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# DSGM Systems

*Making Life Easier for Diabetics™*

## Founding Management Team

### F. Russell Denton, PhD, JD, MBA, CEO

Scientist experienced in managing R&D and device development, patents, partnerships, and medical ventures

### Bill Cross, Founder & President

Serial entrepreneur & a 20 year sales veteran with expertise in financing

### Jen Renshaw, MBA, V.P. Marketing

20 years in education, health & human services and product launches. Advised 100's of start-ups for Columbia University's Entrepreneurship Center

### Chang Quo, PhD, Chief Technical Officer

Georgia Tech Ph.D. in bioengineering

### Conley Ingram, MBA, Head Client Relations

Over 20 years' experience implementing complex client relations services

## Key Advisors

Dr. Charles W. Hofer - Venture Strategy

Dawn Smiley, M.D. - Emory University Medical School, diabetes expert

Ron Arkin, Regulatory Affairs

Donald Prough, M.D. - Co-inventor & distinguished chair in medicine

Rinat Esenaliev, Ph.D. - Co-inventor & tissue metrics pioneer in bioengineering

## Industry

Diagnostic Medical Devices

## Number of Employees

4 FTE – None currently drawing salaries

## Bank

Family Savings FCU, Hiram, GA

## Law Firm

Dan Shmalo, JD, 360 Venture Law

## Amount of Financing Sought

**\$500 K** for design, reduction to laptop scale & data collection **\$5 M** for FDA application, production & distribution

## Current Investors

**Founder, Family & Friends - \$125,000 cash + \$250,000 sweat equity**

**Business Description:** DSGM Systems (hereafter DSGM) is a medical device company whose mission is to commercialize diagnostics that improve the health and lifestyle of diabetics. DSGM's vision is to provide diabetics with disruptive, paradigm shifting products, beginning with the first **highly accurate, non-invasive, needle-free products for the continuous measurement of their blood sugar levels.** DSGM's **Glusonic Alert™** will alert users to changes in their blood sugar levels while during their daily activities, such as shopping, sleeping, driving, etc., and will warn them if their levels are changing too rapidly or are falling too low (< 70 mg/dl) for safety. Longer-term, future DSGM products will offer diabetics a painless opportunity for improved overall blood sugar control through highly accurate, non-invasive, continuous blood sugar monitoring 24/7.

**Diabetes – A Healthcare Crisis:** Diabetes afflicts nearly 27 million Americans (≈10% of the U.S. population) and is especially prevalent among African Americans, Hispanics, obese individuals and the elderly. Another 79 million Americans are pre-diabetic. The growing incidence of obesity is accelerating the onset rate of diabetes in the U.S. and other developed countries. According to the American Diabetes Association, U.S. diabetes-related healthcare costs reached \$218 billion/ year. The market for just blood glucose monitoring supplies is projected to be \$3.7 billion by 2015.

**Hypoglycemia (Low Blood Sugar) - A Dangerous Problem:** Hypoglycemia is the condition that occurs when an individual's blood sugar levels drop below normal [≈ 80-120 mg/dl]. Blood sugar levels below 70 mg/dl are unsafe for all diabetics because at these levels, individuals begin to experience vision problems, disorientation, numbness, trembling, and other complications. Hypoglycemic episodes are especially dangerous while sleeping because unmonitored nighttime "lows" can result in seizures, comas and death, which are the biggest fear of parents & spouses of diabetics. They are also dangerous while driving because in 2007 they lead to accidents that cost \$126 million in property losses, \$148 million in emergency room visits, \$43 million in insurance deductibles, and resulted in **over 1400 deaths.**

**Products:** The **Glusonic Alert™** accurately (≈94% accuracy overall & ≈100% on lows), continuously, and painlessly determines its user's blood sugar concentrations 24/7. It is worn like and looks like a wristwatch and also tells time. It uses a non-invasive Ultrasound technology that measures the changes in its user's skin thickness that are produced almost instantly by changes in the user's blood sugar concentrations. The **Glusonic Alert™** has four components (1) a pair of sensors to capture the ultrasound signals, (2) disposable gel pads that "connect" the ultrasound sensors to the user's skin, (3) a processor that converts the sensor signals into blood sugar level readings, and (4) audible and visual alarms that warn users if their blood sugar levels are trending too low (or high) or changing too rapidly. The **Glusonic Alert's™** initial design is shown below. Users will need to calibrate the first generation **Glusonic Alert™** using a traditional finger stick meter when they first put it on since its Ultrasound sensing requires calibration by a second method. However, use of the **Glusonic Alert™** will eliminate most of the "finger sticks" they would normally do for the rest of the day. Future versions of the **Glusonic Alert™** will use both Ultrasound and Optical Coherence Tomography (OCT) to measure their user's blood sugar concentrations, which will eliminate the need to draw blood to calibrate future **Glusonic Alert's™**. [OCT uses reflected light to measure changes in thickness in superficial skin layers and high-resolution light to measure changes in deeper layers of the skin] Finally, 3rd-generation **Glusonic Alert's™** will synchronize with third party miniature insulin pumps for 24/7 use.

**Figure 1 – The Glusonic Alert™ Watch Model**

Non-invasive,  
Real-time, Glucose  
Trend Information

Alarm Warning of  
Glucose Lows  
& Highs

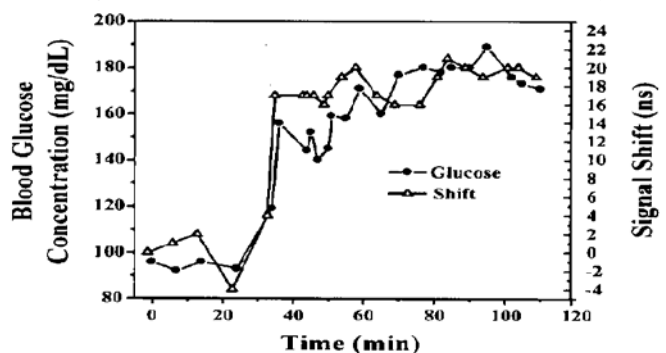
Record pf  
Glucose Data

Test Strip Reader



3-Axis Accelerometer  
Altitude Sensor  
Temperature Sensor  
Battery Sensor  
Time / Stop watch  
USB Port  
1GHz RF / Bluetooth  
Heart Rate

**Figure 2 - The Glusonic Alert's™ Accuracy**



**Current Competition:** The traditional finger stick (invasive) meters of the dominant players (Roche, Abbott, Bayer, J&J) are quite PAINFUL, which is why most diabetics do not use them as frequently as they should. In general, these products are loss leaders, i.e. their owners earn the majority of their profits from the sale of “test” strips. The dominant players’ continuous glucose monitors (CGMs) are expensive (≥\$1,000 retail), invasive, uncomfortable (they require the user to insert a sub-dermal wire to obtain fluid for a glucose reading), have 20 minute data lags and complex protocols (>100 page user-manuals), and their disposables cost ≥\$3,000 annually. Because of these limitations, fewer than 3% of all diabetics use CGMs. Nonetheless, Medtronic, an insulin pump maker, is expanding into the CGM market with its Guardian line. Echo Therapeutics’ Symphony™ CGM wristwatch is in clinical trials. It requires users to shave off their top skin cells to reach live skin where an enzymatic sensor detects glucose from capillaries and wirelessly signals a handheld device. All these technologies “calculate” their user’s blood glucose by electrochemically testing their wet blood or by spectroscopically analyzing their blood to assess its glucose concentrations. Unfortunately, the molecular signature of glucose is so similar to that of water, heparin, and glycogen that all such assessments are highly inaccurate. The key characteristics of all of these meters is summarized below.

The Glusonic Alert™ vs. Other Blood & Interstitial Fluid Glucose Monitors						
Devices	Features	Price	Yearly Cost of Disposables	Ease of Use	Response Lag Time	Non-invasive
Traditional Finger Stick Meters		≈ \$75*	\$120 to patient & \$600 insurance	YES	≤ 10 Seconds	NO
The Glusonic Alert™		≈ \$650	≈ \$750	YES	≤ 5 Seconds <sup>+</sup>	YES
Dexcom Seven		\$1,200	\$3,120	NO	≥ 20 Min	NO
Guardian (Medtronic)		\$1,000	\$4,258	NO	≥ 20 Min	NO

\* Average List Price. Most diabetics wait for the semi-annual “giveaways” to get new meters.

<sup>+</sup> After initial calibration

The development of a continuous, highly accurate, relatively painless glucose monitor has been the “holy grail” of the diabetic testing industry for decades. All prior attempts to develop such a meter have failed for one or more of the following five problems.

User Need	Why Competitive Continuous GMs Have Failed	How GluSonic Alert™ Gets it Right
Comfort	Highly invasive & quite PAINFUL	Non invasive & PAINLESS
Reliability	LOW. All current CGMs have difficulty discriminating between glucose & spectroscopically similar bio-molecules such as water, heparin, glycoproteins & muscle starch	VERY HIGH. Based on tissue thickness that is easily measured with Ultrasound providing ≈ 94% accuracy Overall & ≈100% on Lows
Simplicity	Most are very complex with user manuals over 100 pages long	It WARNS you of dangerous Highs & Lows & gives you an accurate reading at the push of a button
Value	Low. Units cost \$800 to \$1,300 each Annual disposables costs are >\$3,000.	HIGH. It’s retail price will be ≈ \$650 Annual for disposables costs will be ≈ \$750
Speed	VERY SLOW. All readings are ≈ 20 minutes late	VERY FAST. Most readings take ≈ 5 seconds or less

**U.S. Diabetic Markets:** Over 27 million Americans 20 years or older have diabetes and 1.6 million people are newly diagnosed each year according to CDC estimates. Also, over 50 million more are “pre-diabetic,” and all these numbers are rising due to obesity, an aging population, and the high prevalence of diabetes among Hispanics and African Americans. Thus, the total potential U.S. market for the **Glusonic Alert™** exceeds \$9.3 Billion and the total market for sales of **Glusonic Alert™** connective pads exceeds \$11.4 Billion annually. Moreover, the international markets for the **Glusonic Alert™** and its connective pads are more than three times larger than these U.S. totals.

**DSGM’s Target Customers:** America’s 27 million diabetics can be classified into several major market segments, including the following five: (1) Insulin Dependent Diabetics at risk of “Dead in Bed” Syndrome (9.2 M) who have a 10 times greater risk of dying than other diabetics; (2) Diabetic Drivers (16.0 M) who are at risk because of hypoglycemic events while driving, especially the 3.2 M in CA and TX; (3) Frequent Testers (5.0 M) who test their blood 8-10 times or more per day to prevent the complications of diabetes such as heart attack, stroke, kidney failure, retinopathy, and limb amputation; (4) Hypo-Unaware Diabetics (5.2 M) for whom the **Glusonic Alert™** will lower the risks of accidents and injuries, and (5) Diabetic Teens (1.2 M) who have the most vehicle accidents and whose hormonal changes make keeping glucose in a healthy range a major challenge because they are still learning the lifestyle changes needed to manage their diabetes. Initially, DSGM will sell the **Glusonic Alert™** to the insulin dependent, sleep safety market segment. Later, DSGM will partner with physicians, particularly endocrinologists, to address other key market segments such as diabetic drivers and frequent testers. DSGM will work with insurers so that future generations of the **Glusonic Alert™** can be covered by insurance. This will take time, but it’s expected that ≈70% of patients will eventually be covered by insurance.

**Business Model & Distribution:** DSGM will market and sell the **GluSonic Alert™** and the disposables associated with its use. DSGM will contract out the electronic design, size reduction, studies for regulatory clearance, and device production. DSGM already has relationships with its preferred design engineers and a leading manufacturer of electronic medical devices. Initial sales will be made directly to consumers over the web and by drop shipping orders to medical distributors, who will in turn ship directly to retailers such as medical equipment and hospital suppliers. DSGM sell its products internationally through a distribution partner.

**Intellectual Property:** Bill Cross, the inventor of the **Glusonic Alert™**, has filed a utility patent application on the **Glusonic Alert™**. Bill owns 100% of the rights to this pending patent. Dr. Rinat Esenaliev, Ph.D., Department of Anesthesiology at the University of Texas Medical Branch (UTMB) and Donald S. Prough, MD, Professor and UTMB Department Chair, are leading researchers in non-invasive glucose monitoring and have a patent application on the underlying technologies used by the **Glusonic Alert™**. Drs. Esenaliev and Prough own 100% of the rights to their pending patent. **DSGM** is finalizing an exclusive licensing agreement with Drs. Esenaliev and Prough for the use of their pending patent

**Funding Needs & Financial Projections:**

DSGM is seeking \$500,000 to complete miniaturization and further testing of the **Glusonic Alert™**. An additional \$5MM will be needed to launch the **Glusonic Alert™** in late 2013. DSGM projects U.S. sales in excess of \$700 MM by 2016, including recurring revenues from the sale of disposable gel pads & test strips. DSGM’s cumulative unit sales through 2016 is 650,000 units, just 2.7% of the U.S. diabetic market.

	2011	2012	2013	2014	2015	2016
Unit Sales	0	0	10	60	180	400
Sales Revenues	0	0	9,950	81,930	303,354	710,465
Gross Margins	0	0	5,907	46,670	178,000	411,519
Fixed Costs	125	2,135	4,751	23,231	68,030	127,962
Net Income before Taxes	(125)	(2,135)	1,155	15,622	71,480	184,312