

With its Computer-Based Quotient System, Using a Motion-Tacking Sensor to Measure Movements Greater Than 1 Millimeter 50 Times Per Second, BioBDx is Bringing to Market the First FDA Cleared Test to Aid Doctors in the Objective Measurement of ADHD



**Biotechnology
ADHD Diagnostics
(Privately Held)**

**BioBehavioral Diagnostics
(BioBDx)**

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**Byron Hewett
Chairman and CEO**

Company Profile:

Summary of BioBDx:

Proprietary platform technology to objectively measure specific behav-

iors that correlate with brain function and deficits in inhibitory control

- Currently FDA-cleared for the objective measurement of hyperactivity, impulsivity and inattention as an aid in the assessment of ADHD
- Used nationally by neurologists, pediatricians, psychiatrists
- Supported by national group of Key Opinion Leaders
- Broad application to other CNS diseases in the future

**Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine**

CEOCFO: Mr. Hewett, what attracted you personally to take on the CEO role for BioBehavioral Diagnostics?

Mr. Hewett: I was intrigued by the fact that the entire behavioral disorders space is so subjectively based that the context of objective measures in a space like this could be very impactful and meaningful. It also was a personal interest to me because, while I have spent 30 plus years in the diagnostics industry, I also have a son who has ADHD. Over the years, my wife and I have been enormously frustrated with the lack of standardization and objective measures for this disorder. In a lot of ways, I was a frustrated consumer and I wanted to help commercialize a product that could address some of the frustrations we felt in the diagnosis, as well as ongoing management of my son's disorder.

CEOCFO: What is the Quotient System?

Mr. Hewett: The Quotient System is the first test to be FDA cleared to aid doctors in the objective measurement of ADHD. It is a computer-based product that utilizes an infrared motion-tracking sensor to measure movements greater than 1 millimeter 50 times per second. The Quotient measures the ability of the patient to inhibit their natural state. When someone has ADHD, his/her natural state is to always be moving. They are restless, so they tend to act first and think later. They have a tendency to pay attention to anything new that comes along and, as a result, it gets in the way of sustaining their attention. When kids are young, two or three years old, we expect them to run around, be hyperactive, act first and think later, and flip from one thing to the next. As they go to school, we expect them to develop a response inhibition mechanism, or a way to control their body's motion and space. We want them to inhibit their impulsivity and wait to be called upon by the teacher; we want them to ignore distractions so they can focus on the task at hand. By doing so, they can then elevate themselves to be able to function at a higher level. For those diagnosed with ADHD, it is challenging to inhibit those naturally occurring responses. The Quotient ADHD System objectively measures the three core symptom domains of ADHD: hyperactivity, inattention, and impulsivity. Therefore, the claim we have with the FDA is not limited only to the diagnosis of ADHD. We are also able to assess each patient's progress after intervention to see if the treatment is making a difference in their ability to suppress their symptoms.

CEOFO: What knowledge has BioBehavioral Diagnostics developed that has not been available in the past?

Mr. Hewett: The work for this was done in McLean Hospital as a part of the Harvard Partners system. Earlier studies indicated that motion, in and of itself, does not seem to be predictive of ADHD and that attention observed on average over a time span, did not seem to be very predictive of ADHD either. However, Dr. Martin Teicher at McLean Hospital figured out that the data needed to be analyzed differently. We capture information with our motion metrics, which gives us key differentiation in how we measure motion and how we analyze that motion. We also have proprietary attention state analysis, where we look at the patient's ability to sustain their attention and be on task in 30-second blocks across the 15 or 20-minute tests. Therefore, through our algorithms, we can distinguish whether someone is attentive, impulsive, distracted, or disengaged. It turns out that those particular metrics, along with a few others, are much more predictive of whether or not somebody has the disorder than the previously used methods of assessment.

CEOFO: At what age is BioBehavioral Diagnostics able to test?

Mr. Hewett: A patient must be at least six years old to be tested with the Quotient. The test is 15 minutes for children, ages 6-12, and 20 minutes for adolescents and adults, age 13 and over.

CEOFO: Who is using the BioBehavioral Diagnostics products today?

Mr. Hewett: Essentially, we market the Quotient System to those who see a significant number of ADHD patients. An estimated 10% to 12% of children have the disorder and approximately 4% of adults have the disorder. Therefore, about 40% of kids will outgrow it, but 60% will carry those symptoms into adulthood. It turns out that 60% of ADHD in the

United States is being treated by pediatricians because there are not enough specialists available to manage the care of all those patients. So, we market to psychiatrists, pediatric neurologists, neurologists, pediatricians, and psychologists.

CEOFO: Is the medical community and people that should know about BioBehavioral Diagnostics aware of your existence?

Mr. Hewett: I would say that the opinion leaders are pretty aware of us. Innovators and early adopters are also aware of us, but we certainly have a long way to go in terms of market penetration.

CEOFO: How does BioBehavioral Diagnostics reach the potential users?

Mr. Hewett: We attend all the various professional society meetings that are

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- Byron Hewett

relevant to the space. We advertise in professional society journals to clinicians involved in the assessment and management of patients with ADHD. We also have a direct sales organization, a small sales force of six that call on physicians who see a lot of patients with ADHD. Currently, we are in the process of implementing distribution so that we can reach the market more broadly.

CEOFO: Are parents aware of your breakthrough test, and are you able to target parents to encourage them to ask for the Quotient?

Mr. Hewett: Yes, they are aware of us and I think we can. Because we are a small company, we are now in the process of enlarging our marketing footprint. We have a presence on Facebook and Twitter. In addition, we support the meetings for CHADD, a

non-profit organization that provides resources and information to children and adults with ADHD. They had a meeting in Orlando last year and Cleveland the year before. Therefore, we are working to garner the support of the opinion leaders and the local influencers in different geographies. As we gain more traction, it becomes easier for us to reach parents and patients directly.

CEOFO: What is BioBehavioral Diagnostics actually selling; is it hardware, software or a device?

Mr. Hewett: We have a razor/razorblade model. The razor is the Quotient system itself while the razorblades are the patient tests performed by the physicians after purchasing the equipment. We actually have two versions. One is the original Quotient System, which is about 5 feet high and 3 feet wide and weighs about 300 lbs., and costs about \$15,000. Our second system that we introduced to the market in September 2011 is portable, weighs 15 lbs., and costs about \$10,000. The idea is that it can be set up on a tabletop or desktop, in an exam room, or wherever the physician wishes to conduct the test. Physicians like the idea

of a portable system that can be transported from one location to another. When the test is being administered, the child sits in front of the Quotient System and is presented with two stars: an 8-pointed star or a 5-pointed star. They are instructed to hit the spacebar if they see the 8-pointed star but to do nothing if they see the 5-pointed star. The stimulus is in black and white and appears randomly on the computer screen. The shapes are symmetrical so there is no interference from complications like dyslexia. The patient is fitted with a reflector so we can track their micro-movements through an infrared motion tracking system. We therefore capture an enormous amount of information regarding this particular patient's responses and movements during the 15 minute test. Once this is complete, the physician uploads the results over the Internet to our secure

server and receives a report back in under a minute. It is a 7-page report with 19 different metrics that gives the likelihood of this particular patient having ADHD. Percentile scores allow them to compare children to others of the same age and gender, increasing the accuracy of the system further.

CEO CFO: Is it difficult for someone with ADHD to sit through the test?

Mr. Hewett: It is challenging for someone with ADHD to sit through the test. Therefore, the clinician needs to point out to them that it is important that they try their best when taking the test. We also have a practice test that lasts 30 seconds, which allows the administrator to be sure the patient understands and will be able to follow the instructions they are given.

CEO CFO: How many units are in use today?

Mr. Hewett: We currently have about 160 in use throughout the country.

CEO CFO: Are there other indications for the Quotient system?

Mr. Hewett: We are really excited about the opportunities we have for the Quotient System; it turns out that any disorder associated with motion dyscontrol and an impact on cognitive function has a potential application with Quotient. This includes Parkinson's disease and traumatic brain injury. Akathisia, which is a medication-induced motion disorder is also an

appropriate application; so are different forms of dementia. Oftentimes, patients who have suffered head injuries lose some of the response inhibition they once had and Quotient can measure that as well. We have noticed specific signatures when analyzing head injury patients on the Quotient system. Although we do not have any FDA claims around that yet since no clinical trials have been conducted, it is certainly encouraging in terms of the future ability of Quotient to be applied to disorders outside of ADHD.

CEO CFO: Is the test reimbursable or is it just part of the doctor's normal evaluation?

Mr. Hewett: The test is reimbursable.

CEO CFO: What is the financial picture like today for BioBehavioral Diagnostics?

Mr. Hewett: We are in the process of raising a series B round of financing. This next round, we believe, will get us to break-even, so we are looking to raise about \$10 million. We are projecting to break-even in the late summer of next year. It is an exciting business because we are growing pretty fast and we have attractive margins, so we think that this could be a business with real legs. The market opportunity in ADHD alone in the US is about an \$800 million per year, and if you start adding in the market outside of the US and other disorders, the market potential easily exceeds a couple billion dollars.

CEO CFO: What should we expect in the next year or so from BioBehavioral Diagnostics?

Mr. Hewett: We expect a significant increase in the number of systems placed in the market and tests performed compared to past figures. We expect we will continue to have a strong presence of professional society meetings. Meaning that there will be presentations, posters, peer reviewed articles talking about the Quotient System and its applications to ADHD and other disorders. We think that will create further enthusiasm and buzz around what we are doing. Our expectation is to be in a position where we can break even about 15 months or so from now, which is obviously very exciting for all of us.

CEO CFO: Final thoughts, why should investors pay attention to BioBehavioral Diagnostics today?

Mr. Hewett: Today we have a \$2 million revenue run rate and a gross margin of over 73%. Therefore, one can extrapolate very quickly that if on such a modest revenue level we have very attractive gross margins already, as we grow this business and get it to break even, our gross margin will be in the 80s., We think it makes for a very attractive investment. It should drive a high multiple and should result in an excellent exit for investors.





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