CEO CFO

GROVE INSTRUMENTS

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With Diabetes reaching Epidemic Proportions, Grove Instruments Inc. in the Right Market at the Right Time Developing the First FDA Approved, Noninvasive, Painless, Bloodless Portable Glucose Meter that has Achieved ISO 15197 – the International Standard for Glucose Meter Accuracy

Healthcare
Medical Devices

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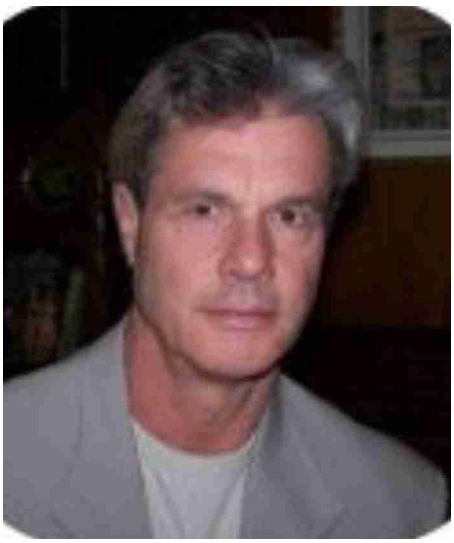

Arthur Combs
CEO

BIO:
Arthur Combs is a physician executive with a lifelong experience in the medical products industry. First, as a customer and expert end-user during more than 20 years in academic medicine in the device and technology-intensive specialty of Critical Care Medicine, and second, as an executive, corporate officer and consultant across the medical products industry.

In 1997, Dr. Combs became the first Medical Director for Mallinckrodt Inc.'s respiratory care business that included Nellcor, Puritan-Bennett, Shiley and Mallinckrodt's own products. From that position he then became Executive VP, R&D. On his watch, Nellcor's 4th generation oximetry platform, the PMA fetal pulse oximeter, and the flagship PB 840 ventilator were cleared and launched. Mallinckrodt was purchased by Tyco International (now Covidien) in 2000.

Dr. Combs has been a retained consultant for HP Medical, Agilent Technologies, Philips Medical Systems, Edwards Life Sciences and many others. His projects have included automated ventilation management, continuous arterial blood gas monitoring, proteomics, molecular diagnostics, noninvasive cardiac output technologies, and tight glycemic control. He has also consulted for numerous Venture Capital firms with a life sciences focus.

As an entrepreneur, Dr. Combs has previously been an officer of 3 start-up medical device companies. Everest Biomedical Instruments, where he was VP, R&D and CMO, sold its first noninvasive product to Viasys Corporation, spun out its second device as BrainScope, Inc. and sold its third noninvasive product and the company to Stryker International in 2005. BMEYE BV of Amsterdam, Netherlands, maker of noninvasive continuous cardiac output technology, hired Dr. Combs as CMO and GM, North America. After BMEYE obtained both CE Mark and US FDA clearance for their Nexfin products, Dr. Combs left to become CEO of Grove Instruments. BMEYE was subsequently acquired by Edwards Life Sciences.

In addition to contributing to the technical and clinical development of more than half a dozen innovative noninvasive medical devices currently on the market, Combs has raised tens of millions of dollars in equity capital, grants, and awards. He is an alumnus of the University of Notre Dame, New York Medical College and Memorial Sloan Kettering Cancer Center. Dr. Combs is co-inventor on 2 issued US patents. He holds honorary fellowships in the American College of Chest Physicians and the American College of Critical Care Medicine.

About Grove Instruments Inc.:
Grove Instruments, Inc. is a medical device company developing the first FDA-approved noninvasive, painless and bloodless portable glucose meter. Grove has a pipeline of noninvasive products including the world's first personal noninvasive glucose meter for use in the lifelong care of the 25 million Americans with diabetes (more than 230 million worldwide). Our patented devices eliminate the pain, high cost, and inconvenience of current blood-based meters. Grove's revolutionary device promotes optimal glucose monitoring and diabetes management thus giving every person with diabetes the opportunity for the dramatic medical and economic benefits of good glycemic (diabetes) control.

Grove has developed a completely painless and noninvasive blood glucose meter that removes all of the barriers to optimal self monitoring of blood glucose. Grove's Glucometer is a truly transformative technology that provides people with diabetes the opportunity to achieve the kind of blood glucose monitoring proven essential to achievement of good outcomes in the life-long management of diabetes.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Combs, you have something that can really change people's lives. Would you tell us what you have developed?

Dr. Combs: I should tell you that this is not our idea; this is an idea that has been around for a long, long time. In fact, in certain circles, whether it is diabetes in general, or medical device, or even diagnostics in particular, noninvasive glucose has been considered the "holy grail" of medical diagnostics for a long time. There are lots of good reasons for that, but speaking from a business perspective, every good entre-preneurial story had somebody with a fire in their belly about it. One of our founders, a forty-year professor at WPI raised two children with type 1diabetes, and has made this his life's work-as one of the founder as the company, and one of the seminal inventors of our solution to the problem.

From the perspective of significance, there are probably two really important things to point out. The first one is that going all the way back to the early 1990's, the New England Journal published a study referred to as the DCCT Trial that showed that when patients measured their sugars, adjusted their medication, and kept their glucose in a good range, there was a genuine outcome improvement. A similar study was done on type 2 diabetics, and published in the Lancet, so we now know that people with diabetes genuinely benefit from optimal testing, optimal medication, optimal glucose control, lifestyle adjustment, and have better outcomes. What does better outcome mean? What it means is that the complications of diabetes can be either delayed, or in fact, avoided; and they are significant. Diabetes is the number one cause of blindness, the number one cause of kidney failure, number one cause of non-traumatic amputation, and contributes to the excess mortality of cardiovascular disease and cerebrovascular disease. It is a worthy goal to have a machine that patients will use and embrace, and have access as a result, to these better outcomes.

The second thing about the significance is the essentially epidemic proportions that diabetes has subsequently achieved. In the United States, the off-quoted statistic is that there are twenty-five million people with diabetes, and there are fifty-nine million with pre-diabetes, who will in fact become diabetic unless there is an intervention. Early in 2010, the World Health Organization estimated the worldwide population of diabetics at two hundred thirty million, and two months later, the New England Journal reported that there were one million in China alone. We also know there is more than that in India, and recently, we are learning that there could be more than that in Indonesia. This is an epidemic disease, and in fact, probably at the present time affects half a billion people.

"The reason we get attention is because we are succeeding where others have failed, and because we are doing new to world technology, meeting an unmet need and addressing a genuine public health problem." - Arthur Combs

CEOCFO: How does the device work? What are the basics?

Dr. Combs: The basics of the device are to detect glucose, which is a six carbon sugar, in the blood stream, in real-time, *in vivo*. That should probably give you an idea of what the technical challenge is. It is not a very large molecule. It is composed entirely of carbon, hydrogen and oxygen, which of course, all organic molecules and pretty much everything in the body is composed of, and it is all swimming in water. Typically, people sample blood to get blood sugar. Our idea is to test by detecting glucose by optical means. We use several diode lasers of very specific wavelengths that have three purposes: one is to track the bloodstream itself, the second is to negate the background, and the third is to specifically detect glucose. It is a light-based optical instrument, no needles, no blood, and no pain.

CEOCFO: What is the accuracy factor?

Dr. Combs: That is a good question. At the end of 2011, just about a year ago this time, we completed a study that showed that we are the fist noninvasive instrument to ever achieve the ISO 15197, international standard for glucose meter accuracy. This is quite a milestone, because heretofore, the only instruments that have ever met that standard have been invasive instruments.

CEOCFO: What is actually happening when you point the device at your body, or whatever you are doing?

Dr. Combs: The device that we qualified against the ISO standard measures blood sugar in the earlobe. The reason we use the earlobe is because the blood flow to the head is the most robust, and most conserved of any place on the body, so it is a good place to get a very good sample of blood. Secondly, the earlobe itself has no cartilage in it, so we have the opportunity to just have soft tissue between the emitter of the light and the detector of the light. The third thing is that most systems that have tried optical means have been frustrated by two problems. The first one is that light in the near infrared spectrum is absorbed heavily by water, and the body is 60% water. The second problem is it is a tiny little molecule, and it is not in very high concentration, so the so-called 'signal-to-noise' ratio is small. It is our patented technology that enables us to negate the background, including

water, and that by itself increases signal-to-noise ratio fifteen hundred fold. I can tell you that the technology has been called out as the technology leader by ten different funded SPIR grants, issued by the National Institutes of Health.

CEOCFO: The user would put the device to their ear, and a minute later—ten seconds later, there is going to be a reading?
Dr. Combs: Twenty seconds later, yes.

CEOCFO: Where are you in the process?
Dr. Combs: The process, of course, is a lengthy process, and it is important to understand that this is a startup company; this is an entrepreneurial endeavor, so we have to have all three masters to serve: technical, clinical and business objectives. From a technical point of view, you always have to prove the technology works. I know this from raising funds, going out and saying, "Well we have a technology…" and they say, "Yeah, yeah, yeah…but does it really work?" You have to show the technology really works. People do not want to hear that, "Well, you know, if you invest, you know, we think we can develop it to a point where it really works." Ours really works; that has been shown *in-vitro*, the accuracy of the device from 50-700 is essentially linear, so we know the device works. The second question is, "Does it work on people?" which is a whole different thing than working *in vitro*. Last year, as I said, we showed that on sixty-three diabetic subjects, for four thousand data pairs, we were able to achieve the required clinical accuracy. Then, the question is, "Yeah, okay fine, but is there a business there? Is there a product there?" We obviously think there is a business there, and a product there, but that is too simple an answer. You have to have something that patients will embrace, something that is practical to use, something that solves the problem, because, I indicated earlier, the key to good outcomes is frequent testing, and people <u>do not</u>. When you ask them why they do not, they tell you, "Because it is painful, it is messy, I do not like blood, it is inconvenient, it is embarrassing, and those strips can cost as much as a dollar a piece, so it is expensive." Our intention is to create a product that solves all of those problems, i.e. removes all of the barriers to optimal testing, and that is the stage we are at right now.

CEOCFO: The ease of use seems pretty obvious. How does the cost factor come into play?
Dr. Combs: There are two ways really to look at it. From a pure cost of care perspective, a typical diabetic spends five times the amount on their healthcare annually that an average citizen does. It costs between $1200-$5000 or more dollars per year for a diabetic to care for himself or herself, and that includes the cost of their testing supplies, medications, and in some cases, sophisticated things like CGM monitors or insulin pumps. We know it is an expensive endeavor, and we have shown that the patients who would test more than once per day there is cost savings to use our device at a reasonable retail price ; and if they test two, three, four, and more times a day, the savings are really quite dramatic, because there is no cost per use.

CEOCFO: Given the standard test, is cost really that big a factor? I think people would be willing to pay quite a lot over and above what they are paying, just not to eliminate blood tests.
Dr. Combs: Of course, there is a market segmentation. There are people of means, particularly who have a child with diabetes who would pay essentially anything to make their child's life easier, less painful, less intrusive, etc… Yes, there is an "early adopters" population of people who, in addition to being early adopters, cost is not really a deterrent. Then, there is a group of people that cost has to be considered, and then there is a group of people that if it is not covered by whatever basic insurance they have—they simply could not approach it. From a market penetration point of view, I think you are exactly right. There is a willing and ready population of early adopters, but the need is very great. There are probably only about a million and a half people with type 1 diabetes in the U.S., but there are five million people on insulin, and we see that as the initial target population. There is a very large waiting, probably ready market entry point, and that includes particularly early adopters.

CEOCFO: How do you work around the entrenched industry for blood tests?
Dr. Combs: That is an excellent question. There is a very famous book called "The Innovator's Dilemma" written by Clayton Christianson from the Harvard Business School, which talks about the management of what is called "disruptive technology", wherein something comes along that is faster, cheaper, better, often times under 'featured' that disrupts a mature and stabile market opportunity. The management of disruptive technology is different from the management of sustaining technology, or adding features.

From the perspective of the strips' market, the strips market is an ultra-mature market. At this present time, they cannot really make the meters smaller or cheaper, they cannot really make the strips faster, the sample of blood smaller, and they really are kind of out of new value propositions to the population. We believe that there is genuine market pull in that: the excitement would be around getting rid of the needles, the blood, the pain, the messiness, inconvenience, embarrassment, etc…, but that has to be managed.

Really, you have asked me a different question. People often times say, "Well, who are your competitors?" The strips business has shown that diabetes is large enough, that there is plenty of room for several large players. Diabetes is a market, and from our perspective, the competition of "could someone else have a noninvasive solution?" is not really where we see the competition. We see the entrenched incumbent that has a very large, high margin business, as being where the real

resistance lay. With all disruptive technologies, what usually ends up happening is that the more visionary incumbent is the one who wants to bring that technology to market. We imagine, and to some extent we believe that large visionary diabetes companies understand that this is an important innovation, and hopefully would want to partner with us to bring it to the population.

CEOCFO: What are the next steps for Grove?
Dr. Combs: The next step, as I indicated, you have to prove your technology works; you have to prove that it clinically works to published standards, and then you have to show that there is a business there. The current goals and the current studies that are ongoing speak directly to the calibration of the instrument in such a manner that we believe we could commercialize the device if we meet these current goals. I cannot go into the details because they are proprietary, but we think we are finally answering the third question, which is "Yeah, but how are you going to make money? Is there a product there?" and that is the immediate goal. We are right now, literally in the throes of that trial.

CEOCFO: You have several fundings; is it enough to keep going the way you need to?
Dr. Combs: It is a funny thing; the cliché is "everything costs twice as much, and takes twice as long as you think", and I think, quite honestly, that in general turns out to be true. Unfortunately, there are also wildcards, and running a privately funded company that is dependent on not only people's passions, but also their sense of wealth and security, and their liquidity made it profoundly difficult in the 2008-2010 timeframe. We were not as robustly funded through those years as we might like to have been, and as a result, these last two years have been really years of high productivity, but largely because we were not resource constrained. We have relied during the lean years on a strong shareholder base, and the fact that we have been frequently awarded and rewarded by public funding sources.

CEOCFO: You have a considerable history in the medical device and the entrepreneurial setting; how are you moving forward?
Dr. Combs: I am a physician by training. I spent twenty-three years in academic medicine. I was recruited to a fortune 500 company to be the first medical director of a more than one billion dollar respiratory care business, and spent three years with Mallinckrodt Inc. where I really became indoctrinated to the world of business, to the world of product development, and to a different set of metrics than I had been used to as a practicing physician. From there, I have now done three startup companies, one of which spun out a technology, so if you count that then it is four, and I have been an officer of three startup companies. By this time, I feel like I understand the blocking and tackling of life sciences-based entrepreneurial companies. I would not ever advertise myself as someone who could run a telecom business, or a financial services business, but life sciences is so particular with regard to the science, the clinical importance, the FDA and other regulatory requirements, the very nature of the go-to-market strategy, it is highly specific in the life sciences; and that is my personal niche.

CEOCFO: We speak with many medical device and drug companies. Why does Grove Instruments stand out for them as well as investors and people in the business community?
Dr. Combs: I will give you not a metaphor, but kind of a frame of reference: when President Obama came in, in his first term, there was huge turnover at the FDA, and there has been a real call for a revamping and modernizing of the FDA, and they have put out a series of criteria that they thought should be applied. They are basically: 1) new to world technology, 2) a genuine, unmet need, and 3) something that is really a public health issue. What we have here at Grove is new to world technology; we have an absolute unmet need, because for twenty years we have had strips and needles, and people simply do not use them, they simply do not. Twenty-one percent of people with type 1 diabetes on insulin never test, NEVER! It is amazing, but it is true. Forty percent of type 2's on insulin do not test. Fully seventy-nine percent of all type 2's, insulin or otherwise do not test, so there is an unmet need; there is no question, and in terms of public health, it does not get bigger than diabetes. Diabetes is twenty-five percent of the Medicare budget; fifteen percent of overall healthcare costs, annual costs, direct and indirect, exceeding two hundred billion dollars, that is just in the U.S. The reason we get attention is because we are succeeding where others have failed, and because we are doing new to world technology, meeting an unmet need and addressing a genuine public health problem.