markets primarily using direct sales. Arizona and California together capture nearly 12% of the Total Available Market, primarily due to the high-risk populace including Pima Indians, Native Americans and Hispanics. Additionally, we have established relationships with clinical sites at these locations.

However, beginning Year 3 distribution will be outsourced to a medical device distributor network such as Cardinal Health to scale the business nationally. Per American Association of Wound Clinics, there are over 1,000 wound care centers in the United States. There are roughly 800-900 managed programs at private wound care centers and an additional 300+ non-managed hospital programs. The biggest concentration is in Florida, Texas, New York and California. The wound care center industry has undergone significant consolidation in

[*] www.diabeticfootonline.com

the last two decades, and it is now dominated by two large companies, Healogics[†] and Paradigm Medical Management[‡], each of which own approximately 500 and 300 wound care centers respectively. seeks to strategically leverage the distributor resources to maximize the market share in these locations geographically.

We envision that our partnership with the distributor will additionally provide inlet into hospitals that provide care for patients with chronic foot wounds. There are over 5,700 hospitals in the U.S., and approximately 5,000 of these hospitals have wound clinics. With the growing prevalence of diabetes it is likely that they will see an increasing number of patients with diabetic foot wounds.

[†] http://www.healogics.com/

[‡] http://www.pmmhealthcare.com/

Customers

Our product will be used for delivering care to patients with diabetic foot ulcers at outpatient clinics, hospitals, urgent care facilities, medical practices (individual/group), long-term care facilities and home health services. It is estimated that there are currently;

a. 1000 Wound Care Centers
b. 5000 Hospitals with wound clinics
c. 8700 Urgent Care Centers
d. 18000 Long Term Care Facilities

Wound care clinics typically provide care for approximately 350-500 patients per clinic with annual patient visits ranging from 10000-15000.

The costs for our product will be covered by the Center for Medicare & Medicaid Services (CMS)[§] and private insurers in the long term, ideally. Typically, the smart wound devices are intended for use weekly for 12 weeks on average per patient based on average wound healing times for diabetic foot wounds. Due to the recent changes in the healthcare landscape in the United States, specifically the introduction of the Affordable Care Act, payment for healthcare is being moved from the pay for service model to the pay for performance model. As such, it is projected that a reimbursement code will not be specifically necessary for the use of product portfolio, as this device will target cost reductions in the system. For more information regarding this change, please refer to the regulatory section of the business plan.

By using a medical device distributor network such as Cardinal Health or Medline, we will leverage existing sales networks to increase accessibility to our product. Medicare in the recent past has approved services for hyperbaric oxygen treatment, electrical stimulation and electromagnetic therapy of wounds. We intend to emulate similar reimbursement approval strategies by demonstrating documented improvement in wound healing and reduction in amputations during our clinical studies planned for Years 1-2.

[§] www.cms.gov

Business Model

Once clinical trials have been completed and FDA clearance has been granted, managerial focus will transition to the full manufacturing, distribution and sale of the devices. Because the core team is comprised of a University of Arizona researcher focused in diabetic foot care, without which the venture would not have been plausible, is projected to pay 3% of revenue to the university.

To reduce capital investment and focus specifically on the research and development of the portfolio of medical devices, full-scale manufacturing will be outsourced to a class 10 clean room facility, which has been approved for FDA Good Manufacturing Practices and will manage inventory on a rolling forecast. Direct sales will be managed by a third party medical device distribution company with a nationwide network to rapidly scale the use of the device at diabetic and wound care clinics around the country. The standard price for a partnership of this manner is 30% of end-user price. This strategy will reduce the need for inflated internal marketing and sales team numbers. In addition the use of a distribution company will reduce the need to directly interface with CMS for payment, which will result in a decrease of receivables.

In terms of device pricing, has developed a variable cost model as a function of percentage point reduction in amputations and the healthcare system savings those avoided amputations will generate. To create this pricing model, it is necessary to assume 100% penetration of the total available market. The table below summarizes the key variables. Major assumptions for this model include:

- is serving 360,000 patients per year, or 100% of the total available market
- Device cost projected at $40.25
- Each amputation has a total economic cost of $109,000
- CMS will require 85% of the yearly savings

- Hospital systems will require ~30% of reimbursement dollars for overhead costs of using the device (nurse and doctor wages, facility costs, etc.)

Reduction in Amputation Rate (%)	Dollars saved due to reduction in amputations (yearly)	Funds available for product reimbursement after CMS/hospital required 90%	Payment per patient (/360,000)	Payment for device after overhead costs for Hospital (70% of previous)
1%	$388,440,000	$58,266,000	$162	$113
2%	$776,880,000	$116,532,000	$324	$227
3%	**$1,165,320,000**	**$174,798,000**	**$486**	**$340**
6%	$2,330,640,000	$349,596,000	$971	$680
9%	$3,495,960,000	$524,394,000	$1,457	$1,020
12%	$4,661,280,000	$1,398,384,000	$3,884	$2,719

Table 4: Relationship between healthcare savings for CMS and pricing strategy for the i-WARM technology.

The team has projected an annual 3% total reduction in amputations from the current baseline of 24%. Based on this, the above chart highlights the per patient reimbursement dollars that would be available to at this economic value. Because has found manufacturer's that are capable of producing the two-piece product for $40.25 the total gross margin for the device would be 88%, as seen below.

Competition

Direct competitors

MC10 specializes in generating IP related to stretchable and conformal electronics. The company has received $60 million in funding to date, the most recent round in January 2014 for $20 million in venture capital. The company has a patent portfolio of 3 issued patents and 19 pending patents, 1 of the issued patents and 5 of the pending applications are titled “Systems, Methods, And Devices Using Stretchable Or Flexible Electronics For Medical Applications”.

One of the issued patents, US8097926, explicitly describes an apparatus comprising of a stretchable substrate, stretchable circuitry to deliver ablative therapy, an array of sensors generating data on an electrical condition of tissue, an output facility comprising a display, and a processing facility in electronic communication with the circuitry. While MC10 is currently not pursuing direct applications of their platform technology for wound care, is investigating the possibility of licensing their technology, given the nature of their intellectual property. Upon submission of our pending patent applications, we will be able to conclusively determine needs for a collaborative relationship with MC10.

Potential Future Competition – Academic Research in Wound Care Devices

While there are not a significant number of advanced wound care players beyond MC10, there is significant research being conducted. These research projects are still in a testing phase and are not currently being commercialized. Current research includes:

- The Materials Science Department at Monash University in Australia is developing a new technology that permits weaving fiber into a bandage that indicates temperature across the wound and surrounding tissue in real time only.
- The Fraunhofer Research Institution in Munich has developed an indicator dye that reacts to different pH values in real time only.
- Dr. George Savage from Silicon Valley also created a wireless medical sensor mounted on a strip, which can measure the temperature of the patient. This device has the potential to transmit data to a doctor and has years of testing left before commercialization.

is closely monitoring these research activities to leverage any future licensing opportunities if any of these technologies are commercialized.

Established Competition

Companies such as Smith & Nephew, 3M, and KCI all produce the conventional wound dressings and appliances used today. Currently, no product released by these companies track or measure wound status. At best, these products are optimized to accelerate healing on a generalized basis but do not help to indicate wound status. 3M offers multiple variations of its Tergaderm™ wound management dressing, with some offerings emphasizing an

…. no current commercial product tracks or measures wound status

increase in patient comfort, reduction in patient pain, rapid absorption, and protection against infection. None of these dressings can measure patient healing.

Smith & Nephew (S&N) offers Biobrane™, a temporary biosynthetic skin dressing designed to decrease pain, increase speed of healing, and decrease length of patient stay. S&N also offers Cadesorb™, a sterile ointment that is intended to control local wound pH and correct the natural balance in chronic wounds to stimulate healing. Other dressings offered by S&N include Jelonet™, a dressing made from open weave gauze that serves as a primary wound contact layer to reduce adherence of dressing.

KCI offers a Graftjacket® regenerative tissue matrix, which is intended for the repair or replacement of damaged or inadequate integumental tissue including diabetic foot ulcers. KCI's Graftjacket® Xpress flowable soft tissue scaffold is intended to support the body's repair of damaged or inadequate tissue. Both products are marketed to support cellular repopulation and revascularization.

Competitive Advantage

competitive advantage is rooted in its team's 17+ years of research experience related to foot wound care for diabetic patients. Dr. has over 10 years of experience in diabetic research as a research scientist and Director of Operations for SALSA, the Southern Arizona Limb Salvage Alliance. Dr. David Armstrong, the Director of SALSA, a prominent researcher and opinion leader in diabetic foot care, will help guide the scope of the clinical research in the appropriate direction towards regulatory clearance and demonstration of product efficacy.

core team and board shares a very keen understanding of diabetic patient wound care. The strength of the team will ensure clinical research is designed to reach commercialization. Upon commercialization, the team's understanding of diabetic wound care will also inform iterative improvements in its wound care devices through continuous R&D. team also possess experience with respect to filling valuable IP, particularly with respect diabetic wound care treatment, and in other critical aspects of IP diligence, including conducting Freedom to Operate searches.

Finally, each device in the product portfolio will feature patented technology that is proprietary to the researchers at This data and technology stems from the team's expertise in conducting clinical research and developing and prototyping products.

Strategies

Regulatory

All devices will require FDA clearance prior to the marketing and sale in the United States market. The first device in the portfolio, which will measure wound temperature and moisture, will target an FDA 510(k) clearance as a Class II medical device. Because classification of any medical device depends on both the intended use and the indications for use this classification is based upon the risk the device poses to the operator and the patient. The non-invasive nature coupled with the risk inherent in taking measurements from the wound surface has placed this device between the highest risk, Class III and the lowest risk Class I.

There are two routes to follow to gain FDA approval to market a medical device: 510(k) and Premarket Approval (PMA). Premarket approval is required when previously untested technology is entering the market. This process is significantly longer than 510(k) clearance, which requires that a device be shown to be substantially equivalent to technology that has been previously approved as safe and effective. In this case, the previously approved technology is known as a predicate device, and is required for the 510(k) process.

As a strategy, the team will target the 510(k) process and will use one of the following predicate devices once design is completed.

Product	Company	Approval Date	510(K) Number
General Purpose Temperature Probe Skin Temperature Probe	DRAEGER MEDICAL GMBH	2/28/13	K121999
Reusable Temperature Probes (M1024254 Skin Temperature Probe Reusable; M1024247 Gp Temperature Probe Adult Reusable)	GE HEALTHCARE	4/27/05	K050837
Skin Temperature Sensing Vinyl Strip	T. G. & E. MEDICAL	3/5/82	K813199

Table 5: Summary of potential predicate devices for FDA 510(K) clearance.

In addition, the team will look to collaborate with the FDA throughout the process to ensure full transparency and reduce the risk of failure of clearance. This strategy will include engaging in a pre-IDE (Investigational Device Exemption) meeting with the FDA to layout the rationale for the 510(k) submission and gain feedback regarding the methods used to establish equivalence.[**]

Once the 510(k) application has been submitted, the FDA has 90 days to respond to a request. The timeline for submission of this application will be identified as design is completed, but is targeted at the beginning of the second year of operations. Once submitted, the team has allocated six months to attend to any needs that surface during the FDA clearance process. During this time, the clinical trials will continue as planned.

The current US Healthcare system is a fee for service model. However, the recently introduced Patient Protection & Affordable Care Act (2010) introduces key changes to transition the current model to fee for performance model or bundled payment model. Per the legislature, beginning 2015, individual physician services will be based on a "value index," creating a new value-based payment modifier that will be used to provide differential payments to physicians based on

[**] http://blog.nyctechconnect.com/2013/09/24/medical-device-startups-and-the-fda/

quality and cost of care”. is building a device that let’s physicians measure wound outcomes, better than the status quo, which is subjective assessment. Identifying infections early will translate into significant cost savings for the physicians as well as the payers. is challenging the status quo to address the changes forthcoming via the Affordable Care Act.

is filling the void for infections management by using smart measurements.

The costs of chronic diabetic wounds are higher due to both the types of different products required and the length of time required for those products to be used. Diabetic wounds are typically dealt with by a combination of debridement, frequent dressing changes, products to address local vascular circulation, negative pressure for wound simplification and antibiotics for infection management. Progress is being made in reducing the associated healing times and the high costs of these interventions, but a large opportunity remains due to rate of infections leading to amputations. is filling the void for infections management by using smart measurements that help identify pathological changes early and improve outcomes as mandated by the Affordable Care Act.

The Center for Medicare and Medicaid Services (CMS) primarily aims to improve community health, increase efficiencies in care delivery across the continuum and lower treatment costs. The decisions taken by wound care physicians to provide care will be key as they now determine CMS commitment to reimburse. CMS assigns a 70% weight given to clinical process metrics and a 30% weight given to patient experience metrics.

The value-based payment modifier for physicians has a projected launch of 2017, where physicians will be mandated to take efficient treatment decisions. Under the current fee for service model, treatment decisions do not affect physician reimbursement, as long as the payer provides coverage. However, this will change post the Affordable Care Act. Furthermore, hospitals will face severe financial penalties if they have a high incidence of thirty-day readmission rates. Currently, thirty-day readmissions account for a quarter of all inpatient expenses for Medicare. Thirty-day readmissions commonly result from an inadequate coordination of care leading to a recurring infection after a patient is discharged.

The Patient Protection & Affordable Care Act merits that diabetes and its complications form a critical segment due to significant associated cost savings. In 2010, the total direct cost of diabetes care was approximately $116 billion and $58 billion in indirect costs due to disability, work loss, and premature mortality. Appropriate coordination of care through standard of care treatments in conjunction with product offering will ease the burden for physicians to focus on good quality clinical care without worrying about the reimbursement coverage.

Intellectual Property

patent pending technology is currently under review for patentability and freedom to operate search. We envision a provisional patent application by end of August 2014 for our core technology. Our patent strategy is focused on 3 parallel paths, namely:

1. Skin surface sensing using advanced bio-conductive materials along with flexible electronics.

2. Telemetrics for harnessing connected health technologies and integration with electronic medical records.
3. Data analytics for providing thresholds for infection detection and monitoring its progression.

This application will be filed in conjunction with Arizona Board of Regents and agreed upon terms and condition for licensing this back into for commercialization. Typically, ABOR charges 3-5% licensing fee in the form of royalties from product sales.

Additionally, we are investigating a potential licensing agreement with MC10 Inc., Boston to use their patented tissue health monitoring technology for developing i-WARM. We believe significant synergies between wearable technologies and specialized electrical sensors manufactured by MC10, Inc. that can potentially shorten our sales cycle.

Sales and Marketing

Sales

will contract sales to a national distributor that specializes in direct sales with hospitals and clinics. Distributor networks that sell smaller-priced medical devices include Cardinal Health. This is the most immediate path to national revenue and permits to focus on its core competency of research and design. anticipates that through a distributor network, it will achieve 16% of the Total Available Market by year 5. Market reimbursement terms for device distributors are roughly 30% of top-line sales.

Marketing

will pursue numerous marketing tactics for lead and demand generation. These include:

- **Peer Reviewed Journals:** The most important marketing literature for includes the result of clinical research conducted by its team and its clinical research partners. Randomized controlled in conjunction with prospective intervention studies with conclusive favorable results will maximize likelihood of securing a network distributor with favorable terms and also assists in utilizing a “pull” strategy to educate the market to request the devices. intends to publish in top ranking peer-reviewed journals with high impact factors including Diabetes Care, Diabetic Medicine, Journal of Diabetes Science & Technology and Diabetic Research & Clinical Practice. These journals are circulated either monthly and quarterly internationally. Dr. is on the Editorial Board for Journal of Diabetes Science & Technology and has published over 30 research papers with 300 citations.
- **Informational website:** An informational website that describes products, and offers a page that permits for hospitals and clinics to order devices. The company website will also host instructional videos and literature to help nurses and doctors read the wound tracker data as well as configure the tracker and device to correctly measure wound temperature. Manuals and white paper downloadable PDF documents will also

be available on the company website. For content marketing, this website will also host educational articles regarding diabetic foot treatment best practices.

- **Search Engine Optimization:** In the US, there are approximately 375,000 yearly searches on Google for terms related to diabetic foot wounds. It would take an estimated 2-3 years to get website listed as a result on the first page of Google's search engine results page.
- **Trade shows:** The team will also attend tradeshows related to diabetes and wound care to increase exposure among potential customers and acquirers. Applicable trade shows in the US include, but not limited to:

S No	Trade Show/Event	Location	Costs of Exhibiting
1	DF-Con	LA, California (Annual)	$2000+
2	SAWC	Dallas, Texas (Annual)	$2000+
3	American Diabetes Association (ADA)	Various, USA (Annual)	$3000+
4	American Podiatric Medical Association (APMA)	Various, USA (Annual)	$3000+

Table 6: List of potential trade shows and wound care meetings.

- **Press:** will approach news outlets such as NPR, BBC, Fast Company, and Venture Beat with suggested content for them to publish. This will not only increase our website's reach to readers of these publications, but will also enhance our website's Google page rank by establishing an index of valuable backlinks.
- **White Papers and Sell Sheets:** Once integrated with a distributor network, it will still be the responsibility of to provide the chosen distributor with informational documents to facilitate the sale of the devices on location.

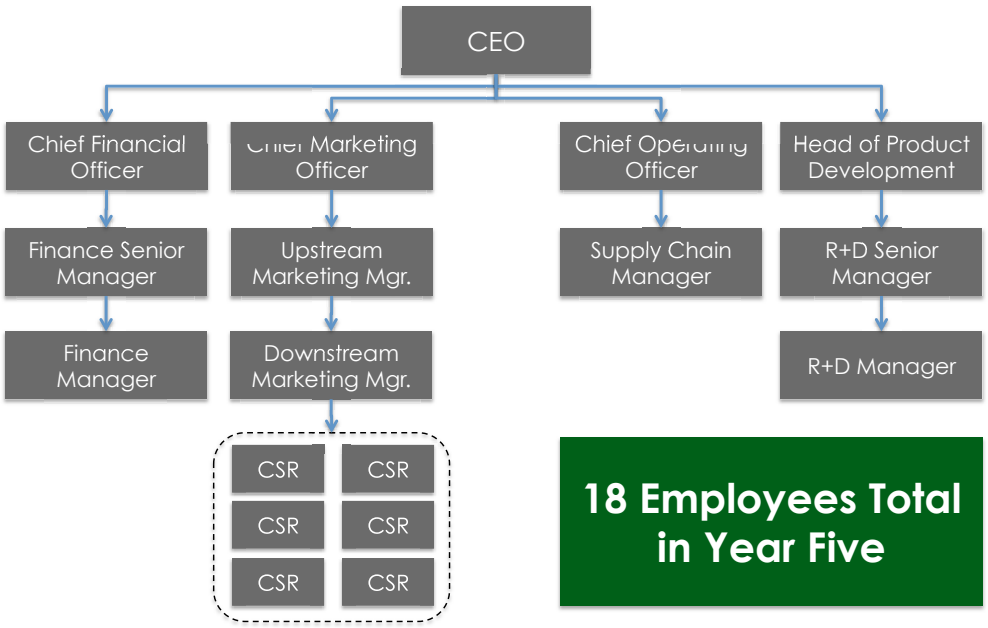
Operations

The operations of can be viewed as both external and internal. Externally, the operations of will be significantly streamlined after both the manufacturing and the distribution of the medical device portfolio has been outsourced. This outsourcing is necessary to the success of the venture, as the capital investment required to create a facility capable of producing the devices would make the venture insolvent. Additionally, a direct sales force is expensive to maintain, and takes significant time to scale. By utilizing a third party distributor, will be able to draw upon an already existing and entrenched network after device and economic effectiveness has been proved. This outsourcing is possible due to the high gross profit margins of 88% when the product is priced at its clinical value. The first manufacturer found to be acceptable is an organization based in Tucson, AZ, named Mastek-InnerStep. The proximity of this organization to and their willingness to work with startups in terms of prototyping devices, were the factors that contributed directly to their selection.

However, because does not own the facility, inventory management will be a critical success factor. As such, orders will be completed on a rolling 30-day forecast to ensure devices are available for shipment while stockpile is reduced. This ability to build and ship in a "just in time" method is made possible by utilizing the distribution company for the delivery of the devices, which will reduce the organizations need to deal directly with CMS reimbursement, and instead take payment from the distributor. This will reduce the receivables timeline from 90 days to closer to 60 days and free a significant amount of cash for investment in other business priorities. In addition, because the distribution company will be responsible for the customer facing supply chain, bulk orders can be shipped to satellite locations, reducing the need for expensive localized shipments from the manufacturer. As scales during each of the first three years of sales (years 3-5) it will become necessary to find additional manufacturing capacity to ensure inventories are covered.

It is important to note, the team is targeting a small number of direct sales at the end of year two to the five wound care clinics that will take part in the clinical trials. This brief period of sales will be based on the efficacy of the product through the trials, and no additional marketing will be necessary. It is currently projected that device approval will have been granted at the time of these sales. These five clinics, which will each serve greater than 250 annual patients, represent the beachhead for product. Sales into these customers will facilitate the creation of a relationship with a nationwide distribution service.

Internally, will be managed by the five founders and will scale to add 13 additional employees upon full entry of the market with a contracted distributor network in year three. The majority of the executive positions will have two direct reports, a senior manager and a manager, with the exception of the Chief Marketing Officer, who in addition to an upstream and downstream manager, will also have six customer service representatives who will manage the daily interactions with the distributor network. An organizational chart for year three and beyond is below.



Research and Development

intends to prioritize prototype development, patent application submission and regulatory submissions. However, we will simultaneously be conducting proof of concept studies at Southern Arizona Limb Salvage Alliance (SALSA), University of Arizona. Additionally, we are engaged with collaborators overseas to conduct an outcomes study to demonstrate the efficacy of wound health measurement. We are in negotiations to agree on a timeline and funding requirements. These studies overseas are for the purposes of satisfying potential investors regarding product efficacy but do not meet FDA requirements for US clinical sites

One of the major pivotal steps in strategy to provide product efficacy data through the means of a randomized clinical trial comparing our product with the current gold standard. Of the total of 154,978 clinical trials listed on clinicaltrials.gov (the federal studies repository), there are a total of 115 open studies for “Diabetic Foot Ulcers.” There are 20 studies (~17%) specifically studying clinical applications and efficacy for wound dressings. This provides evidence for the competitive landscape in this sector and accesses the potential clinical partners who would translate into potential customers subsequently ($122 million Total Available Market growing at 5% annually).

Per the counsel from our reimbursement specialist, we have formalized a team of key opinion leaders in wound care and diabetic foot care to enable us in developing an effective protocol for an economic study aimed at CMS’s healthcare savings. This group includes David G Armstrong (University of Arizona, Tucson), Lawrence A Lavery (UT Southwestern Medical Center, Dallas), Jane Mohler (University of Arizona, Tucson) and Wendel (University of Arizona, Tucson).

Business Funding

is focused on capitalizing on the government funded Small Business Innovation Research grant process to complete the research necessary during year one and begin distribution of product at the end of year two of operations. Two members of the team have significant experience with these proposals, being awarded greater than $5 million throughout their careers. The funding will be allocated as listed below:

Source of Funds	Specific activity	Funds required	Deliverable	Delivery by
Founders' Fund / SBIR Phase I	Continue prototype development, patent filing, FDA 510(k) filing, expert counsel for reimbursement and trials planning	$150,000	Product prototypes tested in laboratory and clinic. Identify expert counsel for CMS interactions and clinical trials planning.	September, 2015
Sub-Total Initial Funding Required		**$150,000**		
SBIR Phase II	Clinical Trials	$500,000	FDA clearance, randomized clinical trial proving technology effectiveness	2015-2018 (Ongoing)
	Product manufacturing & clinical sites liaison		Provide finished product for clinical study and initial sales	2015-2018 (Ongoing)
Working Capital	Series A Funding to facilitate rapid growth phase and CMS liaison	$250,000	Implement distributor network and support company operations.	2016-2018 (Ongoing)
Total Capital Required		**$900,000**		

Table 7: Use of funds description.

The founder's fund will cover employee needs in the first months of operations as the SBIR Phase I Grant application is completed. The targeted date for submission of the Phase I Grant is the August 5th deadline, after which the team expects to hear positively and receive funding by the end of December 2014.

These funds will cover much of the initial clinical research needed to identify the appropriate thresholds. The Phase II Grant will be submitted in April of 2015. Finally, to scale to full production once FDA approval is granted and contracts have been signed with a medical device distributor, it will be necessary to take on a small amount of investment to ensure available cash for initial inventory purchases.

Risk Analysis

Technology Risk

The most pressing risk for at the outset is the completion of the research that will indicate the thresholds of infection onset regarding temperature and moisture in the wound. This research is time sensitive and must be published in a peer-reviewed journal to be accepted by the medical community and the FDA. It is possible this research will have a longer timeline than originally expected, due to unforeseen complications with patient or system characteristics. The mitigating factors for this risk is the combined 17+ years of clinical research experience as well as access to patients at the world renowned Southern Arizona Limb Salvage Alliance.

Financing Risk

Another risk would be the failure to secure financing to run clinical trials to demonstrate efficacy. The team is targeting all non-dilutive funding from the Small Business Innovation Research Grant funds, which are not guaranteed. Once the Phase I Grant has been approved, the acceptance of the Phase II Grant is roughly 50%. If either of these grant rounds are not approved, it will be necessary for to seek either angel or venture capital investment, which will dilute the founder's shares in the organization.

Regulatory and Reimbursement Risk

Finally, the changes outlined in Patient Protection and Affordable Care Act also pose a significant risk if their implementation is delayed. The team intends to engage with CMS and private payers with the goal of minimizing effects of any such changes and learn about any new relevant legislature that affects clinical reimbursement. If the care of diabetic foot patients is not bundled, as it has stated to be, a full economic trial will be necessary to gain reimbursement coding under the auspices of CMS. To mitigate this risk the team is concurrently funding the randomized control trial to understand economic efficiency in the market to justify pricing to CMS.

Financial Projections

The financial projections are based off a device total treatment price of $340 per patient. Per CDC data, we have additionally assumed a 5% growth rate in Diabetes, which increases our total available market from 360,000 patients in year 1 to 437,582 patients in Year 5.

Our initial target market from months 20-24 includes the clinical centers that are a part of our research trials in the states of Arizona and California, and we would be selling approximately 1250 devices. Following this, we would be using a national distributor to facilitate a nationwide distribution of our product. We estimate that we would be able to have a market penetration of approximately 4%, 8% and 16% in years three, four and five respectively in our niche market.

Table below summarizes five-year income statement summary.

Year->	**1**	**2**	**3**	**4**	**5**
Gross Sales	-	425,000	5,916,000	11,832,000	23,664,000
Returns	-	(4,250)	(59,160)	(118,320)	(236,640)
Net Sales	-	420,750	5,856,840	11,713,680	23,427,360
COGS	-	50,313	700,350	1,400,700	2,801,400
Gross Margin	-	370,438	5,156,490	10,312,980	20,625,960
Op. Expenses					
Compensation & Payroll taxes	68,711	68,711	1,044,980	1,097,229	1,152,091
Depreciation	-	-	9,048	9,870	9,870
Distributor fee	-	127,500	1,774,800	3,549,600	7,099,200
Licensing fee	-	12,750	177,480	354,960	709,920
R & D	49,992	339,996	1,468,800	2,937,600	4,406,400
Lawyer fee	-	40,000	-	-	-
Website	-	5,400	1,200	1,200	1,200
Utilities	-	-	6,000	6,000	6,000
Supplies	2,400	3,000	10,200	10,200	10,200
T&E	6,000	12,000	12,000	12,000	12,000
Shipping	2,400	2,400	6,000	12,000	24,000
Consulting	2,000	2,000	2,000	2,000	2,000
Software	-	-	18,000	-	-
Accounting	-	2,400	4,800	14,400	28,800
Telephone	1,920	1,920	17,280	17,280	17,280
Rent	-	-	54,000	54,000	54,000
Employee Ins.	4,800	4,800	43,200	43,200	43,200
Gen. Liability	-	24,996	24,996	24,996	24,996
E & O	-	9,996	9,996	9,996	9,996
Employee Theft Ins.	-	2,496	2,496	2,496	2,496
Total Op. Ex.	138,223	660,365	4,687,276	8,159,027	13,613,649
EBIT	(138,223)	(289,928)	469,214	2,153,953	7,012,311
Taxes	-	-	(16,237)	(851,673)	(2,772,668)
Net Income	**(138,223)**	**(289,928)**	**452,978**	**1,302,280**	**4,239,643**

Table 8: Summary of 5-year financial projections.

Net income in years 1 and 2 above are negative. Table 7 provides a breakdown for compensation and payroll tax expenses over 5 years.

Compensation & payroll taxes	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Salaries & Wages	$57,600	$57,600	$876,000	$919,800	$965,790
Pay roll taxes	$4,406	$4,406	$67,014	$70,365	$73,883
Employee benefits	$6,705	$6,705	$101,966	$107,065	$112,418
Total	$68,711	$68,711	$1,044,980	$1,097,229	$1,152,091

Table 9: Breakdown of operating expenses.

Table below provides financial summary as a function of served available market.

	Year 1	**Year 2**	**Year 3**	**Year 4**	**Year 5**
Served market description	Iterative Design	Clinical Trials in AZ & CA	Nationwide Distributor		
Served market size	$0	$425,000	$122,400,000	$122,400,000	$122,400,000
Share of served market	0	100% (of clinical research sites in our study in AZ & CA)	4%	8%	16%
Revenues	**$0**	**$420,750**	**$5,856,840**	**$11,713,680**	**$23,427,360**
Expenditures	**$138,223**	**$660,365**	**$4,687,276**	**$8,159,027**	**$13,613,649**
Net Income (After Taxes)	**($138,223)**	**($289,928)**	**$452,978**	**$1,302,280**	**$4,239,643**

Table 10: Financial summary as a function of served available market.

Exit strategy

harvesting strategy is to sell the company in an outright sale to an outside buyer for a valuation price.

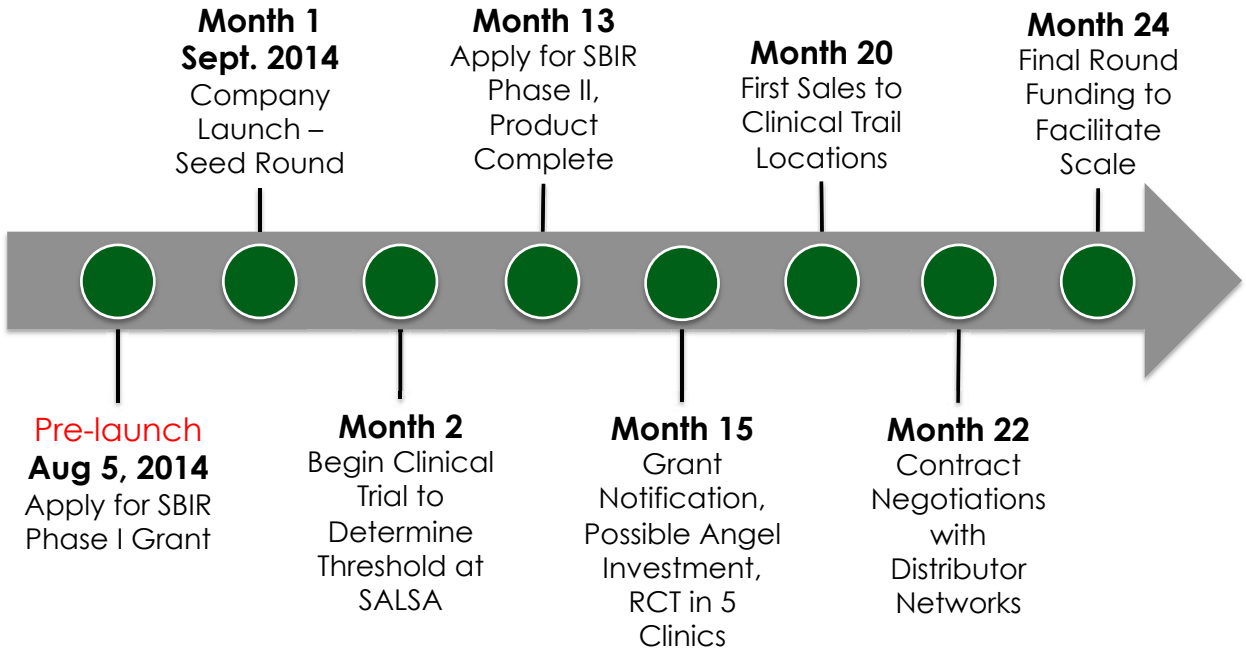
Any of the current market leaders are likely candidates, however, KCI which is a $3.4 billion wound care industry dominating the advanced wound therapies sector is the most likely buyer, as they could significantly benefit from a closed loop approach, as offered by the i-WARM technology, that could seamlessly integrate with their current portfolio.

In July 2013, KCI acquired UK based Systagenix, an advanced wound care products company for $485 million. Systagenix, formerly part of Johnson & Johnson, has 800 employees and supplies 20 million wound dressings in 100 countries. This recent acquisition bodes well for KCI's $1.7 billion acquisition of New Jersey based regenerative medicine outfit Lifecell in 2008. KCI intends to merge these two acquisitions and redefine itself as a wound care, biologics and regenerative medicine company. Consequently, KCI also recently sold its therapeutic business for $275 million, in cash, which is not aligned with KCI new strategy to focus on its flagship negative pressure wound therapy (NPWT) and complimentary wound diagnostics that enhance the value for NPWT.

According to our sensitivity analysis, we require a 9% market penetration at Year 5 to be a viable company. With a 9% market penetration, our Year 5 net income is $1.4 million, providing an exit value of $14 million, assuming a 10X multiple typical for medical device start ups. However, the financial projections are illustrated for Year 5 market penetration at 16%, given the anticipated demand for our product, owing to its clinical and economic benefits. With 16% market penetration at Year 5, has a net income of $4.2 million providing an exit value of $42 million, assuming a 10X multiple.

Timeline

The basic timeline for the organization over the next two years is detailed below. If grant funding is not allocated the team will turn directly to angel investors to bring the business forward.



Appendices

Balance sheet

Year	1	2	3	4	5
Ending	Aug-15	Aug-16	Aug-17	Aug-18	Aug-19
Projected Balance Sheets ($s)					
ASSETS					
Current Assets					
Cash	25,842	195,204	533,747	1,456,984	4,675,673
Accounts Receivable	-	191,250	1,109,250	2,218,500	4,437,000
Inventory	-	87,544	175,088	350,175	-
Other	-	-	54,000	108,000	162,000
Total Current Assets	25,842	473,998	1,872,085	4,133,659	9,274,673
Property and Equipment	-	-	48,000	48,000	48,000
(less accumulated depreciation)	-	-	(9,048)	(18,918)	(28,788)
Net Property and Equipment	-	-	38,953	29,083	19,213
Other Assets	-	-	-	-	-
TOTAL ASSETS	25,842	473,998	1,911,037	4,162,742	9,293,885
LIABILITIES AND					
MEMBERS' CAPITAL					
Liabilities					
Current Liabilities					
Accounts Payable	14,065	252,149	986,210	1,935,635	2,827,135
Other Current Payables	-	-	-	-	-
Pre-Existing Debt	-	-	-	-	-
Current Portion of L-T Debt	-	-	-	-	-
Total Current Liabilities	14,065	252,149	986,210	1,935,635	2,827,135
Long-Term Debt	-	-	-	-	-
Total Liabilities	14,065	252,149	986,210	1,935,635	2,827,135
Members' Capital					
Members' Paid-In Capital	150,000	650,000	900,000	900,000	900,000
Undistributed Members' Earnings	(138,223)	(428,151)	24,827	1,327,107	5,566,750
Less: Members' Interest Repurchased	-	-	-	-	-
Total Members' Capital	11,777	221,849	924,827	2,227,107	6,466,750
TOTAL LIABILITIES AND					
MEMBERS' CAPITAL	25,842	473,998	1,911,037	4,162,742	9,293,885

Statement of Cash Flows

CASH FLOWS FROM OPERATIONS					
Net income	(138,223)	(289,928)	452,978	1,302,280	4,239,643
Adjustments to reconcile net income					
to cash flows from operations					
Depreciation	-	-	9,048	9,870	9,870
Accounts receivable	-	(191,250)	(918,000)	(1,109,250)	(2,218,500)
Inventory	-	(87,544)	(87,544)	(175,088)	350,175
Other current assets	-	-	(54,000)	(54,000)	(54,000)
Accounts payable	14,065	238,084	734,061	949,425	891,500
Other current payables	-	-	-	-	-
Pre-existing debt	-	-	-	-	-
TOTAL CASH FLOWS FROM					
OPERATIONS	(124,158)	(330,638)	136,543	923,237	3,218,688
CASH FLOWS FROM INVESTING					
ACTIVITIES					
Purchase of equipment	-	-	(48,000)	-	-
Other Assets	-	-	-	-	-
TOTAL CASH FLOWS FROM					
INVESTING ACTIVITIES	-	-	(48,000)	-	-
CASH FLOW BEFORE					
FINANCING	(124,158)	(330,638)	88,543	923,237	3,218,688
CASH FLOWS FROM FINANCING					
ACTIVITIES					
Borrowing of long-term debt	-	-	-	-	-
Repayment of long-term debt	-	-	-	-	-
CASH FLOW BEFORE					
MEMBERS' CONTRIBUTIONS	(124,158)	(330,638)	88,543	923,237	3,218,688
Members' Capital Contributions	150,000	500,000	250,000	-	-
Members' Interest Repurchased	-	-	-	-	-
TOTAL CASH FLOWS FROM FINANCING ACTIVITIES	150,000	500,000	250,000	-	-
NET CASH FLOWS	25,842	169,362	338,543	923,237	3,218,688
CASH, BEGINNING OF PERIOD	-	25,842	195,204	533,747	1,456,984
CASH, END OF PERIOD	25,842	195,204	533,747	1,456,984	4,675,673

Bibliography

1. Rice, J.B., et al., *Burden of diabetic foot ulcers for medicare and private insurers.* Diabetes Care, 2014. **37**(3): p. 651-8.
2. Boulton, A.J., et al., *The global burden of diabetic foot disease.* Lancet, 2005. **366**(9498): p. 1719-1724.
3. Moulik, P.K., R. Mtonga, and G.V. Gill, *Amputation and mortality in new-onset diabetic foot ulcers stratified by etiology.* Diabetes Care, 2003. **26**(2): p. 491-4.
4. Armstrong, D.G., J. Wrobel, and J.M. Robbins, *Guest Editorial: are diabetes-related wounds and amputations worse than cancer?* Int Wound J, 2007. **4**(4): p. 286-7.
5. Barshes, N.R., et al., *The system of care for the diabetic foot: objectives, outcomes, and opportunities.* Diabet Foot Ankle, 2013. **4**.
6. Wukich, D.K., et al., *Inpatient management of diabetic foot disorders: a clinical guide.* Diabetes Care, 2013. **36**(9): p. 2862-71.
7. Singh, N., D.G. Armstrong, and B.A. Lipsky, *Preventing foot ulcers in patients with diabetes.* Jama, 2005. **293**(2): p. 217-28.
8. Wu, S.C., W. Marston, and D.G. Armstrong, *Wound care: the role of advanced wound-healing technologies.* Journal of the American Podiatric Medical Association, 2010. **100**(5): p. 385-94.
9. Lipsky, B.A., et al., *2012 infectious diseases society of america clinical practice guideline for the diagnosis and treatment of diabetic foot infections.* J Am Podiatr Med Assoc, 2013. **103**(1): p. 2-7.
10. Bharara, M., J. Schoess, and D.G. Armstrong, *Coming events cast their shadows before: detecting inflammation in the acute diabetic foot and the foot in remission.* Diabetes/metabolism research and reviews, 2012. **28 Suppl 1**: p. 15-20.
11. Armstrong, D.G., et al., *Does dermal thermometry predict clinical outcome in diabetic foot infection? Analysis of data from the SIDESTEP* trial.* Int Wound J, 2006. **3**(4): p. 302-7.
12. Armstrong, D.G. and B.A. Lipsky, *Diabetic foot infections: stepwise medical and surgical management.* Int Wound Journal, 2004. **1**(2): p. 123-132.
13. Murff, R.T., et al., *How effective is manual palpation in detecting subtle temperature differences?* Clin Podiatr Med Surg, 1998. **15**(1): p. 151-4.
14. Hazenberg, C.E., et al., *Assessment of Signs of Foot Infection in Diabetes Patients Using Photographic Foot Imaging and Infrared Thermography.* Diabetes Technol Ther, 2014.
15. Lipsky, B.A., et al., *Clinical predictors of treatment failure for diabetic foot infections: data from a prospective trial.* Int Wound J, 2007. **4**(1): p. 30-8.
16. International working group on the diabetic foot, *International Consensus on the Diabetic Foot*, J. Apelqvist, et al., Editors. 1999, International Working Group on the Diabetic Foot: Maastricht.