Automated Scoring Software for Sleep Studies done at Home or in the Lab

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CEOCFO: *Mr. Fernandez, would you tell us about EnsoData?*
Mr. Fernandez: Our vision is to bring a massive efficiency time savings and cost savings to healthcare through the use of artificial intelligence technologies and big data. In today's healthcare realm, more and more data is being collected each day whether from diagnostic centers, increasingly connected therapeutic devices, real-time monitoring in the operating room and ICU, home health and wearable devices for chronic disease patients. Medical data generated in unprecedented volume, variety, velocity, and veracity is collected at the terabyte scale in sleep clinics and health systems more broadly every day. Our physicians and clinicians have a decreasingly effective ability to deal with it on a human scale. In our view it is going to be necessary to have artificial intelligence technologies that ingest these massive amounts of data to automatically analyze it, provide continuous automated expert monitoring, and distill down the most important aspects of it for clinicians to interpret and use to take action.

CEOCFO: *Many companies have gone beyond Big Data Analytics to just wanting to get reports. Do you find that healthcare is a bit late to understanding that would be a better approach?*
Mr. Fernandez: I think that based on the regulatory environment through the FDA and HIPAA and through the criticality of providing healthcare services and being responsible for peoples' lives, healthcare has always been one of the last industries to adopt some of the major technological advancement that we have seen over the last few decades. As many folks know, machine learning and artificial intelligence technologies would become absolutely ubiquitous in consumer computing technologies with things like SIRI and Alexa, Google Search and Google Maps, Facebook newsfeed and Tesla self-driving vehicles. We interact with these technologies every day and maybe every hour as regular consumers but as patients I think we rarely use these technologies or are impacted by them today because we are just starting to see the proliferation into healthcare.

CEOCFO: *What is Enso doing to help solve the gap?*
Mr. Fernandez: Enso Data is creating a big data in advance algorithm engine that ingests waveform sensor data and automates real-time monitoring, pattern recognitions and trend identification. Our first product applies that engine to the analysis of sleep data and in doing so, automates one of the most arduous and time-consuming data analysis tasks in all of healthcare that humans perform today and that is called sleep scoring.

CEOCFO: *Why did you start with sleep?*
Mr. Fernandez: We started with sleep because we saw the opportunity that was very broad and very immediate and we wanted to go after it. We know that in the US the Center for Disease Control and the American Institute of Medicine have estimated that fifty to seventy million Americans are affected by some kind of sleep or wakefulness disorder. Among

those, 29 million estimated with sleep apnea. Researchers go on to estimate that 80% to 90% of the folks with sleep apnea are undiagnosed, unaware and untreated. So this if left untreated leads to severe complications later in life such as high blood pressure, hypertension, depression, metabolic disorders, drowsy driving. It contributes to about $150 billion in avoidable costs a year in the US. Based on that, there is a large opportunity. There is a large undiagnosed population. When we understand that our current capacity for sleep testing, it seems like we will not be able to scale out healthcare to effectively diagnose and treat this whole population. We are trying to provide the tools that will allow our clinicians to increase their productive capabilities to be able to scale out medicines to effectively reach this huge population.

CEOCFO: *EnsoSleep recently received FDA clearance. Would you explain how it works and how it compares with other methods available today?*
Mr. Fernandez: EnsoSleep is a cloud based software program that automatically uploads and analyzes and download analysis and reports for sleep sessions. In comparison to other products out there, I think EnsoSleep needs to provide the fastest, most accurate, most reliable results delivering time-savings across two key dimensions; one delivering high-quality scoring results the first time that match the gold standard and match the American Academy of Sleep Medicine guidelines and recommendations. They are delivered through a fully automated process. There is a computerization of clinicians' workflows and burnout associated with and it is one of the biggest problems. Therefore, using this technology is a way that improves the workflow instead of adding additional steps and computerization to it.

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CEOCFO: *Would you explain the engagement with the physician and the patient and how information is measured?*
Mr. Fernandez: The way it works is for example with a 20-bed sleep lab, patients will come in overnight and they will have a number of different physiological vitals recorded through sensors and will measure six different brain waves and four different respiratory signals including airflow and respiratory effort, blood oxygen saturation and heart rate, movement from the legs from the chin and eyes and several other symptoms as well. We take that data in a patient that sleeps six to eight hours and at the beginning of the morning if everybody slept eight hours, we have 160 hours of potentially twenty different sensors. We will have to go look through all of that data, sample anywhere from 100 to 500 times per second and tag and mark each time a patient stops breathing, almost stops breathing, wakes up, has a blood oxygen desaturation change, neurological arousal, movement event, and a number of other key physiological events to identify. That process is called scoring, and with EnsoSleep, the scoring process is fully automated by our big data and advanced algorithm powered software.

CEOCFO: *What were the challenges in creating the technology to measure so many different items?*
Mr. Fernandez: One of the biggest challenges is in how big the data is. There are a lot of companies out there that are doing data. Each patient sleep study can be about a gigabyte of data. With every thousand patients, you have dozens terabyte. So far, our software has analyzed more than fifteen thousand patients. We would have more than a dozen terabytes of data and developing novel artificial intelligence algorithms and computational infrastructure that can support that, has been a tremendous engineering challenge but one that we really enjoy and have been successful at through drug development.

CEOCFO: *Now that you have FDA approval, what are the next steps?*
Mr. Fernandez: The primary focus is to get technology out there into as any clinicians hands as possible and to work closely with them to make sure that we are delivering the efficiencies that they are looking for, delivering on cost savings, putting money back in their pockets and going beyond being a software company by engaging with them to help them increase their productivity, improve their patient provider satisfaction and experience and utilize their time-savings to provide additional procedures that can generate revenue and increase patient access. This will help patients get the treatment to transform their lives.

CEOCFO: *Have the sleep doctors been looking for a better way?*
Mr. Fernandez: This is not a brand-new idea. Our market researchers have shown that out of the current US sleep centers, only estimated 86% of them are utilizing a fully manual scoring process meaning end-to-end human review with no automated components whatsoever. You think about the market, the big competitor is obviously the status quo. Other companies that have tried to do this, in our view have not been able to crack the nut and on kind of a basic level customers are looking for more efficiency, speed and accuracy out of the product. We are hoping to get into this market to over deliver on those key performance metrics and to potentially be a last mover in this market to solve this problem.

CEOCFO: *How are you able to garner the attention that you need?*
Mr. Fernandez: We are trying hard to participate in the sleep medical community to contribute our original medical research through publications and talks at the upcoming American Academy of Sleep Medicine in Boston in June. We will be presenting there on machine learning and artificial intelligence applications for analyzing sleep data. I think that we are trying to build credibility by participating in the community and contributing valuable knowledge and the things that we have learned for valuable things that we have learned for other folks to take advantage of as well. There are a lot of physicians out there who know that there are better uses for their time and expertise than kind of munging around through electrophysiological data. With major milestones like the AlphaGo victory and the overall progress of Artificial Intelligence, they know that in 2017, we have come to the time where our analytical capability can truly start to become as good as humans through these complex tasks. They will have the choice for whether they want to continue doing that themselves or whether they will want to partner with technology and form a human/computer collaboration to multiply the amount of work that they would be able to do and the amount of patients they would be able to help.

CEOCFO: *Would you tell us what you learned as you were developing Enso Sleep and what changed from your original concept?*
Mr. Fernandez: I think the biggest thing we learned while we were developing it was how important the work flow was to clinicians. The biggest revision that we made was changing the technology from the previous to what we call the current zero-click work flow. Once you download our software, it is similar to a Google Drive or drop-box; it completely automates the syncing of files so you don't have to worry about uploads or backups yourself. You download it once and it will automatically facilitate the thinking and the networking of your files and a make sure they are always up in the cloud backed-up, analyzed in the trend that they should be with literally zero clicks necessary.

CEOCFO: *What is the potential of the eventual business model?*
Mr. Fernandez: We think that our business model is waiting to serve multi-billion dollar market in healthcare. There are several other products that we view as obvious applications of our advanced algorithm and big data processing engine. Some of the ones we are most excited about are applying our automated Pattern Recognition and trend prediction for real-time monitoring in highly acute environments like the intensive are unit and operating room. In many areas in healthcare they use the exact same sensors, as we analyze the sleep data so the applicability of what we have already built is immense for a lot of other applications.

CEOCFO: *Are you seeking funding or partnerships or investors?*
Mr. Fernandez: I think we are always looking for good opportunities. We closed our Series B round of funding around this time last year for $550,000 led by HealthX Ventures, and we previously raised $12,000 from the Y Combinator Fellowship program. Currently we are focused on growth and getting the product out there as well as continuing to build traction and momentum in the market. We will be doing some fundraising over the next twelve to eighteen months.

CEOCFO: *It is a crowded field Is it a little easier to garner attention in the sleep arena as it is more focused?*
Mr. Fernandez: I definitely think that is correct. That is one of the big advantages for our company, starting in the sleep business. Even though we want to pursue these other markets down the road, we decided to start in sleep because it is a tight-knit medical community. From a technological standpoint, it is not as fast-moving as higher dollar and higher emphasized areas like cardiology. I think from a competitive standpoint we are able to come in and outwork, out-innovate and out-execute the bigger companies. We are able to move at a faster pace and deliver better products. We are also able to connect to the customer in a way that is a lot more frictionless than it would be if we were in a more competitive space within healthcare. This is a great place to start, build out our core competencies in these artificial intelligence technologies, big data, getting through the regulatory system efficiently and then going ahead to translate those same exact capabilities to these other important medical areas of product lines.